

Comment-Response Document (CRD) 2017-17

CRD 2 to NPA 2017-17 'HEMS'

RELATED NPA: 2017-17 — RELATED OPINION: No XX/202X — RELATED ED DECISION: 202X/XXX/R — RMT.0492 & RMT.0493

DD.MM.202X [= DATE OF ADOPTION]



In responding to the comments, the following terminology has been applied to attest EASA's position:

- (a) **Accepted** EASA agrees with the comment and any proposed amendment is wholly transferred to the revised text.
- (b) **Partially accepted** EASA either agrees partially with the comment or agrees with it but the proposed amendment is only partially transferred to the revised text.
- (c) **Noted** EASA acknowledges the comment but no change to the existing text is considered necessary.
- (d) Not accepted The comment or proposed amendment is not shared by EASA.



Individual comments and responses — HEMS

omment	54 comment by: PRESIDENT & SECRETAIRE GENERAL DU SYNDICAT
	COMMENTAIRES SNPNAC SUR LA NPA 2017/17
	Il est nécessaire de laisser les États membres, l'organisateur du temps de travail des navigateurs opérant en SMUH et SMUA, en fonction des spécificités propres à chaque région de Santé.
	Les appels d'offres sont constitués par les cahiers des charges rédigées par les autorités de Santé régionales suivant un schéma national.
	En France, les entreprises de transport public qui ont reçu un agrément SMUH ou SMUA sont rémunérées par le ministère de la Santé grâce aux fonds publics.
	Pour mettre en œuvre une telle NPA et en particulier le titre CS FTL.3.2.10, il faut créer un système associatif comparable à celui de la REGA suisse ou de l'ADAC allemand.
	This would behaviour the impact financial important that they need to the mise en place d'un nouveau mode d'organisation du travail des navigateurs à travers cette NPA 2017/17. Malheureusement, le fonctionnement du Transport sanitaire français par voie aérienne, repose entièrement des entreprises privées.
	Il existe au niveau national une convention collective des personnels navigants techniques des exploitants d'hélicoptères, qui dans son annexe II organisent le temps de travail et de reposer des navigants en SMUH.
	Il est donc impératif de laisser les partenaires sociaux s'entendre pour réformer cette convention sur le temps de travail des navigants.
	L'application de cette NPA constituait l'arrêt du fonctionnement du Transport sanitaire en France.
	Les entreprises de transport public sous agrément SMUH ou SMUA ont déjà investi beaucoup d'argent pour répondre aux appels d'offres de renouvellement ou de création de marchés de SAMU héliportés.
	L'état français n'a plus les moyens de financer ce service aux populations et de modifier cette NPA, le temps de travail dans ce domaine très spécifique de l'aéronautique.
	Le danger de cette réorganisation prévue par ce nouveau texte est que notre système de transport sanitaire héliporté cesse de fonctionner à cause des coûts d'exploitation que trop chers.
	Des centaines d'hommes et de femmes se sont trouvés privés d'emploi, sans pouvoir continuer d'assurer ce service de transport sanitaire, indispensable à nos concitoyens.

**** * * * **** Pour toutes ces raisons, le SNPNAC, syndicat principal des navigateurs, représentant de 98% des équipements en France, s'oppose à l'application de ce texte et demande son retrait définitif.

English version

It is necessary to leave the Member States, the organizer of the working time of the navigators operating in SMUH and SMUA, according to the specificities specific to each region of Health. Calls for tenders are made up of the specifications drafted by the regional health authorities according to a national plan.

In France, public transport companies that have received a SMUH or SMUA accreditation are remunerated by the Ministry of Health from public funds.

To implement such a NPA and in particular the title CS FTL.3.2.10, it is necessary to create an associative system comparable to that of the Swiss REGA or the German ADAC.

This would be important for the financial impact that they need to set up a new way of organizing the work of browsers through this NPA 2017/17. Unfortunately, the operation of French Air Transport by air rests entirely with private companies.

There is a collective agreement at the national level for the technical flight crews of helicopter operators, who in Annex II organize the working and resting time of aircrew in HEMS. It is therefore imperative to let the social partners agree to reform this convention on the working time of seafarers.

The application of this NPA constituted the cessation of the operation of the Transport sanitaire in France. The SMUH or SMUA licensed public transportation companies have already invested a lot of money to respond to the call for tenders for the renewal or creation of helicopter-borne UAS markets. The French state no longer has the means to finance this service to the population and to modify this NPA, the working time in this very specific field of aeronautics.

The danger of this reorganization foreseen by this new text is that our helicopter transport system ceases to function because of the operating costs that are too expensive. Hundreds of men and women have been deprived of jobs, without being able to continue providing this health transport service, which is essential for our fellow citizens.

For all these reasons, the SNPNAC, the main union of navigators, representing 98% of the equipment in France, opposes the application of this text and asks for its final withdrawal.

response Noted

The impact assessment (IA) to NPA 2017-17 did not evaluate the impact of the proposed FTL requirements for HEMS on Member States' health care and social systems from a macroeconomic perspective.

Regulation (EU) No 965/2012, in general, and the FTL requirements, in particular, do not regulate social aspects, although enhanced safety requirements may result in social benefits for individuals.

From a safety perspective, the IA estimated that the potential safety benefit for HEMS operators would be limited.



Recognising the importance of HEMS operations for the European communities as well as the diversity in HEMS systems established in the Member States, EASA decided to separate the HEMS proposal from further rulemaking process under RMT.0492 & RMT.0493.

A future common FTL framework in the domain of HEMS that provides for flexibility and continuation of existing safe practices, will likely be established under RMT.0494 FTL rules for helicopter commercial operations. Feedback from stakeholders indicates that while there is no unanimous support for RMT.0494, there is enough strong support from a significant number of stakeholders to recommend keeping the rulemaking task in the EPAS.

It should be noted, however, that the analysis of fatigue-related safety events demonstrates that a direct link between fatigue, FTL and safety events is very often not evident. Fatigue cannot easily be isolated from other (human) factors that influence crew performance. Also, the investigation of fatigue can vary considerably depending on the background, expertise and focus of the safety investigator(s) involved. There is no agreed definition of a 'fatigue-related safety occurrence'. It is well known that the current system of investigation of aviation occurrences is not particularly apt to identifying *pilot fatigue* as an immediate contributing factor.

Member States' national regulations applicable to HEMS are in most cases the result of a political compromise. Some of these regulations may be lacking contemporary scientific understanding of human performance limitations and of sleep science. For example, transient and cumulative fatigue and its impact on circadian rhythm may not be very well addressed. On the other side, national regulations do not increase compliance costs and are, therefore, preferred by operators.

comment 85

comment by: Nils Boether

Auf der Luftrettungsstation Christoph 31 Berlin wird bereits seit 2 Jahren aufgrund gestiegener Einsatzzahlen ein Doppelschichtsystem auf einer Primär-Retttungshubschrauber-Tagstation 9 Monate pro Jahr umgesetzt. Im einklang mit der 2.DVLuftBO und den in den Arbeitsverträgen festgelegten Arbeitsstundenzahlen (2000h exklusive Urlaub) wurde eine Betriebsvereinbarung für das Schichtmodell festgelegt.

Diese Betriebsvereinbarung wird bei Inkrafttreten der neuen EASA FTL auf den meisten "Rettungshubschraubertagstationen" in ähnlicher Form angewendet werden müssen.

Sollten keine weiteren Regelungen zur neuen EASA FTL bezüglich der Arbeitszeiten/tagen von Hubschrauberbesatzungen im HEMS Flugbetrieb geben, halte ich die neuen EASA FTL für einen Rückschritt. Vor allem für die Flugsicherheit.

Zur Beründung meiner Meinung, die sich vor allem aus den Erfahrungen des Schichtbetriebs auf der Rettungshubschraubertagstation Chritoph 31 begründet:

1. gemäß 2. DVLuftBo sind die Dienstperioden aufgrund von Ruhezeitenverkürzungen auf 8,5 Stunden im Sommerhalbjahr auf 4 Tage beschränkt. Im Schichtbetrieb gibt es diese Beschänkungen nicht mehr. Daraus resultieren längere Dienstperioden 7-8Tage die meist



belastender sind, als 4 Tage am Stück auf der Station zu verbringen, um dann wieder eine längere Erholungphase zu erhalten.

2. Aufgrund des höheren Personalaufwands durch eine Doppelschicht wird die Erholungszeit meist auf das Minimum beschränkt (7-8Tage Dienst, dann 48Stdn Pause, dann oft wieder 7-8Tage Dienst). Im aktuellen Schichtbetrieb Christoph 31 eine übliche Praxis.

3. Die längeren Dienstperioden führen zu mehr Arbeitstagen, da die Arbeitsstundenleistung pro Arbeitstag sinkt. Um noch Zeit mit der Familie/Freunden zu verbringen, ist ein tägliches Pendeln oft notwendig. Das tägliche Pendeln führt zu einer weiteren Belastung.

4. Sollten die neuen EASA FTL eingeführt werden, sollten Regelungen über maximale Dienstperioden (4-5 Tage), sowie Regelungen über Wochenendarbeit und Ruheperioden festgelegt werden.

5. Ich sehe mit den neuen EASA FTL keine Erleichterung auf die Hubschrauberbesatzungen zukommen. Eher eine zusätzliche Belastung und Erschwernis der Arbeitsbedingungen.

response

Please see the answer to comment # 54

comment	86 comment by: AIR ZERMATT AG				
	Attachments <u>#1</u> <u>#2</u>				
	<u>General comments to the NPA FTL 2017-17 with reference to Figure 1 (see attachment)</u>				
	 Overall, the draft regulation is too complex in order to be operationalized; The implementation of the proposed FTL regulation would require to hire additional crew members in order to be compliant; The significant need of more crew members would lead to a gap of qualified personnel – because the qualified personnel is not available. Overall market is no sufficient to sustainably feed the market with the demand of qualified personnel organically; New crew members must be hired and trained to meet the basic HEMS requirements, leading to excessive training costs; More crews with low experience would be on duty due to the induced demand by EASA FTL (today even if prospects meet the EASA requirements, the upgrading to a HEMS pilot is based on an individua assessment/personal fit) à this would reduce today's high safety and quality levels. Hiring additional crew members leads to a rise of salary costs, which then togethe with the higher training costs lead to an excessive rise of the overall HEMS operating costs. 				

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

- Equally-staying turnover, but higher salary costs will lead to lower overall salaries. à this would lead to social tension and lower the attractiveness of the job, enlarging the gap of qualified personnel.
- Further the increase of costs, <u>lead to an increase of pressure for</u> <u>commercial rescue companies</u>. In order to cope with higher expenditures, turnover must be increased, hence more risks are being taken by the crews in order to execute more HEMS missions in order to increase turnover. à this would reduce today's high safety and quality levels.
- Due to an induced rise of crew members, <u>each crew member conducts less actual</u> <u>flight time</u>, hence builds slower experience. à this would reduce today's high safety and quality levels.

Conclusion:

In the opinion of the industry the implementation would lead to a reduction in safety, excessive rise of the overall HEMS operating costs and the danger of social tension due to the risk of lower salaries. Therefore, the industry suggests to deny the <u>mandatory</u> implementation of the EASA FTL and supports the option 0 of the NPA 2017-17 stated on page 67 article 4.5 and alternatively gives the suggestions stated below.

Suggestion from the industry:

- Due to different operating structures (state vs. commercial or charity funded organizations), different tasks & responsibilities defined by the state and the different geographical environment within the EASA territory, a one-size-fits-all approach does not work and it should be left to the national authorities to regulate FTL (closeness to operators, practical knowledge of operations). E.g. Switzerland has a FTL regulation in place since 1990, which has proven itself as effective and efficient in regards to safety and quality;
- For cross border operations, member states should regulate FTL with bilateral agreements.

response

Please see the answer to comment # 54

comment 218

comment by: ADAC Luftrettung gGmbH

Die bisher verwendete Regelung der FDuRZ in der 2.DV LuftBO, welche auf einer wissenschaftlichen Studie beruht, hat sich in der Vergangenheit bewährt. In 50 Jahren HEMS Betrieb hat es keinen Flugunfall auf Grund von Fatigue gegeben. Sie ermöglicht ein Maximum an Flugsicherheit bei gleichzeitiger Aufgabenerfüllung.

Verglichen mit der Tätigkeit eines Piloten im gewerblichen Passagier-/Cargotransport, der während eines Flugdienstes zum Großteil fliegerische Tätigkeiten wahrnimmt, ist der zeitliche Anteil an fliegerischen Tätigkeit eines HEMS-Piloten pro Diensttag deutlich geringer. Wartezeiten an der Einsatzstelle und bei Patientenübergabe beinhalten wenige bis keine fliegerischen Tätigkeiten und führen deshalb zu weniger Ermüdung als die

**** **** ununterbrochene Flugüberwachung/-durchführung eines Airline-Piloten der eine 16h-FDP durcharbeiten darf.

Bei Einführung der FTL Regelung wie sie zum jetzigen Zeitpunkt geplant ist, wäre die deutschlandweite Einführung von Schichtdienst im HEMS-Flugbetrieb unausweichlich. Dies würde für Piloten die nicht in der direkten Umgebung der Heimatstation wohnen zu erheblich mehr Diensttagen und damit zu erheblich mehr An/Abreisezeit sowie Reisekosten führen. In meinem Fall würde daraus der mit der FTL beabsichtigte Flugsicherheitsgewinn nicht nur negiert, sonder sogar umgekehrt. Im Endeffekt würde die erhöhte Reisezeit zu einer erheblichen Mehrbelastung führen. Ein Umzug in die Nähe der Heimatstation ist aus persönlichen Gründen nicht möglich. Der durch die FTL verursachte indirekte Umzugszwang (Erbringung der Arbeitsleistung ohne Umzug finanziell/zeitlich nicht mehr durchführbar) stellt ein Eingriff in meine Grundrechte dar.

Eine Kopplung der Flugzeitbegrenzung an einen Autopiloten ist nicht sinvoll, da ein Autopilot im Primärflugbetrieb nur sehr eingeschränkt nutzbar ist. Im Sekundärflugbetrieb ist dieser zwar eher nutzbar, jedoch kann nicht generell von einer Entlastung durch einen AP ausgegangen werden.

response

Please see the answer to comment # 54

comment 434

comment by: ANWB MAA

As the HEMS operations are highly effected by local circumstances (commuting distances, duration average flight, remote areas, number of missions a day) it would be more feasible and make more sense to have a national FTL that will be applicable to all HEMS operators operating in that specific country. This FTL should be a performance based FTL (see option 1 next paige). To obtain a level playing field any operator applying for a HEMS operation will fulfil the requirements of that country.

The national FTL needs to be based on scientific research taking all the mentioned above into account.

The proposal as it is right now will drive the national healthcare to high costs. An investment for a country without any prove that the present FTL isn't safe enough or doesn't fit the local HEMS operation.

As long as the proposal provide deviations for specific areas (remote) and countries (norway specifically mentioned) there still will be no level playing field. The question is if the EU countries really bother about the level playing field at this point if the required investments will be so high. Perhaps a survey at that point can be worthwhile.

Worrisome is it to see that the helicopter industry has an important influence on the proposals. In this NPA an inexplicable distinction is made for the operations with or without autopilots. No evidence is given why this give such a longer FDP or FT.

On average the costs will raise with at least 1 miliion euro per year for the HEMS operation in the Netherlands.

**** *. .*

Individual comments and responses — HEMS

response	Please see the answer to comment # 54.		
L			
comment	440 comment by: UFH French Helicopters Association		
	The Union Française de l'Helicoptere (UFH) is the French Helicopter association. Our organization is the French member of the European Helicopter Association. It gathers the 6 bodies that are representing the helicopter industry in France, including the SNEH, which is the Rotorcraft commercial operators association, and the helicopter branch of the FNAM.		
Concerning the present NPA 2017/17, logically, our analysis has been twined with has been provided by FNAM. The comment that have been sent to the agency are obvidentical, in order to mark our full approval of it.			
response	Please see the answer to comment # 54.		
comment	445 comment by: <i>Hélicoptères de France</i>		
	Attachments <u>#3</u> <u>#4</u> <u>#5</u> <u>#6</u> <u>#7</u> <u>#8</u>		
	 Introduction: The comments hereafter shall be considered as an identification of some of the major issues the French industry asks EASA to discuss with third-parties before any publication of the proposed regulation. In consequence, the following comments shall not be considered: As a recognition of the third-parties consultation process carried out by the European Parliament and of the Council; As an acceptance or an acknowledgement of the proposed regulation, as a whole or of any part of it; As exhaustive: the fact that some articles (or any part of them) are not commented does not mean Hélicoptères de France has (or may has) no comments about them, neither Hélicoptères de France accepts or acknowledges them. All the following comments are thus limited to our understanding of the effectively published proposed regulation, notwithstanding their consistency with any other pieces of regulation. 		
	General comments : Hélicoptères de France thanks EASA for the will of harmonizing the applicable dispositions in terms of flight time limitations for HEMS operations throughout Europe in order to warrantee a high level of safety.		
	However, considering the HEMS national specificities (French HEMS missions represent 17% of the European HEMS missions), a proportionate approach tailored to the local specificities needs to be considered. The current RIA of this NPA should be further developed for a better maturity and should take into account the French national specificities. (Cf. comments #59 to 64) Generally speaking, Hélicoptères de France thinks that the proposed requirements for HEMS would benefit and enhance safety in being clearer and more user friendly. The proposed requirements for HEMS show numerous inconsistencies (there are some numbering issues, nonsenses and contradictions leading to misunderstandings of this NPA). Therefore, it is really hard for the Profession to elaborate final and comprehensive comments due to the difficulty in comprehension of this proposed regulation.		

For instance, the structure and the references within this NPA lead to confusion regarding the applicability of the Certification Specifications for HEMS, indeed it is not explicit whether:

• All the CS.FTL.3 requirements shall be applicable "in block"

• The CS requirements should apply depending on what is said in the implementing rule

• Cherry-picking is allowed (Cf. comments #18.1, #25, #30.1, #39, #40)

It is feared that the complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation which is contrary to the safety goal.

In order to comment properly the proposed requirements, the stakeholders need to understand the whole proposition. Numerous points merit clarification. The comments made thereafter need to be analyzed in light of Hélicoptères de France's current understanding of this NPA.

At the time being, Hélicoptères de France fears that each and every stakeholder will interpret this NPA according to its understanding which might act as a hindrance to the level playing field contrary to the initial goal.

French Organization

In France, the HEMS is a peculiar matter since it is a public service delegation from the Directorate of Health Care Supply (Direction Générale de l'Offre des Soins – DGOS) branch of the French Health Ministry.

HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care services is a public service defined in the French Health Code & a sovereign prerogative), with groupings of medical equipment and skills.

HEMS in France is both operated by private operators and the State (Civil Security, Gendarmerie or Army) for the sake of the DGOS.

Regarding the private operators, there are 49 HEMS bases (corresponding to a total of 47 HEMS helicopters) in metropolitan France and overseas (including in Cayenne and in the Reunion Island) whose air transport business is conducted by 5 operators. These operators' helicopters are based at the hospital for which they work and are permanently equipped with medical equipment.

The contracts are awarded by each hospital or are pooled at pilot hospital which is responsible for the public contract and which, in some cases, spreads the flight hours between each hospital keeping a helicopter based for its sanitary transport needs.

Additionally, the State may charter private operators to operate HEMS operations on its behalf. Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved.

Such a possibility shall remain for "Force majeure", in respect of the sovereignty of each Member State facing major health crisis.

Although delegated to private operators, the HEMS in France remains a public service mission whose latitude for the application of the newly proposed Article 8 of this NPA applies for the Member States at any time.

#2 major characteristics

2 major characteristics arise from the French healthcare organization:

• The operational readiness with really short response time in order to warrantee the patient's odds of survival (3 work paces are in force in France : H12, H14 and H24 operations; to simplify, only the H12 example will be developed afterwards)



• The unpredictability of the flight times

This is the current French HEMS organization, linked with the French Health Ministry nowadays. In France, the President of the Republic and his government has made the commitment to the French people to warrantee an access to emergency care in less than 30 minutes from anywhere on the French territory.

Considering the unpredictability of the HEMS operations, the flight times are not known in advance and cannot be scheduled ex-ante. Hence, all the CAT.A FTL philosophy (building a FDP and a DP around sectors [FT] and computing the duration of the required rest that has to be taken before the next FDP as Max [12h; Previous DP]) does not suit the HEMS operations. The FDP's content cannot be scheduled in advance (unscheduled allocation in a scheduled FDP).

Hence, the attempt to adapt the CAT.A FTL implementing rules to the specificities of the HEMS leads to a dead-end since the philosophy is completely different. Therefore, it may be considered if elaborating a new regulation from scratch would not be more appropriate.

French rostering organization

In France, the most usual rostering is usually 7 days ON at home base / 7 days OFF (implying a rest period + FDP < 24h, 7 times in a row), with a need for a H12 operational readiness (or a 12h shift in H24). This proposed European regulation, does not allow the French operators to comply with the French work pace defined and contracted by the French healthcare system. Moreover, in order to ensure a better quality of teamwork and to enhance safety, the French rostering organization is the same for pilots and doctors, they work in the same time slots (H12 or H14). Hence, all these new requirements will lead to amend all the French Health National practices (to that extend, the analysis of EASA would gain from considering further all economic and social issues it will raise).

Indeed, considering the French work pace:

On the one hand, in the proposed European regulation, there is a minimum duration for preflight of 30 minutes. This new requirement of a 30 minutes pre-flight will imply either a 30 minutes increase of the FDP or a 30 min decrease of the operational readiness. In France, 7% i of flights saving lives would be impossible with a 30 minutes pre-flight. (cf. illustrative Table in attachment)

On the other hand, in the proposed European regulation, there is a minimum duration for postflight at the end of (the last flight time of) the FDP of 15 minutes (and Hélicoptères de France would like to highlight the fact that the definition of this post-flight seems unclear and may lead to confusion). This new requirement of a 15 minutes post-flight at the end of (the last flight time of) the FDP will imply both a 15 minutes increase of the DP and a 15 minutes decrease of the time slot available for the required rest.

Besides, if the FDP is lasting more than 10h, a 1 hour break is requested in the proposed dispositions of the NPA for single pilot + 1 TCM operations. In France all scheduled effective operational FDPs are 12h as explained before, so the 1h break requirement will always need to be fulfilled. Just as for flight times, due to the unpredictability of the HEMS missions, the break has to be unscheduled and the operator should ensure ex-post that the break requirement has been fulfilled for pilots. Besides the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour. Else, this will would overlap with national social regulations and the definition of working time.

Therefore, considering the French work pace, in order to have a 12h operational readiness with the proposed FTL European requirements, there is always a need for at least a 12h30 max FDP (which implies a 12h45 DP) with a 1h unscheduled time period allowed for physiological needs (which cannot be a rest period free of all duties). As a consequence, the time slot available for rest is 11h15 (24h - 12h45 = 11h15) while the rest required by this NPA would be 12h45. Therefore, all French HEMS operators will need to use systematically reduced rest and thus, all French HEMS operators will need to have a FRM (which seems disproportionate to the size of the involved operators). Moreover, as soon

as there is one scheduled FDP lasting more than 12h (always the case in France since there is always a need for at least a 12h30 FDP), no more than 4 consecutive FDPs can be scheduled. Thus, the usual French rostering 7 days ON at home base / 7 days OFF cannot be respected, despite its efficiency in terms of safety, fatigue and quality of life for crews, has been proven from experience. As said in the RIA, no risk has been shown regarding safety or fatigue with the current regulation. Indeed, the total amount of flight times for pilots is quite low, a lot of time can be spent for rest, and the working pace of 7 days ON / 7 days OFF does not appear more tiring. On the contrary, the working pace of 7 days ON

/ 7 days OFF is better for the labor organization and is bringing a better quality of life for pilots who do not live near the HEMS operating base. Indeed pilots prefer to work 7 days in a row and then be 7 days OFF instead of working 1 day and resting the next day (which appears more tedious and exhaustive).

Conclusion

The impact of the implementation of European FTL regulation for HEMS in France goes beyond the French operators. It is a complete change of the whole French Health care system which might be necessary. Thus, it would be appreciated if the RIA addresses the impacts on the national policy for emergency access to care and the Government Health policy, etc. Many lifesavings would be impossible with proposed FTL schemes.

(Cf. attachments S1, S2, S3 and S4)

As a consequence, 3 options emerge and are listed here below, ranked according to their level of relevance for Hélicoptères de France:

OPTION A or option 0 of the RIA

This option, whose choice relies on the Member States (MS) or EASA's decision, corresponds to the option 0 described in the RIA: no policy change. Safety impact, social impact and economic impact are neutral or having a little impact. The solution 0 is the proper answer to a one size fits all model which is not applicable to the industry. The FTL shall stay in the hand of the local authority. The well functioning current national FTL schemes are enforced since years, no excessive fatigue has been demonstrated and the current national system provides French operators with satisfaction. Besides, in the EMS safety risk assessment of this NPA, it is written that "Even with the caveats about underreporting of fatigue as a causal factor it would appear from the occurrence data that the controls that have been in place to manage fatigue in European EMS have generally been effective. Compared to the social benefits from EMS operations in terms of patient safety and health (see below), the overall safety balance (flight safety v patient safety) is very positive". Hélicoptères de France strongly asks this option to be considered by EASA and the Member States: "no change in the existing situation; HEMS continue to be regulated under MS national rules".

OPTION B

This option consists in a total revamp of the NPA 2017-17 for HEMS. Hélicoptères de France asks for a completely new proposal, distinguishing the HEMS from AEMS and Air Taxi as no operational



comparison can be made between the fundamentals of these different activities and respecting the following principles:

• Basing an alternative proposal on:

o 14h Standby / 10h Rest with a commander's discretion applicable in case of unforeseen circumstances

o short-time operational readiness for ready-to-go EMS take-off

o rostering of 7 days ON / 7 days OFF

o flight time limitations to be discussed within this frame

Hélicoptères de France asks for this option to be considered in the Comment Response Document (CRD) with the elaboration of a sound RIA. Moreover, Hélicoptères de France would be happy to offer its expertise to discuss and study this subject with EASA policy officers. Besides, for clarity reasons, this would imply to separate, regarding the FTL scope, the HEMS from CAT, Air Taxi and AEMS operations.

OPTION C

If these 2 first options are not retained, Hélicoptères de France asks for this proposed NPA to be amended and reviewed as stated in the following comments. The proposed requirements, as it is, will lead to amend Health National regulations and it will request more crew, more constraints, more costs with a low added safety value as stated in the RIA. The main proposals are laid down here below:

• The "Flight time" (instead of "sector" whose definition is now restricted to aeroplanes) in all the requirements should not be scheduled as they cannot be in real life

• The travelling time between multiple HEMS operating bases of the home base should be increased a minima to 120 minutes (instead of 60 minutes) and in case of change of home base, the ERRP after starting duty (and not the one prior to starting duty) should be increased to allow the continuity of the operations

• The duration of pre-flight, post-flight or inter-flights should be suppressed and replaced by "a sufficient time determined by the operator and specified in the operating manual" (in France, 7%i of flights saving lives would be impossible with a 30 minutes preflight, cf. illustrative Table in attachment)

• No limitations on the number of consecutive FDP lasting more than 12h should be made between 2 extended recovery rest periods

• For single-pilot + 1 TCM operations, in the case of a FDP lasting more than 10h, the break should be unscheduled and the operator should ensure ex-post that the break requirement has been fulfilled for pilots as they cannot be in real life

• The commander's discretion prior to take-off under unforeseen circumstances needs to be extended to all the EMS payload and not only limited to the patient and extended up to 2 hours for 1 pilot + 1 TCM operations (in France, 3%i of flights saving lives would be impossible with a commander's discretion capped to 1 hour, cf. illustrative Table in attachment)

 \bullet The limitations of the maximum values for continuous FT need to be increased by at least 1 hour

• The limitations of the maximum values for total flight time within a FDP need to be increased by at least 1 hour

• The 10% allowance between scheduled and actual FDP is not appropriate with the HEMS operations and needs to be suppressed

• The standby needs to be reviewed else it will never be used

These elements of the aforementioned proposal form an integrated whole, they are each and all interrelated and interdependent.



Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 13 of 585

The 3 options all respect the general FTL philosophy and the learnings of fatigue impact assessments.

This proposal would increase by 20% the French State budget allocated for the HEMS activity which is not affordable according to the French State.

Since the objective of this regulation is not flight safety but the harmonization of the different national regulations regarding HEMS, the text should not have the opposite effect leading to less level playing field. If the proposed dispositions are inapplicable, there may be non-binding opt-in / opt-out system possibilities (through the newly proposed Article 8 of this NPA). Misunderstanding or interpretation of National level of a far too complex regulation for small operators might also lead to lower level playing field.

response

Please see the answer to comment # 54.

comment 457 comment by: FNAM/SNEH Attachments #9 #10 #11 #12 #13 FNAM (Fédération Nationale de l'Aviation Marchande) is the French Aviation Industry Federation/ Trade Association for Air Transport, gathering the following members: CSTA: French Airlines Professional Union (incl. Air France) **SNEH: French Helicopters Operators Professional Union** • CSAE: French Handling Operators Professional Union GIPAG: French General Aviation Operators Professional Union • GPMA: French Ground Operations Operators Professional Union • EBAA France: French Business Airlines Professional Union And the following associated members: **FPDC:** French Drone Professional Union • **UAF:** French Airports Professional Union Introduction: The comments hereafter shall be considered as an identification of some of the major issues the French industry asks EASA to discuss with third-parties before any publication of the proposed regulation. In consequence, the following comments shall not be considered: As a recognition of the third-parties consultation process carried out by the • European Parliament and of the Council; As an acceptance or an acknowledgement of the proposed regulation, as a whole or of any part of it; As exhaustive: the fact that some articles (or any part of them) are not commented • does not mean FNAM and SNEH have (or may have) no comments about them, neither FNAM and SNEH accept or acknowledge them. All the following comments are thus limited to our understanding of the effectively published proposed

regulation, notwithstanding their consistency with any other pieces of regulation.



General comments :

FNAM and SNEH thank EASA for the will of harmonizing the applicable dispositions in terms of flight time limitations for HEMS operations throughout Europe in order to warrantee a high level of safety. However, considering the HEMS national specificities (French HEMS missions represent 17% of the European HEMS missions), a proportionate approach tailored to the local specificities needs to be considered. The current RIA of this NPA should be further developed for a better maturity and should take into account the French national specificities.

(Cf. comments #517 to 521)

Generally speaking, FNAM and SNEH think that the proposed requirements for HEMS would benefit and enhance safety in being clearer and more user friendly. The proposed requirements for HEMS show numerous inconsistencies (there are some numbering issues, nonsenses and contradictions leading to misunderstandings of this NPA). Therefore, it is really hard for the Profession to elaborate final and comprehensive comments due to the difficulty in comprehension of this proposed regulation.

For instance, the structure and the references within this NPA lead to confusion regarding the applicability of the Certification Specifications for HEMS, indeed it is not explicit whether:

- All the CS.FTL.3 requirements shall be applicable "in block"
- The CS requirements should apply depending on what is said in the implementing rule
- Cherry-picking is allowed

(Cf. comments #473, #478, #496, #510, #511)

It is feared that the complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation which is contrary to the safety goal.

In order to comment properly the proposed requirements, the stakeholders need to understand the whole proposition. Numerous points merit clarification. The comments made thereafter need to be analyzed in light of FNAM and SNEH's current understanding of this NPA.

At the time being, FNAM and SNEH fear that each and every stakeholder will interpret this NPA according to its understanding which might act as a hindrance to the level playing field contrary to the initial goal.

French Organization

In France, the HEMS is a peculiar matter since it is a public service delegation from the Directorate of Health Care Supply (Direction Générale de l'Offre des Soins – DGOS) branch of the French Health Ministry.

HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care services is a public servicedefined in the French Health Code & a sovereign prerogative), with groupings of medical equipment and skills.

HEMS in France is both operated by private operators and the State(Civil Security, Gendarmerie or Army) for the sake of the DGOS.

Regarding the private operators, there are 49 HEMS bases (corresponding to a total of 47 HEMS helicopters) in metropolitan France and overseas (including in Cayenne and in the Reunion Island) whose air transport business is conducted by 5 operators. These operators' helicopters are based at the hospital for which they work and are permanently equipped with medical equipment.

**** * * The contracts are awarded by each hospital or are pooled at pilot hospital which is responsible for the public contract and which, in some cases, spreads the flight hours between each hospital keeping a helicopter based for its sanitary transport needs.

Additionally, the State may charter private operators to operate HEMS operations on its behalf.

Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved.

Such a possibility shall remain for "Force majeure", in respect of the sovereignty of each Member State facing major health crisis.

Although delegated to private operators, the HEMS in France remains a public service mission whose latitude for the application of the newly proposed Article 8 of this NPA applies for the Member States at any time.

#2 major characteristics

2 major characteristics arise from the French healthcare organization:

- The operational readiness with really short response time in order to warrantee the patient's odds of survival (3 work paces are in force in France : H12, H14 and H24 operations; to simplify, only the H12 example will be developed afterwards)
- The unpredictability of the flight times

This is the current French HEMS organization, linked with the French Health Ministry nowadays. In France, the President of the Republic and his government has made the commitment to the French people to warrantee an access to emergency care in less than 30 minutes from anywhere on the French territory.

Considering the unpredictability of the HEMS operations, the flight times are not known in advance and cannot be scheduled *ex-ante*. Hence, all the CAT.A FTL philosophy (building a FDP and a DP around sectors [FT] and computing the duration of the required rest that has to be taken before the next FDP as Max [12h ; Previous DP]) does not suit the HEMS operations. The FDP's content cannot be scheduled in advance (unscheduled allocation in a scheduled FDP).

Hence, the attempt to adapt the CAT.A FTL implementing rules to the specificities of the HEMS leads to a dead-end since the philosophy is completely different. Therefore, it may be considered if elaborating a new regulation from scratch would not be more appropriate.

French rostering organization

In France, the most usual rostering is usually 7 days ON at home base / 7 days OFF (implying a rest period + FDP < 24h, 7 times in a row), with a need for a H12 operational readiness (or a 12h shift in H24). This proposed European regulation, does not allow the French operators to comply with the French work pace defined and contracted by the French healthcare system. Moreover, in order to ensure a better quality of teamwork and to enhance safety, the French rostering organization is the same for pilots and doctors, they work in the same time slots (H12 or H14). Hence, all these new requirements will lead to amend all the French Health National practices (to that extend, the analysis of EASA would gain from considering further all economic and social issues it will raise). Indeed, considering the French work pace:

On the one hand, in the proposed European regulation, there is a minimum duration for pre-flight of 30 minutes. This new requirement of a 30 minutes pre-flight will imply either a 30 minutes increase of the FDP or a 30 min decrease of the operational readiness. In France, 7%ⁱ of flights saving lives would be impossible with a 30 minutes preflight. (cf. SNEH illustrative Table in attachment)

On the other hand, in the proposed European regulation, there is a minimum duration for post-flight at the end of (the last flight time of) the FDP of 15 minutes (and FNAM and SNEH would like to highlight the fact that the definition of this post-flight seems unclear and may lead to confusion). This new requirement of a 15 minutes post-flight at the end of (the last flight time of) the FDP will imply both a 15 minutes increase of the DP and a 15 minutes decrease of the time slot available for the required rest.

Besides, if the FDP is lasting more than 10h, a 1 hour break is requested in the proposed dispositions of the NPA for single pilot + 1 TCM operations. In France all scheduled effective operational FDPs are 12h as explained before, so the 1h break requirement will always need to be fulfilled. Just as for flight times, due to the unpredictability of the HEMS missions, the break has to be unscheduled and the operator should ensure *ex-post* that the break requirement has been fulfilled for pilots. Besides the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour. Else, this will would overlap with national social regulations and the definition of working time.

Therefore, considering the French work pace, in order to have a 12h operational readiness with the proposed FTL European requirements, there is always a need for at least a 12h30 max FDP (which implies a 12h45 DP) with a 1h unscheduled time period allowed for physiological needs (which cannot be a rest period free of all duties). As a consequence, the time slot available for rest is 11h15 (24h - 12h45 = 11h15) while the rest required by this NPA would be 12h45. Therefore, all French HEMS operators will need to use systematically reduced rest and thus, all French HEMS operators will need to have a FRM (which seems disproportionate to the size of the involved operators). Moreover, as soon as there is one scheduled FDP lasting more than 12h (always the case in France since there is always a need for at least a 12h30 FDP), no more than 4 consecutive FDPs can be scheduled. Thus, the usual French rostering 7 days ON at home base / 7 days OFF cannot be respected, despite its efficiency in terms of safety, fatigue and quality of life for crews, has been proven from experience. As said in the RIA, no risk has been shown regarding safety or fatigue with the current regulation. Indeed, the total amount of flight times for pilots is quite low, a lot of time can be spent for rest, and the working pace of 7 days ON / 7 days OFF does not appear more tiring. On the contrary, the working pace of 7 days ON / 7 days OFF is better for the labor organization and is bringing a better quality of life for pilots who do not live near the HEMS operating base. Indeed pilots prefer to work 7 days in a row and then be 7 days OFF instead of working 1 day and resting the next day (which appears more tedious and exhaustive). ***

Conclusion

The impact of the implementation of European FTL regulation for HEMS in France goes beyond the French operators. It is a complete change of the whole French Health care system which might be necessary. Thus, it would be appreciated if the RIA addresses the impacts on the national policy for emergency access to care and the Government Health policy, etc.

Many lifesavings would be impossible with proposed FTL schemes. (Cf. attachments S1, S2, S3 and S4)



As a consequence, 3 options emerge and are listed here below, ranked according to their level of relevance for FNAM and SNEH:

OPTION A or option 0 of the RIA

This option, whose choice relies on the Member States (MS) or EASA's decision, corresponds to the option 0 described in the RIA: no policy change. Safety impact, social impact and economic impact are neutral or having a little impact. The solution 0 is the proper answer to a one size fits all model which is not applicable to the industry. The FTL shall stay in the hand of the local authority. The well-functioning current national FTL schemes are enforced for years, no excessive fatigue has been demonstrated and the current national system provides French operators with satisfaction. Besides, in the EMS safety risk assessment of this NPA, it is written that *"Even with the caveats about under-reporting of fatigue as a causal factor it would appear from the occurrence data that the controls that have been in place to manage fatigue in European EMS have generally been effective. Compared to the social benefits from EMS operations in terms of patient safety and health (see below), the overall safety balance (flight safety v patient safety) is very positive". FNAM and SNEH strongly ask this option to be considered by EASA and the Member States : <i>"no change in the existing situation; HEMS continue to be regulated under MS national rules".*

OPTION B

This option consists in a total revamp of the NPA 2017-17 for HEMS. FNAM and SNEH ask for a completely new proposal, distinguishing the HEMS from AEMS and Air Taxi as no operational comparison can be made between the fundamentals of these different activities and respecting the following principles:

- Basing an alternative proposal on:
 - 14h Standby / 10h Rest with a commander's discretion applicable in case of unforeseen circumstances
 - o short-time operational readiness for ready-to-go EMS take-off
 - rostering of 7 days ON / 7 days OFF
 - o flight time limitations to be discussed within this frame

FNAM and SNEH ask for this option to be considered in the Comment Response Document (CRD) with the elaboration of a sound RIA. Moreover, FNAM and SNEH would be happy to offer its expertise to discuss and study this subject with EASA policy officers. Besides, for clarity reasons, this would imply to separate, regarding the FTL scope, the HEMS from CAT, Air Taxi and AEMS operations.

OPTION C

If these 2 first options are not retained, FNAM and SNEH ask for this proposed NPA to be amended and reviewed as stated in the following comments. The proposed requirements, as it is, will lead to amend Health National regulations and it will request more crew, more constraints, more costs with a low added safety value as stated in the RIA. The main proposals are laid down here below:

• The "Flight time" (instead of "sector" whose definition is now restricted to aeroplanes) in all the requirements should not be scheduled as they cannot be in real life



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

	 The travelling time between multiple HEMS operating bases of the home base should be increased a minima to 120 minutes (instead of 60 minutes) and in case of change of home base, the ERRP after starting duty (and not the one prior to starting duty) should be increased to allow the continuity of the operations The duration of pre-flight, post-flight or inter-flights should be suppressed and replaced by "a sufficient time determined by the operator and specified in the operating manual" (in France, 7%¹of flights saving lives would be impossible with a 30 minutes preflight, cf. SNEH illustrative Table in attachment) No limitations on the number of consecutive FDP lasting more than 12h should be made between 2 extended recovery rest periods For single-pilot + 1 TCM operations, in the case of a FDP lasting more than 10h, the break should be unscheduled and the operator should ensure ex-post that the break requirement has been fulfilled for pilots as they cannot be in real life The commander's discretion prior to take-off under unforeseen circumstances needs to be extended to all the EMS payload and not only limited to the patient and extended up to 2 hours for 1 pilot + 1 TCM operations (in France, 3%¹ of flights saving lives would be impossible with a commander's discretion capped to 1 hour, cf. SNEH illustrative Table in attachment) The limitations of the maximum values for continuous FT need to be increased by at least 1 hour The limitations of the maximum values for total flight time within a FDP need to be increased by at least 1 hour The 10% allowance between scheduled and actual FDP is not appropriate with the HEMS operations and needs to be suppressed The standby needs to be reviewed else it will never be used
	These elements of the aforementioned proposal form an integrated whole, they are each and all interrelated and interdependent.
	The 3 options all respect the general FTL philosophy and the learnings of fatigue impact
	assessments. This proposal would increase by 20% the French State budget allocated for the HEMS activity which is not affordable according to the French State. Since the objective of this regulation is not flight safety but the harmonization of the different national regulations regarding HEMS, the text should not have the opposite effect leading to less level playing field. If the proposed dispositions are inapplicable, there may be non-binding opt-in / opt-out system possibilities (through the newly proposed Article 8 of this NPA). Misunderstanding or interpretation of National level of a far too complex regulation for small operators might also lead to lower level playing field.
response	Please see the answer to comment # 54.

comment 524

comment by: ADAC Luftrettung gGmbH

This new regulation aims to increase flight safety on one hand and harmonization of the natonal regulations on the other hand. But harmonization does not make sence in this context, when different requirements of member states are not considered.



With the 2. DVLuftBO § 22-23 of the German FTL regulation, there is a well proven FTL regulation exspecially for HEMS in force for years, that is based on a scientific studie and takes into account the special circumstances in our country our environment. Today we have a history of more than 50 years of HEMS operation in Germany. Never in this period of time FTL or fatigue have been reported as a reason for an accident or incident. International accident investigations in HEMS operations (referenced in Attachment II of NPA 2017-17) that identified fatigue as a major contributor to the accident have one thing in common: exceedance of existing regulations. Therefor new regulations won't mitigate the risk since they don't fight the root cause.

Formal error: expert opinions discussed in RMT.0492 / RMT.0493 are not considered in the rule making. NPA development and publication without implementation of interested parties.

What scientific research results lead to the definition of maximum daily flight time and length of duty periods? There is no reference to any special study focusing on HEMS.

In fixed wing operations a 16h FDP is allowed although pilots need to be alert all the time to react to any unforeseen event e.g. warning lights et cetera. In HEMS operations cockpit time is limited to single legs with an average length of less than 20 minutes. This discriminates HEMS against fixed wing pilots.

There is no similar regulation for CAT operations with helicopters other than HEMS. Instead national law of the member states is still in place that allows for much more flight time. This is a disadvantage for HEMS pilots.

Due to the possible variations of split duty the length of a daily duty period is not predictable in advance. With that uncertainty planning is impossible for crews as well as operators.

Today rescue helicopter availability time in Germany is limited to 14:45h (+ pre- and post flight checks). To cover this period in accordance with NPA 2017-17, it would be necessary to implement shift duties. This will lead to an additional requirement of up to 30% more CHPL pilots. Such an amount of qualified personnel is currently not available on the market (extra cost, strong social impact on working conditions of pilots).

This impact is insufficiently considered in the NPA development.

Additional number of pilots in combination with constant level of mission frequency and flight time will lead to less mission experience for every single crew member that needs to be compensated with additional training and training flights (high financial impact).

Impact on privacy and fundamental rights due to reduced rest prerequisite to sleep at home base. Crew members have to stay on base during their rest period although they are free of duty.

Due to the diversity of possible exemptions, NPA 2017-17 is difficult to handle for the personnel because they need to calculate FDP and duty time in relation with breaks all the time. Advance planning of mission availability is not possible.



For crew living more than 90 minutes away from home base, guidance material recommends to consider making arrangements for temporary accommodation closer to their home base.

This is an unacceptable interference with fundamental rights and has high financial impact either on crew or on operator.

Limitation of flight time depending on autopilot availability is not self-explaining, because there is no legal need to use the autopilot.

Question: What scientific data led to these limits with or without autopilot? If this limitation is based on fixed wing operation research, is it allowed to transfer the same times to rotor wing operation without further research?

A comparative study performed by DLR in 2017 showed in preliminary results that by changing the roster to 2-shift duties, subjective stress was increased by additional travel time, more frequent changes between duty periods and private time, unreliable/unplannable shift changes etc. This leads to a decrease of flight safety rather than an intended increase.

response

Please see the answer to comment # 54.

comment 546 comment by: Rüdiger Neu

Ziel der Verordnung soll eine Erhöhung der Flugsicherheit und eine Harmonisierung der Vorschriften sein. Eine Harmonisierung macht dabei aber keinen Sinn, wenn die unterschiedlichen Bedürfnisse und Belange der Mitgliedsstaaten dadurch nicht mehr berücksichtigt werden können.

In Deutschland gibt es mit der 2. DVLuftBO eine seit vielen Jahren bewährte FTL-Regelung für HEMS, welche auf einer wissenschaftlichen Studie basiert und die speziellen Bedingungen des Betriebs unseres Landes berücksichtigt.

Seit über 50 Jahren gibt es nun HEMS in Deutschland. In den ganzen Jahren ist es noch zu keinem Flugunfall oder Incident aufgrund von Flugdienst- und Ruhezeiten bzw. "Fatigue" gekommen.

Ggf. Formfehler, da auf die Experten der RMT.0492 / RMT.0493 nicht eingegangen wurde und nun die NPA eigenständig entworfen und veröffentlicht wurde.

Worin liegen die wissenschaftlichen Erkenntnisse für die Festlegungen, insbesondere der Flugstundenzahlen und Länge der jeweiligen Perioden? Der NPA ist zu entnehmen, dass keine spezielle Studie in Hinblick auf HEMS erhoben wurde?

Eine 16h-FDP ist im Flächenflugbereich problemlos möglich und dies obwohl die Piloten in der gesamten Zeit aufmerksam sein müssen, da jeden Moment eine Warnlampe oder anderes Ereignis stattfinden könnte. Im HEMS Betrieb besteht die fliegerische Aufgabe bei einem Rettungseinsatz in zeitlich kurzen Legs von durchschnittlich < 20 Minuten. Insofern besteht hier eine deutliche Benachteiligung.



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 21 of 585

Da es noch keine FTL für die Arbeitsfliegerei gibt könnte diese avisierte Regelung eine
Benachteiligung darstellen.

Durch die verschiedenen Varianten der Split Duty ist für den Piloten zum Dienstbeginn nicht klar, wie lange die FDP dauern kann. Dies macht eine Dienstplanung sowohl für den Piloten als auch für das Unternehmen unmöglich.

Da in Deutschland oftmals die Vorhaltezeit eines Rettungshubschraubers bei max. 14:45 Stunden liegt (zuzüglich der Vor- und Nachflugkontrollen), würde dies zwangsläufig zu einem Schichtdienst führen, wodurch die Anzahl der CHPL Piloten bis zu 30% aufgestockt werden müsste. Eine solche Anzahl von qualifizierten Piloten ist zurzeit auf dem Markt nicht verfügbar (hohe finanzielle Aufwendung, starker Einfluss auf die sozialen Bedingungen der Piloten). Dieser Impact ist im Rahmen der NPA nicht ausreichend berücksichtigt.

Eine Erhöhung der Pilotenanzahl bei gleichbleibender Einsatzfrequenz führt bei dem einzelnen Besatzungsmitglied zu einer geringeren Einsatzerfahrung, die dann ggf. durch Schulungen und Übungsflüge kompensiert werden müsste. (hohe finanzielle Aufwendung).

Einschränkung und Eingriff in die Privatsphäre und Grundrechte, da bei reduced rest auf Station geschlafen werden muss. Die Besatzungsmitglieder wären über Tage auf Station "eingesperrt", obwohl sie in der Ruhezeit frei hätten.

Die vorgeschlagene Regelung ist nicht praxistauglich, da der Pilot ständig die Zeiten im Auge haben muss. Eine Vorausplanung der Einsatzverfügbarkeit ist somit unmöglich.

Wohnt man mehr als 90 Minuten von der Station entfernt, so wird im guidance material empfohlen sich in der Nähe eine Unterkunft zu suchen. Dies beschränkt die freie Wahl des Wohnorts und stellt einen unzulässigen Eingriff in die Grundrechte dar.

Die Abhängigkeit der Flugzeitbegrenzung gekoppelt an einen Autopiloten (AP) kann nicht nachvollzogen werden, da die Nutzung des AP nicht zwingend ist. Fragestellung hierzu: Auf welcher Datenbasis wurde die Flugzeitbegrenzung mit und ohne AP festgelegt? Falls die Festlegung aus der Flächenfliegerei stammt, ist sie überhaupt auf die Hubschrauberfliegerei übertragbar?

Die vergleichende Studie der DLR in 2017 hat gezeigt, dass subjektiv die Belastung durch die Reisezeiten, den Wechsel zwischen Dienstbetrieb und Privat, sowie die unregelmäßigen/unplanbaren Wechselzeiten der Schichten durch das Einsatzaufkommen zugenommen hat und dadurch die Flugsicherheit eher gefährdet als verbessert wird.

response

Please see the answer to comment # 54.

comment 572

comment by: FinnHEMS Oy

Attachment #14

FinnHEMS Oy, as the national administrative unit for HEMS-operations in Finland, has the following general comments regarding the NPA 2017-17:



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 22 of 585 FinnHEMS is in favor of harmonization and standardization of the European regulations for helicopter operations to guarantee a high level of safety taking into account our following comments.

It shall be noted that in this NPA it is indeed acknowledged that there are no indications that the existing FTL requirements for HEMS, which are currently under national authority approvals, pose a flight safety problem.

The current finnish national regulation OPS M3-2 has made possible HEMS duty periods of 24-72 hours taking account the minimum standby time without duties during duty periods and the minimum rest time required after the duty period. This system has been in use for over 10 years in Finland and is proven to be very suitable concerning the national circumstances.

Preliminary results of an ongoing research of the Finnish Institute of Occupational Health together with FinnHEMS Research and Development Unit focusing on the "Working hours, sleep and sleepiness in HEMS personnel in Finland" reveals quite clearly that pilots and HEMS crew members experience little low alertness on duty regardless of whether the duty period is 24 or 48 hours. This study confirms the experience of the finnish HEMS branch during the last over ten years. These preliminary results are attached to this comment and the final report later this year will be available upon request.

The HEMS Duty Shifts up to 72 hours should be made possible also in the future to preserve effectiveness in operations because Finland is a sparsely populated country with long distances (up to 1000km) between crew homes and HEMS bases.

Several well proven mitigating actions are presently used to minimize the risks of tiredness during duty periods. These are for example the effective use of FRMS, strict requirements of rest without duties within duty periods, automated calculations of actual required rest requirements and use of standby by crews.

As a conclusion, FinnHEMS:

(1) strongly requests that HEMS would be separated from this set of regulation and a new NPA specific for HEMS FTL to be developed, taking into account relevant and updated scientific knowledge, when available

or;

(2) if (1) above is not possible, then FinnHEMS requests that the "Active Standby"-concept suggested by the finnish aviation authority Trafi is added to the rule (to be able to continue to operate as per today)

response

Please see the answer to comment # 54.

comment 637

comment by: Oya Vendée Hélicoptères

**** * * ***

Attachments <u>#15</u> <u>#16</u> <u>#17</u> <u>#18</u> <u>#19</u>

- OYA Vendée Hélicoptères : French helicopter operator in l'Ile d'Yeu
- SNEH: French Helicopters Operators Professional Union

Introduction:

The comments hereafter shall be considered as an identification of some of the major issues OYA Vendée Hélicoptères asks EASA to discuss with third-parties before any publication of the proposed regulation. In consequence, the following comments shall not be considered:

- As a recognition of the third-parties consultation process carried out by the European Parliament and of the Council;
- As an acceptance or an acknowledgement of the proposed regulation, as a whole or of any part of it;
- As exhaustive: the fact that some articles (or any part of them) are not commented does not mean OYA has (or may has) no comments about them, neither OYA accepts or acknowledge them. All the following comments are thus limited to our understanding of the effectively published proposed regulation, notwithstanding their consistency with any other pieces of regulation.

General comments :

OYA thanks EASA for the will of harmonizing the applicable dispositions in terms of flight time limitations for HEMS operations throughout Europe in order to warrantee a high level of safety. However, considering the HEMS national specificities (French HEMS missions represent 17% of the European HEMS missions), a proportionate approach tailored to the local specificities needs to be considered. The current RIA of this NPA should be further developed for a better maturity and should take into account the French national specificities.

(Cf. comments #696 to 700)

Generally speaking, OYA thinks that the proposed requirements for HEMS would benefit and enhance safety in being clearer and more user friendly. The proposed requirements for HEMS show numerous inconsistencies (there are some numbering issues, nonsenses and contradictions leading to misunderstandings of this NPA). Therefore, it is really hard for the Profession to elaborate final and comprehensive comments due to the difficulty in comprehension of this proposed regulation.

For instance, the structure and the references within this NPA lead to confusion regarding the applicability of the Certification Specifications for HEMS, indeed it is not explicit whether:

All the CS.FTL.3 requirements shall be applicable "in block"

- The CS requirements should apply depending on what is said in the implementing rule
- Cherry-picking is allowed

(Cf. comments #653, #658, #676, #689, #690)

 TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.
 Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.
 Page 24 of 585

It is feared that the complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation which is contrary to the safety goal.

In order to comment properly the proposed requirements, the stakeholders need to understand the whole proposition. Numerous points merit clarification. The comments made thereafter need to be analyzed in light of OYA's current understanding of this NPA.

At the time being, OYA fears that each and every stakeholder will interpret this NPA according to its understanding which might act as a hindrance to the level playing field contrary to the initial goal.

French Organization

In France, the HEMS is a peculiar matter since it is a public service delegation from the Directorate of Health Care Supply (Direction Générale de l'Offre des Soins – DGOS) branch of the French Health Ministry.

HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care services is a public servicedefined in the French Health Code & a sovereign prerogative), with groupings of medical equipment and skills.

HEMS in France is both operated by private operators and the State(Civil Security, Gendarmerie or Army) for the sake of the DGOS.

Regarding the private operators, there are 49 HEMS bases (corresponding to a total of 47 HEMS helicopters) in metropolitan France and overseas (including in Cayenne and in the Reunion Island) whose air transport business is conducted by 5 operators. These operators' helicopters are based at the hospital for which they work and are permanently equipped with medical equipment.

The contracts are awarded by each hospital or are pooled at pilot hospital which is responsible for the public contract and which, in some cases, spreads the flight hours between each hospital keeping a helicopter based for its sanitary transport needs.

Additionally, the State may charter private operators to operate HEMS operations on its behalf.

Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved. Such a possibility shall remain for "Force majeure", in respect of the sovereignty of each Member State facing major health crisis.

Although delegated to private operators, the HEMS in France remains a public service mission whose latitude for the application of the newly proposed Article 8 of this NPA applies for the Member States at any time.

#2 major characteristics

2 major characteristics arise from the French healthcare organization:

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 25 of 585

- The operational readiness with really short response time in order to warrantee the patient's odds of survival (3 work paces are in force in France : H12, H14 and H24 operations; to simplify, only the H12 example will be developed afterwards)
- The unpredictability of the flight times

This is the current French HEMS organization, linked with the French Health Ministry nowadays. In France, the President of the Republic and his government has made the commitment to the French people to warrantee an access to emergency care in less than 30 minutes from anywhere on the French territory.

Considering the unpredictability of the HEMS operations, the flight times are not known in advance and cannot be scheduled ex-ante. Hence, all the CAT.A FTL philosophy (building a FDP and a DP around sectors [FT] and computing the duration of the required rest that has to be taken before the next FDP as Max [12h ; Previous DP]) does not suit the HEMS operations. The FDP's content cannot be scheduled in advance (unscheduled allocation in a scheduled FDP).

Hence, the attempt to adapt the CAT.A FTL implementing rules to the specificities of the HEMS leads to a dead-end since the philosophy is completely different. Therefore, it may be considered if elaborating a new regulation from scratch would not be more appropriate. ***

French rostering organization

In France, the most usual rostering is usually 7 days ON at home base / 7 days OFF (implying a rest period + FDP < 24h, 7 times in a row), with a need for a H12 operational readiness (or a 12h shift in H24). This proposed European regulation, does not allow the French operators to comply with the French work pace defined and contracted by the French healthcare system. Moreover, in order to ensure a better quality of teamwork and to enhance safety, the French rostering organization is the same for pilots and doctors, they work in the same time slots (H12 or H14). Hence, all these new requirements will lead to amend all the French Health National practices (to that extend, the analysis of EASA would gain from considering further all economic and social issues it will raise).

Indeed, considering the French work pace:

On the one hand, in the proposed European regulation, there is a minimum duration for pre-flight of 30 minutes. This new requirement of a 30 minutes pre-flight will imply either a 30 minutes increase of the FDP or a 30 min decrease of the operational readiness. In France, 7%ⁱ of flights saving lives would be impossible with a 30 minutes preflight. (cf. SNEH illustrative Table in attachment)

On the other hand, in the proposed European regulation, there is a minimum duration for post-flight at the end of (the last flight time of) the FDP of 15 minutes (OYA would like to highlight the fact that the definition of this postflight seems unclear and may lead to confusion). This new requirement of a 15 minutes post-flight at the end of (the last flight time of) the FDP will imply both a 15 minutes increase of the DP and a 15 minutes decrease of the time slot available for the required rest.

**** * * *+.+* Besides, if the FDP is lasting more than 10h, a 1 hour break is requested in the proposed dispositions of the NPA for single pilot + 1 TCM operations. In France all scheduled effective operational FDPs are 12h as explained before, so the 1h break requirement will always need to be fulfilled. Just as for flight times, due to the unpredictability of the HEMS missions, the break has to be unscheduled and the operator should ensure ex-post that the break requirement has been fulfilled for pilots. Besides the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour. Else, this will would overlap with national social regulations and the definition of working time.

Therefore, considering the French work pace, in order to have a 12h operational readiness with the proposed FTL European requirements, there is always a need for at least a 12h30 max FDP (which implies a 12h45 DP) with a 1h unscheduled time period allowed for physiological needs (which cannot be a rest period free of all duties). As a consequence, the time slot available for rest is 11h15 (24h - 12h45 = 11h15) while the rest required by this NPA would be 12h45. Therefore, all French HEMS operators will need to use systematically reduced rest and thus, all French HEMS operators will need to have a FRM (which seems disproportionate to the size of the involved operators). Moreover, as soon as there is one scheduled FDP lasting more than 12h (always the case in France since there is always a need for at least a 12h30 FDP), no more than 4 consecutive FDPs can be scheduled. Thus, the usual French rostering 7 days ON at home base / 7 days OFF cannot be respected, despite its efficiency in terms of safety, fatigue and quality of life for crews, has been proven from experience. As said in the RIA, no risk has been shown regarding safety or fatigue with the current regulation. Indeed, the total amount of flight times for pilots is quite low, a lot of time can be spent for rest, and the working pace of 7 days ON / 7 days OFF does not appear more tiring. On the contrary, the working pace of 7 days ON / 7 days OFF is better for the labor organization and is bringing a better quality of life for pilots who do not live near the HEMS operating base. Indeed pilots prefer to work 7 days in a row and then be 7 days OFF instead of working 1 day and resting the next day (which appears more tedious and exhaustive).

Conclusion

The impact of the implementation of European FTL regulation for HEMS in France goes beyond the French operators. It is a complete change of the whole French Health care system which might be necessary. Thus, it would be appreciated if the RIA addresses the impacts on the national policy for emergency access to care and the Government Health policy, etc.

Many lifesavings would be impossible with proposed FTL schemes. (Cf. attachments S1, S2, S3 and S4)

As a consequence, 3 options emerge and are listed here below, ranked according to their level of relevance for OYA:

OPTION A or option 0 of the RIA

This option, whose choice relies on the Member States (MS) or

EASA's decision, corresponds to the option 0 described in the RIA: no policy change. Safety impact, social impact and economic impact are neutral or having a little impact. The solution 0 is the proper answer to a one size fits all model which is not applicable to the industry. The FTL shall stay in the hand of the local authority. The well-functioning current

**** * * *+.+* national FTL schemes are enforced for years, no excessive fatigue has been demonstrated and the current national system provides French operators with satisfaction. Besides, in the EMS safety risk assessment of this NPA, it is written that "Even with the caveats about under-reporting of fatigue as a causal factor it would appear from the occurrence data that the controls that have been in place to manage fatigue in European EMS have generally been effective. Compared to the social benefits from EMS operations in terms of patient safety and health (see below), the overall safety balance (flight safety v patient safety) is very positive". OYA strongly asks this option to be considered by EASA and the Member States : "no change in the existing situation; HEMS continue to be regulated under MS national rules".

OPTION B

This option consists in a total revamp of the NPA 2017-17 for HEMS. OYA asks for a completely new proposal, distinguishing the HEMS from AEMS and Air Taxi as no operational comparison can be made between the fundamentals of these different activities and respecting the following principles:

- Basing an alternative proposal on:
 - 14h standby / 10h Rest with a commander's discretion applicable in case of unforseen circumstances
 - o short-time operational readiness for ready-to-go EMS take off
 - rostering of 7 days ON / 7 days OFF
 - \circ ~ flight time limitations to be discussed within this frame

OYA asks for this option to be considered in the Comment Response Document (CRD) with the elaboration of a sound RIA. Moreover, OYA would be happy to offer its expertise to discuss and study this subject with EASA policy officers. Besides, for clarity reasons, this would imply to separate, regarding the FTL scope, the HEMS from CAT, Air Taxi and AEMS operations.

OPTION C

If these 2 first options are not retained, OYA asks for this proposed NPA to be amended and reviewed as stated in the following comments. The proposed requirements, as it is, will lead to amend Health National regulations and it will request more crew, more constraints, more costs with a low added safety value as stated in the RIA. The main proposals are laid down here below:

- The "Flight time" (instead of "sector" whose definition is now restricted to aeroplanes) in all the requirements should not be scheduled as they cannot be in real life
- The travelling time between multiple HEMS operating bases of the home base should be increased a minima to 120 minutes (instead of 60 minutes) and in case of change of home base, the ERRP after starting duty (and not the one prior to starting duty) should be increased to allow the continuity of the operations
- The duration of pre-flight, post-flight or inter-flights should be suppressed and replaced by "a sufficient time determined by the operator and specified in the operating manual" (in France, 7%ⁱof flights saving lives would be impossible with a 30 minutes preflight, cf. SNEH illustrative Table in attachment)

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.Page 28 of 585

- No limitations on the number of consecutive FDP lasting more than 12h should be made between 2 extended recovery rest periods
- For single-pilot + 1 TCM operations, in the case of a FDP lasting more than 10h, the break should be unscheduled and the operator should ensure ex-post that the break requirement has been fulfilled for pilots as they cannot be in real life
- The commander's discretion prior to take-off under unforeseen circumstances needs to be extended to all the EMS payload and not only limited to the patient and extended up to 2 hours for 1 pilot + 1 TCM operations (in France, 3%ⁱ of flights saving lives would be impossible with a commander's discretion capped to 1 hour, cf. SNEH illustrative Table in attachment)
- The limitations of the maximum values for continuous FT need to be increased by at least 1 hour
- The limitations of the maximum values for total flight time within a FDP need to be increased by at least 1 hour
- The 10% allowance between scheduled and actual FDP is not appropriate with the HEMS operations and needs to be suppressed
- The standby needs to be reviewed else it will never be used

These elements of the aforementioned proposal form an integrated whole, they are each and all interrelated and interdependent.

The 3 options all respect the general FTL philosophy and the learnings of fatigue impact assessments.

This proposal would increase by 20% the French State budget allocated for the HEMS activity which is not affordable according to the French State.

Since the objective of this regulation is not flight safety but the harmonization of the different national regulations regarding HEMS, the text should not have the opposite effect leading to less level playing field. If the proposed dispositions are inapplicable, there may be non-binding opt-in / opt-out system possibilities (through the newly proposed Article 8 of this NPA). Misunderstanding or interpretation of National level of a far too complex regulation for small operators might also lead to lower level playing field.

response

Please see the answer to comment # 54.

comment 802

comment by: European Helicopter Association (EHA)

Page 29 of 585

The European Helicopter Association (EHA) is in favor of harmonization and standardization of the European regulations for helicopter operations to guarantee a high level of safety.

However, when harmonization is mainly pursued in the name of a level playing field that is hardly applicable to FTL schemes, we believe that the main objective is destined to fail. The concept of level playing field is also reflected in the NPA where it is indeed acknowledged that there are no indications that the existing FTL requirements for HEMS, which are currently under national authority approvals, pose a flight safety problem.

**** * * *** We believe and are providing evidence through our comments, that this NPA instead of increasing the overall safety of the HEMS operations, will potentially create more problems like for example having to amend in some countries the national health regulations, having to require more crew, more constraints and more costs with a low added safety value.

The European HEMS operations is characterized by a vast number of different operating patterns. The diversified operating patterns have been developed and matured over a long period of time and are necessary to perform safe and affordable HEMS operations in very different operating environments and in accordance with different requirements (including national laws concerning ambulance and rescue services). The different operating patterns are the result of many factors (as presented in the EHA/EHAC FTL data collection), many of them with a direct impact on suitable FTL schemes.

We believe that harmonizing and standardizing European HEMS FTL requirements is not practicable unless the harmonization and standardization is at a framework level where the actual details are left up to the national authorities.

It is the EHA's opinion that the parts of the NPA pertaining to HEMS have been conceived using a general lack of supporting data, an incomplete pre-RIA report and very few relevant or outdated scientific publications concerning fatigue in HEMS operation. Furthermore, obtaining sufficient data during the rule making process has been a challenge. The specific objective of this proposal was to establish an improved and proportionate Europe-wide basis for regulating flight and duty times and rest periods for HEMS, based on scientific knowledge and established best practices. We feel that this has not been achieved.

Therefore, we are of the opinion that the new FTL requirements for HEMS, as envisioned in the NPA, will force many operators to use Article 14-6 or 22-2 flexibility provision and apply for an Individual Flight Time Specification Scheme (IFTSS), i.e. "Option 1 - Flexible approach". This means that the objectives of the new FTL for HEMS will not be achieved as far as contributing to the high uniform level of civil aviation safety, providing a level playing field and facilitate the free movement of goods, persons and services.

EHA believes that "Option 2 - Fully prescriptive approach" would make it very difficult to recruit suitable experienced/qualified crew members and at the same time it will lead to a lack of recency (the same amount of missions would be flown by a substantially higher number of crew members (in many cases by as much as 44% more crew members sharing basically same amount of missions). To maintain the same level of service and safety standard, the cost increase would typically run in the range of 20% to 49%. Although HEMS is a Commercial Air Transportation (CAT) task, HEMS are typically a public service matter funded by tax money. The health authorities in many Member States will not be able to handle these type of cost increases. The alternative is a substantial reduction of the overall level of safety and/or service, but this is a scenario that cannot be accepted either. Additionally, the risk of fatigue will potentially increase, in many cases, due to heavy commuting.

EHA agrees that "Option 1 - Flexible approach" could work as it would have the benefit of forcing the operators to demonstrate a safe operation. According to information given to the EHA, an operator with only two HEMS operating bases has estimated a cost, excluding authority fees, of up to 300 000 \in to establish an IFTSS and then 20 000 \in per year to maintain it. Another operator with 12 HEMS operating bases has estimated a cost, excluding authority fees, of 600 000 \in to establish, and then another 40 000 \notin per year to

maintain, an IFTSS. As obtaining an IFTSS is quite costly, this will not be practicable for many small operators or their customers (state, county etc.) and at the end, it would also prevent new operators to enter the market or for established operators to expand. Another important concern is that the FTL itself would still limit somehow what can be achieved with an IFTSS, thus leading to many of the negative safety impacts of "Option 2 – Fully prescriptive approach".

In conclusion, it is EHA's view that EASA has been given an impossible task under the present circumstances and that at least for the time being, the only suitable solution for HEMS FTL is "Option 0 - No policy change" as it will have a neutral safety impact, if operations remain predominantly in the Member State that issues the Air Operator Certificate.

EHA would be happy to assist EASA during the development of a new NPA specific for HEMS FTL where relevant and updated scientific knowledge, when available, is used.

response

Please see the answer to comment # 54.

comment	870 comment by: Stephanie Selim	
	DGAC France would like to thank EASA for this NPA and the harmonisation it will bring in terms of flight times limitations.	
response	Please see the answer to comment # 54.	

comment 872

comment by: Stephanie Selim

General comments about HEMS operations :

However, considering the HEMS operations, we think that this NPA is not mature enough and this subject would need a sound RIA taking into account the different types of organisations in the different countries. Currently, this RIA does not consider the national health care systems. It appears to us that this NPA does not fit the French organisation of health care and would lead

to an additional expense of 15 million euros according to French Health's Ministry that it will not be possible to engage for the State, for a benefit in terms of safety which is not demonstrated by the RIA.

HEMS organisation in France:

In France, HEMS is a public service delegation from the Directorate of Health Care Supply (Direction Générale de l'Offre des Soins – DGOS) branch of the French Health's Ministry. HEMS depends on the organisation of the French healthcare system (the permanence and continuity of care services is a public service defined in the French Health Code & a sovereign prerogative), with groupings of medical equipment and skills. The financing of HeliSMUR (helicopters provided for Emergency Medical Services in France) is guaranteed by a national endowment allocated to hospitals headquarters of HeliSMUR by the Health's Ministry.



HEMS in France is both operated by private operators and State (Civil Security, Gendarmerie or Army) for the sake of the DGOS.

Regarding the private operators, there are 49 HEMS bases (corresponding to a total of 47 HEMS helicopters) in metropolitan France and overseas (including French Guyana and Reunion Island) whose air transport business is conducted by 5 operators. These operators' helicopters are based in the hospital for which they work and are permanently equipped with medical equipment. Only 11 HeliSMUR bases can have a highly complementarity with the State helicopter fleet due to their proximity to coastal zone or mountain zone, allowing rapid support in the case of reduced availability of the HeliSMUR.

The contracts are awarded by each hospital or are pooled at a pilot hospital which is responsible for the public contract and which, in some cases, spreads the flight hours between each hospital keeping a helicopter based for its sanitary transport needs.

In France, the most usual rostering is usually 7 days ON at HEMS base / 7 days OFF, with a need for a H12 operational readiness (or a 12h shift in H24). The operating range of HeliSMUR is 12 hours for 16 bases (15 helicopters), 14 hours for 15 bases (14 helicopters) and 24 hours for 18 bases (18 helicopters). The organizations of session are built on similar working hours for doctors and crews, ie 12 hours or 14 hours, to facilitate their operation on similar work schedules. These principles consolidate the quality and safety of teamwork, whether medical or flying.

Contrary to other European countries, helicopters are located on the landing platform of hospitals rather than domestic aerodromes. This location is useful to avoid ground relays when aircraft are positioned on airfields away from hospitals.

This positioning of the helicopters on the hospitals allows triggering without wasting time for the patient, medical teams being close to the crews.

HeliSMUR are helicopters equipped with biomedical equipment to take care of patients which are fixed in the passenger compartment for safety, which does not allow to quickly transfer the equipment to another aircraft.

In 2016, the annual HeliSMUR activity represented 11,000 HEMS interventions for victims outside hospitals and 17,500 HEMS interventions for urgent transfers of patients between hospitals. The current policy is to reinforce the use of the helicopter vector in these time slots of activity, thanks to an increased recourse of the doctors control centre for this means of intervention to optimize its availability with regard to the saved time for the victim and the operating cost of this vector.

HEMS pilots workload in France:

Currently, the flight time per crew remains low with an average of 1h30 per day, which requires increased vigilance from operators and pilots to maintain skills. The periods of inactivity for the crews are currently significant in view of averages of 1h30 flight time per 12h duty time. Flight crews fly between 90 and 150h a year, which is very low for professional flight crews, and far from what is developed in the NPA. It is also underlined that single-pilot operations in HEMS are now not "real" single-pilot operations as pilots are assisted by a TCM who can alleviate the pilot's tasks. HEMS operations are mostly urgent missions unpredictable in time, of short flight time (between 30 minutes to 45 minutes, and less than 50 NM), most for vital traumatic emergencies where the rapid availability of the medical teams and the helicopter remains the priority standard and outside the hospital domain like near a road during an accident.

Other missions of longer flight time where hospital medical teams ensure between two hospitals with known FATO the care of a patient whose state urgently requires intensive treatment of resuscitation during his transfer (flight time between 45 minutes to and 75 minutes). Most of them deal with cardiac surgery, neurosurgery and paediatric vital emergencies.

Economic impact of the NPA:

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.Page 32 of 585Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.Page 32 of 585

	Regarding the economic dimension for France, the new regulation will have a huge economic impact on the public expenditure of the French State and ultimately on the population in the HEMS service. According to the French Health Ministry, the impact would represent an additional expense of 15 million euros, which it will not be possible to engage for the State. In the event that the need for an increase in the number of pilots and TCM to carry out the activity is not possible for reasons of unavailable resources or budgetary cost, the reduction in the amplitude of access to the helicopter HEMS would be considerable with a loss of 1 825 hours or 152 days of availability for emergency medical service operations. This situation is not acceptable for France.
	<u>Conclusion:</u> In France, the President of the Republic and his Government have made the commitment to guarantee an access to emergency care in less than 30 mn from everywhere on the French territory. This assumes both operational readiness for EMS, especially thanks to ready-to-go helicopters take-offs, and unpredictability of flight times. The proposed measures of this NPA regarding for example the break for FDP over 10 hours (CS.FTL.3 205 (b)(2)), or the minimum duration of the pre-flight (which activates FDP) and post-flight duties (CS.FTL.3 205 (b)(4)) are non-consistent with the unpredictable nature of HEMS operations. Moreover, they will have a huge economic and social impact in France. In addition, reducing duty time will increase the number of pilots needed to guarantee the same HEMS activity, which could become an issue considering both the lack of experienced pilots on the labour market and the reduction of flying time per pilot who already fly very few hours per year as commercial pilots and for whom fatigue is not an issue, which creates a new risk of skill maintenance. Finally, this NPA, which is presented as not being an improvement for safety in the RIA, will have negative impacts on safety, besides negative social and economic impacts.
	That is the reasons why DGAC France would like the future FTL opinion not to take consideration of HEMS operations as proposed and choses the option 0 described in the RIA (no policy change). However, if this French position is not accepted, we provide hereafter detailed comments about proposed measures on HEMS in the HEMS part of the NPA.
response	Please see the answer to comment # 54.
comment	873 comment by: Stephanie Selim
	General comment on duty times :
	This NPA places on the same level flights to perform an air-taxi or EMS operation on one hand, and return flights at home base when no passenger is on-board on the other hand. We assume that these return flights at home base with no passenger on-board are not CAT flights (even if the flight is performed with an EMS aircraft equipped with medical supplies). Alleviations should be provided to allow pilots and their aircraft to come back to home base.
response	Please see the answer to comment # 54.
comment	874 comment by: Stephanie Selim
	General comment on implementation :



As a general comment, we also would like to ask for a 2 years deadline for this new regulation, as it will be a big change for operators, especially for HEMS operators if our proposal to remove HEMS from this text is not accepted. It should be noted that the subject is complex, especially for small operators, which includes for instance the definition of individual schemes and FRM. Regarding requirements submitted to FRM, experience has shown that it's necessary to develop data and skills, and a 2 year period to implement such an FRM seems to be an appropriate time frame.

response

Please see the answer to comment # 54.

comment 875 comment by: Luftfahrt-Bundesamt Attachments #20 #21 The LBA would like to give the following general comment: The implementation of the provisions envisaged with NPA 2017-17 would have a massive negative impact on the emergency medical service operations subject to public law in Germany as well as for air taxi operations. For HEMS, for example, our national provisions in accordance with §§ 21 to 22 of the 2. DV LuftBO (2nd national implementing order of the German regulation governing the operation of aviation products) would be superseded by the envisaged amendments on the EU level. In this connection we recognize no benefit of the proposed amendments. On the contrary: According to the "ADAC" emergency medical operations in Germany could not be carried out except with shift duties which would result in a remarkable increase in costs and in an increasing pilots' discontent. Establishing shift duties requires approx. 30% more staff. However, on the European market for experienced pilots there is not enough qualified personnel available who would meet the requirements of Regulation (EU) 965/2012. Consequently, maintaining the civil rescue system in Germany, as implemented and established today, would not be possible. Several years would pass for the recruiting and qualification of new staff, which could then only be ensured by a corresponding transitional period and with enormous costs. At this point we would like to refer to the comments of "ADAC and Air Hamburg. The objections made are obvious to us and can only be reiterated. Consequently, we would like to refrain from further comments on the individual points and instead, fully support the statements of ADAC and Air Hamburg. ADAC and Air Hamburg should independently use the CRT. Nevertheless, to enable better identification, please find enclosed the corresponding comments in PDF format. Please see the answer to comment # 54. response comment 972 comment by: Vesa REMES



EASA has requested a statement from the operators concerning the new NPA. In the background there is probably an effort to harmonize regulations and a concern over the alertness of the flight staff during work.

Because of the concern over the personnel alertness and sufficient rest during working hours and also over a longer working period, we would like to present a few counterproductive matters with respect to the new legislation.

The nature of HEMS work differs considerably from normal commercial aviation: the working hours are not uninterrupted work for the whole period, but include quiet periods of standby time without duties during which it is possible to rest and recuperate. Between the flight tasks the personnel stays in home-like premises, where it is possible to retire to rest at any hour. Personnel is encouraged to use this option for their benefit. The National Institute for Health and Welfare has completed an alertness survey for SHT's flight staff in 2017. The results show that the flying personnel do not see the present working schedule as a burden and is very well able to keep alert during the working shift. For these reasons it would be rational for the legislation to take into account the exceptional nature of the HEMS work.

The working and rest periods are monitored minute by minute during the working shifts and also between the shifts according to the Finnish aviation regulation on working hours OPS M3-2. If the regulated rest periods are not fulfilled, the duty is discontinued. Also, if the personnel are experiencing fatigue they consider influencing their performance, they have a right to discontinue the duty. There are no sanctions to personnel if the duty is discontinued.

Present working schedule is well tolerated and well liked among the personnel. It has been adhered to for over 10 years with Finnish Regional State Administrative Agency's (AVI) approval. Against statistical odds, there has been no accidents during that time, which indicates the safety and successfulness of the system.

Changing of the working schedule to make shifts shorter would lead to each worker to have double amount of shorter shifts, meaning less rest days. This kind of working schedule was tried out among the HEMS crew members at the beginning months of the base FH30. The collective experience among the HEMS crew members following the reduction of the rest days was the accumulation of fatigue. Change between day and night shift led to disruption of the circadian rhythm. It was considered difficult to get daytime rest between shifts. Present working schedule allows more rest days over a certain period, leading to a better recovery. Changing the present schedule would also lead to part of the personnel having to spend nights between shifts at the workplace due to insufficient traffic communication or long distances. Also the commuting time would double. Both factors would have a detrimental impact on recovery.

Refering to above mentioned matters we put forth a proposition for EASA to consider the special characteristics of the HEMS work and the established operating methods that have proved effective over the years and to allow the operations to be continued in accordance with national regulations.

Signed



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	Jouni Romppanen	Pilot
	Markus Lumme	Pilot
	Anssi Vuolle	Pilot
	Jonne Lundberg	Pilot
	Petteri Jokinen	Pilot
	Olli Piirainen	Pilot
	Heikki Aarela	HEMS crew member
	Petteri Rusi	HEMS crew member
	Juha Leppänen	HEMS crew member
	Simo Ahti	HEMS crew member
	Teppo Koskue	HEMS crew
	Antti Pesonen	Pilot
	Hannu Elomaa	Pilot
	Olli Kylänpää	Pilot
	Jarmo Hillberg	Pilot
	Ari Suutarinen	Pilot
	Aaron Marttila	HEMS crew member
	Juha Taaveli	HEMS crew member
	Timo Jaarinen	HEMS crew member
	Mika Arponen	HEMS crew member
	Juhani Tomminen	HEMS crew member
	Marc Roiha	HEMS crew member
	Samuli Nykänen	Pilot
	Ville Pääkkönen	Pilot
	Antti Peurala	Pilot
	Pertti Matilainen	Pilot
	Jari Fomin	Pilot
	Ville-Pekka Kilpeläinen	Pilot
	Juuso Pykälistö	Pilot
	Janne Virtanen	HEMS crew member
	Vesa Remes	HEMS crew member
	Ville Mikkonen	HEMS crew member
	Satu Yliherne	HEMS crew member
	Pekka Leppänen	HEMS crew member
	Matti Mikkonen	HEMS crew member
	Marko Sorsa	HEMS crew member
esponse	Please see the answer to comment	# 54

comment

1006

comment by: MBH SAMU

Attachments <u>#27</u> <u>#28</u> <u>#29</u> <u>#30</u> <u>#31</u>



 ${\tt TE.RPRO.00064-008} \ {\tt C} \ {\tt European} \ {\tt Union} \ {\tt Aviation} \ {\tt Safety} \ {\tt Agency}. \ {\tt All} \ {\tt rights} \ {\tt reserved}. \ {\tt ISO} \ {\tt 9001} \ {\tt certified}.$ Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 36 of 585

- Mont Blanc Hélicoptères (MBH) : French helicopter operator in the Alps
- SNEH: French Helicopters Operators Professional Union

Introduction:

The comments hereafter shall be considered as an

identification of some of the major issues MBH asks EASA to discuss with third-parties before any publication of the proposed regulation. In consequence, the following comments shall not be considered:

- As a recognition of the third-parties consultation process carried out by the European Parliament and of the Council;
- As an acceptance or an acknowledgement of the proposed regulation, as a whole or of any part of it;
- As exhaustive: the fact that some articles (or any part of them) are not commented does not mean MBH has (or may has) no comments about them, neither MBH accepts or acknowledge them. All the following comments are thus limited to our understanding of the effectively published proposed regulation, notwithstanding their consistency with any other pieces of regulation.

General comments :

MBH thanks EASA for the will of harmonizing the applicable dispositions in terms of flight time limitations for HEMS operations throughout Europe in order to warrantee a high level of safety. However, considering the HEMS national specificities (French HEMS missions represent 17% of the European HEMS missions), a proportionate approach tailored to the local specificities needs to be considered. The current RIA of this NPA should be further developed for a better maturity and should take into account the French national specificities.

(Cf. comments #985 to 989)

Generally speaking, MBH thinks that the proposed requirements for HEMS would benefit and enhance safety in being clearer and more user friendly. The proposed requirements for HEMS show numerous inconsistencies (there are some numbering issues, nonsenses and contradictions leading to misunderstandings of this NPA). Therefore, it is really hard for the Profession to elaborate final and comprehensive comments due to the difficulty in comprehension of this proposed regulation.

For instance, the structure and the references within this NPA lead to confusion regarding the applicability of the Certification Specifications for HEMS, indeed it is not explicit whether:

- All the CS.FTL.3 requirements shall be applicable "in block"
- The CS requirements should apply depending on what is said in the implementing rule
- Cherry-picking is allowed

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 37 of 585 (Cf. comments #926, #933 #958, #975, #977)

It is feared that the complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation which is contrary to the safety goal.

In order to comment properly the proposed requirements, the stakeholders need to understand the whole proposition. Numerous points merit clarification. The comments made thereafter need to be analyzed in light of MBH's current understanding of this NPA.

At the time being, MBH fears that each and every stakeholder will interpret this NPA according to its understanding which might act as a hindrance to the level playing field contrary to the initial goal.

French Organization

In France, the HEMS is a peculiar matter since it is a public service delegation from the Directorate of Health Care Supply (Direction Générale de l'Offre des Soins – DGOS) branch of the French Health Ministry.

HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care services is a public servicedefined in the French Health Code & a sovereign prerogative), with groupings of medical equipment and skills.

HEMS in France is both operated by private operators and the State(Civil Security, Gendarmerie or Army) for the sake of the DGOS.

Regarding the private operators, there are 49 HEMS bases (corresponding to a total of 47 HEMS helicopters) in

metropolitan France and overseas (including in Cayenne and in the Reunion Island) whose air transport business is conducted by 5 operators. These operators' helicopters are based at the hospital for which they work and are permanently equipped with medical equipment.

The contracts are awarded by each hospital or are pooled at pilot hospital which is responsible for the public contract and which, in some cases, spreads the flight hours between each hospital keeping a helicopter based for its sanitary transport needs.

Additionally, the State may charter private operators to operate HEMS operations on its behalf.

Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved.

Such a possibility shall remain for "Force majeure", in respect of the sovereignty of each Member State facing major health crisis.

Although delegated to private operators, the HEMS in France remains a public service mission whose latitude for the application of the newly proposed Article 8 of this NPA applies for the Member States at any time.

#2 major characteristics

2 major characteristics arise from the French healthcare organization:

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page

- The operational readiness with really short response time in order to warrantee the patient's odds of survival (3 work paces are in force in France : H12, H14 and H24 operations; to simplify, only the H12 example will be developed afterwards)
- The unpredictability of the flight times

This is the current French HEMS organization, linked with the French Health Ministry nowadays. In France, the President of the Republic and his government has made the commitment to the French people to warrantee an access to emergency care in less than 30 minutes from anywhere on the French territory.

Considering the unpredictability of the HEMS operations, the flight times are not known in advance and cannot be scheduled ex-ante. Hence, all the CAT.A FTL philosophy (building a FDP and a DP around sectors [FT] and computing the duration of the required rest that has to be taken before the next FDP as Max [12h ; Previous DP]) does not suit the HEMS operations. The FDP's content cannot be scheduled in advance (unscheduled allocation in a scheduled FDP).

Hence, the attempt to adapt the CAT.A FTL implementing rules to the specificities of the HEMS leads to a dead-end since the philosophy is completely different. Therefore, it may be considered if elaborating a new regulation from scratch would not be more appropriate.

French rostering organization

In France, the most usual rostering is usually 7 days ON at home base / 7 days OFF (implying a rest period + FDP < 24h, 7 times in a row), with a need for a H12 operational readiness (or a 12h shift in H24). This proposed European regulation, does not allow the French operators to comply with the French work pace defined and contracted by the French healthcare system. Moreover, in order to ensure a better quality of teamwork and to enhance safety, the French rostering organization is the same for pilots and doctors, they work in the same time slots (H12 or H14). Hence, all these new requirements will lead to amend all the French Health National practices (to that extend, the analysis of EASA would gain from considering further all economic and social issues it will raise).

Indeed, considering the French work pace:

On the one hand, in the proposed European regulation, there is a minimum duration for pre-flight of 30 minutes. This new requirement of a 30 minutes pre-flight will imply either a 30 minutes increase of the FDP or a 30 min decrease of the operational readiness. In France, 7%ⁱ of flights saving lives would be impossible with a 30 minutes preflight. (cf. SNEH illustrative Table in attachment)

On the other hand, in the proposed European regulation, there is a minimum duration for post-flight at the end of (the last flight time of) the FDP of 15 minutes (MBH would like to highlight the fact that the definition of this postflight seems unclear and may lead to confusion). This new requirement of a 15 minutes post-flight at the end of (the last flight time of) the FDP will imply both a 15 minutes increase of the DP and a 15 minutes decrease of the time slot available for the required rest.

Besides, if the FDP is lasting more than 10h, a 1 hour break is requested in the proposed dispositions of the NPA for single pilot + 1 TCM operations. In France all scheduled effective operational FDPs are 12h as explained before, so the 1h break requirement will always need to be fulfilled. Just as for flight times, due to the unpredictability of the HEMS missions, the break has to be unscheduled and the operator should ensure ex-post that the break requirement has been fulfilled for pilots. Besides the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour. Else, this will would overlap with national social regulations and the definition of working time.

Therefore, considering the French work pace, in order to have a 12h operational readiness with the proposed FTL European requirements, there is always a need for at least a 12h30 max FDP (which implies a 12h45 DP) with a 1h unscheduled time period allowed for physiological needs (which cannot be a rest period free of all duties). As a consequence, the time slot available for rest is 11h15 (24h - 12h45 = 11h15) while the rest required by this NPA would be 12h45. Therefore, all French HEMS operators will need to use systematically reduced rest and thus, all French HEMS operators will need to have a FRM (which seems disproportionate to the size of the involved operators). Moreover, as soon as there is one scheduled FDP lasting more than 12h (always the case in France since there is always a need for at least a 12h30 FDP), no more than 4 consecutive FDPs can be scheduled. Thus, the usual French rostering 7 days ON at home base / 7 days OFF cannot be respected, despite its efficiency in terms of safety, fatigue and quality of life for crews, has been proven from experience. As said in the RIA, no risk has been shown regarding safety or fatigue with the current regulation. Indeed, the total amount of flight times for pilots is quite low, a lot of time can be spent for rest, and the working pace of 7 days ON / 7 days OFF does not appear more tiring. On the contrary, the working pace of 7 days ON / 7 days OFF is better for the labor organization and is bringing a better quality of life for pilots who do not live near the HEMS operating base. Indeed pilots prefer to work 7 days in a row and then be 7 days OFF instead of working 1 day and resting the next day (which appears more tedious and exhaustive).

Conclusion

The impact of the implementation of European FTL regulation for HEMS in France goes beyond the French operators. It is a complete change of the whole French Health care system which might be necessary. Thus, it would be appreciated if the RIA addresses the impacts on the national policy for emergency access to care and the Government Health policy, etc.

Many lifesavings would be impossible with proposed FTL schemes. (Cf. attachments S1, S2, S3 and S4)

As a consequence, 3 options emerge and are listed here below, ranked according to their level of relevance for MBH:

OPTION A or option 0 of the RIA

This option, whose choice relies on the Member States (MS) or

EASA's decision, corresponds to the option 0 described in the RIA: no policy change. Safety impact, social impact and economic impact are neutral or having a little impact. The solution 0 is the proper answer to a one size fits all model which is not applicable to the industry. The FTL shall stay in the hand of the local authority. The well-functioning current

**** * * *+ * national FTL schemes are enforced for years, no excessive fatigue has been demonstrated and the current national system provides French operators with satisfaction. Besides, in the EMS safety risk assessment of this NPA, it is written that "Even with the caveats about under-reporting of fatigue as a causal factor it would appear from the occurrence data that the controls that have been in place to manage fatigue in European EMS have generally been effective. Compared to the social benefits from EMS operations in terms of patient safety and health (see below), the overall safety balance (flight safety v patient safety) is very positive". MBH strongly asks this option to be considered by EASA and the Member States : "no change in the existing situation; HEMS continue to be regulated under MS national rules".

OPTION B

This option consists in a total revamp of the NPA 2017-17 for HEMS. MBH asks for a completely new proposal, distinguishing the HEMS from AEMS and Air Taxi as no operational comparison can be made between the fundamentals of these different activities and respecting the following principles:

- Basing an alternative proposal on:
 - 14h standby / 10h Rest with a commander's discretion applicable in case of unforseen circumstances
 - o short-time operational readiness for ready-to-go EMS take off
 - rostering of 7 days ON / 7 days OFF
 - $\circ \quad$ flight time limitations to be discussed within this frame

MBH asks for this option to be considered in the Comment Response Document (CRD) with the elaboration of a sound RIA. Moreover, MBH would be happy to offer its expertise to discuss and study this subject with EASA policy officers. Besides, for clarity reasons, this would imply to separate, regarding the FTL scope, the HEMS from CAT, Air Taxi and AEMS operations.

OPTION C

If these 2 first options are not retained, MBH asks for this proposed NPA to be amended and reviewed as stated in the following comments. The proposed requirements, as it is, will lead to amend Health National regulations and it will request more crew, more constraints, more costs with a low added safety value as stated in the RIA. The main proposals are laid down here below:

- The "Flight time" (instead of "sector" whose definition is now restricted to aeroplanes) in all the requirements should not be scheduled as they cannot be in real life
- The travelling time between multiple HEMS operating bases of the home base should be increased a minima to 120 minutes (instead of 60 minutes) and in case of change of home base, the ERRP after starting duty (and not the one prior to starting duty) should be increased to allow the continuity of the operations
- The duration of pre-flight, post-flight or inter-flights should be suppressed and replaced by "a sufficient time determined by the operator and specified in the

Page 41 of 585

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

operating manual" (in France, 7%ⁱof flights saving lives would be impossible with a 30 minutes preflight, cf. SNEH illustrative Table in attachment) No limitations on the number of consecutive FDP lasting more than 12h should be made between 2 extended recovery rest periods For single-pilot + 1 TCM operations, in the case of a FDP lasting more than 10h, the break should be unscheduled and the operator should ensure ex-post that the break requirement has been fulfilled for pilots as they cannot be in real life The commander's discretion prior to take-off under unforeseen circumstances needs to be extended to all the EMS payload and not only limited to the patient and extended up to 2 hours for 1 pilot + 1 TCM operations (in France, 3%ⁱ of flights saving lives would be impossible with a commander's discretion capped to 1 hour, cf. SNEH illustrative Table in attachment) The limitations of the maximum values for continuous FT need to be increased by at least 1 hour The limitations of the maximum values for total flight time within a FDP need to be increased by at least 1 hour The 10% allowance between scheduled and actual FDP is not appropriate with the HEMS operations and needs to be suppressed The standby needs to be reviewed else it will never be used These elements of the aforementioned proposal form an integrated whole, they are each and all interrelated and interdependent. *** The 3 options all respect the general FTL philosophy and the learnings of fatigue impact assessments. This proposal would increase by 20% the French State budget allocated for the HEMS activity which is not affordable according to the French State. Since the objective of this regulation is not flight safety but the harmonization of the different national regulations regarding HEMS, the text should not have the opposite effect leading to less level playing field. If the proposed dispositions are inapplicable, there may be non-binding opt-in / opt-out system possibilities (through the newly proposed Article 8 of this NPA). Misunderstanding or interpretation of National level of a far too complex regulation for small operators might also lead to lower level playing field. Please see the answer to comment # 54 response

comment 1019

comment by: European Cockpit Association

ECA welcomes the idea of a common approach to the FTL for operations of emergency medical services by aeroplanes and helicopters. At the same time, we note with disappointment that the content of the NPA 2017-17 deviates significantly from the recommendation of the rulemaking group (RMT.0346) involved in the drafting phase.



In ECA's view, the proposal as it stands - will not help to prevent fatigue in HEMS operations.

Often the HEMS bases are located in (sometimes very) remote areas, where living is not attractive, jobs for partners are poorly available and/or where limited education opportunities (e.g. for children) are available.. Pilots are often not willing to live in these areas with their families and are usually commuting – sometimes long distances – from their living space to their working places. The laws of many countries do not allow to force the employees to move their home close to the working place.

The new rule would – like it is proposed – lead to shift duty at the majority of the HEMS bases, with the effect of a lot of additional duty days for the flight crews, to fulfill the obligations of their working contract. This leads forcibly to less days for recreation. This effect is exaggerated by additional time spent on commuting during the off days, which should be used for recreation and recovery from fatigue. While the flight crew is spending less time at home, their family is usually demanding them more during their days at home with family business, again preventing them from adequate rest.

Taking into account, that HEMS operations – although commercial operations – is usually/often financed by charity organizations, social insurance, registered societies or else, with the consequence of (sometimes very) limited financial assets, this regulation can have a dramatic impact on these operations. Servicing times of HEMS operations will be cut down, where limited funds or a low mission rate will not allow/justify additional staffing.

This altogether would lead to a major social and economic impact – in contradiction to EASA perception in the NPA - for the vast majority of HEMS operations in Europe.

To avoid these fundamental disadvantages there are two possibilities to raise the level of safety, by limiting the disadvantages to an acceptable level.

One is to follow the recommendations of the rulemaking group. This would have the effect, that the duty and stand by times would be significantly cut down to a safer level in most of the operations, with only a limited and tolerable negative economic and social impact.

E.g. HEMS business in many operations is highly seasonal due to the usual operation of a HEMS helicopter during daylight. In summertime working times of 250 hours in a month are not unusual – and even up to 300 hours is not rare. With the recommendation of the RMG the amount of duty hours within 28 days would be reduced to 190 hours in 28 days. Presently it is in some countries possible to have up to 7 conductive duty days with rest times below 10 hours; the proposal of the RMG would reduce the nights with a rest of below 10 hours to one night in between to extended recovery rest periods. This are only two examples of the huge improvements of the regulation recommended by the RMG. This recommendation is underlined by a study of the DLR, therefore exactly geared to the needs of this business – in contrast to the studies mentioned in the NPA.

The second solution is a different approach, which assures safe fatigue rules, a certain amount of harmonization, although being able and flexible enough to adopt to local and approved systems, with much less economic and social impact: Some of the general HEMS limitations should be shifted to the implementing rules; like cumulative duty times within 28 days, minimum of time available for sleeping within 24 hours and between two duties, maximum time awake, maximum duty days and minimum off days in a defined period and maximum active time within being on alert times. This should give a solid, safe and fatigue limiting basis for all HEMS operation. In this case the other routine related limitations should be shifted to AMC or the guidance material to give

**** * * **** the local authorities the possibility to adopt their own FTL-scheme adjusted to flight safety, their experience and the needs of their health system.

EASA has acknowledged (also in the NPA) that there are no indications that the existing FTL requirements for HEMS, which are under national authority approvals, pose a flight safety problem. It does not mean that there are operations that could not be run in a better/safer way/course. But to our knowledge there is only one accident all over Europe during the whole history of HEMS operation which has a proven direct relationship to fatigue; the BK117 at Weilheim/Teck on September, 28th of 2005 (BFU 3X171-05). The BFU found, that as one of the major systematic reasons for this accident, the overall load of the pilot, especially the amount of additional activities he was assigned to (including his private situation), had led to this tragic event. BFU states in the report, that he made no use of taking relief for his additional duties.

This assists the opinion of our HEMS experts, that the major problems in the present operation schemes are not the long duties itself, rather than cumulative fatigue and break times which are not used for relaxing, but for other tasks and functions during long duties.

response

Please see the answer to comment # 54

comment | 1178

comment by: SAF

Attachments <u>#32</u> <u>#33</u> <u>#34</u> <u>#35</u> <u>#36</u>

- SAF Group : French helicopter operator
- SNEH: French Helicopters Operators Professional Union

Introduction:

The comments hereafter shall be considered as an

identification of some of the major issues SAF asks EASA to discuss with third-parties before any publication of the proposed regulation. In consequence, the following comments shall not be considered:

- As a recognition of the third-parties consultation process carried out by the European Parliament and of the Council;
- As an acceptance or an acknowledgement of the proposed regulation, as a whole or of any part of it;
- As exhaustive: the fact that some articles (or any part of them) are not commented does not mean SAF has (or may has) no comments about them, neither SAF accepts or acknowledge them. All the following comments are thus limited to our understanding of the effectively published proposed regulation, notwithstanding their consistency with any other pieces of regulation.

General comments:

 TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.
 Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.
 Page 44 of 585

SAF thanks EASA for the will of harmonizing the applicable dispositions in terms of flight time limitations for HEMS operations throughout Europe in order to warrantee a high level of safety. However, considering the HEMS national specificities (French HEMS missions represent 17% of the European HEMS missions), a proportionate approach tailored to the local specificities needs to be considered. The current RIA of this NPA should be further developed for a better maturity and should take into account the French national specificities.

(Cf. comments #1246 to 1250)

Generally speaking, SAF thinks that the proposed requirements for HEMS would benefit and enhance safety in being clearer and more user friendly. The proposed requirements for HEMS show numerous inconsistencies (there are some numbering issues, nonsenses and contradictions leading to misunderstandings of this NPA). Therefore, it is really hard for the Profession to elaborate final and comprehensive comments due to the difficulty in comprehension of this proposed regulation.

For instance, the structure and the references within this NPA lead to confusion regarding the applicability of the Certification Specifications for HEMS, indeed it is not explicit whether:

- All the CS.FTL.3 requirements shall be applicable "in block"
- The CS requirements should apply depending on what is said in the implementing rule
- Cherry-picking is allowed

(Cf. comments #1199, #1208, #1226, #1239, #1240)

It is feared that the complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation which is contrary to the safety goal.

In order to comment properly the proposed requirements, the stakeholders need to understand the whole proposition. Numerous points merit clarification. The comments made thereafter need to be analyzed in light of SAF's current understanding of this NPA.

At the time being, SAF fears that each and every stakeholder will interpret this NPA according to its understanding which might act as a hindrance to the level playing field contrary to the initial goal.

French Organization

In France, the HEMS is a peculiar matter since it is a public service delegation from the Directorate of Health Care Supply (Direction Générale de l'Offre des Soins – DGOS) branch of the French Health Ministry.

HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care

services is a public serviced of in the French Health Code & a sovereign prerogative), with groupings of medical equipment and skills.

HEMS in France is both operated by private operators and the State(Civil Security, Gendarmerie or Army) for the sake of the DGOS.

Regarding the private operators, there are 49 HEMS bases (corresponding to a total of 47 HEMS helicopters) in

metropolitan France and overseas (including in Cayenne and in the Reunion Island) whose air transport business is conducted by 5 operators. These operators' helicopters are based at the hospital for which they work and are permanently equipped with medical equipment.

The contracts are awarded by each hospital or are pooled at pilot hospital which is responsible for the public contract and which, in some cases, spreads the flight hours between each hospital keeping a helicopter based for its sanitary transport needs.

Additionally, the State may charter private operators to operate HEMS operations on its behalf.

Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved.

Such a possibility shall remain for "Force majeure", in respect of the sovereignty of each Member State facing major health crisis.

Although delegated to private operators, the HEMS in France remains a public service mission whose latitude for the application of the newly proposed Article 8 of this NPA applies for the Member States at any time.

#2 major characteristics

2 major characteristics arise from the French healthcare organization:

- The operational readiness with really short response time in order to warrantee the patient's odds of survival (3 work paces are in force in France : H12, H14 and H24 operations; to simplify, only the H12 example will be developed afterwards)
- The unpredictability of the flight times

This is the current French HEMS organization, linked with the French Health Ministry nowadays. In France, the President of the Republic and his government has made the commitment to the French people to warrantee an access to emergency care in less than 30 minutes from anywhere on the French territory.

Considering the unpredictability of the HEMS operations, the flight times are not known in advance and cannot be scheduled ex-ante.Hence, all the CAT.A FTL philosophy (building a FDP and a DP around sectors [FT] and computing the duration of the required rest that has to be taken before the next FDP as Max [12h ; Previous DP]) does not suit the HEMS operations. The FDP's content cannot be scheduled in advance (unscheduled allocation in a scheduled FDP).

Hence, the attempt to adapt the CAT.A FTL implementing rules to the specificities of the HEMS leads to a dead-end since the philosophy is completely different. Therefore, it may

be considered if elaborating a new regulation from scratch would not be more appropriate.

French rostering organization

In France, the most usual rostering is usually 7 days ON at home base / 7 days OFF (implying a rest period + FDP < 24h, 7 times in a row), with a need for a H12 operational readiness (or a 12h shift in H24). This proposed European regulation, does not allow the French operators to comply with the French work pace defined and contracted by the French healthcare system. Moreover, in order to ensure a better quality of teamwork and to enhance safety, the French rostering organization is the same for pilots and doctors, they work in the same time slots (H12 or H14). Hence, all these new requirements will lead to amend all the French Health National practices (to that extend, the analysis of EASA would gain from considering further all economic and social issues it will raise).

Indeed, considering the French work pace:

On the one hand, in the proposed European regulation, there is a minimum duration for pre-flight of 30 minutes. This new requirement of a 30 minutes pre-flight will imply either a 30 minutes increase of the FDP or a 30 min decrease of the operational readiness. In France, 7%¹ of flights saving lives would be impossible with a 30 minutes preflight. (cf. SNEH illustrative Table in attachment)

On the other hand, in the proposed European regulation, there is a minimum duration for post-flight at the end of (the last flight time of) the FDP of 15 minutes (SAF would like to highlight the fact that the definition of this postflight seems unclear and may lead to confusion). This new requirement of a 15 minutes post-flight at the end of (the last flight time of) the FDP will imply both a 15 minutes increase of the DP and a 15 minutes decrease of the time slot available for the required rest.

Besides, if the FDP is lasting more than 10h, a 1 hour break is requested in the proposed dispositions of the NPA for single pilot + 1 TCM operations. In France all scheduled effective operational FDPs are 12h as explained before, so the 1h break requirement will always need to be fulfilled. Just as for flight times, due to the unpredictability of the HEMS missions, the break has to be unscheduled and the operator should ensure ex-post that the break requirement has been fulfilled for pilots. Besides the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour. Else, this will would overlap with national social regulations and the definition of working time.

Therefore, considering the French work pace, in order to have a 12h operational readiness with the proposed FTL European requirements, there is always a need for at least a 12h30 max FDP (which implies a 12h45 DP) with a 1h unscheduled time period allowed for physiological needs (which cannot be a rest period free of all duties). As a consequence, the time slot available for rest is 11h15 (24h - 12h45 = 11h15) while the rest required by this NPA would be 12h45. Therefore, all French HEMS operators will need to use systematically reduced rest and thus, all French HEMS operators will need to have a FRM (which seems disproportionate to the size of the involved operators).

**** * * Moreover, as soon as there is one scheduled FDP lasting more than 12h (always the case in France since there is always a need for at least a 12h30 FDP), no more than 4 consecutive FDPs can be scheduled. Thus, the usual French rostering 7 days ON at home base / 7 days OFF cannot be respected, despite its efficiency in terms of safety, fatigue and quality of life for crews, has been proven from experience. As said in the RIA, no risk has been shown regarding safety or fatigue with the current regulation. Indeed, the total amount of flight times for pilots is quite low, a lot of time can be spent for rest, and the working pace of 7 days ON / 7 days OFF does not appear more tiring. On the contrary, the working pace of 7 days ON / 7 days OFF is better for the labor organization and is bringing a better quality of life for pilots who do not live near the HEMS operating base. Indeed pilots prefer to work 7 days in a row and then be 7 days OFF instead of working 1 day and resting the next day (which appears more tedious and exhaustive).

Conclusion

The impact of the implementation of European FTL regulation for HEMS in France goes beyond the French operators. It is a complete change of the whole French Health care system which might be necessary. Thus, it would be appreciated if the RIA addresses the impacts on the national policy for emergency access to care and the Government Health policy, etc.

Many lifesavings would be impossible with proposed FTL schemes.

(Cf. attachments S1, S2, S3 and S4)

As a consequence, 3 options emerge and are listed here below, ranked according to their level of relevance for SAF:

OPTION A or option 0 of the RIA

This option, whose choice relies on the Member States (MS) or

EASA's decision, corresponds to the option 0 described in the RIA: no policy change. Safety impact, social impact and economic impact are neutral or having a little impact. The solution 0 is the proper answer to a one size fits all model which is not applicable to the industry. The FTL shall stay in the hand of the local authority. The well-functioning current national FTL schemes are enforced for years, no excessive fatigue has been demonstrated and the current national system provides French operators with satisfaction. Besides, in the EMS safety risk assessment of this NPA, it is written that "Even with the caveats about under-reporting of fatigue as a causal factor it would appear from the occurrence data that the controls that have been in place to manage fatigue in European EMS have generally been effective. Compared to the social benefits from EMS operations in terms of patient safety and health (see below), the overall safety balance (flight safety v patient safety) is very positive". SAF strongly asks this option to be considered by EASA and the Member States: "no change in the existing situation; HEMS continue to be regulated under MS national rules".

OPTION B

This option consists in a total revamp of the NPA 2017-17 for HEMS. SAF asks for a completely new proposal, distinguishing the HEMS from AEMS and Air Taxi as no



operational comparison can be made between the fundamentals of these different activities and respecting the following principles:

- Basing an alternative proposal on:
 - 14h standby / 10h Rest with a commander's discretion applicable in case of unforseen circumstances
 - o short-time operational readiness for ready-to-go EMS take off
 - rostering of 7 days ON / 7 days OFF
 - flight time limitations to be discussed within this frame

SAF asks for this option to be considered in the Comment Response Document (CRD) with the elaboration of a sound RIA. Moreover, SAF would be happy to offer its expertise to discuss and study this subject with EASA policy officers. Besides, for clarity reasons, this would imply to separate, regarding the FTL scope, the HEMS from CAT, Air Taxi and AEMS operations.

OPTION C

If these 2 first options are not retained, SAF asks for this proposed NPA to be amended and reviewed as stated in the following comments. The proposed requirements, as it is, will lead to amend Health National regulations and it will request more crew, more constraints, more costs with a low added safety value as stated in the RIA. The main proposals are laid down here below:

- The "Flight time" (instead of "sector" whose definition is now restricted to aeroplanes) in all the requirements should not be scheduled as they cannot be in real life
- The travelling time between multiple HEMS operating bases of the home base should be increased a minima to 120 minutes (instead of 60 minutes) and in case of change of home base, the ERRP after starting duty (and not the one prior to starting duty) should be increased to allow the continuity of the operations
- The duration of pre-flight, post-flight or inter-flights should be suppressed and replaced by "a sufficient time determined by the operator and specified in the operating manual" (in France, 7%ⁱ of flights saving lives would be impossible with a 30 minutes preflight, cf. SNEH illustrative Table in attachment)
- No limitations on the number of consecutive FDP lasting more than 12h should be made between 2 extended recovery rest periods
- For single-pilot + 1 TCM operations, in the case of a FDP lasting more than 10h, the break should be unscheduled and the operator should ensure ex-post that the break requirement has been fulfilled for pilots as they cannot be in real life
- The commander's discretion prior to take-off under unforeseen circumstances needs to be extended to all the EMS payload and not only limited to the patient and extended up to 2 hours for 1 pilot + 1 TCM operations (in France, 3%ⁱ of flights saving lives would be impossible with a commander's discretion capped to 1 hour, cf. SNEH illustrative Table in attachment)
- The limitations of the maximum values for continuous FT need to be increased by at least 1 hour
- The limitations of the maximum values for total flight time within a FDP need to be increased by at least 1 hour

- The 10% allowance between scheduled and actual FDP is not appropriate with the HEMS operations and needs to be suppressed
- The standby needs to be reviewed else it will never be used

These elements of the aforementioned proposal form an integrated whole, they are each and all interrelated and interdependent.

The 3 options all respect the general FTL philosophy and the learnings of fatigue impact assessments.

This proposal would increase by 20% the French State budget allocated for the HEMS activity which is not affordable according to the French State.

Since the objective of this regulation is not flight safety but the harmonization of the different national regulations regarding HEMS, the text should not have the opposite effect leading to less level playing field. If the proposed dispositions are inapplicable, there may be non-binding opt-in / opt-out system possibilities (through the newly proposed Article 8 of this NPA). Misunderstanding or interpretation of National level of a far too complex regulation for small operators might also lead to lower level playing field.

response

Please see the answer to comment # 54

comment	1207 0	omment by: Skärgårdshavets Helikoptertjänst Ab
	be continued in accordance with nation	IT) supports option 0, in which operations are to al regulations. NPA 2017-17 does not take aracteristics nor of the established operating r the years.
	compliance with the Working Hours Act provisions of the Working Hours Act wh	cy (AVI) is the national authority that monitors (605/1996). AVI can grant exemptions from the en the deviation is well founded. In Finland, ciple of immediate readiness, for which reason the provisions of the Working Hours Act.
response	Please see the answer to comment # 54	
comment	1253 comm	ent by: Finnish Helicopter Pilots Association FHPA
	Attachments <u>#37</u> <u>#38</u> <u>#39</u> <u>#40</u> <u>#41</u>	

**** * * *** Finnish Helicopter Pilots Association FHPA's comments to NPA 2017-17

Finnish Helicopter Pilots Association FHPA represents all Helicopter Emergency Medical Services pilots flying in Finland. Our members consist only of HEMS Rotary Wing pilots and currently approximately 70 percent of HEMS pilots are members of the Finnish Helicopter Pilots Association. FHPA is part of Finnish Pilots Association FPA.

Finnish HEMS operations are fully government funded by Ministry of Social Affairs and Health. FinnHEMS is a non-profit administrative organisation, which is owned by hospital districts. The current FinnHEMS contract is for two flight operators operating six HEMS bases in the country and is a ten year contract. Operators are Skägårdshavets Helikoptertjänst (3 bases + 1 air ambulance base outside of FinnHEMS contract) and Babcock Scandinavian AirAmbulance (3 bases).

HEMS operations are conducted 24/7 under Visual Flight Rules with Night Vision Imaging System NVIS aided night operations and Instrument Flight Rules. Five operating bases have on duty crews of 1 pilot plus HEMS Technical Crew and one base has on duty crew of two pilots.

National aviation regulation OPS M3-2 issued by Finnish Civil Aviation Authority, which regulates and rules HEMS duty and flight time limitations in Finland. OPS M3-2 was issued back in 2003 and minor adjustments were made in 2008. This means that Finnish HEMS operations have been following the same crew flight and duty time limitations for 15 years.

There are zero examples where the limitations of OPS M3-2 have resulted in reduced aviation safety. To this day the total number of fatal or airframe loss accidents in Finnish HEMS operations is zero.

Mainly our HEMS duty shift consists of two consecutive flight duty periods. FDP is 24 hours and shall include a total rest time regulated by OPS M3-2. For example in single pilot HEMS operations the first FDP shall include at least 9 hours of time which shall not include any duties, i.e rest time. There should be at least a 2 hour period between duties that shall contain no duties for it to count as rest. Rest time counts as FDP time. Also the first FDP in single pilot HEMS operations is allowed to contain a maximum of 11 hours of flight time. The second and third FDPs are more strict and limit flight and duty time even more. The minimum rest time for 3 consecutive FDPs (72h) in SP HEMS operations is 33 hours, 27 hours for multi pilot HEMS operations. See 7.2 "Flight and duty time limitations" in OPS M3-2. The three northern HEMS bases use 3 consecutive FDPs that shape a HEMS working shift during weekends.

OPS M3-2 limits the maximum duty time per 30 day period to 192 hours, which can be raised to 216 hours for a mandatory reason. But for example the BSAA HEMS pilots' collective agreement limits duty time per a calendar month to 168 hours maximum, 160 hours if any training takes place during said month outside duty shifts. Hours are then counted as overtime all the way to the regulation maximum or less hours are planned for the next month to compensate. Pilot's permission is needed for overtime work. BSAA publishes 4 month rosters at a time, collective agreement requires so.

**** * * * HEMS pilots' flight hours remain remarkably low annually (60 to 200 flight hours a year, even when working full roster) compared to the current maximum allowed by authorities (900 flight hours).

It is rarely that the pilots have their active duty time arrive to maximum within FDPs and are not permitted to continue duty. Still, backup crews are rostered.

The majority of pilots do not live in the vicinity of HEMS bases, on the contrary. Travelling between home and workplace may be significant and takes a considerable amount of time.

Many of the pilots have commute time between home and work in excess of three hours and travel by plane. For example majority of BSAA pilots commute by regional commercial flights from southern Finland to northern HEMS bases.

Travelling by public transport is more challenging during weekends and certain holidays, etc. fewer regional commercial transport flights or none at all. Time spent during work travelling does not count as rest time for the required rest periods. The now proposed FTL model does not suit these commuters at all. Also, the proposed FTL model makes it practically impossible for the Northern bases to continue operating.

The unanimous opinion of every FHPA member is to not have our current flight and duty time limitations and roster model changed from OPS M3-2 radically. We stand with the HEMS operators and Finnish CAA on this issue and agree on our common goal to maintain this overall very proven and working duty scheme.

It is extremely important to note that hospital districts require all HEMS pilots to be proficient in Finnish language, this limits the pilot pool available to HEMS operations in Finland. The already marginal pilot offering would not be sufficient enough to meet the increased demand of HEMS pilots this proposed FTL model brings.

Attached are current FCAA's OPS M3-2 and two Aero Medical Examiners' educated opinions (they view the current rostel model as positive and working) regarding the current roster model plus few statements from EU directive.

Respectfully,

Helsinki 27.02.2018

Toni-Petteri Nikulin

Chairman of the Board, Finnish Helicopter Pilots Association FHPA Marko Malinen Vice Chairman

response

Please see the answer to comment # 54

comment | 1255

comment by: Skärgårdshavets Helikoptertjänst Ab

**** * * *** The Finnish aviation regulation on working hours OPS M3-2 enables 4x24h standby shifts, but AVI's exemption limits the working time of pilots to 2x24h in HEMS operations. In addition to the maximum flight time, OPS M3-2 specifies the minimum rest time for each 24h shift. AVI's exemption requires that both flight time and rest time be monitored actively.

response

Please see the answer to comment # 54

comment	1256 comment by: Skärgårdshavets Helikoptertjänst Ab
	The working and rest time monitoring system automatically reports any deviations from the maximum and minimum working and rest time requirements to a reporting system, where they are analysed monthly. Based on these analyses, most of the deviations relate to the nature of the job, i.e. the unit is still carrying out a task when the shift ends, or completing a task takes significantly longer than normal. Due to active monitoring, deviations due to some other reason are rare.
response	Please see the answer to comment # 54

comment	1257 comment by: Skärgårdshavets Helikoptertjänst Ab
	Attachment <u>#42</u>
	The National Institute for Health and Welfare completed an alertness survey on SHT's flight staff in 2017. Based on the survey, the pilots or Hems Crew Members (HCMs) do not especially suffer from tiredness.
	Short conclusion of the research;
	"Results show that pilots and HEMS Crew Members experience only infrequently low alertness on duty, regardless of whether their duty is 24 hours or 48 hours. When they do experience low alertness, it is most often related to waking up from sleep at night, in the morning or after a nap.
	Other experiences of low alertness are rare: within all 48h duties (n=104), only 3 individuals (n=23) in 4 duties experienced low alertness that was not related to waking up from sleep. There was no
	statistically significant difference in the amount of sleep on duty between those who didn't experience low alertness and those who did."
response	Please see the answer to comment # 54

comment | 1258

comment by: Skärgårdshavets Helikoptertjänst Ab



	A new HEMS base started operations in 2012. Twelve-hour standby shifts were tested at the new base, but according to HCMs, 12h standby shifts are more demanding than standby shifts of 24h or longer. As a result, by agreement with the employer 12h standby shifts were discontinued.
response	Please see the answer to comment # 54
comment	1259 comment by: Skärgårdshavets Helikoptertjänst Ab
	Finland is a sparsely populated country where distances are long. For this reason, the staff does not live next to the base. Shifting to 12h standby shifts would have a negative or very negative impact on over half of SHT's flight staff. This would require that SHT have to rent a flat close to each base to make it more practical for staff members who live far from the base to complete several 12h standby shifts. Therefore, the 12h model would increase the costs and reduce the wellbeing of the staff.
response	Please see the answer to comment # 54

comment	1261	comment by: Skärgårdshavets Helikoptertjänst Ab
	Even though the number of HEMS tasks is high, the number of flight hours for each pilot is small. Depending on the base, the average flight time is 8-14 minutes per task, and the total number of flight tasks in the three bases is around 7000 a year. Flight times will become even shorter in the future when two new bases will be established in Finland. This means that the pilots must acquire flight hours, including NVIS and IFR, outside the standby shifts in order to fulfil the recency requirements, which will increase costs and make planning of shifts more difficult. Recent experience is not subject of this NPA but it may have impact to it.	
	Skärgårdshavets Helikoptertjänst Ab, Pi	ilots and HEMS Crew Members.
response	Please see the answer to comment # 54	1
comment	1362	comment by: <i>B. Wagner</i>
	der NPA in Bezug auf HEMS. AEMS, SPC	ommentare beziehen sich nur auf die Regelungen) und ATXO werden mangels Kenntnis der mir kommentiert. Die Kommentare stellen ar.

Die Neuregelung hat gemäß Executive Summary folgende zwei wesentliche Ziele im Bereich HEMS: Harmonisierung und Verbesserung der Flugsicherheit. Das soll gemäß der übergeordneten Grundverordnung ohne oder mit geringen wirtschaftlichen und sozialen Einschränkungen erfolgen. Im Folgenden werden die beiden Ziele im Einzelnen beleuchtet.

**** * * *** Aus der Sicht eines HEMS Piloten erscheint die Idee, eine Harmonisierung der Flugzeitenregelung auf europäischer Ebene anzustreben zunächst logisch, um eine Chancengleichheit zwischen den Betreibern bei Ausschreibungen europaweit zu ermöglichen. Jedoch ergibt ein genauerer Blick auf die nationalen Besonderheiten der einzelnen Rettungsdienststrukturen ein differenziertes Bild, das den Ansatz der Harmonisierung in diesem Bereich in Frage stellt.

Die Luftrettung in jedem einzelnen Land basiert auf den vorhandenen nationalen Rettungsdienststrukturen. Diese sind aufgrund der unterschiedlichen Voraussetzungen wie Geographie, Infrastruktur, Ausbildungslevel der Rettungsdienstmitarbeiter, Verfügbarkeit von Fachkräften, nationalen und teilweise regionalen Gesetzen und vielen weiteren Faktoren europaweit sehr inhomogen aufgestellt. In vielen Ländern haben sich über die Jahre Luftrettungssysteme entwickelt, die genau zu ihrem Bodenrettungssytem passen und die dort vorhandenen Lücken schliessen. Entsprechend wurde auch die nationale Gesetzgebung in Bezug auf Flugdienst- und Ruhezeiten über die Jahre dem jeweiligen Bedarf angepasst entwickelt und in vielen Jahren mit Millionen von Flugstunden in der Praxis erprobt. Dabei sollte immer (und für Deutschland ist es tatsächlich so) die Einsatzbereitschaft zum Wohle des Patienten im Vordergrund stehen, jedoch ohne dabei ein inakzeptables Risiko einzugehen. Die hervorragende Unfallstatistik der letzten Jahre im Bereich der Luftrettung in Bezug auf Fatigue zeugt von diesem funktionierenden Grundsatz und der Effektivität der bestehenden Gesetzgebung.

Zum Herstellen einer Chancengleichheit müsste also zunächst die Harmonisierung der Struktur des Rettungswesens allgemein auf europäischer Ebene erfolgen. Solange dies nicht der Fall ist, werden Ausschreibungen für Stationen in unterschiedlichen Regionen immer sehr stark voneinander abweichende Anforderungen auf die Verfügbarkeit und auch sehr stark unterschiedliche Auslastungen der Crews zur Folge haben. Diesen Unterschieden müsste das neue Regelwerk Rechnung tragen. Das wird nur möglich durch ein großes und unübersichtliches Regelwerk mit vielen Ausnahmen und Sonderregelungen. Je komplexer die Neuregelung jedoch wird, umso höher ist zum einen die Belastung für die Besatzungen bei der Umsetzung (erhöhte Arbeitsbelastung ---> verminderte Situational Awareness ---> erhöhtes Risiko von Fehlern) und zum anderen das Risiko der falschen oder unterschiedlichen Auslegung von Abschnitten der Texte.

Dabei besteht im Prinzip ja schon jetzt Chancengleichheit für die Betreiber, da die Anforderungen an die Verfügbarkeit für alle gleich in der Auschreibung definiert sind. Ein einfacher Satz im Abschnitt HEMS FTL, der die Nutzung der jeweils geltenden nationalen Regelungen für den Ort der ausgeschriebenen Station verbindlich vorschreibt, egal von welcher Behörde das AOC ausgestellt wurde, könnte also schon zu der angestrebten Chancengleichheit und Rechtssicherheit führen.

Somit bleibt als weitere Begründung zur Neuregelung der FTL im Bereich HEMS eine erwartete Steigerung der Flugsicherheit. Dies soll durch wissenschaftlich belegte Ruhezeitmodelle sichergestellt werden, die geeignet sind, Fatigue zu vermeiden und die Arbeitsbelastung der Besatzungen so zu limitieren, dass zu jedem Zeitpunkt innerhalb einer Dienstperiode eine ausreichende Fitness möglich ist.

Dass heißt also zunächst, geeignete Modelle zu entwickeln. Dafür sind jedoch die in der NPA referenzierten Studien in keinster Weise geeignet. Keine der Studien betrachtet das sehr spezielle Umfeld HEMS, erst recht nicht europaweit übergreifend. Die

**** * * * Ruhezeitmodelle, die zur Entwicklung der NPA als Grundlage genommen wurden, berücksichtigen alle nicht den speziellen Arbeitsrhythmus in der Luftrettung. Die Auslastung hängt von dem Einsatzaufkommen ab, dass nicht vorhergeplant werden kann und auch immer starken Schwankungen unterliegt.

Dementsprechend sind die vorgeschlagenen zeitlichen Beschränkungen weder praxistauglich noch wissenschaftlich belegt. Stattdessen tragen sie an vielen Stellen nicht den Erfordernissen der Luftrettung Rechnung und führen zu einem Mehrbedarf an Piloten und eine Verteilung der Einsätze und damit Flugzeit auf eine größere Anzahl von Piloten. Im Endergebnis sind also mehr Piloten mit weniger Erfahrung im Einsatz, was meiner Meinung nach genau das Gegenteil der Zielsetzung bewirkt, nämlich eine Reduzierung der Flugsicherheit.

Abschliessend kann man also sagen, dass mit dem vorliegenden Entwurf keines der angestrebten Ziele erreicht werden kann. Dafür sind aber Nebenwirkungen im wirtschaftlichen und sozialen Bereich zu erwarten, denen bei der Beurteilung durch die EASA viel zu wenig Beachtung beigemessen wurde. Zum einen führt der zusätzliche Bedarf an qualifiziertem Personal zu hohen Kosten für die Betreiber, die diese auf die Gesundheitssysteme umlegen müssen. Sollte dies nicht möglich sein, ist die Existenz dieser Betreiber gefährdet. Zum anderen führt die Einschränkung von Bereitschaftszeiten zu einer geringeren Abdeckung des Rettungsbedarfs und somit direkt zu gesundheitlichen Folgen für die betroffenen Patienten. Eine weitere Einschränkung im sozialen Bereich betrifft die Attraktivität des Arbeitsplatzes in der Luftrettung. Durch die vorgeschlagene Neuregelung werden Dienstmodelle in Frage gestellt, die sich seit Jahren etabliert und mit zur Attraktivität des Berufes beigetragen haben. Fallen diese weg, könnte das zu einer Abwanderung des eh nur spärlich vorhandenen qualifizierten Personals in ander Bereiche der Industrie führen und somit ebenfalls dazu beitragen, die Flugsicherheit zu reduzieren, da damit auch Erfahrung abwandert.

Diese Risiken sollten realistischer beurteilt werden und bei der Neufassung der vorliegenden NPA ausreichend Beachtung finden.

Lösungsvorschlag: Implementierung der Teile ATXO und AEMS und Beibehaltung der nationalen Regelungen im HEMS Bereich bei gleichzeitiger Sicherstellung der Chancengleichheit durch verbindliche Vorgabe, welche nationalen Regelungen wo Anwendung finden.

response

Please see the answer to comment # 54

comment 1376

comment by: Swiss Air-Ambulance Rega

Attachment #44

With the NPA 2017-17, EASA is aiming to achieve a harmonised, Europe-wide regulation on flight times for emergency medical services by air (HEMS and AEMS) and commercial air transport (CAT).



The comments and suggested additions to this NPA generally refer only to emergency medical services by air (EMS operations; HEMS and AEMS), unless specified otherwise.

In Europe, there are currently a myriad different regulations on flight times and rest periods. In the scope of EASA's vision and mission to bring about a complete harmonisation of aviation standards, in a nearly five-year process the draft of harmonised flight time limitations (FTL) was prepared in this NPA 2017-17 by external experts as well as EASA employees. A Europe-wide FTL regulation is meant both to increase flight safety and achieve a "level playing field" for the implementing companies, as sought by EASA. In addition, this would facilitate the regulatory oversight by EASA and the responsible national aviation authorities. The extent to which EASA has any authority at all to regulate aviation competition in the scope of its "level playing field" objective must be critically scrutinised, because this mission cannot be identified from the existing Basic Regulation (Regulation (EC) No 216/2008); however, this is not the subject of these comments.

As clearly demonstrated by the documents and statements of the expert group (RMT), it was very difficult and sometimes even cumbersome for the expert group itself to reach a consensus on the very different national EMS operations for the draft regulation. In this draft, the harmonisation, which is reasonable in many cases, made it necessary to sacrifice likewise reasonable as well as tried-and-tested regulations on national and various flight time and rest time rules. However, these non-harmonised regulations have taken the national needs of EMS operations into account much more comprehensively than the present draft ever could.

In addition, there have been no known severe incidents, accidents or even fatalities in several million air rescue missions in Europe in recent decades, which are based on shortcomings in the national flight time and rest time regulations or shortcomings as a result of fatigue and/or lack of sleep. In many countries, the FTL regulations already have a scientific basis, for example, the Second Implementing Regulation of the Aircraft Operations Order (DVLuftBO) in Germany or the Rega Flight Time and Rest Time Regulations approved by the Swiss Federal Office of Civil Aviation (FOCA).

Conversely, the scientific and operational foundations of the planned EASA FTL regulation in accordance with NPA 2017-17 are not comprehensible. No known studies on fatigue or lack of sleep specifically relating to air rescue were included in the NPA. The comparative study by DLR (German Aerospace Center) in 2017 showed that subjectively the strain has increased as a result of travel time, the switch between service duty and private, as well as the irregular/unpredictable shift changes caused by deployment, and in consequence, flight safety is more at risk than improved.

Even EASA concludes in its Regulatory Impact Analysis (RIA) that the introduction of the harmonised FTL rule will not lead to an improvement in air safety, but it is associated with high costs for companies and the entire economy. In the event of the present draft not being applied, the impact for HEMS is assessed as neutral according to No 4.4 (Impact Assessment), whereas application, which is associated with substantial costs and outlay, would only have a slightly positive effect. In the event of a complete implementation, the expected consequences in EASA's view would even be "highly negative" in terms of the social and economic consequences, with a minimal positive impact on safety at most.

The situation is different for AEMS operations, because these are coordinated with the air taxi operations regulations. In our view, there are substantial disadvantages in the areas of

"standby other than airport standby" and "extension of max basic FDP due to on-board rest", which distinctly affect the *raison d'être* of repatriation operations.

In consideration of the information and the results and forecasts of EASA in the NPA 2017-17 as well as our own experience from over 65 years of air rescue operations by helicopter and fixed-wing aircraft, we firmly believe that such a compulsory harmonisation of air rescue operators in Europe should be avoided. Both the cost-consequence estimate for the planned implementation of EASA's FTL regulation and for the case of non-implementation do not allow for any other sustainable and reasonable outcome. We therefore make the following

Proposal:

- 1. To follow option 0 as stated on page 67 (para 4.5) and to reject the submitted draft NPA 2017-17 for HEMS operators.
- 2. To continue to uphold the existing national flight time and rest time regulations and to continue to adapt them to the national requirements of the respective air rescue and medical systems in the States through the national authorities in coordination with EASA.

Alternatively, if the above proposals cannot be taken into consideration, contrary to expectations, we urge the consideration of the following comments and additions to the presented draft NPA 2017-17.

response

Please see the answer to comment # 54.

comment | 1417

comment by: Svensk Luftambulans

As one of two HEMS operators in Sweden we operate three HEMS bases in Sweden and this NPA will have a major impact in our operation and economics, but most important on flight safety. As several of the HEMS bases in Sweden are in sparsely populated areas with few missions (average 800 / year). Sweden like the rest of Nordic countries have established 24 hours stand-by schemes and in our case normally 5/15 roster that minimise commuting but still have a good safety record.

In Sweden today, the HEMS don't have National coverage but the intention is to build up a National coverage. This will increase the total number of operational HEMS units. This NPA will demand an additional increase of crew members to employ. Our estimate is a 30% increase of pilots and HEMS crew members.

Safety:

EASA has acknowledged, and you can also see this in the NPA, that there are no indications that the existing FTL requirements for Helicopter Emergency Medical Services (HEMS), under National authority approvals, poses a flight safety problem. So, the only goal is merely to harmonize and standardize. This, however, will create risks in other areas.

A substantial increase in the number of crew members for Swedish operators, will most probably not lead a substantial increase in the number of HEMS missions.



A reduced number of missions and flight time per crew member will lead to lost skill and currency that cannot completely be compensated for by more training.

A large increase in the demand for crew members, especially pilots, may lead to a shortage of suitable pilots.

It will also be difficult to find these pilots at the same time as we increase the number of HEMS units to have the National coverage.

As we operate MP and SP day and night with NVIS and also IFR we have high requirements when recruiting.

For the operators to reduce the experience requirements (down to the authority requirements) and/or accept less suitable crew members can have a negative impact on the established safety level.

Public safety may decrease as the availability of helicopters due to increased costs can't be financed and the planed National coverage can't be fulfilled.

There is also a risk that crew members will suffer more from fatigue when commuting more frequently to remote bases in rural areas.

Economy:

Decreased productivity and increased cost for crews due to increased cost for salaries, pensions, training (initial and recurrent). Extra helicopters or Simulators may be necessary to provide extra training for non-current pilots. This will also lead to extra cost for maintenance, maintenance personnel, insurance, etc.

The health authorities will bear the cost in many instances.

The cost of commuting and/or extra housing/living quarters will increase for the crew members (or the operators).

Social impact:

As the health authorities will bear the added cost there may be a decreased availability of helicopter when they cut down on existing bases and the plan to have a national coverage will be endangered. This can lead to a reduced quality of life for some patients that will not reach an adequate level of care in time.

There may be a destructive effect on crew members social life through increased frequency of commuting and more periods away from home.

Individual Flight Time Specification Schemes

EASA does not want to force operation that is currently run in a safe manner to change drastically.

Mitigating measures can be put in place by, or that are already in place with operators can be used to achieve an adequate level of protection against fatigue. One of the most important is the crew members ability and requirement to cancel operations when they reach FTL limitations or even earlier if they feel not fit for flight. This happens in average five to ten times a year in our operations. This ability and obligation is one of the key factors in the safety records in terms of FTL in "Nordic" operations how do one describe that.

Option 1 - Flexible approach" would have the benefit of forcing the operators to demonstrate a safe operation. This will be quite costly and not practicable for many small operators and would also at the end lead to significant barriers of entry.

Costs that would enhance safety more if spent on other safety issues like crew training. As said earlier there is no indication that FTL is a safety issue.

Conclusion



We therefore urge EASA to incorporate "Nordic" schemes to the regulation that has been in operational use with a safety record and in an SMS perspective is well balanced between cost and safety.

response

Please see the answer to comment # 54

comment | 1474

comment by: Finnish Transport Safety Agency

Attachment #45

Finland would like to thank EASA for development of further FTL rules. We support the proposed FTL rules for CAT air taxi operations, emergency medical service operations with aeroplanes and CAT single-pilot operations with few comments. However, for emergency medical operations with helicopters (HEMS) we propose another solution.

In Finland's opinion HEMS operations should comply with the applicable requirements of the national law of the Member State in which the operator has its principal place of business. The proposed FTL requirements as they are, would require Finnish HEMS operators to hire at least 25% more crew. This would lead to lack of qualified and experienced pilots, and lack of financial recourses to continue operations at the same level as now. It should also be estimated what effect of more pilots flying less hours would have in the flight safety.

The HEMS operations are required in Finland by law, in order to ensure equal availability of medical services for all inhabitants. The main problem in the proposed FTL requirements is the lack of possibility for rolling 24 h standby.

The proposed NPA would also cause problems for helicopter operators who operate both HEMS and other CAT and SPO to roster and calculate flight and duty hours. It would be less problematic to include all helicopter operations under the EASA FTL rules at the same time. Common FTL requirements, if established, should take into account the different nature of HEMS operations within and between countries. The HEMS operational area and accessibility, the number and length of the operations, geographical environment, weather and use of VFR/IFR/NVIS operations differ.

If HEMS operations will be included in the FTL requirements later on, it would be utmost important to include possibility for rolling 24 hours standby period. This has been common practice in Finland for 15 years and in use also in other European countries. There has been recent study (see attachment) of working hours, sleep and sleepiness in HEMS personnel in Finland. Results show that pilots and HEMS crew members experience only infrequently low alertness on duty.

If FTL requirements for HEMS are laid down, Finland proposes the concept for rolling 24 hours standby period, which we have named *active standby*. Active standby includes *active duty* and *inactive duty*, and may last up to 72 hours. During this period crew stays at the base, and flight time and active duty time are limited during the rolling 24 h period. During inactive duty crew has possibility to rest. Active standby concept works well in Finland, as

average active duty during 24 h period may be as low as 3,5 hours. It also takes into account the unpredictable nature of HEMS operations. One Finnish operator has tested 12 h standby roster, which HEMS crew experienced heavier than rolling 24 h standby roster.

Most of the Finnish HEMS pilots live far away from the base, therefore travelling time is a big issue when planning the rosters. In addition to flying, HEMS pilots in Finland are required to participate the medical care situation and shall therefore be able to speak Finnish. This is limiting factor to increase the pool of sufficiently experienced pilots from abroad. In addition the government funding of HEMS is based on the fixed cost of 10 year agreement between the operator and HEMS service provider.

There has been no accidents or incidents in HEMS operations during the term of the national FTL regulation. There are less than 10 fatigue related reports per year in HEMS in the whole Finland. Finnish HEMS operations have good reporting culture in a just culture environment.

response Please see the answer to comment # 54

1996. Diese Studie wurde in keinster Weise berücksichtigt, obwohl sie die einzige, existierende Studie zum Zeitpunkt der RMT war. Zwischenzeitlich haben die Norweger, Italiener und Deutschen jeweils eine Studie zu dem Thema durchgeführt. Man sollte die	comment	1499 comment by: ADAC Luftrettung gGmbH
		berücksichtigt. In Europa gibt es eine FTL, die sogar speziell für HEMS angepasst wurde. Dies basiert auf einer wissentschaftlichen Studie der DLR (German Aerospace Center) aus 1996. Diese Studie wurde in keinster Weise berücksichtigt, obwohl sie die einzige, existierende Studie zum Zeitpunkt der RMT war. Zwischenzeitlich haben die Norweger, Italiener und Deutschen jeweils eine Studie zu dem Thema durchgeführt. Man sollte die Erkenntnisse nun auch für das CRD nutzen und wirklich auf wissentschaftlicher Basis eine
response Please see the answer to comment # 54	response	Please see the answer to comment # 54

comment	1318 comment by: Elilombarda
	Attachment <u>#43</u>
	The attached file is a copy of the comments inserted into the CRD, for a better reading.
response	Please see the answer to comment # 54
comment	1502 comment by: LPR
	Attachment <u>#46</u>

**** * * * TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 61 of 585

response Please see the answer to comment # 54

comment	1520	comment by: Air Ambulance Services of Norway
	Comments on NPA 2017-17 General	
		vay (Luftambulansetjenesten HF, shortened LAT HF) is e for all air ambulance (AEMS and HEMS) in Norway ment.
	e e	11 years with civilian AOC-holders to operate our 13 ey are all on 24/7 duty, and perform about 20 000 air year.
	world. With the new contracts starti new aircraft (9) and helicopters (17) with requirements regarding fligh	modern and advanced air ambulance services in the ng in 2018 (HEMS) and 2019 (AEMS) we will have branc with the highest safety standards available, combined at crew training, fatigue risk management system aspects of the service that well exceeds the EASA and
	the conclusion in a national study parts of Norwegian domestic helico at the same high safety level as offsh J., Heide; B., Lillehammer, G. Aas	egarded as very safe at today's level, and this was also of 2014 which compared safety and risks in different pter operations. The HEMS service was described to be nore helicopter operations in Norway (Bye, R.J., Seljelid prang, B., Antonsen, S. Vinnem, J.E., Bø, B. (2013) er - <i>Hovedrapport</i> . [Safety study inland helicopters –
	Our AEMS service is based on the pr	resent EASA regulations. Our comments to the NPA are hanges to the HEMS regulations, which are regulated
	Comments	
	states (mix of day and night services LAT HF finds that a continued legisla to ensure a safe and proper HEMS o	variety of HEMS services performed in their member , IFR, NVG, single/two pilot operations, SAR and so on) ation by the national aviation authority is the best way peration in each member state. This will also cover the he HEMS service is an integrated part of the nationa orway.
	applying for an Individual Flight Tim Risk Management Systems. This wi level playing field. It will favor th participate in the next tender proce will be almost impossible for other c	MS services, it will end up with almost all operators be Specification Scheme (IFTSS), based on their Fatigue II, contrary to the intentions of the NPA, not lead to a be operators in service in i.e. Norway, as they car ess offering a number of crews based on their IFTSS. If ontenders to compete with, as they have no such IFTSS gher number of crews. This will favour operators that

 TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.
 Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.
 Page 62 of 585

are well established in future competitions in an unfair way. This undermines the idea behind the EU-wide rules for public procurement and the rules of competition.

The HEMS operation in Norway is a national service, and less than 0.5 % of the HEMS missions performed per year are to neighboring countries.

LAT HF considers that the best way to ensure a level playing field will be to continue to have a national HEMS regulation. This will ensure that all operators can participate in future tender processes based on the public and known national regulations (as opposed to competing with the present operators who probably have an IFTSS, unwilling to share all the details).

Intended increase in safety

The HEMS service is characterized by a low number of flight hours per crew per year. In Norway the average crew member has about 200 flight hours per year. This is considered low from a flight safety aspect, given the extreme variety of missions and qualifications the crews are required to hold). Today the crews can, based on national legislation, count a 24- hour duty on base as less than 24 hours (on average 16 hours) towards the annual 2000 hour limit. If the NPA is passed this will no longer be possible, and can cause a need to increase the number of crews by as much as 44 % to meet the requirements in the NPA. This will end up in the same number of flight hours divided by a substantially higher number of crews, ending up in a critically low number of flight hours per crew per year.

The fixed wing air ambulance operation in Norway produces about 10 000 flight hours a year distributed on 9 aircraft. A high number of the flights are into short fields, with steep approaches during night time in the winter. The national authorities require the operator to give the crew special training and recency to operate into these special category airfields. With current flight time limitation it is hard for the operator to keep the crew current at all times. With the proposed limitations more pilots will be needed to deliver 24/7 service. This will lead to less flying per pilot, decreased regularity and in the end decreased level of safety.

LAT HF finds the <u>suggested change to be the largest identified risk towards flight safety in</u> <u>our service today</u>. If the NPA is passed, we strongly suggest that operators will be granted an IFTSS (based on their FRMS) that allows them to continue with 24-hour duty periods, but counting as less than 24 hours towards the annual 2000 hour limit.

<u>Costs</u>

As described above; the suggested FTL can end up in a need for up to 44 % more crews. Next to the helicopters, the crews are the most expensive part of the service (salaries, training and pensions). The number of missions will not increase by the increase of crews. LAT HF will need to buy more helicopters, fly several thousand training hours in helicopters and simulators to partly compensate for the drop in annual flight hours per crew. Without going into detail; - the potential increase in costs for the Norwegian service could be more than 10 million Euro per year.

Summary

The NPA states that the "proposed changes are expected to improve safety..... and ensure harmonisation across the EU", furthermore to "ensure a level playing field and improved safety".

In the NPA EMS Safety Risk Assessment (4.1.4.1) it is acknowledged that fatigue is at a very low occurrence, and that *"the controls that have been in place to manage fatigue in European EMS have generally been effective"*.



The NPA describes the safety, social and economic impacts of the suggested FTL (based on option 0, 1 and 2). LAT HF would emphasize the major safety risk an increase in crews could cause, in addition to a tremendous increase in costs.

Based on the:

- reduced ability for operators to participate on a level playing field,
- flight safety risks associated with the need for more crews and
- substantial increase in costs

The Air Ambulance Services of Norway (LAT HF) can only recommend Option 0 for HEMS (No policy change). The other options will lead to one or more of the consequences listed above, without any positive effects to our service.

Kind regards, Øyvind Juell Managing director (CEO) Air Ambulance Services of Norway

response

Please see the answer to comment # 54

comment	771 comment by: Yorkshire Air Ambulance
	Comments submitted hereafter reflect not only the position of the Yorkshire Air Ambulance, but broadly reflect the views of the British Helicopter Association, a trade body supporting all UK HEMS operators and affliated to the European Helicopter Association. From the outset, harmonising an FTL for these two disparate activities (air ambulance with aeroplances and HEMS with helicopters) was always likely to be challenging. The BHA suggest that a separate FTL needs to be developed for both activities, and offers to work alongside both the EHA and EASA to achieve this goal.
response	Please see the answer to comment # 54.
comment	171 comment by: Marc Rothenhäusler
	Durch eine Neuregelung der Flight Time Limitiation versuchen sie eine Vereinheitlichung zu erreichen, jedoch sind in jedem Land die unterschiedlichsten Gegebenheiten hinsichtlich der medizinischen Versorgung gegeben. Der größte Anteil an Hems Einsätzen in Europa werden in Deutschland geflogen, jedoch wird von Ihnen Deutschland nicht ausreichend berücksichtigt. Die Deutsche Luftrettung ist in Deutschland nicht wie in anderen Ländern als Ergänzung zum bodengebunden Rettungsdienst zu sehen, sondern fester Bestandteil des Rettungsdienstes, was auch in den Rettungsdienstgesetzen der einzelnen Bundesländern so geregelt ist! Die von Ihnen angestrebten Ziele würden einen massiven Einschnitt in die medizinische Versorgung in Notfällen für die Bevölkerung bedeuten.

**** ****

Sie ziehen wissenschaftliche Studien heran mit denen sie argumentieren die Flugsicherheit erhöhen zu müssen. Jedoch fehlen hier die Quellen der Studien. Ich bitte sie diese zu nennen. response Please see the answer to comment # 54. comment 525 comment by: ADAC Luftrettung gGmbH According to the document, the objective of this NPA is to develop a harmonized set of FTL rules across the European Union. The "main market" Germany with almost half of all HEMS missions flown in Europe is not taken into account enough. In Germany HEMS is an integral part of the rescue system that is also deep seated in national law concerning rescue. It is not add on service to regular rescue services like in most of the other European countries. This condition is misjudged completely by EASA. The planned rules according to this NPA would have severe negative impact on the German rescue system. EASA expects to improve flight safety by using scientific principles. Nevertheless there is no evidence of any scientific studies providing these principles especially for HEMS operation. We expect some more explanatory details on this issue. Please see the answer to comment # 54. response comment 547 comment by: Rüdiger Neu Durch die avisierte Regelung soll laut EASA eine Harmonisierung der FTL in Europa erreicht werden. Dabei wird jedoch der "Hauptmarkt" Deutschland mit fast der Hälfte aller in Europa geflogenen HEMS Einsätze nicht ausreichend berücksichtigt. In Deutschland handelt es sich bei HEMS um einen festen Bestandteil der Bevölkerungsvorsorge, der so auch in den jeweiligen Rettungsdienstgesetzen verankert ist. Es geht hierbei nicht nur, wie in den meisten anderen Ländern, um eine Ergänzung des bodengebundenen Rettungsdienstes. Diesen Umstand verkennt die EASA gänzlich. Die avisierten Regelungen hätten ganz erhebliche negative Auswirkungen auf die Notfallversorgung in Deutschland. Für die Erhöhung der Flugsicherheit werden angebliche wissenschaftliche Prinzipien angeführt, jedoch findet man keinen Hinweis auf welche wissenschaftlichen Studien sich bezogen wird. Hier erwarten wir deutlich mehr Transparenz. Please see the answer to comment # 54. response 582 comment comment by: NOLAS EASA has acknowledged that, and this is indeed clearly stated in the NPA, there are no indications that the existing FTL requirements for HEMS, which is under national authority approvals, poses a flight safety problem. We do understand that it does not mean that

**** * * *** there are operations that could be run in a better/safer way course. However, presently this means that the goal is merely to harmonize and standardize the regulations.

It is our point of view that the NPA, as far as HEMS goes, has been conceived using a general lack of supporting data, an incomplete pre-RIA report by DNV and very few (relevant) or outdated scientific publications concerning fatigue in HEMS. This has led to an NPA that is quite redundant to ensure that it covers all aspects of risk of fatigue in all European HEMS operation.

The new FTL requirements for HEMS as envisioned in the NPA, will not meet most operators requirements and to continue their operation, which in the vast majority of cases is run in a safe manner with regards to fatigue, they will have to use the Regulation (EC) No 216/2008 Article 14-6 or 22-2 flexibility provision and apply for an Individual Flight Time Specification Scheme (i.e. Option 1 - Flexible approach). This would certainly be the case for our operation (Our operation is 24/7 with a crew that has, in general, a 7/14/7/21 roster for pilots and a 7/21 roster for HEMS technical crew members in an operating environment characterized by a low number of missions per day).

So, while we do agree fully with the principles of the objective of the NPA, we believe that harmonization and standardization will not be achieved and cannot be achieved in an industry that operates in such a contextual way in such a vast area as Europe.

The European HEMS operating patterns are highly diversified (not only between countries, but also within countries) and have been developed and matured over a long period of time. The diversified operating patterns are necessary to perform safe and affordable HEMS operations in very different operating environments and in accordance with different requirements. Harmonizing and standardizing might not be the way to go unless the harmonization and standardization is at a framework level where the actual details are left up to the national authorities.

While we believe that "Option 0 - No policy change" would work quite well for most Member States, we do recognize that "Option 1 - Flexible approach" could have the benefit of forcing the operators to demonstrate a safe operation. This will be quite costly and not practicable for many small operators, however and would also at the end lead to significant barriers of entry.

"Option 2 – Fully prescriptive approach" would, as stated in the NPA, have a "Positive low benefits" for safety pertaining to the risk of fatigue, but we doubt it. For many operators/member states the envisioned safety benefits to guard against fatigue could be nullified due to the extra amount of commuting, which is itself causing extra stress and fatigue, that would be introduced. Furthermore, the regulation would have a negative impact on the service in way too many other cases. It will have a negative impact on social aspects for the "customers" (i.e. the patients) due to a lowered availability of the service), the public and the crew members. For the operation in Norway (a period of 6 + 2 + 2 years commencing 1.6.2018), Option 2 would incur an estimated cost of 250 million NOK (25 660 000 €) per year if the intention would be to maintain the same level of service and safety standard (amount to be verified by our customer). HEMS in Norway, while a CAT operation, is a public service matter and this cost increase would have to be carried by our customer and public funding. This cost increase, without adding any measurable safety benefit for the operation, is not acceptable. The alternative is a substantial reduction of the overall level of safety and/or service, but this is a scenario that cannot be accepted

**** * * **** either. Additionally, the risk of fatigue will potentially increase, in many cases, due to heavy commuting.

Other factors negative for flight safety would be introduced as well. These negative factors would include accepting lowered standards (due to difficulties in recruiting suitably experienced, qualified crew members with the proper attitude) and a lack of recency (the same amount of missions would have to be flown by a substantially higher number of crew members.

In conclusion, NLA believes that that EASA has been given an impossible task under the present circumstances and that at least for the time being, the only suitable solution for HEMS FTL is "Option 0 - No policy change" as it will have a neutral safety impact, if operations remain predominantly in the Member State that issues the Air Operator Certificate. A new NPA specific for HEMS FTL should be developed and we are happy to assist, in any capacity, for all HEMS FTL matters pertaining to Scandinavian operations.

As the regulations envisaged in the NPA is so far off from our operating concept and pattern, we can only provide constructive comments on principles and major issues.

response

Please see the answer to comment # 54.

comment	760 comment by: DRF-Luftrettung
	HEMS Operators very often perform their tasks in the field of public health insurances. Economic changes and social impacts lead to increased wages which will not always be covered by the health system. We therefore assume that many HEMS operators will have to use the flexibility provisions. This will jeopardies all efforts of harmonization. Instead of 31 national regulations we will end up with 360 individually based Flight time specification schemes.
	According to article 2 of the basic regulation, this NPA is therefore not valuable to provide a level playing field for all actors in the common European aviation market and to facilitate free movements of persons and services
response	Please see the answer to comment # 54.

comment 792

comment by: Yorkshire Air Ambulance

The BHA welcomes any attempt by EASA to provide a level playing field in the scope of a HEMS FTL, but the current NPA falls short of achieving this objective. Feedback from realworld experience was quite limited, and probably not comprehensive enough to cover all eventualities. Equally, by EASA's own admission, the scientific evidence is patchy and provides few obvious criteria to nessitate significant changes to National FTLs. Overall, the BHA position will be to support EASA by adopting Option 1 - Flexible Approach. However, further industry consultation must take place to deliver substantial alterations to this NPA,

**** * **** otherwise operators will be forced to apply for individual FTSS and thus the common purpose of a uniform FTL will be lost.

response

Please see the answer to comment # 54.

comment 1326

comment by: Civil Aviation Authority of Norway

General comment:

We recognize the efforts that has been made to develop this rulemaking proposal. We generally support the proposal with regard to ATXO, AEMS and single pilot operations. On HEMS operations we recognize the difficulties for establishing common European rules due to the nature of these air services and the variety of how HEMS is regulated in the

different EU and EFTA states. Due to the demography and the topographical characteristics in Norway, HEMS services is widely used as the only practical means for emergency medical transport. HEMS bases are spread out across the country, and the operation is typically characterized by stand-by duty which is performed by crew who lives in other parts of the country, and a relatively low number of flights during each duty period. If the proposed HEMS FTL rules were to be applied to this operation, many of the highly negative effects recognized by EASA in the impact assessment would apply. If this proposal is adopted we therefore expect that we have to exclude most of our HEMS base from applying the regulation by using the proposed amendment to Article 8. In that respect we support the "Option 1 - flexible approach" which has been taken with regard to regulating FTL for HEMS. The disadvantage of this approach is however a lack of harmonization of FTL requirements across Europe. Additionally, if the possibility for establishing individual FTL schemes will be widely used (something we suspect will be the case), this will put considerable workload and cost on operators, NAAs and on EASA. The possible economic benefits an efficiency gains resulting from harmonized rules, such as creating a common market for such services and a level playing field, will then risk failing. We therefore ask EASA to consider if the proposal regarding HEMS FTL rules is sufficiently mature to be put forward. In our view the "Option 0 –no policy change" is preferable for HEMS FTL until a proposal which is better adapted to the specific nature of HEMS operations can be put forward.

response

Please see the answer to comment # 54.

comment	1416 comment by: FinnHEMS Oy
	-Aircrew members will not benefit because more aircrew must be hired => less flighthours for crews
response	Please see the answer to comment # 54.
comment	3 comment by: DHV e.V.

Extension submission of comments NPA 2017-17

**** * * ***

 TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

 Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

 Page

NPA 2017-17 "Flight Time Limitations for commercial air transport operations of emergency medical services…" has been published on October 27th. The deadline for submission of comments is 31 January 2018.

Our members, ADAC Luftrettung and DRF Luftrettung, the two biggest HEMS operator in Germany carried out a scientific study this summer. The study is make in cooperation with the German Aerospace Center (DLR) and compares the actual duty schemes with future shift duty schemes.

The results of the study are expected by the beginning of February 2018.

These results will enable us to give adequate and scientific based comments on the NPA. Theerefore we apply for an extension of the submission of comments until **31 March 2018**.

response

See Comments response period was extended until 31 March 2018.

1. About this NPA

2.1. Why we need to change the rules issue/rationale

comment 91 comment by: B. Wagner Die aufgeführten Datenquellen decken nicht den HEMS Bereich ab. Einzige Quelle mit HEMS Bezug ist Samel et al, 2004. Diese Studie kommt allerdings nicht zu neuen oder besseren Erkenntnissen, als bereits in der 2. DVLuft BO festgelegt sind. Keine Veranlassung, von den bestehenden Regelungen überhaupt abzuweichen, ausser zur europaweiten Harmonisierung. Dies wird jedoch aufgrund der völlig unterschiedlich aufgestellten nationalen Rettungsdienststrukturen nicht gelingen können und dazu führen, dass es eine Vielzahl nationaler Ausnahmen geben wird. Please see the answer to comment # 54. response comment 1419 comment by: FinnHEMS Oy There seems to be very few relevant data sources reverting to HEMS. Please see the answer to comment # 54. response



gency of the European Unior

p. 3-4

comment 172 comment by: Marc Rothenhäusler Der tägliche Ablauf von Hems Einsätzen findet überwiegend unter VFR - Bedingungen. Zwischen den Einsätzen finden oft längere Pausen statt auf Station mit der Möglichkeit Ruhezeit einzuhalten. Dazu kommt, dass selbst an Einsatzstellen keine Arbeit des Piloten notwendig ist, wir natürlich nicht Ruhen können aber nicht aktiv und anstrengend arbeiten sondern einfach nur warten, bis die Besatzung zurückkommt. Einen Vergleich mit Flächenpiloten zu ziehen ist vollkommen nicht möglich, welche unter Umständen stundenlang im Cockpit verbringen. Hubschraubern ist es auch möglich in den meisten Fällen einer Notsituation eine sofortige Landung durchzuführen. Daher komme ich zu der Meinung, dass eine Verschärfung der Flight Time Limitation und Vereinheitlichung der Regeelung für den Flächenflugbetrieb und den Hems Flugebtrieb nicht richtig ist! Please see the answer to comment # 54. response

comment	220 comment by: ADAC Luftrettung gGmbH
	Im HEMS Flugbetrieb entstehen teilweise lange Pausen zwischen Einsätzen. Unter anderem deshalb ist die Belastung eines Airline-Piloten nicht direkt mit einem HEMS- Piloten vergleichbar, und entsprechende Studien sind nicht zwangsläufig übertragbar.
response	Please see the answer to comment # 54.

comment	248	comment by: European Helicopter Association (EHA)
	ADAC (Germany), DRF (Germany) and LAR (Luxembourg):	
	2.1 Para 11	
	HEMS is mostly on-demand VFR operations and (long) breaks at home base. Therefor the work load cannot be compared to the work load of a fixed wing crew that often lasts for several hours. Additionally if emergency conditions occur in a helicopter an emergency landing is possible almost everywhere. That's why it makes no sense to adopt rules developed by use or scientific studies performed in fixed wing operations.	
response	Please see the answer to comment	# 54.

*** * * ***

comment	377 comment by: Joachim J. Janezic (Institute for Austrian and International Aviation law)
	Art 5 para 1 second sentence TEU provides: "The use of Union competences is governed by the principles of subsidiarity and proportionality.
	Art 5 para 3 TEU provides "Under the principle of subsidiarity, in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level."
	The NPA in question is related to a regulatory subject which does not fall within the exclusive competence of the EU but rather within the shared competence in transport matters (Art 2 para 2 in conjunction with Art 4 para 2 lit g and Art 100 para 2 TFEU), since the Basic Regulation 216/2008 is based on Art 80 EC (now Art 100 TFEU) and the NPA in question will at the end of the rulemaking process form the base for an implementing regulation. According to its wording the principle of subsidiarity calls for two requirements: A test of comparative efficiency, looking at the capacity of Member States for problemsolving, which must be negative in outcome, and a test of added value in EU regulation, which must be positive in outcome. EASA observes in the NPA that HEMS operations usually remain within the territory of the Member State in which they are conducted. EASA has neither demonstrated why national regulation cannot adequately guarantee the safety of such operations, nor has it shown any added value in EU regulation. Hence, EU regulation on the subject would clearly violate the principle of subsidiarity, and any such implementing regulation would be null and void according to Art 263 TFEU.
response	Not accepted. HEMS operations are already regulated by EU Regulation 965/2012. The only element of HEMS that is still under national regulation is FTL. According to your logic, that Regulation has been violating the principle of subsidiarity since 2012. In fact, EU Regulation 965/2012 effectively applies from 2014 by EU Member States and European operators and individual crew members, without any legal action being brought against it on that ground.

comment

378

comment by: Joachim J. Janezic (Institute for Austrian and International Aviation Iaw)

In some countries of the European Union HEMS is considered to be a service in public interest which leads to the conclusion that financing such systems is part of the public healthcare system.

HEMS therefore is based on contracts between state authorities on the one hand and HEMS operators on the other. These contracts are the result of call for tenders and a following bidding process and have a certain agreed duration. This system of contracts (involving federal governments, district governments and social security institutions) is very complex, well-balanced, fragile but working.

**** * * *** Changing the facts which have an impact to the cost to which an operator is able to render its services would require to change these contracts if the changes of facts are above a certain threshold. Since the rules proposed in the NPA would result in an increase of the pilot's and HEMS-CM's headcount of about 40% of FTE the changes to be expected are very well above any such threshold.

Having in mind the complexity of the negotiations for these contracts in the past and fearing that new contracts will not be in place before the new rules enter into force, we believe that these rules might endanger a very important piece of the public healthcare system and therefore the life and Health of the public.

Considering on the one hand the fact that there is literally <u>no positive impact on aviation</u> <u>safety</u> to be expected and on the other hand the potential negative effects for the public, we are strongly concerned that the rules exceed what is necessary to achieve the objectives of the Treaties of the European Union and therefore infringe Article 5 para 4 TEU and – since the NPA is supposed to result in a Commission Regulation – the Protocol on the Application of the Principles of Subsidiarity and Proportionality. Any such implementing regulation would be null and void according to Art 263 TFEU.

Considering the aim of the NPA to level the playing field amongst European HEMS operators EASA does obviously not realize that HEMS primarily is a national (domestic) type of operation; cross-border HEMS missions are less than 5% of all HEMS missions flown in Austria. Also from this point of view the idea of a level playing field is on the one hand not necessary (again subsidiarity and proportionality) and on the other hand not within the scope of EASA (E A SAFETY A) since it is not safety critical at all.

response

Please see the answer to comment # 377 and # 54.

comment	414 comment by: UFH French Helicopters Association	
	The operational justifications expressed in this chapter n°2 of the NPA do not correspond to operating conditions of the HEMS encountered on the French national territory. Indeed, it is stated that:	
	 An activity of up to 20 flights over a period of a few hours 	
	 o This level of activity is unknown in France (in average less than 2 missions i.e 4 flights) • Unknown landing sites 	
	o In France, 75% of the flights are performed between 2 hospitals' helipads duly mapped	
	• Daily duty period of 15h or 16h are guoted	
	o In France, such duration of duty period are not performed in the national territory (French scheduled effective operational FDP are lasting 12h)	
	The fatigue risk generated by the HEMS activity in France must therefore be properly assessed:	
	• It is mostly a local transport activity (the average HEMS leg for SNEH is less than 50NM or less than 25 minutes of flight timei), which is most often performed between 2 well known HEMS operating bases.	
	• In average, the total flight time per FDP (in France, FDPs are currently scheduled at 12h excluding the pre-flight) is ranged between 30 min and 1h30i	
	• The annual rest periods are ranged between 199 days and 220 days per yeari	

Considering the same fatigue evaluation than for CAT.A FTL rules does not seem justified. This is reinforced by the impact study presented in chapter 4 of the NPA 2017-17. Generally speaking, FNAM would welcome a new RIA better reflecting the reality of the operations.

Besides fatigue, this NPA will lead, for single pilot + 1 TCM operations, to double the crews for H12/24 operational readiness and to increase by 50% the crew for H24 operational readiness.

As a consequence, the NPA's proposed dispositions will lead to diminish the flight safety due to a lack of practical recent experience for pilots. Indeed, if these proposed requirements are implemented, the pilots would fly 1.5 times to half-time less. As a consequence, only 50% to 66% of the flight times flown by a given pilot nowadays would be performed by this same pilot if applying this NPA. Besides, HEMS pilots are scarce resources in France, and this NPA would lead to hire 120 additional pilots and 120 additional TCM in order to offer the same quality of HEMS activity in France. This represents an additional cost of 20% for the whole French HEMS State Budget. It is likely that such a massive recruitment would not be achievable and would thus result in a significant reduction in the quality of the French Healthcare system.

At the moment in France, crews are flying between 80 to 140 flight hours in average per year which is already low for a professional pilot activity. With the new proposed requirements of the NPA, pilots would only be able to fly between 40 to 90 flight hours per year which barely corresponds to an aeroclub activity. The pilots activity level could thus reach less than 5 hours of flight per month on a 24H/24 HEMS operating base resulting in a loss of skills which is detrimental to flight safety

response

Please see the answer to comment # 54.

comment	446 comment by: Hélicoptères de France
	The operational justifications expressed in this chapter n°2 of the NPA do not correspond to operating conditions of the HEMS encountered on the French national territory. Indeed, it is stated that:
	 An activity of up to 20 flights over a period of a few hours
	 o This level of activity is unknown in France (in average less than 2 missions i.e 4 flights) Unknown landing sites
	o In France, 75% of the flights are performed between 2 hospitals' helipads duly mapped
	• Daily duty period of 15h or 16h are quoted
	o In France, such duration of duty period are not performed in the national territory (French scheduled effective operational FDP are lasting 12h)
	The fatigue risk generated by the HEMS activity in France must therefore be properl assessed:
	• It is mostly a local transport activity (the average HEMS leg for SNEH is less than 50NN or less than 25 minutes of flight timei), which is most often performed between 2 we known HEMS operating bases.
	• In average, the total flight time per FDP (in France, FDPs are currently scheduled at 12h
	excluding the pre-flight) is ranged between 30 min and 1h30i
	• The annual rest periods are ranged between 199 days and 220 days per yeari
	Considering the same fatigue evaluation than for CAT.A FTL rules does not seem justified

**** * * * * * * This is reinforced by the impact study presented in chapter 4 of the NPA 2017-17. Generally speaking, Hélicoptères de France would welcome a new RIA better reflecting the reality of the operations.

Besides fatigue, this NPA will lead, for single pilot + 1 TCM operations, to double the crews for H12/24 operational readiness and to increase by 50% the crew for H24 operational readiness.

As a consequence, the NPA's proposed dispositions will lead to diminish the flight safety due to a lack of practical recent experience for pilots. Indeed, if these proposed requirements are implemented, the pilots would fly 1.5 times to half-time less. As a consequence, only 50% to 66% of the flight times flown by a given pilot nowadays would be performed by this same pilot if applying this NPA. Besides, HEMS pilots are scarce resources in France, and this NPA would lead to hire 120 additional pilots and 120 additional TCM in order to offer the same quality of HEMS activity in France. This represents an additional cost of 20% for the whole French HEMS State Budget. It is likely that such a massive recruitment would not be achievable and would thus result in a significant reduction in the quality of the French Healthcare system.

At the moment in France, crews are flying between 80 to 140 flight hours in average per year which is already low for a professional pilot activity. With the new proposed requirements of the NPA, pilots would only be able to fly between 40 to 90 flight hours per year which barely corresponds to an aeroclub activity. The pilots activity level could thus reach less than 5 hours of flight per month on a 24H/24 HEMS operating base resulting in a loss of skills which is detrimental to flight safety (cf. attachment "synthèse SNEH").

response

Please see the answer to comment # 54.

comment 458 comment by: FNAM/SNEH Attachment #49 The operational justifications expressed in this chapter n°2 of the NPA do not correspond to operating conditions of the HEMS encountered on the French national territory. Indeed, it is stated that: An activity of up to 20 flights over a period of a few hours This level of activity is unknown in France (in average less than 2 0 missions *i.e* 4 flights) Unknown landing sites In France, 75% of the flights are performed between 2 hospitals' helipads 0 duly mapped Daily duty period of 15h or 16h are quoted In France, such duration of duty period are not performed in the national territory (French scheduled effective operational FDP are lasting 12h) The fatigue risk generated by the HEMS activity in France must therefore be properly assessed:

- It is mostly a local transport activity (the average HEMS leg for SNEH is less than 50NM or less than 25 minutes of flight timeⁱ), which is most often performed between 2 well known HEMS operating bases.
- In average, the total flight time per FDP (in France, FDPs are currently scheduled at 12h excluding the pre-flight) is ranged between 30 min and 1h30ⁱ
- The annual rest periods are ranged between 199 days and 220 days per yearⁱ

Considering the same fatigue evaluation than for CAT.A FTL rules does not seem justified. This is reinforced by the impact study presented in chapter 4 of the NPA 2017-17.

Generally speaking, FNAM and SNEH would welcome a new RIA better reflecting the reality of the operations.

Besides fatigue, this NPA will lead, for single pilot + 1 TCM operations, to double the crews for H12/24 operational readiness and to increase by 50% the crew for H24 operational readiness.

As a consequence, the NPA's proposed dispositions will lead to diminish the flight safety due to a lack of practical recent experience for pilots. Indeed, if these proposed requirements are implemented, the pilots would fly 1.5 times to half-time less. As a consequence, only 50% to 66% of the flight times flown by a given pilot nowadays would be performed by this same pilot if applying this NPA. Besides, HEMS pilots are scarce resources in France, and this NPA would lead to hire 120 additional pilots and 120 additional TCM in order to offer the same quality of HEMS activity in France. This represents an additional cost of 20% for the whole French HEMS State Budget. It is likely that such a massive recruitment would not be achievable and would thus result in a significant reduction in the quality of the French Healthcare system.

At the moment in France, crews are flying between 80 to 140 flight hours in average per year which is already low for a professional pilot activity. With the new proposed requirements of the NPA, pilots would only be able to fly between 40 to 90 flight hours per year which barely corresponds to an aeroclub activity. The pilots activity level could thus reach less than 5 hours of flight per month on a 24H/24 HEMS operating base resulting in a loss of skills which is detrimental to flight safety (cf. attachment "synthèse SNEH").

response

Please see the answer to comment # 54.

comment 523

comment by: ADAC Luftrettung gGmbH

This new regulation aims to increase flight safety on cone hand and harmonization of the natonal regulations on the other hand. But harmonization does not make sence in this context, when different requirements of member states are not considered.



With the 2. DVLuftBO § 22-23 of the German FTL regulation, there is a well proven FTL regulation exspecially for HEMS in force for years, that is based on a scientific studie and takes into account the special circumstances in our country our environment.

HEMS is mostly on-demand VFR operations and (long) breaks at home base. Therefor the work load cannot be compared to the work load of a fixed wing crew that often lasts for several hours. Additionally if emergency conditions occur in a helicopter an emergency landing is possible almost everywhere. That's why it makes no sense to adopt rules developed by use of scientific studies performed in fixed wing operations.

response

Please see the answer to comment # 54.

comment 548 comment by: Rüdiger Neu HEMS ist meist geprägt durch VFR-Flugbetrieb und (lange) Pausen auf der Station. Somit ist die Belastung gegenüber einem Flächenflugbetrieb mit mehreren zusammenhängenden Stunden Cockpit-Arbeit nicht vergleichbar. Ebenso ist in besonderen Notlagen eine schnelle Landung mit einem Hubschrauber meist überall möglich. Somit kann eine Verschärfung der Regelungen, sowie die Anwendung wissenschaftlicher Studien im Flächenflugbetrieb nicht für HEMS herangezogen werden. Please see the answer to comment # 54. response

comment	638 comment by: <i>Oya Vendée Hélicoptères</i>
	Attachment <u>#50</u>
	The operational justifications expressed in this chapter n°2 of the NPA do not correspond to operating conditions of the HEMS encountered on the French national territory.
	Indeed, it is stated that:
	 An activity of up to 20 flights over a period of a few hours This level of activity is unknown in France (in average less than 2 missions i.e 4 flights) Unknown landing sites In France, 75% of the flights are performed between 2 hospitals' helipads duly mapped Daily duty period of 15h or 16h are quoted In France, such duration of duty period are not performed in the national territory (French scheduled effective operational FDP are lasting 12h)
	The fatigue risk generated by the HEMS activity in France must therefore be properly assessed:



- It is mostly a local transport activity (the average HEMS leg for OYA is less than 50NM or less than 25 minutes of flight timei), which is most often performed between 2 well known HEMS operating bases.
- In average, the total flight time per FDP (in France, FDPs are currently scheduled at 12h excluding the pre-flight) is ranged between 30 min and 1h30i
- The annual rest periods are ranged between 199 days and 220 days per year

Considering the same fatigue evaluation than for CAT.A FTL rules does not seem justified. This is reinforced by the impact study presented in chapter 4 of the NPA 2017-17.

Generally speaking, OYA would welcome a new RIA better reflecting the reality of the operations.

Besides fatigue, this NPA will lead, for single pilot + 1 TCM operations, to double the crews for H12/24 operational readiness and to increase by 50% the crew for H24 operational readiness.

As a consequence, the NPA's proposed dispositions will lead to diminish the flight safety due to a lack of practical recent experience for pilots. Indeed, if these proposed requirements are implemented, the pilots would fly 1.5 times to half-time less. As a consequence, only 50% to 66% of the flight times flown by a given pilot nowadays would be performed by this same pilot if applying this NPA. Besides, HEMS pilots are scarce resources in France, and this NPA would lead to hire 120 additional pilots and 120 additional TCM in order to offer the same quality of HEMS activity in France. This represents an additional cost of 20% for the whole French HEMS State Budget. It is likely that such a massive recruitment would not be achievable and would thus result in a significant reduction in the quality of the French Healthcare system.

At the moment in France, crews are flying between 80 to 140 flight hours in average per year which is already low for a professional pilot activity. With the new proposed requirements of the NPA, pilots would only be able to fly between 40 to 90 flight hours per year which barely corresponds to an aeroclub activity. The pilots activity level could thus reach less than 5 hours of flight per month on a 24H/24 HEMS operating base resulting in a loss of skills which is detrimental to flight safety (cf. attachment "synthèse SNEH").

response

Please see the answer to comment # 54.

comment 901

comment by: MBH SAMU

Attachment <u>#51</u>

The operational justifications expressed in this chapter n°2 of the NPA do not correspond to operating conditions of the HEMS encountered on the French national territory.

Indeed, it is stated that:



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 77 of 585

- An activity of up to 20 flights over a period of a few hours
 - This level of activity is unknown in France (in average less than 2 missions i.e 4 flights)
- Unknown landing sites
- In France, 75% of the flights are performed between 2 hospitals' helipads duly mapped
- Daily duty period of 15h or 16h are quoted
 - In France, such duration of duty period are not performed in the national territory (French scheduled effective operational FDP are lasting 12h)

The fatigue risk generated by the HEMS activity in France must therefore be properly assessed:

- It is mostly a local transport activity (the average HEMS leg for MBH is less than 50NM or less than 25 minutes of flight timei), which is most often performed between 2 well known HEMS operating bases.
- In average, the total flight time per FDP (in France, FDPs are currently scheduled at 12h excluding the pre-flight) is ranged between 30 min and 1h30i
- The annual rest periods are ranged between 199 days and 220 days per year

Considering the same fatigue evaluation than for CAT.A FTL rules does not seem justified. This is reinforced by the impact study presented in chapter 4 of the NPA 2017-17.

Generally speaking, MBH would welcome a new RIA better reflecting the reality of the operations.

Besides fatigue, this NPA will lead, for single pilot + 1 TCM operations, to double the crews for H12/24 operational readiness and to increase by 50% the crew for H24 operational readiness.

As a consequence, the NPA's proposed dispositions will lead to diminish the flight safety due to a lack of practical recent experience for pilots. Indeed, if these proposed requirements are implemented, the pilots would fly 1.5 times to half-time less. As a consequence, only 50% to 66% of the flight times flown by a given pilot nowadays would be performed by this same pilot if applying this NPA. Besides, HEMS pilots are scarce resources in France, and this NPA would lead to hire 120 additional pilots and 120 additional TCM in order to offer the same quality of HEMS activity in France. This represents an additional cost of 20% for the whole French HEMS State Budget. It is likely that such a massive recruitment would not be achievable and would thus result in a significant reduction in the quality of the French Healthcare system.

At the moment in France, crews are flying between 80 to 140 flight hours in average per year which is already low for a professional pilot activity. With the new proposed requirements of the NPA, pilots would only be able to fly between 40 to 90 flight hours per year which barely corresponds to an aeroclub activity. The pilots activity level could thus

**** * * ****

	reach less than 5 hours of flight per month on a 24H/24 HEMS operating base resulting in a loss of skills which is detrimental to flight safety (cf. attachment "synthèse SNEH").						
response	Please see the answer to comment # 54.						
comment	1179 comment by: SAF						
	Attachment <u>#52</u>						
	The operational justifications expressed in this chapter n°2 of						
	the NPA do not correspond to operating conditions of the						
	HEMS encountered on the French national territory.						
	Indeed, it is stated that:						
	 An activity of up to 20 flights over a period of a few hours This level of activity is unknown in France (in average less than 2 missions i.e 4 flights) Unknown landing sites In France, 75% of the flights are performed between 2 hospitals' helipads duly mapped Daily duty period of 15h or 16h are quoted In France, such duration of duty period are not performed in the national territory (French scheduled effective operational FDP are lasting 12h) 						
	The fatigue risk generated by the HEMS activity in France must therefore be properly assessed:						
	 It is mostly a local transport activity (the average HEMS leg for SAF is less than 50NM or less than 25 minutes of flight timei), which is most often performed between 2 well known HEMS operating bases. In average, the total flight time per FDP (in France, FDPs are currently scheduled at 12h excluding the pre-flight) is ranged between 30 min and 1h30i The annual rest periods are ranged between 199 days and 220 days per year 						
	Considering the same fatigue evaluation than for CAT.A FTL rules does not seem justified.						
	This is reinforced by the impact study presented in chapter 4 of the NPA 2017-17.						

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Generally speaking, SAF would welcome a new RIA better reflecting the reality of the operations.

Besides fatigue, this NPA will lead, for single pilot + 1 TCM operations, to double the crews for H12/24 operational readiness and to increase by 50% the crew for H24 operational readiness.

As a consequence, the NPA's proposed dispositions will lead to diminish the flight safety due to a lack of practical recent experience for pilots. Indeed, if these proposed requirements are implemented, the pilots would fly 1.5 times to half-time less. As a consequence, only 50% to 66% of the flight times flown by a given pilot nowadays would be performed by this same pilot if applying this NPA. Besides, HEMS pilots are scarce resources in France, and this NPA would lead to hire 120 additional pilots and 120 additional TCM in order to offer the same quality of HEMS activity in France. This represents an additional cost of 20% for the whole French HEMS State Budget. It is likely that such a massive recruitment would not be achievable and would thus result in a significant reduction in the quality of the French Healthcare system.

At the moment in France, crews are flying between 80 to 140 flight hours in average per year which is already low for a professional pilot activity. With the new proposed requirements of the NPA, pilots would only be able to fly between 40 to 90 flight hours per year which barely corresponds to an aeroclub activity. The pilots activity level could thus reach less than 5 hours of flight per month on a 24H/24 HEMS operating base resulting in a loss of skills which is detrimental to flight safety (cf. attachment "synthèse SNEH").

response Please see the answer to comment # 54.

comment	173 comment by: Marc Rothenhäusler
	Eine Vereinheitlichung des Hems Flugbetriebs europaweit ist meines Erachtens nicht tragbar, da die Luftrettung in den einzelnen Ländern unterschiedlichst eingesetzt wird und einen unterschiedlichen Stellenwert in der Patientenversorgung hat. So ist die Luftrettung in Deutschland in der notärztlichen Versorgung der Bevölkerung gar nicht mehr weg zu denken, wohingegen in anderen Ländern das Hauptaugenemrk auf dem sekundären Transport von Patienten liegt!
response	Please see the answer to comment # 54.

comment249comment by: European Helicopter Association (EHA)ADAC (Germany), DRF (Germany) and LAR (Luxembourg):2.2In European countries, HEMS operation as part of the complete rescue system varies
depending on geographical conditions and existing ground based services. With these
prerequisites a harmonization in this special field of operation is neither reasonable nor

*** * * *** desirable. In Germany for instance, use of helicopters is an integral part of patient care, especially acute care. Other countries focus more on subordinated patient transport.

response

Please see the answer to comment # 54.

2.2. What we want to achieve - objectives

comment	309	comment by: European Helicopter Association (EHA)				
	NORSK LUFTAMBULANSE AS (Norway):					
"The specific objective of this proposal is to establish an improved and Europe-wide basis for regulating flight and duty times and rest periods for HI scientific knowledge and established best practices."						
	Comment: Exactly what scientific knowledge does this refer to? The scientif NPA is based on are inconclusive, not fully relevant or dated when it perta With reference to this, who decides what "best practices" are?					
response	Please see the answer t	o comment # 54				
	L					
comment	358	comment by: European Helicopter Association (EHA)				
	BHA (UK)					
	Europe-wide basis for r	of this proposal is to establish an improved and proportionate egulating flight and duty times and rest periods for HEMS, based on d established best practices".				
	small sample (<20) of a 'Best practices' is a pej	, does this refer to the study by FRMSc, which only looked at a very r taxi pilots, using their own commercial algorithms such at SAFE? orative term and probably shouldn't be used. Who has sufficient at "best practice" is for everyone?				
response	Please see the answer t	o comment # 54				
	1					
comment	526	comment by: ADAC Luftrettung gGmbH				
	- ·	HEMS operation as part of the complete rescue system varies hical conditions and existing ground based services. With these				



p. 6

prerequisites a harmonization in this special field of operation is neither reasonable nor desirable. In Germany for instance, use of helicopters is an integral part of patient care, especially acute care. Other countries focus more on subordinated patient transport.

response Please see the answer to comment # 54

comment 549

comment by: Rüdiger Neu

Da dem HEMS-Betrieb in den europäischen Ländern ein jeweils unterschiedlicher Stellenwert im Rahmen der Notfallversorgung zukommt und insofern auch die geographischen Gegebenheiten und die medizinische Versorgung unterschiedlich sind, ist eine einheitliche Regelung in diesem speziellen Anwendungsgebiet überhaupt nicht möglich und auch nicht wünschenswert. In Deutschland ist der Einsatz von Hubschraubern beispielsweise fester Bestandteil der notärztlichen Versorgung der Bevölkerung, insbesondere in der Akutmedizin. In anderen Ländern liegt z.B. der nachgeordnete Patiententransport im Fokus.

response

Please see the answer to comment # 54.

comment	584 comment by: NOLAS
	"The specific objective of this proposal is to establish an improved and proportionate Europe- wide basis for regulating flight and duty times and rest periods for HEMS, based on scientific knowledge and established best practices."
	Comment: Exactly what scientific knowledge does this refer to? The scientific studies this NPA is based on are inconclusive, not fully relevant or dated when it pertains to HEMS. With reference to this, who decides what "best practices" are?
response	Please see the answer to comment # 54
commer	t 741 comment by: DRF-Luftrettung

**** ****

General

We welcome the intention of the EASA to further enhance the safety of air operations by means of extensions to Regulation (EU) 965/2012 relating to flight time limitations. We are pleased to use the opportunity to comment on the EASA legislative proposals for the safe implementation of HEMS flight operations. We consider it reasonable to adapt the legal situation on FTL throughout all member states in order to strengthen the acceptance of the air rescue service throughout Europe and the aviation safety awareness within the crews.

Talking about the development of the NPA 2017-17, one main goal of the EASA was the harmonization of the FTL all over the member states. The conclusion of the EASA to follow a flexible approach is neither appropriate to achieve this goal nor is the justification for option 1 comprehensive. To many factors leading to the conclusion have to be questioned. With nearly 90.000 HEMS Mission each year the German HEMS Operators fly more than 40% of the HEMS Missions counted by all 27 member states and the four associates. We therefore consider ourselves to be competent enough, to look at the new proposals from the German sight of view.

Harmonization issues

HEMS Operators very often perform their tasks in the field of public health insurances. Economic changes and social impacts lead to increased wages which will not always be covered by the health system. We therefore assume that many HEMS operators will have to use the flexibility provisions. This will jeopardies all efforts of harmonization. Instead of 31 national regulations we will end up with 360 individually based Flight time specification schemes.

According to article 2 of the basic regulation, this NPA is therefore not valuable to provide a level playing field for all actors in the common European aviation market and to facilitate free movements of persons and services.

Studies and best practice

The specific objective of this proposal is to establish an improved and proportionate Europe-wide basis for regulating flight and duty times and rest periods for HEMS, based on scientific knowledge and established best practices.

We have to question very critically the scientific studies and knowledges which have been used. In attachment 2 of the NPA we find some references to studies, which are not aviation based but relate to truck drivers, oil rig workers and railroad drivers which examine fatigue in the field of ground based transportation companies, automobile factories and more.

Here we see one large field, where the data is not appropriate to be compared with the HEMS service. Working as employer in a factory always means, that from beginning of the shift until the late end there are no extended break times more than the national labor time regulations.

Looking at the tables in Attachment 1 – data collection of EMS FTL provisions we have to state clear, that although the daily duty period may be up to 16 hours, the flight duty period is limited to a much lesser value. In practice this means, that if the HEMS Crew has to fly multiple missions a day, the flight duty time increases and the crew has to quit the service before the duty period is expired. On the other hand are flights at the end of the duty day only possible, when the crew had some hours rest in between.

Fatigue in the HEMS Operation is therefore minimized due to early ends or several breaks in between and cannot be compared with scientific studies in other branches.

An agency of the European Union

We would like to point out one more mentioned study, where data collection and conclusion do not fit the actual fatigue based evidences.

The EASA takes the Study of Goodes from 2003 (Journal of safety research 2003) and states, that working hours more than 12 hours a day have a more than 5 time larger risk of fatigue related incidents.

Goodes did not compare EMS but commercial American air traffic and used the so called Chi square to combine two totally different sets of statistic. His first set was the accident statistic from 1978 to 1999 with 55 accidents. His second setup was a set of the working hours from 10 aircraft carriers taken in one month in 1999.

His conclusion was, that 5% of human factor accidents where related to pilots working more than 13 hours. The ratio taken from the working hours showed him, that in this specific one month period only 1% of the pilots worked more than 13 hours.

Combining these both ratios he concluded, that the risk is more than 5 times higher than for the working shifts with less than 13 hours working time.

Looking at this study, you can read, that Goodes is only writing about human error accidents, not fatigue related accidents. For human errors CRM is the relevant tool not FTL. We cannot see the reason, why the EASA takes statistics with values as old as nearly 40 years, to set up scenarios of fatigue related problems.

In the list of the scientific studies we missed the <u>only</u> study for fatigue related flight time limitations of helicopter pilots in the HEMS services from the German center of aeronautics and space (DLR), which came 1996 to the conclusion, that duty periods up to 15:30 hrs are a reasonable compromise between the demands of the rescue service and flight safety. The study end with the sentence, that It could be used as a basis for harmonization at European level.

This study was not used in the preparation of the NPA and we have heard rumors, that the results of the study where to old to be transferred to the modern demands of the HEMS Service. If this statement of the task group is verified, we have to ask about all the old studies (see Attachment 2 of the NPA) from the early 1990 to 2000 and why these have been used to create a scenario of safety risks in the field of HEMS Services all tough they do not cover HEMS Operations.

Please remember, that since 1996 the German HEMS Operators have flown most likely more than 1.600.000 HEMS Missions with about 4.000.000 sectors without any fatigue related incident or accident.

We think, that this fact is decisive to think about the German regulations as basis for a new harmonized EASA wide flight time specification.

Comment to safety Impact

Regarding the flexible Approach in comparison to the safety impact the EASA expects a positive low benefit.

We do not agree with the manner, in which this conclusion was argued. The Attachment II stated in the period of 1971 to 2012 only three accidents, where fatigue was found as contributing factor. According to the EASA statement this is about 1.3% of all EMS occurrences from the ICAO ADFREP database.

We have to question the data from the ADREP Database, because the EASA didn't explain, if the 395 EMS related accidents where based on a world wide search or on a query only for the EU region.

The number looks quite high compared to the data from the German federal bureau of aircraft accident investigation (BFU). In the period from 1989 to 2007 there have been only 14 fatal accidents related to HEMS operation in Germany. As stated in the beginning, German HEMS makes up nearly 40% of all HEMS Missions flown in the EASA member



states. Therefore we consider the database as not relevant for the EASA kind of argumentation.

Furthermore, if we compare the 3 accidents with the number of sectors flown in these 40 years (estimated more than 8 Mill), it is very clear, that fatigue is not a factor, where the safety of HEMS missions is jeopardized.

Additionally the NPA states, that the current situation would remain acceptable, if HEMS operations were conducted predominantly in the Member State that issued the AOC.

From the German side of view, there are isolated cross border missions, but these starts and ends always in the member state issuing the AOC. As shown in the beginning, HEMS is mainly government founded and assists the ground based national rescue system. We do not see the point in the argumentation of the EASA that this situation will change in the near future in terms of number of HEMS bases to be established across Europe and the number of services to be available cross-border.

Also the next EASA statement regarding the safety aspects cannot be followed from our side of view. "Discrepancies between national FTL regimes might make it difficult for operators to conduct HEMS outside their principal home base."

Our Opinion is that discrepancies between FTL regimes within the scope of the operators due to individual flight time schedules make it impossible to establish common rules for tenders and to give national ministries the chance to compare, which operator will have the best safety policy regarding fatigue.

All together we came to the conclusion, that the new proposals will not enhance the flight safety and fatigue management and that the EASA conclusion has to be rethought with appropriate studies and the safety records from HEMS Missions in the last decade. The EASA itself made some presumptions like to consider, that option 1 may provide some low positive benefits. Within the scope of this highly difficult theme, considerations should not be used to argue about changing an existing, functioning and safe System of national flight time limitations.

This is also more important, while the EASA will keep normal CAT Operations (i.E. passenger transport with one pilot) within the national scope. For germany this means, that with single pilot CAT the existing rules stay in place, while in HEMS operations with 2 pilots or one pilot and HEMS-TC way more restrictive rules apply. Ridiculous!

Comment to social impact

Regarding the flexible Approach in comparison to the social impact the EASA expects a neutral result.

In fact, we estimate a negative outcome. In Summer 2017 the ADAC and the DRF started a scientific study with the German center of aeronautics and space (DLR). Unfortunately the scientific outcome will not be published by the DLR before the midst of march. From the point of view from the participating pilots we can already tell, that no one was fond working in a system with 2 shifts for rescue helicopters during the day time.

Working in the rescue service will soon become unattractive, which leads to reduced safety due to the fact, that experienced pilots will join other services.

The impact of the NPA is mainly, that the operators have to recruit and employ more pilots. The European market for experienced HEMS Pilots is more or less nonexistent. We are afraid, that this will lead to deterioration in flight safety.

Assuming that there are not enough trained pilots, the operator have to reduce there common working schedule, which will lead to a deteoration in the provision of the HEMS

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

operating hours. Furthermore this will have immediate effect to the number of HEMS missions, treated persons and patients transported.

Thinking of need for relocation or more travelling time due to the FTL changes, also the work/life balance will deteriorate together with the social acceptance of the HEMS Business and the Crews involved.

The DNR Study "Preliminary Analysis of Potential Regulatory Impacts – EMS" comes to the conclusion, that these task where relevant regarding possible social impacts.

Being objective we cannot go conform with the EASA expectation of a neutral result. Instead we think, that the social impact has to be downgraded

Comment to economic impact

The EASA rule making group itself came to the conclusion, that the economical impact of option 1 - the flexible approach to a new regulation - has to be classified as medium negative.

Here we cannot follow the argumentation in total. The difference between the fully prescriptive and the flexible approach is based on the fact, that in option 1 the operator will have the opportunity to set up individual flight time schemes as where in option 2 the operators stick to the new regulations and recruit new pilots.

Option 2 is considered as highly negative.

To avoid these highly negative impacts we assume, that nearly every HEMS operator will set up individual flight time schedules / schemes. The operators have to set up scientific based studies with a medical expertise. Due to the fact, that some operators have multiple HEMS operating bases with 24/7 h or bases only during daytime and these bases differs sometimes totally in the amount of flight times, duty times and mission complexity and also the daily missions flown, each base has to be evaluated separately.

Worst case will be 360 individually based flight time schemes. According to regulation/EU) 216-2008 Article 22 Chapter (2)(c) the EASA has only 1 month for the assessment.

The EASA estimates in the first year 11 derogations with about 800 hours for the evaluation. These figures do not match the current evaluations with up to 800 hours a single complex derogation flight time scheme.

We do not see the EASA capable of handling the derogations in the given time frames of the basic regulation.

The case study of the EASA came to the conclusion, to employ a forth pilot during the summer season. They did not mention, how this will fit into the regulations in cause 5 of the Council Directive 1999/70/EC of 28 June 1999 concerning the framework agreement on fixed-term work.

To prevent abuse arising from the use of successive fixed-term employment contracts or relationships, the member states did set up regulations regarding:

(a) objective reasons justifying the renewal of such contracts;(b) the maximum total duration of successive fixed-term employment contracts;(c) the number of renewals of such contracts.

In Germany this means, if a pilot more is employed more than two times, he will automatically become a fixed-term employer.

The impacts of these multiple short term employments have not been considered by the EASA.

We therefore consider even the flexible approach (option 1) as highly negative. **Conclusion**



	Comparing the EASA conclusion					
		Safety Impact		Social impac	t Economical impac	t
	Option 1	Option 1 Positive low benefit		neutral	Medium negative	
	With our conclusion					
		Safety Impact	Socia	l impact	Economical impact	
	Option 1	neutral	Medi	um negative	Highly negative	
	we really have to question, if the NPA 2017-17 is appropriate to enhance the safety HEMS operations. We would like the EASA to think about FTL from the operators and pilots view of sigl With the support of the competent operators, EASA should conduct a continuo monitoring over a period of minimum 5 years about the present provisions concerni flight and duty time limitations and rest requirements to get a updated evidence bas judgement of the safety of the existing flight time regulations. Until the end of this evaluation the existing national regulations should stay in place.			rs and pilots view of sight. Ild conduct a continuous sent provisions concerning a updated evidence based		
response	Please see the answer to comment # 54.					
comment	1429				C	omment by: FinnHEMS Oy
	"The specific objective of this proposal is to establish an improved and proportionate Europe- wide basis for regulating flight and duty times and rest periods for HEMS, based on scientific knowledge and established best practices."					

COMMENT: Exactly what scientific knowledge does this refer to? The scientific studies this NPA is based on are mostly inconclusive, not fully relevant or out-dated when it concerns HEMS.

response F

Please see the answer to comment # 54

2.3. How we want to achieve it - overview of the proposals

p. 6-7

comment 221

comment by: ADAC Luftrettung gGmbH

**** * * *** Bei Anwendung einer "best practice" gem. Präambel müsste für den HEMS-Flugbetrieb die bisherige Regelung (2.DV LuftBO) sowie die deutsche Studie aus den 1990er Jahren berücksichtigt werden.

response Ple

Please see the answer to comment # 54.

comment	250 comment by: European Helicopter Association (EHA)
	ADAC (Germany), DRF (Germany) and LAR (Luxembourg):
	2.3
	According to this paragraph the NPA should take into account best practices in the field of HEMS operations. However neither the experience with 2.DVLuftBO nor the existing German study from the 90's have been sufficiently considered. Here the rule making process of EASA seems to be inconsistent.
response	Please see the answer to comment # 54.

comment	527comment by: ADAC Luftrettung gGmbH
	According to this paragraph the NPA should take into account best practices in the field of HEMS operations. However neither the experience with special German FTL regulation nor the existing German study from the 96's have been sufficiently considered. Here the rule making process of EASA seems to be inconsistent.
response	Please see the answer to comment # 54.

comment	550 comment by: <i>Rüdiger Neu</i>
	Gemäß Präambel dieser NPA soll unter anderem die "best practice" berücksichtigt werden, jedoch wurden sowohl die Erfahrungen der 2. DVLuftBO, als auch die existierende Studie aus Deutschland aus 1996 nicht hinreichend berücksichtigt. Hier widerspricht sich die EASA selbst.
response	Please see the answer to comment # 54.

comment	761 comment by: DRF-Luftrettung
	The specific objective of this proposal is to establish an improved and proportionate Europe-wide basis for regulating flight and duty times and rest periods for HEMS, based on scientific knowledge and established best practices.

**** * *** We have to question very critically the scientific studies and knowledges which have been used. In attachment 2 of the NPA we find some references to studies, which are not aviation based but relate to truck drivers, oil rig workers and railroad drivers which examine fatigue in the field of ground based transportation companies, automobile factories and more.

Here we see one large field, where the data is not appropriate to be compared with the HEMS service. Working as employer in a factory always means, that from beginning of the shift until the late end there are no extended break times more than the national labor time regulations.

Looking at the tables in Attachment 1 – data collection of EMS FTL provisions we have to state clear, that although the daily duty period may be up to 16 hours, the flight duty period is limited to a much lesser value. In practice this means, that if the HEMS Crew has to fly multiple missions a day, the flight duty time increases and the crew has to quit the service before the duty period is expired. On the other hand are flights at the end of the duty day only possible, when the crew had some hours rest in between.

Fatigue in the HEMS Operation is therefore minimized due to early ends or several breaks in between and cannot be compared with scientific studies in other branches.

We would like to point out one more mentioned study, where data collection and conclusion do not fit the actual fatigue based evidences.

The EASA takes the Study of Goodes from 2003 (Journal of safety research 2003) and states, that working hours more than 12 hours a day have a more than 5 time larger risk of fatigue related incidents.

Goodes did not compare EMS but commercial American air traffic and used the so called Chi square to combine two totally different sets of statistic. His first set was the accident statistic from 1978 to 1999 with 55 accidents. His second setup was a set of the working hours from 10 aircraft carriers taken in one month in 1999.

His conclusion was, that 5% of human factor accidents where related to pilots working more than 13 hours. The ratio taken from the working hours showed him, that in this specific one month period only 1% of the pilots worked more than 13 hours.

Combining these both ratios he concluded, that the risk is more than 5 times higher than for the working shifts with less than 13 hours working time.

Looking at this study, you can read, that Goodes is only writing about human error accidents, not fatigue related accidents. For human errors CRM is the relevant tool not FTL. We cannot see the reason, why the EASA takes statistics with values as old as nearly 40 years, to set up scenarios of fatigue related problems.

In the list of the scientific studies we missed the <u>only</u> study for fatigue related flight time limitations of helicopter pilots in the HEMS services from the German center of aeronautics and space (DLR), which came 1996 to the conclusion, that duty periods up to 15:30 hrs are a reasonable compromise between the demands of the rescue service and flight safety. The study end with the sentence, that It could be used as a basis for harmonization at European level.

This study was not used in the preparation of the NPA and we have heard rumors, that the results of the study where to old to be transferred to the modern demands of the HEMS Service. If this statement of the task group is verified, we have to ask about all the old studies (see Attachment 2 of the NPA) from the early 1990 to 2000 and why these have been used to create a scenario of safety risks in the field of HEMS Services all tough they do not cover HEMS Operations.

Please remember, that since 1996 the German HEMS Operators have flown most likely more than 1.600.000 HEMS Missions with about 4.000.000 sectors without any fatigue related incident or accident.

We think, that this fact is decisive to think about the German regulations as basis for a new harmonized EASA wide flight time specification.

response

Please see the answer to comment # 54.

3.1. Draft cover regulation

p. 8-9

comment	269	comment by: European Helicopter Association (EHA)
	SHA (Switzerland) 3.1.1	
	Can you confirm that where alternation of the possible or ineffective we are exclu	ative ground emergency medical services are not ded from this regulation?
response	Please see the answer to comment	# 54.

comment	213	comment by: Frederique ARONICA Health s' Minsitry France
	Attachments <u>#53</u> <u>#54</u>	
	Development of FTL for commercial air transport operations of emergency medical services by aeroplanes and helicopters and Update and harmonisation of FTL for commercial air transport by aeroplane for air taxi operations and single-pilot operations taking into account operational experience and recent scientific evidence Affect rules : Regulation (EU) N° 965/2012	
	Article 8-Flight time limitations	
	medical services, as well as C medical services, shall be sub are emergency medical serv	nes, including air taxi, single-pilot operations and emergency CAT operations with helicopters for the purpose of emergency oject to the requirements of Subpart FTL of Annex III. Excluded vice operations with helicopters conducted exclusively in an native ground emergency medical services are not possible or
		ch HEMS : in French Guyana and in the Reunion island as we previously re alternative ground emergency medical services are not

French Guyana : It is impossible to go from Cayenne to Maripasoula in Amazonia by land, which gives particular importance to these air links (at least 1 hour 15 to join Cayenne-Maripasoula).

Reunion island : Mafate is located in the central area of Reunion. No road serves the interior of the circus where 700 inhabitants live : access is only possible by footpaths or by helicopter. It is a hotspot for hiking tourism in Reunion Island. The isolation of Mafate, far from the roads, imposes a specific way of life and organization.

Comments Article 8-Flight time limitations :

The rule is amended as follows : France, as member state requests that French Guyana and Reunion are excluded from development of FTL for HEMS.

response

Please see the answer to comment # 54.

comment 232

comment by: Federal Office of Civil Aviation (FOCA), Switzerland

Comment FOCA: The exclusion of HEMS operations conducted exclusively in an operating area, where alternative ground emergency medical services are not possible or are ineffective, as defined by the Member State, is in contradiction to the principal of the Basic Regulation regarding the provision of a level playing field for all actors in the internal aviation market. Furthermore, as a consequence of it's application, numerous HEMS operating bases within alpine countries would be excluded and accordingly not regulated. In Switzerland, most HEMS operating bases are situated in a mountainous environment.

FOCA suggests to amend Article 8 Flight Time limitations as below:

Proposal FOCA:

'Article 8 Flight time limitations

 CAT operations with aeroplanes, including air taxi, single-pilot operations and emergency medical services, as well as CAT operations with helicopters for the purpose of emergency medical services, shall be subject to the requirements of Subpart FTL of Annex III. Excluded are emergency medical service operations with helicopters conducted exclusively in an operating area, where alternative ground emergency medical services are not possible or are ineffective, as defined by the Member State.

response

Please see the answer to comment # 54.

comment 301

comment by: European Helicopter Association (EHA)

OEAMTC (Austria)

Article YY

Regulation (EU) No 965/2012 is amended as follows:



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Article 8 is replaced by the following:

[...]

Excluded are emergency medical service operations with helicopters conducted exclusively in an operating area, where alternative ground emergency medical services are not possible or are ineffective, as defined by the Member State.

COMMENT

Who is responsible to decide or judge if an alternative ground emergency service is ineffective? It is not the competence of the competent authority.

In case of catastrophic events or events with large impact on a certain region or its population there must be a provision within PART ORO.FTL to allow the operator to act out of this legal framework.

response

Please see the answer to comment # 54.

comment 329

comment by: European Helicopter Association (EHA)

FNAM (France)

#1

AGREEMENT

The FNAM would like to thank the EASA for having excluded "emergency medical service operations with helicopters conducted exclusively in an operating area, where alternative ground emergency medical services are not possible or are ineffective, as defined by the Member State." Indeed, this is very useful in France since some HEMS operators have their HEMS base on an island (for instance on *l'ile d'Yeu and overseas territories*) and cannot be reached in an effective time and/or effective condition for the sake of the safe transportation of the patient by ground emergency medical services.

#2

HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care services is a public service & a sovereign prerogative), with groupings of medical equipment and skills.

HEMS in France is both operated by private operators and state operators.

State may charter private operators to operate HEMS operations on its behalf.

Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved.

Such a possibility shall remain for "Force majeure" and be introduced within the IR, in respect of the sovereignty of each Member State facing major health crisis.

For example, in France, private operators of helicopters were chartered to ensure airlift rotations during recent Millas train disaster on December, the 14th of 2017. Besides, Helicopter Nuclear Response Team are partially delegated to a private operator.

Therefore, the FNAM suggests adding a specific paragraph in this implementing rule allowing HEMS pilots to derogate from these requirements in case of Force Majeure as it is already the case in the Current French National Regulation.

PROPOSAL

For illustrative purposes, in France the following article is applied in case of « Force Majeure » : « Il peut être dérogé aux limitations mentionnées à la présente section dans les conditions suivantes :

1. Vols urgents, dont l'exécution immédiate est nécessaire :



a) Pour prévenir des accidents imminents et organiser des mesures de sauvetage, ou pour réparer des accidents survenus soit au matériel, soit aux installations ;
b) Pour assurer le dépannage des aéronefs.
2. Pour assurer l'achèvement d'une période de vol que des circonstances exceptionnelles n'auraient pas permis d'effectuer dans les limites préétablies.
3. Vols exécutés dans l'intérêt de la sûreté ou de la défense nationale ou d'un service public sur ordre du Gouvernement constatant la nécessité de la dérogation ; la limite est à fixer par le ministre chargé de l'aviation civile. » (ref CAC D 422-12)
response

comment	379 comment by: Joachim J. Janezic (Institute for Austrian and International Aviation law)
	To Article 8:
	There is an exclusion of certain HEMS operations where ground based EMS are "not possible or ineffective". According to the rationals (page16 of the NPA) it will be up to the competent authority of a Member State to decide whether a certain operation is "not possible or ineffective".
	"Competent authority" in this context means the competent authority according to ORO.GEN.105, which is an aviation authority. It remains fully unclear how an aviation authority should judge the possibility or efficiency of a ground based EMS. This decision requires in-depth knowledge of organizing and administrating EMS which clearly is a domain of healthcare agencies and authorities and (even clearer) not of aviation authorities which do not have any competencies or knowledge in this area.
response	Please see the answer to comment # 54
comment	415 comment by: UFH French Helicopters Association
	AGREEMENT UFH would like to thank EASA for having excluded "emergency medical service operations with helicopters conducted exclusively in an operating area, where alternative ground emergency medical services are not possible or are ineffective, as defined by the Member State." Indeed, this is very useful in France since some HEMS operators have their HEMS base on an island (for instance on l'ile d'Yeu and overseas territories) and cannot be reached in an effective time and/or effective condition for the sake of the safe transportation of the patient by ground emergency medical services. This is also the case for French Guyana and the Reunion Island due to their landscape features. Additionally, FNAM would like to point out that this exemption should also apply for mixed operations when a helicopter dedicated to EMS, and operated usually in an operating area where alternative ground emergency medical services are not possible or are ineffective, is brought to fly exceptionally in a non-exempted operating area. #2

**** *____ the organization and expenses about Health Care in each Memberstate is out of the scope of the European Union power, as are the labor regulations. UFH expectes hard difficulties to achieve a regulation that could match each individual State situation, HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care services is a public service & a sovereign prerogative), with groupings of medical equipment and skills. HEMS in France is both operated by private operators and the State. State may charter private operators to operate HEMS operations on its behalf. Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved. Such a possibility shall remain for "Force majeure" and be introduced within the IR, in respect of the sovereignty of each Member State facing major health crisis. For example, in France, private operators of helicopters were chartered to ensure airlift rotations during recent Millas train disaster on December, the 14th of 2017. Besides, Helicopter Nuclear Response Team are partially delegated to a private operator. Therefore, UFH supports the FNAM suggests to add a specific paragraph in this implementing rule allowing HEMS pilots to derogate from these requirements in case of Force Majeure as it is already the case in the Current French National Regulation. PROPOSAL For illustrative purposes, in France the following article is applied in case of « Force Majeure » : « Il peut être dérogé aux limitations mentionnées à la présente section dans les conditions suivantes : 1. Vols urgents, dont l'exécution immédiate est nécessaire : a) Pour prévenir des accidents imminents et organiser des mesures de sauvetage, ou pour réparer des accidents survenus soit au matériel, soit aux installations ; b) Pour assurer le dépannage des aéronefs. 2. Pour assurer l'achèvement d'une période de vol que des circonstances exceptionnelles n'auraient pas permis d'effectuer dans les limites préétablies. 3. Vols exécutés dans l'intérêt de la sûreté ou de la défense nationale ou d'un service public sur ordre du Gouvernement constatant la nécessité de la dérogation ; la limite est à fixer par le ministre chargé de l'aviation civile. » (ref CAC D 422-12) Please see the answer to comment # 54.

comment 447

response

comment by: Hélicoptères de France

#1

AGREEMENT

Hélicoptères de France would like to thank EASA for having excluded "emergency medical service operations with helicopters conducted exclusively in an operating area, where alternative ground emergency medical services are not possible or are ineffective, as defined by the Member State." Indeed, this is very useful in France since some HEMS operators have their HEMS base on an island (for instance on

I'ile d'Yeu and overseas territories) and cannot be reached in an effective time and/or effective condition for the sake of the safe transportation of the patient by ground emergency medical services.

**** **** This is also the case for French Guyana and the Reunion Island due to their landscape features.

Additionally, Hélicoptères de France would like to point out that this exemption should also apply for mixed operations when a helicopter dedicated to EMS, and operated usually in an operating area where alternative ground emergency medical services are not possible or are ineffective, is brought to fly exceptionally in a non-exempted operating area.

#2

HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care services is a public service & a sovereign prerogative), with groupings of medical equipment and skills.

HEMS in France is both operated by private operators and the State.

State may charter private operators to operate HEMS operations on its behalf.

Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved.

Such a possibility shall remain for "Force majeure" and be introduced within the IR, in respect of the sovereignty of each Member State facing major health crisis.

For example, in France, private operators of helicopters were chartered to ensure airlift rotations during recent Millas train disaster on December, the 14th of 2017. Besides, Helicopter Nuclear Response Team are partially delegated to a private operator.

Therefore, Hélicoptères de France suggest adding a specific paragraph in this implementing rule allowing HEMS pilots to derogate from these requirements in case of Force Majeure as it is already the case in the Current French National Regulation.

PROPOSAL

For illustrative purposes, in France the following article is applied in case of « Force Majeure » :

« Il peut être dérogé aux limitations mentionnées à la présente section dans les conditions suivantes :

1. Vols urgents, dont l'exécution immédiate est nécessaire :

a) Pour prévenir des accidents imminents et organiser des mesures de sauvetage, ou pour réparer des

accidents survenus soit au matériel, soit aux installations ;

b) Pour assurer le dépannage des aéronefs.

2. Pour assurer l'achèvement d'une période de vol que des circonstances exceptionnelles n'auraient pas permis d'effectuer dans les limites préétablies.

3. Vols exécutés dans l'intérêt de la sûreté ou de la défense nationale ou d'un service public sur ordre du Gouvernement constatant la nécessité de la dérogation ; la limite est à fixer par le ministre chargé de l'aviation civile. » (ref CAC D 422-12)

response

Please see the answer to comment # 54.

comment 459

comment by: FNAM/SNEH

AGREEMENT

FNAM and SNEH would like to thank EASA for having excluded "emergency medical service operations with helicopters conducted exclusively in an operating area, where alternative



ground emergency medical services are not possible or are ineffective, as defined by the Member State." Indeed, this is very useful in France since some HEMS operators have their HEMS base on an island (for instance on *l'ile d'Yeu* and overseas territories) and cannot be reached in an effective time and/or effective condition for the sake of the safe transportation of the patient by ground emergency medical services. This is also the case for French Guyana and the Reunion Island due to their landscape features. Additionally, FNAM and SNEH would like to point out that this exemption should also apply for mixed operations when a helicopter dedicated to EMS, and operated usually in an operating area where alternative ground emergency medical services are not possible or are ineffective, is brought to fly exceptionally in a non-exempted operating area.

response

Please see the answer to comment # 54.

comment 460 comment by: FNAM/SNEH HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care services is a public service & a sovereign prerogative), with groupings of medical equipment and skills. HEMS in France is both operated by private operators and the State. State may charter private operators to operate HEMS operations on its behalf. Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved. Such a possibility shall remain for "Force majeure" and be introduced within the IR, in respect of the sovereignty of each Member State facing major health crisis. For example, in France, private operators of helicopters were chartered to ensure airlift rotations during recent Millas train disaster on December, the 14th of 2017. Besides, Helicopter Nuclear Response Team are partially delegated to a private operator. Therefore, FNAM and SNEH suggest adding a specific paragraph in this implementing rule allowing HEMS pilots to derogate from these requirements in case of Force Majeure as it is already the case in the Current French National Regulation. PROPOSAL For illustrative purposes, in France the following article is applied in case of « Force Majeure » : « Il peut être dérogé aux limitations mentionnées à la présente section dans les conditions suivantes : 1. Vols urgents, dont l'exécution immédiate est nécessaire : a) Pour prévenir des accidents imminents et organiser des mesures de sauvetage, ou pour réparer des accidents survenus soit au matériel, soit aux installations ; b) Pour assurer le dépannage des aéronefs. 2. Pour assurer l'achèvement d'une période de vol que des circonstances exceptionnelles n'auraient pas permis d'effectuer dans les limites préétablies. 3. Vols exécutés dans l'intérêt de la sûreté ou de la défense nationale ou d'un service public sur ordre du Gouvernement constatant la nécessité de la dérogation ; la limite est à fixer par le ministre chargé de l'aviation civile. » (ref CAC D 422-12) Please see the answer to comment # 54. response

**** * * ***

comment 573 comment by: FinnHEMS Oy Excluded are emergency medical service operations with helicopters conducted exclusively in an operating area, where alternative ground emergency medical services are not possible or are ineffective, as defined by the Member State." COMMENT: It could be easily argued that all ground EMS services are "ineffective" in comparison to airborne services, making this FTL is non-applicable. Please see the answer to comment # 54 response comment 586 comment by: NOLAS "Excluded are emergency medical service operations with helicopters conducted exclusively in an operating area, where alternative ground emergency medical services are not possible or are ineffective, as defined by the Member State." **Comment:** This is highly relevant for operation serving remote areas, where also the mission rate is low. However, here it is important to emphasize that it is not always the location of the HEMS operating base that is relevant, but the actual area served. For example, a helicopter can be based in a city, while serving exclusively remote areas. Also, the wording "ineffective" should perhaps be reviewed as most medical personnel or operators could argue that the majority of road transport could be "ineffective" as compared to helicopter transport. response Please see the answer to comment # 54

comment 639

comment by: Oya Vendée Hélicoptères

AGREEMENT

OYA would like to thank EASA for having excluded "emergency medical service operations with helicopters conducted exclusively in an operating area, where alternative ground emergency medical services are not possible or are ineffective, as defined by the Member State." Indeed, this is very useful in France since some HEMS operators have their HEMS base on an island (for instance on l'ile d'Yeu and overseas territories) and cannot be reached in an effective time and/or effective condition for the sake of the safe transportation of the patient by ground emergency medical services. This is also the case for French Guyana and the Reunion Island due to their landscape features. Additionally, OYA would like to point out that this exemption should also apply for mixed operations when a helicopter dedicated to EMS, and operated usually in an operating area where alternative ground emergency medical services are not possible or are ineffective, is brought to fly exceptionally in a non-exempted operating area.

response Please see the answer to comment # 54.

**** **** comment 640

comment by: Oya Vendée Hélicoptères

HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care services is a public service & a sovereign prerogative), with groupings of medical equipment and skills. HEMS in France is both operated by private operators and the State. State may charter private operators to operate HEMS operations on its behalf. Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved. Such a possibility shall remain for "Force majeure" and be introduced within the IR, in respect of the sovereignty of each Member State facing major health crisis.

For example, in France, private operators of helicopters were chartered to ensure airlift rotations during recent Millas train disaster on December, the 14th of 2017. Besides, Helicopter Nuclear Response Team are partially delegated to a private operator.

Therefore, OYA suggests adding a specific paragraph in this implementing rule allowing HEMS pilots to derogate from these requirements in case of Force Majeure as it is already the case in the Current French National Regulation.

PROPOSAL

For illustrative purposes, in France the following article is applied in case of « Force Majeure » :

« Il peut être dérogé aux limitations mentionnées à la présente section dans les conditions suivantes :

1. Vols urgents, dont l'exécution immédiate est nécessaire :

a) Pour prévenir des accidents imminents et organiser des mesures de sauvetage, ou pour réparer des accidents survenus soit au matériel, soit aux installations ;

b) Pour assurer le dépannage des aéronefs.

2. Pour assurer l'achèvement d'une période de vol que des circonstances exceptionnelles n'auraient pas permis d'effectuer dans les limites préétablies.

3. Vols exécutés dans l'intérêt de la sûreté ou de la défense nationale ou d'un service public sur ordre du Gouvernement constatant la nécessité de la dérogation ; la limite est à fixer par le ministre chargé de l'aviation civile. » (ref CAC D 422-12)

response

Please see the answer to comment # 54.

comment 711

comment by: ÖAMTC Helicopter Air Rescue (Austria)

Article 8 Flight time limitations

[...]

Who is responsible to decide or judge if an ambulance system is ineffective? It is not the competence of the competent authority.



766

comment

comment by: AECA helicopteros.

Individual comments and responses - HEMS

response	Please see the answer to comment # 54

Clarify the 'operating area' concept, using a CS or definitions page. Justification.- Being a concept that is left to the states definition, it is convenient to start from common criteria to avoid definitions that can be very diverse, making impossible the harmonization Please see the answer to comment # 54

comment 902 comment by: MBH SAMU AGREEMENT MBH would like to thank EASA for having excluded "emergency medical service operations with helicopters conducted exclusively in an operating area, where alternative ground emergency medical services are not possible or are ineffective, as defined by the Member State." Indeed, this is very useful in France since some HEMS operators have their HEMS base on an island (for instance on l'ile d'Yeu and overseas territories) and cannot be reached in an effective time and/or effective condition for the sake of the safe transportation of the patient by ground emergency medical services. This is also the case for French Guyana and the Reunion Island due to their landscape features. Additionally, MBH would like to point out that this exemption should also apply for mixed operations when a helicopter dedicated to EMS, and operated usually in an operating area where alternative ground emergency medical services are not possible or are ineffective, is brought to fly exceptionally in a non-exempted operating area. Please see the answer to comment # 54. response 903 comment comment by: MBH SAMU HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care services is a public service & a sovereign prerogative), with groupings of medical equipment and skills. HEMS in France is both operated by private operators and the State. State may charter private operators to operate HEMS operations on its behalf. Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved. Such a possibility shall remain for "Force majeure" and be introduced within the IR, in respect of the sovereignty of each Member State facing major health crisis.

*** * * *. .*

For example, in France, private operators of helicopters were chartered to ensure airlift rotations during recent Millas train disaster on December, the 14th of 2017. Besides, Helicopter Nuclear Response Team are partially delegated to a private operator. Therefore, MBH suggests adding a specific paragraph in this implementing rule allowing HEMS pilots to derogate from these requirements in case of Force Majeure as it is already the case in the Current French National Regulation. PROPOSAL For illustrative purposes, in France the following article is applied in case of « Force Majeure » : « Il peut être dérogé aux limitations mentionnées à la présente section dans les conditions suivantes : 1. Vols urgents, dont l'exécution immédiate est nécessaire : a) Pour prévenir des accidents imminents et organiser des mesures de sauvetage, ou pour réparer des accidents survenus soit au matériel, soit aux installations ; b) Pour assurer le dépannage des aéronefs. 2. Pour assurer l'achèvement d'une période de vol que des circonstances exceptionnelles n'auraient pas permis d'effectuer dans les limites préétablies. 3. Vols exécutés dans l'intérêt de la sûreté ou de la défense nationale ou d'un service public sur ordre du Gouvernement constatant la nécessité de la dérogation ; la limite est à fixer par le ministre chargé de l'aviation civile. » (ref CAC D 422-12) Please see the answer to comment # 54. response 908 comment comment by: AESA

New Article 8 of UE 965/2012 includes the statement "Excluded are emergency medical service operations with helicopters conducted exclusively in an operating area where alternative ground emergency medical services are not possible or are ineffective..."

In a general way, if helicopter is selected for an emergency medical operation, with its high associated cost, is because of ground service is not effective in that case or area. From this point of view, every HEMS operation could be excluded from new FTL.

It would be necessary further explanation about this statement.

Point 2 of Article 8 could include "CAT operations with helicopters, other than emergency medical services excluding those where alternative ground emergency are not possible or ineffective, and CAT operations ...". Otherwise, the exclusion of point 1 is not included.

response

Please see the answer to comment # 54.

comment 1066

comment by: European Cockpit Association



 TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.
 Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.
 Page 100 of 585

Commented text (page 8): Excluded are emergency medical service operations with helicopters conducted exclusively in an operating area, where alternative ground emergency medical services are not possible or are ineffective, as defined by the Member State.

ECA comment:

ECA strongly opposes this new wording. Also, this proposal was never discussed in the Rulemaking Group.

The proposed wording is providing for too much interpretation, since HEMS business itself is for rescuing people in areas, where other medical service is inappropriate. Either this rule is a safe and appropriate rule, then it should come into effect for every HEMS operation, or it is not safe and appropriate.

Saving lives should never be a reason to endanger an aircraft, its occupants or people on the ground.

response

Please see the answer to comment # 54.

comment 1

nt *1180*

AGREEMENT

SAF would like to thank EASA for having excluded "emergency medical service operations with helicopters conducted exclusively in an operating area, where alternative ground emergency medical services are not possible or are ineffective, as defined by the Member State." Indeed, this is very useful in France since some HEMS operators have their HEMS base on an island (for instance on l'ile d'Yeu and overseas territories) and cannot be reached in an effective time and/or effective condition for the sake of the safe transportation of the patient by ground emergency medical services. This is also the case for French Guyana and the Reunion Island due to their landscape features. Additionally, SAF would like to point out that this exemption should also apply for mixed operations when a helicopter dedicated to EMS, and operated usually in an operating area where alternative ground emergency medical services are not possible or are ineffective, is brought to fly exceptionally in a non-exempted operating area.

response

Please see the answer to comment # 54.

comment 1181

comment by: SAF

comment by: SAF

HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care services is a public service & a sovereign prerogative), with groupings of medical equipment and skills. HEMS in France is both operated by private operators and the State. State may charter private operators to operate HEMS operations on its behalf. Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved. Such a possibility

**** * * * ***

	shall remain for "Force majeure" and be introduced within the IR, in respect of the sovereignty of each Member State facing major health crisis.
	For example, in France, private operators of helicopters were chartered to ensure airlift rotations during recent Millas train disaster on December, the 14th of 2017. Besides Helicopter Nuclear Response Team are partially delegated to a private operator.
	Therefore, SAF suggests adding a specific paragraph in this implementing rule allowing HEMS pilots to derogate from these requirements in case of Force Majeure as it is already the case in the Current French National Regulation.
	PROPOSAL
	For illustrative purposes, in France the following article is applied in case of « Force Majeure »:
	« Il peut être dérogé aux limitations mentionnées à la présente section dans les conditions suivantes :
	1. Vols urgents, dont l'exécution immédiate est nécessaire :
	 a) Pour prévenir des accidents imminents et organiser des mesures de sauvetage, ou pour réparer des accidents survenus soit au matériel, soit aux installations ; b) Pour assurer le dépannage des aéronefs.
	 Pour assurer l'achèvement d'une période de vol que des circonstances exceptionnelles n'auraient pas permis d'effectuer dans les limites préétablies.
	3. Vols exécutés dans l'intérêt de la sûreté ou de la défense nationale ou d'un service public
	sur ordre du Gouvernement constatant la nécessité de la dérogation ; la limite est à fixe
	par le ministre chargé de l'aviation civile. » (ref CAC D 422-12)
esponse	Please see the answer to comment # 54.

comment	1319 comment by: SAS
	The amendment to 1. <i>CAT operations</i> appears to put into question the applicability of the whole NPA to the vast majority of HEMS operations in the UK. All UK HEMS operations are conducted in a specified local operating area, although alternative ground emergency medical services are possible, they are ineffective at delivering some of the services provided by HEMS aircraft. For example, HEMS aircraft often carry higher level medical personnel such as pre-hospital Doctors and specialist medical equipment not found on ground emergency services. In other situations it could be said that the ground medical services are ineffective at getting a patient to hospital in a suitable timeframe for the injuries or ailments with which they are suffering.
response	Please see the answer to comment # 54
comment	1339comment by: ENAC
	Art.8 The new Art.8 excludes the applicability of the HEMS FTL requirements to HEMS operations that take place in areas where alternative ground services are not possible or ineffective.

**** * * *** It is not specified what requirements shall apply to those HEMS operators who perform medical services in those area. This lack of clear rules could lead to potential unsafe situations.

Furthermore, since CAA has not control on every single HEMS mission, for the purpose of the oversight, it would be very difficult to verify compliance with the FTL limitations on HEMS operators because It would be impossible to verify if the operator flew in or out the established areas. This in consideration that the Italy has an extensive part of the territory where the ground service is impossible or ineffective (Sicilian and Tyrrhenian islands, Alps and Apennines mountains)

For the above reasons ENAC proposes to stand by with the HEMS FTL rulemaking until further clarifications and exlude HEMS FTL from the NPA 2017-17.

response Ple

Please see the answer to comment # 54

comment	1363	comment by: Civil Aviation Authority of Norway
	avoid the highly ne	clude such HEMS services is supported and is considered necessary to gative impacts the proposed HEMS rules will have on these remote I in the impact assessment of this NPA.
response	Please see the answ	rer to comment # 54.
comment	1431	comment by: COPAC COLEGIO OFICIAL DE PILOTOS DE LA AVIACIÓN COMERCIAL
	operaciones HEMS conducted exclusive services are not pos aplicaría la norma normales, pero que	t time limitations" se excluye la aplicación de esta NPA a algunas de las "Excluded are emergency medical service operations with helicopters ly in an operating area, where alternative ground emergency medical ssible or are ineffective, as defined by the Member State" ¿Cómo se para el caso de aeronaves que se encuentren en bases en áreas pueden atender servicios en dichas áreas donde servicios alternativos sibles o inefectivos?
response	Please see the answ	er to comment # 54.
comment	1464	comment by: Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)

3.1 Article YY

"1. CAT operations . . . Excluded are emergency medical service operations with helicopters conducted exclusively in an operating area, where alternative ground emergency medical services are not possible or are ineffective, as defined by the Member State."



Enhance the exclusion to be valid for HEMS operations *mainly* in an operating area where alternative ground emergency medical services are not possible, etc.... By changing in this manner, it would be possible to allow operators who usually operate in remote areas but on occasions do transports to more congested parts of the country.

response

Please see the answer to comment # 54.

3.1. ORO.FTL.100

p. 9

comment	270 cor	nment by: European Helicopter Association (EHA)	
	SHA (Switzerland) 3.1.2		
	Regulation is applicable to CAT operations with helicopters / how is it intended to work for operators like us flying daily under CAT, SPO, National. What will be applicable and how?		
response	Please see the answer to comment # 54		

comment	330	comment by: European Helicopter Association (EHA)
	FNAM (France)	
	flight duties, does not have the sam cabin crew members. No European requirements for TCM the AirOps and does not originate FTL, through the proposal ORO.FTL of this NPA, seems to place TCM and flight safety requirements for TCM, operators and this aspect must not	ber (TCM) who supports the pilot while ground or in- the social regulatory framework than the pilots nor the are described in the Aircrew. They are all described in from the ICAO SARPs. Nevertheless, the scope of the 100 (<i>'HEMS crew members'</i>) and the other proposals d pilots at the same level. This will have impacts on the but it will also have an economic and social impact for be neglected.
	the flight safety impact.	assess the economic and social impacts in addition to
response	Please see the answer to comment	# 54



comment	416	comment by: UFH French Helicopters Association
	flight duties, does not have the sam cabin crew members. No European requirements for TCM in the AirOps and does not originate FTL, through the proposal ORO.FTL. of this NPA, seems to place TCM and the flight safety requirements for TC impact for operators and this aspec	to further develop the economic and social impacts in
response	Please see the answer to comment	# 54
	L	
comment	448	comment by: Hélicoptères de France

ISSUE
.000

In France, the technical crew member (TCM) who supports the pilot while ground or inflight duties, does not have the same social regulatory framework than the pilots nor the cabin crew members.

No European requirements for TCM are described in the Aircrew. They are all described in the AirOps and does not originate from the ICAO SARPs. Nevertheless, the scope of the FTL, through the proposal ORO.FTL.100 ('HEMS crew members') and the other proposals of this NPA, seems to place TCM and pilots at the same level. This will have impacts on the flight safety requirements for TCM, but it will also have an economic and social impact for operators and this aspect must not be neglected.

Hélicoptères de France thinks it would be beneficial to further develop the economic and social impacts in the RIA in addition to the flight safety impact.

response

Please see the answer to comment # 54

comment 461

comment by: FNAM/SNEH

ISSUE

In France, the technical crew member (TCM) who supports the pilot while ground or inflight duties, does not have the same social regulatory framework than the pilots nor the cabin crew members.

No European requirements for TCM are described in the Aircrew. They are all described in the AirOps and does not originate from the ICAO SARPs. Nevertheless, the scope of the FTL, through the proposal ORO.FTL.100 (*'HEMS crew members'*) and the other proposals of this NPA, seems to place TCM and pilots at the same level. This will have impacts on the



response	flight safety requirements for TCM, but it will also have an economic and social impact for operators and this aspect must not be neglected. FNAM and SNEH think it would be beneficial to further develop the economic and social impacts in the RIA in addition to the flight safety impact. Please see the answer to comment # 54
comment	641 comment by: Oya Vendée Hélicoptères
	 ISSUE In France, the technical crew member (TCM) who supports the pilot while ground or inflight duties, does not have the same social regulatory framework than the pilots nor the cabin crew members. No European requirements for TCM are described in the Aircrew. They are all described in the AirOps and does not originate from the ICAO SARPs. Nevertheless, the scope of the FTL, through the proposal ORO.FTL.100 ('HEMS crew members') and the other proposals of this NPA, seems to place TCM and pilots at the same level. This will have impacts on the flight safety requirements for TCM, but it will also have an economic and social impact for operators and this aspect must not be neglected. OYA thinks it would be beneficial to further develop the economic and social impacts in the RIA in addition to the flight safety impact.
response	Please see the answer to comment # 54
comment	904 comment by: <i>MBH SAMU</i>

ISSUE

In France, the technical crew member (TCM) who supports the pilot while ground or inflight duties, does not have the same social regulatory framework than the pilots nor the cabin crew members.

No European requirements for TCM are described in the Aircrew. They are all described in the AirOps and does not originate from the ICAO SARPs. Nevertheless, the scope of the FTL, through the proposal ORO.FTL.100 ('HEMS crew members') and the other proposals of this NPA, seems to place TCM and pilots at the same level. This will have impacts on the flight safety requirements for TCM, but it will also have an economic and social impact for operators and this aspect must not be neglected.

MBH thinks it would be beneficial to further develop the economic and social impacts in the RIA in addition to the flight safety impact.

response

Please see the answer to comment # 54

comment | *1182*

comment by: SAF



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 106 of 585

p. 9-10

ISSUE

In France, the technical crew member (TCM) who supports the pilot while ground or inflight duties, does not have the same social regulatory framework than the pilots nor the cabin crew members.

No European requirements for TCM are described in the Aircrew. They are all described in the AirOps and does not originate from the ICAO SARPs. Nevertheless, the scope of the FTL, through the proposal ORO.FTL.100 ('HEMS crew members') and the other proposals of this NPA, seems to place TCM and pilots at the same level. This will have impacts on the flight safety requirements for TCM, but it will also have an economic and social impact for operators and this aspect must not be neglected.

SAF thinks it would be beneficial to further develop the economic and social impacts in the RIA in addition to the flight safety impact.

response

Please see the answer to comment # 54

3.1. ORO.FTL.105

comment 92 comment by: B. Wagner (30) 'single-pilot operation' for HEMS muss auch die Möglichkeit einschliessen, dass der Pilot während einzelner Sektoren alleine an Bord sein darf, wenn der HEMS TC aus medizinischer Notwendigkeit den Arzt und den Patienten bodengebunden begleitet. Please see the answer to comment # 54 response comment 107 comment by: UK CAA Page No: 10 Paragraph No: ORO.FTL.105, (29) Definitions "EMS flight" **Comment:** The definition has been adapted from the HEMS definition but it is missing the requirement that the helicopter must be operating under a HEMS approval. This is an important reference within the HEMS definition and needs to be consistent within this definition. Justification: Clarity and consistency Proposed Text: "... or helicopter (operating under a HEMS approval) ..."



Individual comments and responses — HEMS

response	Please see the answer to comment # 54.

comment	271	comment by: European Helicopter Association (EHA)
	SHA (Switzerland) 30	
		ngle pilot is defined with one pilot and one HEMS crew A single pilot operation means one pilot only. This needs to
response	Please see the answer to comment # 54	
comment	302	comment by: European Helicopter Association (EHA)
comment	302	comment by: European Helicopter Association (EHA)



OEAMTC (Austria)

ORO.FTL.105 Definitions

For the purpose of this Subpart, the following definitions shall apply:

[...]

(29) 'EMS flight' means a flight with an aeroplane (AEMS) or helicopter (HEMS) carrying out emergency medical service operations, the purpose of which is to facilitate emergency medical assistance, where immediate and rapid transportation is essential, by carrying at least one of the following:

(a) medical personnel;

(b) medical supplies (equipment, blood, organs, drugs);

(c) ill or injured persons and other persons directly involved.

A sector flown to position an aircraft to the operating base before or after an EMS flight is considered part of that flight.

COMMENT(S)

With sector not defined for helicopters are the fights to the operating base before or after an HEMS flight considered part of that flight? If HEMS is not to be included in the definition then the definition must be changed to read: A sector flown to position an aircraft to the operating base before or after an AEMS flight is considered part of that flight

ORO.FTL.105 Definitions

For the purpose of this Subpart, the following definitions shall apply: [...]

(30) 'single-pilot operation' means, in the case of aeroplanes, an operation with one pilot or, in the case of HEMS, an operation with one pilot and one HEMS crew member.

COMMENT(S)

The HEMS concept of operating a mixed crew in which tasks are shared differs considerably from a true single pilot concept since cockpit workload is divided and monitoring is taking place. There are no credits for this sharing of workload in terms of FTL however the HEMS TCM must adhere to the FTL. Credits should be given for the mixed crew concept and be treated same as two-pilots.

response

Please see the answer to comment # 54

comment	331	comment by: European Helicopter Association (EHA)
	FNAM (France)	
	#1 (5) "augmented flight crew" ADD an ON-BOARD REST DEFINITIO ISSUE The FNAM thinks a clear and precise	N e definition of on-board rest shall be provided.



The notion is not easy to understand as it can be on the ground or in-flight and may lead to misunderstanding and subjective interpretations. This shall be applicable for split duty but also for standby, especially for split duty. (cf. split duty and standby comments) Moreover, the FNAM doesn't understand why the on-board rest is associated with the notion of augmented flight crew. Indeed, a non-augmented crew is able to have on-board rest since it can be taken on the ground. PROPOSAL Provide a clear and precise definition for on-board rest. #2 (24) 'sector' AGREEMENT The FNAM agrees to replace in the 'sector' definition 'aircraft' by 'aeroplane'. The notion of 'sector' is therefore not defined anymore for helicopters and thus not applicable for **HEMS** operations. The FNAM would like the Agency to keep this change - and the reason why - in mind when the EASA extends FTL to other CAT operations with helicopters. #3 (29) 'EMS flight' ISSUE According to the definition of a sector (§24) in ORO.FTL.105, the notion of sector is not applicable to HEMS operations. However, the notion of sector appears in the EMS flight definition (§29) although the EMS flight definition shall apply for HEMS operations. (Cf. comment #14.3) Besides, the helicopter by itself is part of the medical supplies which cannot be dissociated. Thus, it should be precise in the paragraph (29)(b). PROPOSAL Replace the paragraph (b) by the following: (b) medical supplies (equipment including the helicopter by itself, blood, organs, drugs);" Replace the sentence in §29: "A sector flown to position an aircraft to the operating base before or after an EMS flight is considered part of that flight." by "A flight flown to position an aircraft to the operating base before or after an EMS flight is considered part of that emergency medical service." Please see the answer to comment # 54

response

comment 360

comment by: European Helicopter Association (EHA)

BHA (UK)

"break' means a period of time within an flight duty period, shorter than a rest period, counting as duty and during which a crew member is free of all tasks; "

Comment:

Poor definition. A break is a period when crew members are "free of all tasks," but a duty period ends when a crew members are "free of all duties." What's the difference?

"'sector' means the segment of an FDP between an aircraft aeroplane first moving for the purpose of taking off until it comes to rest after landing on the designated parking position."

Comment:

With change of text, this definition now excludes rotorcraft, contrary to the explanatory notes.

"'single-pilot operation' means, in the case of aeroplanes, an operation with one pilot or, in the case of HEMS, an operation with one pilot and one HEMS crew member."

Comment:

Agreed, but elsewhere in the document FDPs and fatigue levels are considered based on SP experience alone, and take no account of shared responsibilities.

response

Please see the answer to comment # 54

omment	417 comment by: UFH French Helicopters Association
	ADD an ON-BOARD REST DEFINITION
	ISSUE
	French stakeholders think that a clear and precise definition of on-board rest shall be provided.
	The notion is not easy to understand as it can be on the ground or in-flight and may lead to misunderstanding and subjective interpretations.
	This shall be applicable for split duty but also for standby.
	Moreover, we do not understand why the on-board rest is associated with the notion of augmented flight crew. Indeed, a non-augmented crew is able to have on-board rest since it can be taken on the ground.
	PROPOSAL
	Provide a clear and precise definition for on-board rest.
	#2
	(24) 'sector'
	AGREEMENT
	UFH agrees to replace in the 'sector' definition 'aircraft' by 'aeroplane'. The notion of 'sector' is therefore not defined anymore for helicopters and thus not applicable for HEMS operations.
	UFH supports the proposal of FNAM to the Agency to keep this change - and the reason why - in mind when EASA extends FTL to other CAT operations with helicopters.
	#3
	(29) 'EMS flight'
	ISSUE
	According to the definition of a sector (§24) in ORO.FTL.105, the notion of sector is not applicable to HEMS operations. However, the notion of sector appears in the EMS flight definition (§29) although the EMS flight definition shall apply for HEMS operations. (Cf. comment #14.3)

Besides, the helicopter by itself is part of the medical supplies which cannot be
dissociated. Thus, it should be precise in the paragraph (29)(b).
PROPOSAL
Replace the paragraph (b) by the following:

"(b) medical supplies (equipment including the helicopter by itself, blood, organs,
drugs);"

Replace the sentence in §29:

"A sector flown to position an aircraft to the operating base before or after an EMS flight
is considered part of that flight."

by "A flight flown to position an aircraft to the operating base before or after an EMS
flight is considered part of that emergency medical service."responsePlease see the answer to comment # 54

comment	462	comment by: FNAM/SNEH
	(5) "augmented flight crew"	
	ADD an ON-BOARD REST DEFINITION	
	ISSUE	
	FNAM and SNEH think a clear and precise definition of on-boa The notion is not easy to understand as it can be on the grou to misunderstanding and subjective interpretations.	•
	This shall be applicable for split duty but also for standby.	
	Moreover, FNAM and SNEH don't understand why the on-boar notion of augmented flight crew. Indeed, a non-augmented cr rest since it can be taken on the ground.	
	PROPOSAL	
	Provide a clear and precise definition for on-board rest.	
response	Please see the answer to comment # 54	

comment	463	comment by: FNAM/SNEH
	(24) 'sector' AGREEMENT	



FNAM and SNEH agree to replace in the 'sector' definition 'aircraft' by 'aeroplane'. The notion of 'sector' is therefore not defined anymore for helicopters and thus not applicable for HEMS operations. FNAM and SNEH would like the Agency to keep this change - and the reason why - in mind when EASA extends FTL to other CAT operations with helicopters.

response

Please see the answer to comment # 54

comment	464 comment by: FNAM/SNEH
	(29) 'EMS flight' ISSUE
	According to the definition of a sector (§24) in ORO.FTL.105, the notion of sector is not applicable to HEMS operations. However, the notion of sector appears in the EMS flight definition (§29) although the EMS flight definition shall apply for HEMS operations. Besides, the helicopter by itself is part of the medical supplies which cannot be dissociated. Thus, it should be precise in the paragraph (29)(b).
	PROPOSAL
	Replace the paragraph (b) by the following: "(b) medical supplies (equipment including the helicopter by itself, blood, organs, drugs);"
	Replace the sentence in §29:
	"A sector flown to position an aircraft to the operating base before or after an EMS flight is considered part of that flight."
	by "A flight flown to position an aircraft to the operating base before or after an EMS flight is considered part of that emergency medical service."
response	Please see the answer to comment # 54
comment	574 comment by: FinnHEMS Oy
	"Single-pilot operation" means something else than operations with one pilot and one HEMS-crew member.
response	Please see the answer to comment # 54
comment	642 comment by: Oya Vendée Hélicoptères
	(5) "augmented flight crew" ADD an ON-BOARD REST DEFINITION ISSUE
	OYA thinks a clear and precise definition of on-board rest shall be provided.

The notion is not easy to understand as it can be on the ground or in-flight and may lead to misunderstanding and subjective interpretations. This shall be applicable for split duty but also for standby. Moreover, OYA doesn't understand why the on-board rest is associated with the notion of augmented flight crew. Indeed, a non-augmented crew is able to have on-board rest since it can be taken on the ground. PROPOSAL

Provide a clear and precise definition for on-board rest.

Please see the answer to comment # 54

response

comment	643	comment by: Oya Vendée Hélicoptères
	(24) 'sector' AGREEMENT	
	'sector' is therefore not defined HEMS operations.	ctor' definition 'aircraft' by 'aeroplane'. The notion of anymore for helicopters and thus not applicable for eep this change - and the reason why - in mind when EASA
	extends FTL to other CAT operat	· · · · · · · · · · · · · · · · · · ·
response	Please see the answer to commo	ent # 54
comment	644	comment by: Oya Vendée Hélicoptères
	(29) 'EMS flight' ISSUE	
		scatter (\$24) in OBO FTI 105, the nation of conter is not

According to the definition of a sector (§24) in ORO.FTL.105, the notion of sector is not applicable to HEMS operations. However, the notion of sector appears in the EMS flight definition (§29) although the EMS flight definition shall apply for HEMS operations.

Besides, the helicopter by itself is part of the medical supplies which cannot be dissociated. Thus, it should be precise in the paragraph (29)(b).

PROPOSAL

Replace the paragraph (b) by the following:

"(b) medical supplies (equipment including the helicopter by itself, blood, organs, drugs);" Replace the sentence in §29:

"A sector flown to position an aircraft to the operating base before or after an EMS flight is considered part of that flight."

by

"A flight flown to position an aircraft to the operating base before or after an EMS flight is considered part of that emergency medical service."



Individual comments and responses - HEMS

response Ple

Please see the answer to comment # 54

comment	882 comment by: Stephanie Selim
	Definition (24) 'sector'
	 Technical comment – If the word « sector » only concerns aeroplanes, it should be deleted in all points where it still appears and could concern HEMS operations, as: - the last sentence of definition n°29 which concerns AEMS and HEMS, and it could be replaced for example by the word « flight », - ORO.FTL.110 i) - in CS.FTL.3.205 b) (page 36).
response	Please see the answer to comment # 54

comment	906 comment by: MBH SAMU
	(5) "augmented flight crew"
	ADD an ON-BOARD REST DEFINITION ISSUE
	MBH thinks a clear and precise definition of on-board rest shall be provided.
	The notion is not easy to understand as it can be on the ground or in-flight and may lead to misunderstanding and subjective interpretations. This shall be applicable for split duty but also for standby.
	This shall be applicable for split duty but also for standby.
	Moreover, MBH doesn't understand why the on-board rest is associated with the notion
	of augmented flight crew. Indeed, a non-augmented crew is able to have on-board rest since it can be taken on the ground.
	since it can be taken on the ground.
	PROPOSAL
	Provide a clear and precise definition for on-board rest.
response	Please see the answer to comment # 54
comment	907 comment by: MBH SAMU
	(24) 'sector'
	AGREEMENT

**** * * *** TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 115 of 585

MBH agrees to replace in the 'sector' definition 'aircraft' by 'aeroplane'. The notion of 'sector' is therefore not defined anymore for helicopters and thus not applicable for HEMS operations. MBH would like the Agency to keep this change - and the reason why - in mind when EASA extends FTL to other CAT operations with helicopters.

response

Please see the answer to comment # 54

comment	913 comment by: MBH SAMU
	 (29) 'EMS flight' ISSUE According to the definition of a sector (§24) in ORO.FTL.105, the notion of sector is not applicable to HEMS operations. However, the notion of sector appears in the EMS flight definition (§29) although the EMS flight definition shall apply for HEMS operations. Besides, the helicopter by itself is part of the medical supplies which cannot be dissociated. Thus, it should be precise in the paragraph (29)(b). PROPOSAL
	Replace the paragraph (b) by the following: "(b) medical supplies (equipment including the helicopter by itself, blood, organs, drugs);" Replace the sentence in §29: "A sector flown to position an aircraft to the operating base before or after an EMS flight is considered part of that flight." by
	"A flight flown to position an aircraft to the operating base before or after an EMS flight is considered part of that emergency medical service."
response	Please see the answer to comment # 54

comment	919 comment by: AESA
	Definition of "sector" has been changed replacing "aircraft" by "aeroplane" so helicopters are excluded from definition. Then, sector is used in CS.3 (e.g. in CS.3.205(b)). Since the meaning of "sector" usually is different for aeroplanes and helicopters, a definition of "sector" for helicopters should be added.
response	Please see the answer to comment # 54
comment	919 comment by: AESA
	Definition of "sector" has been changed replacing "aircraft" by "aeroplane" so helicopters are excluded from definition. Then, sector is used in CS.3 (e.g. in CS.3.205(b)).

**** * * *** TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.Page 116 of 585

	Since the meaning of "sector" usually is different for aeroplanes and helicopters, a definition of "sector" for helicopters should be added.	
response	Please see the answer to comment # 54	
comment	1365 comment by: Civil Aviation Authority of Norway	
	On the definition of "single pilot operation": Annex V (Part SPA) to Reg. 965/2012 already uses the term "HEMS technical crew member". See also the definition of technical crew member in annex I to Reg. 965/2012. The terminology should be consistent if the term "HEMS crew member" refer to the same group of persons.	
response	Please see the answer to comment # 54	
comment	1383 comment by: Swiss Air-Ambulance Rega	
	(No. 29) The definition has been adapted from the HEMS definition but it is missing the requirement that the helicopter must be operating under a HEMS approval. This is an important reference within the HEMS definition and needs to be consistent within this definition.	
	Proposed amendment: " or helicopter (operating under a HEMS approval)"	
response	e Please see the answer to comment # 54	
comment	1393 comment by: European Helicopter Association (EHA)	
comment	Deutscher Hubschrauber Verband / DHV (Germany)	
	Paragraph No: ORO.FTL.105, (13) Definitions "flight time"	
	Comment: The word "total" is missing from this definition and should be included as per PART.FCL.010, Definition for Flight time: "for aeroplanes, touring motor gliders and powered-lift, it means the total time from the moment an aircraft first moves for the purpose of taking off until the moment it finally comes to rest at the end of the flight; for helicopters, it means the total time from the moment a helicopter's rotor blades start	
	turning until the moment the helicopter finally comes to rest at the end of the flight, and the rotor blades are stopped."	

	Justification: Consistency Proposed Text: Include the word "total" in the definition in line with the PART FCL definition.
	Paragraph No: ORO.FTL.105, (29) Definitions "EMS flight"
	Comment: The definition has been adapted from the HEMS definition but it is missing the requirement that the helicopter must be operating under a HEMS approval. This is an important reference within the HEMS definition and needs to be consistent within this definition. Justification: Clarity and consistency Proposed Text: " or helicopter (operating under a HEMS approval)"
response	Please see the answer to comment # 54
comment	1432 comment by: COPAC COLEGIO OFICIAL DE PILOTOS DE LA AVIACIÓN COMERCIAL
	Según ORO.FTL.105. (29), en la definición de EMS flight se indica entre otros "(…) by carring at least one of the following: (a) medical personel (…)". Según esta definición, ¿todos aquellos servicios SAR que van dotados con personal médico pasarían a tratarse como HEMS? La pregunta viene motivada porque esta definición entra en conflicto con la definición SAR de la Normativa del Estado Miembro español.
response	Please see the answer to comment # 54

comment	1454comment by: Association of Air Ambulances	
	Paragraph 24 has been amended to relate the definition of a 'sector' to aeroplanes only. The new paragraph 29 refers to HEMS and states "A sector flown to position an aircraft for an EMS flight." An EMS flight is stated to be a flight by an aeroplane or a helicopter. The amended wording of paragraph 24 is wrong and needs to be reversed to read "between and aircraft first moving"	
response	Please see the answer to comment # 54	
comment	1483comment by: Finnish Transport Safety Agency	
	In order to establish rolling 24 hour standby for HEMS, following amendments are proposed.	



Reasoning: New definitions 'active standby', 'active duty period ('ADP')', 'inactive duty period' ('IDP')' and 'relief crew' are essential to regulate active standby which differs from the current standby. Active standby is duty time, during which the pilots are immediately ready for HEMS tasks organised by the air operator.

Active duty period (ADP) comprises of flying duty (FDP) and duty time used for other tasks, as requested by the operator. When there are no tasks, the duty time is counted as inactive duty. However, the inactive duty is not counted as a rest. The flight time and ADP during rolling 24 hour period are limited, and the maximum active duty can be maximum 72 hours see CS.FTL.3.207.

Proposal:

Add new definitions in ORO.FTL.105 as follows:

(31) 'active standby' means a duty period when the flight crew members are immediately prepared to start performing tasks. Active standby includes active duty and inactive duty. Active standby has to be planned in the duty roster.

(32) 'active duty period ('ADP')' means FDP and all other tasks performed for the air operator which are not directly related to flying FDP, such as office work, aircraft inspections, loading, servicing or training organised by the air operator.

(33) 'inactive duty period ('IDP')' means all other time than ADP during the active standby. The crew member must spent IDP in a place with facilities for washing and sleeping, such as a suitable accommodation in HEMS operating base or hotel room. IDP is not counted as a rest.

(34) 'relief crew' means HEMS crew member available to receive an assignment for an active standby, as required by the operator and as specified in the operations manual.

response

Please see the answer to comment # 54

comment

140

comment by: CAA-NL

ORO.FTL.105 Definitions

Comment:

In the definition of 'sector' the requirement for helicopters is missing. With the replacement of aircraft by aeroplane the definition of sector is not applicable to helicopters anymore. Is it the intention not to apply this for helicopter operations and only relate to flight time? Also for helicopter operations the start and landing is the most intense part of the flight. When the duration of a typical heli-flight may be shorter it might be reasonable to take higher figures for the related use of sectors within the calculations for helicopter operations but not to delete this completely from the calculations of FDP max.

Individual comments and responses - HEMS

response

Please see the answer to comment # 54

	p. 10
comment	332 comment by: European Helicopter Association (EHA)
	FNAM (France)
	#1
	(i) AGREEMENT
	The paragraph (i) refers to sectors. Since the 'sector' definition does not apply anymore for HEMS
	operations, flight times (FT) shall not be scheduled before HEMS operations and are therefore
	unpredictable inside a given FDP (by definition of HEMS) (Cf. comment #14.2) The FNAM fully agrees with the fact that FT cannot and shall not be scheduled before
	HEMS operations.
	Only FDP shall and can be scheduled. #2
	(k)
	ISSUE
	No RIA is given to reduce from 33% (general rules for CAT operations) to 10% (proposed for HEMS operations) the allowance between scheduled and actual FDP.
	The notion of scheduled FT is a non-sense for HEMS, where emergency destinations are hazardous but remain closeby. Thus, the hazard does not belong on determining flight time, but on when the last flight is performed.
	The incertitude over max FDP is thus very low for mostly short helicopters legs, with no or low ATC constraints.
	In France, the average flight time is 25 minutes for HEMS, <i>i.e</i> 50 minutes back and force (1 mission)i:
	• Incertitude allowance over the FT would thus be 2,5min, which is not significative and contrary
	to aeroplane CAT operations, has very low impact on the time of the end of the FDP • Incertitude allowance over the FDP would thus not depend on the FT, but on the time spent grounded on the emergency site to take HEMS material (mostly, the patient, whe stabilized and declared transportable by the medical staff)
	Thus, this provision seems irrelevant for HEMS. Therefore, the FNAM thinks an allowance between scheduled and actual FDP of 10% is not appropriate for HEMS operations. Hence, the FNAM suggests applying the same allowance between scheduled and actual FDP than the one used for CAT, <i>i.e</i> 33%.
	PROPOSAL:
	Replace the paragraph (k) by the following: "(k) in AEMS operations, change a schedule
	adapt crew arrangements, if the actual operation exceeds the maximum FDP on any EN operating base on more than 10 % of the FDPs in any 3 months. In HEMS operations,

	change a schedule or adapt crew arrangements, if the actual operation exceeds the maximum FDP on any EMS operating base on more than 33 % of the FDPs in any 3 months".
response	Please see the answer to comment # 54
comment	418 comment by: UFH French Helicopters Association
	(i) AGREEMENT
	The paragraph (i) refers to sectors. Since the 'sector' definition does not apply anymore for HEMS operations, flight times (FT) shall not be scheduled before HEMS operations and are therefore unpredictable inside a given FDP (by definition of HEMS) (Cf. comment #14.2)
	FNAM fully agrees with the fact that FT cannot and shall not be scheduled before HEMS operations.
	Only FDP shall and can be scheduled. #2 (k)
	ISSUE No RIA is given to reduce from 33% (general rules for CAT operations) to 10% (proposed for HEMS operations) the allowance between scheduled and actual FDP.
	The notion of scheduled FT is a non-sense for HEMS, where emergency destinations are hazardous but remain closeby. Thus, the hazard does not belong on determining flight time, but on when the last flight is performed.
	The incertitude over max FDP is thus very low for mostly short helicopters legs, with no or low ATC constraints.
	In France, the average flight time for operators is 25 minutes for HEMS, i.e 50 minutes back and forth (1 mission)i:
	• Incertitude allowance over the FT would thus be 2,5min, which is not significative and contrary to aeroplane CAT operations, has very low impact on the time of the end of the FDP
	• Incertitude allowance over the FDP would thus not depend on the FT, but on the time spent grounded on the emergency site to take HEMS material (mostly, the patient, when stabilized and declared transportable by the medical staff) Thus, this provision seems irrelevant for HEMS.
	Therefore, we think an allowance between scheduled and actual FDP of 10% is not appropriate for HEMS operations and should be suppressed. PROPOSAL:
	Replace the paragraph (k) by the following: "(k) in AEMS operations, change a schedule or adapt crew arrangements, if the actual operation exceeds the maximum FDP on any EMS operating base on more than 10 % of the FDPs in any 3 months."
response	Please see the answer to comment # 54

comment

465

comment by: FNAM/SNEH

	 (i) AGREEMENT The paragraph (i) refers to sectors. Since the 'sector' definition does not apply anymore for HEMS operations, flight times (FT) shall not be scheduled before HEMS operations and are therefore unpredictable inside a given FDP (by definition of HEMS) (Cf. comment #463) FNAM and SNEH fully agree with the fact that FT cannot and shall not be scheduled before HEMS operations. Only FDP shall and can be scheduled.
response	Please see the answer to comment # 54
comment	 466 comment by: FNAM/SNEH (k) ISSUE No RIA is given to reduce from 33% (general rules for CAT operations) to 10% (proposed for HEMS operations) the allowance between scheduled and actual FDP. The notion of scheduled FT is a non-sense for HEMS, where emergency destinations are hazardous but remain closeby. Thus, the hazard does not belong on determining flight time, but on when the last flight is performed. The incertitude over max FDP is thus very low for mostly short helicopters legs, with no or low ATC constraints. In France, the average flight time for SNEH is 25 minutes for HEMS, <i>i.e</i> 50 minutes back and forth (1 mission):
	 Incertitude allowance over the FT would thus be 2,5min, which is not significative and contrary to aeroplane CAT operations, has very low impact on the time of the end of the FDP Incertitude allowance over the FDP would thus not depend on the FT, but on the time spent grounded on the emergency site to take HEMS material (mostly, the patient, when stabilized and declared transportable by the medical staff)
	Thus, this provision seems irrelevant for HEMS. Therefore, FNAM and SNEH think an allowance between scheduled and actual FDP of 10% is not appropriate for HEMS operations and should be suppressed.
	PROPOSAL: Replace the paragraph (k) by the following: "(k) in AEMS operations, change a schedule or adapt crew arrangements, if the actual operation exceeds the maximum FDP on any EMS operating base on more than 10 % of the FDPs in any 3 months."
response	Please see the answer to comment # 54

comment

645

comment by: Oya Vendée Hélicoptères

 TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.
 Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.
 Page 122 of 585

	 (i) AGREEMENT The paragraph (i) refers to sectors. Since the 'sector' definition does not apply anymore for HEMS operations, flight times (FT) shall not be scheduled before HEMS operations and are therefore unpredictable inside a given FDP (by definition of HEMS) (Cf. comment #643) OYA fully agrees with the fact that FT cannot and shall not be scheduled before HEMS operations. Only FDP shall and can be scheduled.
response	Please see the answer to comment # 54
comment	646 comment by: Oya Vendée Hélicoptères
	(k)
	ISSUE No RIA is given to reduce from 33% (general rules for CAT operations) to 10% (proposed for HEMS operations) the allowance between scheduled and actual FDP. The notion of scheduled FT is a non-sense for HEMS, where emergency destinations are hazardous but remain closeby. Thus, the hazard does not belong on determining flight time, but on when the last flight is performed. The incertitude over max FDP is thus very low for mostly short helicopters legs, with no or low ATC constraints. In France, the average flight time for OYA is 25 minutes for HEMS, <i>i.e</i> 50 minutes back and forth (1 mission):
	 Incertitude allowance over the FT would thus be 2,5min, which is not significative and contrary to aeroplane CAT operations, has very low impact on the time of the end of the FDP Incertitude allowance over the FDP would thus not depend on the FT, but on the time spent grounded on the emergency site to take HEMS material (mostly, the patient, when stabilized and declared transportable by the medical staff)
	Thus, this provision seems irrelevant for HEMS. Therefore, OYA thinks an allowance between scheduled and actual FDP of 10% is not appropriate for HEMS operations and should be suppressed. PROPOSAL:
	Replace the paragraph (k) by the following: "(k) in AEMS operations, change a schedule or adapt crew arrangements, if the actual operation exceeds the maximum FDP on any EMS operating base on more than 10 % of the FDPs in any 3 months."
response	Please see the answer to comment # 54

comment	767 comment by: AECA helicopteros.
	(j) Delete 'except for EMS operations'. (k) Delete all paragraph (k)
	Justification (j) Why the difference between CAT (33%) and EMS (10%)? (k) Reducing the percentage of enlargement reduces flexibility and, consequently, the capacity to respond. It shold be taken into account that we provide emergency services and reduce the flexibility to make it difficult to provide adequate services or even somes services could not be performed if is maintained the 10% of extension. In no case we are faced with scheduled services such as CAT, since you never know in advance when the event arises.
response	Please see the answer to comment # 54
comment	914 comment by: MBH SAMU
	(i) AGREEMENT The paragraph (i) refers to sectors. Since the 'sector' definition does not apply anymore for HEMS operations, flight times (FT) shall not be scheduled before HEMS operations and are therefore unpredictable inside a given FDP (by definition of HEMS) (Cf. comment #907)
	MBH fully agrees with the fact that FT cannot and shall not be scheduled before HEMS operations. Only FDP shall and can be scheduled.
response	Please see the answer to comment # 54.
comment	916 comment by: MBH SAMU
	 (k) ISSUE No RIA is given to reduce from 33% (general rules for CAT operations) to 10% (proposed for HEMS operations) the allowance between scheduled and actual FDP. The notion of scheduled FT is a non-sense for HEMS, where emergency destinations are hazardous but remain closeby. Thus, the hazard does not belong on determining flight time, but on when the last flight is performed. The incertitude over max FDP is thus very low for mostly short helicopters legs, with no or low ATC constraints. In France, the average flight time for MBH is 25 minutes for HEMS, <i>i.e</i> 50 minutes back and forth (1 mission):

An agency of the European Union

	 Incertitude allowance over the FT would thus be 2,5min, which is not significative and contrary to aeroplane CAT operations, has very low impact on the time of the end of the FDP Incertitude allowance over the FDP would thus not depend on the FT, but on the time spent grounded on the emergency site to take HEMS material (mostly, the patient, when stabilized and declared transportable by the medical staff)
	Thus, this provision seems irrelevant for HEMS. Therefore, MBH thinks an allowance between scheduled and actual FDP of 10% is not appropriate for HEMS operations and should be suppressed. PROPOSAL:
	Replace the paragraph (k) by the following: "(k) in AEMS operations, change a schedule or adapt crew arrangements, if the actual operation exceeds the maximum FDP on any EMS operating base on more than 10 % of the FDPs in any 3 months."
response	Please see the answer to comment # 54.

comment	1187 comment by: SAF
	(i)
	AGREEMENT
	The paragraph (i) refers to sectors. Since the 'sector' definition does not apply anymore for HEMS operations, flight times (FT) shall not be scheduled before HEMS operations and are therefore unpredictable inside a given FDP (by definition of HEMS) (Cf. comment #1184)
	SAF fully agrees with the fact that FT cannot and shall not be scheduled before HEMS operations. Only FDP shall and can be scheduled.
response	Please see the answer to comment # 54.
comment	1188 comment by: SAF
	(k)
	ISSUE
	No RIA is given to reduce from 33% (general rules for CAT operations) to 10% (proposed for HEMS operations) the allowance between scheduled and actual FDP.

*** * * * *

 TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.
 Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.
 Page 125 of 585

The notion of scheduled FT is a non-sense for HEMS, where emergency destinations are hazardous but remain closeby. Thus, the hazard does not belong on determining flight time, but on when the last flight is performed.

The incertitude over max FDP is thus very low for mostly short helicopters legs, with no or low ATC constraints.

In France, the average flight time for SAF is 25 minutes for HEMS, *i.e* 50 minutes back and forth (1 mission):

- Incertitude allowance over the FT would thus be 2,5min, which is not significative and contrary to aeroplane CAT operations, has very low impact on the time of the end of the FDP
- Incertitude allowance over the FDP would thus not depend on the FT, but on the time spent grounded on the emergency site to take HEMS material (mostly, the patient, when stabilized and declared transportable by the medical staff)

Thus, this provision seems irrelevant for HEMS.

Therefore, SAF thinks an allowance between scheduled and actual FDP of 10% is not appropriate for HEMS operations and should be suppressed.

PROPOSAL:

Replace the paragraph (k) by the following: "(k) in AEMS operations, change a schedule or adapt crew arrangements, if the actual operation exceeds the maximum FDP on any EMS operating base on more than 10 % of the FDPs in any 3 months."

response

Please see the answer to comment # 54.

1265 comment comment by: Hélicoptères de France #1 (i) AGREEMENT The paragraph (i) refers to sectors. Since the 'sector' definition does not apply anymore for HEMS operations, flight times (FT) shall not be scheduled before HEMS operations and are therefore unpredictable inside a given FDP (by definition of HEMS) (Cf. comment #14.2) HDF fully agree with the fact that FT cannot and shall not be scheduled before HEMS operations. Only FDP shall and can be scheduled. #2 (k) ISSUE No RIA is given to reduce from 33% (general rules for CAT operations) to 10% (proposed for HEMS operations) the allowance between scheduled and actual FDP. The notion of scheduled FT is a non-sense for HEMS, where emergency destinations are hazardous but remain closeby. Thus, the hazard does not belong on determining flight time, but on when the last flight is performed. TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 126 of 585

The incertitude over max FDP is thus very low for mostly short helicopters legs, with no or low ATC constraints. In France, the average flight time for SNEH is 25 minutes for HEMS, i.e 50 minutes back and forth (1 mission)i: Incertitude allowance over the FT would thus be 2,5min, which is not significative and contrary to aeroplane CAT operations, has very low impact on the time of the end of the FDP NPA 2017-17 | HEMS Comments | FNAM & SNEH 14/57 Incertitude allowance over the FDP would thus not depend on the FT, but on the time spent grounded on the emergency site to take HEMS material (mostly, the patient, when stabilized and declared transportable by the medical staff) Thus, this provision seems irrelevant for HEMS. Therefore, HDF thinks an allowance between scheduled and actual FDP of 10% is not appropriate for HEMS operations and should be suppressed. **PROPOSAL:** Replace the paragraph (k) by the following: "(k) in AEMS operations, change a schedule or adapt crew arrangements, if the actual operation exceeds the maximum FDP on any EMS operating base on more than 10 % of the FDPs in any 3 months."

response

3.1. ORO.FTL.120 p. 10

Please see the answer to comment # 54.

comment	222 comment by: ADAC Luftrettung gGmbH
	Ein Unternehmen muss ein FRM durchführen wenn dies im Abschnitt "certification specification" gefordert ist. Da dies im Abschnitt FTL.3.235 nur bei "reduced rest" gefordert ist, ist bei Schichtbetrieb oder Einhaltung der vorgeschriebenen Ruhezeit dennoch ein FRM von Nöten?
response	Please see the answer to comment # 54
comment	251 comment by: European Helicopter Association (EHA)
	ADAC (Germany), DRF (Germany) and LAR (Luxembourg):
	(a) Fatigue Risk Management
	Question: the operator shall implement and maintain a FRM if required in certification specifications. This is only the case in CS FTL3.235 "reduced rest". Is the assumption correct, that FRM is not necessary in case of regular rest periods like for instance a roster with only 8 hour FDP?

Individual comments and responses - HEMS

response	Please see the answer to comment # 54
comment	361 comment by: European Helicopter Association (EHA)BHA (UK)
	"ORO.FTL.120 Fatigue risk management (FRM) [] (b) The FRM established, implemented and maintained shall provide for a continuous improvement to the overall performance of the FRM and shall include:
	[] SECTION 2 Commercial Air Transport Operators [] "
	Comment: From the main FTL scheme, ORO.FTL.200 _ Home Base - would go here. Have the authors considered what impact this may have for TCMs?
response	Please see the answer to comment # 54
comment	528 comment by: ADAC Luftrettung gGmbH
	Question: the operator shall implement and maintain a FRM if required in certification specifications. This is only the case in CS FTL3.235 "reduced rest". Is the assumption correct, that FRM is not necessary in case of regular rest periods like for instance a roster with only 8 hour FDP or the rest time after a FDP is greater than the FDP?
response	Please see the answer to comment # 54
comment	551 comment by: <i>Rüdiger Neu</i>
	Fragestellung: Das Unternehmen muss ein FRM haben und weiterführen, wenn dies im Abschnitt C&S certification specification gefordert wird. Dies ist nur im Abschnitt bei der CS FTL.3.235 "reduced rest" gefordert. Ist es richtig, dass ein FRM bei einem Schichtbetrieb oder der Einhaltung der regulären Ruhezeiten dann nicht benötigt werden?
response	Please see the answer to comment # 54

Individual comments and responses - HEMS

comment	742 comment by: DRF-Luftrettung
	Question: the operator shall implement and maintain a FRM if required in certification specifications.
	This is only the case in CS FTL3.235 "reduced rest". Is the assumption correct, that FRM is not necessary in case of regular rest periods like for instance a roster with only 8 hour FDP?
response	Please see the answer to comment # 54
comment	1384 comment by: Swiss Air-Ambulance Rega
	Question: The operator must have and maintain an FRM if this is required in the CS section. This is only required in the section on "reduced rest" of CS FTL.3.235. Is it correct that an FRM is not necessary for shift operation or in adherence to regular rest times?
response	Please see the answer to comment # 54

3.1. ORO.FTL.205	p. 10-13

comment	59 comment by: London's Air Ambulance
	ORO.FTL.205(b) There is no mention in this paragraph of the FDP table for two-pilot HEMS which is at
	CS.FTL.3.205. Elsewhere in the amended IR there is reference to CS.FTL so it would be useful and aid clarity if a new paragraph ORO.FTL.205(b)(8) was adding:
	"In the case of two-pilot HEMS operations, the FDP limitation stated in CS.FTL.3(a) Table 1, are applicable."
	It is our opinion that a definition of Multi-Pilot operation rather than Two-Pilot operations.
response	Please see the answer to comment # 54.

comment

272 comment by: European Helicopter Association (EHA)

SHA (Switzerland) Table 5



 TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

 Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.
 Page 129 of 585

	Table 5 is defined with sectors but sectors are only for airplanes see article 29 page 10.
response	Please see the answer to comment # 54
comment	273 comment by: European Helicopter Association (EHA)
	SHA (Switzerland) Flight time for each sector limited to 2 h without autopilot : this is discriminating for helicopter and shall be amended at least at 2h30 (fuel limit). Moreover, the article is confusing between EMS and HEMS.
response	Please see the answer to comment # 54

comment	333 comment by: European Helicopter Association (EHA)
	FNAM (France)
	#1(a)(1) ISSUE
	The paragraph (a)(1) seems redundant with the prescriptions of the paragraph (b). The FNAM suggests clarifying the writing.
	PROPOSAL: Suppress the newly added paragraph (a)(1). #2(b)
	GENERAL REMARK regarding the notion of a Daily FDP
	For small FT as currently operated in HEMS, it is possible to have multiple FDP within the same day. For instance: One FDP from 07:00 to 8:30 followed by a 12h rest period and then a FDP from 20:30 to 22h. #3ISSUE
	The paragraph (b)(7) seems redundant with the prescriptions of the paragraph (a)(1). Besides, the FNAM would like to highlight that other cases (such as non-acclimatized crew, etc.) are not considered for HEMS by this regulation. Besides there is a need for extensions of the FDP in HEMS operations. The FNAM suggests suppressing the wording "without the use of extensions". PROPOSAL
	Suppress the wording "without the use of extensions" newly added in the title (b) and in the content of the paragraph (b)(7):
	"(b) Basic maximum daily FDP

**** * ****

[...]

(7) Flight time specification schemes in HEMS operations shall specify the maximum daily FDP for acclimatised crew members in accordance with the certification specification applicable to those operations."

#4(c)AGREEMENT

The paragraph (c) is not applicable for HEMS operations since only cabin crew are mentioned (not the TCM). None of the missions of the TCM is to prepare the flight, therefore, the notion of pre-flight is not applicable for TCM. That is why the FNAM agrees not to add the notion of TCM in this paragraph.

#5 (f) UNFORESEEN CIRCONSTANCES FOR HEMS

ISSUE

(Cf. comment #29.2)

FORCE MAJEURE

HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care services is a public service & a sovereign prerogative), with groupings of medical equipment and skills.

HEMS in France is both operated by private operators and state operators. State may charter private operators to operate HEMS operations on its behalf. Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved. Such a possibility shall remain for "Force majeure" and be introduced within the IR, in respect of the sovereignty of each Member State facing major health crisis. For example, in France, private operators of helicopters were chartered to ensure airlift rotations during recent Millas train disaster on December, the 14th of 2017. Besides, Helicopter Nuclear Response Team are partially delegated to a private operator.

Therefore, the FNAM suggests adding a specific paragraph in this implementing rule allowing HEMS pilots to derogate from these requirements in case of Force Majeure as it is already the case in the Current French National Regulation. PROPOSAL

For illustrative purposes, in France the following article is applied in case of « Force Majeure » :

" Il peut être dérogé aux limitations mentionnées à la présente section dans les conditions suivantes :

1. Vols urgents, dont l'exécution immédiate est nécessaire :

a) Pour prévenir des accidents imminents et organiser des mesures de sauvetage, ou pour réparer des accidents survenus soit au matériel, soit aux installations ;

b) Pour assurer le dépannage des aéronefs.

2. Pour assurer l'achèvement d'une période de vol que des circonstances exceptionnelles n'auraient pas permis d'effectuer dans les limites préétablies.

3. Vols exécutés dans l'intérêt de la sûreté ou de la défense nationale ou d'un service public sur ordre du Gouvernement constatant la nécessité de la dérogation ; la limite est à fixer par le ministre chargé de l'aviation civile. " (Ref : CAC D422-12) #6 AMC1 ORO FTL 205 (f) ISSUE

The paragraph (b)(6) of the AMC1 ORO.FTL.205(f) refers to sectors. Since the 'sector' definition does not apply anymore for HEMS operations, flight times shall not be scheduled before HEMS operations and are therefore unpredictable inside a given FDP (by definition of HEMS). To ensure consistency, the number of sectors in the paragraph (b)(6) of the AMC cannot be applied for HEMS operations.

Otherwise it is not consistent with the ORO.FTL.105 (§24). It should be clarified it in the AMC. (Cf. comment #14.2)

	PROPOSAL "(6) increased number of sectors, except for HEMS."
response	Please see the answer to comment # 54.
comment	362 comment by: European Helicopter Association (EHA)
	BHA (UK)
	Table 5
	Comment: Did this table really have to be so complicated, with time intervals of just fifteen minutes? I would challenge any scientist to prove that such small variations could ever make a demonstrable difference to flight safety.
	"(d1) Maximum daily FDP for acclimatised crew members in two-pilot air taxi and AEMS operations with the use of extensions without on-board rest "
	Comment: Unable to comment on air taxi and AEMS operations, because all feedback received was from HEMS operators.
response	Please see the answer to comment # 54

comment	381 comment by: Joachim J. Janezic (Institute for Austrian and International Aviation law)
	ORO.FTL.205(b)(7) and (f)(7)
	It is expected that most European HEMS operators will apply for deviations according to Article 22 Basic Regulation and flight time specification schemes according to ORO.FTL.125. Since this will lead to a deviation from the CS (but not from the Part- ORO.FTL itself!) it remains unclear what effect such a deviation might cause on the rule ORO.FTL.205(b)(7) and (f)(7) stating "in accordance with the certification specification". The possibility to obtain an approval for a deviation should be addressed in this rule.
response	Please see the answer to comment # 54

comment	391 comment by: European Helicopter Association (EHA)
	SHA (Switzerland)
	Comment: Daily FDP shall be increased to 12h for unknown state of acclimatisation as long as you have no jetlag.
response	Please see the answer to comment # 54
comment	419 comment by: UFH French Helicopters Association
	(a)(1)ISSUE
	The paragraph (a)(1) seems redundant with the prescriptions of the paragraph (b). FNAM suggests clarifying the writing.
	PROPOSAL: Suppress the newly added paragraph (a)(1).
	#2(b) GENERAL REMARK regarding the notion of a Daily FDP
	For small FT as currently operated in HEMS, it is possible to have multiple FDP within the same day. For instance: One FDP from 07:00 to 8:30 followed by a 12h rest period and then a FDP from 20:30 to 22h. #3 ISSUE
	The paragraph (b)(7) seems redundant with the prescriptions of the paragraph (a)(1). Besides, we would like to highlight that other cases (such as non-acclimatized crew, etc.) are not considered for HEMS by this regulation. Besides there is a need for extensions of the FDP in HEMS operations. We suggests suppressing the wording "without the use of extensions".
	PROPOSAL Suppress the wording "without the use of extensions" newly added in the title (b) and in the content of the paragraph (b)(7): "(b) Basic maximum daily FDP
	 [] (7) Flight time specification schemes in HEMS operations shall specify the maximum daily FDP for acclimatised crew members in accordance with the certification specification applicable to those operations." #4(c) AGREEMENT
	The paragraph (c) is not applicable for HEMS operations since only cabin crew are mentioned (not the TCM). None of the missions of the TCM is to prepare the flight, therefore, the notion of pre-flight is not applicable for TCM. That is why FNAM agrees not to add the notion of TCM in this paragraph.
	#5 (f) UNFORESEEN CIRCONSTANCES FOR HEMS ISSUE (Cf. comment #29.2) FORCE MAJEURE
	HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care services is a public service & a sovereign prerogative), with groupings of medical equipment and skills.
	HEMS in France is both operated by private operators and the State.

State may charter private operators to operate HEMS operations on its behalf. Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved. Such a possibility shall remain for "Force majeure" and be introduced within the IR, in respect of the sovereignty of each Member State facing major health crisis. For example, in France, private operators of helicopters were chartered to ensure airlift rotations during recent Millas train disaster on December, the 14th of 2017. Besides, Helicopter Nuclear Response Team are partially delegated to a private operator. Therefore, UFH supports FNAM suggestion to add a specific paragraph in this implementing rule allowing HEMS pilots to derogate from these requirements in case of Force Majeure as it is already the case in the Current French National Regulation. PROPOSAL

For illustrative purposes, in France the following article is applied in case of « Force Majeure » :

" Il peut être dérogé aux limitations mentionnées à la présente section dans les conditions suivantes :

1. Vols urgents, dont l'exécution immédiate est nécessaire :

a) Pour prévenir des accidents imminents et organiser des mesures de sauvetage, ou pour réparer des accidents survenus soit au matériel, soit aux installations ;

b) Pour assurer le dépannage des aéronefs.

2. Pour assurer l'achèvement d'une période de vol que des circonstances exceptionnelles n'auraient pas permis d'effectuer dans les limites préétablies.

3. Vols exécutés dans l'intérêt de la sûreté ou de la défense nationale ou d'un service public sur ordre du Gouvernement constatant la nécessité de la dérogation ; la limite est à fixer par le ministre chargé de l'aviation civile." (Ref : CAC D422-12) #6 AMC1 ORO FTL 205 (f)

ISSUE

The paragraph (b)(6) of the AMC1 ORO.FTL.205(f) refers to sectors. Since the 'sector' definition does not apply anymore for HEMS operations, flight times shall not be scheduled before HEMS operations and are therefore unpredictable inside a given FDP (by definition of HEMS). To ensure consistency, the number of sectors in the paragraph (b)(6) of the AMC cannot be applied for HEMS operations.

Otherwise it is not consistent with the ORO.FTL.105 (§24). It should be clarified it in the AMC. (Cf. comment #14.2)

PROPOSAL "(6) increased number of sectors, except for HEMS." (b) ISSUE

In the paragraph (b), it is not explicit whether:

• All the CS.FTL.3 requirements shall be applicable "in block"

• The CS requirements should apply depending on what is said in the implementing rule

• Cherry-picking is allowed

Indeed, two options seem to be presented, one described in ORO.FTL.210 (a) and another in CS.3.210.

In that way, the CS is a substitution of the IR, which is not the aim and the statute of a CS. The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #24, #25, #30.1, #39, #40)

Therefore, UFH suggests listing the two options in the CS.FTL.3.210 instead of having one described in the IR and one in the CS.

PROPOSAL

In ORO.FTL.210 (b)

Suppress point (1) and (2) and only let:

"The total duty periods to which an individual crew member may be assigned in HEMS



operation is established in accordance with the certification specification applicable to HEMS operations." In CS FTL.3.210: "The total duty periods to which an individual crew member may be assigned in HEMS operation shall not exceed any of the following limits: OPTION 1: (1) 60 duty hours in any 7 consecutive days; (2) 110 duty hours in any 14 consecutive days; and (3) 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period. OR OPTION 2 (taking into account the revisited version of the initial CS, explained in the comment #30): (1) 110 duty hours in any 14 consecutive days, on the condition that: the minimum recurrent extended recovery rest period required under ORO.FTL.235(d) shall be increased to include 4 local nights or 3 local nights under the principles of a FRM. (2) 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period." #2 (d) ISSUE The definition of the mixed AEMS / HEMS operations is not precise and may lead to confusion. Indeed, it is not the philosophy of CAT operations to possess multiple type ratings for pilots especially aeroplane vs helicopter. The wording used is confusion and can be understood in different ways: Mixed AEMS / CAT operations Mixed HEMS / CAT operations Mixed AEMS / HEMS operations We cannot comment this proposal since no definition of the mixed AEMS / HEMS operations has been written. When a clear definition of the mixed AEMS / HEMS operations is provided, UFH will see with EBAA and FNAM to give a French opinion on the proposal. PROPOSAL Precise the definition of mixed AEMS / HEMS operations. Please see the answer to comment # 54 467 comment by: FNAM/SNEH (a)(1) ISSUE The paragraph (a)(1) seems redundant with the prescriptions of the paragraph (b). FNAM and SNEH suggest clarifying the writing. PROPOSAL: Suppress the newly added paragraph (a)(1). Please see the answer to comment # 54

response

comment

response

omment	468 comment by: FNAM/SNEH
	(b) GENERAL REMARK regarding the notion of a <u>Daily</u> FDP For small FT as currently operated in HEMS, it is possible to have multiple FDP within the same day. For instance: One FDP from 07:00 to 8:30 followed by a 12h rest period and then a FDP from 20:30 to 22h.
esponse	See the answer to comment # 54.
omment	469 comment by: FNAM/SNEH
	ISSUE The paragraph (b)(7) seems redundant with the prescriptions of the paragraph (a)(1). Besides, FNAM and SNEH would like to highlight that other cases (such as non- acclimatized crew, etc.) are not considered for HEMS by this regulation. Besides there is need for extensions of the FDP in HEMS operations. FNAM and SNEH suggest suppressin the wording "without the use of extensions".
	PROPOSAL Suppress the wording "without the use of extensions" newly added in the title (b) and in the content of the paragraph (b)(7): "(b) Basic maximum daily FDP []
	(7) Flight time specification schemes in HEMS operations shall specify the maximum daily FDP for acclimatised crew members in accordance with the certification specification applicable to those operations."

comment	470 comment by: FNAM/SNEH
	(c) AGREEMENT The paragraph (c) is not applicable for HEMS operations since only cabin crew are mentioned (not the TCM). None of the missions of the TCM is to prepare the flight, therefore, the notion of pre-flight is not applicable for TCM. That is why FNAM and SNEH agree not to add the notion of TCM in this paragraph.
response	See the answer to comment # 54.



comment	471	comment by: FNAM/SNEH
	ISSUE	I CIRCONSTANCES FOR HEMS
	(Cf. comment #4	491)
	FORCE MAJEUR	E
	organization of services is a pub equipment and HEMS in France	y linked with national health, security and safety. HEMS depends on the the French healthcare system (the permanence and continuity of care lic service & a sovereign prerogative), with groupings of medical skills. is both operated by private operators and the State. er private operators to operate HEMS operations on its behalf.
		regulation thus allows, by sovereign decision of the State, to grant IEMS operations as far as national health, security or safety is involved.
	Such a possibilit	y shall remain for "Force majeure" and be introduced within the IR, in overeignty of each Member State facing major health crisis.
	rotations during	France, private operators of helicopters were chartered to ensure airlift recent Millas train disaster on December, the 14 th of 2017. Besides, ear Response Team are partially delegated to a private operator.
	allowing HEMS	A and SNEH suggest adding a specific paragraph in this implementing rule pilots to derogate from these requirements in case of Force Majeure as it use in the Current French National Regulation.
		ourposes, in France the following article is applied in case of « Force
	Majeure » : " Il peut être dél suivantes :	rogé aux limitations mentionnées à la présente section dans les conditions
	a) Pour prévenir réparer des acci	dont l'exécution immédiate est nécessaire : des accidents imminents et organiser des mesures de sauvetage, ou pour dents survenus soit au matériel, soit aux installations ; le dépannage des aéronefs.
		l'achèvement d'une période de vol que des circonstances exceptionnelles ermis d'effectuer dans les limites préétablies.
	public sur ordre	dans l'intérêt de la sûreté ou de la défense nationale ou d'un service du Gouvernement constatant la nécessité de la dérogation ; la limite est à stre chargé de l'aviation civile." (Ref : CAC D422-12)
response	See the answer	to comment # 54.
comment	472	comment by: FNAM/SNEH
	AMC1 ORO FTL ISSUE	205 (f)



	The paragraph (b)(6) of the AMC1 ORO.FTL.205(f) refers to sectors. Since the 'sector' definition does not apply anymore for HEMS operations, flight times shall not be scheduled before HEMS operations and are therefore unpredictable inside a given FDP (by definition of HEMS). To ensure consistency, the number of sectors in the paragraph (b)(6) of the AMC cannot be applied for HEMS operations. Otherwise it is not consistent with the ORO.FTL.105 (§24). It should be clarified in the AMC. (Cf. comment #463)
	PROPOSAL "(6) increased number of sectors, except for HEMS."
response	See the answer to comment # 54.
comment	647 comment by: Oya Vendée Hélicoptères
	(a)(1) ISSUE The paragraph (a)(1) seems redundant with the prescriptions of the paragraph (b). OYA suggests clarifying the writing.
	PROPOSAL: Suppress the newly added paragraph (a)(1).
response	See the answer to comment # 54.
comment	648 comment by: Oya Vendée Hélicoptères
	(b) GENERAL REMARK regarding the notion of a <u>Daily</u> FDP For small FT as currently operated in HEMS, it is possible to have multiple FDP within the same day.
	For instance: One FDP from 07:00 to 8:30 followed by a 12h rest period and then a FDP from 20:30 to 22h.
response	See the answer to comment # 54.
comment	649 comment by: Oya Vendée Hélicoptères
	ISSUE The paragraph (b)(7) seems redundant with the prescriptions of the paragraph (a)(1). Besides, OYA would like to highlight that other cases (such as non-acclimatized crew, etc.) are not considered for HEMS by this regulation. Besides there is a need for extensions of the FDP in HEMS operations. OYA suggests suppressing the wording "without the use of extensions".
	PROPOSAL Suppress the wording " <i>without the use of extensions</i> " newly added in the title (b) and in the content of the paragraph (b)(7):

	"(b) Basic maximum daily FDP [] (7) Flight time specification schemes in HEMS operations shall specify the maximum daily FDP for acclimatised crew members in accordance with the certification specification applicable to those operations."
response	See the answer to comment # 54.
comment	650 comment by: Oya Vendée Hélicoptères
	(c) AGREEMENT The paragraph (c) is not applicable for HEMS operations since only cabin crew are mentioned (not the TCM). None of the missions of the TCM is to prepare the flight, therefore, the notion of pre-flight is not applicable for TCM. That is why OYA agrees not to add the notion of TCM in this paragraph.
response	See the answer to comment # 54.
comment	651 comment by: <i>Oya Vendée Hélicoptères</i>
	 (f) UNFORESEEN CIRCONSTANCES FOR HEMS ISSUE (Cf. comment #671) FORCE MAJEURE HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care services is a public service & a sovereign prerogative), with groupings of medical equipment and skills. HEMS in France is both operated by private operators and the State. State may charter private operators to operate HEMS operations on its behalf. Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved. Such a possibility shall remain for "Force majeure" and be introduced within the IR, in respect of the sovereignty of each Member State facing major health crisis. For example, in France, private operators of helicopters were chartered to ensure airlift rotations during recent Millas train disaster on December, the 14th of 2017. Besides, Helicopter Nuclear Response Team are partially delegated to a private operator. Therefore, OYA suggests adding a specific paragraph in this implementing rule allowing HEMS pilots to derogate from these requirements in case of Force Majeure as it is already the case in the Current French National Regulation. PROPOSAL For illustrative purposes, in France the following article is applied in case of « Force Majeure » : <i>" Il peut être dérogé aux limitations mentionnées à la présente section dans les conditions suivantes : 1. Vols urgents, dont l'exécution immédiate est nécessaire : 1. Vols urgents, dont l'exécution immédiate est nécessaire </i>



	 a) Pour prévenir des accidents imminents et organiser des mesures de sauvetage, ou pour réparer des accidents survenus soit au matériel, soit aux installations ; b) Pour assurer le dépannage des aéronefs. 2. Pour assurer l'achèvement d'une période de vol que des circonstances exceptionnelles n'auraient pas permis d'effectuer dans les limites préétablies. 3. Vols exécutés dans l'intérêt de la sûreté ou de la défense nationale ou d'un service public sur ordre du Gouvernement constatant la nécessité de la dérogation ; la limite est à fixer par le ministre chargé de l'aviation civile." (Ref : CAC D422-12)
response	See the answer to comment # 54.
comment	652 comment by: Oya Vendée Hélicoptères
	AMC1 ORO FTL 205 (f) ISSUE The paragraph (b)(6) of the AMC1 ORO.FTL.205(f) refers to sectors. Since the 'sector' definition does not apply anymore for HEMS operations, flight times shall not be scheduled before HEMS operations and are therefore unpredictable inside a given FDP (by definition of HEMS). To ensure consistency, the number of sectors in the paragraph (b)(6) of the AMC cannot be applied for HEMS operations. Otherwise it is not consistent with the ORO.FTL.105 (§24). It should be clarified in the AMC. (Cf. comment #643) PROPOSAL
	<i>"(6) increased number of sectors, except for HEMS."</i>
response	See the answer to comment # 54.
comment	812 comment by: Yorkshire Air Ambulance
	From the main FTL scheme, ORO.FTL.200 - Home Base - goes above here. Have the authors considered what impact the impositon of a Home Base may have for TCMs, and how it might conflict with contractual obligations elsewhere?
response	See the answer to comment #54.
comment	826 comment by: Yorkshire Air Ambulance Did this table really have to be so complicated, with time intervals of just fifteen minutes? I would challenge any scientist to prove that such small variations could ever make a demonstrable difference to flight safety. Suggest it is redrafted to be more useable by both crews and operators.

**** TE * * Pr ****

Individual comments and responses - HEMS

response	See the answer to comment #54.
comment	828 comment by: Yorkshire Air Ambulance
	Unable to make useful comments on air taxi and AEMS operations, because all feedback received was from HEMS operators.
response	See the answer to comment #54.
comment	917 comment by: MBH SAMU

917 comment by: MBH SAMU
(a)(1) ISSUE The paragraph (a)(1) seems redundant with the prescriptions of the paragraph (b). MBH suggests clarifying the writing.
PROPOSAL: Suppress the newly added paragraph (a)(1).
See the answer to comment #54.
918 comment by: MBH SAMU
(b) GENERAL REMARK regarding the notion of a <u>Daily</u> FDP For small FT as currently operated in HEMS, it is possible to have multiple FDP within the same day.
For instance: One FDP from 07:00 to 8:30 followed by a 12h rest period and then a FDP from 20:30 to 22h.
See the answer to comment #54.
920 comment by: MBH SAMU
ISSUE The paragraph (b)(7) seems redundant with the prescriptions of the paragraph (a)(1). Besides, MBH would like to highlight that other cases (such as non-acclimatized crew, etc.) are not considered for HEMS by this regulation. Besides there is a need for extensions of the FDP in HEMS operations. MBH suggests suppressing the wording <i>"without the use of extensions"</i> . PROPOSAL

	Suppress the wording "without the use of extensions" newly added in the title (b) and in the content of the paragraph (b)(7): "(b) Basic maximum daily FDP [] (7) Flight time specification schemes in HEMS operations shall specify the maximum daily FDP for acclimatised crew members in accordance with the certification specification
response	applicable to those operations." See the answer to comment #54.
response	
comment	921 comment by: MBH SAMU
	(c) AGREEMENT
	The paragraph (c) is not applicable for HEMS operations since only cabin crew are mentioned (not the TCM). None of the missions of the TCM is to prepare the flight, therefore, the notion of pre-flight is not applicable for TCM. That is why MBH agrees not to add the notion of TCM in this paragraph.
response	See the answer to comment #54.
comment	922 comment by: MBH SAMU
	 (f) UNFORESEEN CIRCONSTANCES FOR HEMS ISSUE (Cf. comment #952) FORCE MAJEURE HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care services is a public service & a sovereign prerogative), with groupings of medical equipment and skills. HEMS in France is both operated by private operators and the State. State may charter private operators to operate HEMS operations on its behalf. Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved. Such a possibility shall remain for "Force majeure" and be introduced within the IR, in respect of the sovereignty of each Member State facing major health crisis. For example, in France, private operators of helicopters were chartered to ensure airlift rotations during recent Millas train disaster on December, the 14th of 2017. Besides, Helicopter Nuclear Response Team are partially delegated to a private operator. Therefore, MBH suggests adding a specific paragraph in this implementing rule allowing HEMS pilots to derogate from these requirements in case of Force Majeure as it is already the case in the Current French National Regulation.
	PROPOSAL For illustrative purposes, in France the following article is applied in case of « Force Majeure » :



	 <i>" Il peut être dérogé aux limitations mentionnées à la présente section dans les conditions suivantes :</i> 1. Vols urgents, dont l'exécution immédiate est nécessaire : a) Pour prévenir des accidents imminents et organiser des mesures de sauvetage, ou pour réparer des accidents survenus soit au matériel, soit aux installations ; b) Pour assurer le dépannage des aéronefs. 2. Pour assurer l'achèvement d'une période de vol que des circonstances exceptionnelles n'auraient pas permis d'effectuer dans les limites préétablies. 3. Vols exécutés dans l'intérêt de la sûreté ou de la défense nationale ou d'un service public sur ordre du Gouvernement constatant la nécessité de la dérogation ; la limite est à fixer par le ministre chargé de l'aviation civile. " (Ref : CAC D422-12)
response	See the answer to comment #54.
comment	924 Comment by: MBH SAMU AMC1 ORO FTL 205 (f)ISSUE The paragraph (b)(6) of the AMC1 ORO.FTL.205(f) refers to sectors. Since the 'sector' definition does not apply anymore for HEMS operations, flight times shall not be scheduled before HEMS operations and are therefore unpredictable inside a given FDP (by definition of HEMS). To ensure consistency, the number of sectors in the paragraph (b)(6) of the AMC cannot be applied for HEMS operations. Otherwise it is not consistent with the ORO.FTL.105 (§24). It should be clarified in the AMC. (Cf. comment #907) PROPOSAL "(6) increased number of sectors, except for HEMS."
response	See the answer to comment #54.
comment	 334 comment by: European Helicopter Association (EHA) FNAM (France) #1 (b) ISSUE In the paragraph (b), it is not explicit whether: All the CS.FTL.3 requirements shall be applicable "in block" The CS requirements should apply depending on what is said in the implementing rule Cherry-picking is allowed Indeed, two options seem to be presented, one described in ORO.FTL.210 (a) and another in CS.3.210. In that way, the CS is a substitution of the IR, which is not the aim and the statute of a CS. The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #24, #25, #30.1, #39, #40)



Therefore, the FNAM suggests listing the two options in the CS.FTL.3.210 instead of having one described in the IR and one in the CS. PROPOSAL In ORO.FTL.210 (b) Suppress point (1) and (2) and only let: "The total duty periods to which an individual crew member may be assigned in HEMS operation is established in accordance with the certification specification applicable to HEMS operations." In CS FTL.3.210: "The total duty periods to which an individual crew member may be assigned in HEMS operation shall not exceed either of the following limits: **OPTION 1:** (1) 60 duty hours in any 7 consecutive days; (2) 110 duty hours in any 14 consecutive days; and (3) 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period. OR OPTION 2 (taking into account the revisited version of the initial CS, explained in the comment #30): (1) 110 duty hours in any 14 consecutive days, on the condition that: *i. the minimum recurrent extended recovery rest period required under ORO.FTL.235(d)* shall be increased to include 4 local nights or 3 local nights under the principles of a FRM. (2) 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period." #2 (d) ISSUE The definition of the mixed AEMS / HEMS operations is not precise and may lead to confusion. Indeed, it is not the philosophy of CAT operations to possess multiple type ratings for pilots especially aeroplane vs helicopter. The wording used is confusion and can be understood in different ways: Mixed AEMS / CAT operations Mixed HEMS / CAT operations Mixed AEMS / HEMS operations The FNAM cannot comment this proposal since no definition of the mixed AEMS / HEMS operations has been written. When a clear definition of the mixed AEMS / HEMS operations is provided, the FNAM will give an opinion on the proposal. PROPOSAL Precise the definition of mixed AEMS / HEMS operations. See the answer to comment #54. 363 comment by: European Helicopter Association (EHA) BHA (UK)



TE.RPRO.00064-008 $\ensuremath{\mathbb{C}}$ European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 144 of 585

response

comment

"(a) (2)"

	These limits are more frequently used by F/W operators. In the UK, only 60 hours in 7 days and 200 hours in 28 days (CAP371) were applicable to helicopter operations, so this NPA has reduced (by 10 hours) a limit which has been permitted since 1975. Where is the evidence that this improves safety?
	"(b) (2)" See comments relating to this option in the CS section.
response	See the answer to comment #54
comment	<pre>382 comment by: Joachim J. Janezic (Institute for Austrian and International Aviation law)</pre>
	To ORO.FTL.210(b)(2): It is expected that most European HEMS operators will apply for deviations according to Article 22 Basic Regulation and flight time specification schemes according to ORO.FTL.125. Since this will lead to a deviation from the CS (but not from the Part- ORO.FTL itself!) it remains unclear what effect such a deviation might cause on the rule ORO.FTL.210 (b)(2) stating "in accordance with the certification specification". The possibility to obtain an approval for a deviation should be addressed in this rule.
response	See the answer to comment #54
comment	473 (b)
	ISSUE In the paragraph (b), it is not explicit whether:
	 All the CS.FTL.3 requirements shall be applicable "in block" The CS requirements should apply depending on what is said in the implementing rule Cherry-picking is allowed
	Indeed, two options seem to be presented, one described in ORO.FTL.210 (a) and another in CS.3.210. In that way, the CS is a substitution of the IR, which is not the aim and the statute of a CS. The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #477, #478, #496, #510, #511)
	Therefore, FNAM and SNEH suggest listing the two options in the CS.FTL.3.210 instead of having one described in the IR and one in the CS.
	PROPOSAL In ORO.FTL.210 (b)



Suppress point (1) and (2) and only let: "The total duty periods to which an individual crew member may be assigned in HEMS operation is established in accordance with the certification specification applicable to HEMS operations."
In CS FTL.3.210: <i>"The total duty periods to which an individual crew member may be assigned in HEMS operation shall not exceed any of the following limits:</i>
OPTION 1:
 60 duty hours in any 7 consecutive days; 110 duty hours in any 14 consecutive days; and 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period.
OR
 OPTION 2 (taking into account the revisited version of the initial CS, explained in the comment #496 to 501): (1) 110 duty hours in any 14 consecutive days, on the condition that: the minimum recurrent extended recovery rest period required under ORO.FTL.235(d) shall be increased to include 4 local nights or 3 local nights under the principles of a FRM. (2) 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period."
See the answer to comment #54
474 comment by: FNAM/SNEH
(d) ISSUE The definition of the mixed AEMS / HEMS operations is not precise and may lead to confusion. Indeed, it is not the philosophy of CAT operations to possess multiple type ratings for pilots especially aeroplane vs helicopter. The wording used is confusing and can be understood in different ways:
 Mixed AEMS / CAT operations Mixed HEMS / CAT operations Mixed AEMS / HEMS operations

**** * * ***

response

comment

FNAM and SNEH cannot comment this proposal since no definition of the mixed AEMS / HEMS operations has been written. When a clear definition of the mixed AEMS / HEMS operations is provided, FNAM and SNEH will give an opinion on the proposal.

PROPOSAL
Precise the definition of mixed AEMS / HEMS operations.responseSee the answer to comment #54

comment	653 comment by: Oya Vendée Hélicoptères
	(b)
	ISSUE
	In the paragraph (b), it is not explicit whether:
	All the CC ETL 2 menuines and shall be any list black.
	 All the CS.FTL.3 requirements shall be applicable "in block" The CS requirements should apply depending on what is said in the
	implementing rule
	Cherry-picking is allowed
	Indeed, two options seem to be presented, one described in ORO.FTL.210 (a) and
	another in CS.3.210. In that way, the CS is a substitution of the IR, which is not the aim
	and the statute of a CS. The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #657, #658, #676, #689,
	#690)
	Therefore, OYA suggests listing the two options in the CS.FTL.3.210 instead of having one
	described in the IR and one in the CS.
	PROPOSAL
	In ORO.FTL.210 (b) Suppress point (1) and (2) and only let:
	"The total duty periods to which an individual crew member may be assigned in HEMS
	operation is established in accordance with the certification specification applicable to
	HEMS operations."
	In CS FTL.3.210:
	"The total duty periods to which an individual crew member may be assigned in HEMS
	operation shall not exceed any of the following limits:
	OPTION 1:
	1. 60 duty hours in any 7 consecutive days;
	2. 110 duty hours in any 14 consecutive days; and

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 147 of 585

3. 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period. OR OPTION 2 (taking into account the revisited version of the initial CS, explained in the comment #676 to 681): (1) 110 duty hours in any 14 consecutive days, on the condition that: the minimum recurrent extended recovery rest period required under ORO.FTL.235(d) shall be increased to include 4 local nights or 3 local nights under the principles of a FRM. (2) 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period." See the answer to comment #54 response 654 comment comment by: Oya Vendée Hélicoptères (d) ISSUE The definition of the mixed AEMS / HEMS operations is not precise and may lead to confusion. Indeed, it is not the philosophy of CAT operations to possess multiple type ratings for pilots especially aeroplane vs helicopter. The wording used is confusing and can be understood in different ways: Mixed AEMS / CAT operations Mixed HEMS / CAT operations Mixed AEMS / HEMS operations OYA cannot comment this proposal since no definition of the mixed AEMS / HEMS operations has been written. When a clear definition of the mixed AEMS / HEMS operations is provided, OYA will give an opinion on the proposal. PROPOSAL Precise the definition of mixed AEMS / HEMS operations. See the answer to comment #54 response 830 comment comment by: Yorkshire Air Ambulance These limits are more frequently used by F/W operators. In the UK, only 60 hours in 7 days and 200 hours in 28 days (CAP371) were applicable to helicopter operations, so this NPA has reduced (by 10 hours) a limit which has been permitted since 1975. Where is



	the evidence that this improves safety? Also, 190 hours in 28 days unfairly penalises an equal time 4-on, 4-off roster, which results in 192 duty hours on the 28th day.
response	Please see the answer to comment # 54
comment	923 comment by: AESA
	Point (e)(1) refers to Table 1 in ORO.FTL.205(b)(1). That table doesn't exist. It must be Table 2.
response	See the answer to comment #54.
comment	926 comment by: MBH SAMU
	(b) ISSUE In the paragraph (b), it is not explicit whether:
	 All the CS.FTL.3 requirements shall be applicable "in block" The CS requirements should apply depending on what is said in the implementing rule Cherry-picking is allowed
	Indeed, two options seem to be presented, one described in ORO.FTL.210 (a) and another in CS.3.210. In that way, the CS is a substitution of the IR, which is not the aim and the statute of a CS. The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #932, #933, #958, #975, #977)
	Therefore, MBH suggests listing the two options in the CS.FTL.3.210 instead of having one described in the IR and one in the CS.
	PROPOSAL In ORO.FTL.210 (b) Suppress point (1) and (2) and only let: "The total duty periods to which an individual crew member may be assigned in HEMS operation is established in accordance with the certification specification applicable to HEMS operations."
	In CS FTL.3.210: <i>"The total duty periods to which an individual crew member may be assigned in HEMS operation shall not exceed any of the following limits:</i>
	OPTION 1:

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

	 60 duty hours in any 7 consecutive days; 110 duty hours in any 14 consecutive days; and 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period.
	OR
	 OPTION 2 (taking into account the revisited version of the initial CS, explained in the comment #958 to 965): (1) 110 duty hours in any 14 consecutive days, on the condition that: the minimum recurrent extended recovery rest period required under ORO.FTL.235(d) shall be increased to include 4 local nights or 3 local nights under the principles of a FRM.
	(2) 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period."
response	See the answer to comment #54.
comment	927 comment by: MBH SAMU
	(d) ISSUE The definition of the mixed AEMS / HEMS operations is not precise and may lead to confusion. Indeed, it is not the philosophy of CAT operations to possess multiple type ratings for pilots especially aeroplane <i>vs</i> helicopter. The wording used is confusing and can be understood in different ways:
	 Mixed AEMS / CAT operations Mixed HEMS / CAT operations Mixed AEMS / HEMS operations
	MBH cannot comment this proposal since no definition of the mixed AEMS / HEMS operations has been written. When a clear definition of the mixed AEMS / HEMS operations is provided, MBH will give an opinion on the proposal.
	PROPOSAL Precise the definition of mixed AEMS / HEMS operations.
response	See the answer to comment #54.
comment	1078 comment by: FNAM

**** * * * ****

 TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.
 Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.
 Page 150 of 585

(c)

	 ISSUE The definition of the mixed AEMS / HEMS operations is not precise and may lead to confusion. Indeed, it is not the philosophy of CAT operations to possess multiple type ratings for pilots especially aeroplane vs helicopter. The wording used is confusion and can be understood in different ways: Mixed AEMS / CAT operations Mixed HEMS / CAT operations Mixed AEMS / HEMS operations 	
	FNAM and EBAA France cannot comment this proposal since no definition of the mixed AEMS / HEMS operations has been written. When a clear definition of the mixed AEMS / HEMS operations is provided, FNAM and EBAA France will give an opinion on the proposal.	
	PROPOSAL Precise the definition of mixed AEMS / HEMS operations	
response	See the answer to comment #54.	
comment	1081 comment by: FNAM	
	 (d) ISSUE The definition of the mixed AEMS / HEMS operations is not precise and may lead to confusion. Indeed, it is not the philosophy of CAT operations to possess multiple type ratings for pilots especially aeroplane vs helicopter. The wording used is confusion and can be understood in different ways: Mixed AEMS / CAT operations Mixed HEMS / CAT operations Mixed HEMS / CAT operations 	
	Mixed AEMS / HEMS operations	
	FNAM and EBAA France cannot comment this proposal since no definition of the mixed AEMS / HEMS operations has been written. When a clear definition of the mixed AEMS / HEMS operations is provided, FNAM and EBAA France will give an opinion on the proposal.	
	PROPOSAL Precise the definition of mixed AEMS / HEMS operations.	
response	See the answer to comment #54.	



comment	1099 comment by: European Cockpit Association
	Commented text: ORO.FTL.210 The duty periods to which an individual crew member may be assigned in HEMS operations is established: (1) in accordance with (a); or (2) in accordance with the limits specified in the certifaction specifications applicable to HEMS operations.
	ECA comment: We strongly recommmend to add: <i>but should never exceed (a) (3) 190 duty hours in any</i> <i>28 consecutive days</i> . If this cumulative time is kept including all times on alert, this is a huge improvement and a large step forwards to flight safety. This limit may not be possible to be by passed, even not by a CS/IFTSS.
response	See the answer to comment #54.
comment	1199 comment by: SAF
	(b ISSUE In the paragraph (b), it is not explicit whether:
	 All the CS.FTL.3 requirements shall be applicable "in block" The CS requirements should apply depending on what is said in the implementing rule Cherry-picking is allowed
	Indeed, two options seem to be presented, one described in ORO.FTL.210 (a) and another in CS.3.210. In that way, the CS is a substitution of the IR, which is not the aim and the statute of a CS. The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #1205, #1208, #1226, #1239, #1240)
	Therefore, SAF suggests listing the two options in the CS.FTL.3.210 instead of having one described in the IR and one in the CS.
	PROPOSAL In ORO.FTL.210 (b) Suppress point (1) and (2) and only let: "The total duty periods to which an individual crew member may be assigned in HEMS operation is established in accordance with the certification specification applicable to HEMS operations."
	In CS FTL.3.210:
	<i>"The total duty periods to which an individual crew member may be assigned in HEMS operation shall not exceed any of the following limits:</i>



OPTION 1: 1. 60 duty hours in any 7 consecutive days; 2. 110 duty hours in any 14 consecutive days; and 3. 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period. OR OPTION 2 (taking into account the revisited version of the initial CS, explained in the comment #1226 to 1231): (1) 110 duty hours in any 14 consecutive days, on the condition that: the minimum recurrent extended recovery rest period required under ORO.FTL.235(d) shall be increased to include 4 local nights or 3 local nights under the principles of a FRM. (2) 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period." response See the answer to comment #54. comment 1200 comment by: SAF (d) ISSUE The definition of the mixed AEMS / HEMS operations is not precise and may lead to confusion. Indeed, it is not the philosophy of CAT operations to possess multiple type ratings for pilots especially aeroplane vs helicopter. The wording used is confusing and can be understood in different ways: Mixed AEMS / CAT operations Mixed HEMS / CAT operations Mixed AEMS / HEMS operations • SAF cannot comment this proposal since no definition of the mixed AEMS / HEMS operations has been written. When a clear definition of the mixed AEMS / HEMS operations is provided, SAF will give an opinion on the proposal. PROPOSAL Precise the definition of mixed AEMS / HEMS operations. response See the answer to comment #54.

comment

1268

comment by: *Hélicoptères de France*

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 153 of 585 #1 (b)

ISSUE

In the paragraph (b), it is not explicit whether:

• All the CS.FTL.3 requirements shall be applicable "in block"

• The CS requirements should apply depending on what is said in the implementing rule

• Cherry-picking is allowed

Indeed, two options seem to be presented, one described in ORO.FTL.210 (a) and another in CS.3.210.

In that way, the CS is a substitution of the IR, which is not the aim and the statute of a CS. The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #24, #25, #30.1, #39, #40)

Therefore, HDF suggests listing the two options in the CS.FTL.3.210 instead of having one described in the IR and one in the CS.

PROPOSAL

In ORO.FTL.210 (b)

Suppress point (1) and (2) and only let:

"The total duty periods to which an individual crew member may be assigned in HEMS operation is established in accordance with the certification specification applicable to HEMS operations."

In CS FTL.3.210:

"The total duty periods to which an individual crew member may be assigned in HEMS operation shall not exceed any of the following limits:

OPTION 1:

(1) 60 duty hours in any 7 consecutive days;

(2) 110 duty hours in any 14 consecutive days; and

(3) 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period.

OR

OPTION 2 (taking into account the revisited version of the initial CS, explained in the comment #30):

(1) 110 duty hours in any 14 consecutive days, on the condition that:

i. the minimum recurrent extended recovery rest period required under ORO.FTL.235(d) shall be increased to include 4 local nights or 3 local nights under the principles of a FRM.
(2) 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period."

#2

(d)

ISSUE

The definition of the mixed AEMS / HEMS operations is not precise and may lead to confusion. Indeed, it is not the philosophy of CAT operations to possess multiple type ratings for pilots especially aeroplane vs helicopter. The wording used is confusing and can be understood in different ways:

- Mixed AEMS / CAT operations
- Mixed HEMS / CAT operations
- Mixed AEMS / HEMS operations

agency of the European Unior

	HDF cannot comment this proposal since no definition of the mixed AEMS / HEMS operations has been written. When a clear definition of the mixed AEMS / HEMS operations is provided, HDF will give an opinion on the proposal. PROPOSAL Precise the definition of mixed AEMS / HEMS operations.
response	See the answer to comment #54.
comment	1267 comment by: Hélicoptères de France
	#1 The paragraph (a)(1) seems redundant with the prescriptions of the paragraph (b). HDF suggests clarifying the writing. PROPOSAL:
	Suppress the newly added paragraph (a)(1).
	#2 GENERAL REMARK regarding the notion of a Daily FDP For small FT as currently operated in HEMS, it is possible to have multiple FDP within the same day. For instance: One FDP from 07:00 to 8:30 followed by a 12h rest period and then a FDP from 20:30 to 22h.
	#3 The paragraph (b)(7) seems redundant with the prescriptions of the paragraph (a)(1). Besides, HDF would like to highlight that other cases (such as non-acclimatized crew, etc.) are not considered for HEMS by this regulation. Besides there is a need for extensions of the FDP in HEMS operations. HDF suggests suppressing the wording "without the use of extensions". PROPOSAL
	Suppress the wording "without the use of extensions" newly added in the title (b) and in the content of the paragraph (b)(7): "(b) Basic maximum daily FDP
	[] (7) Flight time specification schemes in HEMS operations shall specify the maximum daily FDP for acclimatised crew members in accordance with the certification specification applicable to those operations."
	#4 The paragraph (c) is not applicable for HEMS operations since only cabin crew are mentioned (not the TCM). None of the missions of the TCM is to prepare the flight, therefore, the notion of pre-flight is not applicable for TCM. That is why HDF agrees not to add the notion of TCM in this paragraph.
	#5 (f) UNFORESEEN CIRCONSTANCES FOR HEMS (Cf. comment #29.2) FORCE MAJEURE
	HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care services is a public service & a sovereign prerogative), with groupings of medical equipment and skills.
	HEMS in France is both operated by private operators and the State. State may charter private operators to operate HEMS operations on its behalf.

	Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved. Such a possibility shall remain for "Force majeure" and be introduced within the IR, in respect of the sovereignty of each Member State facing major health crisis.
	For example, in France, private operators of helicopters were chartered to ensure airlift rotations during recent Millas train disaster on December, the 14th of 2017. Besides, Helicopter Nuclear Response Team are partially delegated to a private operator. Therefore, HDF suggests adding a specific paragraph in this implementing rule allowing HEMS pilots to derogate from these requirements in case of Force Majeure as it is already the case in the Current French National Regulation.
	PROPOSAL For illustrative purposes, in France the following article is applied in case of « Force Majeure » :
	" Il peut être dérogé aux limitations mentionnées à la présente section dans les conditions suivantes :
	 Vols urgents, dont l'exécution immédiate est nécessaire : a) Pour prévenir des accidents imminents et organiser des mesures de sauvetage, ou pour réparer des accidents survenus soit au matériel, soit aux installations ; b) Pour assurer le dépannage des aéronefs.
	2. Pour assurer l'achèvement d'une période de vol que des circonstances exceptionnelles n'auraient pas permis d'effectuer dans les limites préétablies.
	 3. Vols exécutés dans l'intérêt de la sûreté ou de la défense nationale ou d'un service public sur ordre du Gouvernement constatant la nécessité de la dérogation ; la limite est à fixer par le ministre chargé de l'aviation civile." (Ref : CAC D422-12)
	#6 AMC1 ORO FTL 205 (f) The paragraph (b)(6) of the AMC1 ORO.FTL.205(f) refers to sectors. Since the 'sector' definition does not apply anymore for HEMS operations, flight times shall not be scheduled before HEMS operations and are therefore unpredictable inside a given FDP (by definition of HEMS). To ensure consistency, the number of sectors in the paragraph (b)(6) of the AMC cannot be applied for HEMS operations. Otherwise it is not consistent with the ORO.FTL.105 (§24). It should be clarified in the AMC. (Cf. comment #14.2) PROPOSAL
	"(6) increased number of sectors, except for HEMS."
response	Please see the answer to comment # 54
comment	1332 comment by: ENAC
	Point (c) It is not clear what "mixed AEMS/HEMS" operations means. Furthermore the text of point (c) would be easier to understand if it was written like point (a).
response	See the answer to comment #54.



comment	1190 comment by: SAF
	(b) GENERAL REMARK regarding the notion of a <u>Daily</u> FDP
	For small FT as currently operated in HEMS, it is possible to have multiple FDP within the same day. For instance: One FDP from 07:00 to 8:30 followed by a 12h rest period and then a FDP from 20:30 to 22h.
response	Please see the answer to comment # 54
comment	1191 comment by: SAF
	The paragraph (b)(7) seems redundant with the prescriptions of the paragraph (a)(1). Besides, SAF would like to highlight that other cases (such as non-acclimatized crew, etc.) are not considered for HEMS by this regulation. Besides there is a need for extensions of the FDP in HEMS operations. SAF suggests suppressing the wording "without the use of extensions".
	PROPOSAL
	Suppress the wording "without the use of extensions" newly added in the title (b) and in the content of the paragraph (b)(7):
	"(b) Basic maximum daily FDP
	(7) Flight time specification schemes in HEMS operations shall specify the maximum daily FDP for acclimatised crew members in accordance with the certification specification applicable to those operations."
response	Please see the answer to comment # 54
ſ	
comment	1194 comment by: SAF
	(c)



response	AGREEMENT The paragraph (c) is not applicable for HEMS operations since only cabin crew are mentioned (not the TCM). None of the missions of the TCM is to prepare the flight, therefore, the notion of pre-flight is not applicable for TCM. That is why SAF agrees not to add the notion of TCM in this paragraph. Please see the answer to comment # 54
	1105
comment	1195 comment by: SAF
	(f) UNFORESEEN CIRCONSTANCES FOR HEMS
	ISSUE
	(Cf. comment #1221)
	FORCE MAJEURE
	HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care services is a public service & a sovereign prerogative), with groupings of medical equipment and skills.
	HEMS in France is both operated by private operators and the State.
	State may charter private operators to operate HEMS operations on its behalf.
	Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved.
	Such a possibility shall remain for "Force majeure" and be introduced within the IR, in respect of the sovereignty of each Member State facing major health crisis.
	For example, in France, private operators of helicopters were chartered to ensure airlift rotations during recent Millas train disaster on December, the 14 th of 2017. Besides, Helicopter Nuclear Response Team are partially delegated to a private operator.
	Therefore, SAF suggests adding a specific paragraph in this implementing rule allowing HEMS pilots to derogate from these requirements in case of Force Majeure as it is already the case in the Current French National Regulation.
	PROPOSAL

	For illustrative purposes, in France the following article is applied in case of « Force Majeure » :
	<i>" Il peut être dérogé aux limitations mentionnées à la présente section dans les conditions suivantes :</i>
	1. Vols urgents, dont l'exécution immédiate est nécessaire :
	a) Pour prévenir des accidents imminents et organiser des mesures de sauvetage, ou pour réparer des accidents survenus soit au matériel, soit aux installations ;
	b) Pour assurer le dépannage des aéronefs.
	2. Pour assurer l'achèvement d'une période de vol que des circonstances exceptionnelles n'auraient pas permis d'effectuer dans les limites préétablies.
	3. Vols exécutés dans l'intérêt de la sûreté ou de la défense nationale ou d'un service public sur ordre du Gouvernement constatant la nécessité de la dérogation ; la limite est à fixer par le ministre chargé de l'aviation civile." (Ref : CAC D422-12)
response	Please see the answer to comment # 54
comment	1196 comment by: SAF
comment	1196 comment by: SAF AMC1 ORO FTL 205 (f)
comment	
comment	AMC1 ORO FTL 205 (f) The paragraph (b)(6) of the AMC1 ORO.FTL.205(f) refers to sectors. Since the 'sector' definition does not apply anymore for HEMS operations, flight times shall not be scheduled before HEMS operations and are therefore unpredictable inside a given FDP (by definition of HEMS). To ensure consistency, the number of sectors in the paragraph (b)(6) of the AMC cannot be applied for HEMS operations. Otherwise it is not consistent
comment	AMC1 ORO FTL 205 (f) The paragraph (b)(6) of the AMC1 ORO.FTL.205(f) refers to sectors. Since the 'sector' definition does not apply anymore for HEMS operations, flight times shall not be scheduled before HEMS operations and are therefore unpredictable inside a given FDP (by definition of HEMS). To ensure consistency, the number of sectors in the paragraph (b)(6) of the AMC cannot be applied for HEMS operations. Otherwise it is not consistent with the ORO.FTL.105 (§24). It should be clarified in the AMC. (Cf. comment #1184)

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

Individual comments and responses - HEMS

3.1. ORO.FTL.215

p. 10

comment	335 comment by: European Helicopter Association (EHA)
	FNAM (France)
	 (a) ISSUE The paragraph (a) refers to 'sectors'. Since the 'sector' definition does not apply anymore for HEMS operations, flight times shall not be scheduled before HEMS operations and are therefore unpredictable inside a given FDP (by definition of HEMS). (Cf. comment #14.2) In that way, it is not clear whether the positioning requirement (a) is applicable to HEMS operations.
	PROPOSAL Rephrase as follows: "(a) Positioning after reporting but prior to operating shall be counted as FDP. For other CAT operations than HEMS, it shall not count as a sector;"
response	See the answer to comment #54.
comment	475 comment by: FNAM/SNEH
	(a) ISSUE The paragraph (a) refers to 'sectors'. Since the 'sector' definition does not apply anymore for HEMS operations, flight times shall not be scheduled before HEMS operations and are therefore unpredictable inside a given FDP (by definition of HEMS). (Cf. comment #463) In that way, it is not clear whether the positioning requirement (a) is applicable to HEMS operations.
	PROPOSAL Rephrase as follows: "(a) Positioning after reporting but prior to operating shall be counted as FDP. For other CAT operations than HEMS, it shall not count as a sector;"
response	See the answer to comment #54.
comment	655 comment by: <i>Oya Vendée Hélicoptères</i>
	(a) ISSUE



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 160 of 585

Page 161 of 585

The paragraph (a) refers to 'sectors'. Since the 'sector' definition does not apply anymore for HEMS operations, flight times shall not be scheduled before HEMS operations and are therefore unpredictable inside a given FDP (by definition of HEMS). (Cf. comment #643) In that way, it is not clear whether the positioning requirement (a) is applicable to HEMS operations.
PROPOSAL Rephrase as follows: "(a) Positioning after reporting but prior to operating shall be counted as FDP. For other CAT operations than HEMS, it shall not count as a sector;"
See the answer to comment #54.
928 comment by: MBH SAMU
(a) ISSUE The paragraph (a) refers to 'sectors'. Since the 'sector' definition does not apply anymore for HEMS operations, flight times shall not be scheduled before HEMS operations and are therefore unpredictable inside a given FDP (by definition of HEMS). (Cf. comment #907) In that way, it is not clear whether the positioning requirement (a) is applicable to HEMS operations.
PROPOSAL Rephrase as follows: "(a) Positioning after reporting but prior to operating shall be counted as FDP. For other CAT operations than HEMS, it shall not count as a sector;"
See the answer to comment #54.
1201 comment by: SAF
 (a) ISSUE The paragraph (a) refers to 'sectors'. Since the 'sector' definition does not apply anymore for HEMS operations, flight times shall not be scheduled before HEMS operations and are therefore unpredictable inside a given FDP (by definition of HEMS). (Cf. comment #1184) In that way, it is not clear whether the positioning requirement (a) is applicable to HEMS operations. PROPOSAL Rephrase as follows: "(a) Positioning after reporting but prior to operating shall be counted as FDP. For other CAT operations than HEMS, it shall not count as a sector;"

Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

Individual comments and responses - HEMS

esponse	See the answer to comment #54.
omment	1269 comment by: Hélicoptères de France
	(a)
	ISSUE The paragraph (a) refers to 'sectors'. Since the 'sector' definition does not apply anymore for HEMS
	operations, flight times shall not be scheduled before HEMS operations and are therefore unpredictable inside a given FDP (by definition of HEMS). (Cf. comment #14.2)
	In that way, it is not clear whether the positioning requirement (a) is applicable to HEMS operations. PROPOSAL
	Rephrase as follows: "(a) Positioning after reporting but prior to operating shall be counted as FDP. For other CAT
	operations
	than HEMS, it shall not count as a sector;"
3.1. ORO.FT	See the answer to comment #54.
esponse	See the answer to comment #54.
.1. ORO.FT	See the answer to comment #54. L.220 94 comment by: B. Wagner zu (b): Es gibt keine wissenschaftlichen Grundlagen, die diesen Ansatz unterstützen. Ob und wie eine Pause zur FDP anzurechnen ist, sollte von den äusseren Umständen abhänger
.1. ORO.FT	See the answer to comment #54. L.220 94 comment by: B. Wagner zu (b): Es gibt keine wissenschaftlichen Grundlagen, die diesen Ansatz unterstützen. Ob und wie eine Pause zur FDP anzurechnen ist, sollte von den äusseren Umständen abhängen
.1. ORO.FT	See the answer to comment #54. L.220 94 comment by: B. Wagner zu (b): Es gibt keine wissenschaftlichen Grundlagen, die diesen Ansatz unterstützen. Ob und wie eine Pause zur FDP anzurechnen ist, sollte von den äusseren Umständen abhänger in denen die Pausenzeit stattfindet. So kann man z.B. einen Ruheraum an einem Flughafen, der vielleicht von fremden Crews ebenso genutzt wird und der eventuell durch äussere Störfaktoren keine Ruhemöglichkeit bietet nicht mit einer HEMS Station vergleichen, die komfortable Ruheräume für jedes Crewmitglied bietet. Vorschlag für eine Änderung des Textes:
3.1. ORO.FT	See the answer to comment #54. L.220 94 comment by: B. Wagner zu (b): Es gibt keine wissenschaftlichen Grundlagen, die diesen Ansatz unterstützen. Ob und wie eine Pause zur FDP anzurechnen ist, sollte von den äusseren Umständen abhänger in denen die Pausenzeit stattfindet. So kann man z.B. einen Ruheraum an einem Flughafen, de vielleicht von fremden Crews ebenso genutzt wird und der eventuell durch äussere Störfaktoren keine Ruhemöglichkeit bietet nicht mit einer HEMS Station vergleichen, die komfortable Ruheräume für jedes Crewmitglied bietet. Vorschlag für eine Änderung des Textes: "(b) the breaks on the ground shall count in full as FDP, except facilities provided to the crew
	See the answer to comment #54. L.220 p. 1 94 comment by: B. Wagner zu (b): Es gibt keine wissenschaftlichen Grundlagen, die diesen Ansatz unterstützen. Ob und wie eine Pause zur FDP anzurechnen ist, sollte von den äusseren Umständen abhänger in denen die Pausenzeit stattfindet. So kann man z.B. einen Ruheraum an einem Flughafen, de vielleicht von fremden Crews ebenso genutzt wird und der eventuell durch äussere Störfaktoren keine Ruhemöglichkeit bietet nicht mit einer HEMS Station vergleichen, die komfortable Ruheräume für jedes Crewmitglied bietet. Vorschlag für eine Änderung des Textes: "(b) the breaks on the ground shall count in full as FDP, except facilities provided to the crew member to rest are equipped as follows: one room per crew member, air condition, possibility to dim the light also during day time to be defined"

ORO.FTL.220



comment	95 comment by: B. Wagner
	zu (c): mit dieser Einschränkung kann man Split duty im HEMS Bereich nicht nutzen, wenn es am
	nötigsten wäre, in den Monaten mit langen Dienstzeiten. Sinnvoller wäre eine Beschränkung auf z.B. maximal 3 oder 4 Tage in Folge.
response	See the answer to comment #54.
comment	336 comment by: European Helicopter Association (EHA)
	FNAM (France)
	(a)
	ISSUE Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since flight times are unpredictable and cannot be scheduled within a FDP, the same has to be applied for breaks in split duty. Besides the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour. Under these conditions, the FNAM agrees and thanks the EASA for introducing the
	possibility of split duty for HEMS activities with unscheduled breaks. The operator should ensure ex-post that the break requirement has been fulfilled for pilots. Therefore, to ensure split duty is adapted to HEMS operations, the FNAM suggests writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the operation. Such a break may be monitored ex-post by the operator SMS, under the principle of the fatigue risk management.
	PROPOSAL
	Rephrase the paragraph (a) as follows: "(a) The operator ensures ex-post that at least one break of minimum 60 consecutive
	minutes if taken in a suitable accommodation, or at least 2 hours, if taken in accommodation"
response	Please see the answer to comment # 54
comment	476 comment by: FNAM/SNEH
	Attachments <u>#57</u> <u>#58</u> <u>#59</u> <u>#60</u>
	(a)
	ISSUE Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since
	flight times are unpredictable and cannot be scheduled within a FDP, the same has to be applied for breaks in split duty. Besides the wording "break" should be rethought to make

An agency of the European Union

it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour. Under these conditions, FNAM and SNEH agree and thanks EASA for introducing the possibility of split duty for HEMS activities with unscheduled breaks. The operator should ensure ex-post that the break requirement has been fulfilled for pilots. (Cf. attachments S1, S2, S3 and S4 illustrating this break issue)

Therefore, to ensure split duty is adapted to HEMS operations, FNAM and SNEH suggest writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the operation. Such a break may be monitored ex-post by the operator SMS, under the principles of the fatigue risk management.

PROPOSAL

Rephrase the paragraph (a) as follows: "(a) The operator ensures ex-post that at least one break of minimum 60 consecutive minutes if taken in a suitable accommodation, or at least 2 hours, if taken in accommodation"

response

See the answer to comment #54.

comment

comment by: Oya Vendée Hélicoptères

Attachments #61 #62 #63 #64

(a)

656

ISSUE

Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since flight times are unpredictable and cannot be scheduled within a FDP, the same has to be applied for breaks in split duty. Besides the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour.

Under these conditions, OYA agrees and thanks EASA for introducing the possibility of split duty for HEMS activities with unscheduled breaks. The operator should ensure expost that the break requirement has been fulfilled for pilots.

(Cf. attachments S1, S2, S3 and S4 illustrating this break issue)

Therefore, to ensure split duty is adapted to HEMS operations, OYA suggests writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the operation. Such a break may be monitored ex-post by the operator SMS, under the principles of the fatigue risk management.

PROPOSAL Rephrase the paragraph (a) as follows:

"(a) The operator ensures ex-post that at least one break of minimum 60 consecutive minutes if taken in a suitable accommodation, or at least 2 hours, if taken in accommodation"



response	See the answer to comment #54.
comment	768 comment by: AECA helicopteros.
	Questions needing answer in regulation:
	 Does the application of this concept require an explicit notification to the pilot or is sufficient for him to remain in the base without functions? If notification is necessary, how is done? Would it be necessary to notify the beginning and end of the break?
response	See the answer to comment #54.
comment	929 comment by: MBH SAMU
	Attachments <u>#65</u> <u>#66</u> <u>#67</u> <u>#68</u>
	(a)
	ISSUE Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since
	flight times in fitting are unpredictable inside a given FDF, by definition of fitting. Since flight times are unpredictable and cannot be scheduled within a FDP, the same has to be applied for breaks in split duty. Besides the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour. Under these conditions, MBH agrees and thanks EASA for introducing the possibility of split duty for HEMS activities with unscheduled breaks. The operator should ensure ex- post that the break requirement has been fulfilled for pilots. (Cf. attachments S1, S2, S3 and S4 illustrating this break issue)
	Therefore, to ensure split duty is adapted to HEMS operations, MBH suggests writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the operation. Such a break may be monitored ex-post by the operator SMS, under the principles of the fatigue risk management.
	PROPOSAL Rephrase the paragraph (a) as follows: "(a) The operator ensures ex-post that at least one break of minimum 60 consecutive minutes if taken in a suitable accommodation, or at least 2 hours, if taken in accommodation"
response	See the answer to comment #54.
comment	1204 comment by: SAF

	Attachments <u>#69</u> <u>#70</u> <u>#71</u> <u>#72</u>
	(a)
	ISSUE
	Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since flight times are unpredictable and cannot be scheduled within a FDP, the same has to be applied for breaks in split duty. Besides the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour.
	Under these conditions, SAF agrees and thanks EASA for introducing the possibility of split duty for HEMS activities with unscheduled breaks. The operator should ensure expost that the break requirement has been fulfilled for pilots.
	(Cf. attachments S1, S2, S3 and S4 illustrating this break issue)
	Therefore, to ensure split duty is adapted to HEMS operations, SAF suggests writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the operation. Such a break may be monitored ex-post by the operator SMS, under the principles of the fatigue risk management.
	PROPOSAL
	Rephrase the paragraph (a) as follows:
	<i>"(a) The operator ensures ex-post that at least one break of minimum 60 consecutive minutes if taken in a suitable accommodation, or at least 2 hours, if taken in accommodation"</i>
response	See the answer to comment #54.
comment	1270 comment by: Hélicoptères de France
	 (a) ISSUE Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since flight times are unpredictable and cannot be scheduled within a FDP, the same has to be applied for breaks in split duty. Besides the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour. Under these conditions, HDF agrees and thanks EASA for introducing the possibility of split duty for HEMS activities with unscheduled breaks. The operator should ensure expost that the break requirement has been fulfilled for pilots. (Cf. attachments S1, S2, S3 and S4 illustrating this break issue) Therefore, to ensure split duty is adapted to HEMS operations, HDF suggests writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the

**** ****

	operation. Such a break may be monitored ex-post by the operator SMS, under the principles of the fatigue risk management. PROPOSAL Rephrase the paragraph (a) as follows: "(a) The operator ensures ex-post that at least one break of minimum 60 consecutive minutes if taken in a suitable accommodation, or at least 2 hours, if taken in accommodation"
response	See the answer to comment #54.

3.1. ORO.FTL.225 Standby and duties at the airport

р. 14-15

comment	 89 comment by: AIR ZERMATT AG The NPA does not consider the case where crew members live close to the HEMS operating base and may return to their home during rest periods and standby time. Additional terminology "on-call-duty" should be implemented and defined as follows: <i>Time in which the crew member is permanently available on the order of the operator and is ready to fly. In doing so, the crew member stays at home or at another suitable location, which offers the opportunity for private activities and rest. On-call-duty can be counted as rest time.</i> «On-call-duty» is counted as free time and hence shall be excluded from the overall duty time.
response	See the answer to comment #54.
comment	180 comment by: ANSMUH
	In the airplane field, the standby is used to allow the availability of one or more crews to substitute their colleagues or to provide for an off-schedule flight in case of contingent problems. There can be an airport standby and other than airport standby. The actual FTL Regulation and the NPA for air taxi define the duty periods based on the response time. In particular it is defined that the airport standby is considered in full as duty period (ORO.FTL.225(c)), but it does not say that the standby at the HEMS operating base is counted as duty period as well, but only when executing some duties (ORO.FTL.225(d)):
	(c) airport standby shall count in full as duty period for the purpose of points ORO.FTL.210 (a) and (b) and ORO.FTL.235;
	(d) any duty at the airport or at the HEMS operating base, as applicable, shall count in full as duty period and the FDP shall count in full from the airport duty reporting time;
	Airplane standby at the airport generally gives the pilot, once he is tasked, the needed time to plan for the flight and for all the ground necessities, thus allowing a response

time from 30 minutes from take-off or above. Because of this readiness, and because he is waiting in an operating place (the airport), all the time spent in standby is counted as duty.

On the other hand, for the HEMS pilot waiting for a flight in a HEMS base (i.e. an operating place like the airport standby but defined as "other than airport standby") it is left to the operator defining the amount of time to be counted as duty in its manuals.

Currently in France standby is counted as duty time. If this NPA is applied there is a strong chance that social movements will appear very quickly to refuse it.

Proposal:

ORO.FTL.225

Standby and duties at the airport or at the HEMS operating base If an operator assigns crew members to standby or to any duty at the airport or at the HEMS operating base, the following shall apply in accordance with the certification specifications applicable to the type of operation:

(a) standby and any duty at the airport or at the HEMS operating base, as applicable, shall be in the roster and the start and end time of standby shall be defined and notified in advance to the crew members concerned to provide them with the opportunity to plan adequate rest;

(b) a crew member is considered on airport standby or on standby at the HEMS operating base from reporting at the reporting point until the end of the notified standby period;

(c) airport standby or standby at the HEMS operating base shall count in full as duty period for the purpose of points ORO.FTL.210 (a) and (b) and ORO.FTL.235;

(d) any duty at the airport or at the HEMS operating base, as applicable, shall count in full as duty period and the FDP shall count in full from the airport duty reporting time; (e) the operator shall provide accommodation to the crew member on airport standby or on standby at the HEMS operating base.

(f) flight time specification schemes established in accordance with the certification specifications applicable to the type of operations shall specify the following elements:

(1) the maximum duration of any standby;

(2) the impact of the time spent on standby on the maximum FDP that may be assigned, taking into account facilities provided to the crew member to rest, and other relevant factors such as:

- the need for immediate readiness of the crew member,

- the interference of standby with sleep, and

 sufficient notification to protect a sleep opportunity between the call for duty and the assigned FDP;

(3) the minimum rest period following standby which does not lead to assignment of an FDP;

(4) how time spent on standby other than airport standby shall be counted for the purpose of cumulative duty periods.



Individual comments and responses - HEMS

response	See the answer to comment #54.
comment	937 comment by: AESA Point (c) establish that airport standby count in full as duty, but it doesn't mention that HEMS base standby count full as duty. Correct sentence must be "Airport standby or standby at the HEMS operating base shall count in full"
response	See the answer to comment #54.
comment	1316 comment by: Elilombarda
	 ORO.FTL.225 Standby and duties at the airport or at the HEMS operating base With regard to 'Standby' in HEMS operations, the following applies: ORO.FTL.105 (25) - 'standby' ORO.FTL.105 (27) - 'other standby' ORO.FTL.225 Standby and duties at the airport or at the HEMS operating base (and related AMC/GM) CS FTL.3.225 Standby and duties at the HEMS operating base Neither the ORO.FTL.225 nor the CS FTL.3.225 report minimum limits for the calculation of the HEMS duty time based on the response time or on the location where the crew shall wait. Typical HEMS duty daily shift is an uninterrupted duty of 8 to 14 hours (presently maximum 13 hours in Italy) where the crew is requested to take off in a time that varies from down to 5 minutes to up to 30 minutes from the time the mission is assigned. The crew shall remain in the base, close to the helicopter, and use the limited time available before take-off for planning purposes. Due to these HEMS operations peculiarities, the crew readiness is maximum, even if there are few or no flights at all during the day. For this reasons, it is not possible to consider the HEMS crews cannot be considered in "standby' while waiting for a mission assignment "at HEMS operating base", but they are in a full duty time. Moreover, the whole time shall be considered as FDP, because "ready to fly anytime". Only standby outside the HEMS operating base ('other standby'), i.e. when the crew is allowed to walk away from the operating base ('other standby', i.e. when the crew is allowed to walk away from the operating base, can be counted partially as duty time. In this case, the minimum standby time shall be 90 minutes, in order to give the crew the necessary time to reach the base, plan for the flight, make the necessary phone calls and open and pre-flight the helicopter.

	Suggested NPA amendment ORO.FTL.225 Standby and duties at the airport or at the HEMS operating base If an operator assigns crew members to standby or to any duty at the airport or at the HEMS operating base, the following shall apply in accordance with the certification specifications applicable to the type of operation: () (c) (c) airport standby shall count in full as duty period for the purpose of points ORO.FTL.210 (a) and (b) and ORO.FTL.235; (d) (d) standby at the HEMS operating base shall count in full as flight duty period (FDP) for the purpose of points ORO.FTL.210 (a) and (b) and ORO.FTL.235;
response	See the answer to comment #54.
comment	1333 comment by: ENAC
	 Point (d) To be consistent with previous point (c), the following phrase should be added to the text: "for the purpose of ORO.FTL.210". HEMS crew are usually standing by in the HEMS operating base ready to take off in few minutes. It is not clear if that status is considered "duty at the HEMS operating base", where DP/FDP count from reporting, or "stand-by at the HEMS operating base" as in CS FTL.3.225.
response	See the answer to comment #54.
comment	1338 comment by: ENAC
	Neither the ORO.FTL.225 nor the CS FTL.3.225 report minimum limits for the calculation of the duty time based on the response time or on the location where the crew shall wait. Typical HEMS duty daily shift is an uninterrupted duty of 8 to 14 hours (presently maximum 13 hours in Italy) where the crew is requested to take off in a time that varies from down to 5 minutes to up to 30 minutes from the mission assignment. The crew shall remain in the base, close to the helicopter, and use the limited time available before take-off for planning purposes. Due to these HEMS operations peculiarities, the crew readiness is maximum, even if there are few or no flight at all during the day. For this reasons, it is not possible to consider the HEMS crew in 'standby', as intended for airplane airport standby, because the HEMS readiness is much more demanding. Based on these considerations, it is felt that HEMS crews cannot be considered in "standby at HEMS operating base" and, in any case, the whole time shall be considered as FDP, because "ready to fly anytime".
	Only standby outside the HEMS operating base, i.e. when the crew is allowed to walk away from the operating base, can be counted partially as duty time. In this case the

An agency of the European Union

	minimum standby time shall be 90 minutes, in order to give the crew the necessary time to reach the base, plan for the flight, open and pre-flight the helicopter.
response	See the answer to comment #54.
comment	1387 comment by: Swiss Air-Ambulance Rega
	The NPA does not consider the case where crew members live close to the HEMS operating base and may return to their home during rest periods and standby time. Additional terminology "on-call-duty" should be implemented and defined. «On-call-duty» is counted as free time and hence shall be excluded from the overall duty time.
	Proposed amendment: Time in which the crew member is permanently available on the order of the operator and is ready to fly. In doing so, the crew member stays at home or at another suitable location, which offers the opportunity for private activities and rest. On-call-duty can be counted as rest time.
response	See the answer to comment #54.

Rationale for the implementing rules

p. 15-18

comment	145 comment by: CAA-NL
	Page 16, Rational number 3
	Comment: This rational state that the definition of sector has been adapted to include helicopters. The opposite is proposed, by changing aircraft into aeroplane helicopters are excluded. See also remark related.
response	See the answer to comment #54.
comment	275 comment by: European Helicopter Association (EHA)
	SHA (Switzerland) Point 8 the text allows some alleviations and if this is acceptable to the agency it shall be accepted for all HEMS operations and it shall be possible to continue to work under national regulation as they are best adapted.

response	See the answer to comment #54.
comment	299 comment by: Federal Office of Civil Aviation (FOCA), Switzerland
	<i>Comment FOCA:</i> Most transportations with helicopters are more effective/efficient than ground transportation. That's why the helicopter is used. Even within urban areas (towns, cities) the helicopter transport is often more effective/efficient than a transport by an ambulance. The argumentation within the "rationale for the IRs" (<i>see p. 15-16 "() helicopters for the purpose of emergency medical services. It, however, excludes from the scope certain HEMS conducted exclusively in areas where an alternative ground transportation is not possible or is ineffective, to be defined by the competent authority of a Member State. This will allow a number of socially important operations to continue to exist, as any reduction in the duty and flight hours will further reduce the anyway low number of missions. Those impacts are expected to have a detrimental effect on pilots' proficiency, costs for new recruitment and pilot training")</i> will not only allow the continuation of current national duty regulations, where scientific principles have not been used so far. Therefore, an exception from FTL shall only be applicable to HEMS operations conducted from a HEMS base located in a remote area. Remote areas may characterized by a low density of population, low density of motorway networks or long-distance transfers to metropolitan or urban centers (i.e. Lapland). Otherwise, most of the HEMS operations within the Alpine region may be excluded from more safe FTL regulations.
response	See the answer to comment #54.
comment	311 comment by: European Helicopter Association (EHA) NORSK LUFTAMBULANSE AS (Norway): "Article 8 'Flight time limitations' of Regulation (EU) No 965/2012 is extended to now include air taxi, single-pilot and emergency medical service operations, with aeroplanes, as well as CAT operations with helicopters for the purpose of emergency medical services. It, however, excludes from the scope certain HEMS conducted exclusively in areas where an alternative ground transportation is not possible or is ineffective, to be defined by the competent authority of a Member State. This will allow a number of socially important operations to continue to exist, as any reduction in the duty and flight hours will further reduce the anyway low number of missions. Those impacts are expected to have a detrimental effect on pilots' proficiency, costs for new recruitment and pilot training."

**** * * P

location of example, the word operators	t : This is highly relevant for operation serving remote areas, where also the ate is low. However, here it is important to emphasize that it is not always the of the HEMS operating base that is relevant, but the actual area served. For a helicopter can be based in a city, while serving exclusively remote areas. Also ing "ineffective" should perhaps be reviewed as most medical personnel or s could argue that the majority of road transport could be "ineffective" as d to helicopter transport.
especially	TL.100 is amended to also include HEMS crew members. HEMS operations, daily missions, are typically operated by mixed crews consisting of a pilot and a w member who assists the PIC. This justifies the application of the same FTL both."
of a "pilo technical	t: As the HEMS technical crew member typically have the monitoring functions t monitoring" this is sensible. However, it should be described how HEMS crew members, that are perhaps not working only for the operator providing 5, should account for work or duty in other organizations or for other 5.
	TL.105 — the definitions of (13) 'flight time' and (24) 'sector' have been to include both operations with aeroplanes and helicopters."
Commen	t: 'sector' is not applicable for helicopters.
See the a	nswer to comment #54.
364	comment by: European Helicopter Association (EHA)
BHA (UK)	
of Regula emergene helicopte the scope transport	<i>Flight time limitations'</i> tion (EU) No 965/2012 is extended to now include air taxi, single-pilot and cy medical service operations, with aeroplanes, as well as CAT operations with rs for the purpose of emergency medical services. It, however, excludes from e certain HEMS conducted exclusively in areas where an alternative ground ation is not possible or is ineffective, to be defined by the competent authority aber State. "
Commen	t: ous comment on poor choice of words.
See previ	

Comment:



response

comment

	While explaining that TCMs should be included into an FTL scheme, there is no consideration given for the self-evident fact that TCMs will not actually be controlling/commanding an aircraft and, much like cabin crew, would be better served with some alleviations. Also, no attempt has been made to account for how TCMs should account for extra-curricular work they may conduct outside of the flight environment.
	"3. ORO.FTL.105 — the definitions of (13) 'flight time' and (24) 'sector' have been adapted to include both operations with aeroplanes and helicopters. "
	Comment: No it hasn't.
	"5. ORO.FTL.105 — a new definition (30) 'single-pilot operation' is included to avoid potential misinterpretation, especially as regards daily HEMS operations where a HEMS crew member is needed to assist the pilot."
	Comment: See previous comments. Although the NPA recognises the value of TCMs and brings them within the scope of an FTL scheme, no fatigue credit is given for SP + TCM in the HEMS role vs SP air-taxi/AEMS.
	"14. ORO.FTL.21 -Point (b) is replaced by new text providing HEMS operators with the flexibility to choose either the cumulative duty limits of scheduled and charter operations or those that are more adapted to the nature of HEMS operations. The cumulative duty periods in HEMS are governed by Member States' national law, this flexibility will allow the continuation of national practices that are deemed to be safe; "
	Comment: I would dispute that it achieves this objective because, for example, the 'flexibility' described would not allow the continuation of UK national practices.
response	See the answer to comment #54.
comment	588 comment by: NOLAS
	"1. ORO.FTL.100 is amended to also include HEMS crew members. HEMS operations, especially daily missions, are typically operated by mixed crews consisting of a pilot and a HEMS crew member who assists the PIC. This justifies the application of the same FTL regime to both."
	Comment: As the HEMS technical crew member typically have the monitoring functions of a "pilot monitoring" this is sensible. However, it should be described how HEMS technical crew members, that are perhaps not working only for the operator providing the HEMS, should account for work or duty in other organizations or for other operators.
response	See the answer to comment #54.



comment	589 comment by: NOLAS
	"3. ORO.FTL.105 — the definitions of (13) 'flight time' and (24) 'sector' have been adapted to include both operations with aeroplanes and helicopters."
	Comment: 'sector' is not applicable for helicopters.
response	See the answer to comment #54.
comment	831 comment by: Yorkshire Air Ambulance
	While explaining that TCMs should be included into an FTL scheme, there is no consideration given for the self-evident fact that TCMs will not actually be controlling/commanding an aircraft and, much like cabin crew, would be better served with some alleviations. Also, no attempt has been made to account for how TCMs should account for extra-curricular work they may conduct outside of the flight environment.
response	See the answer to comment #54.
comment	832 comment by: Yorkshire Air Ambulance
	See previous comments. Although the NPA recognises the value of TCMs and brings them within the scope of an FTL scheme, no fatigue credit is given for SP + TCM in the HEMS role vs SP air-taxi/AEMS.
response	See the answer to comment #54.
comment	833 comment by: Yorkshire Air Ambulance
	I would dispute that it achieves this objective because, for example, the 'flexibility' described would not allow the continuation of UK national practices.
response	See the answer to comment #54.
commont	1111 comment by: European Cockpit Association
comment	1111 comment by: European Cockpit Association
	Commented text: Rationale for the implementing rules — Point (b) is replaced by new text providing HEMS operators with the flexibility to choose either the cumulative duty limits of scheduled and charter operations or those that are more adapted to the nature of HEMS operations. The cumulative duty periods in

	HEMS are governed by Member States' national law, this flexibility will allow the continuation of national practices that are deemed to be safe;
	ECA comment: ECA recommends keeping the 2000h/y and 190h/28 day limit as an overall limit (implementing rule) and enable required flexibility by Member States national law
response	See the answer to comment #54.
comment	1320 comment by: SAS
	Clarificaton on the applicability of this extention to UK HEMS is required. Given the social importance of service is without question and often ground transportation would render any further medical intervention useless and ineffective.
response	See the answer to comment #54.
comment	 1462 comment by: European Cockpit Association Commented provision: Cumulative flight times ECA expresses strong support for the lower cumulative limits in CS2 and point out that any relaxing of FDPs and other flexibilities beyond CAT FTLs are absolutely contingent on these limits staying as they are. Additionally, the workloads of the pilots examined in the FRMSc study which is used to justify this approach were significantly less than these limits on average. Proposal: We would therefore strongly recommend reduced cumulative duty limits as well. Positioning ECA expresses strong support for the new provisions on positioning in air taxi operations where positioning is very prevalent. Maintaining these provisions is absolutely necessary little means and environment of the provision of the strong is deviced on the strong is a strong benchave and the strong is deviced on the strong is a strong benchave and the strong is strong benchave and the strong is absolutely necessary little means and the strong is strong benchave and the strong is strong benchave and the strong is strong benchave and the strong is strong in a strong benchave and the strong is strong in a strong in a strong is absolutely necessary little means and strong is strong benchave and the strong is strong is strong is absolutely necessary little means and the strong is strong in a strong is strong is strong in a strong is strong in a strong is strong is absolutely necessary is the strong is strong is absolutely necessary is the strong is strong is strong in a strong is strong in a strong is strong is strong is strong in a strong is strong is strong in a strong is strong is strong is strong is strong is strong is strong in a strong is strong is strong is strong is strong in a strong is strong is strong is str
response	if the more permissive provisions elsewhere are to remain justified. See the answer to comment #54.
comment	587 comment by: NOLAS
	"Article 8 'Flight time limitations' of Regulation (EU) No 965/2012 is extended to now include air taxi, single-pilot and emergency medical service operations, with aeroplanes, as well as CAT operations with helicopters for the purpose of emergency medical services. It, however, excludes from the scope certain HEMS conducted exclusively in areas where an alternative ground transportation is not possible or is ineffective, to be defined by the competent authority of a Member State. This will allow a number of socially important operations to continue to exist, as any reduction in the duty and flight

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 176 of 585

**** ****

	 hours will further reduce the anyway low number of missions. Those impacts are expected to have a detrimental effect on pilots' proficiency, costs for new recruitment and pilot training." Comment: This is highly relevant for operation serving remote areas, where also the mission rate is low. However, here it is important to emphasize that it is not always the location of the HEMS operating base that is relevant, but the actual area served. For example, a helicopter can be based in a city, while serving exclusively remote areas. Also, the wording "ineffective" should perhaps be reviewed as most medical personnel or operators could argue that the majority of road transport could be "ineffective" as
response	compared to helicopter transport. See the answer to comment #54.
response	
comment	1340 comment by: Elilombarda
	See comment to CS FTL.3.205 Flight duty period (FDP) — HEMS for rationale.
	Suggested NPA amendment
	ORO.FTL.235 Rest periods
	()
	Recurrent extended recovery rest periods
	Flight time specification schemes shall specify recurrent extended recovery rest periods to compensate for cumulative fatigue. The minimum recurrent extended recovery rest period shall be 36 hours, including 2 local nights, and in any case the time between the end of one recurrent extended recovery rest period and the start of the next extended recovery rest period shall not be more than 168 hours, or 336 hours for HEMS. The recurrent extended recovery rest period shall be increased to 2 local days twice every month.
response	See the answer to comment #54.
comment	1420 comment by: Svensk Luftambulans
	 HEMS conducted exclusively in areas where an alternative ground transportation is not possible or is ineffective, Comment: This is highly relevant for operation serving remote areas, where also the mission rate is low. The wording "ineffective" must be clarified as there are areas with other means of transportations, but due to the sparsely population and large areas to be covered, Helicopter is the only alternate when it comes to time critical patients. Which guidelines have NAA on this?

response	See the answer to comment #54.
comment	1285 comment by: Hélicoptères de France
	 (b) ISSUE: The paragraph (b) of this GM refers simultaneously to the ORO and the CS. The wording used: "using the appropriate table ORO.FTL.205 (b) or the certification specifications applicable to the type of operation" is very confusing especially the terms "or". It is not explicit whether: All the CS.FTL.3 requirements shall be applicable "in block" The CS requirements should apply depending on what is said in the implementing rule Cherry-picking is allowed The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #18.1, #24, #25, #30.1, #40) PROPOSAL: Rewrite to clarify as follows: "(b) The maximum daily FDP for acclimatised crew members is determined by using respectively tables of ORO.FTL.205(b) or of the relevant certification specifications applicable to the type of operations with the reference time of the point of departure. As soon as 48 hours have elapsed, the state of acclimatisation is derived from the time elapsed since reporting at reference time and the number of time zones crossed."
response	See the answer to comment #54.

comment	349 comment by: European Helicopter Association (EHA)
	FNAM (France)
	ISSUE:
	The paragraph (b) of this GM refers simultaneously to the ORO and the CS. The wording used: "using the appropriate table ORO.FTL.205 (b) or the certification specifications applicable to the type of operation" is very confusing especially the terms "or". It is not explicit whether:
	• All the CS.FTL.3 requirements shall be applicable "in block"
	 The CS requirements should apply depending on what is said in the implementing rule Cherry-picking is allowed
	The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation.
	(Cf. comments #18.1, #24, #25, #30.1, #40)
	PROPOSAL:
	Rewrite to clarify as follows:
	"(b) The maximum daily FDP for acclimatised crew members is determined by using respectively tables of ORO.FTL.205(b) or of the relevant certification specifications
	respectively tubles of OKO.FTL.205(b) of of the relevant certification specifications



	applicable to the type of operations with the reference time of the point of departure. As soon as 48 hours have elapsed, the state of acclimatisation is derived from the time elapsed since reporting at reference time and the number of time zones crossed."
response	See the answer to comment #54.
comment	510 comment by: FNAM/SNEH
	(b) ISSUE:
	The paragraph (b) of this GM refers simultaneously to the ORO and the CS. The wording used: <i>"using the appropriate table ORO.FTL.205 (b) or the certification specifications applicable to the type of operation"</i> is very confusing especially the terms <i>"or"</i> . It is not explicit whether:
	 All the CS.FTL.3 requirements shall be applicable "in block" The CS requirements should apply depending on what is said in the implementing rule Cherry-picking is allowed
	The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #473, #477, #478, #496, #511)
	PROPOSAL: Rewrite to clarify as follows: "(b) The maximum daily FDP for acclimatised crew members is determined by using respectively tables of ORO.FTL.205(b) or of the relevant certification specifications applicable to the type of operations with the reference time of the point of departure. As soon as 48 hours have elapsed, the state of acclimatisation is derived from the time elapsed since reporting at reference time and the number of time zones crossed."
response	See the answer to comment #54.
comment	689 comment by: Oya Vendée Hélicoptères
	(b) ISSUE: The paragraph (b) of this GM refers simultaneously to the ORO and the CS. The wording used: <i>"using the appropriate table ORO.FTL.205 (b) or the certification specifications</i>
	<i>applicable to the type of operation</i> " is very confusing especially the terms " <i>or</i> ". It is not explicit whether:
	All the CS.FTL.3 requirements shall be applicable "in block"



	 The CS requirements should apply depending on what is said in the implementing rule Cherry-picking is allowed
	The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #653, #657, #658, #676, #690)
	PROPOSAL: Rewrite to clarify as follows: "(b) The maximum daily FDP for acclimatised crew members is determined by using respectively tables of ORO.FTL.205(b) or of the relevant certification specifications applicable to the type of operations with the reference time of the point of departure. As soon as 48 hours have elapsed, the state of acclimatisation is derived from the time elapsed since reporting at reference time and the number of time zones crossed."
response	See the answer to comment #54.
	975 comment by: MBH SAMU
comment	975 comment by: <i>MBH SAMU</i> ISSUE: The paragraph (b) of this GM refers simultaneously to the ORO and the CS. The wording used: <i>"using the appropriate table ORO.FTL.205 (b) or the certification specifications applicable to the type of operation"</i> is very confusing especially the terms <i>"or"</i> . It is not explicit whether:
	 All the CS.FTL.3 requirements shall be applicable "in block" The CS requirements should apply depending on what is said in the implementing rule Cherry-picking is allowed
	The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #926, #932, #933, #958, #977)
	PROPOSAL: Rewrite to clarify as follows:
	"(b) The maximum daily FDP for acclimatised crew members is determined by using respectively tables of ORO.FTL.205(b) or of the relevant certification specifications applicable to the type of operations with the reference time of the point of departure. As soon as 48 hours have elapsed, the state of acclimatisation is derived from the time elapsed since reporting at reference time and the number of time zones crossed."
response	See the answer to comment #54.



comment	1239 comment by: SAF
	ISSUE: The paragraph (b) of this GM refers simultaneously to the ORO and the CS. The wording used: "using the appropriate table ORO.FTL.205 (b) or the certification specifications applicable to the type of operation" is very confusing especially the terms "or". It is not explicit whether:
	 All the CS.FTL.3 requirements shall be applicable "in block" The CS requirements should apply depending on what is said in the implementing rule Cherry-picking is allowed
	The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation.
	(Cf. comments #1199, #1205, #1208, #1226, #1240)
	PROPOSAL: Rewrite to clarify as follows: "(b) The maximum daily FDP for acclimatised crew members is determined by using respectively tables of ORO.FTL.205(b) or of the relevant certification specifications applicable to the type of operations with the reference time of the point of departure. As soon as 48 hours have elapsed, the state of acclimatisation is derived from the time elapsed since reporting at reference time and the number of time zones crossed."
response	See the answer to comment #54.
comment	1286 comment by: Hélicoptères de France
	 ISSUE: This GM refers simultaneously to the ORO and the CS. It is not explicit whether: All the CS.FTL.3 requirements shall be applicable "in block" The CS requirements should apply depending on what is said in the implementing rule Cherry-picking is allowed The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #18.1, #24, #25, #30.1, #39) PROPOSAL: Rewrite to clarify.
response	See the answer to comment #54.

comment

350

comment by: European Helicopter Association (EHA)

** ** * * * *

	 FNAM (France) ISSUE: This GM refers simultaneously to the ORO and the CS. It is not explicit whether: All the CS.FTL.3 requirements shall be applicable "in block" The CS requirements should apply depending on what is said in the implementing rule Cherry-picking is allowed The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #18.1, #24, #25, #30.1, #39) PROPOSAL: Rewrite to clarify.
response	See the answer to comment #54.
comment	511 comment by: FNAM/SNEH
	ISSUE: This GM refers simultaneously to the ORO and the CS. It is not explicit whether:
	 All the CS.FTL.3 requirements shall be applicable "in block" The CS requirements should apply depending on what is said in the implementing rule Cherry-picking is allowed
	The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #473, #477, #478, #496, #510)
	PROPOSAL: Rewrite to clarify.
response	See the answer to comment #54.
comment	690 comment by: Oya Vendée Hélicoptères
	ISSUE: This GM refers simultaneously to the ORO and the CS. It is not explicit whether:
	 All the CS.FTL.3 requirements shall be applicable "in block" The CS requirements should apply depending on what is said in the implementing rule Cherry-picking is allowed
	The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #653, #657, #658, #676, #689)
	PROPOSAL: Rewrite to clarify.

**** ****

response	See the answer to comment #54.
comment	977 comment by: <i>MBH SAMU</i>
	ISSUE: This GM refers simultaneously to the ORO and the CS. It is not explicit whether:
	 All the CS.FTL.3 requirements shall be applicable "in block" The CS requirements should apply depending on what is said in the implementing rule Cherry-picking is allowed
	The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #926, #932, #933, #958, #975)
	PROPOSAL: Rewrite to clarify.
response	See the answer to comment #54.
comment	1240 comment by: SAF
	ISSUE: This GM refers simultaneously to the ORO and the CS. It is not explicit whether:
	 All the CS.FTL.3 requirements shall be applicable "in block" The CS requirements should apply depending on what is said in the implementing rule Cherry-picking is allowed
	The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation.
	(Cf. comments #1199, #1205, #1208, #1226, #1239)
	PROPOSAL: Rewrite to clarify.
response	See the answer to comment #54.
comment	1288 comment by: Hélicoptères de France
	(c) ISSUE



	"The workload and stress levels of single-pilots operations" wording omits that HEMS single-pilots are conducted by TWO technical crew members: one pilot and one TCM. They are not PEQ1 operations. The requirement for a TCM is justified by the fact that the TCM is deemed to be a mitigation measure and to enhance the safety of single-pilot + 1 TCM HEMS operations Therefore, TCM shall be quoted whenever taking into account workload and stress levels of singlepilots operations. PROPOSAL Supplement (c) by " (c) The workload and stress levels of single-pilots operations, including the benefits of the presence of a TCM;"
response	See the answer to comment #54.
comment	11 comment by: TG
	Diese Faktoren sind so unglaublich unterschiedlich von HEMS-Base zu HEMS-Base, dass nur individuelle Lösungen (wie z. B. in Berlin) helfen. Die Hubschrauber sind zudem heute auch ohne Autopilot derart leicht zu fliegen, dass auch hier kein Unterschied zu machen ist. Das Wetter ist der einzige Faktor der unberechenbar ist und zu Spitzenstress führen kann - das aber äusserst selten!
	Auf einzelne "Großkampftage" folgen auch immer wieder Tage ohne Flug oder mit > 7 Stunden nichts-tun Warum Fatigue? Hier muss der Mittelwert berücksichtigt werden und nicht ein Spitzenwert gekappt
response	See the answer to comment #54.

comment	352 comment by: European Helicopter Association (EHA)
	FNAM (France)
	(c)
	ISSUE "The workload and stress levels of single-pilots operations" wording omits that HEMS single-pilots are conducted by TWO technical crew members: one pilot and one TCM. They are not PEQ1 operations.
	The requirement for a TCM is justified by the fact that the TCM is deemed to be a mitigation measure and to enhance the safety of single-pilot + 1 TCM HEMS operations Therefore, TCM shall be quoted whenever taking into account workload and stress levels
	of singlepilots operations. PROPOSAL
	Supplement (c) by
	" (c) The workload and stress levels of single-pilots operations, including the benefits of the presence of a TCM;"



Individual comments and responses — HEMS

response	See the answer to comment #54.
	,
comment	403 comment by: European Helicopter Association (EHA)
	OEATMC (Austria):
	 CS FTL.3.235 Rest periods — HEMS (a) Reduced rest in HEMS operations complies with the following: (1) The minimum rest period may be reduced to 10 hours, only if taken at the HEMS operating base with a suitable accommodation provided by the operator.
	COMMENT(S)
	The pilot living in vicinity of the base has to stay on the base? Even thought he would be at home within a couple of minutes?
response	See the answer to comment #54.
comment	513 comment by: FNAM/SNEH
	(c) ISSUE " <i>The workload and stress levels of single-pilots operations</i> " wording omits that HEMS single- pilots are conducted by TWO technical crew members: one pilot and one TCM. They are not PEQ1 operations. The requirement for a TCM is justified by the fact that the TCM is deemed to be a mitigation measure and to enhance the safety of single-pilot + 1 TCM HEMS operations Therefore, TCM shall be quoted whenever taking into account workload and stress levels of single-pilots operations.
	PROPOSAL Supplement (c) by " (c) The workload and stress levels of single-pilots operations, including the benefits of the presence of a TCM;"
response	See the answer to comment #54.
comment	692 comment by: Oya Vendée Hélicoptères
	(c) ISSUE " <i>The workload and stress levels of single-pilots operations</i> " wording omits that HEMS single- pilots are conducted by TWO technical crew members: one pilot and one TCM. They are not PEQ1 operations. The requirement for a TCM is justified by the fact that the TCM is deemed to be a mitigation measure and to enhance the safety of single-pilot + 1 TCM HEMS operations Therefore, TCM shall be quoted whenever taking into account workload and stress levels of single-pilots operations.

	PROPOSAL Supplement (c) by " (c) The workload and stress levels of single-pilots operations, including the benefits of the presence of a TCM;
response	See the answer to comment #54.
comment	734 comment by: ÖAMTC Helicopter Air Rescue (Austria)
	AMC3 ORO.FLT.120 (b)(4)(d)
	[] the permanent hands-on flying on aircraft not equipped with autopilot []
	Considering an average of 8min sector time possibly in alpine valleys, it creates more risk to focus on AP-Systems engagements versus flying hands on. Besides the distraction on focusing inside the aircraft, the fatigue aspect on 8min flight can be neglected.
response	See the answer to comment #54.
comment	751 comment by: DRF-Luftrettung
	(I) Helicopter flying is hands on flying due to the aero dynamical properties of the aircraft itself. This cannot account for any additional fatigue because it's the usual way of flying for helicopter pilots.
	(II) According to the German Health and Safety regulations wearing a helmet is required for the safety of the crew. Your proposal now suggests, not to wear a helmet to reduce fatigue related risks.
response	See the answer to comment #54.
comment	979 comment by: MBH SAMU
	(c) ISSUE " <i>The workload and stress levels of single-pilots operations</i> " wording omits that HEMS single-pilots are conducted by TWO technical crew members: one pilot and one TCM. They are not PEQ1 operations. The requirement for a TCM is justified by the fact that the TCM is deemed to be a mitigation measure and to enhance the safety of single-pilot + 1 TCM HEMS operations Therefore, TCM shall be quoted whenever taking into account workload and stress levels of single-pilots operations. PROPOSAL

	Supplement (c) by "(c) The workload and stress levels of single-pilots operations, including the benefits of the presence of a TCM;
response	See the answer to comment #54.
comment	1242 comment by: SAF
	 (c) ISSUE "The workload and stress levels of single-pilots operations" wording omits that HEMS single-pilots are conducted by TWO technical crew members: one pilot and one TCM. They are not PEQ1 operations. The requirement for a TCM is justified by the fact that the TCM is deemed to be a mitigation measure and to enhance the safety of single-pilot + 1 TCM HEMS operations Therefore, TCM shall be quoted whenever taking into account workload and stress levels of single-pilots operations.
	Supplement (c) by "(c) The workload and stress levels of single-pilots operations, including the benefits of the presence of a TCM;
response	See the answer to comment #54.
comment	1289 comment by: Hélicoptères de France (b)(7)(a)
	ISSUE The Technical Crew Member has been added although he was already included thanks to the previous wording "and all other involved personnel []". Since AMC1 ORO.FTL.120(b)(7) is a general CAT AMC which is applicable to all activities: CAT.A,CAT.HEMS, etc., operational specification shall not be added. The TCM is specific to HEMS operations and thus, it should not be quoted in the AMC1 ORO.FTL.120(b)(7). This additional wording seems confusing for other activities than HEMS and does not bring any additional safety enhancement. Reversely, HEMS are not concerned by cabin crew.
	PROPOSAL HDF proposes to let unchanged as regards to TCM and add a specification for cabin crew in (a): "(a) training programmes to ensure competency commensurate with the roles and responsibilities of management, flight crew, cabin crew whenever required, and all other involved personnel under the planned FRM; and"

Individual comments and responses - HEMS

response	See the answer to comment #54.
comment	1357 comment by: European Cockpit Association
	Commented text: AMC3 ORO.FTL.120(b)(4) Fatigue risk management (FRM) In addition to AMC1 ORO.FTL.120(b)(4), HEMS operators should also take into account hazards specific to HEMS operations, such as the following:
	ECA Comment: Any HEMS operation exeeding 12 hours of alertness/FDP should be under FRM - this should be an IR.
response	See the answer to comment #54.
comment	353 comment by: European Helicopter Association (EHA)
	FNAM (France)
	 (b)(7)(a) ISSUE The Technical Crew Member has been added although he was already included thanks to the previous wording "and all other involved personnel []". Since AMC1 ORO.FTL.120(b)(7) is a general CAT AMC which is applicable to all activities: CAT.A, CAT.HEMS, etc., operational specification shall not be added. The TCM is specific to HEMS operations and thus, it should not be quoted in the AMC1 ORO.FTL.120(b)(7). This additional wording seems confusing for other activities than HEMS and does not bring any additional safety enhancement. Reversely, HEMS are not concerned by cabin crew. PROPOSAL The FNAM proposes to let unchanged as regards to TCM and add a specification for cabin crew in (a): "(a) training programmes to ensure competency commensurate with the roles and responsibilities of management, flight crew, cabin crew whenever required, technical crew and all other involved personnel under the planned FRM; and"
response	See the answer to comment #54.
comment	514 comment by: FNAM/SNEH
	(b)(7)(a) ISSUE

	The Technical Crew Member has been added although he was already included thanks to the previous wording "and all other involved personnel[]". Since AMC1 ORO.FTL.120(b)(7) is a general CAT AMC which is applicable to all activities: CAT.A, CAT.HEMS, etc., operational specification shall not be added. The TCM is specific to HEMS operations and thus, it should not be quoted in the AMC1 ORO.FTL.120(b)(7). This additional wording seems confusing for other activities than HEMS and does not bring any additional safety enhancement. Reversely, HEMS are not concerned by cabin crew. PROPOSAL FNAM and SNEH propose to let unchanged as regards to TCM and add a specification for cabin crew in (a): "(a) training programmes to ensure competency commensurate with the roles and responsibilities of management, flight crew, cabin crew whenever required, and all other involved personnel under the planned FRM; and"
response	See the answer to comment #54.
comment	 693 comment by: Oya Vendée Hélicoptères (b)(7)(a) ISSUE The Technical Crew Member has been added although he was already included thanks to the previous wording "and all other involved personnel[]". Since AMC1 ORO.FTL.120(b)(7) is a general CAT AMC which is applicable to all activities: CAT.A, CAT.HEMS, etc., operational specification shall not be added. The TCM is specific to HEMS operations and thus, it should not be quoted in the AMC1 ORO.FTL.120(b)(7). This additional wording seems confusing for other activities than HEMS and does not bring any additional safety enhancement. Reversely, HEMS are not concerned by cabin crew. PROPOSAL OYA proposes to let unchanged as regards to TCM and add a specification for cabin crew in (a): "(a) training programmes to ensure competency commensurate with the roles and responsibilities of management, flight crew, cabin crew whenever required, and all other involved personnel under the planned FRM; and"
response	See the answer to comment #54.
comment	980 comment by: MBH SAMU (b)(7)(a) ISSUE



net/internet. Page 189 of 585

	The Technical Crew Member has been added although he was already included thanks to the previous wording "and all other involved personnel[]". Since AMC1 ORO.FTL.120(b)(7) is a general CAT AMC which is applicable to all activities: CAT.A, CAT.HEMS, etc., operational specification shall not be added. The TCM is specific to HEMS operations and thus, it should not be quoted in the AMC1 ORO.FTL.120(b)(7). This additional wording seems confusing for other activities than HEMS and does not bring any additional safety enhancement. Reversely, HEMS are not concerned by cabin crew. PROPOSAL MBH proposes to let unchanged as regards to TCM and add a specification for cabin crew in (a): "(a) training programmes to ensure competency commensurate with the roles and responsibilities of management, flight crew, cabin crew whenever required, and all other involved personnel under the planned FRM; and"
response	See the answer to comment #54.
2010-000	
comment	1243 comment by: SAF
	 (b)(7)(a) ISSUE The Technical Crew Member has been added although he was already included thanks to the previous wording "<i>and all other involved personnel</i>[]". Since AMC1 ORO.FTL.120(b)(7) is a general CAT AMC which is applicable to all activities: CAT.A, CAT.HEMS, etc., operational specification shall not be added. The TCM is specific to HEMS operations and thus, it should not be quoted in the AMC1 ORO.FTL.120(b)(7). This additional wording seems confusing for other activities than HEMS and does not bring any additional safety enhancement.
	Reversely, HEMS are not concerned by cabin crew. PROPOSAL SAF proposes to let unchanged as regards to TCM and add a specification for cabin crew
	in (a): "(a) training programmes to ensure competency commensurate with the roles and responsibilities of management, flight crew, cabin crew whenever required, and all other involved personnel under the planned FRM; and"
response	See the answer to comment #54.
comment	225 comment by: ANSMUH Proposal following my comments to CS ETL 2 200 Home base HEMS
	Proposal following my comments to CS FTL.3.200 Home base — HEMS

(b) By way of derogation from point (a), and in mutual agreement between the operator and the crew, the operator may assign the operator's principal place of business as crew member's HEMS home base. **Proposal:** GM1 ORO.FTL.200 Home base TRAVELLING TIME Crew members should consider making arrangements for temporary accommodation closer to their home base, if the travelling time from their residence to their home base usually exceeds 90 minutes. If the operator assign the operator's principal place of business as crew member's HEMS home base, the operator must make the necessary to find a proper accomodation is arranged in case the travelling time from their residence exceeds 90 minutes. See the answer to comment #54. 30 Good morning, I read the proposal of 'EASA in question, specifically the part concerning the duty time and rest of the crews HEMS HELICOPTERS, Pilots and HEMS CREW MEMBER, personally I see no advantage neither in safety nor in the aspect of the rest, on the contrary, I think that in this way we add a factor of greater stress, because the "REST" in base does not allow to detach completely, as it happens now doing the 7 days, or in the case of technicians 15 days, in addition, this will entail a problem for all those who live far from the bases, which obviously can not return from their families, and this would create many problems that result in greater stress for the person, and therefore, a nontranquility on the spot in work, (HF) in addition, the same companies will be taken to hire staff at the external bases with the consequences of the case. The figure of the MH will not be more polyvalent as now (MH and Technician) so it will still be necessary to present a technician on the base. I believe that right now exists the right relationship in terms of duty time and rest times, and that our reality is better than many others, in terms of safety, also considering our national territory, which can not be said to be an easy orography and therefore already in itself challenging under all the profiles. We can not pretend to equate what happens in fixed wing companies with the reality of helicopters, our work environment is always "HOSTILE", EASA should separate the two realities at least for what concerns the operational aspects. I would suggest to EASA, to leave the shifts as they are now, continuing to maintain the right compromise between work and life. Greeting Guido Luca Galante

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 191 of 585

response

comment

comment 354 comment by: European Helicopter Association (EHA) FNAM (France) ISSUE Due to multiple Flight Times inside a unique FDP, the FNAM underlines that the defir of post flight duty is non-consistent with the usual definition of post-flight: • Which starts at the end (of the last FT) of the FDP • Assuming the FDP ends with the last FT • Though for HEMS operations FT are unpredictable and scheduled FDP may end lon, after the last effective FT Thus, for HEMS operations, it is not clear if the post-flight does belong or not to the F depending on the end of the last FT. This definition does not correspond to the definition of the proposal which defines a post-flight after each flight time returning to HEMS operating base within the same F Therefore, the FNAM has suggested to clarify the use of the terms of "post flight" du since they are confusing for HEMS. As a consequence, the FNAM suggests specifying the post-flight time within this AM0 concerns the time for the duties just after the last FT of a FDP, if it is what is meant b	5
 FNAM (France) ISSUE Due to multiple Flight Times inside a unique FDP, the FNAM underlines that the defir of post flight duty is non-consistent with the usual definition of post-flight: Which starts at the end (of the last FT) of the FDP Assuming the FDP ends with the last FT Though for HEMS operations FT are unpredictable and scheduled FDP may end long after the last effective FT Thus, for HEMS operations, it is not clear if the post-flight does belong or not to the F depending on the end of the last FT. This definition does not correspond to the definition of the proposal which defines a post-flight after each flight time returning to HEMS operating base within the same F Therefore, the FNAM has suggested to clarify the use of the terms of "post flight" du since they are confusing for HEMS. As a consequence, the FNAM suggests specifying the post-flight time within this AMO 	5
ISSUE Due to multiple Flight Times inside a unique FDP, the FNAM underlines that the defir of post flight duty is non-consistent with the usual definition of post-flight: • Which starts at the end (of the last FT) of the FDP • Assuming the FDP ends with the last FT • Though for HEMS operations FT are unpredictable and scheduled FDP may end lon after the last effective FT Thus, for HEMS operations, it is not clear if the post-flight does belong or not to the F depending on the end of the last FT. This definition does not correspond to the definition of the proposal which defines a post-flight after each flight time returning to HEMS operating base within the same F Therefore, the FNAM has suggested to clarify the use of the terms of "post flight" du since they are confusing for HEMS. As a consequence, the FNAM suggests specifying the post-flight time within this AMO	5
 Due to multiple Flight Times inside a unique FDP, the FNAM underlines that the define of post flight duty is non-consistent with the usual definition of post-flight: Which starts at the end (of the last FT) of the FDP Assuming the FDP ends with the last FT Though for HEMS operations FT are unpredictable and scheduled FDP may end long after the last effective FT Thus, for HEMS operations, it is not clear if the post-flight does belong or not to the F depending on the end of the last FT. This definition does not correspond to the definition of the proposal which defines a post-flight after each flight time returning to HEMS operating base within the same F Therefore, the FNAM has suggested to clarify the use of the terms of "post flight" du since they are confusing for HEMS. As a consequence, the FNAM suggests specifying the post-flight time within this AMO 	5
after the last effective FT Thus, for HEMS operations, it is not clear if the post-flight does belong or not to the F depending on the end of the last FT. This definition does not correspond to the definition of the proposal which defines a post-flight after each flight time returning to HEMS operating base within the same F Therefore, the FNAM has suggested to clarify the use of the terms of "post flight" du since they are confusing for HEMS. As a consequence, the FNAM suggests specifying the post-flight time within this AMO	
This definition does not correspond to the definition of the proposal which defines a post-flight after each flight time returning to HEMS operating base within the same F Therefore, the FNAM has suggested to clarify the use of the terms of "post flight" du since they are confusing for HEMS. As a consequence, the FNAM suggests specifying the post-flight time within this AMC	
regulation for HEMS operations	ies
(Cf. comments #28.5 & #31.1) PROPOSAL "POST-FLIGHT DUTIES The operator should specify post-flight duty times immediately succeding the last flig journey (FT) within a given FDP taking into account the aircraft type, the type of oper and the condition of the airport, landing site or HEMS operating base, as applicable."	
response See the answer to comment #54.	
comment 433 comment by: UFH French Helicopters Association	
 ISSUE Due to multiple flight times inside a unique FDP, UFH underlines that the definition of post flight duty is non-consistent with the usual definition of post-flight: Which starts at the end (of the last FT) of the FDP Assuming the FDP ends with the last FT Though for HEMS operations FT are unpredictable and scheduled FDP may end long after the last effective FT Thus, for HEMS operations, it is not clear if the post-flight does belong or not to the F depending on the end of the last FT. (Cf. attachments S2, S3 and S4 illustrating the post flight issue) This definition does not correspond to the definition of the proposal which defines a 	g

response

comment

Therefore, FNAM has suggested to clarify the use of the terms of "post flight" duties since they are confusing for HEMS. As a consequence, UFH suggests specifying the post-flight time within this AMC concerns the time for the duties just after the last FT of a FDP, if it is what is meant by the regulation for HEMS operations (Cf. comments #28.5 & #31.1) PROPOSAL **"POST-FLIGHT DUTIES** The operator should specify post-flight duty times immediately succeding the last flight journey (FT) within a given FDP taking into account the aircraft type, the type of operation and the condition of the airport, landing site or HEMS operating base, as applicable." See the answer to comment #54. 515 comment by: FNAM/SNEH Attachments #241 #242 #243 ISSUE Due to multiple flight times inside a unique FDP, FNAM and SNEH underline that the definition of post flight duty is non-consistent with the usual definition of post-flight: Which starts at the end (of the last FT) of the FDP Assuming the FDP ends with the last FT Though for HEMS operations FT are unpredictable and scheduled FDP may end • long after the last effective FT Thus, for HEMS operations, it is not clear if the post-flight does belong or not to the FDP depending on the end of the last FT. (Cf. attachments S2, S3 and S4 illustrating the post flight issue) This definition does not correspond to the definition of the proposal which defines a post-flight after each flight time returning to HEMS operating base within the same FDP. Therefore, FNAM and SNEH have suggested to clarify the use of the terms of "post flight" duties since they are confusing for HEMS. As a consequence, FNAM and SNEH suggest specifying the post-flight time within this AMC concerns the time for the duties just after the last FT of a FDP, if it is what is meant by the regulation for HEMS operations (Cf. comments #486 & #502) PROPOSAL **"POST-FLIGHT DUTIES** The operator should specify post-flight duty times immediately succeding the last flight journey (FT) within a given FDP taking into account the aircraft type, the type of operation and the condition of the airport, landing site or HEMS operating base, as applicable."



response	See the answer to comment #54.
comment	694 comment by: Oya Vendée Hélicoptères
	Attachments <u>#244</u> <u>#245</u> <u>#246</u>
	ISSUE
	Due to multiple flight times inside a unique FDP, OYA underlines that the definition of post flight duty is non-consistent with the usual definition of post-flight:
	 Which starts at the end (of the last FT) of the FDP Assuming the FDP ends with the last FT
	 Though for HEMS operations FT are unpredictable and scheduled FDP may end long after the last effective FT
	Thus, for HEMS operations, it is not clear if the post-flight does belong or not to the FDP depending on the end of the last FT.
	(Cf. attachments S2, S3 and S4 illustrating the post flight issue)
	This definition does not correspond to the definition of the proposal which defines a post-flight after each flight time returning to HEMS operating base within the same FDP. Therefore, OYA has suggested to clarify the use of the terms of "post flight" duties since they are confusing for HEMS.
	As a consequence, OYA suggests specifying the post-flight time within this AMC concerns the time for the duties just after the last FT of a FDP, if it is what is meant by the regulation for HEMS operations (Cf. comments #666 & #682)
	PROPOSAL "POST-FLIGHT DUTIES
	The operator should specify post-flight duty times immediately succeding the last flight journey (FT) within a given FDP taking into account the aircraft type, the type of operation and the condition of the airport, landing site or HEMS operating base, as applicable."
response	See the answer to comment #54.
comment	982 comment by: MBH SAMU
	Attachments <u>#247</u> <u>#248</u> <u>#249</u>
	ISSUE Due to multiple flight times inside a unique FDP, MBH underlines that the definition of post flight duty is non-consistent with the usual definition of post-flight:

	 Which starts at the end (of the last FT) of the FDP Assuming the FDP ends with the last FT Though for HEMS operations FT are unpredictable and scheduled FDP may end long after the last effective FT
	Thus, for HEMS operations, it is not clear if the post-flight does belong or not to the FDP depending on the end of the last FT. (Cf. attachments S2, S3 and S4 illustrating the post flight issue)
	This definition does not correspond to the definition of the proposal which defines a post-flight after each flight time returning to HEMS operating base within the same FDP. Therefore, MBH has suggested to clarify the use of the terms of "post flight" duties since they are confusing for HEMS.
	As a consequence, MBH suggests specifying the post-flight time within this AMC concerns the time for the duties just after the last FT of a FDP, if it is what is meant by the regulation for HEMS operations (Cf. comments #944 & #966)
	PROPOSAL "POST-FLIGHT DUTIES The operator should specify post-flight duty times immediately succeding the last flight journey (FT) within a given FDP taking into account the aircraft type, the type of operation and the condition of the airport, landing site or HEMS operating base, as applicable."
response	See the answer to comment #54.
comment	1244 comment by: SAF
	Attachments <u>#250</u> <u>#251</u> <u>#252</u>
	ISSUE Due to multiple flight times inside a unique FDP, SAF underlines that the definition of post flight duty is non-consistent with the usual definition of post-flight:
	• Which starts at the end (of the last FT) of the FDP
	 Assuming the FDP ends with the last FT Though for HEMS operations FT are unpredictable and scheduled FDP may end long after the last effective FT
	Thus, for HEMS operations, it is not clear if the post-flight does belong or not to the FDP depending on the end of the last FT.
	(Cf. attachments S2, S3 and S4 illustrating the post flight issue)
	This definition does not correspond to the definition of the proposal which defines a post-flight after each flight time returning to HEMS operating base within the same FDP.



Therefore, SAF has suggested to clarify the use of the terms of "post flight" duties since they are confusing for HEMS.

As a consequence, SAF suggests specifying the post-flight time within this AMC concerns the time for the duties just after the last FT of a FDP, if it is what is meant by the regulation for HEMS operations

(Cf. comments #1216 & #1232)

PROPOSAL

"POST-FLIGHT DUTIES

The operator should specify post-flight duty times immediately succeding the last flight journey (FT) within a given FDP taking into account the aircraft type, the type of operation and the condition of the airport, landing site or HEMS operating base, as applicable."

response

See the answer to comment #54.

comment	1291 comment by: <i>Hélicoptères de France</i>
	ISSUE Due to multiple flight times inside a unique FDP, HDF underlines that the definition of post flight duty is non-consistent with the usual definition of post-flight: • Which starts at the end (of the last FT) of the FDP • Assuming the FDP ends with the last FT • Though for HEMS operations FT are unpredictable and scheduled FDP may end long after the last effective FT Thus, for HEMS operations, it is not clear if the post-flight does belong or not to the FDP depending on the end of the last FT. (Cf. attachments S2, S3 and S4 illustrating the post flight issue) This definition does not correspond to the definition of the proposal which defines a post-flight after each flight time returning to HEMS operating base within the same FDP. Therefore, FNAM and SNEH have suggested to clarify the use of the terms of "post flight" duties since they are confusing for HEMS. As a consequence, HDF suggests specifying the post-flight time within this AMC concerns the time for the duties just after the last FT of a FDP, if it is what is meant by the regulation for HEMS operations (Cf. comments #28.5 & #31.1) PROPOSAL "POST-FLIGHT DUTIES The operator should specify post-flight duty times immediately succeding the last flight journey (FT) within a given FDP taking into account the aircraft type, the type of operation and the condition of the airport, landing site or HEMS operating base, as applicable."
response	See the answer to comment #54.
comment	318 comment by: European Helicopter Association (EHA)

*** * *

NORSK LUFTAMBULANSE AS (Norway): "44. AMC2 ORO.FTL.110(a) 'PUBLICATION OF ROSTERED REST PERIODS IN AIR TAXI, AEMS AND HEMS OPERATIONS' — a new AMC that requires pre-planning and publishing of extended recovery rest periods 7 days in advance. The 7-day advance is based on the consensus of the rulemaking group. The purpose of pre-planning is to allow crew members to manage their sleep periods and allow for an appropriate work-life balance, referring to being able to plan visits to administration, doctors, dentists etc." **Comment:** We publish rosters minimum three months in advance (normally in January for the whole year). CAT rosters must be published over 14 days in advance. While it has no effect on us, what is the rationale behind having only 7 days for HEMS? As commuting is so common in HEMS, at least regulation for CAT rostering should be adhered to. See the answer to comment #54. response 372 comment comment by: European Helicopter Association (EHA) BHA (UK) "44. AMC2 ORO.FTL.110(a) 'PUBLICATION OF ROSTERED REST PERIODS IN AIR TAXI, AEMS AND HEMS OPERATIONS' — a new AMC that requires pre-planning and publishing of extended recovery rest periods 7 days in advance. The 7-day advance is based on the consensus of the rulemaking group. The purpose of pre-planning is to allow crew members to manage their sleep periods and allow for an appropriate work-life balance, referring in particular to being able to plan visits to administration, doctors, dentists etc. " Comment: Unsure of the purpose of this? CAT rosters need to be published >14 days in advance, why should HEMS operations get alleviation? See the answer to comment #54. response 599 comment comment by: NOLAS "44. AMC2 ORO.FTL.110(a) 'PUBLICATION OF ROSTERED REST PERIODS IN AIR TAXI, AEMS AND HEMS OPERATIONS' — a new AMC that requires pre-planning and publishing of extended recovery rest periods 7 days in advance. The 7-day advance is based on the consensus of the rulemaking group. The purpose of pre-planning is to allow crew members to manage their sleep periods and allow for an appropriate work-life balance, referring to being able to plan visits to administration, doctors, dentists etc." **Comment:** We publish rosters minimum three months in advance (normally in January for the whole year). CAT rosters must be published over 14 days in advance. While it has no effect on us, what is the rationale behind having only 7 days for HEMS? As commuting is so common in HEMS, at least regulation for CAT rostering should be adhered to.

**** * * * *

response	See the answer to comment #54.
comment	848 comment by: Yorkshire Air Ambulance
	CAT rosters need to be published >14 days in advance, why should HEMS operations get alleviation?
response	See the answer to comment #54.
comment	691 comment by: Oya Vendée Hélicoptères
comment	
	AGREEMENT 7-days prior notice for publishing rostered rest period in HEMS better suits the activity than the 14-days prior notice in CAT scheduled and charter operations. OYA agrees and would like to thank EASA for this proposal, also limited to extended recovery rest periods.
response	See the answer to comment #54.
comment	1287 comment by: Hélicoptères de France
	AGREEMENT 7-days prior notice for publishing rostered rest period in HEMS better suits the activity than the 14-days prior notice in CAT scheduled and charter operations. HDF agrees and would like to thank EASA for this proposal, also limited to extended recovery rest periods.
response	See the answer to comment #54.
comment	512 comment by: FNAM/SNEH
	AGREEMENT 7-days prior notice for publishing rostered rest period in HEMS better suits the activity than the 14-days prior notice in CAT scheduled and charter operations. FNAM and SNEH agree and would like to thank EASA for this proposal, also limited to extended recovery rest periods.
response	See the answer to comment #54.

comment

978

comment by: MBH SAMU

	AGREEMENT 7-days prior notice for publishing rostered rest period in HEMS better suits the activity than the 14-days prior notice in CAT scheduled and charter operations. MBH agrees and would like to thank EASA for this proposal, also limited to extended recovery rest periods.
response	See the answer to comment #54.
comment	1241 comment by: SAF
	AGREEMENT
	7-days prior notice for publishing rostered rest period in HEMS better suits the activity than the 14-days prior notice in CAT scheduled and charter operations. SAF agrees and would like to thank EASA for this proposal, also limited to extended recovery rest periods.
response	See the answer to comment #54.
comment	539comment by: ADAC Luftrettung gGmbH
	Helicopter flying is hands on flying due to the aero dynamical properties of the aircraft itself. This cannot account for any additional fatigue because it's the usual way of flying for helicopter pilots. According to DIN EN 13718-2 wearing a helmet is required.
response	See the answer to comment #54.
comment	560 comment by: Rüdiger Neu
	Hands on Flüge sind die normale Arbeitsweise eines Hubschrauberpiloten, somit kann dies keinen Faktor für Ermüdung darstellen.
	Eine Tragepflicht von Helmen wird durch weitere Rechtsvorschriften vorgeschrieben z.B. DIN EN 13718-2.
response	See the answer to comment #54.
comment	729 comment by: ADAC
	Hier bleibt es dem verantwortlichen Kapitän grundsätzlich selbst überlassen, Pausen zu machen. Dies ist Kapitänsentscheidung. Es müssen keine Einsätze geflogen werden, wenn der Kapitän müde oder erschöpft ist. Er kann selbständig Pausen anordnen. Dies ist im Handbuch so manifestiert.

**** ****

response	See the answer to comment #54.
comment	25 comment by: Johannes Brantz
	Comment on Commuting
	The current commuting efforts of German HEMS pilots are very high, as your analysis also shows.
	With FTL you suggest that Flight Crews should move close to the HEMS operating base to avoid fatigue caused by a long commute.
	I do appreciate your effort that accounts for this fact. I would like to bring to your attention that I see a risk that this proposal will not reduce fatigue significantly for 2 reasons:
	1. Flight crews will not get moving expenses reimbursed, so moving on there own expense imposes a economical risk
	This will lead to high threshold for individuals to actually move closer to there Home Base 2. The first reason exists because of the second reason: Many HEMS pilots want to or have to change there assigned HEMS Home Base for personal as well as economical reasons driven by the operator.
	This increases the economical risk created by reason #1 which in fact will not significantly reduce fatigue in my opinion
response	See the answer to comment #54.

comment	260 comment by: European Helicopter Association (EHA)
	ADAC (Germany), DRF (Germany) and LAR (Luxembourg): This paragraph suggests to arrange for accommodation close to base for a crew member who is living more than 90 minutes away from his assigned home base. This is contradicting the fundamental right of free movement.
response	See the answer to comment #54.
comment	355 comment by: European Helicopter Association (EHA)
	FNAM (France)
	Standby Other than Airport Standby Notification #1
	ISSUE
	The FNAM underlines that there are two GM1 ORO.FTL.225. It can be confusing and may
	lead to misunderstanding. The FNAM suggests adding a precision in the title in the manner to differentiate the two GM.



	 PROPOSAL Replace the titles of these GM by the following: GM1 ORO.FTL.225 (Standby other than airport standby notification) => GM1 ORO.FTL.225.A GM1 ORO.FTL.225 (Awake time) => GM1 ORO.FTL.225.B
response	See the answer to comment #54.
comment	516 comment by: FNAM/SNEH
	Standby Other than Airport Standby Notification
	ISSUE FNAM and SNEH underline that there are two GM1 ORO.FTL.225. It can be confusing and may lead to misunderstanding. FNAM and SNEH suggest adding a precision in the title in the manner to differentiate the two GM.
	PROPOSAL Replace the titles of these GM by the following:
	 GM1 ORO.FTL.225 (Standby other than airport standby notification) => GM1 ORO.FTL.225.A GM1 ORO.FTL.225 (Awake time) => GM1 ORO.FTL.225.B
response	See the answer to comment #54.
comment	541 comment by: ADAC Luftrettung gGmbH
	This paragraph refers to an awake time of 18 hours which leaves some space for the rest of this regulation.
response	See the answer to comment #54.
comment	695 comment by: Oya Vendée Hélicoptères
	Standby Other than Airport Standby Notification
	ISSUE OYA underlines that there are two GM1 ORO.FTL.225. It can be confusing and may lead to misunderstanding. OYA suggests adding a precision in the title in the manner to differentiate the two GM.
	PROPOSAL



	Replace the titles of these GM by the following:
	 GM1 ORO.FTL.225 (Standby other than airport standby notification) => GM1 ORO.FTL.225.A GM1 ORO.FTL 225 (Auroka time) => GM1 ORO.FTL 225 P
	 GM1 ORO.FTL.225 (Awake time) => GM1 ORO.FTL.225.B
response	See the answer to comment #54.
comment	983 comment by: MBH SAMU
	Standby Other than Airport Standby Notification
	ISSUE MBH underlines that there are two GM1 ORO.FTL.225. It can be confusing and may lead to misunderstanding. MBH suggests adding a precision in the title in the manner to differentiate the two GM.
	PROPOSAL Replace the titles of these GM by the following:
	 GM1 ORO.FTL.225 (Standby other than airport standby notification) => GM1 ORO.FTL.225.A GM1 ORO.FTL.225 (Awake time) => GM1 ORO.FTL.225.B
response	See the answer to comment #54.
comment	1245 comment by: SAF
	Standby Other than Airport Standby Notification
	ISSUE
	SAF underlines that there are two GM1 ORO.FTL.225. It can be confusing and may lead to misunderstanding. SAF suggests adding a precision in the title in the manner to differentiate the two GM.
	PROPOSAL Replace the titles of these GM by the following:
	 GM1 ORO.FTL.225 (Standby other than airport standby notification) => GM1 ORO.FTL.225.A GM1 ORO.FTL.225 (Awake time) => GM1 ORO.FTL.225.B

See the answer to comment #54. response 1292 comment comment by: Hélicoptères de France Standby Other than Airport Standby Notification #1 ISSUE HDF underlines that there are two GM1 ORO.FTL.225. It can be confusing and may lead to misunderstanding. HDF suggests adding a precision in the title in the manner to differentiate the two GM. PROPOSAL Replace the titles of these GM by the following: GM1 ORO.FTL.225 (Standby other than airport standby notification) => GM1 ORO.FTL.225.A GM1 ORO.FTL.225 (Awake time) => GM1 ORO.FTL.225.B See the answer to comment #54. response comment by: Joachim J. Janezic (Institute for Austrian and International Aviation comment 389 law) To AMC2 ORO.FTL.110(a): It remains unclear what the difference between "rostered extended recovery rest period" and "recurrent extended recovery rest period" (ref. CS FTL 3.235) is supposed to be. If these two terms mean the same, we recommend to use the same term. If they are different use more descriptive wording to make clear what the terms really mean. response See the answer to comment #54. 122 comment comment by: UK CAA Page No: 43 Paragraph No: AMC3 ORO.FTL.120(b)(4) Fatigue risk management (FRM) **Comment:** References to NVIS and the fatigue that is potentially generated through their use are included in GM1 SPA.NVIS.140 Information and Documentation which cites fatigue due to NVIS in several areas (3.2.2.2 and 3.2.1.4). This element should be specifically referenced in this list rather than included in the vague reference in (f) "helmet / survival suit". Justification: Consistency of the application of the applicable requirements and the extent to which using NVIS could generate fatigue of the crew.

	Proposed Text: Add "(g) The specific fatigue generated when wearing of NVIS."
response	See the answer to comment #54.
comment	395 comment by: European Helicopter Association (EHA)
	ADAC (Germany), DRF (Germany) and LAR (Luxembourg):
	AMC3 ORO.FTL.1208b)(4)
	Comment: Helicopter flying is hands on flying due to the aero dynamical properties of the aircraft itself. This cannot account for any additional fatigue because it's the usual way of flying for helicopter pilots. According to DIN EN 13718-2 wearing a helmet is required.
response	See the answer to comment #54.
comment	1405comment by: Swiss Air-Ambulance Rega
	References to NVIS and the fatigue that is potentially generated through their use are included in GM1 SPA.NVIS.140 Information and Documentation which cites fatigue due to NVIS in several areas (3.2.2.2 and 3.2.1.4). This element should be specifically referenced in this list rather than included in the vague reference in (f) "helmet / survival suit".
	Proposed amendment: Add "(g) The specific fatigue generated when wearing of NVIS."
response	See the answer to comment #54.
comment	1358 comment by: European Cockpit Association
	Commented text: GM1 ORO.FTL.200 Home base TRAVELLING TIME Crew members should consider making arrangements for temporary accommodation closer to their home base, if the travelling time from their residence to their home base usually exceeds 90 minutes.
	ECA Comment: National laws of members states often do not allow operators/employers to make living restrictions for their employees. In addition, this is unrealistic, because of CS FTL.3.200 where there is no restriction for the operator about changing the home base How often will the flight crew member have to change his living place? This becomes even less useful if a multiple HEMS base is assigned as home base; this restricts the possible living

p. 34

response	arrangements of the crew to an unacceptable level. If this is required/desired, then it has to be the operator's responsibility, to arrange temporary accommodation. There is a misunderstanding about what home base is. Anyway, HEMS operations are outside this proposal.
comment	1428 comment by: Bartosz Fibingier
	AMC1 ORO.FTL.210(c)(f) and GM1 ORO.FTL.205(a)(1) could be published as one AMC.
response	HEMS is not part of this proposal, therefore these texts have been removed.
comment	261 comment by: European Helicopter Association (EHA)
	ADAC (Germany), DRF (Germany) and LAR (Luxembourg):
	This paragraph refers to an awake time of 18 hours which leaves some space for the rest of this regulation.
response	HEMS is not part of this proposal.

3.2. Draft certification specifications - CS.FTL.3

comment	477 comment by: FNAM/SNEH
	GENERAL ISSUE It is not explicit whether:
	 All the CS.FTL.3 requirements shall be applicable "in block" The CS requirements should apply depending on what is said in the implementing rules Cherry-picking is allowed
	The complexity of this proposal will lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #473, #478, #496, #510, #511)
	GENERAL PROPOSAL

	Clarify the writing when there is a possibility of applying the CS requirements and / or the IR.
response	See the answer to comment #54.
comment	530comment by: ADAC Luftrettung gGmbH
	For using Art. 22 and having a own certificatin specificatin there is the need for a scientific study, this makes the process expensive and for smaler operator impossible.
	If an operator has its own CS, it is almost impossible for an other operator to take over this base. Herewith it is a monopoly for the actuell operator and a fair market and an open compettition are not possible.
	If operator or states make there own CS, there will be again no harmonization like EASA wanted.
response	See the answer to comment #54.
comment	657 comment by: <i>Oya Vendée Hélicoptères</i>
	GENERAL ISSUE It is not explicit whether:
	 All the CS.FTL.3 requirements shall be applicable "in block" The CS requirements should apply depending on what is said in the implementing rules Cherry-picking is allowed
	The complexity of this proposal will lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #653, #658, #676, #689, #690)
	GENERAL PROPOSAL Clarify the writing when there is a possibility of applying the CS requirements and / or the IR.
response	See the answer to comment #54.
comment	932 comment by: MBH SAMU
	GENERAL ISSUE

**** * * *** It is not explicit whether:

- All the CS.FTL.3 requirements shall be applicable "in block"
- The CS requirements should apply depending on what is said in the implementing rules
- Cherry-picking is allowed

The complexity of this proposal will lead to misunderstanding and thus wrong application of the regulation.

(Cf. comments #926, #933, #958, #975, #977)

GENERAL PROPOSAL

Clarify the writing when there is a possibility of applying the CS requirements and / or the IR.

response

See the answer to comment #54.

comment1021comment by: Stephanie SelimGeneral comment :As mentionned in the general comments of the NPA, DGAC requests for HEMS operations
to be removed from this NPA
and choses the option 0 described in the RIA (no policy change)...
However, if this French position is not accepted, we provide hereafter detailed comments
about proposed measures on HEMS in the HEMS part of the NPA.responseSee the answer to comment #54.

comment	1205 comment by: SAF
	GENERAL ISSUE It is not explicit whether:
	 All the CS.FTL.3 requirements shall be applicable "in block" The CS requirements should apply depending on what is said in the implementing rules Cherry-picking is allowed
	The complexity of this proposal will lead to misunderstanding and thus wrong application of the regulation.

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.Page 207 of 585

	(Cf. comments #1199, #1208, #1226, #1239, #1240)	
	GENERAL PROPOSAL Clarify the writing when there is a possibility of applying the CS requirements and / or the IR.	
response	See the answer to comment #54.	

comment	1271 comment by: Hélicoptères de France
	 GENERAL ISSUE It is not explicit whether: All the CS.FTL.3 requirements shall be applicable "in block" The CS requirements should apply depending on what is said in the implementing rule Cherry-picking is allowed The complexity of this proposal will lead to misunderstanding and thus wrong application of the regulation.
	(Cf. comments #18.1, #25, #30.1, #39, #40) GENERAL PROPOSAL Clarify the writing when there is a possibility of applying the CS requirements and / or the IR.
response	See the answer to comment #54.

CS FTL.3.100

p. 34

comment	338	comment by: European Helicopter Association (EHA)
	FNAM (France)	
	they should apply depending on what is said in the For instance, the ORO.FTL.210 (b)(2 • The IR: ORO.FTL.210 (a) • Or the HEMS CS.FTL (figures in tak	precising explicitly what and when the requirements of
	PROPOSAL	



 TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

 Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

 Page

	Rewrite: "A CAT operator shall apply the requirements of the following certification for each and every
	emergency medical service operations by helicopters (HEMS)" (if it is what is meant)
response	See the answer to comment #54.
comment	478 comment by: FNAM/SNEH
	ISSUE It is not explicit whether all the CS.FTL.3 requirements shall be applicable "in block" or i they should apply depending on what is said in the implementing rule or if it is possible to "cherry-pick".
	For instance, the ORO.FTL.210 (b)(2) lets the choice between applying DP max times from
	 The IR: ORO.FTL.210 (a) Or the HEMS CS.FTL (figures in table CS.FTL.3.210)
	FNAM and SNEH suggest rewriting and precising explicitly what and when th requirements of CS.FTL HEMS apply. (Cf. comments #473, #477, #496, #510, #511)
	PROPOSAL Rewrite: "A CAT operator shall apply the requirements of the following certification for eac and every emergency medical service operations by helicopters (HEMS)" (if it is what i meant).
response	See the answer to comment #54.
comment	658 comment by: Oya Vendée Hélicoptère.
	ISSUE It is not explicit whether all the CS.FTL.3 requirements shall be applicable "in block" or they should apply depending on what is said in the implementing rule or if it is possible t "cherry-pick".
	For instance, the ORO.FTL.210 (b)(2) lets the choice between applying DP max times from
	 The IR: ORO.FTL.210 (a) Or the HEMS CS.FTL (figures in table CS.FTL.3.210)
	OYA suggests rewriting and precising explicitly what and when the requirements of CS.FT HEMS apply.



	PROPOSAL Rewrite: "A CAT operator shall apply the requirements of the following certification for each and every emergency medical service operations by helicopters (HEMS)" (if it is what is meant).
response	See the answer to comment #54.
comment	933 comment by: MBH SAMU
	ISSUE
	It is not explicit whether all the CS.FTL.3 requirements shall be applicable "in block" or if they should apply depending on what is said in the implementing rule or if it is possible to "cherry-pick".
	For instance, the ORO.FTL.210 (b)(2) lets the choice between applying DP max times from:
	The IR: ORO.FTL.210 (a)
	Or the HEMS CS.FTL (figures in table CS.FTL.3.210)
	MBH suggests rewriting and precising explicitly what and when the requirements of CS.FTL
	HEMS apply. (Cf. comments #926, #932, #958, #975, #977)
	PROPOSAL
	Rewrite: "A CAT operator shall apply the requirements of the following certification for each and every emergency medical service operations by helicopters (HEMS)" (if it is what is meant).
response	See the answer to comment #54.
comment	1208 comment by: SAF
	ISSUE
	It is not explicit whether all the CS.FTL.3 requirements shall be applicable "in block" or if they should apply depending on what is said in the implementing rule or if it is possible to "cherry-pick".
	For instance, the ORO.FTL.210 (b)(2) lets the choice between applying DP max times from:
	 The IR: ORO.FTL.210 (a) Or the HEMS CS.FTL (figures in table CS.FTL.3.210)



SAF suggests rewriting and precising explicitly what and when the requirements of CS.FTL HEMS apply.

(Cf. comments #1199, #1205, #1226, #1239, #1240)

PROPOSAL

Rewrite: "A CAT operator shall apply the requirements of the following certification for each and every emergency medical service operations by helicopters (HEMS)" (if it is what is meant).

response

See the answer to comment #54.

comment	1272 comment by: Hélicoptères de France
	ISSUE It is not explicit whether all the CS.FTL.3 requirements shall be applicable "in block" or if they should apply depending on what is said in the implementing rule or if it is possible to "cherry-pick". For instance, the ORO.FTL.210 (b)(2) lets the choice between applying DP max times from: • The IR: ORO.FTL.210 (a) • Or the HEMS CS.FTL (figures in table CS.FTL.3.210) HDF suggests rewriting and precising explicitly what and when the requirements of CS.FTL HEMS apply. (Cf. comments #18.1, #24, #30.1, #39, #40)
	PROPOSAL Rewrite: "A CAT operator shall apply the requirements of the following certification for each and every emergency medical service operations by helicopters (HEMS)" (if it is what is meant).
response	See the answer to comment #54.

GM1 CS FTL.3.100

p. 34

comment	304	comment by: European Helicopter Association (EHA)
	OEAMTC (Austria)	
	GM1 CS FTL 3.100 Applicability	
	include positioning the helicopter at	the full duration of a HEMS flight, a HEMS flight may fter the patient is unloaded from the helicopter to rating base for the next HEMS flight.
	COMMENT(S)	

Why may only positioning to a HEMS operating base after a patient is unloaded from the helicopter be included in the HEMS flight? What is the difference with AEMS (reference ORO.FTL.105 Definitions (29) where a positioning to the operating base before and after an EMS flight are considered part of that flight? What happens if no patient is taken onboard at all (patient deceased or transported by

ground emergency medical services) and why should this make a difference?

response

See the answer to comment #54.

comment	339	comment by: European Helicopter Association (EHA)		
	FNAM (France)			
	-	the fact post-positioning flights should also be considered as HEMS		
	continuity of the em medical staff / mater	sitioning flights should also be considered as HEMS flights, to ensure ergency service operations: for instance, helicopter going and taking ial from a third-place before flying to emergency site.		
	ORO.FTL.105 (§29), k Furthermore, the HE every kind of HEMS	vertheless considered as part of the HEMS flight according to the IR but this is not stated in this GM and it may lead to misunderstanding. MS payload shall not be limited to "patient" but extended to each and 6 necessary material (medical personnel, medical supplies such as the helicopter, blood, organs or drugs, ill or injured persons and other lved)		
	This wording is not c (Cf. comments #14.3	onsistent with the EMS payload defined in ORO.FTL.105 (§29).		
	In order to ensure c	onsistency within this NPA, the FNAM suggests using the wording of MS flight payload ORO.FTL.105 (§29) in the GM1 CS FTL.3.100.		
	PROPOSAL			
		of the GM1 CS FTL.3.100 by the following: y continuity for the full duration of a HEMS flight, a HEMS flight may a		
	and post-positioning	the helicopter before and/or after the HEMS payload (medical upplies such as equipment including the helicopter, blood, organs or		
	to operate the emer	other persons directly involved) is carried by the helicopter to enable it gency medical service from the time it is launched till the helicopter operating base for the next HEMS flight."		
response	See the answer to comment #54.			
	<u> </u>			
comment	420	comment by: UFH French Helicopters Association		

omment by: UFH French Helicopters Association

Same as comment # 339



An agency of the European Union

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

Individual comments and responses - HEMS

response	See the answer to comment #54.
comment	479 comment by: FNAM/SNEH
comment	Same as comment # 339
response	See the answer to comment #54.
comment	659 comment by: Oya Vendée Hélicoptères
	Same as comment # 339
response	See the answer to comment #54.
comment	781 comment by: AECA helicopteros.
	Change GM1 CS FTL 3.100 into CS2 FTL.3.100
	Justification Due to the importance of its content and for a better guarantee of the HEMS condition of the return flight.
response	See the answer to comment #54.
comment	934 comment by: MBH SAMU
	Same as comment # 339
response	See the answer to comment #54.
comment	1088 comment by: Stephanie Selim
	Technical comment- This GM does not bring any additional guidance, since everything is already in 'EMS flight' definition (cf. last sentence). Moreover, it brings confusion with the commander's discretion impossibility to extend FDP after the last take-off if the patient is not on board (see also CS FTL.2.205 corresponding comment). It is proposed to delete it.
response	See the answer to comment #54.

**** TE. * * Prc

Individual comments and responses - HEMS

comment	1209 comment by: SAF
	Same as comment # 339
response	See the answer to comment #54.
comment	1273 comment by: <i>Hélicoptères de France</i>
	Same as comment # 339
response	Please see the answer to comment # 54
comment	1404 comment by: Swiss Air-Ambulance Rega
	To ensure regulatory continuity for the full duration of a HEMS flight, a HEMS flight may include positioning the helicopter after the patient is unloaded from the helicopter to enable it to return to the HEMS operating base for the next HEMS flight.
response	Please see the answer to comment # 54

CS FTL.3.200	p. 34

comment	4 comment by: <i>TG</i>
	Die tatsächliche Belastung des Piloten auf dem Weg zur Arbeit ist nicht durch eine fixierte Ruhezeit abgedeckt. 72h/3N ist viel zu lang.
response	Please see the answer to comment # 54
comment	97 comment by: <i>B. Wagner</i>
	genauere Erläuterung erforderlich:
	Auf was bezieht sich der Term: "in case of change of home base"?
	Trifft dies auf ieden Wechsel zwischen den unter (a) (2) zugewiesenen Stationen zu? Oder

gilt das im Falle einer dauerhaften Versetzung nur einmalig? Oder betrifft es Piloten, die außerhalb ihrer nach (a) (1) zugewiesenen Station fallweise eingesetzt werden sollen?

**** ****

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

Diese Einschränkung nimmt den Dienstplanern jegliche Flexibilität und ist nur durch unwirtschaftlich hohen Personalaufwand realisierbar. (Immer Personal im Standby halten, das mindestens die 72h Ruhezeit hatte) Ein Wechsel der Station innerhalb eines Standby Zeitraums würde erst nach 72h Ruhezeit

Ein Wechsel der Station innerhalb eines Standby Zeitraums würde erst nach 72h Ruhezeit möglich sein.

response

e Please see the answer to comment # 54

comment	118 comment by: UK CAA
	Page No: 34
	Paragraph No: CS FTL.3.200(a)(2) Home Base HEMS
	Comment: Further clarity on this requirement is needed as it could be misinterpreted as it is written. By referring to travelling time between any of the multiple HEMS operating bases, it could be interpreted that the 60 minutes was between any pairings of the HEMS operating bases rather than 60 minutes between all of them. The purpose is that the crew member can drive from any of the nominated HEMS operating bases to all of the other nominated multiple bases within 60 minutes.
	Justification: Clarity and to prevent excess build-up of fatigue prior to reporting at base.
	Proposed Text: Amend to read: "(2) multiple HEMS operating bases where the travelling time between all of the nominated bases does not exceed 60 minutes under normal operating conditions".
response	Please see the answer to comment # 54

comment	181 comment by: ANSMUH
	CS FTL.3.200 Home. Base - HEMS (a) (2) Multiple HEMS operating bases.
	The asset that the NPA suggests is to have all (most) pilots have their residences in the operating base place. It's impossible in France, because most of the pilots are separated by more than 60 minutes from her/his operating base.
	This will have an economic and social impact on pilots who will be forced to take acommodation within 60 minutes of the operating bases. They will face a high increase of expenses, creating a problem in actual crew's contracts and remuneration.
	Proposal: CS FTL.3.200 Home base — HEMS
	 (a) The home base is assigned to each crew member with a high degree of permanence and may either be: (1) a single HEMS operating base; or



(2) multiple HEMS operating bases if the travelling time between any of these HEMS operating bases does not exceed 60 minutes under usual conditions.

(b) By way of derogation from point (a), the operator may assign a different crew member's HEMS home base provided that, during duty periods, a proper accomodation is arranged in case the travelling time from their residence exceeds 90 minutes.

(c) (b) In the case of a change of home base, the recurrent extended recovery rest period prior to starting duty at the new home base is increased once to 72 hours, including 3 local nights. Travelling time between the former home base and the new home base is positioning or flight duty period.

response

Please see the answer to comment # 54

comment 223 comment by: ADAC Luftrettung gGmbH Was ist unter einer "change of home base" zu verstehen? Eine dauerhafte Versetzung an einen anderen Standort? Oder auch ein kurzfristiger temporärer Wechsel (Krankheitsvertretung) sowie wechselnde Stationen bei Springerpiloten? # 54 respo

comment	252 comment by: European Helicopter Association (EHA)		
	ADAC (Germany), DRF (Germany) and LAR (Luxembourg):		
	(a) A crew member, either pilot or TC HEMS shall be assigned to one home base. In caseof more than one home base, traveling time between bases under normal circumstances shall be less than 1 hour.		
	Question: Is it required to assign every crew member to a home base or to assign every base to a crew member?		
	(b) In case of change of home base the recurrent extended recovery rest period is		
	increased once to 72 hours including 3 local nights and travelling time counts as positioning or FDP.		
	Question: What is the meaning of "change of home base" in this context? Long-		
	termrelocation to another base or short-term temporary changes (e.g. caused by illness)or changing bases of reserve pilots.		
response	Please see the answer to comment # 54		
comment	296 comment by: European Helicopter Association (EHA)		

BABCOCK ITALY

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 216 of 585 CS FTL 3.200 Home Base - HEMS GM1 ORO.FTL.200 Home base Travelling Time

Why we want to change

The actual definition of Home base will reduce flexibility on rostering pilots and it will lead to a lack of crew on the not very populated areas resulting in an increasing of the HEMS cost.

o What we propose

CS FTL.3.200 Home base — HEMS

(a) The home base is assigned to each crew member *on the publication of rosters for a block of consecutive FDP* with a high degree of permanence and may either be:

(1) a single HEMS operating base; or

(2) multiple HEMS operating bases if the travelling time between any of these HEMS operating bases does not exceed 60 minutes under usual conditions.

(b) In the case of a change of home base, the recurrent extended recovery rest period prior to starting duty at the new home base is increased once to 72 hours, including 3 local nights. Travelling time between the former home base and the new home base is positioning or flight duty period.

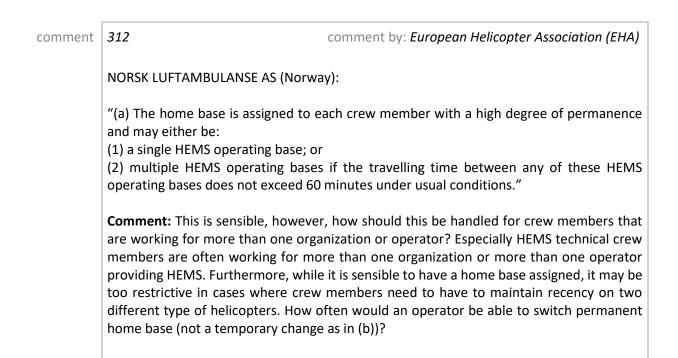
GM1 ORO.FTL.200 Home base

TRAVELLING TIME

Crew members should consider making arrangements *in accord with the company*, for temporary accommodation closer to their home base, if the travelling time from their residence to their home base usually exceeds 90 minutes.

response

Please see the answer to comment # 54





Page 218 of 585

Would it be feasible to have home base decided upon publication of roster provided that the roster is published long time enough in advance?

Furthermore, there is a need for clarification. The text as written could be interpreted as 60 minutes is between 60 minutes between all the HEMS operating bases in question or as 60 minutes between any two HEMS of them.

We also wonder where the 60 minutes come from. In "48. GM1 ORO.FTL.200 'TRAVELLING TIME'" 90 minutes is used. Wouldn't 90 minutes be as appropriate as 60 minutes?

response

Please see the answer to comment # 54

340 comment comment by: European Helicopter Association (EHA) FNAM (France) ISSUE The FNAM would like to thank the EASA for introducing the possibility of multiple HEMS operatingbases corresponding to a home base. Indeed, in HEMS activity, multiple HEMS operating bases are frequently used. The notion of home base for HEMS operators is very different from the one defined in CAT operations with aeroplanes. First, the proposal of a 60 minutes threshold to separate those 'multiple HEMS operating bases' is notconsistent with the 90 minutes threshold deemed to be safe and accepted between the residence of the crew and their home base. Then, in France, an HEMS operating base can either be a hospital (the pilot has a room / suitableaccommodation in the hospital) or for instance a drop zone at a summit of the slopes with an adjoiningdedicated room (suitable accommodation) for the pilot. The French multiple HEMS operating bases may be mostly used in the mountains. They can begeographically close. However, the time spent to reach another HEMS operating base by road can berather long. For instance, 60 minutes is far too short to reach another close hospital located in anothervalley or to reach the drop zone at the summit of the slopes. It is obvious that using a helicopter to reach this other HEMS operating base will decline considerablythis time spent. Thus, any home base change would imply a recurrent extended recovery rest increased to 72h PRIORto starting duty at the new base: • Even if moving from a HEMS operating base in a hospital to geographically nearby drop zoneat a summit • Even if there is no significant added travel time from the residence to the other HEMSoperating baseAs a consequence, 1/ If the possibility of multiple HEMS operating bases as a home base is to allow a given crew to workon different nearby HEMS operating bases / hospitals for France, the threshold of 60 minutes is notsufficient and should be extended to 90 min, which is by the way considered as acceptable for traveltime between residence and home base. 2/ If the possibility of changing home base is to allow to replace an ill crew from another base, thechange of home base should allow to warranty the continuity of the HEMS operations. In France, themost usual rostering is usually 7 days ON at home base / 7 days OFF. It would be simply impossible to replace a pilot by changing the home base by another for currentFrench 5 days ON / 2 days OFF.

The extended recovery rest period taken prior to starting duty may not allow the replacement of an illcrew from a base by another crew from another base as it will imply a 4-days delay.

The FNAM suggests that the extension of the extended recovery rest period occurs on the extended recovery rest period following the change and not prior starting duty at the new home base. Otherwise, this provision will be inoperative in real life, since most of the operators will change of crew (replacingan ill crew) in 'back-to-back' without changing the home base.

Moreover, for fatigue mitigation, it is already required that the haul between the former and the newhome base is considered as positioning or FDP.

PROPOSAL

Replace the content of this paragraph by the following:

"(a) The home base is assigned to each crew member with a high degree of permanence and may

(1) a single HEMS operating base; or

(2) multiple HEMS operating bases if the travelling time between any of these HEMS operatingbases does not exceed 90 minutes under usual conditions.

(b) In the case of a change of home base, the recurrent extended recovery rest period following thestarting duty at the new home base is increased once to 72 hours, including 3 local nights.

Travelling time between the former home base and the new home base is positioning or flightduty period."

response Please see the answer to comment # 54

comment	366	comment by: European Helicopter Association (EHA)
	ВНА (UK)	
	"CS FTL.3.200 Home base — HEMS	(a) (1)"
		ents about TCMs. If they are employed by a third-party nsideration been given to the impact this arrangement n?
response	Please see the answer to comment	¥ 54

comment	396	comment by: European Helicopter Association (EHA)
	OEAMTC (Austria).	
	CS FTL.3.200 Home base — HEMS []	



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 219 of 585 (2) multiple HEMS operating bases if the travelling time between any of these HEMS operating bases

does not exceed 60 minutes under usual conditions.

COMMENT(S)

Why would travelling time between multiple HEMS operating bases be restricted to 60 minutesinstead of 90 minutes (reference GM1 CS FTL.1.200 Home base)? This seems rather arbitrary. Due toAustria's geography most operating bases are separated more than 60 minutes travelling time (bycar), in fact most operating bases in Europe are separated more than 60 minutes travelling time (bycar). Crew usually travel the day before the first of (in our case 7) consecutive FDP and stay on or

very near the HEMS operating base throughout these consecutive FDPs. Counting the travel time aspositioning because the definition of multiple bases is unusable this reduces the number of consecutive duties.

CS FTL.3.200 Home base — HEMS

[...]

(b) In the case of a change of home base, the recurrent extended recovery rest period prior tostarting duty at the new home base is increased once to 72 hours, including 3 local nights. Travellingtime between the former home base and the new home base is positioning or flight duty period.

COMMENT(S)

Unworkable if the travelling times in CS FTL.3.200 Home base — HEMS (a)(2) remain 60 minutes.

response

Please see the answer to comment # 54

comment	397	comment by: European Helicopter Association (EHA)
	OEAMTC (Austria).	
	Page 34 and 26	
	COMMENT(S) CS FTL 3.205 Numbering is used for	two chapters
response	Please see the answer to comment	# 54
	1	

comment405comment by: ANWB MAAWhy state a new limit of 60 minutes as there is already a travel limit of 90 minutes
(ORO.FTL.200). Suggest to keep it 90 minutes for both



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.Page 220 of 585

Individual comments and responses - HEMS

response	Please see the answer to comment # 54
comment	421 comment by: UFH French Helicopters Association
	Same as comment # 340
response	Please see the answer to comment # 54
comment	480 comment by: FNAM/SNEH
	Same as comment # 3340.
response	Please see the answer to comment # 54
comment	529 comment by: ADAC Luftrettung gGmbH
	 (a) A crew member, either pilot or TC HEMS shall be assigned to one home base. In case of more than one home base, traveling time between bases under normal circumstances shall be less than 1 hour. Question: Is it required to assign every crew member to a home base or to assign every base to a crew member?
	 (b) In case of change of home base the recurrent extended recovery rest period is increased once to 72 hours including 3 local nights and travelling time counts as positioning or FDP. Question: What is the meaning of "change of home base" in this context? Long-term
	relocation to another base or short-term temporary changes (e.g. caused by illness) or changing bases of reserve pilots.
response	Please see the answer to comment # 54
comment	552 comment by: <i>Rüdiger Neu</i>
	 (a) Ein Besatzungsmitglied, sowohl Pilot als auch HEMS TC, müssen einer Station zugeordnet sein. Sind es mehrere Stationen, muss die Reisezeit im Normalfall < 1 Stunde betragen. Fragestellung: Müssen jeder Station Besatzungsmitglieder zugeordnet werden oder muss jedem Besatzungsmitglied eine Station zugeordnet werden? Somit wäre der Einsatz der Flexpiloten stark eingeschränkt.

**** TI * * Pi **** (b) Bei einem Wechsel der Heimatstation muss einmalig eine 72 stündige Ruhezeit (min.
 3 Nächte) eingehalten werden und die Reisezeit zählt als Flugdienstzeit (FDP).
 Fragestellung: Ist mit "change of home base" eine dauerhafte Versetzung an einen anderen
 Standort gemeint, oder soll dies auch für kurzfristige, temporäre Wechsel (z.B.
 Krankheitsvertretung) oder wechselnde Stationen der Flexpiloten (Spinger) gelten?

response

Please see the answer to comment # 54

comment	581 comment by: FinnHEMS Oy
	(a)(2)if the travelling time between any of these HEMS operating bases does not exceed 60 minutes under usual conditions.
	COMMENT: Finland is a sparsely populated country with long distances (up to 1000km) between crew homes and HEMS bases. It is necessary to increase the time requirement to be able to use pilots flexibly between two or three bases.
	SUGGESTION: Increase the amount of minutes to 240 minutes.
response	Please see the answer to comment # 54

comment	660	comment by: Oya Vendée Hélicoptères
	Same as comment # 340	
response	Please see the answer to comment # 54	

comment	721	comment by: ÖAMTC Helicopter Air Rescue (Austria)
	CS FTL.3.200 (a) (2)	
	"Multiple home bases" are irrelevan 60min reachable	t as across Europe there are hardly any bases within
response	Please see the answer to comment #	54

comment743comment by: DRF-LuftrettungPage 34 – CS.FTL.3.200 Home Base
(a) A crew member, either pilot or TC HEMS shall be assigned to one home base. In case
of more than one home base, traveling time between bases under normal
circumstances shall be less than 1 hour.

**** * * ***

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 222 of 585 Question: Is it required to assign every crew member to a home base or to assign every base to a crew member?

(b) In case of change of home base the recurrent extended recovery rest period is increased once to 72 hours including 3 local nights and travelling time counts as positioning or FDP.

Question: What is the meaning of "change of home base" in this context? Long-term relocation to another base or short-term temporary changes (e.g. caused by illness) or changing bases of reserve pilots.

response

Please see the answer to comment # 54

comment	782 comment by: AECA helicopteros.	
	Question needing answer by regulation:	
	In case of base change for emergency reasons, the pilot need specific training, regarding the new base?	
response	Please see the answer to comment # 54	

comment	809 comment by: Babcock Mission Critical Services Limited
	It could be understood that if you have a pilot assigned to one HEMS home base and you scheduled this pilot to one or several duties to another base, the operator must let him rest 72 hours with 3 local nights between the positioning and the first duty.
	We think it must only apply if you change the home base of the pilot as a <i>permanent assignment</i> , not as a result of, for example, if a pilot is sick and you need to roster immediately another pilot assigned to other home base.
	Revise "Home base" definition:
	CS FTL.2.200 Home base — air taxi and AEMS
	(a) The home base is any location assigned to the crew member with a high degree of permanence.
	(b) In the case of a change of home base, the recurrent extended recovery rest period prior to starting duty at the new home base is increased once to 72 hours, including 3 local nights. Travelling time between the former home base and the new home base is considered Positioning in accordance with ORO.FTL.215.
	CS.FTL.3.200 Home Base – HEMS



(a) The home base is any location assigned to the crew member with a high degree of permanence.

(b) In the case of a change of home base, the recurrent extended recovery rest period prior to starting duty at the new home base is increased once to 72 hours, including 3 local nights. Travelling time between the former home base and the new home base is considered Positioning in accordance with ORO.FTL.215

GM.CS.FTL.2/3.200 (a) Home Base

In case of a touring pilot, their main place of residence may be considered as their home base. In this case fatigue protection is provided by all travelling to/from a HEMS operating base, as being considered as positioning within the FDP.

response

Please see the answer to comment # 54

comment	836 comment by: Yorkshire Air Ambulance	
	This is good, but see previous comments about TCMs. If they are employed by a third- party but engaged in HEMS activity, has consideration been given to the impact this arrangement may have on Home Base assignation?	
response	Please see the answer to comment # 54	

comment	898 comment by: Stephanie Selim
	<u>CS FTL.3.200 (a)(1)(2) :</u>
	Technical comment – DGAC would like to thank EASA for introducing the possibility of multiple HEMS operating bases corresponding to a home base. Indeed, in HEMS activity, multiple HEMS operating bases are frequently used. The notion of home base for HEMS operators is very different from the one defined in CAT operations with aeroplanes. However, the French multiple HEMS operating bases may be mostly used in the mountains. They can be geographically close. However, the time spent to reach another HEMS operating base by road can be rather long. For instance, 60 minutes is far too short to reach another close hospital located in another valley or to reach the drop zone at the summit of the slopes. Consequently, the threshold of 60 minutes is not sufficient and should be extended to 120 min.
response	Please see the answer to comment # 54

comment 899

comment by: Stephanie Selim

**** * * ***

	<u>CS FTL.3.200 (b) :</u>	
	first recurrent extended recovery re	uggested: "In the case of a change of home base, the st period prior to starting duty at the new home base ing 3 local nights. Travelling time between the former is positioning."
response	Please see the answer to comment #	54
comment	935	comment by: <i>MBH SAMU</i>
	Same as comment # 340	
response	Please see the answer to comment #	54
comment	1112	comment by: European Cockpit Association
	Commented text: CS FTL.3.200 Home base — HEMS (a) The home base is assigned to eac and may either be: ECA comment: "High degree of permanence" needs	ch crew member with a high degree of permanence to be defined.
		ed to avoid paying travelling allowances. more than two times within 365 days"
response	Please see the answer to comment # 54	
comment	1210	comment by: <i>SAF</i>
	Same as comment # 340	
response	Please see the answer to comment #	54
comment	1274	comment by: Hélicoptères de France
	Same as comment # 340	
response	Please see the answer to comment #	54

**** * * *** comment | 1300

comment by: Elilombarda

HOME BASE

With regard to 'home base' in HEMS operations, the following applies: ORO.FTL.105 (14) - 'home base' ORO.FTL.200 Home base GM1 ORO.FTL.2004. CS FTL.3.200 Home base — HEMS CS FTL.3.200 Home base — HEMS

Presently, some European countries are organised with 7/7 rosters and they allow crews to keep their residence and families away from the operating base. The crews travel to the assigned operating base, where a proper accommodation is available, in order to fulfil the roster and then they travel back to their residences for the recurrent extended recovery rest period. Existing contracts between crews and operators, and existing agreements with crews' associations, reflect the resulting logistic and economic facts.

HEMS bases are spread out in several places around the country, each with one helicopter and the minimum required personnel, i.e. few persons.

Operators generally have several bases far away from their principal place of business. HEMS bases are likely to be changed (win/lose contracts by the operator), sometimes in very few years, so the operator and the personnel have to re-organise logistically.

Some operators, especially small and medium operators, need to keep the crews proficient in more than one base in order to keep enough flexibility with logistical and operative necessities, like change of helicopter type, crews necessities (leave, unavailability, training, etc.), crew turnover (dismissed, hired, etc.), and so on. Moreover, the operator can have bases in very different flying environments (sea, mountain, big cities, heavy air traffic area). If the crew is forced to fly in only one base (and environment) for most of time, the operator will not be able to adequately substitute a missing crew in another base. This will eventually reduce flight safety.

Crew flying opportunities can change dramatically from one HEMS base to another. There are operating bases with a high rate of daily flights, while others with very few hours of flight per month. Because of this, HEMS operators may elect to roster the crews in more than one base, in order to give the personnel the same flying and professional opportunities.

While in an airplane carrier company most of crews are assigned on the same operating base (an airport), where they can be substituted in case of necessity, HEMS operating bases have a reduced number of minimum necessary crews per each base. Assigning a unique and defined home base to each crew in an operating base would limit the operator's possibility to properly manage the various day-by-day necessities.

In Italy, the crew's home base is assigned at the operator's principal place of business. The crews maintain their residence at their family place, unlinked from the possible operating base, and they travel from their own residence to the assigned operating base for the shift. At the end of the shift they return to their family residences. The rosters are defined by the Italian Authority of 7 days of shift, followed by 7 days of rest (recurrent extended recovery rest period), and it was allowed up to 14 days on and 14 days off. Travel expenses to/from



operating bases, proper accommodation at the operating base area and daily allowances are on operator's expenses. These reduced expenses are part of the crew's actual salary purchasing power. Basic salaries, defined by trade union agreements, reflect this logistical and operative organisation.

The 'home base', as proposed by the NPA, will definitely create an economical and organisational weak point for the crews, substantially reducing their overall income (increased expenses) and reducing the time spent with their families. This will very probably, induce social and economical tensions with the operators, crews discontent, increased stress levels (family, economical, etc.), potentially affecting the final safety of flight.

It is suggested to allow the operator to assign the home base at his principal place of business.

Suggested NPA amendment

GM1 ORO.FTL.200 Home base TRAVELLING TIME

Crew members should consider making arrangements for temporary accommodation closer to their home base, if the travelling time from their residence to their home base usually exceeds 90 minutes.

CS FTL.3.200 Home base — HEMS

(a) The home base is assigned to each crew member at the operator's main place of business with a high degree of permanence and may either be: (1) a single HEMS operating base; or

(2) multiple HEMS operating bases if the travelling time between any of these HEMS operating bases does not exceed 60 minutes under usual conditions.

(b) In the case of a change of home base, the recurrent extended recovery rest period prior to starting duty at the new home base is increased once to 72 hours, including 3 local nights. Travelling time between the former home base and the new home base is positioning or flight duty period.

IMPACT ANALYSIS

Before suggested changes: SAFETY **OPERATOR – NEUTRAL** CREWS – NEGATIVE – Will increase tension with operators, and will introduce logistical and economical disadvantages for crews, increasing disappointment and stress.

LOGISTIC

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

	OPERATOR – IMPROVED – Traveling and accommodation organisation are not due to the operators anymore. CREWS – NEGATIVE - Traveling and accommodation organisation are due to the crews.
	<u>ECONOMIC</u> OPERATOR – IMPROVED – Traveling, accommodation and daily allowance expenses are not due to the operator any more.
	CREWS – HIGLY NEGATIVE – Traveling and accommodation expenses are due to the crews. Daily allowance are not received by the crews any more.
	After suggested changes: <u>SAFETY</u> OPERATOR – NEUTRAL – No changes to present asset. CREWS – NEUTRAL – No changes to present asset.
	<u>LOGISTIC</u> OPERATOR – NEUTRAL - The operator will continue with the existing organisation. CREWS – NEUTRAL - The crew will continue with the existing organisation.
	ECONOMIC OPERATOR – NEUTRAL. The operator will continue with the existing organisation.
	CREWS – NEUTRAL. The crew will continue with the existing organisation.
response	Please see the answer to comment # 54

comment	1321 comment by: SAS
	The use of 'Floater' or 'Touring' pilots to fill shifts at different HEMS units to cover absences for sickness/training/currency, is essential to the smooth and continued operation of HEMS units. With the addition of this part of the NPA, if a pilot (or HEMS TCM) went absent at short notice it could lead to a HEMS aircraft being offline for 72hours. As required above to permit 'a change of home base'. The only alternative would be to employ an extra pilot for every home base, this would be at great expense to charities and HEMS operators. More importantly, this would cause a reduction in the duty and flight hours of those pilots to a level that could have a detrimental effect on pilot's proficiency.
response	Please see the answer to comment # 54

comment	1336	comment by: ENAC
	Same as comment # 1300	
response	Please see the answer to comment # 54	



comment	1388 comment by: Swiss Air-Ambulance Rega
	Further clarity on this requirement is needed as it could be misinterpreted as it is written. By referring to travelling time between any of the multiple HEMS operating bases, it could be interpreted that the 60 minutes was between any pairings of the HEMS operating bases rather than 60 minutes between all of them. The purpose is that the crew member can drive from any of the nominated HEMS operating bases to all of the other nominated multiple bases within 60 minutes.
	Assignment of pilots A crew member, both pilot and HEMS TC, must be assigned to a base. If there are multiple bases, the travel time must be less than one hour. Question: Must crew members be assigned to each base or must a base be assigned to each crew member? In such a case, the use of stand-in pilots to ensure operational capability in the short term would be heavily limited.
	<u>Change of home base</u> In the event of a change of home base, a 72-hour resting period (min. three nights) must be observed once and the travel time is counted as flight duty period (FDP).
	Question: Does "change of home base" mean a permanent transfer to another location or is this supposed to apply also to short-term, temporary changes (e.g. sickness absence cover) or changing home bases of stand-in pilots
	Proposed amendment: (2) multiple HEMS operating bases where the travelling time between all of the nominated bases does not exceed 60 minutes under normal operating conditions. The travelling time shall be at least equal to the time to commute from home to the previsouly designated operating base.
response	Please see the answer to comment # 54
comment	1436 comment by: COPAC COLEGIO OFICIAL DE PILOTOS DE LA AVIACIÓN COMERCIAL
	CS FTL.3.200 (b), ¿este apartado implica que si un piloto vuela habitualmente en una base, si se le traslada a otra base situada a 200 km, no puede producirse hasta 72 horas después de haber llegado a la nueva base? ¿En qué otros términos es aplicable este punto?
response	Please see the answer to comment # 54

comment1468comment by: Swedish Transport Agency, Civil Aviation Department
(Transportstyrelsen, Luftfartsavdelningen)"(a)(1) a single HEMS operating base;"The HEMS operating base should also be valid for rest facilities close to the base. The
conditions for close at the HEMS operating base could be defined as a maximum traveling
time to the HEMS operating base.responsePlease see the answer to comment # 54

CS FTL.3.205	p. 34-36

comment	1	comment by: <i>Kevin Hogan</i>
		, 5
	autopilot is typically one word:	
	https://en.oxforddictionaries.com/definition/autopilot	
	Also, in section 4.1.4.1, database is usually one word:	
	https://en.oxforddictionaries.com/definition/database	
response	Please see the answer to comment # 54	
response		

comment	64 comment by: London's Air Ambulance
	CS.FTL.3.205 states that for two-pilot HEMS operations, the FDP limitation data in table 1 is applicable, and hence applicable to LAA HEMS operations. Subparagraph (a)(3) states that the operations manual shall specify a minimum of 30 minutes for pre-flight duties and 15 minutes for post flight duties "for every flight returning to the HEMS operating base." For a short sector HEMS operation like London's Air Ambulance where the average sector duration is historically 6 minutes the imposition of the 15 minute post flight duty embargo for every flight returning to the HEMS operating base is a major operational limitation. This needs to be clarified as previously the 15 minutes of post flight duty period was applied after the last flight of the duty day.
response	Please see the answer to comment # 54
comment	88 comment by: AIR ZERMATT AG

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 230 of 585 The conditions should be adapted to the following:

Continuous FT is limited in all cases to 7 hours per day. Exceptionally, the flight time on one day per calendar month may not exceed 8 hours.
For FDPs of over <u>12</u> hours to a max of **14 hours**, the operator ensures at least one break of minimum 120 consecutive minutes (split duty) [...]
To be removed in order to reduce complexity.
Ok.

Table 2:
Should be deleted in order to reduce complexity and the flight time values in table 2 should be adapted as follows (no matter with or without autopilot):

60 flight hours in 14 days;
110 flight hours in 28 days;
280 flight hours in three calendar months;
900 flight hours per calendar year.

response

comment 98

comment by: B. Wagner

zu (a) (1) + (2):

Die Anforderung einer festen, sichergestellten Pause ist nicht rettungsdiensttauglich. Alarmierungen sind nicht planbar, dementsprechend auch nicht die Pausen.

Grundsätzlich wäre es im Sinne der Crews, nicht den ganzen Tag über ihre Zeiten mitkalkulieren zu müssen, die auch noch unterschiedlich für single pilot und two-pilot operations sind. Damit steigt gegen Ende der Schicht bei Alarmierung die Arbeitsbelastung der Crew, weil zusätzliches Augenmerk auf die maximal mögliche FDP und Blockzeit gelegt werden muss. Gegen Ende einer Schicht sollte aber die Aufmerksamkeit der Crew zu 100% im Cockpit sein und nicht durch äussere Faktoren zusätzlich gemindert werden.

Dies führt zu einer erhöhten Arbeitsbelastung bei gleichzeitig geminderter Situational Awareness und damit zu Einschränkungen in der Flugsicherheit.

response

Please see the answer to comment # 54

Please see the answer to comment # 54

comment 100

comment by: B. Wagner

Attachment #85

zu Table 2:

welche wissenschaftlichen Grundlagen führen zu den Unterscheidungen der maximal möglichen Blockzeiten mit und ohne Autopilot?

**** * *** Die in der NPA zitierten Studien beziehen sich zum größten Teil auf AEMS, ATXO. HEMS wurde nicht betrachtet. Es gibt aktuelle Studien zum Thema automatisiertes Fahren, die eher darauf hinweisen, dass eine hochgradige Automatisierung eine schnelle Ermüdung fördert. Siehe Anhang Die Begrenzung der maximal möglichen Flugzeit ohne Autopilot für single pilot operation auf weniger als 05:00 stellt eine deutliche Einschränkung für den HEMS Betrieb in Deutschland dar und lässt sich auch nicht rechtfertigen, wenn parallel dazu in der CAT Fliegerei viel längere Zeiten möglich sind. response

comment	101comment by: B. Wagner
	zu (c): Welche wissenschaftliche Grundlage rechtfertigt die Unterscheidung zwischen Ruhezeit auf der HEMS Station im Vergleich zu Ruhezeit daheim, wenn die Entfernung zwischen Daheim und Station z.B. weniger als 30 Minuten beträgt? Entweder von der Länge der Anreise abhängig definieren oder streichen
response	Please see the answer to comment # 54

comment	102 comment by: B. Wagner
	zu (d):
	Startet die 4 Tage Periode bereits mit der Anreise am Tag zuvor (falls erforderlich, da man ja nach (c) gezwungen ist, auf der Station zu übernachten, wenn man die verlängerten FDP nutzen möchte)?
	Was passiert, wenn mit Split duty oder Kommandantenentscheid der Dienst auf mehr als 14:00h verlängert werden muss? Muss der Pilot dann am nächsten Tag ersetzt werden oder kann er die 4 Tage Periode weiter arbeiten?
	Hier sind weitere Erläuterungen notwendig. Sollte der Pilot ersetzt werden müssen, fällt diese Entscheidung eventuell so spät am Abend, dass kein Ersatz mehr informiert werden kann, ohne dessen Anspruch auf 8 Stunden ungestörte Ruhe gemäß 230 (e) zu stören. Diese beiden Punkte widersprechen sich in besagtem Fall und führen auf jeden Fall zu einer Missachtung der FTL Regelungen.
response	Please see the answer to comment # 54
comment	119 comment by: UK CAA
	Page No: 34/35

**** * * ***

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 232 of 585 Paragraph No: CS FTL.3.205(a)(1) and (b)(2) Flight duty period (FDP) - HEMS

Comment: The requirement for the operator to ensure that there is at least one break is supported. However, it is unclear that this should be planned within the FDP rather than retrospectively achieved. For this break to be meaningful within the times likely for sleep it needs to be planned, recognising that there may need to be flexibility on the day.

Justification: Clarity of the application of the requirement.

Please see the answer to comment # 54

Proposed Text: "... the operator plans and ensures at least one break...."

response

comment	120 comment by: UK CAA
	Page No: 34/35
	Paragraph No: CS FTL.3.205(a)(1) and (b)(2) Flight duty period (FDP) - HEMS
	Comment: There needs to be specific AMC material developed to support training and awareness of the use of breaks within duties at times where the crew member is encouraged to sleep. This is to ensure that all those involved (crew members and those involved in planning the flights) understand and provide the necessary support for the crew to be fit to operate the flight.
	EASA is requested to develop specific training requirements and guidance material to ensure that crew and the operators understand how to: identify the times likely for sleep; the best use of the opportunities to sleep; how to manage sleep inertia issues; and, the impact of the commercial pressures of the operation.
	Justification: Time pressures and the emergency nature of callouts at short notice, especially as part of a block of long duties, may mean crew members commencing a flight whilst suffering from sleep inertia.
response	Please see the answer to comment # 54

comment 174

comment by: Marc Rothenhäusler

Die nach ORO.FTL.105 Nr. 12 definierte Flugdienstzeit ist nicht kompatibel zum HEMS Betrieb. Im Hems Betrieb wartet das Team auf der jeweiligen Station auf einen Einsatzalarm. Es ist schlicht und ergfreifend überhaupt nicht absehbar, wann der erste Einsatz beginnt, zu genüge kommt es vor, dass mehrere Stunden vergehn bis der erste Einsatz stattfindet. Dies muss Berücksichtigt werden, da sonst die Flugdienstzeit beinahe gleich wäre wie die Dienstzeit, was eine massive Herabsetzung zum heutigen Betrieb darstellt! Hierzu muss wie bisher auch eine Unterbrechung der Flugdienstzeit bei Pausen größer 60 Minuten beibehlaten werden.

**** * * ***

	Desweiteren werden die Flugzeiten ohne Autopilot deutlich zu gering angesetzt, im Vergleich mit der Arbeitsfliegerei wo auf die Hilfe des Autopiloten komplett verzichtet wird.
response	Please see the answer to comment # 54
comment	175 comment by: Marc Rothenhäusler
	In der Festlegung der maximalen Flugzeit ist eine zu geringe Stundenzahl festgesetzt worden. Im Betrieb von 1 Pilot + Autopilot sollten die gleichen Zeiten gelten als im Zweimanncockpit. Da die Unterstützung eines Autopiloten mit der eines weiteren zu vregleichen ist! Zeiten könnten sein Ein Pilot Ohne AP = 5h maximale Flugzeit / ein Pilot + AP = 7h max. Flugzeit
response	Please see the answer to comment # 54
comment	176 comment by: Marc Rothenhäusler
	Welche Fluzeitenbeschränkunge sind bei der CAT bzw. Arbeitsfliegeri festgesetzt? In diesen Bereichen müssetn dann ja noch geringere Werte angesetzt werden, da die Belastung eine höhere ist! Wieso wird eine max. Flugzeit abhängig gemacht vom Dienstbeginn, hier wird im CAT - Bereich auch nicht unr
response	Please see the answer to comment # 54
comment	182 comment by: ANSMU
It is felt that the "standby" section of the CS for HEMS operations is not sufficient articulated. As presently defined in the NPA, the operator is allowed to use the so order to systematically assign rosters at the operating base with long periods of st counting those as full duty periods, in case no flight is requested during the daily sh the personnel could undergo long periods at the operator's disposal with little til duty. This is particularly true in operating bases where the actual number of assigned m and there can be a consistent part of the day without flights. In particular, night shi end with few mission assignments. If the operator defines the shift as 2 hours for paperwork (20:00-22:00) and 10 hours of standby for take-off within 30 minutes fr 08:00), in case of no flight requests the pilot will end up with a 12-hours availability environment (inside the operating base), but with only 2 hours of recorded duty til This kind of roster can became a regular everyday planning, permitting continu availability with very little duty period, thus influencing the duty, rest and recur	

**** * **

recovery rest periods. This will also influence the count of the 2000 hours of working time as per Council Directive 2000/79/EC.

This is why we consider that the concept of FDP on HEMS is not in adequacy with the HEMS world, especialy in France and other country in Europe.

Presently, some European countries, like in France, are organised with 7/7 rosters, and they allow crews to keep their residence and families away from the operating base. The crews travel to the assigned operating base, where a proper accommodation is available, in order to fulfil the roster and then they travel back to their residences for the recurrent extended recovery rest period. Existing contracts between crews and operators, and existing agreements with crews' associations, reflect the resulting logistic and economic facts.

If it is requested that the home base be assigned at a specific operating base it will have a negative impact on crew's family and economic aspects.

In France there are 3 types of HEMS duty period:

- H12: start of HEMS standby 8am, and end at 8pm, with or without mission assignments.(10 % of French HEMS Base)

- H24: The HEMS standby is divided by 2 H12. First H12: Start of HEMS standby: 8am, and end at 8pm. Second H12 with another crew start at 8pm and end at 8am. With or without mission assignments. (50% of French HEMS Base)

- H14: start of HEMS standby 8am, and end at 10pm (40% of French HEMS Base) with or without mission assignments.

CS FTL.3.205 Flight duty period (FDP) — HEMS

A specific HEMS FDP should be defined according to the following definition:

A HEMS FDP is any time during which a person operates in an aircraft as a member of its crew, and starts when a crew member is required by an operator to commence a HEMS standby and ends when the crew member is free from the HEMS standby. The HEMS FDP includes standby at the operating base, post and pre-flight duties, flights, and all types of duties, without exceeding the maximum daily HEMS FDP specified in CS FTL.3.205(a) or (b) and not exceeding 14 hours.

CS FTL 3.205 (b) (2)

The minimum of 1 hour break of FDP over 10 hours, and 2 hours on 14 hours FDP's.

Unaceptable for the French State, and other country in Europe.

This is unacceptable to stop the HEMS during these periods. The French State is currently paying for a continuous service. It's not feasible to use additional pilots to be on standby or reserve during these periods to have a continuous service.

Economic and social impact: Strong for France.

CS FTL 3.205 (d) (e)

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 235 of 585



The operator may assign a block of up to 4 consecutive FDPs of more than 12 hours, but less than 14 hours.

In France, HEMS shifts are 7D ON and 7D OFF. We consider 4/4 too short, especially if you have to travel to the base from a distance.

If the pilot's residence is away from the operating base (most of the pilots in France), then a 4/4 shift will hardly allow him to go back home.

Consequences: The crew must move from his/hers own residence to the operating base, because the shifts could became too tight (4/4) to be convenient to go back to her actual residence and family place. It will have an strong economic, social, and family impact.

The French social and employer partners have signed the Annex 2 of the collective convention of the HEMS, wich regulates the periods of duty, rest, maximum hours of flight, etc.... The NPAs want to replace this convention. The risk is a strong social movement in France if these CS FTL 3.205 (d) (e) is validated.

Since 1987 there no has been HEMS accident in France. Since July 18, 2003 annex 2 of the pilots collective convention is valid without major incidents.

Contacts with pilots, HEMS crew members, HEMS organisations and aviation associations indicate that this kind of roster is well accepted by all personnel and that generally the stress build up during the 7-day-shift is well managed by them.

Generally, stress comes from fatigue, especially when facing intense flying days. In order to overcome this issue a possible barrier would be the reduction of the FDP in those days when a flying hour's limit is exceeded – i.e. "If the 'maximum daily FT – (minus) 2h' is exceeded, on that day the maximum FDP is reduced to maximum 12 hours".

Security impact: No. We don't see a security gain for France. The current mode of operation regulated by annex 2 of the collective convention has proven by no HEMS accident since its application.

Social Impact: Strong for the life of the crews.

Economic impact: Strong for the operationality of the French HEMS.

Proposal:

CS FTL.3.205 HEMS Flight duty period (HEMS FDP)

Definition:

A HEMS FDP is any time during which a person operates in an aircraft as a member of its crew, and starts when a crew member is required by an operator to commence a HEMS standby and ends when the crew member is free from this HEMS standby. The HEMS FDP includes standby at the operating base, post and pre-flight duties, flights, and all types of duties, without exceeding the maximum daily HEMS FDP specified in CS FTL.3.205(a) or (b) and not exceeding 14 hours.

CS FTL.3.205 Flight duty period (FDP) — HEMS



Maximum basic daily FDP in HEMS operations under ORO.FTL.205(b)(7) The maximum basic daily FDP without the use of extensions for acclimatised crew members in HEMS operations is established as follows:

(a) For two-pilot HEMS operations, the basic maximum daily FDP and the maximum flight time within that FDP are established in accordance with Table 1 and comply with the following conditions:

(1) For FDPs of over 12 hours, the operator ensures at least one break of minimum 60 consecutive minutes or more within each FDP at the HEMS operating base at times that ensure likelihood of sleep and provides suitable accommodation for the purpose of breaks at the HEMS operating base;

 (2) The time for breaks constitutes 50 % of the time over 12 hours and excludes the necessary time for post- and pre-flight duties; and

(1) If the maximum daily flight (FT), in accordance with the table 1, minus 2 hours on that day, the maximum FDP is reduced to maximum 12 hours.

(2) (3) The operator specifies in the operations manual a minimum of 30 minutes for the first pre-flight duties performed at the beginning of the FDP and a minimum of 15 minutes for post-flight duties for every flight returning to the HEMS operating base.

(b) For single-pilot HEMS operations, the basic maximum daily FDP and the maximum FT within that FDP are limited in accordance with Table 2, and comply with all the following conditions:

(1) Continuous FT is limited in all cases to 4 hours with autopilot and to 2 hours without autopilot;

(2) For FDPs of over 10 hours, the operator ensures at least one break of minimum 60 consecutive minutes within each FDP at the HEMS operating base at times that ensure likelihood of sleep and provides suitable accommodation for the purpose of breaks at the HEMS operating base;

 (3) The time for breaks constitutes 50 % of the time over 10 hours and excludes the necessary time for post- and pre-flight duties;

(2) If the maximum daily flight (FT), in accordance with the table 2, minus 2 hours on that day, the maximum FDP is reduced to maximum 12 hours.

(3) (4) The operator specifies in the operations manual, a minimum of 30 minutes for the first pre-flight duties performed at the beginning of the FDP and a minimum of 15 minutes for post-flight duties for every flight returning to the HEMS operating base.

(c) If the rest period before reporting for the FDP is taken at the HEMS operating base, the limits of Table 1 for reporting times between 0730-0959 also apply for reporting times between 0630–0729.

(d) The operator may assign a block of up to <u>4.7</u> consecutive FDPs of more than 12 hours, but less than 14 hours, if the following conditions are met:

(1) the rest period preceding the first FDP is at least 36 hours including 2 local nights; and

(2) the rest period provided after completion of the series of consecutive FDPs is at least 84 hours including 4 local nights.

response

Please see the answer to comment # 54



comment 216

comment by: Frederique ARONICA Health s' Minsitry France

Attachments #86 #87 #88

Impact assessment "CS-FTL.3.205 Flight duty period (FDP) – HEMS" on French HEMS : **All HEMS operations are single pilot with TCM (table single-pilot HEMS operations).** French HeliSMUR have fluctuating hours of permanence due to different periods aeronautical of activity (day-night), noise abatment and seasonal flows of tourism activity from 6.00 am to 10.00 am (Amiens HeliSMUR base open at 9:30 am from 9:30 pm).

(1) The introduction of a reference time rule based on the time of taking duty is a real source of confusion for crew members, medical team, and operators. As previously notified, pilots of the HEMS have an average flight duration of 1h30 per day with significant standby times. A HEMS pilot in France has an activity of 90 hours per year.

Reducing duty time will increase the number of pilots needed to guarantee the same HEMS activity. This measure poses several difficulties, the first one being the lack of experienced pilots on the labor market, and the second one the reduction of flying time per pilot, which creates a new risk concerning the maintenance of skills.

In several case, an HEMS could pick up a patient in a hospital to bring it to a third hospital. This mission called "triangulars" in France is common. Sometimes HEMS crew upload patient ou add fuel with rotor running. In these cases, pilots could not either achieve the return way without the patient, or worse, the availability for HEMS operations would be compromised until the end of the flight duty period of the pilot. The postponement for HEMS activity to favour state helicopters is not always possible. The increase of crews to anticipate this risk of availability would be a source of significant additional expenses. As we have mentioned, pilots HEMS fly only 90 hours a year so there was no report significant fatigue by the crews.

(1). In case of the continuous FT limited to 4 hours with autopilot and to 2 hours without autopilot, this rule impacts Cayenne HeliSMUR base (French Guyana). Every year, the rule would be exceeded because we totalise in 2015, 2016 and 2017 an average of 3 days will an activity longer than 6 hours. So France, as member state requests that French Guyana and as Reunion are excluded from development of FTL for HEMS (Art. 8).

(2 & 3). After, the rule imposes for single-pilot a break after 10 hours of FDP to prevent risk fatigue for the crew. However, setting the time of the break in the day, does not take into account that the crew might need to take this break before the 10 th hour of FDP at his request, or blocks the possibility to reconcile the break with a period of inactivity (due to bad meteorologicals conditions). In addition, it does not allow the pooling of crews, when tit enables to continue to assure the HEMS activity thanks to the mobilisation of multiples teams

Finally, the accommodation type described as simple "accommodation" instead of "suitable accomadation" as defined in ORO FTL 105 would be sufficient for a crew of 2 people needing a break of one hour.



Case 1 : Application of FTL : a break after 10 hours for single-pilot with same number of crew :

A break after 10 hours of FDP involves a suspension activity on each base of HEMS french hospital (H12 / H14 or H24). Hospital activity is not predictable, especially emergency medical services. **A break during FDP does not allow to cover an emergency mission.** This is not acceptable because given the loss of luck for the population to access emergency medical help. An other HEMS s'organisation must be define by France.

Case 2: Application of FTL a break after 10 hours for single-pilot with same service ability The preliminary work of companies indicates the need to recruit 50% of crew for a H24 activity and to double all crews in case of H12 & H14 activity.

- First impact : France has not enough ressources on crew to be conforme to FTL a break after 10 hours for single-pilot.
- Second impact : Add crew involves new cost.

The impacts of CS-FTL.3.205 Flight duty period are estimated for France at 15 millions of euros each year (French market is close to 80 millions of euros a year)

The new regulation will have a huge economic impact on public expenses of the French State and ultimately on the participation of the population in the HEMS service.

(4) The rule imposes a minimum of 30 minutes for the first pre-flight duties performed at the beginning of the FDP. This measure hight impacts the availability of crews to perform HEMS operations. Feedback indicate that 20 minutes are sufficient to prepare the first flight and this organization does not question the prerogatives of the captain who is the only one to decide on the mission and the time of takeoff.

Unforeseen circumstances in flight operations- Commander's discretion in HEMS under ORO FTL 205 (f).

The rule "Unforeseen circumstances in flight operations" :

The conditions to modify the limits on flight duty, duty and rest periods by the commander in the case of unforeseen circumstances in HEMS flight operations which occur at or after the reporting time, or at the end of the FDP, comply with the following :

(a) The maximum basic daily FDP may be increased for HEMS by up to 1 hour for singlepilot operation or by up to 2 hours for two-pilot operation.

(b) If on the final sector within the FDP the allowed increase under (a) is further exceeded because of unforeseen circumstances after take-off, the flight may continue to the planned destination or alternate aerodrome. If unforeseen circumstances occur just before take-off on the final sector, the allowed increase may only be exceeded to transport the patient.

(c) If commander discretion is used in any HEMS operating base more than 10 % of the total FDP over a 3-month period, the schedule and crew resources of the HEMS operating base are reviewed and adapted.

Impact assessment "CS-FTL.3.205 Flight duty period (FDP) – HEMS" on French HEMS : The operating range of HeliSMUR is 12 hours for 16 bases, 14 hours for 15 bases and 24 hours for 18 bases. If, on these bases, the rule introduce an interruption of the HEMS



permanence of 1 hour for 15 bases, 2 hours for 14 bases and 2 hours for 17 bases, the consequences would be :

* The impact of this measure if we guarantee the same level of operation emergency access SMUH is to recruit about 240 pilots and TCM for all HEMS bases. This measure would represent an additional expense of 15 million euros per year that would be difficult to commit for the State.

*In the event that the increase in the number of pilots and TCM to carry out the activity would not be feasible for reasons of unavailable humans resources or funding, the reduction in the disponibility of HEMS helicopter would be considerable. The reduction in the capacity of access of HEMS is estimated with a loss of 1 825 hours or 152 days of avaibility for operations emergency medical service. This situation is difficult to envisage given the increased risk of loss of opportunity for the population.

The rule opposes the return of the medical team because the patient isn't on board and creates a risk related to the unavailability of the doctor for another HEMS so the operations HEMS would be interrupted. This also results in a loss of luck for other wounded patients who would require an operation of emergency service HEMS. This case occurs when the crew is engaged in an operation HEMS outside the hospital, for example a car accident in an isolated area and far from the base. If the injured dies on site, it's not possible in France to bring back a body on board. So, if the return sector flight is greater than the captain's discretion, the crew and the medical team would be blocked without the possibility to come back to the base. In this situation, the operations HEMS would be interrupted again.

Comments "CS-FTL.3.205 Flight duty period (FDP) - HEMS" :

The maximum daily FDP in hours, single-pilot HEMS operation, could be put at 4 hours whatever the start of FDP. This rule could be transitory and lasts, for 5 years after the publication of FTL regulation. Thus, operators engaged in public procurement contracts with hospitals, have time to adapt and have helicopters with PA.

We request that wathever the flights the crew could be flight out the presence of a patient on board, which allows the return of the crews and the medical team and the helicopter on the hospital headquarters of the activity HEMS. So availability for HEMS operations will be guarantee.

We request that in compliance with aeronautical safety, pilots have all the updated data for the pre-flight tasks, and that the pre-flight time in early FDP is at least 20 minutes instead of 30 minutes. The captain remains the onely one to decide the moment of the mission.

We request that the rule lightened as long as no event related to the crew fatigue was reported in HEMS operation. The proposed amendment is for a break time adjustment of 25% over 12 hours. The break should not be scheduled at a fixed time during the HEMS activity in accomodation as defined in ORO.FTL.105. instead of suitable accommodation. And, given the low daily activity of the HEMS in France, in case of pilot inactivity of at least one hour, this time can be likened to the daily break imposed by the regulations.

comment 224

comment by: ADAC Luftrettung gGmbH

CS.FTL.205(a)

Wie kann eine "likelihood of sleep" objektiv Festgestellt werden? Dieser Passus kann so nicht erhalten bleiben.



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 240 of 585 Abs. (a) (2) Wann beginnt die FDP? Übergabezeiten FDP oder DT?

Die Definition der FDP geht davon aus, dass ein Besatzungsmitglied das einen Dienst antritt einen Flugabschnitt oder mehrere Flugabschnitte zeitnah durchführt. Dies ist für den HEMS Betrieb nicht zutreffend, da für die HEMS Crew der erste Einsatz oft erst Stunden nach Dienstantritt ausgelöst wird. Es ist folglich bei Dienstantritt garnicht absehbar wann der erste Flugabschnitt beginnt. Dies muss bei der Definition der FDP berücksichtigt werden, da sonst im HEMS Betrieb die FDP=DP wäre, was eine erhebliche Einschränkung für HEMS-Betreiber ggü. den jetzigen Regularien darstellen würde. Pausen von min. 1h könnten z.B. die FDP unterbrechen.

Da keine wissenschaftliche Studie zum HEMS-Betrieb genannt wird stellt sich die Frage auf welcher Grundlage die Zeiten der Table 1 und 2 festgelegt wurden? Eine max FT für den SP Betrieb ohne AP von teilweise 3 Stunden ist im Vergleich zur Arbeitsfliegerei, bei der ebenfalls selten ein AP vorhanden ist/genutzt werden kann, inakzeptabel.

CS.FTL.205(b)

Table 2 Ein Flug mit einem Piloten und AP muss mindestens genausoviel FT ermöglichen wie ein Flug mit 2 Piloten. Sinnvoll erscheinen 5h ohne AP und 7h FT mit AP.

Warum soll bei HEMS eine FT auf Grund des Dienstbeginns angepasst werden, während dies bei CAT nicht durchgeführt wird?

CS.FTL.205(d) Beinhalten die 4 FDPs die Reisezeiten gem CS.FTL.3.200(b)?

response

Please see the answer to comment # 54

comment	253	comment by: European Helicopter Association (EHA)
		(Germany) and LAR (Luxembourg):
	CS.FTL.205 (a)	OP in two-pilot HEMS operations according to table 1. For FDPs over
		ensures at least one break of minimum 60 minutes at times that
		definition of the term "ensures likelihood of sleep" in practice?
	Thiscompletely contraction in HEMS.	licts the idea of availability times for rescue missions and is useless
	Therefore it must be de	eleted from the regulation completely.
	Para. a2: The time for b	preaks constitutes 50% of the time over 12 hours.
	Question: Is time for br needs tobe more than	eaks calculated by adding all break times but only one of them 60 minutes?
	Question: When does F	DP start / is handover FDP or DT?
		ccording to ORO.FTL.105 (12) is based on the assumption that a
	crewmember reports for	or duty that includes one or more sectors. This definition doesn't
	fit to HEMSoperations.	One basic principle of HEMS is that the crew awaits an incoming
	alert at the home base.	Therefor when reporting for duty it is not sure if or when a

	mission alert and thus a sectorwill occur. Frequently the first mission takes place several hours after reporting without anysectors in between. This fact needs to be considered in the definition of FDP for HEMS, otherwiseFDP and duty period are almost the same in HEMS operations. Compared to the current systemthis would pose a massive constraint for operators.
	Possible solution:
	Breaks of more than 60 minutes between sectors interrupt FDP. Remark on table 1 and 2:
	What's the origin of the times? What data is used to define them? There is no evidence of anyscientific study of HEMS operation that could lead to such definitions. Especially maximum flighttimes for single pilot operation without autopilot (e.g. 03:00 hours) are much too restrictive. Thesetime limitations are unacceptable particularly in comparison with other CAT helicopter operations that take place completely without autopilot. CS.FTL.205 (b)
	Maximum basic daily FDP in single-pilot HEMS operations according to table 2. For FDPs over10 hours the operator ensures at least one break of minimum 60 minutes at times that ensurelikelihood of sleep.
	Question: What is the definition of the term "ensures likelihood of sleep" in practice? Thiscompletely contradicts the idea of availability times for rescue missions and is useless in HEMS.
	Therefore, it must be deleted from the regulation completely.
	Para. b3: The time for breaks constitutes 50% of the time over 10 hours.
	Question: Is time for breaks calculated by adding all break times but only one of them needs tobe more than 60 minutes?
	Table 2: Maximum flight time limits are unacceptable, too low and presented without any datajustification.
	Possible solution after more than 40 years of HEMS operation:
	Single pilot without autopilot: max. 5 h, single pilot with autopilot: max. 7 h.
	Question: What limits are planned for CAT operations such as logging or other aerial
	work? Theyare flying most of their flights without autopilot, so their flight time limits
	must be even morerestrictive than in HEMS. If not, this would be a disadvantage for HEMS operators.
	The dependency between time of reporting for duty and maximum allowable flight time is notforeseen in CAT operations and therefor poses another disadvantage for HEMS operators.
response	Please see the answer to comment # 54

comment 277

comment by: European Helicopter Association (EHA)

SHA (Switzerland) CS FTL 3.205 (b

Sectors are defined for airplane so why do have limitations for sector s?

An agency of the European Union

Individual comments and responses - HEMS

response	Please see the answer to comment # 54		
comment	280 comment by: European Helicopter Association (EHA)		
	ADAC (Germany), DRF (Germany) and LAR (Luxembourg):		
	CS FTL 3.205 (a) (3)		
	Problem: HEMS Service is unpredictable and after returning to the base the next alert may start after 3 or 4 minutes. Nobody can grant this 15 min period without interfering with the rescue order.		
	Solution: Minimum of 15 minutes for post flight duties at the end of the day		
response	Please see the answer to comment # 54		
comment	284 comment by: European Helicopter Association (EHA)		
	ADAC (Germany), DRF (Germany) and LAR (Luxembourg):		
	CS FTL 3.205 Table 1		
	Problem: Standardized schedules should give for day and night pilots the same FDP at HEMS- bases with 24 / 7 working times. This is not possible for the maximum FDP of 12 hours, because we		
	need at least an overlapping period of 30 min for the pre-flight checks		
	Solution: Alter the max. FDP between 1400 and 0629 to read 12:30! This allows for evenly spread schedules		
	i.e.: Shift 1 from 0630 to 1900 Shift 2 from 1830 to 0700		
response	Please see the answer to comment # 54		
comment	285 comment by: European Helicopter Association (EHA)		
	ADAC (Germany), DRF (Germany) and LAR (Luxembourg):		



response

CS FTL 3.205 (d)

· · · · · · · · · · · · · · · · · · ·	
As soon as the FDP is between 12 and 14 hours long a block of consecutive FDPs is limited	
to 4 days. The rest period preceding the first FDP is at least 36 hours including two local	
nights, the current system requires only 24 hours in advance. The rest period provided	
after completion of the series of consecutive FDPs is at least 60 hours including 3 local	
nights, the current system allows for 48 hours.	
Question: Is travelling time in accordance with CS.FTL.3.200 (b) part of these 4 FDPs?	
If this is the case it will reduce the time on base of each pilot during times with more than	
12 hours	
FDP to 2-3 days. The use of reserve pilots for only 2 consecutive days would pose an	
economicburden to the operator.	
Question: What happens on 24h bases in case of a single exceedance of the 12 hour FDP?	
Willthe length of the duty block be automatically be shortened to 4 days instead of 7 as	
scheduled?	
This would lead to an additional limit regarding these bases, because they will have to	
changetheir current attractive 7 day blocks to 4 day blocks. This is expected to further	
reduce theattractivity of 24 h bases for pilots especially when they don't live close to their	
home base.	
Split duty is not accounted for in this paragraph. Or is this paragraph not relevant for split	
duty?	
Using split duty would allow for FDP of more than 14 hours. Currently there is no further	
regulation provided for FDP of more than 14 hours.	
Please see the answer to comment # 54	1

295 comment comment by: European Helicopter Association (EHA) BABCOCK ITALY CS FTL 3.205 Table 2 -Why we want to change As it is the table 2 for single-pilot HEMS operations it will disrupt the actual roster of 7 days on 7 days off, increasing enormously the operational HEMS cost for the companies and for the National Health Care Systems.-What we propose We propose to add a point e) allowing a block of max 7 consecutive FDP of 13 hours. This will be in accordance at the max FDP of 110 hours per 14 days (13 hours x7 days =91 hours) and it will assure adaily rest of 11 hours at the HEMS home base. The rest period preceding the first FDP and the rest period provided after completion of a series of FDP isproportional augmented compare to the point d) in order to assure a max FDP of 91 hours in a 14 days period as acompensation. (e) The operator may assign a block of up to 7 consecutive FDPs of more than 12 hours, up to 13 hours, if thefollowing conditions are met: (1) the rest period preceding the first FDP is at least 48 hours including 3 local nights; and (2) the rest period provided after completion of the series of consecutive FDPs is at least 96 hours including 4 localnights."



response Please see the answer to comment # 54 comment 297 comment by: European Helicopter Association (EHA) BABCOCK ITALY CS FTL 3.205 Table 2 (c) If the rest period before reporting for the FDP is taken at the HEMS operating base, the limits of Table 1 for reporting times between 0730-0959 also apply for reporting times between 0630o Why we want to change We are not the owners of our Hems operating base and we can't provide an arrangement for the crew but we provide comfortable hotels accommodation close to the base with the same amount of hours in term of sleep opportunities. o What we propose CS FTL.3.205 Flight duty period (FDP) — HEMS Table 2 (c) If the rest period before reporting for the FDP is taken at the HEMS operating base or at a suitable accommodation close to the HEMS operating base, the limits of Table 1 for reporting times between 0730-0959 also apply for reporting times between 0630-Please see the answer to comment # 54 response

comment | 300

comment by: European Helicopter Association (EHA)

BABCOCK ITALY

CS FTL 3.205 Maximum basic daily FDP in HEMS operations under ORO.FTL.205(b)(7)

The maximum basic daily FDP without the use of extensions for acclimatised crew members in HEMS operations is established as follows:

(a) For two-pilot HEMS operations, the basic maximum daily FDP and the maximum flight time within that FDP are established in accordance with Table 1 and comply with the following conditions:

o Why we want to change

There are no reason to consider the HCM max FDP as the single pilot, they could be compare to the two-pilot HEMS operations.

o What we propose

CS FTL.3.205 Flight duty period (FDP) — HEMS Maximum basic daily FDP in HEMS operations under ORO.FTL.205(b)(7)



The maximum basic daily FDP without the use of extensions for acclimatised crew members in HEMS operations is established as follows:

(a) For two-pilot HEMS operations *and in any case for the HEMS Crew Members*, the basic maximum daily FDP and the maximum flight time within that FDP are established in accordance with Table 1 and comply with the following conditions: (...)

response

Please see the answer to comment # 54

comment 313

comment by: European Helicopter Association (EHA)

NORSK LUFTAMBULANSE AS (Norway)

"Maximum basic daily FDP in HEMS operations under ORO.FTL.205(b)(7)

(1) For FDPs of over 12 hours, the operator ensures at least one break of minimum 60 consecutive minutes or more within each FDP at the HEMS operating base at times that ensure likelihood of sleep and provides suitable accommodation for the purpose of breaks at the HEMS operating base;"

Comment: The concept of breaks for HEMS operations is not useable and should be handled differently by using a concept of "maximum active time" and "passive time" when calculating duty time. CAT.GEN.MPA.100(e)(1) already put the responsibility on commanders not to fly when fatigued. Furthermore, as the text is written, one could interpret this break would be in addition to the specific duration for a meal opportunity described in ORO.FTL.240 – Nutrition, which would be unnecessary.

Furthermore, the concept of breaks is very unclear, especially regarding how this should be planned. <u>Shall the break or breaks be pre-planned or may they have been achieved retrospectively?</u>

As mentioned in the comment to CS FTL.3.205 Flight duty period (FDP) — HEMS, NPA p 36 and CS FTL.3.210 Flight times and duty periods — HEMS, NPA p 75 below prescribing breaks is not a practicable solution and the concept of breaks is very unclear, especially regarding how this should be planned. An easier approach would be a concept comprising a maximum Duty Period with a maximum Flight Duty Period comprising "Passive time" and "Active time". Refer to explanation in comment to CS FTL.3.205 Flight duty period (FDP) — HEMS, NPA p 36 and CS FTL.3.210 Flight times and duty periods — HEMS, NPA p 75 below.

(c) If the rest period before reporting for the FDP is taken at the HEMS operating base, the limits of Table 1 for reporting times between 0730-0959 also apply for reporting times between 0630–0729.

Comment: While our HEMS operating bases include suitable accommodation, there is not enough accommodation to cater for crew that are to report for duty. Furthermore, many HEMS operating bases in Europe does not have suitable accommodation at the base, but close by. This should be reflected. Suitable accommodation close to the HEMS operating base should be acceptable.

(d) The operator may assign a block of up to 4 consecutive FDPs of more than 12 hours, but less than 14 hours, if the following conditions are met:

**** * **** (1) the rest period preceding the first FDP is at least 36 hours including 2 local nights; and (2) the rest period provided after completion of the series of consecutive FDPs is at least 60 hours including 3 local nights.

Comment: While not fully relevant for us, we note that this will make it impossible to have operation with a roster that includes 7 days on and then a long period off (1, 2 or 3 weeks) which is a common practice in HEMS operations. The increased number of commutes would increase both fatigue and incur substantial costs on the national health care systems.

response

Please see the answer to comment # 54

comment	314	comment by: European Helicopter Association (EHA)
	NORSK LUFTAM	BULANSE AS (Norway):
	(2) For FDPs of consecutive mir	c daily FDP in HEMS operations under ORO.FTL.205(b)(7) over 10 hours, the operator ensures at least one break of minimum 60 nutes within each FDP at the HEMS operating base at times that ensure ep and provides suitable accommodation for the purpose of breaks at the base;"
	40 years withour length, it is the duty period. Cre	brway 12+ hours Single Pilot HEMS has been common practice for close to t any incidents relating to fatigue. If the flight duty period is of a reasonable number of duty periods that induced fatigue, not the length of the flight ws involved in HEMS operation typically have ample time for rest and food ng breaks is not a practicable solution.
response	Please see the a	nswer to comment # 54

comment	367	comment by: European Helicopter Association (EHA)
	BHA (UK)	
	"CS FTL.3.205 Flight duty period (FD	P) — HEMS (a)(1)"
	CAT.GEN.MPA.100(e)(1) already pla fatigued. An appropriate statement Also, the text indicates such bread duration for a meal opportunity, as o	HEMS operations is unnecessary because ices an obligation on commanders not to fly when to this effect would be better justified. iss are in addition to operators providing a specific described at ORO.FTL.240 - Nutrition. able accommodation will have a significant negative e.
	"(2)"	

**** * * *** TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

Comment: By my calculations, this means a one-hour break every 14-hour FDP. "(3)" Comment: Specifying fifteen-minute post-flight duties after every flight returning to the HEMS operating base is completely unacceptable. What is the rationale for introducing such a limit? For most HEMS units doing several missions every day, this could result in an additional hour of aircraft unavailability. Curiously, the text only specifies a HEMS operating base, and not if the aircraft pre-positions elsewhere? "(b)(2)" Comments: In the UK, 12-hour SP HEMS shifts have been commonplace for many years, without any fatigue-related incidents. Cumulative duty periods induce tiredness, not the length of a single FDP (within reason). HEMS pilots have plenty of time in a normal shift to rest, and achieve comfort and food breaks. Introducing a prescriptive break is punitive and antithesis to the HEMS philosophy. The introduction of a one-hour break in an FDP>10 hours is contradicted by the rationale text in para. 34 which states: "Basic maximum FDPs of more than 12 hours are possible only if crew members can benefit from at least one break of at least 60 consecutive minutes." Please see the answer to comment # 54 response comment comment by: Joachim J. Janezic (Institute for Austrian and International Aviation 387 law) In the first of the two CSs FTL 3.205(c) (page 36) a reference must be made not only to Table 1 but also to Table 2. Please see the answer to comment # 54 response response Please see the answer to comment # 54 comment 398 comment by: European Helicopter Association (EHA) OEAMTC (Austria): CS FTL.3.205 Flight duty period (FDP) — HEMS Maximum basic daily FDP in HEMS operations under ORO.FTL.205(b)(7) The maximum basic daily FDP without the use of extensions for acclimatized crew members in HEMSoperations is established as follows: [...]

(b) For single-pilot HEMS operations, the basic maximum daily FDP and the maximum FT within thatFDP are limited in accordance with Table 2, and comply with all the following conditions:(..)

COMMENT(S)

The concept of operating a mixed crew in which tasks are shared differs considerably from a truesingle pilot concept since cockpit workload is divided and monitoring is taking place. There are nocredits for this sharing of workload in terms of FTL however the HEMS TCM must adhere to the FTL.

Credits should be given for the mixed crew concept and be treated same as two-pilots.

CS FTL.3.205 Flight duty period (FDP) — HEMS

Maximum basic daily FDP in HEMS operations under ORO.FTL.205(b)(7)

The maximum basic daily FDP without the use of extensions for acclimatized crew members in HEMSoperations is established as follows:

[...]

(b) For single-pilot HEMS operations, the basic maximum daily FDP and the maximum FT within thatFDP are limited in accordance with Table 2, and comply with all the following conditions:

(1) Continuous FT is limited in all cases to 4 hours with autopilot and to 2 hours without autopilot;

COMMENT(S)

We appreciate considering autopilot systems as a support for the flight crew. But in view of the factthat AP systems create a complex work environment we do not understand that not having an APreduces allowable flight time up to 2 (!!!) hours per day (This reduction seems not to be an evidencedbased approach). An average leg in the air rescue throughout Austria is just above 8 minutes. In most missions this puts the use of AP systems in question.

CS FTL.3.205 Flight duty period (FDP) — HEMS

Maximum basic daily FDP in HEMS operations under ORO.FTL.205(b)(7)

The maximum basic daily FDP without the use of extensions for acclimatized crew members in HEMSoperations is established as follows:

[...]

(b) For single-pilot HEMS operations, the basic maximum daily FDP and the maximum FT within thatFDP are limited in accordance with Table 2, and comply with all the following conditions:

[...]

(2) For FDPs of over 10 hours, the operator ensures at least one break of minimum 60 consecutive

minutes within each FDP at the HEMS operating base at times that ensure likelihood of sleep and

provides suitable accommodation for the purpose of breaks at the HEMS operating base;

COMMENT(S)

The concept of a 60 consecutive minutes break must be clarified to be 60 consecutive minutes onbase without activities (no preflight, no flying or other duties, no post flight). These 60 consecutiveminutes must not be planned, nor shall they lead to unavailability and may be assigned retrospectively.



According to most contracts with state authorities in Austria it is a requirement to be airborne withina few minutes (max. 4min) after receiving an emergency dispatch call. The following mission ormissions have an undetermined duration. Therefore it is not possible to schedule predeterminedbreaks during a shift without taking the helicopter out of service. Besides the fact that this would bean infringement of existing contracts with state authorities (guaranteed hours of service) this would

also cause an unacceptable burden to healthcare for potential patients (i.e. the total population of a certain region). An alleged but not verifiable benefit for flight safety (in terms of fatigue only) wouldcause a tremendous negative and disproportional effect to the public.

In the Austrian duty roster allowing up to 15.5h FDP per day retrospective analysis of 12.000 dutydays in the last two years shows there are only 0.21% of the duties which did not have at least one 80consecutive minutes break (accounting for a 15 minutes post flight plus 60 minutes break plus 5minute margin).

CS FTL.3.205 Flight duty period (FDP) — HEMS

Maximum basic daily FDP in HEMS operations under ORO.FTL.205(b)(7)

The maximum basic daily FDP without the use of extensions for acclimatized crew members in HEMSoperations is established as follows:

[...]

(b) For single-pilot HEMS operations, the basic maximum daily FDP and the maximum FT within thatFDP are limited in accordance with Table 2, and comply with all the following conditions:

[...]

(4) The operator specifies in the operations manual, a minimum of 30 minutes for the first pre-flight

duties performed at the beginning of the FDP and a minimum of 15 minutes for post-flight duties for

every flight returning to the HEMS operating base.

COMMENT(S)

A post flight is required for every flight returning to the base? Meaning for six flights returning tobase 1.5 hours post flight are required? Does this means during this 15 minute periods no newmissions may be accepted? It should be possible to react to a new mission within the 15 minutespost flight period or only one such period should be required at the end of the FDP.

response

Please see the answer to comment # 54

comment 406

comment by: ANWB MAA

We didn't see any evidence the AP will have any effect on the fatigue of the crew in high density areas. In those areas in the Netherlands the average flight time is around 10 minutes including take-off and landing. Using an AP in this short flight will not make any sense. The article doesn't state any guidelines in the use of the AP - so having an AP seems to be relevant, but using it not: is this the influence of the helicopter industry who prefer to sell more expensive AP machines? Additional costs for the Netherlands will be 26 million euros to replace the helicopters by those with an AP

**** * * *** response Please

Please see the answer to comment # 54

comment	422 comment by: UFH French Helicopters Association
	#3 CONTINUOUS FLIGHT TIME LIMITATION IN SINGLE-PILOT + TCM
	ISSUE We highlight the too restrictive limitation of total flight time for the single-pilot + TCM operations(b)(1). Indeed, the proposal constrains the continuous flight time for single- pilot + TCM operations: • with autopilot at 4 hours
	• without autopilot at 2 hours Some rescues and patient transportation, like severe burned patients, will not be possible with the 2hours limitation without the autopilot. Indeed, these flights can be a haul from Lyon to Paris whichlasts more than 2h and they are necessary because the transport by road is not considered sufficiently effective considering the patient's condition. These flights are usually flown with lighter helicopter without autopilot because they can fly longerdistances (4h30 of autonomy) than heavy helicopters. These flights are usually scheduled from a knownhelipad in a hospital to another known helipad in another
	hospital and correspond more to the scopeof commercial sanitary flights not yet defined by EASA than the HEMS scope. In addition, it is usual to keep the engine running (the rotor blades are still turning while loading thehelicopter between two legs or three legs in case of a triangular mission, i.e the single-pilot + TCM takeofffrom the home base, pick up a patient at a given hospital to
	finally bring him at the plannedhospital). Thus, according to the definition of a Flight Time in ORO.FTL.105(13), these two legs areconsidered as a unique flight time. In that way, the limitation of 2 hours for an equipage with a singlepilot+ TCM is too restrictive. Moreover, in HEMS, a single-pilot does not fly alone, he is assisted by a Technical Crew Member (whichis a recent additional EASA requirement). In that way, the risk of fatigue is lower since the TCM isassisting the pilot in non-piloting tasks and is contributing to the safety of the flight.
	De facto, single pilot HEMS operations are in fact 2 technical crews operations (1 pilot + 1 TCM). By parallelism, no suchtotal flight time limitation has been defined for 2 technical crews operations (2 pilots). No RIA is given to justify this proposal.
	Besides, HEMS pilots are scarce resources in France, and this NPA would lead to hire 120 additionalpilots and 120 additional TCM in order to offer the same quality of HEMS activity in France. Thisrepresents an additional cost of 20% for the whole French HEMS State Budget. It is likely that such amassive recruitment would not be achievable and would thus result in a significant reduction in thequality of the French Healthcare system. Considering the limited range of heavy helicopter with
	autopilot, the lack of ATPL(H) pilots in France (for acting as commander for 2 pilots HEMS operations)and considering the fleet currently assigned to hospitals in France (with single-pilot certified helicopterand no flight standard for 2 pilots operations), the sum of the previous constraints leads to theimpossibility to transport this kind of patient by road or air.
	It is necessary to increase the limitation of continuous flight time described in this paragraph. This willnot have a major impact on the fatigue of the pilots since most of the



HEMS flights have a unit flighttime ranged around 25 minutes for SNEH, i.e 50 minutes back and forth (1 mission)i and this extension of the continuous flight time limitation will be used for a few and very specific missions. However, in

order to ensure it does not have an impact on the fatigue of the crew member, FNAM suggests usingthe possibility of having a 4 hours continuous flight time for single-pilots + TCM without autopilot underthe principles of a FRM.

Thus, we agree with the proposal of FNAM for single-pilot + TCM without autopilot to:

• Have an augmentation of this limitation to 3 hours

• Increase the limitation to 4 hours under the principles of a FRM

Otherwise, it would be beneficial to further develop the RIA basing it on experience and safety recordson this subject, in order to better assess the economic and social impacts in addition to the flight safetyimpact.

PROPOSAL

Replace the paragraph (b)(1) by the following:

"(1) Continuous FT is limited in all cases to 4 hours with autopilot and to 3 hours withoutautopilot. These limitations can be increased by 1 hour under the principles of a FRM;"

(a)(1)(a)(2)

ISSUE

Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since flight times areunpredictable and cannot be scheduled within a FDP, the same has to be applied for breaks. Besidesthe wording "break" should be rethought to make it easy to understand that this period is a timeallowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour.

As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, theopportunity for a 1h hour break is warranted.

Indeed, given the following aspects (Table 1 of this CS):

• Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break witha maximum Total Flight Time with autopilot = 9 hours which means at least 3 to 5 no-flown hours

• Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break witha maximum Total Flight Time without autopilot = 7 hours which means at least 5 to 7 no-flownhours

There is always a room for such a 1h break in a suitable accommodation at HEMS operating base.

Such a break may be monitored ex-post by the operator SMS, under the principles of the fatigue riskmanagement.

Therefore, under the above risk analysis and under a monitoring following the principles of a fatiguerisk management, FNAM suggests writing clearly in the regulation that in HEMS, breaks do not have tobe scheduled before the operation.

(Cf. comment #30.3)

PROPOSAL

Rephrase the paragraph (a)(1) as follows:

"(1) For FDP over 12 hours, the operator ensures ex-post that at least one break of minimum 60consecutive minutes within each FDP at the HEMS operating base at times that ensure likelihood ofsleep and provides suitable accommodation for the purpose of breaks at the HEMS operating base.

Fatigue risk management principles may be applied to monitor this break."



(a3) and (b4)

ISSUE

UFH agrees a minimum time shall be taken to ensure the safety of the flight:

• Before the 1st flight of the crew, by preparing the aircraft, and

• After each flight, by reporting flight and aircraft information

Due to the life-threatening emergency operation in HEMS, these times shall be as short as possible tomaximize operational availability and response time. In that way, in France, the contractual time forthe National Health Authorities between the launch of a HEMS flight and the effective take-off is 7minutes. Indeed, when a patient needs essential lifesaving measures, after 30 minutes, there are

almost no chance to save the life of the patient. Thus, the first patient of a FDP will have no chance of survival due to EASA proposition of having a minimum preflight time of 30 minutes at the beginning of the FDP. Moreover, French numbers underlines that 7% i of the HEMS take-off preformed within the first 30 minutes of the FDP. (Cf. SNEH illustrative Table in attachment in the FNAM comments)

Whatever the number of life that would not have been saved during these 30 minutes, no loss wouldbe politically and socially acceptable.

With the same philosophy, the proposed requirement of having a minimum post flight period of 15minutes at each HEMS operating base returns will reduce the chance of survival by 8 minutes for thenext patient in case of close consecutive missions.

To illustrate those two issues, let's take the example of 2 unpredicted HEMS operations within thesame FDP:

• 1st launch at the start of the FDP, at 8h00 with a mission with 2 flight times of 10 minutes(mission back and forth)

o This requires a 30-minutes preflight then a 15-minute post flight

2nd launch at 12h00: no preflight required because the preflight has already been done

• Further operations: no preflight required as far as preflight is already done

This example highlights the lack of efficiency of having a long pre-flight at the beginning of the FDPbefore the first flight time and no preflight requirement for the following flight time though it occurs 4hours after the initial checks.

Moreover, due to multiple flight times inside a unique FDP, FNAM underlines that the definition of postflight duty is non-consistent with the usual definition of post-flight:

• Which starts at the end (of the last FT) of the FDP.

• Assuming the FDP ends with the last FT

• Though for HEMS operations FT are unpredictable and scheduled FDP may end long after thelast effective FT

Thus, for HEMS operations, it is not clear if the post-flight does belong or not to the FDP depending on the end of the last FT.

This definition does not correspond to the definition of the proposal which defines a post-flight aftereach flight time returning to HEMS operating base within the same FDP. Therefore, FNAM suggests suppressing the post flight duties since they are confusing and replacing it by a proportionate pre-flighttime before any take-off from the HEMS operating base.

For French HEMS services, the suitable accommodation is nearby the helicopter. According to French experience, the effective time for preparing a new flight is 7 minutes. This reduction from 15 minutes to this current value of 7 minutes for pre-flight time before any takeofffrom the HEMS operating base will not impact the level of safety, otherwise it would be beneficial further develop the RIA in order to base it on experience and safety records on this subject.

On the other hand, FNAM agrees these requirements do not apply for the Technical Crew Membersince TCM function does not include the flight preparation.



(Cf. comment #44)In consequence, the proposal does not demonstrate safety improvement in all cases, in particular whenseveral flight times are allocated in the same FDP and suppress life opportunity for the 1st patient if the emergency occurs in the first 30 minutes of the FDP and the next ones in case of airlift multiple rotations. Thus, we propose:

• To reduce the minimum duration of initial preflight from 30 minutes to 15 minutes (inclusion of the helicopter checks); this proposal does not affect the cammander's prerogatives sincehe remains the one to make the final decision regarding the take-off time

• To dissociate from the above the time for the operational preparation of further individualflight time

• To replace the notion of "post-flight" by "operational pre-flight at the HEMS operating base"

• To set the minimum duration of "operational pre-flight at the HEMS operating base" at 7minutes instead of 15 minutes for the post-flight between 2 FT at the HEMS operating base

PROPOSAL

Replace the paragraph (a)(3) and (b)(4) by the following:

"(a) [...]

(3) The operator specifies in the operations manual a minimum of 15 minutes for the initial pre-flight duties performed at the beginning of the FDP and a minimum of 7 minutes for operational pre-flight duties before each flight taking-off from the HEMS operating base."

"(b) [...]

(4) The operator specifies in the operations manual a minimum of 15 minutes for the initialpre-flight duties performed by the pilot at the beginning of the FDP and a minimum of 7 minutes foroperational pre-flight duties performed by the pilot before each flight taking-off from the HEMSoperating base. Pre-flights duties do not apply to TCM." #6

(c)

ISSUE

UFH highlights that the proposition in point (c) shall apply for both:

• Two-pilots operations: Table 1; and

• Single-pilot + 1 TCM operations: Table 2

Indeed, the proposed mitigation is met in both operations by offering suitable accommodation atHEMS operating base (Cf. point (b)(2) and (a)(1)): the rest and mitigated resulting fatigue are the samethus the alleviation shall be the same. PROPOSAL

Replace paragraph(c) by the following:

"If the rest period before reporting for the FDP is taken at the HEMS operating base, the limits of Table 1 for two-pilots operations and Table 2 for single-pilot operations, for reporting times between 0730-0959 also apply for reporting times between 0630-0729."

Table 2

ISSUE

would like to highlight that the total flight time limitation for single-pilot + TCM operations

without the use of autopilot are too restrictive especially the following ones:

- FDP starting between 06:30-06-59 => maximum total flight time = 3:30
- FDP starting between 12:00-13:59 => maximum total flight time = 3:30

**** **** • FDP starting between 4:00-06:29 => maximum total flight time = 3:00 There is no regulation in France on this subject for HEMS operations, with no reported inherent safetyissue through experience.

A further developed RIA based on experience and safety records on this subject would be beneficial, in order to assess the economic and social impacts in addition to the flight safety impact.

In CAT provisions, when the operator has implemented a FRM, it is considered as a valuable mitigation allow for the FDP to be increased by 1hour, in some cases. Thus, in the same philosophy than for CAT operations, FNAM proposes to increase all total flight timelimitations by 1 hour under the principles of a FRM. PROPOSAL

Add the following sentence below the Table 2:

"The maximum Flight Time in Table 2 can be increased by 1 hour under the principles of a FRM"

#8 MITIGATION AFTER A BLOCK OF UP TO 4 CONSECUTIVE FDP OF MORE THAN 12 HOURS

(Cf. attachments S1, S2, S3 and S4 illustrating the reduced rest and the 12h operational readinessissues)

(d)

ISSUE

On the one hand, UFH underlines the French regulation historically proposes several rostering cyclesfor HEMS operations that are currently used with an excellent safety track record demonstrated by experience:

• 7 days ON / 7 days OFF with a limitation of 14 hours of duties for 24 hours

• 5 days ON / 2 days OFF with a limitation of 12 hours of duties for 24 hours

• 12 days ON / 6 days OFF with a limitation of 12 hours of duties for 24 hours

Therefore, most hospitals / HEMS organizations have a contractual engagement with the NationalHealth Authority over a rolling 24 hours period: 12 hours of HEMS operative availability and 12 hoursOFF.

According to the Agency requirement on the pre-flight and post-flight minimum times (Cf. #28.5), anHEMS organization will yet roster cycle with a FDP of 12h30 and a Duty Period of 12h45 to ensure theyfollow their engagement with hospitals. Thus, all HEMS operators will have to schedule:

• More than 12h FDP for each and every shift

• Reduced rest of more than 10h amongst a 11h15 available time for rest according toCS.FTL.3.235 to reengage at the same time the day after under the principles of a FRM.Moreover, due to short and continuous flight times with a total flight time limited per Table 2 and which are in average 1h30 per 12 hours of shifts (with an average leg of 25 minfor SNEH)i in France, the fatigue will not be an issue for FDP ranged from 12h up to 14h. Indeed,

according to the requirements (a)(1) and (b)(2), all HEMS organizations shall provide suitableaccommodation at the HEMS operating base, thus pilots can have breaks in comfortable placesbetween two flight times. These pilots have to have their rest at the HEMS operating base which is considered as a mitigation measure.

This is also a safety improvement because the rest is at the HEMS operating base which is considered as a mitigation measure.

Furthermore, no demonstration nor RIA is given to justify the point (d), while the current rostering inFrance on this subject for HEMS operations has not reported inherent safety issue through experience.

On the other hand, most of the French pilots are "faux-basés", meaning they spend 7 days working athome base and then 7 days of rest at home which can be at 500

 kilometers from home base. Therefore, most of French HEMS pilots prefer the cycle 7 days ON / 7 days OFF for their quality of life which willbe limited by the requirement (d). Nevertheless, the provisions of (d) implies at least 4 days ON per 3 days OFF, which appears counterproductive for social issues and crew quality of life.
 PROPOSAL Replace paragraph (d) by the following: "If an operator assigns two or more consecutive FDPs of more than 12h, the following conditions shallbe met: (1) The rest period preceding the first FDP is at least 36 hours including 2 local nights; and (2) The rest period provided after completion of the series of consecutive FDPs is at least 60 hoursincluding 3 local nights. A block of more than 4 consecutive FDPs of more than 12hours can be scheduled under the principlesof a FRM."
 response

comment	481 comment by: FNAM/SNEH	
	CS FTL.3.205 Maximum basic daily FDP in HEMS under ORO.FTL.205 (b)(7)	
	There are two CS FTL.3.205 (with exactly the same title), which introduces complet uncertainty and may lead to misunderstanding. FNAM and SNEH suggest adding precisions in the title of this paragraph in order to que make the link with the ORO paragraph involved.	
	PROPOSAL Replace the title of this CS by: "CS FTL.3.205 (b)(7)"	
response	Please see the answer to comment # 54	

comment	482 comment by: FNAM/SNEH	
	CS FTL.3.205 Maximum basic daily FDP in HEMS under ORO.FTL.205 (b)(7)	
	REMARK For small FT as currently operated in HEMS, it is possible to have multiple FDP within the same day. For instance: One FDP from 07:00 to 8:30 followed by a 12h rest period and then a FDP from 20:30 to 22h.	
response	Please see the answer to comment # 54	



comment 483

comment by: FNAM/SNEH

Attachment <u>#89</u>

CS FTL.3.205 Maximum basic daily FDP in HEMS under ORO.FTL.205 (b)(7)

CONTINUOUS FLIGHT TIME LIMITATION IN SINGLE-PILOT + TCM

(Cf. attachment S4 illustrating this continuous flight time limitation in single-pilot + TCM issue)

(b)(1)

ISSUE

FNAM and SNEH highlight the too restrictive limitation of total flight time for the singlepilot + TCM operations (b)(1). Indeed, the proposal constrains the continuous flight time for single-pilot + TCM operations:

- with autopilot at 4 hours
- without autopilot at 2 hours

Some rescues and patient transportation, like severe burned patients, will not be possible with the 2 hours limitation without the autopilot. Indeed, these flights can be a haul from Lyon to Paris which lasts more than 2h and they are necessary because the transport by road is not considered sufficiently effective considering the patient's condition.

These flights are usually flown with lighter helicopter without autopilot because they can fly longer distances (4h30 of autonomy) than heavy helicopters. These flights are usually scheduled from a known helipad in a hospital to another known helipad in another hospital and correspond more to the scope of commercial sanitary flights not yet defined by EASA than the HEMS scope.

In addition, it is usual to keep the engine running (the rotor blades are still turning while loading the helicopter between two legs or three legs in case of a triangular mission, *i.e* the single-pilot + TCM take-off from the home base, pick up a patient at a given hospital to finally bring him at the planned hospital). Thus, according to the definition of a Flight Time in ORO.FTL.105(13), these two legs are considered as a unique flight time. In that way, the limitation of 2 hours for an equipage with a single-pilot + TCM is too restrictive.

Moreover, in HEMS, a single-pilot does not fly alone, he is assisted by a Technical Crew Member (which is a recent additional EASA requirement). In that way, the risk of fatigue is lower since the TCM is assisting the pilot in non-piloting tasks and is contributing to the safety of the flight. *De facto*, single-pilot HEMS operations are in fact 2 technical crews operations (1 pilot + 1 TCM). By parallelism, no such total flight time limitation has been defined for 2 technical crews operations (2 pilots). No RIA is given to justify this proposal.

Besides, HEMS pilots are scarce resources in France, and this NPA would lead to hire 120 additional pilots and 120 additional TCM in order to offer the same quality of HEMS activity in France. This represents an additional cost of 20% for the whole French HEMS State Budget. It is likely that such a massive recruitment would not be achievable and would thus result in a significant reduction in the quality of the French Healthcare system. Considering

**** **** the limited range of heavy helicopter with autopilot, the lack of ATPL(H) pilots in France (for acting as commander for 2 pilots HEMS operations) and considering the fleet currently assigned to hospitals in France (with single-pilot certified helicopter and no flight standard for 2 pilots operations), the sum of the previous constraints leads to the impossibility to transport this kind of patient by road or air.

It is necessary to increase the limitation of continuous flight time described in this paragraph. This will not have a major impact on the fatigue of the pilots since most of the HEMS flights have a unit flight time ranged around 25 minutes for SNEH, *i.e* 50 minutes back and forth (1 mission)ⁱ and this extension of the continuous flight time limitation will be used for a few and very specific missions. However, in order to ensure it does not have an impact on the fatigue of the crew member, FNAM and SNEH suggest using the possibility of having a 4 hours continuous flight time for single-pilots + TCM without autopilot under the principles of a FRM.

Thus, FNAM and SNEH propose for single-pilot + TCM without autopilot to:

- Have an augmentation of this limitation to 3 hours
- Increase the limitation to 4 hours under the principles of a FRM

Otherwise, it would be beneficial to further develop the RIA basing it on experience and safety records on this subject, in order to better assess the economic and social impacts in addition to the flight safety impact.

PROPOSAL

Replace the paragraph (b)(1) by the following: "(1) Continuous FT is limited in all cases to 4 hours with autopilot and to 3 hours without autopilot. These limitations can be increased by 1 hour under the principles of a FRM;"

response

Please see the answer to comment # 54

comment	484 comment by: FNAM/SNEH
	BREAK PERIODS for two-pilots HEMS operations (a)(1)(a)(2) ISSUE
	Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since flight times are unpredictable and cannot be scheduled within a FDP, the same has to be applied for breaks. Besides the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour.
	As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, the opportunity for a 1h hour break is warranted. Indeed, given the following aspects (Table 1 of this CS):
	 Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time with autopilot = 9 hours which means at least 3 to 5 no-flown hours



An agency of the European Union

• Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time without autopilot = 7 hours which means at least 5 to 7 no-flown hours

There is always a room for such a 1h break in a suitable accommodation at HEMS operating base.

Such a break may be monitored *ex-post* by the operator SMS, under the principles of the fatigue risk management.

Therefore, under the above risk analysis and under a monitoring following the principles of a fatigue risk management, FNAM and SNEH suggest writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the operation. (Cf. comment #498)

PROPOSAL

Rephrase the paragraph (a)(1) as follows:

"(1) For FDP over 12 hours, the operator ensures ex-post that at least one break of minimum 60 consecutive minutes within each FDP at the HEMS operating base at times that ensure likelihood of sleep and provides suitable accommodation for the purpose of breaks at the HEMS operating base. Fatigue risk management principles may be applied to monitor this break."

response

Please see the answer to comment # 54

comment	485 comment by: FNAM/SNEH
	Attachments <u>#90</u> <u>#91</u> <u>#92</u> <u>#93</u>
	Same comment as # 484.
response	Please see the answer to comment # 54

comment	486 comment by: FNAM/SNEH
	Attachments <u>#94</u> <u>#95</u> <u>#96</u> <u>#97</u> <u>#98</u>
	PRE AND POST FLIGHT MINIMUM TIME (Cf. attachments S1, S2, S3 and S4 illustrating this pre and post flight minimum time issue)
	(a3) and (b4) ISSUE FNAM and SNEH agree a minimum time shall be taken to ensure the safety of the flight:
	 Before the 1st flight of the crew, by preparing the aircraft, and After each flight, by reporting flight and aircraft information



Due to the life-threatening emergency operation in HEMS, these times shall be as short as possible to maximize operational availability and response time. In that way, in France, the contractual time for the National Health Authorities between the launch of a HEMS flight and the effective take-off is 7 minutes. Indeed, when a patient needs essential life-saving measures, after 30 minutes, there are almost no chance to save the life of the patient. Thus, the first patient of a FDP will have no chance of survival due to EASA proposition of having a minimum preflight time of 30 minutes at the beginning of the FDP. Moreover, French numbers underlines that 7%ⁱ of the HEMS take-off preformed within the first 30 minutes of the FDP. (Cf. SNEH illustrative Table in attachment)

Whatever the number of life that would not have been saved during these 30 minutes, no loss would be politically and socially acceptable.

With the same philosophy, the proposed requirement of having a minimum post flight period of 15 minutes at each HEMS operating base returns will reduce the chance of survival by 8 minutes for the next patient in case of close consecutive missions.

To illustrate those two issues, let's take the example of 2 unpredicted HEMS operations within the same FDP:

- 1st launch at the start of the FDP, at 8h00 with a mission with 2 flight times of 10 minutes (mission back and forth)
 - \circ $\;$ This requires a 30-minutes preflight then a 15-minute post flight
- 2nd launch at 12h00: no preflight required because the preflight has already been done
- Further operations: no preflight required as far as preflight is already done

This example highlights the lack of efficiency of having a long pre-flight at the beginning of the FDP before the first flight time and no preflight requirement for the following flight time though it occurs 4 hours after the initial checks.

Moreover, due to multiple flight times inside a unique FDP, FNAM and SNEH underline that the definition of post flight duty is non-consistent with the usual definition of post-flight:

- Which starts at the end (of the last FT) of the FDP
- Assuming the FDP ends with the last FT
- Though for HEMS operations FT are unpredictable and scheduled FDP may end long after the last effective FT

Thus, for HEMS operations, it is not clear if the post-flight does belong or not to the FDP depending on the end of the last FT.

This definition does not correspond to the definition of the proposal which defines a postflight after each flight time returning to HEMS operating base within the same FDP. Therefore, FNAM and SNEH suggest suppressing the post flight duties since they are confusing and replacing it by a proportionate pre-flight time before any take-off from the HEMS operating base.

**<u>*</u> T

For French HEMS services, the suitable accommodation is nearby the helicopter.

On the other hand, FNAM and SNEH agree these requirements do not apply for the Technical Crew Member since TCM function does not include the flight preparation. (Cf. comment #513)

In consequence, the proposal does not demonstrate safety improvement in all cases, in particular when several flight times are allocated in the same FDP and suppress life opportunity for the 1st patient if the emergency occurs in the first 30 minutes of the FDP and the next ones in case of airlift multiple rotations. Thus, FNAM and SNEH propose:

- To suppress the minimum duration of initial preflight of 30 minutes and to replace it by "a sufficient time determined by the operator and specified in the operating manual"; this proposal does not affect the commander's prerogatives since he remains the one to make the final decision regarding the take-off time
- To dissociate from the above the time for the operational preparation of further individual flight time
- To replace the notion of "post-flight" by "operational pre-flight at the HEMS operating base"
- To suppress the minimum duration of "operational pre-flight at the HEMS operating base" at and to replace it by "a sufficient time determined by the operator and specified in the operating manual" instead of the proposed required 15 minutes for the post-flight between 2 FT at the HEMS operating base

(Cf. comment #502)

PROPOSAL

Replace the paragraph (a)(3) and (b)(4) by the following:

"(a) [...]

(3) A sufficient time is determined by the operator and specified in the operating manual for the initial

pre-flight duties performed at the beginning of the FDP and for

operational pre-flight duties before each flight taking-off from the HEMS operating base."

"(b) [...]

(4) A sufficient time is determined by the operator and specified in the operating manual for the initial

pre-flight duties performed at the beginning of the FDP and for

operational pre-flight duties before each flight taking-off from the HEMS operating base. Pre-flights duties do not apply to TCM.". Pre-flights duties do not apply to TCM."

response

Please see the answer to comment # 54

comment	487	comment by: FNAM/SNEH
	(c)	

**** * * *** TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

* Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 261 of 585

ISSUEFNAM and SNEH highlight that the proposition in point (c) shall apply for both:• Two-pilots operations: Table 1; and• Single-pilot + 1 TCM operations: Table 2Indeed, the proposed mitigation is met in both operations by offering suitable
accommodation at HEMS operating base (Cf. point (b)(2) and (a)(1)): the rest and mitigated
resulting fatigue are the same thus the alleviation shall be the same.PROPOSAL
Replace paragraph(c) by the following:
"If the rest period before reporting for the FDP is taken at the HEMS operating base, the
limits of
Table 1 for two-pilots operations and Table 2 for single-pilot operations, for reporting times
between 0730-0959 also apply for reporting times between 0630-0729."responsePlease see the answer to comment # 54

comment 488

comment by: FNAM/SNEH

Attachments <u>#99</u> <u>#100</u> <u>#101</u> <u>#102</u>

SINGLE-PILOT + TCM TOTAL FT LIMITATION

(Cf. attachments S1, S2, S3 and S4 illustrating this total flight time limitation issue)

Table 2

ISSUE

FNAM and SNEH would like to highlight that the total flight time limitation for single-pilot + TCM operations without the use of autopilot are too restrictive especially the following ones:

- FDP starting between 06:30-06-59 => maximum total flight time = 3:30
- FDP starting between 12:00-13:59 => maximum total flight time = 3:30
- FDP starting between 4:00-06:29 => maximum total flight time = 3:00

There is no regulation in France on this subject for HEMS operations, with no reported inherent safety issue through experience.

A further developed RIA based on experience and safety records on this subject would be beneficial, in order to assess the economic and social impacts in addition to the flight safety impact.

In CAT provisions, when the operator has implemented a FRM, it is considered as a valuable mitigation to allow for the FDP to be increased by 1hour, in some cases.

Thus, in the same philosophy than for CAT operations, FNAM and SNEH propose to increase all total flight time limitations by 1 hour under the principles of a FRM.

PROPOSAL Add the following sentence below the Table 2: *"The maximum Flight Time in Table 2 can be increased by 1 hour under the principles of a FRM"*

response

Please see the answer to comment # 54

comment 489

comment by: FNAM/SNEH

Attachments <u>#103</u> <u>#104</u> <u>#105</u> <u>#106</u>

MITIGATION AFTER A BLOCK OF UP TO 4 CONSECUTIVE FDP OF MORE THAN 12 HOURS (Cf. attachments S1, S2, S3 and S4 illustrating the reduced rest and the 12h operational readiness issues)

(d)

ISSUE

On the one hand, FNAM and SNEH underline the French regulation historically proposes several rostering cycles for HEMS operations that are currently used with an excellent safety track record demonstrated by experience:

- 7 days ON / 7 days OFF with a limitation of 14 hours of duties for 24 hours
- 5 days ON / 2 days OFF with a limitation of 12 hours of duties for 24 hours
- 12 days ON / 6 days OFF with a limitation of 12 hours of duties for 24 hours

Therefore, most hospitals / HEMS organizations have a contractual engagement with the National Health Authority over a rolling 24 hours period: 12 hours of HEMS operative availability and 12 hours OFF.

According to the Agency requirement on the pre-flight and post-flight minimum times (Cf. #486), an HEMS organization will yet roster cycle with a FDP of 12h30 and a Duty Period of 12h45 to ensure they follow their engagement with hospitals. Thus, all HEMS operators will have to schedule:

- More than 12h FDP for each and every shift
- Reduced rest of more than 10h amongst a 11h15 available time for rest according to CS.FTL.3.235 to reengage at the same time the day after under the principles of a FRM

Moreover, FNAM and SNEH highlight that, due to short and continuous flight times with a total flight time limited per Table 2 and which are in average 1h30 per 12 hours of shifts

(with an average leg of 25 min for SNEH)ⁱ in France, the fatigue will not be an issue for FDP ranged from 12h up to 14h. Indeed, according to the requirements (a)(1) and (b)(2), all HEMS organizations shall provide suitable accommodation at the HEMS operating base, thus pilots can have breaks in comfortable places between two flight times. These pilots have to have their rest at the HEMS operating base which is considered as a mitigation measure.

This is also a safety improvement because the rest is at the HEMS operating base which is considered as a mitigation measure.

Furthermore, no demonstration nor RIA is given to justify the point (d), while the current rostering in France on this subject for HEMS operations has not reported inherent safety issue through experience.

On the other hand, most of the French pilots are "faux-basés", meaning they spend 7 days working at home base and then 7 days of rest at home which can be at 500 kilometers from home base. Therefore, most of French HEMS pilots prefer the cycle 7 days ON / 7 days OFF for their quality of life which will be limited by the requirement (d). Nevertheless, the provisions of (d) implies at least 4 days ON per 3 days OFF, which appears counterproductive for social issues and crew quality of life.

PROPOSAL

Replace paragraph (d) by the following:

"If an operator assigns two or more consecutive FDPs of more than 12h, the following conditions shall be met:

- 1. The rest period preceding the first FDP is at least 36 hours including 2 local nights; and
- 2. The rest period provided after completion of the series of consecutive FDPs is at least 60 hours including 3 local nights.

A block of more than 4 consecutive FDPs of more than 12hours can be scheduled under the principles of a FRM."

response

Please see the answer to comment # 54

comment 532

comment by: ADAC Luftrettung gGmbH

Maximum basic daily FDP in two-pilot HEMS operations according to table 1. For FDPs over 12 hours the operator ensures at least one break of minimum 60 minutes at times that ensure likelihood of sleep.

Question: What is the definition of the term "ensures likelihood of sleep" in practice? This completely contradicts the idea of availability times for rescue missions and is useless in HEMS. Therefore it must be deleted from the regulation completely.

Para. a2: The time for breaks constitutes 50% of the time over 12 hours. Question: Is time for breaks calculated by adding all break times but only one of them needs to be more than 60 minutes? Question: When does FDP start / is handover FDP or DT?

The definition of FDP according to ORO.FTL.105 (12) is based on the assumption that a crew member reports for duty that includes one or more sectors. This definition doesn't fit to HEMS operations. One basic principle of HEMS is that the crew awaits an incoming alert at the home base. Therefor when reporting for duty it is not sure if or when a mission alert and thus a sector will occur. Frequently the first mission takes place several hours after reporting without any sectors in between. This fact needs to be considered in the definition of FDP for HEMS, otherwise FDP and duty period are almost the same in HEMS operations. Compared to the current system this would pose a massive constraint for operators.

Possible solution:

Breaks of more than 60 minutes between sectors interrupt FDP.

Remark on table 1 and 2:

What's the origin of the times? What data is used to define them? There is no evidence of any scientific study of HEMS operation that could lead to such definitions. Especially maximum flight times for single pilot operation without autopilot (e.g. 03:00 hours) are much too restrictive. These time limitations are unacceptable particularly in comparison with other CAT helicopter operations that take place completely without autopilot.

Maximum basic daily FDP in single-pilot HEMS operations according to table 2. For FDPs over 10 hours the operator ensures at least one break of minimum 60 minutes at times that ensure likelihood of sleep.

Question: What is the definition of the term "ensures likelihood of sleep" in practice? This completely contradicts the idea of availability times for rescue missions and is useless in HEMS. Therefore, it must be deleted from the regulation completely.

Para. b3: The time for breaks constitutes 50% of the time over 10 hours.

Question: Is time for breaks calculated by adding all break times but only one of them needs to be more than 60 minutes?

Table 2: Maximum flight time limits are unacceptable, too low and presented without any data justification.

Possible solution after more than 40 years of HEMS operation:

Single pilot without autopilot: max. 5 h, single pilot with autopilot: max. 7 h.

Question: What limits are planned for CAT operations such as logging or other aerial work? They are flying most of their flights without autopilot, so their flight time limits must be even more restrictive than in HEMS. If not, this would be a disadvantage for HEMS operators.

The dependency between time of reporting for duty and maximum allowable flight time is not foreseen in CAT operations and therefor poses another disadvantage for HEMS operators.

As soon as the FDP is between 12 and 14 hours long a block of consecutive FDPs is limited to 4 days. The rest period preceding the first FDP is at least 36 hours including two local nights, the current system requires only 24 hours in advance. The rest period provided after completion of the series of consecutive FDPs is at least 60 hours including 3 local nights, the current system allows for 48 hours.

Question: Is travelling time in accordance with CS.FTL.3.200 (b) part of these 4 FDPs?



If this is the case it will reduce the time on base of each pilot during times with more than 12 hours FDP to 2-3 days. The use of reserve pilots for only 2 consecutive days would pose an economic burden to the operator.

Question: What happens on 24h bases in case of a single exceedance of the 12 hour FDP? Will the length of the duty block be automatically be shortened to 4 days instead of 7 as scheduled? This would lead to an additional limit regarding these bases, because they will have to change their current attractive 7 day blocks to 4 day blocks. This is expected to further reduce the attractivity of 24 h bases for pilots especially when they don't live close to their home base.

Split duty is not accounted for in this paragraph. Or is this paragraph not relevant for split duty? Using split duty would allow for FDP of more than 14 hours. Currently there is no further regulation provided for FDP of more than 14 hours.

response

Please see the answer to comment # 54

comment 553

comment by: Rüdiger Neu

Maximale Flugdienstzeit (FDP) bei 2-Piloten siehe Tabelle 1. Werden die 12 Stunden überschritten, muss mindestens eine zusammenhängende Stunde (> 60 Minuten) Pause an der Station eingehalten werden, mit der Wahrscheinlichkeit schlafen zu können. Fragestellung: Wie ist eine Wahrscheinlichkeit in der Praxis zu bewerten (time that ensure likelihood of sleep)? Dies ist absolut unpraktikabel, dieser Passus muss gestrichen werden.

Abs. a2: Die Summe der Pausen muss 50% der Zeit sein, die mehr als 12 Stunden beinhalten. Fragestellung: Berechnet sich die Pausenzeit der Summe aller Pausen, jedoch muss nur eine der Pausen > 60 Minuten sein?

Fragestellung: Wann beginnt FDP / Übergabezeiten FDP oder DT?

Die Definition der FDP nach ORO.FTL.105 Nr. 12 stellt darauf ab, dass der Dienst, zu dem sich das Besatzungsmitglied meldet, einen Flugabschnitt oder eine Abfolge von Flugabschnitten beinhaltet. Diese Definition passt für HEMS-Betrieb nicht. HEMS ist davon gekennzeichnet, dass die Besatzung an der home base auf die Alarmierung zu einem Einsatz wartet. Insofern ist bei der Anmeldung noch gar nicht absehbar, ob bzw. wann ein Flugabschnitt stattfindet. Es kommt regelmäßig vor, dass der erste Einsatz erst mehrere Stunden nach Anmeldung erfolgt. Dies muss im Rahmen der Definition Berücksichtigung finden, sonst wäre die FDP im Rahmen von HEMS-Betrieb nahezu deckungsgleich mit der Dienstzeit (duty period), was eine erhebliche Einschränkung der Betreiber im Gegensatz zum heutigen System darstellen würde. Eine mögliche Lösung wäre hier, dass Pausen zwischen einzelnen Einsätzen, die mindestens 60 zusammenhängende Minuten dauern, die FDP unterbrechen.

Anmerkung zu Table 1 und 2: woher kommen dieses Zeiten? Aufgrund welcher Datengrundlage wurde dies festgelegt? Es ist keine wissenschaftliche Studie zum HEMS-Betrieb ersichtlich oder genannt, die diese willkürlich festgelegten Zeiten belegt? Im Übrigen sind die maximalen Flugzeiten ohne Autopilot (Max FT without autopilot) insbesondere im Single-Pilot-Betrieb mit teilweise nur drei Stunden deutlich zu knapp

bemessen. Insbesondere im Vergleich zur Arbeitsfliegerei, die stets ohne Autopilot stattfindet, sind die hier festgelegten Zeiten geradezu inakzeptabel.

Maximale Flugdienstzeit (FDP) bei einem Piloten siehe Tabelle 2. Werden die 10 Stunden überschritten, muss mindestens eine zusammenhängende Stunde (> 60 Minuten) Pause an der Station eingehalten werden, mit der Wahrscheinlichkeit schlafen zu können. Fragestellung: Wie ist eine Wahrscheinlichkeit zu bewerten (time that ensure likelihood of sleep? Dies ist absolut unpraktikabel, dieser Passus muss gestrichen werden.

Abs. b3 Die Summe der Pausen muss 50% der Zeit sein, die mehr als 10 Stunden beinhalten. Fragestellung: Die Pausenzeit errechnet sich aus der Summe aller Pausen, jedoch muss nur eine der Pausen > 60 Minuten sein?

Table2: Die festgelegten max. Flugzeiten sind nicht akzeptabel, sind zu gering und entbehren jeglicher Grundlage. Zumindest sollten beim Betrieb mit einem Piloten und Autopilot (AP) die gleichen Flugstunden möglich sein, wie bei zwei Piloten. Der AP unterstützt das manuelle Fliegen genauso wie ein weiterer Pilot. Empfehlung: Ein Pilot ohne AP max. 5h, ein Pilot mit AP 7h.

Fragestellung: Wo liegen die Flugzeitenbeschränkungen bei CAT und der Arbeitsfliegerei? Werden dort noch geringere Flugzeiten festgelegt?

Eine Abhängigkeit zwischen dem Dienstbeginn und der max. Flugzeit ist ebenfalls nicht akzeptabel, wird auch nicht bei CAT unterschieden. Dies wäre eine unzulässige Ungleichbehandlung.

response

Please see the answer to comment # 54

comment	580 comment by: FinnHEMS Oy
	(a)(3)and a minimum of 15 minutes for post-flight duties for every flight returning to the HEMS operating base.
	COMMENT: A post flight duty cannot be required for every flight returning to the base. This means that during this 15 minute period no new missions cannot be accepted? It should be possible to react to a new mission directly after returning to the base.
response	Please see the answer to comment # 54
comment	590 comment by: NOLAS
	"(a) The home base is assigned to each crew member with a high degree of permanence and may either be:

(1) a single HEMS operating base; or

(2) multiple HEMS operating bases if the travelling time between any of these HEMS operating bases does not exceed 60 minutes under usual conditions."

Comment: This is sensible, however, how should this be handled for crew members that are working for more than one organization or operator? Especially HEMS technical crew members are often working for more than one organization or more than one operator providing HEMS. Furthermore, while it is sensible to have a home base assigned, it may be too restrictive in cases where crew members need to have to maintain recency on two different type of helicopters. How often would an operator be able to switch permanent home base (not a temporary change as in (b))?

Would it be feasible to have home base decided upon publication of roster provided that the roster is published long time enough in advance?

Furthermore, there is a need for clarification. The text as written could be interpreted as 60 minutes is between 60 minutes between all the HEMS operating bases in question or as 60 minutes between any two HEMS of them.

We also wonder where the 60 minutes come from. In "48. GM1 ORO.FTL.200 'TRAVELLING TIME'" 90 minutes is used. Wouldn't 90 minutes be as appropriate as 60 minutes?

response

Please see the answer to comment # 54

comment 591

comment by: NOLAS

"Maximum basic daily FDP in HEMS operations under ORO.FTL.205(b)(7)

(1) For FDPs of over 12 hours, the operator ensures at least one break of minimum 60 consecutive minutes or more within each FDP at the HEMS operating base at times that ensure likelihood of sleep and provides suitable accommodation for the purpose of breaks at the HEMS operating base;"

Comment: The concept of breaks for HEMS operations is not useable and should be handled differently by using a concept of "maximum active time" and "passive time" when calculating duty time. CAT.GEN.MPA.100(e)(1) already put the responsibility on commanders not to fly when fatigued. Furthermore, as the text is written, one could interpret this break would be in addition to the specific duration for a meal opportunity described in ORO.FTL.240 – Nutrition, which would be unnecessary.

Furthermore, the concept of breaks is very unclear, especially regarding how this should be planned. <u>Shall the break or breaks be pre-planned or may they have been achieved retrospectively?</u>

As mentioned in the comment to CS FTL.3.205 Flight duty period (FDP) — HEMS, NPA p 36 and CS FTL.3.210 Flight times and duty periods — HEMS, NPA p 75 below prescribing breaks is not a practicable solution and the concept of breaks is very unclear, especially regarding how this should be planned. An easier approach would be a concept comprising a maximum Duty Period with a maximum Flight Duty Period comprising "Passive time" and "Active time". Refer to explanation in comment to CS FTL.3.205 Flight duty period (FDP) — HEMS, NPA p 36 and CS FTL.3.210 Flight times and duty periods — HEMS, NPA p 75 below.



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 268 of 585

response	Please see the answer to comment # 54	
comment	592 comment by: NOLAS	
	(c) If the rest period before reporting for the FDP is taken at the HEMS operating base, th limits of Table 1 for reporting times between 0730-0959 also apply for reporting time between 0630–0729.	
	Comment: While our HEMS operating bases include suitable accommodation, there is not enough accommodation to cater for crew that are to report for duty. Furthermore, many HEMS operating bases in Europe does not have suitable accommodation at the base, but close by. This should be reflected. Suitable accommodation close to the HEMS operating base should be acceptable.	
response	Please see the answer to comment # 54	
comment	593 comment by: NOLAS	
	 (d) The operator may assign a block of up to 4 consecutive FDPs of more than 12 hours but less than 14 hours, if the following conditions are met: (1) the rest period preceding the first FDP is at least 36 hours including 2 local nights; and (2) the rest period provided after completion of the series of consecutive FDPs is at least 60 hours including 3 local nights. 	
	Comment: While not fully relevant for us, we note that this will make it impossible to have operation with a roster that includes 7 days on and then a long period off (1, 2 or 3 weeks) which is a common practice in HEMS operations. The increased number of commutes would increase both fatigue and incur substantial costs on the national health care systems.	
response	Please see the answer to comment # 54	
comment	594 comment by: NOLAS	
	"Maximum basic daily FDP in HEMS operations under ORO.FTL.205(b)(7) (2) For FDPs of over 10 hours, the operator ensures at least one break of minimum 60 consecutive minutes within each FDP at the HEMS operating base at times that ensure likelihood of sleep and provides suitable accommodation for the purpose of breaks at the HEMS operating base;"	
	Comment: In Norway 12+ hours Single Pilot HEMS has been common practice for close to 40 years without any incidents relating to fatigue. If the flight duty period is of a reasonable length, it is the number of duty periods that induced fatigue, not the length of the flight	



	duty period. Crews involved in HEMS operation typically have ample time for rest and food intake. <u>Prescribing breaks is not a practicable solution.</u>	
response	nse Please see the answer to comment # 54	
comment	661	comment by: Oya Vendée Hélicoptères
	CS FTL.3.205 Maximum basic daily FDP in HEMS under ORO.FTL.205 (b)(7)	
	There are two CS FTL.3.205 (with exactly the same title), which introduces complexity, uncertainty and may lead to misunderstanding. OYA suggests adding precisions in the title of this paragraph in order to quickly make the link with the ORO paragraph involved.	
	PROPOSAL Replace the title of this CS by: "CS FTL.3.20	05 (b)(7)"
response	Please see the answer to comment # 54	
comment	662	comment by: Oya Vendée Hélicoptères

CS FTL.3.205 Maximum basic daily FDP in HEMS under ORO.FTL.205 (b)(7)

REMARK

For small FT as currently operated in HEMS, it is possible to have multiple FDP within the same day.

For instance: One FDP from 07:00 to 8:30 followed by a 12h rest period and then a FDP from 20:30 to 22h.

response

Please see the answer to comment # 54

comment663comment by: Oya Vendée HélicoptèresAttachment #107CS FTL.3.205 Maximum basic daily FDP in HEMS under ORO.FTL.205 (b)(7)CONTINUOUS FLIGHT TIME LIMITATION IN SINGLE-PILOT + TCM
(Cf. attachment S4 illustrating this continuous flight time limitation in single-pilot + TCM issue)(b)(1)
ISSUE
OYA highlights the too restrictive limitation of total flight time for the single-pilot + TCM operations
(b)(1). Indeed, the proposal constrains the continuous flight time for single-pilot + TCM operations:



 TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.
 Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.
 Page 270 of 585

- with autopilot at 4 hours
- without autopilot at 2 hours

Some rescues and patient transportation, like severe burned patients, will not be possible with the 2 hours limitation without the autopilot. Indeed, these flights can be a haul from Lyon to Paris which lasts more than 2h and they are necessary because the transport by road is not considered sufficiently effective considering the patient's condition.

These flights are usually flown with lighter helicopter without autopilot because they can fly longer distances (4h30 of autonomy) than heavy helicopters. These flights are usually scheduled from a known helipad in a hospital to another known helipad in another hospital and correspond more to the scope of commercial sanitary flights not yet defined by EASA than the HEMS scope.

In addition, it is usual to keep the engine running (the rotor blades are still turning while loading the helicopter between two legs or three legs in case of a triangular mission, *i.e* the single-pilot + TCM take-off from the home base, pick up a patient at a given hospital to finally bring him at the planned hospital). Thus, according to the definition of a Flight Time in ORO.FTL.105(13), these two legs are considered as a unique flight time. In that way, the limitation of 2 hours for an equipage with a single-pilot + TCM is too restrictive.

Moreover, in HEMS, a single-pilot does not fly alone, he is assisted by a Technical Crew Member (which is a recent additional EASA requirement). In that way, the risk of fatigue is lower since the TCM is assisting the pilot in non-piloting tasks and is contributing to the safety of the flight. *De facto*, single-pilot HEMS operations are in fact 2 technical crews operations (1 pilot + 1 TCM). By parallelism, no such total flight time limitation has been defined for 2 technical crews operations (2 pilots).

No RIA is given to justify this proposal.

Besides, HEMS pilots are scarce resources in France, and this NPA would lead to hire 120 additional pilots and 120 additional TCM in order to offer the same quality of HEMS activity in France. This represents an additional cost of 20% for the whole French HEMS State Budget. It is likely that such a massive recruitment would not be achievable and would thus result in a significant reduction in the quality of the French Healthcare system. Considering the limited range of heavy helicopter with autopilot, the lack of ATPL(H) pilots in France (for acting as commander for 2 pilots HEMS operations) and considering the fleet currently assigned to hospitals in France (with single-pilot certified helicopter and no flight standard for 2 pilots operations), the sum of the previous constraints leads to the impossibility to transport this kind of patient by road or air.

It is necessary to increase the limitation of continuous flight time described in this paragraph. This will not have a major impact on the fatigue of the pilots since most of the HEMS flights have a unit flight time ranged around 25 minutes for OYA, *i.e* 50 minutes back and forth (1 mission)ⁱ and this extension of the continuous flight time limitation will be used for a few and very specific missions. However, in order to ensure it does not have an impact on the fatigue of the crew member, OYA suggests using the possibility of having a 4 hours continuous flight time for single-pilots + TCM without autopilot under the principles of a FRM.

Thus, OYA proposes for single-pilot + TCM without autopilot to:

- Have an augmentation of this limitation to 3 hours
- Increase the limitation to 4 hours under the principles of a FRM



An agency of the European Union

Otherwise, it would be beneficial to further develop the RIA basing it on experience and safety records on this subject, in order to better assess the economic and social impacts in addition to the flight safety impact.

PROPOSAL

Replace the paragraph (b)(1) by the following: *"(1) Continuous FT is limited in all cases to 4 hours with autopilot and to 3 hours without*

autopilot. These limitations can be increased by 1 hour under the principles of a FRM;"

response

Please see the answer to comment # 54

comment	664 comment by: <i>Oya Vendée Hélicoptères</i>
	BREAK PERIODS for two-pilots HEMS operations (a)(1)(a)(2) ISSUE Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since flight times are unpredictable and cannot be scheduled within a FDP, the same has to be applied for breaks. Besides the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour. As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, the opportunity for a 1h hour break is warranted. Indeed, given the following aspects (Table 1 of this CS):
	 Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time with autopilot = 9 hours which means at least 3 to 5 no-flown hours Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time without autopilot = 7 hours which means at least 5 to 7 no-flown hours
	There is always a room for such a 1h break in a suitable accommodation at HEMS operating base. Such a break may be monitored <i>ex-post</i> by the operator SMS, under the principles of the fatigue risk management. Therefore, under the above risk analysis and under a monitoring following the principles of a fatigue risk management, OYA suggests writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the operation. (Cf. comment #678)
	PROPOSAL Rephrase the paragraph (a)(1) as follows:

 TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.
 Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.
 Page 272 of 585

"(1) For FDP over 12 hours, the operator ensures ex-post that at least one break of minimum 60 consecutive minutes within each FDP at the HEMS operating base at times that ensure likelihood of sleep and provides suitable accommodation for the purpose of breaks at the HEMS operating base. Fatigue risk management principles may be applied to monitor this break."

response

Please see the answer to comment # 54

comment 665

comment by: Oya Vendée Hélicoptères

Attachments #108 #109 #110 #111

BREAK PERIODS for single-pilot + TCM HEMS operations Cf. attachments S1, S2, S3 and S4 illustrating this break issue

(b)(2)(b)(3) ISSUE

Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since flight times are unpredictable and cannot be scheduled within a FDP, the same has to be applied for breaks. Besides the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour.

As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, the opportunity for a break lasting between 2h and 1h is warranted. Indeed, given the following aspects (Table 2 of this CS):

- Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours for break with a maximum Total Flight Time with autopilot = 7 hours which means at least 5 to 7 no-flown hours
- Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours for break with a maximum Total Flight Time without autopilot = 5 hours which means at least 7 to 9 no-flown hours

There is always a room for such a break lasting between 2h and 1h in a suitable accommodation at HEMS operating base.

Such a break may be monitored *ex-post* by the operator SMS, under the principles of the fatigue risk management.

Therefore, under the above risk analysis and under a monitoring following the principles of a fatigue risk management, OYA suggests writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the operation. (Cf. comment #678)

PROPOSAL Rephrase the paragraph (b)(2) as follows:



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 273 of 585 "(2) For FDP over 10 hours, the operator ensures ex-post that at least one break of minimum 60 consecutive minutes within each FDP at the HEMS operating base at times that ensure likelihood of sleep and provides suitable accommodation for the purpose of breaks at the HEMS operating base. Fatigue risk management principles may be applied to monitor this break."

response

Please see the answer to comment # 54

comment 666

comment by: Oya Vendée Hélicoptères

Attachments #112 #113 #114 #115 #116

PRE AND POST FLIGHT MINIMUM TIME (Cf. attachments S1, S2, S3 and S4 illustrating this pre and post flight minimum time issue)

(a3) and (b4) ISSUE OYA agrees a minimum time shall be taken to ensure the safety of the flight:

- Before the 1st flight of the crew, by preparing the aircraft, and
- After each flight, by reporting flight and aircraft information

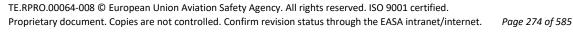
Due to the life-threatening emergency operation in HEMS, these times shall be as short as possible to maximize operational availability and response time. In that way, in France, the contractual time for the National Health Authorities between the launch of a HEMS flight and the effective take-off is 7 minutes. Indeed, when a patient needs essential life-saving measures, after 30 minutes, there are almost no chance to save the life of the patient. Thus, the first patient of a FDP will have no chance of survival due to EASA proposition of having a minimum preflight time of 30 minutes at the beginning of the FDP. Moreover, French numbers underlines that 7%ⁱ of the HEMS take-off preformed within the first 30 minutes of the FDP. (Cf. SNEH illustrative Table in attachment)

Whatever the number of life that would not have been saved during these 30 minutes, no loss would be politically and socially acceptable.

With the same philosophy, the proposed requirement of having a minimum post flight period of 15 minutes at each HEMS operating base returns will reduce the chance of survival by 8 minutes for the next patient in case of close consecutive missions.

To illustrate those two issues, let's take the example of 2 unpredicted HEMS operations within the same FDP:

- 1st launch at the start of the FDP, at 8h00 with a mission with 2 flight times of 10 minutes (mission back and forth)
 - This requires a 30-minutes preflight then a 15-minute post flight
- 2nd launch at 12h00: no preflight required because the preflight has already been done



• Further operations: no preflight required as far as preflight is already done

This example highlights the lack of efficiency of having a long pre-flight at the beginning of the FDP before the first flight time and no preflight requirement for the following flight time though it occurs 4 hours after the initial checks.

Moreover, due to multiple flight times inside a unique FDP, OYA underlines that the definition of post flight duty is non-consistent with the usual definition of post-flight:

- Which starts at the end (of the last FT) of the FDP
- Assuming the FDP ends with the last FT
- Though for HEMS operations FT are unpredictable and scheduled FDP may end long after the last effective FT

Thus, for HEMS operations, it is not clear if the post-flight does belong or not to the FDP depending on the end of the last FT.

This definition does not correspond to the definition of the proposal which defines a post-flight after each flight time returning to HEMS operating base within the same FDP. Therefore, OYA suggests suppressing the post flight duties since they are confusing and replacing it by a proportionate pre-flight time before any take-off from the HEMS operating base.

For French HEMS services, the suitable accommodation is nearby the helicopter.

On the other hand, OYA agrees these requirements do not apply for the Technical Crew Member since TCM function does not include the flight preparation. (Cf. comment #692)

In consequence, the proposal does not demonstrate safety improvement in all cases, in particular when several flight times are allocated in the same FDP and suppress life opportunity for the 1st patient if the emergency occurs in the first 30 minutes of the FDP and the next ones in case of airlift multiple rotations. Thus, OYA proposes:

- To suppress the minimum duration of initial preflight of 30 minutes and to replace it by "a sufficient time determined by the operator and specified in the operating manual"; this proposal does not affect the commander's prerogatives since he remains the one to make the final decision regarding the take-off time
- To dissociate from the above the time for the operational preparation of further individual flight time
- To replace the notion of "post-flight" by "operational pre-flight at the HEMS operating base"
- To suppress the minimum duration of "operational pre-flight at the HEMS operating base" at and to replace it by "a sufficient time determined by the operator and specified in the operating manual" instead of the proposed required 15 minutes for the post-flight between 2 FT at the HEMS operating base

**** * * (Cf. comment #682)
PROPOSAL
Replace the paragraph (a)(3) and (b)(4) by the following:
"(a) [...]
(3) A sufficient time is determined by the operator and specified in the operating manual for the
initial
pre-flight duties performed at the beginning of the FDP and for
operational pre-flight duties before each flight taking-off from the HEMS operating base."
"(b) [...]
(4) A sufficient time is determined by the operator and specified in the operating manual for the
initial

pre-flight duties performed at the beginning of the FDP and for

operational pre-flight duties before each flight taking-off from the HEMS operating base. Preflights duties do not apply to TCM.". Pre-flights duties do not apply to TCM."

response

Please see the answer to comment # 54

comment	667 comment by: <i>Oya Vendée Hélicoptères</i>
	(c) ISSUE OYA highlights that the proposition in point (c) shall apply for both:
 Two-pilots operations: Table 1; and Single-pilot + 1 TCM operations: Table 2 	
	Indeed, the proposed mitigation is met in both operations by offering suitable accommodation at HEMS operating base (Cf. point (b)(2) and (a)(1)): the rest and mitigated resulting fatigue are the same thus the alleviation shall be the same.
	PROPOSAL Replace paragraph(c) by the following: "If the rest period before reporting for the FDP is taken at the HEMS operating base, the
	limits of Table 1 for two-pilots operations and Table 2 for single-pilot operations, for reporting times between 0730-0959 also apply for reporting times between 0630-0729."
response	Please see the answer to comment # 54



comment	668	comment by: Oya Vendée Hélicoptères
	Attachments <u>#117</u> <u>#118</u> <u>#119</u> <u>#120</u>	
	SINGLE-PILOT + TCM TOTAL FT LIMITA (Cf. attachments S1, S2, S3 and S4 illus	TION strating this total flight time limitation issue)
		total flight time limitation for single-pilot + TCM ot are too restrictive especially the following ones:
	• FDP starting between 12:00-1	6-59 => maximum total flight time = 3:30 3:59 => maximum total flight time = 3:30 :29 => maximum total flight time = 3:00
	inherent safety issue through experien A further developed RIA based on exp	his subject for HEMS operations, with no reported nce. erience and safety records on this subject would be omic and social impacts in addition to the flight safety
In CAT provisions, when the operator has implemented a FRM, it is considered mitigation to allow for the FDP to be increased by 1hour, in some cases. Thus, in the same philosophy than for CAT operations, OYA proposes to in flight time limitations by 1 hour under the principles of a FRM.		ncreased by 1hour, in some cases. CAT operations, OYA proposes to increase all total
	PROPOSAL Add the following sentence below the <i>"The maximum Flight Time in Table 2</i> <i>FRM"</i>	Table 2: can be increased by 1 hour under the principles of a
response	Please see the answer to comment # 54	
comment	669	comment by: Oya Vendée Hélicoptères
	Attachments <u>#121</u> <u>#122</u> <u>#123</u> <u>#124</u>	
		0 4 CONSECUTIVE FDP OF MORE THAN 12 HOURS ustrating the reduced rest and the 12h operational
	(d)	

(a) ISSUE

**** **** On the one hand, OYA underlines the French regulation historically proposes several rostering cycles for HEMS operations that are currently used with an excellent safety track record demonstrated by experience:

- 7 days ON / 7 days OFF with a limitation of 14 hours of duties for 24 hours
- 5 days ON / 2 days OFF with a limitation of 12 hours of duties for 24 hours
- 12 days ON / 6 days OFF with a limitation of 12 hours of duties for 24 hours

Therefore, most hospitals / HEMS organizations have a contractual engagement with the National Health Authority over a rolling 24 hours period: 12 hours of HEMS operative availability and 12 hours OFF.

According to the Agency requirement on the pre-flight and post-flight minimum times (Cf. #666), an HEMS organization will yet roster cycle with a FDP of 12h30 and a Duty Period of 12h45 to ensure they follow their engagement with hospitals. Thus, all HEMS operators will have to schedule:

- More than 12h FDP for each and every shift
- Reduced rest of more than 10h amongst a 11h15 available time for rest according to CS.FTL.3.235 to reengage at the same time the day after under the principles of a FRM

Moreover, OYA highlights that, due to short and continuous flight times with a total flight time limited per Table 2 and which are in average 1h30 per 12 hours of shifts (with an average leg of 25 min for OYA)ⁱ in France, the fatigue will not be an issue for FDP ranged from 12h up to 14h. Indeed, according to the requirements (a)(1) and (b)(2), all HEMS organizations shall provide suitable accommodation at the HEMS operating base, thus pilots can have breaks in comfortable places between two flight times. These pilots have to have their rest at the HEMS operating base which is considered as a mitigation measure. This is also a safety improvement because the rest is at the HEMS operating base which is considered as a mitigation measure.

Furthermore, no demonstration nor RIA is given to justify the point (d), while the current rostering in France on this subject for HEMS operations has not reported inherent safety issue through experience.

On the other hand, most of the French pilots are "faux-basés", meaning they spend 7 days working at home base and then 7 days of rest at home which can be at 500 kilometers from home base. Therefore, most of French HEMS pilots prefer the cycle 7 days ON / 7 days OFF for their quality of life which will be limited by the requirement (d). Nevertheless, the provisions of (d) implies at least 4 days ON per 3 days OFF, which appears counterproductive for social issues and crew quality of life.

PROPOSAL

Replace paragraph (d) by the following: "If an operator assigns two or more consecutive FDPs of more than 12h, the following conditions shall be met:



- 1. The rest period preceding the first FDP is at least 36 hours including 2 local nights; and
- 2. The rest period provided after completion of the series of consecutive FDPs is at least 60 hours including 3 local nights.

A block of more than 4 consecutive FDPs of more than 12hours can be scheduled under the principles of a FRM."

response

Please see the answer to comment # 54

comment 712

comment by: ÖAMTC Helicopter Air Rescue (Austria)

Bearing in mind a circadian rhythm, reporting times after BCMT cannot be considered as abnormal working time. Most percentage of the working population starts work in the early morning which constitutes a biological high. The limitation off flight time implies anyway periods of times with low work load. Nevertheless the complex calculation scheme might stress a flight crew even more. Applying this scheme would force the crews to turn down missions during a normal working day in order to implement up to 3 hours of break, this has as a result a negative impact of the availability of the service. In the contrary to EASAs original intention of creating a system with more rest period, this system actually allows less free time. E.g. the operator has to apply a 4 by 4 days roster as otherwise it wouldn't work out with the required local nights. Unfortunately this would mean that an employee would have duty on a minimum of 4 consecutive weekends. Highly negative social impact (just as a social thought this would mean that a relation with a non-aviation related partner, the couple wouldn't meet for a month) Considering that flight crews might not live in the vicinity of the base, this means during a four day off period two days are used for traveling to and from the base only two days are left. If positioning is part of duty time this would limit the period to the maximum of two days with one day of positioning upfront and one day of positioning after the duty.

Pilot's duties are more than the actual HEMS duties. All kinds of tactical trainings on the bases, CRM classes, pilots meetings, trainings for other crewmembers, simulator checks can with this system not be done anymore. Flight crew members are challenged enough to preserve the service. Additional HR costs ranging from 30-45% across Europe would be the result as well as way less proficiency of pilots due to less flight time in probably the same amount and thus a growing safety risk. This is killing the HEMS philosophy!

response

Please see the answer to comment # 54

comment 713

comment by: ÖAMTC Helicopter Air Rescue (Austria)

Table 2 Maximum FT with autopilot

We appreciate considering autopilot systems as a support for the flight crew. But in view of the fact that AP systems create a complex work environment we do not understand that not using the AP reduces average flight time up to 2 (!!!) hours per day (This reduction

	seems not to be an evidenced based approach). An average leg in the air rescue throughout Austria is just above 8min. In most missions this puts the use of AP systems in question (also bear in mind that this means flights through valleys).		
response	Please see the answer to comment # 54		
comment	715 comment by: ÖAMTC Helicopter Air Rescue (Austria)		
	CS FLT 3.205(b)		
	This means that crew will be tempted to turn down missions in the last hour of duty, because for a flight to a trauma center taking more than an hour, crews would be condemned to remain on ground on the hospital (and not being able to return to their homebase). This would mean:		
	 That there is no helicopter available for this specific region anymore The hospital's landing site is blocked for at least another 10 hours (affecting the capacity of the hospital and therefore affecting the health care of third patients) Following multiple other effects like the fact that the helicopter cannot be protected against adverse weather conditions on the hospital site, no adequate protection can be provided 		
response	Please see the answer to comment # 54		
comment	716 comment by: ÖAMTC Helicopter Air Rescue (Austria)		
	CS FTL.3.205(b)(2)		
	[] FDPs over 10 hours, the operator ensures at least one brak of minimum 60 consecutive minutes []		
	Analyzing over 12.000 duty days in the last two years there are only 0,21% of the days which had not 80 consecutive minutes of break (60min + post flight duties). These numbers are for the Austrian duty roster currently allowing up to 15.5h FDP per day.		
response	Please see the answer to comment # 54		
comment	717 comment by: ÖAMTC Helicopter Air Rescue (Austria)		
	CS FTL.3.205(b)(4)		
	[] and a minimum of 15 minutes for post-flight duties for <u>every</u> flight []		

	For every flight? Meaning for six flights post flight duties would require 1,5 hours. Bear in mind that there might be consecutive missions. Post flight duties always require the same amount of time, no matter how many legs. Does this means during this 15min period no new missions may be accepted?		
response	Please see the answer to comment # 54		
comment	718 comment by: ÖAMTC Helicopter Air Rescue (Austria)		
	CS FTL.3.205 (b)(2)		
	HEMS is a non-projectable operation throughout a shift. We do not know when we are dispatched or to which kind of missions. Any mission could turn out way longer, weather might change or patient status requires different attention so planning a 60 minute break ahead would not consider the possible fatal impact on a patient compared to a very manageable low advantage for pilot's fatigue.		
response	Please see the answer to comment # 54		
comment	719 comment by: ÖAMTC Helicopter Air Rescue (Austria)		
	CS FTL.3.205 (c)		
	Shouldn`t this include table 2?		
response	Please see the answer to comment # 54		
comment	723 comment by: ADAC		
	Es ist von vorne herein nie vorhersehbar, wie lange ein Einsatz dauert - daher ist diese Regelung praxisfremd. HEMS-Operation beinhaltet für den Piloten zudem viele Pausen, auch vor Ort, während denen er sich nicht an Bord befindet oder konzentrieren muss. Es ist anders als in der Linienfliegerei über dem Atlantic, wo ein Pilot nicht "Weg" kann. Die Regelung steht im Konflikt mit einer effiziente Einsatzdurchführung und Patientenversorgung.		
response	Please see the answer to comment # 54		
comment	744 comment by: DRF-Luftrettung		
	(I) Maximum basic daily FDP in two-pilot HEMS operations according to table 1. For FDPs over12hours the operator ensures at least one break of minimum 60 minutes at times that ensure likelihood of sleep.		

Question: What is the definition of the term "ensures likelihood of sleep" in practice? This completely contradicts the idea of availability times for rescue missions and is useless in HEMS. Therefore it must be deleted from the regulation completely. (II) The time for breaks constitutes 50% of the time over 12 hours. Question: Is time for breaks calculated by adding all break times but only one of them needs to be more than 60 minutes? Question: When does FDP start / is handover FDP or DT? (III) The definition of FDP according to ORO.FTL.105 (12) is based on the assumption that a crew member reports for duty that includes one or more sectors. This definition doesn't fit to HEMS operations. One basic principle of HEMS is that the crew awaits an incoming alert at the home base. Therefor when reporting for duty it is not sure if or when a mission alert and thus a sector will occur. Frequently the first mission takes place several hours after reporting without any sectors in between. This fact needs to be considered in the definition of FDP for HEMS, otherwise FDP and duty period are almost the same in HEMS operations. Compared to the current system this would pose a massive constraint for operators. Possible solution: Breaks of more than 60 minutes between sectors interrupt FDP. (IV) Remark on table 1 and 2: What's the origin of the times? What data is used to define them? There is no evidence of any scientific study of HEMS operation that could lead to such definitions. Especially maximum flight times for single pilot operation without autopilot (e.g. 03:00 hours) are much too restrictive. These time limitations are unacceptable particularly in comparison with other CAT helicopter operations that take place completely without autopilot Please see the answer to comment # 54 response 745 comment comment by: DRF-Luftrettung (I) Maximum basic daily FDP in single-pilot HEMS operations according to table 2. For FDPs over 10 hours the operator ensures at least one break of minimum 60 minutes at times that ensure likelihood of sleep.

Question: What is the definition of the term "ensures likelihood of sleep" in practice? This

completely contradicts the idea of availability times for rescue missions and is useless in HEMS.

Therefore, it must be deleted from the regulation completely.

(II) he time for breaks constitutes 50% of the time over 10 hours.



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 282 of 585

Question: Is time for breaks calculated by adding all break times but only one of them needs to be more than 60 minutes? (III)Table 2: Maximum flight time limits are unacceptable, too low and presented without any data justification. Possible solution after more than 40 years of HEMS operation: Single pilot without autopilot: max. 5 h, single pilot with autopilot: max. 7 h. (IV) Question: What limits are planned for CAT operations such as logging or other aerial work? They are flying most of their flights without autopilot, so their flight time limits must be even more restrictive than in HEMS. If not, this would be a disadvantage for HEMS operators. The dependency between time of reporting for duty and maximum allowable flight time is not foreseen in CAT operations and therefor poses another disadvantage for HEMS operators. Please see the answer to comment # 54 response

comment	753 comment by: DRF-Luftrettung	
	HEMS Service is unpredictable and after returning to the base the next alert may start after 3 or 4 minutes. Nobody can grant this 15 min period without interfering with the rescue order.	
	Solution: Minimum of 15 minutes for post flight duties at the end of the day	
response	Please see the answer to comment # 54	
comment	756 comment by: DRF-Luftrettung	
	For FDP of 14 hours the time of break has to be 2 hours (50% of the time over 10 hours) but only one has to be consecutive. That means, that any period (i.e 6 x10 minutes) fits into this scheme. The administrative implementation is very exaggerated	
	Solution: Delete sub paragraph 3 in total	
response	Please see the answer to comment # 54	

comment 783 comment by: AECA helicopteros. Regarding the 60 minutes break, is a generic knowledge enough for the pilot or should there be an explicit communication of the start of this break at every opportunity? (page 34) 1) For FDPs of over 12 hours, the operator ensures at least one break of minimum 60 consecutive minutes or more within each FDP at the HEMS operating base at times that ensure likelihood of sleep and provides suitable accommodation for the purpose of breaks at the HEMS operating base; Please see the answer to comment # 54 response comment 784 comment by: AECA helicopteros. 1) For FDPs of over 12 hours, the operator ensures at least one break of minimum 60 consecutive minutes or more within each FDP at the HEMS operating base at times that ensure likelihood of sleep and provides suitable accommodation for the purpose of breaks at the HEMS operating base; Question needing answer by regulation In case of emergency this break could be interrupted to assign duties? Please see the answer to comment # 54 response comment 785 comment by: AECA helicopteros. Tables 1 y 2.- Column "Start of FDP at reference time" Change first and last line, as follows: Sunset-06:59 12:00-16.59 17.00- Sunset Justification.- The proposed classification of the time period is probably valid in the north and center of Europe, but it does not make sense in southern Europe, where 14:00 may be the period of maximum activity with more than 7 hours of light per day ahead in some months of the year. Our proposal is that an adaptation should be allowed to each State, according to its geographical situation. Please see the answer to comment # 54 response

comment 790

comment by: AECA helicopteros.

Table 1 and 2

Column.- Maximum FT without autopilot

Proposal.- Delete column in both tables.

Justification.- Table 1.- "Acclimatised crew members in two pilots HEMS operations", we think that the fact of not carrying an autopilot should not affect the maximum FT since tasks are shared. And in any case, the proposed reduction between 22% and 28% of the hours in the case of having an autopilot, will be unacceptable, putting at risk the adequate provision of the services.

Justification.- Table 2.- "Acclimatised crew members in single pilot HEMS operations", The exaggerated reduction of the proposed FDP time could make the emergency service useless. It would be necessary to stop the activity in some cases, for example, at 3:00 hours, in times of possible maximum activity.

As we told in a previous comment at 14.00h in southern Europe, we are in a period of maximum activity with more than 7 hours of light ahead. For example, in Spain, during the months of April to August, most of the days the sunset is above 21.00 hours.

Or it would be necessary to schedule three or more crews to carry out the service and that does not seem feasible.

response

Please see the answer to comment # 54

comment 791 comment by: AECA helicopteros. CS FTL.3.205. Table 1 and table 2.-In casethat our previous comment (790) was not accepted, change as follows Proposed text: Change "autopilot" to "long term attitude retention system (force-trim) Justification. The maximum flight time for acclimatised crew members (helicopters) limits depend on whether the helicopter has (or hasn't) "autopilot". The definition of autopilot differs from each manufacturer, getting confused about what is the component needed to fulfil (or don't fulfil) the requirement to fly up to one or other limit. We understand that the motivation to limit the maximum flight time is the fatigue cause in case the helicopter requires a pilot to fly all the time hands-on with any kind of system installed which provides a long term attitude retention system for pitch and roll. Common known to have a force trim system which requires an "autopilot" connected Please see the answer to comment # 54 response

comment	818 comment by: Babcock Mission Critical Services Limited		
	The proposed requirement to have a 60-minute break during the FDP is not compatible with the provision of emergency service operations, where by their nature it is not possible to predict when the emergency will occur.		
	How does EASA propose the service is maintained? By the use of additional pilots?		
response	Please see the answer to comment # 54		
comment	819 comment by: Babcock Mission Critical Services Limited		
	Maximum basic daily FDP in hours — Acclimatised crew members in single-pilot HEMS operations		
	As it is the table 2 for single-pilot HEMS operations it will disrupt the existing roster of 7 days on 7 days off, increasing enormously the operational HEMS cost for the companies and for the National Health Care Systems.		
	We propose to add a point e) allowing a block of max 7 consecutive FDP of 13 hours.		
	This will be in accordance at the max FDP of 110 hours per 14 days (13 hours x 7 days =91 hours) and it will assure a daily rest of 11 hours at the HEMS home base.		
	The rest period preceding the first FDP and the rest period provided after completion of a series of FDP is proportional augmented compare to the point d) in order to assure a max FDP of 91 hours in a 14 days period as a compensation.		
	"(e) The operator may assign a block of up to 7 consecutive FDPs of more than 12 hours, up to 13 hours, if the following conditions are met:		
	(1) the rest period preceding the first FDP is at least 48 hours including 3 local nights; and		
	(2) the rest period provided after completion of the series of consecutive FDPs is at least 96 hours including 4 local nights. "		
response	Please see the answer to comment # 54		

comment 821

comment by: Babcock Mission Critical Services Limited

What we (do/)don't agree with;

(c) If the rest period before reporting for the FDP is taken *at the HEMS operating base*, the limits of Table 1 for reporting times between 0730-0959 also apply for reporting times between 0630–0729.



o Why we (do/)don't agree with it;

We are not the owners of our HEMS operating base and we can't provide an arrangement for the crew but we provide comfortable hotels accommodation close to the base with the same amount of hours in term of sleep opportunities.

o What we suggest as an alternative

CS FTL.3.205 Flight duty period (FDP)

(a) If the rest period before reporting for the FDP is taken at the HEMS operating base *or at a suitable accommodation close to the HEMS operating base*, the limits of Table 1 for reporting times between 0730-0959 also apply for reporting times between 0630–0729.

response

Please see the answer to comment # 54

comment	827 comment by: Babcock Mission Critical Services Limited		
	We find the layout and alphanumeric referencing within CS.FTL.x.205 to be ambiguous a hence confusing.		
	In each case, there is more than one instance of the heading, but with different suffix e.g. – AEMS, - ATX and AEMS, - HEMS, etc. and in some cases the only differentiation is t line of text <i>below</i> the header in <i>italics</i> .		
	We recommend that EASA revises the layout of these requirements and/or provide unique alphanumeric references in each case, in order to remove ambiguity and potential confusion, and for ease of reference.		
response	Please see the answer to comment # 54		

comment	834 comm	nent by: Babcock Mission Critical Services Limited		
	EASA does not appear to consider the positive impact of the HCM in single pilot op we believe such operations would be comparable to two-pilot HEMS operations we suggest the following changes:			
	CS FTL.3.205 Flight duty period (FDP) — HEMS			
	Maximum basic daily FDP in HEMS opera	tions under ORO.FTL.205(b)(7)		
	The maximum basic daily FDP withou members in HEMS operations is establish	t the use of extensions for acclimatised crew ned as follows:		



	(a) For two-pilot HEMS operations <i>and single pilot operations with a HEMS Crew Member</i> , the basic maximum daily FDP and the maximum flight time within that FDP are established in accordance with Table 1 and comply with the following conditions		
response	Please see the answer to comment # 54		
comment	837 comment by: Yorkshire Air Ambulance		
	The concept of breaks for HEMS operations is unnecessary because CAT.GEN.MPA.100(e)(1) already places an obligation on commanders not to fly when fatigued. An appropriate statement to this effect would be better justified. Also, the text indicates such breaks are in addition to operators providing a specific duration for a meal opportunity, as described at ORO.FTL.240 - Nutrition.		
response	Please see the answer to comment # 54		
comment	838 comment by: Yorkshire Air Ambulance		
	The requirement for breaks in suitable accommodation will have a significant negative impact for delivery of a HEMS service.		
response	Please see the answer to comment # 54		
comment	839 comment by: Yorkshire Air Ambulance		
	By my calculations, this means a one-hour break every 14-hour FDP.		
response	Please see the answer to comment # 54		
comment	840 comment by: Yorkshire Air Ambulance		
	Specifying fifteen-minute post-flight duties after every flight returning to the HEMS operating base is completely unacceptable. What is the rationale for introducing such a limit? For most HEMS units doing several missions every day, this could result in an additional hour of aircraft unavailability. Curiously, the text only specifies a HEMS operating base, and not if the aircraft pre-positions elsewhere?		
response	Please see the answer to comment # 54		



comment	841 comment by: Yorkshire Air Ambulance
	In the UK, 12-hour SP HEMS shifts have been commonplace for many years, without any fatigue-related incidents. Cumulative duty periods induce tiredness, not the length of a single FDP (within reason). HEMS pilots have plenty of time in a normal shift to rest, and achieve comfort and food breaks. Introducing a prescriptive break is punitive and antithesis to the HEMS philosophy.
response	Please see the answer to comment # 54
comment	842 comment by: Yorkshire Air Ambulance
	The introduction of a one-hour break in an FDP>10 hours is contradicted by the rationale text in para. 34 which states: "Basic maximum FDPs of more than 12 hours are possible only if crew members can benefit from at least one break of at least 60 consecutive minutes."
response	Please see the answer to comment # 54
comment	936 comment by: MBH SAMU
	CS FTL.3.205 Maximum basic daily FDP in HEMS under ORO.FTL.205 (b)(7)
	There are two CS FTL.3.205 (with exactly the same title), which introduces complexity, uncertainty and may lead to misunderstanding. MBH suggests adding precisions in the title of this paragraph in order to quickly make the link with the ORO paragraph involved.
	PROPOSAL
	Replace the title of this CS by: "CS FTL.3.205 (b)(7)"
response	Please see the answer to comment # 54
comment	938 comment by: MBH SAMU
	CS FTL.3.205 Maximum basic daily FDP in HEMS under ORO.FTL.205 (b)(7)
	REMARK For small FT as currently operated in HEMS, it is possible to have multiple FDP within the same day. For instance: One FDP from 07:00 to 8:30 followed by a 12h rest period and then a FDP from 20:30 to 22h.
response	Please see the answer to comment # 54
response	



comment 939

comment by: MBH SAMU

Attachment #125

CS FTL.3.205 Maximum basic daily FDP in HEMS under ORO.FTL.205 (b)(7)

CONTINUOUS FLIGHT TIME LIMITATION IN SINGLE-PILOT + TCM

(Cf. attachment S4 illustrating this continuous flight time limitation in single-pilot + TCM issue)

(b)(1)

ISSUE

MBH highlights the too restrictive limitation of total flight time for the single-pilot + TCM operations (b)(1). Indeed, the proposal constrains the continuous flight time for single-pilot + TCM operations:

- with autopilot at 4 hours
- without autopilot at 2 hours

Some rescues and patient transportation, like severe burned patients, will not be possible with the 2 hours limitation without the autopilot. Indeed, these flights can be a haul from Lyon to Paris which lasts more than 2h and they are necessary because the transport by road is not considered sufficiently effective considering the patient's condition.

These flights are usually flown with lighter helicopter without autopilot because they can fly longer distances (4h30 of autonomy) than heavy helicopters. These flights are usually scheduled from a known helipad in a hospital to another known helipad in another hospital and correspond more to the scope of commercial sanitary flights not yet defined by EASA than the HEMS scope.

In addition, it is usual to keep the engine running (the rotor blades are still turning while loading the helicopter between two legs or three legs in case of a triangular mission, *i.e* the single-pilot + TCM take-off from the home base, pick up a patient at a given hospital to finally bring him at the planned hospital). Thus, according to the definition of a Flight Time in ORO.FTL.105(13), these two legs are considered as a unique flight time. In that way, the limitation of 2 hours for an equipage with a single-pilot + TCM is too restrictive.

Moreover, in HEMS, a single-pilot does not fly alone, he is assisted by a Technical Crew Member (which is a recent additional EASA requirement). In that way, the risk of fatigue is lower since the TCM is assisting the pilot in non-piloting tasks and is contributing to the safety of the flight. *De facto*, single-pilot HEMS operations are in fact 2 technical crews operations (1 pilot + 1 TCM). By parallelism, no such total flight time limitation has been defined for 2 technical crews operations (2 pilots).

No RIA is given to justify this proposal.

Besides, HEMS pilots are scarce resources in France, and this NPA would lead to hire 120 additional pilots and 120 additional TCM in order to offer the same quality of HEMS activity in France. This represents an additional cost of 20% for the whole French HEMS State

Budget. It is likely that such a massive recruitment would not be achievable and would thus result in a significant reduction in the quality of the French Healthcare system. Considering the limited range of heavy helicopter with autopilot, the lack of ATPL(H) pilots in France (for acting as commander for 2 pilots HEMS operations) and considering the fleet currently assigned to hospitals in France (with single-pilot certified helicopter and no flight standard for 2 pilots operations), the sum of the previous constraints leads to the impossibility to transport this kind of patient by road or air.

It is necessary to increase the limitation of continuous flight time described in this paragraph. This will not have a major impact on the fatigue of the pilots since most of the HEMS flights have a unit flight time ranged around 25 minutes for MBH, *i.e* 50 minutes back and forth (1 mission)ⁱ and this extension of the continuous flight time limitation will be used for a few and very specific missions. However, in order to ensure it does not have an impact on the fatigue of the crew member, MBH suggests using the possibility of having a 4 hours continuous flight time for single-pilots + TCM without autopilot under the principles of a FRM.

Thus, MBH proposes for single-pilot + TCM without autopilot to:

- Have an augmentation of this limitation to 3 hours
- Increase the limitation to 4 hours under the principles of a FRM

Otherwise, it would be beneficial to further develop the RIA basing it on experience and safety records on this subject, in order to better assess the economic and social impacts in addition to the flight safety impact.

PROPOSAL

Replace the paragraph (b)(1) by the following: "(1) Continuous FT is limited in all cases to 4 hours with autopilot and to 3 hours without

autopilot. These limitations can be increased by 1 hour under the principles of a FRM;"

response

Please see the answer to comment # 54

comment940comment by: MBH SAMUBREAK PERIODS for two-pilots HEMS operations
(a)(1)(a)(2)
ISSUEBREAK period for two-pilots HEMS operations
(a)(1)(a)(2)
ISSUEFlight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since
flight times are unpredictable and cannot be scheduled within a FDP, the same has to be
applied for breaks. Besides the wording "break" should be rethought to make it easy to
understand that this period is a time allowed for physiological needs, which is different
from a rest period free of all duties, of at least 1 hour.
As a mitigation, it is obvious that due to the very low average reported flight time in HEMS,
the opportunity for a 1h hour break is warranted.
Indeed, given the following aspects (Table 1 of this CS):

- Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time with autopilot = 9 hours which means at least 3 to 5 no-flown hours
- Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time without autopilot = 7 hours which means at least 5 to 7 no-flown hours

There is always a room for such a 1h break in a suitable accommodation at HEMS operating base.

Such a break may be monitored *ex-post* by the operator SMS, under the principles of the fatigue risk management.

Therefore, under the above risk analysis and under a monitoring following the principles of a fatigue risk management, MBH suggests writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the operation.

(Cf. comment #960)

PROPOSAL

Rephrase the paragraph (a)(1) as follows:

"(1) For FDP over 12 hours, the operator ensures ex-post that at least one break of minimum 60 consecutive minutes within each FDP at the HEMS operating base at times that ensure likelihood of sleep and provides suitable accommodation for the purpose of breaks at the HEMS operating base. Fatigue risk management principles may be applied to monitor this break."

response

Please see the answer to comment # 54

comment 941

comment by: MBH SAMU

Attachments #126 #127 #128 #129

BREAK PERIODS for single-pilot + TCM HEMS operations Cf. attachments S1, S2, S3 and S4 illustrating this break issue

(b)(2)(b)(3)

ISSUE

Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since flight times are unpredictable and cannot be scheduled within a FDP, the same has to be applied for breaks. Besides the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour.

As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, the opportunity for a break lasting between 2h and 1h is warranted. Indeed, given the following aspects (Table 2 of this CS):

- Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours for break with a maximum Total Flight Time with autopilot = 7 hours which means at least 5 to 7 no-flown hours
- Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours for break with a maximum Total Flight Time without autopilot = 5 hours which means at least 7 to 9 no-flown hours

There is always a room for such a break lasting between 2h and 1h in a suitable accommodation at HEMS operating base.

Such a break may be monitored *ex-post* by the operator SMS, under the principles of the fatigue risk management.

Therefore, under the above risk analysis and under a monitoring following the principles of a fatigue risk management, MBH suggests writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the operation.

(Cf. comment #960)

PROPOSAL Rephrase the paragraph (b)(2) as follows:

"(2) For FDP over 10 hours, the operator ensures ex-post that at least one break of minimum 60 consecutive minutes within each FDP at the HEMS operating base at times that ensure likelihood of sleep and provides suitable accommodation for the purpose of breaks at the HEMS operating base. Fatigue risk management principles may be applied to monitor this break."

response

Please see the answer to comment # 54

comment944comment by: MBH SAMUAttachments #130 #131 #132 #133 #134PRE AND POST FLIGHT MINIMUM TIME
(Cf. attachments S1, S2, S3 and S4 illustrating this pre and post flight minimum time issue)(a3) and (b4)
ISSUE
MBH agrees a minimum time shall be taken to ensure the safety of the flight:• Before the 1st flight of the crew, by preparing the aircraft, and
• After each flight, by reporting flight and aircraft informationDue to the life-threatening emergency operation in HEMS, these times shall be as short as
possible to maximize operational availability and response time. In that way, in France, the

contractual time for the National Health Authorities between the launch of a HEMS flight and the effective take-off is 7 minutes. Indeed, when a patient needs essential life-saving measures, after 30 minutes, there are almost no chance to save the life of the patient. Thus, the first patient of a FDP will have no chance of survival due to EASA proposition of having a minimum preflight time of 30 minutes at the beginning of the FDP. Moreover, French numbers underlines that 7%¹ of the HEMS take-off preformed within the first 30 minutes of the FDP. (Cf. SNEH illustrative Table in attachment)

Whatever the number of life that would not have been saved during these 30 minutes, no loss would be politically and socially acceptable.

With the same philosophy, the proposed requirement of having a minimum post flight period of 15 minutes at each HEMS operating base returns will reduce the chance of survival by 8 minutes for the next patient in case of close consecutive missions.

To illustrate those two issues, let's take the example of 2 unpredicted HEMS operations within the same FDP:

- 1st launch at the start of the FDP, at 8h00 with a mission with 2 flight times of 10 minutes (mission back and forth)
 - \circ $\;$ This requires a 30-minutes preflight then a 15-minute post flight
- 2nd launch at 12h00: no preflight required because the preflight has already been done
- Further operations: no preflight required as far as preflight is already done

This example highlights the lack of efficiency of having a long pre-flight at the beginning of the FDP before the first flight time and no preflight requirement for the following flight time though it occurs 4 hours after the initial checks.

Moreover, due to multiple flight times inside a unique FDP, MBH underlines that the definition of post flight duty is non-consistent with the usual definition of post-flight:

- Which starts at the end (of the last FT) of the FDP
- Assuming the FDP ends with the last FT
- Though for HEMS operations FT are unpredictable and scheduled FDP may end long after the last effective FT

Thus, for HEMS operations, it is not clear if the post-flight does belong or not to the FDP depending on the end of the last FT.

This definition does not correspond to the definition of the proposal which defines a postflight after each flight time returning to HEMS operating base within the same FDP. Therefore, MBH suggests suppressing the post flight duties since they are confusing and replacing it by a proportionate pre-flight time before any take-off from the HEMS operating base.

For French HEMS services, the suitable accommodation is nearby the helicopter.



On the other hand, MBH agrees these requirements do not apply for the Technical Crew Member since TCM function does not include the flight preparation. (Cf. comment #979)

In consequence, the proposal does not demonstrate safety improvement in all cases, in particular when several flight times are allocated in the same FDP and suppress life opportunity for the 1st patient if the emergency occurs in the first 30 minutes of the FDP and the next ones in case of airlift multiple rotations. Thus, MBH proposes:

- To suppress the minimum duration of initial preflight of 30 minutes and to replace it by *"a sufficient time determined by the operator and specified in the operating manual"*; this proposal does not affect the commander's prerogatives since he remains the one to make the final decision regarding the take-off time
- To dissociate from the above the time for the operational preparation of further individual flight time
- To replace the notion of "post-flight" by "operational pre-flight at the HEMS operating base"
- To suppress the minimum duration of "operational pre-flight at the HEMS operating base" at and to replace it by "a sufficient time determined by the operator and specified in the operating manual" instead of the proposed required 15 minutes for the post-flight between 2 FT at the HEMS operating base

(Cf. comment #966)

PROPOSAL

Replace the paragraph (a)(3) and (b)(4) by the following: "(a) [...] (3) A sufficient time is determined by the operator and specified in the operating manual for the initial

pre-flight duties performed at the beginning of the FDP and for

operational pre-flight duties before each flight taking-off from the HEMS operating base."

"(b) [...]

(4) A sufficient time is determined by the operator and specified in the operating manual for the initial

pre-flight duties performed at the beginning of the FDP and for

operational pre-flight duties before each flight taking-off from the HEMS operating base. Pre-flights duties do not apply to TCM.". Pre-flights duties do not apply to TCM."

response

Please see the answer to comment # 54

comment	945	comment by: MBH SAMU
	(c) ISSUE	



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

* Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 295 of 585

MBH highlights that the proposition in point (c) shall apply for both:

- Two-pilots operations: Table 1; and
- Single-pilot + 1 TCM operations: Table 2

Indeed, the proposed mitigation is met in both operations by offering suitable accommodation at HEMS operating base (Cf. point (b)(2) and (a)(1)): the rest and mitigated resulting fatigue are the same thus the alleviation shall be the same.

PROPOSAL Replace paragraph(c) by the following: *"If the rest period before reporting for the FDP is taken at the HEMS operating base, the limits of Table 1 for two-pilots operations and Table 2 for single-pilot operations, for reporting times between 0730-0959 also apply for reporting times between 0630-0729."*

response

Please see the answer to comment # 54

comment	947 comment by: MBH SAMU
	Attachments <u>#135</u> <u>#136</u> <u>#137</u> <u>#138</u>
	SINGLE-PILOT + TCM TOTAL FT LIMITATION (Cf. attachments S1, S2, S3 and S4 illustrating this total flight time limitation issue)
	Table 2 ISSUE
	MBH would like to highlight that the total flight time limitation for single-pilot + TCM operations without the use of autopilot are too restrictive especially the following ones:
	 FDP starting between 06:30-06-59 => maximum total flight time = 3:30 FDP starting between 12:00-13:59 => maximum total flight time = 3:30 FDP starting between 4:00-06:29 => maximum total flight time = 3:00
	There is no regulation in France on this subject for HEMS operations, with no reported inherent safety issue through experience.
	A further developed RIA based on experience and safety records on this subject would be beneficial, in order to assess the economic and social impacts in addition to the flight safety impact.
	In CAT provisions, when the operator has implemented a FRM, it is considered as a valuable mitigation to allow for the FDP to be increased by 1hour, in some cases. Thus, in the same philosophy than for CAT operations, MBH proposes to increase all total flight time limitations by 1 hour under the principles of a FRM.

PROPOSAL

Add the following sentence below the Table 2:

"The maximum Flight Time in Table 2 can be increased by 1 hour under the principles of a FRM"

response

Please see the answer to comment # 54

comment 950

comment by: MBH SAMU

Attachments #139 #140 #141 #142

MITIGATION AFTER A BLOCK OF UP TO 4 CONSECUTIVE FDP OF MORE THAN 12 HOURS (Cf. attachments S1, S2, S3 and S4 illustrating the reduced rest and the 12h operational readiness issues)

(d)

ISSUE

On the one hand, MBH underlines the French regulation historically proposes several rostering cycles for HEMS operations that are currently used with an excellent safety track record demonstrated by experience:

- 7 days ON / 7 days OFF with a limitation of 14 hours of duties for 24 hours
- 5 days ON / 2 days OFF with a limitation of 12 hours of duties for 24 hours
- 12 days ON / 6 days OFF with a limitation of 12 hours of duties for 24 hours

Therefore, most hospitals / HEMS organizations have a contractual engagement with the National Health Authority over a rolling 24 hours period: 12 hours of HEMS operative availability and 12 hours OFF.

According to the Agency requirement on the pre-flight and post-flight minimum times (Cf. #944), an HEMS organization will yet roster cycle with a FDP of 12h30 and a Duty Period of 12h45 to ensure they follow their engagement with hospitals. Thus, all HEMS operators will have to schedule:

- More than 12h FDP for each and every shift
- Reduced rest of more than 10h amongst a 11h15 available time for rest according to CS.FTL.3.235 to reengage at the same time the day after under the principles of a FRM

Moreover, MBH highlights that, due to short and continuous flight times with a total flight time limited per Table 2 and which are in average 1h30 per 12 hours of shifts (with an average leg of 25 min for MBH)ⁱ in France, the fatigue will not be an issue for FDP ranged from 12h up to 14h. Indeed, according to the requirements (a)(1) and (b)(2), all HEMS organizations shall provide suitable accommodation at the HEMS operating base, thus

pilots can have breaks in comfortable places between two flight times. These pilots have to have their rest at the HEMS operating base which is considered as a mitigation measure. This is also a safety improvement because the rest is at the HEMS operating base which is considered as a mitigation measure. Furthermore, no demonstration nor RIA is given to justify the point (d), while the current rostering in France on this subject for HEMS operations has not reported inherent safety issue through experience. On the other hand, most of the French pilots are "faux-basés", meaning they spend 7 days working at home base and then 7 days of rest at home which can be at 500 kilometers from home base. Therefore, most of French HEMS pilots prefer the cycle 7 days ON / 7 days OFF for their quality of life which will be limited by the requirement (d). Nevertheless, the provisions of (d) implies at least 4 days ON per 3 days OFF, which appears counterproductive for social issues and crew quality of life. PROPOSAL Replace paragraph (d) by the following: "If an operator assigns two or more consecutive FDPs of more than 12h, the following conditions shall be met: 1. The rest period preceding the first FDP is at least 36 hours including 2 local nights; and 2. The rest period provided after completion of the series of consecutive FDPs is at least 60 hours including 3 local nights. A block of more than 4 consecutive FDPs of more than 12 hours can be scheduled under the principles of a FRM."

response

Please see the answer to comment # 54

comment	984 comment by: AE	SA
	Break included in CS FTL.3.205(a)(1) for FDPs over 12 hours, must be rostered in advar by the operator with start and finish time?	ice
response	Please see the answer to comment # 54	

comment 1008

comment by: Stephanie Selim

(b) and Table 2

Technical comment (basic FDP) -

As previously notified, the pilots of the HEMS have mean flight duration of 1h30 per day with significant waiting times. A HEMS pilot in France has an activity of 90 hours per year. Reducing FDP depending on hours of start of FDP will increase the number of pilots needed to guarantee the same HEMS activity. For example, the Bordeaux HeliSMUR begins at 10 am and has a 14 hours vacation. This won't be possible anymore with this NPA with only one pilot. This measure causes several difficulties, the first one being the lack of

experienced pilots on the labor market, and the second one the reduction of flying time per pilot, which creates a new risk that is the maintenance of skills.

We want to mention again that, in single-pilot HEMS operations, the pilot is not alone anymore and is assisted by a TCM. In that way, the risk of fatigue is lower. Hence, his FDP should not be considered as if he was alone.

We ask for, at least, a FDP of 14 hours when the FDP starts at 10.

response

Please see the answer to comment # 54

comment 1009 comment by: Stephanie Selim (b) and Table 2 Technical comment (FT with and without autopilot) – Without autopilot, the proposal leads to 3 hours of maximum FT by night and only 2 continuous FT hours. This proposal may result in big difficulties for some pathologies as highly burn victims because few hospitals are specialised in that kind of pathologies and 2 hours to pick the victim, bring him/her to the specialised centre and come back with the medical team and the helicopter in order to be available for further missions is not possible in 2 hours in all cases. Indeed, these flights can be a haul from Lyon to Paris which lasts more than 2h and they are necessary because the transport by road is not considered sufficiently effective considering the patient's condition. And if an additional flight has to be made during the period when the flight time is limited to 3 hours, this next mission will not be possible either. Moreover, in several cases, a HEMS flight could pick up a patient in a hospital to bring him/her to a third hospital. This mission call "triangulars" in France is common. These flights are usually flown with lighter helicopter without autopilot because they can fly longer distances (4h30 of autonomy) than heavy helicopters. They usually occur from a known helipad in a hospital to another known helipad in another hospital In addition, it is usual to keep the engine running (the rotor blades are still turning while loading the helicopter between two legs or three legs in case of a triangular mission, i.e the single-pilot + TCM take off from the home base, pick up a patient at a given hospital to finally bring him at the planned hospital). Thus, according to the definition of a Flight Time in ORO.FTL.105(13), these two legs are considered as a unique flight time. In that way, the limitation of 2 hours for an equipage with a singlepilot + TCM is too restrictive. It is necessary to increase the limitation of continuous flight time described in this paragraph. This will not have a major impact on the fatigue of the pilots since most of the HEMS flights have a unit flight time ranged around 25 minutes for SNEH, i.e 50 minutes back and forth (1 mission) and this extension of the continuous flight time limitation will be used for a few and very specific missions. Please see the answer to comment # 54 response comment 1010 comment by: Stephanie Selim

(b)(2) and (3) **Technical comment (breaks)** – This proposal has ABSOLUTELY to be deleted. The break can not be scheluled, except if we accept to waive the helicopter for 1 hour,

taking the risk that a patient has to be transported at that moment, which is obviously impossible.

Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since flight times are unpredictable and cannot be scheduled within a FDP, the same has to be applied for breaks.

As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, the opportunity for a 1h hour break is warranted.

Indeed, given the following aspects (Table 1 of this CS):

• Maximum FDP = Ranged between 14 hours and 12 hours with a maximum Total Flight Time with autopilot = 9 hours which means at least 3 to 5 no-flown hours

• Maximum FDP = Ranged between 14 hours and 12 hours with a maximum Total Flight Time without autopilot = 7 hours which means at least 5 to 7 no-flown hours

There is always a room for such a 1h break in an accommodation at HEMS operating base.

response

Please see the answer to comment # 54

comment | 1011

comment by: Stephanie Selim

(b)(4)

Technical comment (pre and post flight duty) -

Due to the life-threatening emergency operation in HEMS, these times shall be as short as possible to maximize operational availability and response time. In that way, in France, the contractual time for the National Health Authorities between the launch of a HEMS flight and the effective take-off is 7 minutes. Indeed, when a patient needs essential life-saving measures, after 30 minutes, there is almost no chance to save the life of the patient. Thus, the first patient of a FDP will have no chance of survival due to this proposition of having a minimum pre-flight time of 30 minutes at the beginning of the FDP.

Moreover, this requirement is a problem regarding the organisation of HEMS operations in France. This pre-flight duty, when carried out, launches the start of the FDP which will cause difficulties with the values of maximum FDP proposed in this NPA, especially considering that FT are low in France, as exposed.

Thus, we ask for the deletion of this requirement which has no equivalent in other types of operations (pre-flight duty exists but does not have a minimum duration).

response

Please see the answer to comment # 54

comment | 1012

comment by: Stephanie Selim

(d)

Technical comment (4 FDP of more than 12h) -

With this proposal, the usual French rostering 7 days ON at home base / 7 days OFF could not be respected anymore, both for 14h vacations, and for the current 12h vacations if our proposal to delete the minimum duration of pre and post-flight duties is not accepted as it will lead to 12h45 of vacation (or hiring new pilots).

Yet, this model has proven its efficiency in terms of safety, fatigue and quality of life for crews. Indeed, the total amount of flight times for pilots is quite low, a lot of time can be spent for rest, and the working pace of 7 days ON / 7 days OFF does not appear more tiring

	(due to short and continuous flight times with a total flight time limited per Table 2 and which are in average 1h30 per 12 hours of shifts (with an average leg of 25 min/30 mn) in France, the fatigue will not be an issue for FDP ranged from 12h up to 14h. Furthermore, no demonstration or RIA is given to justify the point (d).
response	Please see the answer to comment # 54
comment	1114 comment by: European Cockpit Association
	Commented text: CS FTL.3.205 Flight duty period (FDP) — HEMS (1) For FDPs of over 12 hours, the operator ensures at least one break of minimum 60 consecutive minutes or more within each FDP at the HEMS operating base at times that ensure likelihood of sleep and provides suitable accommodation for the purpose of breaks at the HEMS operating base;
	ECA Comment: The Rulemaking Group agreed on minimum break times before to be counted for any kind of reduction of 1 hour - comparable to the min of 90 minutes of in-flight-rest – a break which is lasting less than 1 hour doesn't assure recovering from fatigue, but since suitable accommodation is more relaxing than in-flight-rest 60 min is from ECA's point of view appropriate. This wording is unclear, because the interpretation is possible, that "only one" break must be at least 60 minutes. In addition, the Rulemaking Group agreed, that active time of the dual pilot flight crew is limited to 12 hours within a possible longer duty time. ECA strongly recommends, that this limit of 12h of active time is not exceeded.
response	Please see the answer to comment # 54
comment	1115 comment by: European Cockpit Association
	Commented text: CS FTL.3.205 Flight duty period (FDP) — HEMS (2) The time for breaks constitutes 50 % of the time over 12 hours and excludes the necessary time for post- and pre-flight duties; and
	ECA comment: Agreed by the Rulemaking Group: the total break time must be at least equal to the time over the limiting hours; The time for breaks excludes the necessary time for post- and pre- flight duties; leads to lower limits, more prolongation - from ECA point of view more practicable, clearer and safer approach.
response	Please see the answer to comment # 54

comment	1117	comment by: European Cockpit Association
	consecutive minutes within	iod (FDP) — HEMS urs, the operator ensures at least one break of minimum 60 each FDP at the HEMS operating base at times that ensure ides suitable accommodation for the purpose of breaks at the
		ed on minimum break times before to be counted for any kind reak which is lasting less than 1-hour doesn`t assure recovering
	This wording is unclear, bec to be at least 60 minutes. In the single pilot flight crew i	ause the interpretation is possible, that "only one" break has n addition, the Rulemaking Group agreed, that active time of s limited to 10 hours within a possible longer duty time. ECA this limit of 10h of active time is not exceeded.
response	Please see the answer to con	mment # 54
comment	1118	comment by: European Cockpit Association
	Commented text: (3) The time for breaks const necessary time for post- and	titutes 50 % of the time over 10 hours and excludes the I pre-flight duties;
	over the limiting hours; The	froup: the total break time has to be at least equal to the time time for breaks excludes the necessary time for post- and wer limits, more prolongation - from ECA point of view more r approach.
response	Please see the answer to con	nment # 54
comment	1167	comment by: <i>NHV Group</i>
	Subparagraph (b), point (4). Comment: Limitation given or flight rules type on minim Justification: Option to redu on complexity of mission an Proposed text: (4) The oper	Flight duty period (FDP) - HEMS in point (4) does not reflect impact the complexity of mission num time for pre-flight and post-flight duties. ce these figures or flexibility in applying these limits depending d type of flight rules shall be allowed to the HEMS operators. rator specifies in the operations manual, a minimum time for rformed at the beginning of the FDP and a minimum of time

**** **** for post-flight duties for every flight returning to the HEMS operating base.

1211

response

Please see the answer to comment # 54

comment

comment by: SAF

CS FTL.3.205 Maximum basic daily FDP in HEMS under ORO.FTL.205 (b)(7)

There are two CS FTL.3.205 (with exactly the same title), which introduces complexity, uncertainty and may lead to misunderstanding.

SAF suggests adding precisions in the title of this paragraph in order to quickly make the link with the ORO paragraph involved.

PROPOSAL

Replace the title of this CS by: "CS FTL.3.205 (b)(7)"

response

Please see the answer to comment # 54

comment	1212 comment by: SAF
	CS FTL.3.205 Maximum basic daily FDP in HEMS under ORO.FTL.205 (b)(7)
	REMARK
	For small FT as currently operated in HEMS, it is possible to have multiple FDP within the same day.
	For instance: One FDP from 07:00 to 8:30 followed by a 12h rest period and then a FDP from 20:30 to 22h.
response	Please see the answer to comment # 54
comment	1213 comment by: SAF
	Attachment <u>#143</u>
	CS FTL.3.205 Maximum basic daily FDP in HEMS under ORO.FTL.205 (b)(7)
	CONTINUOUS FLIGHT TIME LIMITATION IN SINGLE-PILOT + TCM

**** **** (Cf. attachment S4 illustrating this continuous flight time limitation in single-pilot + TCM issue)

(b)(1)

ISSUE

SAF highlights the too restrictive limitation of total flight time for the single-pilot + TCM operations (b)(1). Indeed, the proposal constrains the continuous flight time for single-pilot + TCM operations:

- with autopilot at 4 hours
- without autopilot at 2 hours

Some rescues and patient transportation, like severe burned patients, will not be possible with the 2 hours limitation without the autopilot. Indeed, these flights can be a haul from Lyon to Paris which lasts more than 2h and they are necessary because the transport by road is not considered sufficiently effective considering the patient's condition.

These flights are usually flown with lighter helicopter without autopilot because they can fly longer distances (4h30 of autonomy) than heavy helicopters. These flights are usually scheduled from a known helipad in a hospital to another known helipad in another hospital and correspond more to the scope of commercial sanitary flights not yet defined by EASA than the HEMS scope.

In addition, it is usual to keep the engine running (the rotor blades are still turning while loading the helicopter between two legs or three legs in case of a triangular mission, *i.e* the single-pilot + TCM take-off from the home base, pick up a patient at a given hospital to finally bring him at the planned hospital). Thus, according to the definition of a Flight Time in ORO.FTL.105(13), these two legs are considered as a unique flight time. In that way, the limitation of 2 hours for an equipage with a single-pilot + TCM is too restrictive.

Moreover, in HEMS, a single-pilot does not fly alone, he is assisted by a Technical Crew Member (which is a recent additional EASA requirement). In that way, the risk of fatigue is lower since the TCM is assisting the pilot in non-piloting tasks and is contributing to the safety of the flight. *De facto*, single-pilot HEMS operations are in fact 2 technical crews operations (1 pilot + 1 TCM). By parallelism, no such total flight time limitation has been defined for 2 technical crews operations (2 pilots).

No RIA is given to justify this proposal.

Besides, HEMS pilots are scarce resources in France, and this NPA would lead to hire 120 additional pilots and 120 additional TCM in order to offer the same quality of HEMS activity in France. This represents an additional cost of 20% for the whole French HEMS State Budget. It is likely that such a massive recruitment would not be achievable and would thus result in a significant reduction in the quality of the French Healthcare system. Considering the limited range of heavy helicopter with autopilot, the lack of ATPL(H) pilots in France (for acting as commander for 2 pilots HEMS operations) and considering the fleet currently assigned to hospitals in France (with single-pilot certified helicopter and no flight standard

**** * * *+ · +* for 2 pilots operations), the sum of the previous constraints leads to the impossibility to transport this kind of patient by road or air.

It is necessary to increase the limitation of continuous flight time described in this paragraph. This will not have a major impact on the fatigue of the pilots since most of the HEMS flights have a unit flight time ranged around 25 minutes for SAF, *i.e* 50 minutes back and forth (1 mission)ⁱ and this extension of the continuous flight time limitation will be used for a few and very specific missions. However, in order to ensure it does not have an impact on the fatigue of the crew member, SAF suggests using the possibility of having a 4 hours continuous flight time for single-pilots + TCM without autopilot under the principles of a FRM.

Thus, SAF proposes for single-pilot + TCM without autopilot to:

- Have an augmentation of this limitation to 3 hours
- Increase the limitation to 4 hours under the principles of a FRM

Otherwise, it would be beneficial to further develop the RIA basing it on experience and safety records on this subject, in order to better assess the economic and social impacts in addition to the flight safety impact.

PROPOSAL

Replace the paragraph (b)(1) by the following: "(1) Continuous FT is limited in all cases to 4 hours with autopilot and to 3 hours without autopilot. These limitations can be increased by 1 hour under the principles of a FRM;"

response

Please see the answer to comment # 54

comment	1214 comment by: SAF
	BREAK PERIODS for two-pilots HEMS operations
	(a)(1)(a)(2)
	ISSUE
	Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since flight times are unpredictable and cannot be scheduled within a EDP, the same has to be

flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since flight times are unpredictable and cannot be scheduled within a FDP, the same has to be applied for breaks. Besides the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour.

As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, the opportunity for a 1h hour break is warranted.

**** * * *

Indeed, given the following aspects (Table 1 of this CS): Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time with autopilot = 9 hours which means at least 3 to 5 no-flown hours Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time without autopilot = 7 hours which means at least 5 to 7 no-flown hours There is always a room for such a 1h break in a suitable accommodation at HEMS operating base. Such a break may be monitored *ex-post* by the operator SMS, under the principles of the fatigue risk management. Therefore, under the above risk analysis and under a monitoring following the principles of a fatigue risk management, SAF suggests writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the operation. (Cf. comment #1228) PROPOSAL Rephrase the paragraph (a)(1) as follows: "(1) For FDP over 12 hours, the operator ensures ex-post that at least one break of minimum 60 consecutive minutes within each FDP at the HEMS operating base at times that ensure likelihood of sleep and provides suitable accommodation for the purpose of breaks at the HEMS operating base. Fatigue risk management principles may be applied to monitor this break." Please see the answer to comment # 54

comment1215comment by: SAFAttachments #144 #145 #146 #147BREAK PERIODS for single-pilot + TCM HEMS operationsCf. attachments S1, S2, S3 and S4 illustrating this break issue(b)(2)(b)(3)ISSUE

**** * *** response

Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since flight times are unpredictable and cannot be scheduled within a FDP, the same has to be applied for breaks. Besides the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour.

As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, the opportunity for a break lasting between 2h and 1h is warranted.

Indeed, given the following aspects (Table 2 of this CS):

- Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours for break with a maximum Total Flight Time with autopilot = 7 hours which means at least 5 to 7 no-flown hours
- Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours for break with a maximum Total Flight Time without autopilot = 5 hours which means at least 7 to 9 no-flown hours

There is always a room for such a break lasting between 2h and 1h in a suitable accommodation at HEMS operating base.

Such a break may be monitored *ex-post* by the operator SMS, under the principles of the fatigue risk management.

Therefore, under the above risk analysis and under a monitoring following the principles of a fatigue risk management, SAF suggests writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the operation.

(Cf. comment #1228)

PROPOSAL

Rephrase the paragraph (b)(2) as follows:

"(2) For FDP over 10 hours, the operator ensures ex-post that at least one break of minimum 60 consecutive minutes within each FDP at the HEMS operating base at times that ensure likelihood of sleep and provides suitable accommodation for the purpose of breaks at the HEMS operating base. Fatigue risk management principles may be applied to monitor this break."

response

Please see the answer to comment # 54

comment | 1216

comment by: SAF

Attachments <u>#148</u> <u>#149</u> <u>#150</u> <u>#151</u> <u>#152</u>

PRE AND POST FLIGHT MINIMUM TIME



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 307 of 585 (Cf. attachments S1, S2, S3 and S4 illustrating this pre and post flight minimum time issue)

(a3) and (b4)

ISSUE

SAF agrees a minimum time shall be taken to ensure the safety of the flight:

- Before the 1st flight of the crew, by preparing the aircraft, and
- After each flight, by reporting flight and aircraft information

Due to the life-threatening emergency operation in HEMS, these times shall be as short as possible to maximize operational availability and response time. In that way, in France, the contractual time for the National Health Authorities between the launch of a HEMS flight and the effective take-off is 7 minutes. Indeed, when a patient needs essential life-saving measures, after 30 minutes, there are almost no chance to save the life of the patient. Thus, the first patient of a FDP will have no chance of survival due to EASA proposition of having a minimum preflight time of 30 minutes at the beginning of the FDP. Moreover, French numbers underlines that 7%ⁱ of the HEMS take-off preformed within the first 30 minutes of the FDP. (Cf. SNEH illustrative Table in attachment)

Whatever the number of life that would not have been saved during these 30 minutes, no loss would be politically and socially acceptable.

With the same philosophy, the proposed requirement of having a minimum post flight period of 15 minutes at each HEMS operating base returns will reduce the chance of survival by 8 minutes for the next patient in case of close consecutive missions.

To illustrate those two issues, let's take the example of 2 unpredicted HEMS operations within the same FDP:

- 1st launch at the start of the FDP, at 8h00 with a mission with 2 flight times of 10 minutes (mission back and forth)
 - This requires a 30-minutes preflight then a 15-minute post flight
- 2nd launch at 12h00: no preflight required because the preflight has already been done
- Further operations: no preflight required as far as preflight is already done

This example highlights the lack of efficiency of having a long pre-flight at the beginning of the FDP before the first flight time and no preflight requirement for the following flight time though it occurs 4 hours after the initial checks.

Moreover, due to multiple flight times inside a unique FDP, SAF underlines that the definition of post flight duty is non-consistent with the usual definition of post-flight:

- Which starts at the end (of the last FT) of the FDP
- Assuming the FDP ends with the last FT

• Though for HEMS operations FT are unpredictable and scheduled FDP may end long after the last effective FT

Thus, for HEMS operations, it is not clear if the post-flight does belong or not to the FDP depending on the end of the last FT.

This definition does not correspond to the definition of the proposal which defines a postflight after each flight time returning to HEMS operating base within the same FDP. Therefore, SAF suggests suppressing the post flight duties since they are confusing and replacing it by a proportionate pre-flight time before any take-off from the HEMS operating base.

For French HEMS services, the suitable accommodation is nearby the helicopter.

On the other hand, SAF agrees these requirements do not apply for the Technical Crew Member since TCM function does not include the flight preparation.

(Cf. comment #1242)

In consequence, the proposal does not demonstrate safety improvement in all cases, in particular when several flight times are allocated in the same FDP and suppress life opportunity for the 1st patient if the emergency occurs in the first 30 minutes of the FDP and the next ones in case of airlift multiple rotations. Thus, SAF proposes:

- To suppress the minimum duration of initial preflight of 30 minutes and to replace it by "a sufficient time determined by the operator and specified in the operating manual"; this proposal does not affect the commander's prerogatives since he remains the one to make the final decision regarding the take-off time
- To dissociate from the above the time for the operational preparation of further individual flight time
- To replace the notion of "post-flight" by "operational pre-flight at the HEMS operating base"
- To suppress the minimum duration of "operational pre-flight at the HEMS operating base" at and to replace it by "a sufficient time determined by the operator and specified in the operating manual" instead of the proposed required 15 minutes for the post-flight between 2 FT at the HEMS operating base

(Cf. comment #1232)

PROPOSAL

Replace the paragraph (a)(3) and (b)(4) by the following:

"(a) [...]

(3) A sufficient time is determined by the operator and specified in the operating manual for the initial pre-flight duties performed at the beginning of the FDP and for operational pre-flight duties before each flight taking-off from the HEMS operating base."

**** * * * * * * "(b) [...]

(4) A sufficient time is determined by the operator and specified in the operating manual for the initial

pre-flight duties performed at the beginning of the FDP and for operational pre-flight duties before each flight taking-off from the HEMS operating base. Pre-flights duties do not apply to TCM.". Pre-flights duties do not apply to TCM."

response

Please see the answer to comment # 54

comment	1217 comment by: SAF
	(c)
	ISSUE
	SAF highlights that the proposition in point (c) shall apply for both:
	 Two-pilots operations: Table 1; and Single-pilot + 1 TCM operations: Table 2
	Indeed, the proposed mitigation is met in both operations by offering suitable accommodation at HEMS operating base (Cf. point (b)(2) and (a)(1)): the rest and mitigated resulting fatigue are the same thus the alleviation shall be the same.
	PROPOSAL
	Replace paragraph(c) by the following:
	"If the rest period before reporting for the FDP is taken at the HEMS operating base, the limits of
	Table 1 for two-pilots operations and Table 2 for single-pilot operations, for reporting times between 0730-0959 also apply for reporting times between 0630-0729."
response	Please see the answer to comment # 54

comment 1218

comment by: SAF

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

	Attachments <u>#153</u> <u>#154</u> <u>#155</u> <u>#156</u>
	SINGLE-PILOT + TCM TOTAL FT LIMITATION
	(Cf. attachments S1, S2, S3 and S4 illustrating this total flight time limitation issue)
	Table 2
	ISSUE
	SAF would like to highlight that the total flight time limitation for single-pilot + TCM operations without the use of autopilot are too restrictive especially the following ones:
	 FDP starting between 06:30-06-59 => maximum total flight time = 3:30 FDP starting between 12:00-13:59 => maximum total flight time = 3:30 FDP starting between 4:00-06:29 => maximum total flight time = 3:00
	There is no regulation in France on this subject for HEMS operations, with no reported inherent safety issue through experience.
	A further developed RIA based on experience and safety records on this subject would be beneficial, in order to assess the economic and social impacts in addition to the flight safety impact.
	In CAT provisions, when the operator has implemented a FRM, it is considered as a valuable mitigation to allow for the FDP to be increased by 1hour, in some cases.
	Thus, in the same philosophy than for CAT operations, SAF proposes to increase all total flight time limitations by 1 hour under the principles of a FRM.
	PROPOSAL
	Add the following sentence below the Table 2:
	"The maximum Flight Time in Table 2 can be increased by 1 hour under the principles of a FRM"
response	Please see the answer to comment # 54

comment 1219

comment by: SAF

Attachments <u>#157</u> <u>#158</u> <u>#159</u> <u>#160</u>

MITIGATION AFTER A BLOCK OF UP TO 4 CONSECUTIVE FDP OF MORE THAN 12 HOURS



(Cf. attachments S1, S2, S3 and S4 illustrating the reduced rest and the 12h operational readiness issues)

(d)

ISSUE

On the one hand, SAF underlines the French regulation historically proposes several rostering cycles for HEMS operations that are currently used with an excellent safety track record demonstrated by experience:

- 7 days ON / 7 days OFF with a limitation of 14 hours of duties for 24 hours
- 5 days ON / 2 days OFF with a limitation of 12 hours of duties for 24 hours
- 12 days ON / 6 days OFF with a limitation of 12 hours of duties for 24 hours

Therefore, most hospitals / HEMS organizations have a contractual engagement with the National Health Authority over a rolling 24 hours period: 12 hours of HEMS operative availability and 12 hours OFF.

According to the Agency requirement on the pre-flight and post-flight minimum times (Cf. #1216), an HEMS organization will yet roster cycle with a FDP of 12h30 and a Duty Period of 12h45 to ensure they follow their engagement with hospitals. Thus, all HEMS operators will have to schedule:

- More than 12h FDP for each and every shift
- Reduced rest of more than 10h amongst a 11h15 available time for rest according to CS.FTL.3.235 to reengage at the same time the day after under the principles of a FRM

Moreover, SAF highlights that, due to short and continuous flight times with a total flight time limited per Table 2 and which are in average 1h30 per 12 hours of shifts (with an average leg of 25 min for SAF)ⁱ in France, the fatigue will not be an issue for FDP ranged from 12h up to 14h. Indeed, according to the requirements (a)(1) and (b)(2), all HEMS organizations shall provide suitable accommodation at the HEMS operating base, thus pilots can have breaks in comfortable places between two flight times. These pilots have to have their rest at the HEMS operating base which is considered as a mitigation measure.

This is also a safety improvement because the rest is at the HEMS operating base which is considered as a mitigation measure.

Furthermore, no demonstration nor RIA is given to justify the point (d), while the current rostering in France on this subject for HEMS operations has not reported inherent safety issue through experience.

On the other hand, most of the French pilots are "faux-basés", meaning they spend 7 days working at home base and then 7 days of rest at home which can be at 500 kilometers from home base. Therefore, most of French HEMS pilots prefer the cycle 7 days ON / 7 days OFF

**** * * * for their quality of life which will be limited by the requirement (d). Nevertheless, the provisions of (d) implies at least 4 days ON per 3 days OFF, which appears counterproductive for social issues and crew quality of life.

PROPOSAL

Replace paragraph (d) by the following:

"If an operator assigns two or more consecutive FDPs of more than 12h, the following conditions shall be met:

- 1. The rest period preceding the first FDP is at least 36 hours including 2 local nights; and
- 2. The rest period provided after completion of the series of consecutive FDPs is at least 60 hours including 3 local nights.

A block of more than 4 consecutive FDPs of more than 12hours can be scheduled under the principles of a FRM."

response

Please see the answer to comment # 54

comment	1275comment by: Hélicoptères de France
	CS FTL.3.205 Maximum basic daily FDP in HEMS under ORO.FTL.205 (b)(7) #1
	There are two CS FTL.3.205 (with exactly the same title), which introduces complexity, uncertainty and
	may lead to misunderstanding.
	HDF suggests adding precisions in the title of this paragraph in order to quickly make the link with the ORO paragraph involved.
	PROPOSAL
	Replace the title of this CS by: "CS FTL.3.205 (b)(7)"
	#2
	REMARK
	For small FT as currently operated in HEMS, it is possible to have multiple FDP within the same day.
	For instance: One FDP from 07:00 to 8:30 followed by a 12h rest period and then a FDP from 20:30 to
	22h.
	#3 CONTINUOUS FLIGHT TIME LIMITATION IN SINGLE-PILOT + TCM
	(Cf. attachment S4 illustrating this continuous flight time limitation in single-pilot + TCM issue)
	(b)(1)
	ISSUE
	HDF highlights the too restrictive limitation of total flight time for the single-pilot + TCM operations (b)(1). Indeed, the proposal constrains the continuous flight time for single-pilot
	+ TCM
	operations:

 with autopilot at 4 hours without autopilot at 2 hours Some rescues and patient transportation, like severe burned patients, will not be possible with the 2 hours limitation without the autopilot. Indeed, these flights can be a haul from Lyon to Paris which lasts more than 2h and they are necessary because the transport by road is not considered sufficiently effective considering the patient's condition. These flights are usually flown with lighter helicopter without autopilot because they can fly longer distances (4h30 of autonomy) than heavy helicopters. These flights are usually scheduled from a known helipad in a hospital to another known helipad in another hospital and correspond more to the scope of commercial sanitary flights not yet defined by EASA than the HEMS scope. In addition, it is usual to keep the engine running (the rotor blades are still turning while loading the helicopter between two legs or three legs in case of a triangular mission, i.e the single-pilot + TCM takeoff from the home base, pick up a patient at a given hospital to finally bring him at the planned hospital). Thus, according to the definition of a Flight Time in ORO.FTL.105(13), these two legs are considered as a unique flight time. In that way, the limitation of 2 hours for an equipage with a singlepilot + TCM is too restrictive. Moreover, in HEMS, a single-pilot does not fly alone, he is assisted by a Technical Crew Member (which is a recent additional EASA requirement). In that way, the risk of fatigue is lower since the TCM is assisting the pilot in non-piloting tasks and is contributing to the safety of the flight. De facto, single pilot HEMS operations are in fact 2 technical crews operations (1 pilot + 1 TCM). By parallelism, no such total flight time limitation has been defined for 2 technical crews operations (2 pilots). No RIA is given to justify this proposal. Besides, HEMS pilots are scarce resources in France, and this NPA would lead to hire 120 additional pilots and 120 additional TCM in order to offer the same quality of HEMS activity in France. This represents an additional cost of 20% for the whole French HEMS State Budget. It is likely that such a massive recruitment would not be achievable and would thus result in a significant reduction in the quality of the French Healthcare system. Considering the limited range of heavy helicopter with autopilot, the lack of ATPL(H) pilots in France (for acting as commander for 2 pilots HEMS operations) and considering the fleet currently assigned to hospitals in France (with single-pilot certified helicopter



and no flight standard for 2 pilots operations), the sum of the previous constraints leads to the impossibility to transport this kind of patient by road or air. It is necessary to increase the limitation of continuous flight time described in this paragraph. This will not have a major impact on the fatigue of the pilots since most of the HEMS flights have a unit flight time ranged around 25 minutes for SNEH, i.e 50 minutes back and forth (1 mission)i and this extension of the continuous flight time limitation will be used for a few and very specific missions. However, in order to ensure it does not have an impact on the fatigue of the crew member, HDF suggests using the possibility of having a 4 hours continuous flight time for single-pilots + TCM without autopilot under the principles of a FRM. Thus, HDF proposes for single-pilot + TCM without autopilot to: • Have an augmentation of this limitation to 3 hours • Increase the limitation to 4 hours under the principles of a FRM Otherwise, it would be beneficial to further develop the RIA basing it on experience and safety records on this subject, in order to better assess the economic and social impacts in addition to the flight safety impact. PROPOSAL Replace the paragraph (b)(1) by the following: "(1) Continuous FT is limited in all cases to 4 hours with autopilot and to 3 hours without autopilot. These limitations can be increased by 1 hour under the principles of a FRM;" #4.1 BREAK PERIODS for two-pilots HEMS operations (a)(1)(a)(2)ISSUE Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since flight times are unpredictable and cannot be scheduled within a FDP, the same has to be applied for breaks. Besides the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour. As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, the opportunity for a 1h hour break is warranted. Indeed, given the following aspects (Table 1 of this CS): Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time with autopilot = 9 hours which means at least 3 to 5 no-flown hours Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with

**** * * * * * * a maximum Total Flight Time without autopilot = 7 hours which means at least 5 to 7 noflown hours There is always a room for such a 1h break in a suitable accommodation at HEMS operating base. Such a break may be monitored ex-post by the operator SMS, under the principles of the fatigue risk management. Therefore, under the above risk analysis and under a monitoring following the principles of a fatigue risk management, HDF suggests writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the operation. (Cf. comment #30.3) PROPOSAL Rephrase the paragraph (a)(1) as follows: "(1) For FDP over 12 hours, the operator ensures ex-post that at least one break of minimum 60 consecutive minutes within each FDP at the HEMS operating base at times that ensure likelihood of sleep and provides suitable accommodation for the purpose of breaks at the HEMS operating base. Fatigue risk management principles may be applied to monitor this break." #4.2 BREAK PERIODS for single-pilot + TCM HEMS operations Cf. attachments S1, S2, S3 and S4 illustrating this break issue (b)(2)(b)(3)ISSUE Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since flight times are unpredictable and cannot be scheduled within a FDP, the same has to be applied for breaks. Besides the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour. As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, the opportunity for a break lasting between 2h and 1h is warranted. Indeed, given the following aspects (Table 2 of this CS): Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours for break with a maximum Total Flight Time with autopilot = 7 hours which means at least 5 to 7 no-flown hours Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours for break with a maximum Total Flight Time without autopilot = 5 hours which means at least 7 to 9 noflown hours There is always a room for such a break lasting between 2h and 1h in a suitable accommodation at



HEMS operating base. Such a break may be monitored ex-post by the operator SMS, under the principles of the fatigue risk management. Therefore, under the above risk analysis and under a monitoring following the principles of a fatigue risk management, HDF suggests writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the operation. (Cf. comment #30.3) PROPOSAL Rephrase the paragraph (b)(2) as follows: "(2) For FDP over 10 hours, the operator ensures ex-post that at least one break of minimum 60 consecutive minutes within each FDP at the HEMS operating base at times that ensure likelihood of sleep and provides suitable accommodation for the purpose of breaks at the HEMS operating base. Fatigue risk management principles may be applied to monitor this break." **#5 PRE AND POST FLIGHT MINIMUM TIME** (Cf. attachments S1, S2, S3 and S4 illustrating this pre and post flight minimum time issue) (a3) and (b4) ISSUE HDF agrees a minimum time shall be taken to ensure the safety of the flight: • Before the 1st flight of the crew, by preparing the aircraft, and After each flight, by reporting flight and aircraft information Due to the life-threatening emergency operation in HEMS, these times shall be as short as possible to maximize operational availability and response time. In that way, in France, the contractual time for the National Health Authorities between the launch of a HEMS flight and the effective takeoff is 7 minutes. Indeed, when a patient needs essential life-saving measures, after 30 minutes, there are almost no chance to save the life of the patient. Thus, the first patient of a FDP will have no chance of survival due to EASA proposition of having a minimum preflight time of 30 minutes at the beginning of the FDP. Moreover, French numbers underlines that 7% i of the HEMS take-off preformed within the first 30 minutes of the FDP. (Cf. SNEH illustrative Table in attachment) Whatever the number of life that would not have been saved during these 30 minutes, no loss would be politically and socially acceptable. With the same philosophy, the proposed requirement of having a minimum post flight period of 15 minutes at each HEMS operating base returns will reduce the chance of survival by 8 minutes for the next patient in case of close consecutive missions.

To illustrate those two issues, let's take the example of 2 unpredicted HEMS operations within the



same FDP:

• 1st launch at the start of the FDP, at 8h00 with a mission with 2 flight times of 10 minutes (mission back and forth)

o This requires a 30-minutes preflight then a 15-minute post flight

• 2nd launch at 12h00: no preflight required because the preflight has already been done

• Further operations: no preflight required as far as preflight is already done

This example highlights the lack of efficiency of having a long pre-flight at the beginning of the FDP

before the first flight time and no preflight requirement for the following flight time though it occurs 4

hours after the initial checks.

Moreover, due to multiple flight times inside a unique FDP, HDF underlines that the definition of post flight duty is non-consistent with the usual definition of post-flight:

Which starts at the end (of the last FT) of the FDP

• Assuming the FDP ends with the last FT

• Though for HEMS operations FT are unpredictable and scheduled FDP may end long after the

last effective FT

Thus, for HEMS operations, it is not clear if the post-flight does belong or not to the FDP depending on

the end of the last FT.

This definition does not correspond to the definition of the proposal which defines a postflight after

each flight time returning to HEMS operating base within the same FDP. Therefore, HDF suggests suppressing the post flight duties since they are confusing and replacing it by a proportionate

pre-flight time before any take-off from the HEMS operating base.

For French HEMS services, the suitable accommodation is nearby the helicopter.

On the other hand, HDF agrees these requirements do not apply for the Technical Crew Member since TCM function does not include the flight preparation.

(Cf. comment #44)

In consequence, the proposal does not demonstrate safety improvement in all cases, in particular when

several flight times are allocated in the same FDP and suppress life opportunity for the 1st patient if the

emergency occurs in the first 30 minutes of the FDP and the next ones in case of airlift multiple

rotations. Thus, HDF proposes:

 \bullet To suppress the minimum duration of initial preflight of 30 minutes and to replace it by "a

sufficient time determined by the operator and specified in the operating manual"; this proposal does not affect the commander's prerogatives since he remains the one to make the

final decision regarding the take-off time

 \bullet To dissociate from the above the time for the operational preparation of further individual

flight time

• To replace the notion of "post-flight" by "operational pre-flight at the HEMS operating base"



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

• To suppress the minimum duration of "operational pre-flight at the HEMS operating base" at and to replace it by "a sufficient time determined by the operator and specified in the operating manual" instead of the proposed required 15 minutes for the post-flight between 2 FT at the HEMS operating base (Cf. comment #31.1) PROPOSAL Replace the paragraph (a)(3) and (b)(4) by the following: "(a) [...] (3) A sufficient time is determined by the operator and specified in the operating manual for the initial pre-flight duties performed at the beginning of the FDP and for operational pre-flight duties before each flight taking-off from the HEMS operating base." "(b) [...] (4) A sufficient time is determined by the operator and specified in the operating manual for the initial pre-flight duties performed at the beginning of the FDP and for operational pre-flight duties before each flight taking-off from the HEMS operating base. Pre-flights duties do not apply to TCM.". Pre-flights duties do not apply to TCM." #6 (c) ISSUE HDF highlights that the proposition in point (c) shall apply for both: Two-pilots operations: Table 1; and Single-pilot + 1 TCM operations: Table 2 Indeed, the proposed mitigation is met in both operations by offering suitable accommodation at HEMS operating base (Cf. point (b)(2) and (a)(1)): the rest and mitigated resulting fatigue are the same thus the alleviation shall be the same. PROPOSAL Replace paragraph(c) by the following: "If the rest period before reporting for the FDP is taken at the HEMS operating base, the limits of Table 1 for two-pilots operations and Table 2 for single-pilot operations, for reporting times between 0730-0959 also apply for reporting times between 0630-0729." **#7 SINGLE-PILOT + TCM TOTAL FT LIMITATION** (Cf. attachments S1, S2, S3 and S4 illustrating this total flight time limitation issue) Table 2 ISSUE HDF would like to highlight that the total flight time limitation for single-pilot + TCM operations without the use of autopilot are too restrictive especially the following ones: • FDP starting between 06:30-06-59 => maximum total flight time = 3:30 FDP starting between 12:00-13:59 => maximum total flight time = 3:30

• FDP starting between 4:00-06:29 => maximum total flight time = 3:00

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 319 of 585 There is no regulation in France on this subject for HEMS operations, with no reported inherent safety

issue through experience.

A further developed RIA based on experience and safety records on this subject would be beneficial,

in order to assess the economic and social impacts in addition to the flight safety impact. In CAT provisions, when the operator has implemented a FRM, it is considered as a valuable mitigation

to allow for the FDP to be increased by 1hour, in some cases.

Thus, in the same philosophy than for CAT operations, HDF proposes to increase all total flight time limitations by 1 hour under the principles of a FRM.

PROPOSAL

Add the following sentence below the Table 2:

"The maximum Flight Time in Table 2 can be increased by 1 hour under the principles of a FRM"

#8 MITIGATION AFTER A BLOCK OF UP TO 4 CONSECUTIVE FDP OF MORE THAN 12 HOURS (Cf. attachments S1, S2, S3 and S4 illustrating the reduced rest and the 12h operational readiness

issues)

(d)

ISSUE

On the one hand, HDF underlines the French regulation historically proposes several rostering cycles for HEMS operations that are currently used with an excellent safety track record

demonstrated by experience:

• 7 days ON / 7 days OFF with a limitation of 14 hours of duties for 24 hours

• 5 days ON / 2 days OFF with a limitation of 12 hours of duties for 24 hours

• 12 days ON / 6 days OFF with a limitation of 12 hours of duties for 24 hours

Therefore, most hospitals / HEMS organizations have a contractual engagement with the National

Health Authority over a rolling 24 hours period: 12 hours of HEMS operative availability and 12 hours

OFF.

According to the Agency requirement on the pre-flight and post-flight minimum times (Cf. #28.5), an

HEMS organization will yet roster cycle with a FDP of 12h30 and a Duty Period of 12h45 to ensure they

follow their engagement with hospitals. Thus, all HEMS operators will have to schedule: • More than 12h EDP for each and every shift

More than 12h FDP for each and every shift

• Reduced rest of more than 10h amongst a 11h15 available time for rest according to CS.FTL.3.235 to reengage at the same time the day after under the principles of a FRM Moreover, HDFH highlights that, due to short and continuous flight times with a total flight time limited per Table 2 and which are in average 1h30 per 12 hours of shifts (with an average leg of

25 min for SNEH)i in France, the fatigue will not be an issue for FDP ranged from 12h up to 14h. Indeed,

according to the requirements (a)(1) and (b)(2), all HEMS organizations shall provide suitable

accommodation at the HEMS operating base, thus pilots can have breaks in comfortable places



between two flight times. These pilots have to have their rest at the HEMS operating base which is considered as a mitigation measure. This is also a safety improvement because the rest is at the HEMS operating base which is considered as a mitigation measure. Furthermore, no demonstration nor RIA is given to justify the point (d), while the current rostering in France on this subject for HEMS operations has not reported inherent safety issue through experience. On the other hand, most of the French pilots are "faux-basés", meaning they spend 7 days working at home base and then 7 days of rest at home which can be at 500 kilometers from home base. Therefore. most of French HEMS pilots prefer the cycle 7 days ON / 7 days OFF for their quality of life which will be limited by the requirement (d). Nevertheless, the provisions of (d) implies at least 4 days ON per 3 days OFF, which appears counterproductive for social issues and crew quality of life. PROPOSAL Replace paragraph (d) by the following: "If an operator assigns two or more consecutive FDPs of more than 12h, the following conditions shall be met: (1) The rest period preceding the first FDP is at least 36 hours including 2 local nights; and (2) The rest period provided after completion of the series of consecutive FDPs is at least 60 hours including 3 local nights. A block of more than 4 consecutive FDPs of more than 12 hours can be scheduled under the principles of a FRM." Please see the answer to comment # 54

comment	1306 comment by: Elilombarda
	CS FTL.3.205 Flight duty period (FDP) — HEMS
	With regard to 'Duty Period', 'Flight Duty Period (FDP)' and 'Rest Periods' in HEMS operations, the following applies:
	ORO.FTL.105 (11) - 'duty period'
	ORO.FTL.105 (12) - 'flight duty period ('FDP')' ORO.FTL.205 Flight duty period (FDP) (and related AMC/GM)
	ORO.FTL.210 Flight times and duty periods (and related AMC/GM) ORO.FTL.235 Rest periods (and related AMC/GM)
	CS FTL.3.205 Flight duty period (FDP) (and related AMC/GM)
	CS FTL.3.210 Flight times and duty periods (and related AMC/GM) CS FTL.3.235 Rest periods (and related AMC/GM)



response

Some European countries have been organised for several years in 7/7 rosters, with up to 13/14 hours of daily FDP, also in night duties. Italy has been organised in 7/7 and also 14/14 rosters with up to 13 hours of duty time and FDP.

Contacts with pilots, HEMS crew members, HEMS organisations and aviation associations indicate that this kind of roster is well accepted by all personnel and that generally the stress build up during the 7 or 14 day-shift is well managed by them.

In Italy, HEMS rosters are organised in 7/7 with a maximum of 13 hours of duty and FDP time. Italy was organised in 14/14 days rosters for many years. This organisation has been introduced by national Authority (ENAC), and operators, pilots and aviation associations have considered this safe for crew's possible stress build up and required rest necessities.

Generally, stress comes from fatigue, especially when facing intense flying days. A possible barrier to this kind of stress can be by reducing the maximum allowed FDP in those days where the flying time is going to reach the maximum allowed for the day. For example, in a two-pilot HEMS duty day with a FDP of 14 hours, the maximum allowed daily flight time is 9:00 hours. If the crew reaches, during that day, a flight time of 7:00 hours (2 hours before the maximum allowed daily FT), then the maximum FDP in that day will be reduced to maximum 12:00 hours, so the crew can have an increased rest time on the rest of the day.

Breaks do not seem to be an efficient solution for two main reasons:

- The emergency service will be disrupted in a time frame where a mission is likely to be requested (i.e. "at times that ensure likelihood of sleep" - ref. 'CS FTL.3.205(a)(1) - in a daily shift means between 14:00-16:00). This means that the emergency service will be suspended (no helicopter intervention, for example, on car accidents or heart strokes), or that the operator shall provide for a substitute crew during break periods.
- 2. The crew member shall remain in the base (i.e. "at the HEMS operating base" ref. 'CS FTL.3.205(a)(1)) which would partly reduce the rest effect. Breaks and the related rest not always comes from sleep, but sometimes it comes from "mentally breaking" with the operative environment, thus phisically temporarly walk away from the stressing environment.

(1) Continuous FT is limited in all cases to 4 hours with autopilot and to 2 hours without autopilot;

For FDPs of over 10 hours, the operator ensures at least one break of minimum 60 consecutive minutes within each FDP at the HEMS operating base at times that ensure likelihood of sleep and provides suitable accommodation for the purpose of breaks at the HEMS operating base;

(3) (3) The time for breaks constitutes 50 % of the time over 10 hours and excludes the

necessary time for post- and pre-flight duties;-

If the crew reaches a flight time of 2 hours before the maximum allowed daily flight time, as reported in table 2, the maximum FDP on that day is reduced to maximum 12:00 hours.

**** **** The operator specifies in the operations manual, a minimum of 30 minutes for the first preflight duties performed at the beginning of the FDP and a minimum of 15 minutes for postflight duties for every flight returning to the HEMS operating base.

(...) The operator may assign a block of **up to 4 7 consecutive FDPs** of more than 12 hours, but less than 14 hours, if the following conditions are met:

the rest period preceding the first FDP is at least 36 hours including 2 local nights; and

the rest period provided after completion of the series of consecutive FDPs is at least 60 hours including 3 local nights.

response

Please see the answer to comment # 54

comment1322comment by: SASThe majority of single pilot HEMS operations in the UK operate a 12hr FDP. It would be
uncommon to not have a break of 60 minutes at least once in a shift, but to specify a break
through-out which the flight crew could not be disturbed threatens the availability of the
operation. HEMS is an environment where minutes can literally be the difference between
life and death for the patient. GM1 SPA.HEMS.100 - 'The HEMS Philosophy' states that
HEMS flights are able to accept 'potential risk ... to a level proportionate to the task'. This
enforced break would be undermining this HEMS philosophy.responsePlease see the answer to comment # 54

comment 1323

comment by: SAS

Post-flight duties on returning to a HEMS operating base are often minimal. The very nature of HEMS operations leads to extended periods of time waiting, either at HEMS operating sites or a hospitals. It is possible to complete the post-flight duties for each sector at the end of that sector. This renders the stipulation of 'a minimum of 15 minutes for post-flight duties for every flight returning to base' pointless. On the contrary it has the potential to severely affect the effectiveness of an operation. A HEMS crew may only attend 2 jobs in a day, it is perfectly conceivable that these tasking could be within 15min of one another. As stated previously, this is an environment where minutes can literally be the difference between life and death and the patient. With this in mind, this restriction seems both unnecessary and inappropriate.

response

Please see the answer to comment # 54

comment	1337	comment by: ENAC
	ENAC received the following comment from HEMS operators: Breaks do not seem to be an efficient solution for two main reasons: 1) The emergency service will be disrupted in a time frame where a mission is likely to be requested (i.e. "at times that ensure likelihood of sleep" - ref. 'CS FTL.3.205(a)(1) - in a daily shift means between 14:00-16:00). This means that the emergency service will be suspended (no helicopter intervention, for example, on car accidents or heart strokes), or that the operator shall provide for a substitute crew during break periods.	
	 The crew member shall remain in the base (i.e. "at the HEMS operating base" - ref. 'CS FTL.3.205(a)(1)) which would partly reduce the rest effect. 	
response	Please see the answer to comment # 54	
comment	1342	comment by: European Cockpit Association
	Commented text: CS FTL.3.205 Flight duty period (FDP) — HEMS The conditions to modify the limits on flight duty, duty and rest periods by the commander in the case of unforeseen circumstances in HEMS flight operations which occur at or after the reporting time, or at the end of the FDP, comply with the following: ECA Comment:	
	ECA appreciates this approach; this is a major achievement/improvement against fatigue and should be remained in at least the CS.	
response	Please see the answer to comment # 54	
comment	1344	comment by: European Cockpit Association
	General Comment: The commanders discretion is used, the following min rest period - if this is a reduced est - has to be extended by the amount of the extension of the FDP due to the ommanders discretion.	
response	Please see the answer to comment # 54	
comment	1390	comment by: Swiss Air-Ambulance Rega
	<u>CS.FTL.3.205(a)</u> Here, the table establishes "Maximum Flight Duty Period (FDP) for two-pilot operations" according to Table 1. If 12 hours are exceeded, at least one break of an uninterrupted hour	

at the base must be guaranteed, as "time that ensures likelihood of sleep". The assessment of this likelihood in practice is likely to be extremely difficult and not comparable. Hence, this specification lacks practicability and relevance, and the passage should be deleted.

CS.FTL.3.205(a)(2)

The total breaks must constitute 50% of the time over 12 hours. Question: The break time is the total of all breaks, but only one of the breaks must be > 60 minutes?

Question: When does FDP/handover time FDP DT start? or The definition of FDP according to ORO.FTL.105 No 12 states that the duty the crew member reports for contains a sector or a series of sectors. This definition does not work for HEMS operation. HEMS is characterised by the fact that the crew at the home base waits for a mission alert. In this regard, when reporting for duty, it is not foreseeable whether and when a sector will be flown. It is regularly the case that the first mission occurs several hours after reporting for duty. This must be taken into consideration in the definition, otherwise the FDP in the scope of HEMS operation would be nearly identical to the duty period, which would impose substantial limitations on the operator as compared to today's system. One possible solution here would be that breaks between missions that least the last at 60 consecutive minutes interrupt FDP. Comment on Tables 1 and 2: Where do these times come from? What is the underlying data? No scientific study on HEMS operation, which confirms these apparently arbitrarily established times, is evident or mentioned.

CS.FTL.3.205(b)

Maximum flight duty period (FDP) for one pilot, see Table 2. If 10 hours are exceeded, at least one break of an uninterrupted hour (> 60 minutes) at the base must be guaranteed, as "time that ensures likelihood of sleep".

Question: How should likelihood be assessed (time that ensures likelihood of sleep)? This is completely impractical; this passage is to be deleted.

Para. b3: The total breaks must constitute 50% of the time over 10 hours. Question: The break time is calculated as the total of all breaks, but only one of the breaks must be > 60 minutes.

Table 2: The established maximum flight times are unacceptable, too short and are totally
unfounded. As a minimum, the same flight hours should be possible for operation with one
pilot and autopilot (AP) as with two pilots. The AP supports manual flying just as another
pilot does. Recommendation: A pilot without AP max. 5 hours, a pilot with AP 7 hours.
Question: What are the flight time limitations for CAT and aerial work? Will even shorter
flight
times
be
be
established
for
these?
Dependency between the start of duty and the max. flight time is also unacceptable, and
no distinction is made for CAT either. This would represent an inadmissible unequal
treatment.

The concept of operating a mixed crew, in which tasks are shared, differs considerably from a true single pilot concept since cockpit workload is divided and monitoring is taking place. There are no credits for this sharing of workload in terms of FTL however the HEMS TCM must adhere to the FTL. Credits should be given for the mixed crew concept and be treated same as two-pilots.



Proposed amendment:

(1) Continuous FT is limited in all cases to 7 hours per day. Exceptionally, the flight time on one day per calendar month may not exceed 8 hours.

(2) For FDPs of over 12 hours to a max of 14 hours, the operator ensures at least one break of minimum 120 consecutive minutes (split duty) plus a total of 60 minutes during the daytime [...]

То be removed in order reduce (3) to complexity. (4) Ok. Table 2: Should be deleted in order to reduce complexity and the flight time values in table 2 should be adapted as follows (A pilot without AP max. 5 hours, a pilot with AP 7 hours.): 60 flight hours in 14 (1) days;

(2) 110 flight hours in 28 days; (3) 280 flight in calendar months; hours three (4) 900 flight hours per calendar year.

CS.FTL.3.205(b)(2)

There needs to be specific AMC material developed to support training and awareness of the use of breaks within duties at times where the crew member is encouraged to sleep. This is to ensure that all those involved (crew members and those involved in planning the flights) understand and provide the necessary support for the crew to be fit to operate the flight. EASA is requested to develop specific training requirements and guidance material to ensure that crew and the operators understand how to: identify the times likely for sleep; the best use of the opportunities to sleep; how to manage sleep inertia issues; and, the impact of the commercial pressures of the operation.

CS.FTL.3.205(d)

If an FDP is between 12 and 14 hours, the duty period is limited to 4 consecutive days. This must be preceded by a rest period of 36 hours (2 nights); previously, only 24 hours were required. It must be followed by a rest period of 60 hours (3 nights); previously, this was hours. 48

Question: Is the travel time according to CS.FTL.3.200 (b) part of the 4 FDPs? If it was conceived in this way, pilots can only be used on 2 to 3 days if the FDP > 12 hours; this makes the use of flex-time pilots, etc. unprofitable in these times. Question: In the event of a 24-hour base, will the FDP be limited to four days if the 12 hours are exceeded once? This means that planning is limited to just four days. Until now, the 7day duty cycle has been the appealing part of shift duty at a 24-hour base. This would lead to a further loss of acceptance among pilots.

Rega's HEMS FDP is max. 5 d on a mountain base and max. 2 d on a midland base. The expected days of duty shall be based on the expected mission per day, taking seasonal variations into account.

Split duty is not taken into account in this section. Or is this section not relevant for split duty? With spilt duty, FDPs of more than 14 hours would be possible. The consequences of this on planning are not defined.

response

Please see the answer to comment # 54



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

comment	1421	comment by: Svensk Luftambulans
	handled	ot of breaks for HEMS operations is not useable and should be
	differently. An easier a with a	pproach would be a concept comprising a maximum Duty Period
		eriod comprising "Passive time" and "Active time".
response	Please see the answer t	to comment # 54
comment	1422	comment by: Svensk Luftambulans
	Comment: While our H enough	EMS operating bases include suitable accommodation, there is not
		er for crew that are to report for duty.
response	Please see the answer t	to comment # 54
comment	1423	comment by: Svensk Luftambulans
		.2+ hours has been common practice for close to 20 years elating to fatigue. If the flight duty period is of a reasonable length,
	it is the	
	number of duty periods involved	that induced fatigue, not the length of the flight duty period. Crews

in HEMS operation typically have ample time for rest and food intake. Prescribing breaks is not a

practical solution.

response

Please see the answer to comment # 54

comment	1424 comment by: Svensk Luftambulans
	Comment: An easier approach would be a concept comprising a maximum Duty Period with a maximum Flight Duty Period comprising "Passive time" and "Active time". Passive time is calculated as 50% towards the total Flight Duty Time. Active time is calculated as 100% towards the total Flight Duty Time.
response	Please see the answer to comment # 54



comment by: COPAC COLEGIO OFICIAL DE PILOTOS DE LA AVIACIÓN comment 1437 COMERCIAL CS FTL.3.205, se habla de "break", además de otros puntos en los que también se hace referencia a estos mismos "break". ¿Cómo se determina un break? Es decir, ¿se ha de notificar al operador que asigna las misiones que durante un mínimo de 60 minutos no se le puede asignar misión? ¿O no es necesaria la notificación y simplemente la confirmación de que durante dichos 60 minutos mínimo se ha podido descansar? Please see the answer to comment # 54 response 1456 comment comment by: Association of Air Ambulances CS.FTL.3.205 states that for two-pilot HEMS operations, the FDP limitation data in table 1 is applicable, and hence applicable to LAA HEMS operations. Subparagraph (a)(3) states that the operations manual shall specify a minimum of 30 minutes for pre-flight duties and 15 minutes for post flight duties "for every flight returning to the HEMS operating base." For a short sector HEMS operation like London's Air Ambulance where the average sector duration is historically 6 minutes the imposition of the 15 minute post flight duty embargo for every flight returning to the HEMS operating base is a major operational limitation. This needs to be clarified as previously the 15 minutes of post flight duty period was applied after the last flight of the duty day. Just taking a brief look at the returned SRPs, this would have delayed at least 4 responses that I found in one month alone. I think we might have to argue this (a9(3) a minimum of 15 minutes post flight duties for every flight returning to teh HEMS operating base is considered very restrictive and could impact operational service, particularly in the summer A one hour discretion over our current operating system is a reduction in capability There is no guidance surrounding travel arrangements for touring/travelling pilots response

Please see the answer to comment # 54

comment 1487 comment by: Finnish Transport Safety Agency

In order to establish rolling 24 hour standby for HEMS, following amendments are proposed.

Reasoning: Paragraph describes 24 to 72 hours of active standby. FDP or other work required by operator may be associated with this active standby. The safety mitigating action is based on the fact that during active standby the pilot is active only short times. In

Finland the average ADP is only 3,5 hours within rolling 24 hour period. In addition, maximum flight time and ADP during the rolling 24 hours are limited. For this reason, active standby operation ensures an adequate rest to the crew members. Most of the HEMS operations take place in day time, in Finland approximately 15% of HEMS tasks take place during the night.

Proposal:

Add new paragraph CS FTL.3.207 after CS FTL.3.205 as follows:

CS FTL.3.207 Active duty period (ADP) in active standby – HEMS

By way of derogation from CS FTL.3.205, the flight and duty time limitations given below shall apply to active standby in helicopter emergency medical service (HEMS) operations: (a) For two-pilot (table 1) and single-pilot (table 2) HEMS operations, the basic maximum daily ADP and the maximum flight time FT within that ADP are established in accordance with tables and comply with the following conditions:

(1) The active standby is considered to begin when the individual crew member reports for duty, and finishes when crew member stops being on active standby or hands the standby duties over to another person.

(2) Maximum ADP in rolling 24 hour period, for acclimatized crew members are established in accordance with Table 1 and 2:

Table	1
-------	---

Maximum basic daily ADP in hours — Acclimatised crew members in two-pilot HEMS operations

Active standby period	Maximum ADP in rolling 24 hour period	Maximum flight time FT with autopilot in rolling 24 hour period	Maximum flight time FT without autopilot in rolling 24 hour period
24:00	12:00	08:00	06:00
48:00	11:00	07:30	05:30
72:00	10:00	07:00	05:00

Table 2

Maximum basic daily ADP in hours — Acclimatised crew members in single-pilot HEMS operations

Active standby period	Maximum ADP in rolling 24 hour period	Maximum flight time FT with autopilot in rolling 24 hour period	Maximum flight time FT without autopilot in rolling 24 hour period
24:00	12:00	06:00	04:00
48:00	11:00	05:30	03:30
72:00	10:00	05:00	03:00



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 329 of 585

response

Please see the answer to comment # 54

CS FTL.3.205 p. 36

comment	5 comment by: <i>TG</i>
	Die FDP Zeiten lassen sich nicht immer vorhersehen - große Spielräume sind zum Benefit von Patient, Crew und Hubschrauber nötig. Es kann nicht sein, dass eine Crew länger mit der Suche nach Parkmöglichkeiten und Absicherung des Hubschraubers beschäftigt ist als mit einem vielleicht 30-minütigen Flug zur Home-Base. 60h/3N ist viel zu lang vor dem Dienst - kein Benefit.
response	Please see the answer to comment # 54
comment	6 comment by: <i>TG</i>
	Die Berechnung der Folgen von "unforeseen Circumstances" ist erheblich zu kompliziert und für die Dienstplanung und Erfüllung des EMS Auftrages nicht praktikabel.
response	Please see the answer to comment # 54
comment	24 comment by: Johannes Brantz
	60 Minutes guaranteed break at the Home Base
	This is a real plus to manage fatigue, HEMS crews have a high motivation to help patients. Therefore decisions to accept another mission are likely to be made even though the crew would need a break. The guaranteed break helps crews to avoid fatigue.
	Commander's discretion

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

**** * **** Some extensions of Flight Duty Times are accounted for in the FTL by commander's discretion. I would like to bring to your intention that a successful HEMS Mission is the result of an excellent team work.

Therefore I would agree that decisions about extensions should be team decision instead of commander's discretion.

response

Please see the answer to comment # 54

comment	60 comment by: London's Air Ambulance
	This does not read logically. It should be amended to read: "(c) If the total of Commander's discretion used at any HEMS operating base is more than 10 % of the total FDP for a 3-month period, the future schedule of crew resource utilisation of that HEMS operating base is to be reviewed and amended."
response	Please see the answer to comment # 54

comment	65 comment by: London's Air Ambulance
	CS FTL.3.205(b) permits the allowed increase to the FDP to be extended if the unforeseen circumstance (HEMS call) occurs just before take-off on the final sector, but only to transport the patient. If a medical decision is made not to transport the patient by air, this could result in a helicopter being stranded until a rested crew can arrive at the HEMS site to relieve the duty crew. This should be amended to allow either the transport of the patient or an non-HEMS flight to the overnight base.
	This contradicts ORO.FTL.105 (29) A sector flown to position an aircraft to the operating base before or after an EMS flight is considered part of that flight.
response	Please see the answer to comment # 54

comment | 184

comment by: ANSMUH

CS FTL 3.205 FDP

(a) The maximum basic daily FDP may be increased for HEMS by up to 1 hour for singlepilot operation or by up to 2 hours for two-pilot operation.

Actually in France it's possible for an H12 operating base to have a commander's dicretion of 2 hours. For H14, it's impossible to have this commander's discretion, because the minimum rest period is 10 hours.

We want to keep this possibility of 2 hours commander's discretion without restriction of number of pilot. The ideal would be to keep the French system with the obligation of a minimum of 10 hours of rest.

(b) If on the final sector within the FDP the allowed increase under (a) is further exceeded because of unforeseen circumstances after take-off, the flight may continue to the planned destination or alternate aerodrome. If unforeseen circumstances occur just before take-off on the final sector, the allowed increase may only be exceeded to transport the patient.

In France all operating base are located on hospitals. Imagine that for unforeseen circumstances we must go beyond the commander's discretion because the patient must be transported to another hospital than the operating base. Problem: What do we do with the medical team who must return to the operating base after the patient transportation ? How does the crew to find suitable accomodation, if they have to stop taking off an come back to the operating base ? Our proposal would be to give the opportunity to go back to the operating base, provided that it is a minimum of 10 hours of rest after. This is what is happening in France.

Proposal:

CS FTL.3.205 Flight duty period (FDP) — HEMS

Unforeseen circumstances in flight operations — commander's discretion in HEMS under ORO.FTL.205(f)

The conditions to modify the limits on flight duty, duty and rest periods by the commander in the case of unforeseen circumstances in HEMS flight operations which occur at or after the reporting time, or at the end of the FDP, comply with the following:

(a) The maximum basic daily FDP may be increased for HEMS by up to $2 \pm$ hours not exceeding 14 hours FDP for single-pilot operation or by up to 2 hours for two-pilot operation.

(b) If on the final sector within the FDP the allowed increase under (a) is further exceeded because of unforeseen circumstances after take-off, the flight may continue to the planned destination or alternate aerodrome. If unforeseen circumstances occur just before take-off on the final sector, the allowed increase may only be exceeded to go back to the HEMS operating base transport the patient. In that case, the rest period shall be at least 10 hours.

(c) If commander discretion is used in any HEMS operating base more than 10 % of the total FDP over a 3-month period, the schedule and crew resources of the HEMS operating base are reviewed and adapted.

response

Please see the answer to comment # 54



comment	276 comment by: European Helicopter Association (EHA)
	SHA (Switzerland)
	Table 2 The maximum time without autopilot is a nonsense and no difference shall be applicable. They are not such limitations in SPO or CAT and pilots flies often in more demanding work (sling load).
response	Please see the answer to comment # 54
comment	281 comment by: European Helicopter Association (EHA)
	ADAC (Germany), DRF (Germany) and LAR (Luxembourg):
	CS FTL 3.205 (b) (2) & (3)
	Problem: For FDP of 14 hours the time of break has to be 2 hours (50% of the time over 10 hours) but only one has to be consecutive. That means, that any period (i.e 6 x10 minutes) fits into this scheme. The administrative implementation is very exaggerated
	Solution: Delete sub paragraph 3 in total
response	Please see the answer to comment # 54
comment	315 comment by: European Helicopter Association (EHA)
	NORSK LUFTAMBULANSE AS (Norway):
	Comment: (the same comment is placed on page 37 for CS FTL 3.210) NLA presently operates in a system that have one crew on duty for 24/7 for one complete week in a 7 ON/14 OFF/7 ON/21 off for flight crew members and 7 ON / 21 OFF for HEMS technical crew members. As our FRM and sicentific studies has shown, this is apparently conducted in a safe manner and we intend to seek an IFTSS. Having said that, having two crews manning one helicopter for a 24 hour period is quite common pracice in Europe and as we see it, this will no longer be practicable.

For HEMS operating base conducting 24/7 operations:



When operating in compliance with CS FTL.3.205 Flight duty period (FDP) — HEMS and CS FTL.3.210 Flight times and duty periods — HEMS, there is not enough overlap to ensure continuity of the service if only two crews (a "day" and "night" crew) are used to cover a 24-hour period.

With two crews, the maximum of 14 hours and 12 hours FDP limits respectively gives only a maximum of 1 hour overlap in each end. This does not give enough time to dispatch on, and complete a, HEMS mission. Note that this is even if <u>not one single</u> HEMS mission has taken place during the FDP prior to the alarm.

Should an alarm come in shortly (for example 1:30 to 1 hour) before overlap, the mission will have to be postponed until the new crew has commenced their FDP. Alternatively, three crews must be used for every 24-hour period to keep one HEMS operating base operational 24/7.

1:30 to 1 hour before the overlap is just an example. The period necessary to complete a mission is quite contextual and sufficient time is up for discussion, but the question needs to be addressed.

Furthermore, as mentioned in the comment to **CS FTL.3.205 Flight duty period (FDP)** — **HEMS, NPA p 35** above, prescribing breaks is not a practicable solution and the concept of breaks is very unclear, especially regarding how this should be planned.

An easier approach would be a concept comprising a maximum Duty Period with a maximum Flight Duty Period comprising "Passive time" and "Active time". This could look like the following example:

"Passive time" is all the time spent on a HEMS duty period that is not considered to be active time, relaxing, free of all duties except standing by to receive an alarm.

"Active time" is all the time spent pre- and post-flight activities, operation of the helicopter, HEMS missions, rapid response vehicle missions, training, checking, administrative work, meetings, attending a course, simulator, travel etc.

While passive time is the time the crew members are relaxing, the fatigue level is a direct consequence of the circadian rhythm and therefore it is of outmost importance, as far as practicable, to maintain a normal sleep pattern.

Passive time is calculated as 50% towards the total Flight Duty Time. Active time is calculated as 100% towards the total Flight Duty Time.

If reaching any Flight time or Active time limit, the crew member shall go off Active duty.

HEMS:

• Duties such as pre-flight inspection, fuel checks, equipment check, etc. shall be logged as active time;

• Active time is triggered by an alarm and is defined from time of alarm to minimum 1 hour after block-on time. If the time for post flight duties takes more than 1 hour, actual time shall be logged as active time.

Rapid response vehicle operation:

- Between 10:00 and 22:59, Active time is triggered by an alarm and is defined from time of alarm to the time the mission is completed and equipment etc. is resupplied and prepared and as a minimum 15 minutes; and
- Between 23:00 and 09:59, Active time is triggered by an alarm and is defined from time of alarm to minimum 1 hour after returning at the base. If the time for post mission duties takes more than 1-hour, actual time shall be logged as active time.

For HEMS and rapid response vehicle operation:

• If there are less than two hours between on-block and the time of a new alarm, the entire time between on-block and the time of a new alarm counts as Active time.

Other operations (pre-flight, ferry flight, test flight, training flight, etc.):

- Active time is triggered when reporting for duty or commencing preparations and ends minimum 30 minutes after block-on time;
- Related duties such as pre-flight inspection, fuel checks, equipment check, flights registration etc., are not counted separately. This is considered included in the minimum 30 minutes after block-on time; and
- If the time for post flight duties takes more than 30 minutes, actual time shall be logged as Active time.

With a system like this, perhaps a maximum Flight Duty Period of 16 hours could be introduced for a "day crew" with a maximum of 10 or 12 hours total active and passive time. For a "night crew", a maximum of 12 or even 14 hours maximum Flight Duty Period could be used with a maximum of 10 hours of total active time. This system would also allow for sufficient overlap in case of missions just prior to a crew/shift change.

response

Please see the answer to comment # 54



comment 317

comment by: European Helicopter Association (EHA)

NORSK LUFTAMBULANSE AS (Norway):

"Unforeseen circumstances in flight operations — commander's discretion in HEMS under ORO.FTL.205(f)

(a) The maximum basic daily FDP may be increased for HEMS by up to 1 hour for singlepilot operation or by up to 2 hours for two-pilot operation."

Comment: Unforeseen circumstances would typically include only longer time at HEMS operating site or weather. Unforeseen should also should include catastrophic events.

"(b) If on the final sector within the FDP the allowed increase under (a) is further exceeded because of unforeseen circumstances after take-off, the flight may continue to the planned destination or alternate aerodrome. If unforeseen circumstances occur just before take-off on the final sector, the allowed increase may only be exceeded to transport the patient."

Comment: This is too restrictive. After delivering the patient, the crew should be allowed to return to the HEMS operating base (perhaps under the condition that there is suitable accommodation where the crew can rest). Otherwise, the consequence could be that the crew is stuck at a hospital without practical possibility to get rest. Furthermore, the helicopter will also be stuck at a hospital without crew to fly it. On most hospital landing sites, the helicopter would block the helipad for the duration of the stay (i.e. no other helicopters would be able to use the helipad) and in many circumstances also take occupy hospital security personnel. In addition, it is not necessary the case that the relieving crew have a practicable chance to travel from the HEMS operating base to the hospital where the helicopter is parked.

"(c) If commander discretion is used in any HEMS operating base more than 10 % of the total FDP over a 3-month period, the schedule and crew resources of the HEMS operating base are reviewed and adapted.

Comment: While sensible, the should be re-worked to make it easier to understand.

response

Please see the answer to comment # 54

comment 341

comment by: European Helicopter Association (EHA)

FNAM (France)

CS FTL.3.205 Maximum basic daily FDP in HEMS under ORO.FTL.205 (b)(7) #1

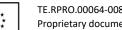


TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 336 of 585 There are two CS FTL.3.205 (with exactly the same title), which introduces complexity, uncertainty and may lead to misunderstanding. The FNAM suggests adding precisions in the title of this paragraph in order to quickly make the link with the ORO paragraph involved. PROPOSAL Replace the title of this CS by: "CS FTL.3.205 (b)(7)" #2 REMARK For small FT as currently operated in HEMS, it is possible to have multiple FDP within the same day. For instance: One FDP from 07:00 to 8:30 followed by a 12h rest period and then a FDP from 20:30 to 22h. #3 CONTINUOUS FLIGHT TIME LIMITATION IN SINGLE-PILOT + TCM (b)(1) ISSUE The FNAM highlights the too restrictive limitation of total flight time for the single-pilot + TCM operations (b)(1). Indeed, the proposal constrains the continuous flight time for single-pilot + TCM operations: with autopilot at 4 hours • without autopilot at 2 hours Some rescues and patient transportation, like severe burned patients, will not be possible with the 2 hours limitation without the autopilot. Indeed, these flights can be a haul from Lyon to Paris which lasts more than 2h and they are necessary because the transport by road is not considered sufficiently effective considering the patient's condition. These flights are usually flown with lighter helicopter without autopilot because they can fly longer distances (4h30 of autonomy) than heavy helicopters. These flights are usually scheduled from a known helipad in a hospital to another known helipad in another hospital and correspond more to the scope of commercial sanitary flights not yet defined by the EASA than the HEMS scope. In addition, it is usual to keep the engine running (the rotor blades are still turning while loading the helicopter between two legs). Thus, according to the definition of a Flight Time in ORO.FTL.105(13), these two legs are considered as a unique flight time. In that way, the limitation of 2 hours for an equipage with a single-pilot + TCM is too restrictive. Moreover, in HEMS, a single-pilot does not fly alone, he is assisted by a Technical Crew Member (which is a recent additional EASA requirement). In that way, the risk of fatigue is lower since the TCM is



assisting the pilot in non-piloting tasks and is contributing to the safety of the flight. De facto, single pilot HEMS operations are in fact 2 technical crews operations (1 pilot + 1 TCM). By parallelism, no such total flight time limitation has been defined for 2 technical crews operations (2 pilots). No RIA is given to justify this proposal. Considering the limited range of heavy helicopter with autopilot, the lack of ATPL(H) pilots in France (for acting as commander for 2 pilots HEMS operations) and considering the fleet currently assigned to hospitals in France (with single-pilot certified helicopter and no flight standard for 2 pilots operations), the sum of the previous constraints leads to the impossibility to transport this kind of patient by road or air. It is necessary to increase the limitation of continuous flight time described in this paragraph. This will not have a major impact on the fatigue of the pilots since most of the HEMS flights have a unit flight time ranged around 25 minutes, *i.e* 50 minutes back and force (1 mission)i and this extension of the continuous flight time limitation will be used for a few and very specific missions. However, in order to ensure it does not have an impact on the fatigue of the crew member, the FNAM suggests using the possibility of having a 4 hours continuous flight time for single-pilots + TCM without autopilot under the principles of a FRM. Thus, the FNAM proposes to for single-pilot + TCM without autopilot: Have an augmentation of this limitation to 3 hours Increase the limitation to 4 hours under the principles of a FRM Otherwise, a sound RIA based on experience and safety records on this subject appears to be necessary, in order to assess the economic and social impacts in addition to the flight safety impact. PROPOSAL Replace the paragraph (b)(1) by the following: "(1) Continuous FT is limited in all cases to 4 hours with autopilot and to 3 hours without autopilot. These limitations can be increased by 1 hour under the principles of a FRM;" #4.1 BREAK PERIODS for two-pilots HEMS operations (a)(1)(a)(2)ISSUE Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since flight times are unpredictable and cannot be scheduled within a FDP, the same has to be applied for breaks. Besides the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour. As a mitigation, it is obvious that due to the very low average reported flight time in HEMS,

the



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

opportunity for a 1h hour break is warranted. Indeed, given the following aspects (Table 1 of this CS): • Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time with autopilot = 9 hours which means at least 3 to 5 no-flown hours Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time without autopilot = 7 hours which means at least 5 to 7 noflown hours There is always a room for such a 1h break in a suitable accommodation at HEMS operating base. Such a break may be monitored ex-post by the operator SMS, under the principle of the fatigue risk management. Therefore, under the above risk analysis and under a monitoring following the principles of a fatigue risk management, the FNAM suggests writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the operation. (Cf. comment #30.3) PROPOSAL Rephrase the paragraph (a)(1) as follows: "(1) For FDP over 12 hours, the operator ensures ex-post that at least one break of minimum 60 consecutive minutes within each FDP at the HEMS operating base at times that ensure likelihood of sleep and provides suitable accommodation for the purpose of breaks at the HEMS operating base. Fatigue risk management principles may be applied to monitor this break." #4.2 BREAK PERIODS for single-pilot + TCM HEMS operations (b)(2)(b)(3)ISSUE Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since flight times are unpredictable and cannot be scheduled within a FDP, the same has to be applied for breaks. Besides the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour. As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, the opportunity for a break lasting between 2h and 1h is warranted. Indeed, given the following aspects (Table 2 of this CS): • Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours for break with a maximum Total Flight Time with autopilot = 7 hours which means at least 5 to 7 no-flown hours

**** * ****

 Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours for break with a maximum Total Flight Time without autopilot = 5 hours which means at least 7 to 9 noflown hours There is always a room for such a break lasting between 2h and 1h in a suitable accommodation at HEMS operating base. Such a break may be monitored ex-post by the operator SMS, under the principle of the fatigue risk management. Therefore, under the above risk analysis and under a monitoring following the principles of a fatigue risk management, the FNAM suggests writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the operation. (Cf. comment #30.3) PROPOSAL Rephrase the paragraph (b)(2) as follows: "(2) For FDP over 10 hours, the operator ensures ex-post that at least one break of minimum 60 consecutive minutes within each FDP at the HEMS operating base at times that ensure likelihood of sleep and provides suitable accommodation for the purpose of breaks at the HEMS operating base. Fatique risk management principles may be applied to monitor this break." #5 PRE AND POST FLIGHT MINIMUM TIME (a3) and (b4) ISSUE The FNAM agrees a minimum time shall be taken to ensure the safety of the flight: • Before the 1st flight of the crew, by preparing the aircraft, and • After each flight, by reporting flight and aircraft information. Due to the life-threatening emergency operation in HEMS, these times shall be as short as possible to maximize operational availability and response time. In that way, in France, the contractual time for the National Health Authorities between the launch of an HEMS flight and the effective take-off is 7 minutes. Indeed, when a patient needs essential life-saving measures, after 30 minutes, there are almost no chance to save the life of the patient. Thus, the first patient of a FDP will have no chance of survival due to the EASA proposition of having a minimum preflight time of 30 minutes at the beginning of the FDP. Moreover, French numbers underlines that 7%i of the HEMS take-off preformed within the first 30 minutes of the FDP. Whatever the number of life that would not have been saved during these 30 minutes, no loss would be politically and socially acceptable. With the same philosophy, the proposed requirement of having a minimum post flight period of 15 TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 340 of 585

minutes at each HEMS operating base returns will reduce the chance of survival by 8 minutes for the

next patient in case of close consecutive missions.

To illustrate those two issues, let's take the example of 2 unpredicted HEMS operations within the

same FDP:

• 1st launch at the start of the FDP, at 8h00 with a mission with 2 flight times of 10 minutes (mission back and forth)

o This requires a 30-minutes preflight then a 15-minute post flight

• 2nd launch at 12h00: no preflight required because the preflight has already been done

• Further operations: no preflight required as far as preflight is already done

This example highlights the lack of efficiency of having a long pre-flight at the beginning of the FDP

before the first flight time and no preflight requirement for the following flight time though it occurs 4

hours after the initial checks.

Moreover, due to multiple Flight Times inside a unique FDP, the FNAM underlines that the definition

of post flight duty is non-consistent with the usual definition of post-flight:

• Which starts at the end (of the last FT) of the FDP

• Assuming the FDP ends with the last FT

• Though for HEMS operations FT are unpredictable and scheduled FDP may end long after the

last effective FT

Thus, for HEMS operations, it is not clear if the post-flight does belong or not to the FDP depending on

the end of the last FT.

This definition does not correspond to the definition of the proposal which defines a post-flight after

each flight time returning to HEMS operating base within the same FDP. Therefore, the FNAM suggests

suppressing the post flight duties since they are confusing and replacing it by a proportionate pre-flight

time before any take-off from the HEMS operating base.

For French HEMS services, the suitable accommodation is nearby the helicopter.

According to French experiences, the effective time for preparing a new flight is 7 minutes. This reduction from 15 minutes to this current value of 7 minutes for pre-flight time before any takeoff

from the HEMS operating base will not impact the level of safety, otherwise a sound RIA based on

experience and safety records on this subject would be appreciated.

On the other hand, the FNAM agrees these requirements do not apply for the Technical Crew Member

since TCM function does not include the flight preparation.

(Cf. comment #44)

In consequence, the proposal does not demonstrate safety improvement in all cases, in particular when

several flight times are allocated in the same FDP and suppress life opportunity for the 1st patient if the

emergency occurs in the first 30 minutes of the FDP and the next ones in case of airlift multiple



rotations. Thus, FNAM proposes: • To reduce the minimum duration of initial preflight from 30 minutes to 15 minutes (inclusion of the helicopter checks) • To dissociate from the above the time for the operational preparation of further individual flight time • To replace the notion of "post-flight" by "operational pre-flight at the HEMS operating base" • To set the minimum duration of "operational pre-flight at the HEMS operating base" at 7 minutes instead of 15 minutes for the post-flight between 2 FT at the HEMS operating base (Cf. comment #31.1) PROPOSAL Replace the paragraph (a)(3) and (b)(4) by the following: "(a) [...] (3) The operator specifies in the operations manual a minimum of 15 minutes for the initial pre-flight duties performed at the beginning of the FDP and a minimum of 7 minutes for post-flight operational pre-flight duties before each flight taking-off from the HEMS operating base." "(b) [...] (4) The operator specifies in the operations manual a minimum of 15 minutes for the initial pre-flight duties performed by the pilot at the beginning of the FDP and a minimum of 7 minutes for post-flight operational pre-flight duties performed by the pilot before each flight taking-off from the HEMS operating base. Pre-flights duties do not apply to TCM." #6 (c) ISSUE The FNAM highlights that the proposition in point (c) shall apply for both: Two-pilots operations: Table 1; and • Single-pilot + 1 TCM operations: Table 2 Indeed, the proposed mitigation is met in both operations by offering suitable accommodation at HEMS operating base (Cf. point (b)(2) and (a)(1)): the rest and mitigated resulting fatigue are the same and the alleviation shall be the same. PROPOSAL Replace paragraph(c) by the following: "If the rest period before reporting for the FDP is taken at the HEMS operating base, the limits of Table 1 for two-pilots operations and Table 2 for single-pilot operations, for reporting times between 0730-0959 also apply for reporting times between 0630-0729." **#7 SINGLE-PILOT + TCM TOTAL FT LIMITATION** Table 2 ISSUE The FNAM would like to highlight that the total Flight Time limitation for single-pilot + TCM operations without the use of autopilot are too restrictive especially the following ones: FDP starting between 06:30-06-59 => maximum total flight time = 3:30

• FDP starting between 12:00-13:59 => maximum total flight time = 3:30

• FDP starting between 4:00-06:29 => maximum total flight time = 3:00

There is no regulation in France on this subject for HEMS operations, with no reported inherent safety

issue through experience.

A sound RIA based on experience and safety records on this subject appears to be necessary, in order

to assess the economic and social impacts in addition to the flight safety impact.

In CAT provisions, when the operator has implemented a FRM, it is considered as a valuable mitigation

to allow for the FDP for pilots to be increased by 1hour, in some cases.

Thus, in the same philosophy than for CAT operations, the FNAM proposes to increase all total flight

time limitations by 1 hour under the principles of a FRM.

PROPOSAL

Add the following sentence below the Table 2:

"The maximum Flight Time in Table 2 can be increased by 1 hour under the principles of a FRM"

#8 MITIGATION AFTER A BLOCK OF UP TO 4 CONSECUTIVE FDP OF MORE THAN 12 HOURS (d)

ISSUE

On the one hand, the FNAM underlines the French regulation historically proposes several rostering

cycles for HEMS operations that are currently used with an excellent safety track record demonstrated

by experience:

• 7 days ON / 7 days OFF with a limitation of 14 hours of duties for 24 hours

• 5 days ON / 2 days OFF with a limitation of 12 hours of duties for 24 hours

• 12 days ON / 6 days OFF with a limitation of 12 hours of duties for 24 hours

Therefore, most hospitals / HEMS organizations have a contractual engagement with the National

Health Authority over a rolling 24 hours period: 12 hours of HEMS operative availability and 12 hours

OFF.

According to the Agency requirement on the pre-flight and post-flight minimum times (Cf. #28.5), an

HEMS organization will yet roster cycle with a FDP of 12h30 and a Duty Period of 12h45 to ensure they

follow their engagement with hospitals. Thus, all HEMS operators will have to schedule: • More than 12h FDP for each and every vacation

• Reduced rest of more than 10h amongst a 11h15 available time for rest according to CS.FTL.3.235 to reengage at the same time the day after under the principles of a FRM Moreover, the FNAM highlights that, due to short and continuous flight times with a total time limited

per Table 2 and which are in average 1h30 per 12 hours of vacations (with an average leg of 25 min)i in

France, the fatigue will not be an issue for FDP ranged from 12h up to 14h. Indeed, according to the

requirements (a)(1) and (b)(2), all HEMS organizations shall provide suitable accommodation at the



TE.RPRO.00064-008 $\ensuremath{\mathbb{C}}$ European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

HEMS operating base, thus pilots can have breaks in comfortable places between two flight times. These pilots have to have their rest at the HEMS operating base which is considered as a mitigation measure. This is also a safety improvement because the rest is at the HEMS operating base which is considered as a mitigation measure. Furthermore, no demonstration nor RIA is given to justify the point (d), while the current rostering in France on this subject for HEMS operations has no reported inherent safety issue through experience. On the other hand, most of the French pilots are "faux-basés", meaning they spend 7 days working at home base and then 7 days of rest at home which can be at 500 kilometers from home base. Therefore, most of French HEMS pilots prefer the cycle 7 days ON / 7 days OFF for their quality of life which will be limited by the requirement (d). Nevertheless, the provisions of (d) implies at least 4 days ON per 3 days OFF, which appears counterproductive for social issues and crew quality of life. PROPOSAL Replace paragraph (d) by the following: "If an operator assigns two or more consecutive FDPs of more than 12h, the following conditions shall be met: (1) The rest period preceding the first FDP is at least 36 hours including 2 local nights; and (2) The rest period provided after completion of the series of consecutive FDPs is at least 60 hours including 3 local nights. A block of more than 4 consecutive FDPs of more than 12hours can be scheduled under the principles of a FRM." Please see the answer to comment # 54

mment	342	comment by: European Helicopter Association (EHA)
	FNAM (France)	
	#1 ISSUE	TANCES FOR HEMS under ORO FTL 205(f)
	0	ns within the titles of the paragraph in order to quickly ed.



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 344 of 585

response

CO

PROPOSAL Replace the title of this CS by: "CS FTL.3.205(f)" #2 **ISSUE - FORCE MAJEURE** (Cf. comment #17.5) HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care services is a public service & a sovereign prerogative), with groupings of medical equipment and skills. HEMS in France is both operated by private operators and state operators. State may charter private operators to operate HEMS operations on its behalf. Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved. Such a possibility shall remain for "Force majeure" and be introduced within the IR, in respect of the sovereignty of each Member State facing major health crisis. For example, in France, private operators of helicopters were chartered to ensure airlift rotations during recent Millas train disaster on December, the 14th of 2017. Besides, Helicopter **Nuclear Response** Team are partially delegated to a private operator. Therefore, the FNAM suggests adding a specific paragraph in this implementing rule allowing HEMS pilots to derogate from these requirements in case of Force Majeure as it is already the case in the Current French National Regulation. PROPOSAL For illustrative purposes, in France the following article is applied in case of « Force Majeure » : "Il peut être dérogé aux limitations mentionnées à la présente section dans les conditions suivantes : 1. Vols urgents, dont l'exécution immédiate est nécessaire : a) Pour prévenir des accidents imminents et organiser des mesures de sauvetage, ou pour réparer des accidents survenus soit au matériel, soit aux installations ; b) Pour assurer le dépannage des aéronefs. 2. Pour assurer l'achèvement d'une période de vol que des circonstances exceptionnelles n'auraient pas permis d'effectuer dans les limites préétablies. Vols exécutés dans l'intérêt de la sûreté ou de la défense nationale ou d'un service public sur ordre du Gouvernement constatant la nécessité de la dérogation ; la limite est à fixer par le ministre chargé de l'aviation civile." (ref CAC D 422-12) #3 + scenario commander's discretion attached (a) ISSUE The paragraph (a) of this CS proposes a 1 hour commander's discretion for single-pilot + TCM HEMS

**** * * *** operations. The FNAM wonders how this value has been chosen by the Agency since there is no justification within the RIA regarding this matter. Currently in France, the regulation allows a 2 hours commander's discretion, including for single-pilot + TCM HEMS operations, with no reported inherent safety issue through experience. This 2 hours commander's discretion is frequently used by single-pilot + TCM HEMS operations in case of emergency for the patient. To illustrate this issue, the FNAM attached a scenario taken from real HEMS operator planning where the commander's discretion (single-pilot + TCM) exceeds 1 hour (in that case, the commander's discretion is of 1h50). Safety record and experience show such an allowance demonstrates a high level of safety, with no accident occurrence when the commander's discretion exceeds 1 hour. For safety reasons, regulation already requires an additional crew member for HEMS, the TCM. Therefore, single-pilot HEMS operations are not PEQ1 operations but 1 single-pilot + 1 TCM contributing to the safety of the flight. As a consequence, commander's discretion should be of 2h for both two-pilots and 1 pilot + 1 TCM, as preexisting in France. Thus, the FNAM suggests a 2 hours commander's discretion for both 1 pilot +TCM and twopilots operations. PROPOSAL Replace the content of the paragraph (a) by the following: "(a) The maximum basic daily FDP may be increased for HEMS by up to 2 hours." #4 (b) ISSUE The paragraph (b) refers to 'sector'. However, the notion of 'sector' is not anymore defined for helicopters (Cf. ORO.FTL.105 (§24)). Therefore, the FNAM suggests replacing the term of sector by the notion of flight time. (Cf. comment #14.2) Besides, the wording 'alternate aerodrome' is used in the paragraph (b) but is not consistent with the activity of HEMS. Therefore, the FNAM suggests replacing this notion of alternate aerodrome by the notion of helipad or drop zone which better suits the activity of the HEMS. PROPOSAL Replace the paragraph (b) by the following: "(b) If on the final flight time within the FDP the allowed increase under (a) is further exceeded because of unforeseen circumstances after take-off, the flight may continue to the planned destination OR ANY OTHER HELIPAD OR DROP ZONE. If unforeseen circumstances occur just before take-off on the final flight time,

the allowed increase may only be exceeded to transport "the patient"." (Cf. comment hereafter) #5 (b) ISSUE In the paragraph (b), the extension of the last flight time before take-off is limited to the case of the transportation of a patient. This is not consistent with the definition of HEMS, which encompasses the following HEMS payload (medical personnel, medical supplies such as equipment, blood, organs or drugs, ill or injured persons and other persons directly involved). Life threatening emergency of a flight is not only conditioned by a patient onboard. It can deal with all the HEMS payload defined in ORO.FTL.105 (§29): medical personnel, medical supplies such as equipment including the helicopter, blood, organs or drugs, ill or injured persons and other persons directly involved. Indeed, it may be urgent for the medical staff to come back to the hospital, to ensure the medical material is available for another operation, etc. The extension of the last flight shall include all the content defined for HEMS payload, for the present or next HEMS operations requiring a quick return to the base without uselessly immobilizing critical material and staff, including the helicopter. That is why the FNAM suggests replacing the term patient used in the paragraph (b) by the HEMS payload defined in this NPA in the ORO.FTL.105 (§29). PROPOSAL Replace the paragraph (b) by the following: "(b) If on the final flight time within the FDP the allowed increase under (a) is further exceeded because of unforeseen circumstances after take-off, the flight may continue to the planned destination or any other helipad or drop zone. If unforeseen circumstances occur just before take-off on the final flight time, the allowed increase may only be exceeded to transport the MEDICAL PERSONNEL, MEDICAL SUPPLIES SUCH AS EQUIPMENT INCLUDING THE HELICOPTER, BLOOD, ORGANS OR DRUGS, ILL OR INJURED PERSONS AND OTHER PERSONS DIRECTLY INVOLVED." #6 (c) ISSUE The paragraph (c) is redundant with the ORO.FTL.110 (k). Both says exactly the same thing. Therefore, in order to make the reading easier, the FNAM suggests not repeating the same ideas in different paragraphs of this NPA. PROPOSAL



Individual comments and responses - HEMS

	Suppress the paragraph (c) of this CS		
response	Please see the answer to comment # 54		
comment	368 comment by: European Helicopter Association (EHA)		
	BHA (UK)		
	"CS FTL.3.205 Flight duty period (FDP) — HEMS (a)"		
	Comment: This should include an exemption for exceptional circumstances in the national interests, or force majeure.		
	"(b)" Comment: This seems unduly prescriptive?		
	"(c)" Comment: Very sensible, but not well-defined.		
response	Please see the answer to comment # 54		
comment	384 comment by: Joachim J. Janezic (Institute for Austrian and International Aviation law)		
	This CS exists twice with the same name which clearly should be avoided to make precise references to the rules.		
response	Please see the answer to comment # 54		
comment	385 comment by: Joachim J. Janezic (Institute for Austrian and International Aviation law)		
response	Please see the answer to comment # 54		
comment	386 comment by: Joachim J. Janezic (Institute for Austrian and International Aviation law)		

**** * * * * In the <u>second</u> of the two CSs FTL 3.205(c) (page 36 last para) an exceedance of a total FDP causes the operator to review and adapt the scheduling with respect to a HEMS operating base. We have to stress that this rule neglects the fact that FDP is something personal (related to a certain pilot) and not related to a certain HEMS operating base. So it does not make any sense to review and adapt the scheduling and crew resources of a certain HEMS operating base if the exceedance of the (personal) FDP was caused for example due to the shifts on other HEMS operating bases.

response

Please see the answer to comment # 54

comment	394 comment by: European Helicopter Association (EHA))
	ADAC (Germany), DRF (Germany) and LAR (Luxembourg):	
	(c) commander discretion	
	Comment: Extension of max FDP by 2 hours (2-pilot crew), 1 hour (single pilot) only to finish eithe	r
	the last flight or the last flight with patient. In addition use of this extension is limited to 10 % of a	
	FDPs	
	of the last 3 months. Compared to the current regulation, this is more limiting due to the exclusive use in relation to the last flight and the transport of the patient to a hospital. The use of the same numbering in two different CS paragraphs is puzzling – max FDP. Implementing this limit seems not reasonable because this can only happen in one mission It	
	can only occur during summer months (long days) and would only lead to changes during summer.	,
	To collect data for this statistic would pose additional work to the crews since they will have to	11
	produce the input. This additional work will be required exatly at that times, where the work load	9
	is already high namely at the end of long FDPs.	
response	Please see the answer to comment # 54	
comment	399 comment by: European Helicopter Association (EHA))
	OAEMTC (Austria):	
	CS FTL.3.205 Flight duty period (FDP) — HEMS Maximum basic daily FDP in HEMS operations under ORO.FTL.205(b)(7)	

The maximum basic daily FDP without the use of extensions for acclimatized crew members in HEMS operations is established as follows:

[...]

Table 2

**** * * *** TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

* Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 349 of 585

COMMENT:

Complex table with FDP reductions to a maximum of 14 hrs. Day HEMS FDP typically starts at sunrise

but no earlier than 06:00hrs LT. Bearing in mind a circadian rhythm, reporting times after BCMT

cannot be considered as abnormal working time. Most percentage of the working population starts

work in the early morning which constitutes a biological high. The limitation off light time implies

anyway periods of times with lower workloads. This regulation would force us to hire and train more

crew (40%) to cover our contracts. In summer 2 shift duties would be required and would reduce the

exposure of pilots and HEMS TCM (i.e. missions per pilot/HEMS TCM). What is the added value for

flight safety when looking at the whole rather than only at fatigue?

CS FTL.3.205 Flight duty period (FDP) — HEMS

Maximum basic daily FDP in HEMS operations under ORO.FTL.205(b)(7)

The maximum basic daily FDP without the use of extensions for acclimatized crew members in HEMS

operations is established as follows:

[...]

(c) If the rest period before reporting for the FDP is taken at the HEMS operating base, the limits of

Table 1 for reporting times between 0730-0959 also apply for reporting times between 0630–0729.

COMMENT(S)

The alleviation is given only for table 1 which is applicable to two pilots only. Shouldn't this also refer

to table 2 to make it applicable to the single pilot operation also?

CS FTL.3.205 Flight duty period (FDP) — HEMS

Maximum basic daily FDP in HEMS operations under ORO.FTL.205 (b)(7) The maximum basic daily FDP without the use of extensions for acclimatized crew

members in HEMS

operations is established as follows:

[...]

(d) The operator may assign a block of up to 4 consecutive FDPs of more than 12 hours, but less than

14 hours, if the following conditions are met: (..)

COMMENTS(S)

A maximum of 4 consecutive duties will lead to an increase of travelling of 78% in terms of cost,

kilometers covered and time compared to our current roster. The number of days which crew is off

and without travel will decrease accordingly from approximately 169 to 137. This has a negative



impact on actual extended recovery periods and turns time off into travelling time. We don't see any

benefit in terms of fatigue reduction.

Crews will have to work in consecutive weekends as a consequence.

CS FTL.3.205 Flight duty period (FDP) — **HEMS** (must be renumbered)

Unforeseen circumstances in flight operations — commander's discretion in HEMS under ORO.FTL.205(f)

[...]

(b) If on the final sector within the FDP the allowed increase under (a) is further exceeded because of

unforeseen circumstances after take-off, the flight may continue to the planned destination or

alternate aerodrome. If unforeseen circumstances occur just before take-off on the final sector, the

allowed increase may only be exceeded to transport the patient.

COMMENT(S)

De text contains the word sector which is not defined for HEMS, see ORO.FTL.105 Definitions (29).

This probably means that crew will be tempted to turn down missions in the last hour of duty,

because for a mission taking more than one hour, crews will be condemned to remain on ground at

the hospital. This could mean:

• Missions are turned down early;

• The mission might end in the field if no patient is to be transported;

• In case a patient has to be transported the hospital's landing site is blocked for at least another

10 hours (affecting the capacity of the hospital and therefore affecting the health care of third

patients);

• Following multiple other effects because the helicopter cannot be protected against adverse

weather conditions on most of the hospital landing sites;

• Crew would need to seek accommodation locally.

i.e. all ends up at the wrong place and likely the crew is to become more fatigued then when

returning to base.

CS FTL.3.205 Flight duty period (FDP) — **HEMS** (must be renumbered)

Unforeseen circumstances in flight operations — commander's discretion in HEMS under ORO.FTL.205(f)

[...]

(c) If commander discretion is used in any HEMS operating base more than 10 % of the total FDP over

a 3-month period, the schedule and crew resources of the HEMS operating base are reviewed and

adapted.

COMMENT(S)



This 10% are probably meant for a base and not FDP, as the FDP would count for an individual person. The total scheduled duties on a base for a three months period equals up to 1267h therefore 10% are 126,7h. As there is 1 additional hour only at commanders discretion allowed, this rule cannot apply in a single pilot operation within a 90-days period. If something else is intended consider revising the text. Please see the answer to comment # 54 comment 407 comment by: ANWB MAA The distinguish between a 2 pilot operation and single pilot operation doesn't match the new insight of EASA on the operation with a HEMS Crew Member as stated in the proposal where the HCM is seen as a relevant member of the crew concept when received adequate training (draft NPA on HEMS DVE). Please see the answer to comment # 54 response comment 408 comment by: ANWB MAA Request to add the sector to fly back to the HEMS station. It's not feasible to have a helicopter at a hospital without any relieve crew Please see the answer to comment # 54

response

response

comment	424 comment by: UFH French Helicopters Association			Association		
	CS FTL.3.205 #1 ISSUE	UNFORESEEN	CIRCONSTANCES	FOR HEMS	under ORO	FTL 205(f)
	There are two misunderstand		which introduces c	omplexity, un	certainty and	may lead to
	We suggest add the	ding precisions	within the titles of	the paragrap	h in order to c	quickly make link
	with	the	ORO	paragra	iph	involved.



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 352 of 585 PROPOSAL Replace the title of this CS by: "CS FTL.3.205(f)" #2 ISSUE FORCE MAJEURE (Cf. comment #17.5) HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care services is a public service & a sovereign prerogative), with groupings of medical equipment and skills. HEMS in France is both operated by private operators and the State. State may charter private operators to operate HEMS operations on its behalf. Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved. Such a possibility shall remain for "Force majeure" and be introduced within the IR, in of the respect each Member State sovereignty of facing major health crisis. For example, in France, private operators of helicopters were chartered to ensure airlift rotations during recent Millas train disaster on December, the 14th of 2017. Besides, Helicopter Nuclear Response Team are partially delegated to a private operator. Therefore, UFHsuggests adding a specific paragraph in this implementing rule allowing HEMS pilots to derogate from these requirements in case of Force Majeure as it is already the case in the Current French National Regulation. PROPOSAL For illustrative purposes, in France the following article is applied in case of « Force Majeure "Il peut être dérogé aux limitations mentionnées à la présente section dans les conditions suivantes l'exécution nécessaire 1. Vols urgents, dont immédiate est a) Pour prévenir des accidents imminents et organiser des mesures de sauvetage, ou pour réparer des accidents matériel, soit installations survenus soit au aux des b) Pour assurer le dépannage aéronefs. 2. Pour assurer l'achèvement d'une période de vol que des circonstances exceptionnelles n'auraient pas permis d'effectuer dans les limites préétablies. 3. Vols exécutés dans l'intérêt de la sûreté ou de la défense nationale ou d'un service public sur ordre du Gouvernement constatant la nécessité de la dérogation ; la limite est à fixer par le ministre chargé civile." CAC de l'aviation (ref D 422-12) #3 discretion attached scenario commander's + (Cf. attachment S2 illustrating this lack of commander's discretion issue) (a)



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

ISSUE The paragraph (a) of this CS proposes a 1 hour commander's discretion for single-pilot + HEMS TCM operations. UFH wonders how this value has been chosen by the Agency since there is no justification within the RIA regarding this matter. Currently in France, the regulation allows a 2 hours commander's discretion, including for single-pilot + TCM HEMS operations, with no reported inherent safety issue through experience. This 2 hours commander's discretion is frequently used by single-pilot + TCM HEMS operations case in of emergency for the patient. In France, 3% i of flights saving lives would be impossible with а commander's discretion capped to 1 hour (cf. SNEH illustrative Table in attachment). To illustrate this issue, UFH attached a scenario taken from real HEMS operator planning where the commander's discretion (single-pilot + TCM) exceeds 1 hour (in that case, the commander's discretion is of 1h50). Safety record and experience show such an allowance demonstrates a high level of safety, with no accident occurrence when the commander's discretion exceeds 1 hour. For safety reasons, regulation already requires an additional crew member for HEMS, the TCM. Therefore, single-pilot HEMS operations are not PEQ1 operations but 1 single-pilot + 1 TCM contributing to the safety of the flight. As a consequence, commander's discretion should be of 2h for both two-pilots and 1 pilot + 1 TCM, as preexisting in France. Thus, we suggest a 2 hours commander's discretion for both 1 pilot +TCM and two-pilots operations. PROPOSAL Replace the content of the paragraph (a) by the following: "(a) The maximum basic daily FDP may be increased for HEMS by up to 2 hours." #4 (b) ISSUE The paragraph (b) refers to 'sector'. However, the notion of 'sector' is not anymore defined for helicopters (Cf. ORO.FTL.105 (§24)). Therefore, UFH suggests replacing the term of sector the by flight notion of time. (Cf. comment #14.2) Besides, the wording 'alternate aerodrome' is used in the paragraph (b) but is not consistent with the activity of HEMS. Therefore, we suggest replacing this notion of alternate aerodrome by the notion of helipad or drop zone which better suits the activity of the HEMS. PROPOSAL Replace the the following: paragraph (b) by "(b) If on the final flight time within the FDP the allowed increase under (a) is further



exceeded because of unforeseen circumstances after take-off, the flight may continue to the planned ANY destination OR OTHER HELIPAD OR DROP ZONE. If unforeseen circumstances occur just before take-off on time, the final flight the allowed increase may only be exceeded to transport "the patient"." (Cf. comment hereafter) #5 (b) ISSUE In the paragraph (b), the extension of the last flight time before take-off is limited to the case the of transportation of a patient. This is not consistent with the definition of HEMS, which encompasses the following HEMS payload (medical personnel, medical supplies such as equipment, blood, organs or drugs, ill injured persons and other persons directly involved). or Life threatening emergency of a flight is not only conditioned by a patient onboard. It can deal with all the HEMS payload defined in ORO.FTL.105 (§29): medical personnel, medical supplies such as equipment including the helicopter, blood, organs or drugs, ill or injured persons and other persons directly involved. Indeed, it may be urgent for the medical staff to come back to the hospital, to ensure available the medical material is for another operation, etc. The extension of the last flight shall include all the content defined for HEMS payload, for the present or next HEMS operations requiring a quick return to the base without uselessly immobilizing critical material staff, including helicopter. and the That is why UFH suggests replacing the term patient used in the paragraph (b) by the HEMS payload defined NPA ORO.FTL.105 in this in the (§29). PROPOSAL Replace the paragraph (b) by the following: (b) If on the final flight time within the FDP the allowed increase under (a) is further exceeded because of unforeseen circumstances after take-off, the flight may continue to the planned destination anv other helipad or drop zone. If unforeseen circumstances occur just before take-off on the final flight time, the allowed increase may only be exceeded to transport the MEDICAL PERSONNEL, MEDICAL SUPPLIES SUCH AS EQUIPMENT INCLUDING THE HELICOPTER, BLOOD, ORGANS OR DRUGS, ILL OR INJURED PERSONS AND OTHER PERSONS DIRECTLY INVOLVED." #6 (c) ISSUE The paragraph (c) is redundant with the ORO.FTL.110 (k). Both says exactly the same thing.



	Therefore, in order to make the r	eading easier, we suggest	: not repeating the same ic	deas in different
	paragraphs PROPOSAL	of	this	NPA.
	Suppress the paragrap	h (c) of this CS.		
response	Please see the answer	to comment # 54		

comment	490 comment by: FNAM/SNEH
	CS FTL.3.205 UNFORESEEN CIRCONSTANCES FOR HEMS under ORO FTL 205(f)
	ISSUE There are two CS FTL.3.205, which introduces complexity, uncertainty and may lead to misunderstanding.
	FNAM and SNEH suggest adding precisions within the titles of the paragraph in order to quickly make the link with the ORO paragraph involved.
	PROPOSAL Replace the title of this CS by: " <i>CS FTL.3.205(f)"</i>
response	Please see the answer to comment # 54

comment	491 comment by: FNAM/SNEH
	CS FTL.3.205 UNFORESEEN CIRCONSTANCES FOR HEMS under ORO FTL 205(f)
	ISSUE - FORCE MAJEURE
	(Cf. comment #471)
	HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care services is a public service & a sovereign prerogative), with groupings of medical equipment and skills.
	HEMS in France is both operated by private operators and the State. State may charter private operators to operate HEMS operations on its behalf. Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved. Such a possibility shall remain for "Force majeure" and be introduced within the IR, in respect of the sovereignty of each Member State facing major health crisis.
	For example, in France, private operators of helicopters were chartered to ensure airlift rotations during recent Millas train disaster on December, the 14 th of 2017. Besides, Helicopter Nuclear Response Team are partially delegated to a private operator.



Therefore, FNAM and SNEH suggest adding a specific paragraph in this implementing rule allowing HEMS pilots to derogate from these requirements in case of Force Majeure as it is already the case in the Current French National Regulation.

PROPOSAL

For illustrative purposes, in France the following article is applied in case of « Force Majeure » :

"Il peut être dérogé aux limitations mentionnées à la présente section dans les conditions suivantes :

1. Vols urgents, dont l'exécution immédiate est nécessaire :

a) Pour prévenir des accidents imminents et organiser des mesures de sauvetage, ou pour réparer des accidents survenus soit au matériel, soit aux installations ;

b) Pour assurer le dépannage des aéronefs.

2. Pour assurer l'achèvement d'une période de vol que des circonstances exceptionnelles n'auraient pas permis d'effectuer dans les limites préétablies.

3. Vols exécutés dans l'intérêt de la sûreté ou de la défense nationale ou d'un service public sur ordre du Gouvernement constatant la nécessité de la dérogation ; la limite est à fixer par le ministre chargé de l'aviation civile." (ref CAC D 422-12)

response

Please see the answer to comment # 54

comment 492

comment by: FNAM/SNEH

Attachments <u>#164</u> <u>#165</u>

(Cf. attachment S2 illustrating this lack of commander's discretion issue)

(a)

ISSUE

The paragraph (a) of this CS proposes a 1 hour commander's discretion for single-pilot + TCM HEMS operations. FNAM and SNEH wonder how this value has been chosen by the Agency since there is no justification within the RIA regarding this matter.

Currently in France, the regulation allows a 2 hours commander's discretion, including for single-pilot + TCM HEMS operations, with no reported inherent safety issue through experience.

This 2 hours commander's discretion is frequently used by single-pilot + TCM HEMS operations in case of emergency for the patient. In France, 3%ⁱof flights saving lives would be impossible with a commander's discretion capped to 1 hour (cf. SNEH illustrative Table in attachment). To illustrate this issue, FNAM and SNEH attached a scenario taken from real HEMS operator planning where the commander's discretion (single-pilot + TCM) exceeds 1 hour (in that case, the commander's discretion is of 1h50).

Safety record and experience show such an allowance demonstrates a high level of safety, with no accident occurrence when the commander's discretion exceeds 1 hour.

For safety reasons, regulation already requires an additional crew member for HEMS, the TCM. Therefore, single-pilot HEMS operations are not PEQ1 operations but 1 single-pilot + 1 TCM contributing to the safety of the flight. As a consequence, commander's discretion should be of 2h for both two-pilots and 1 pilot + 1 TCM, as preexisting in France.



Thus, FNAM and SNEH suggest a 2 hours commander's discretion for both 1 pilot +TCM and two-pilots operations.

PROPOSAL

Replace the content of the paragraph (a) by the following: "(a) The maximum basic daily FDP may be increased for HEMS by up to 2 hours."

response

Please see the answer to comment # 54

comment	493 comment by: FNAM/SNEH
	(b) ISSUE The paragraph (b) refers to 'sector'. However, the notion of 'sector' is not anymore defined for helicopters (Cf. ORO.FTL.105 (§24)). Therefore, FNAM and SNEH suggest replacing the term of sector by the notion of flight time. (Cf. comment #463)
	Besides, the wording 'alternate aerodrome' is used in the paragraph (b) but is not consistent with the activity of HEMS. Therefore, FNAM and SNEH suggest replacing this notion of alternate aerodrome by the notion of helipad or drop zone which better suits the activity of the HEMS.
	PROPOSAL Replace the paragraph (b) by the following: "(b) If on the final flight time within the FDP the allowed increase under (a) is further exceeded because of unforeseen circumstances after take-off, the flight may continue to the planned destination or any other helipad or drop zone. If unforeseen circumstances occur just before take-off on the final flight time, the allowed increase may only be exceeded to transport *the patient*." (Cf. comment hereafter)
response	Please see the answer to comment # 54
comment	494 comment by: FNAM/SNEH
	 (b) ISSUE In the paragraph (b), the extension of the last flight time before take-off is limited to the case of the transportation of a patient. This is not consistent with the definition of HEMS, which encompasses the following HEMS payload (medical personnel, medical supplies such as equipment, blood, organs or drugs, ill or injured persons and other persons directly involved). Life threatening emergency of a flight is not only conditioned by a patient onboard. It can deal with all the HEMS payload defined in ORO.FTL.105 (§29): medical personnel, medical supplies such as equipment including the helicopter, blood, organs or drugs, ill or injured persons and other persons directly involved.

**** * * *** to come back to the hospital, to ensure the medical material is available for another operation, etc.

The extension of the last flight shall include all the content defined for HEMS payload, for the present or next HEMS operations requiring a quick return to the base without uselessly immobilizing critical material and staff, including the helicopter.

That is why FNAM and SNEH suggest replacing the term patient used in the paragraph (b) by the HEMS payload defined in this NPA in the ORO.FTL.105 (§29).

PROPOSAL

Replace the paragraph (b) by the following:

"(b) If on the final flight time within the FDP the allowed increase under (a) is further exceeded because of unforeseen circumstances after take-off, the flight may continue to the planned destination or any other helipad or drop zone. If unforeseen circumstances occur just before take-off on the final flight time, the allowed increase may only be exceeded to transport themedical personnel, medical supplies such as equipment including the helicopter, blood, organs or drugs, ill or injured persons and other persons directly involved."

response

Please see the answer to comment # 54

comment	495 comment by: FNAM/SNEH
	(c) ISSUE The paragraph (c) is redundant with the ORO.FTL.110 (k). Both says exactly the same thing. Therefore, in order to make the reading easier, FNAM and SNEH suggest not repeating the same ideas in different paragraphs of this NPA.
	PROPOSAL Suppress the paragraph (c) of this CS.
response	Please see the answer to comment # 54

comment	533	comment by: ADAC Luftrettung gGmbH
	Extension of max FDP by 2 hours (2-pilot crew the last flight or the last flight with patient. In a % of all FDPs of the last 3 months. Compared to due to the exclusive use in relation to the last hospital.	ddition use of this extension is limited to 10 the current regulation, this is more limiting
	The use of the same numbering in two differen	t CS paragraphs is puzzling – max FDP.
	Implementing this limit seems not reasonable b It can only occur during summer months (long c summer.	

	To collect data for this statistic would pose additional work to the crews since they will have to produce the input. This additional work will be required exactly at that times, where the work load is already high namely at the end of long FDPs.
response	Please see the answer to comment # 54
comment	554 comment by: <i>Rüdiger Neu</i>
	Sobald eine FDP zwischen 12 - 14 Stunden liegt, ist die Dienstperiode auf 4 aufeinanderfolgende Tagen begrenzt. Davor müssen 36 Stunden (2 Nächte) Ruhezeit enthalten, bisher waren hier nur 24 Stunden gefordert. Im Anschluss muss eine Ruhezeit von 60 Stunden (3 Nächte), bisher waren es 48 Stunden.
	Fragestellung: Gehört die Reisezeit gem. CS.FTL.3.200 (b) zu den 4 FDPs? Falls dies so gedacht wäre, könnten Piloten bei FDP > 12 Stunden nur noch an 2-3 Tagen eingesetzt werden, dies macht den Einsatz von Flexpiloten etc. in diesen Zeiten unrentabel.
	Fragestellung: Wird bei einer 24h-Station wird beim einmaligen Überschreiten der 12h FDP auf vier Tage limitiert? Eine Planbarkeit ist somit nur noch beschränkt auf vier Tage möglich. Bisher war beim Schichtdienst auf einer 24h-Station ein Dienstrhythmus von 7 Tagen das Attraktive. Dies würde zu weiterem Akzeptanzverlust bei den Piloten führen.
	Split duty wird in diesem Abschnitt nicht berücksichtigt. Oder ist dieser Abschnitt nicht für Split duty relevant?
	Verlängerung der max. FDP um 2 Stunden (2-Mann-Besatzung), 1 Stunde (1 PiC) nur für die Beendigung des letzten Fluges oder für den Flug mit Patient. Außerdem ist die Nutzung des Kommandantenentscheids limitiert auf 10% der gesamten FDP der letzten 3 Monate. Dieser Passus ist nicht vergleichbar mit dem bisherigen, er dient nur dazu einen Flug zu beenden oder den Patient noch ins Krankenhaus zu bringen. Verwirrend ist die gleiche CS Bezeichnung, wie für die max. FDP.
	Eine Limitierung innerhalb der 3 Monate ist unrealistisch, da dies nur bei einem Einsatz passieren kann. Außerdem könnte es nur im Sommer vorkommen und würde dann nur für diesen zu Dienstplanänderung führen.
	Die Auswertung der 10% Regelung würde einen Mehraufwand für die Besatzungen bedeuten, der genau zu den Zeiten gemacht werden muss, wenn die Belastung für die Besatzungen am größten ist, nämlich an den langen Sommertagen.
response	Please see the answer to comment # 54
comment	595 comment by: NOLAS

Comment:

NLA presently operates in a system that have one crew on duty for 24/7 for one complete week in a 7 ON/14 OFF/7 ON/21 off for flight crew members and 7 ON / 21 OFF for HEMS technical crew members. As our FRM and sicentific studies has shown, this is apparently

**** * * *** conducted in a safe manner and we intend to seek an IFTSS. Having said that, having two crews manning one helicopter for a 24 hour period is quite common pracice in Europe and as we see it, this will no longer be practicable.

For HEMS operating base conducting 24/7 operations:

When operating in compliance with CS FTL.3.205 Flight duty period (FDP) — HEMS and CS FTL.3.210 Flight times and duty periods — HEMS, there is not enough overlap to ensure continuity of the service if only two crews (a "day" and "night" crew) are used to cover a 24-hour period.

With two crews, the maximum of 14 hours and 12 hours FDP limits respectively gives only a maximum of 1 hour overlap in each end. This does not give enough time to dispatch on, and complete a, HEMS mission. Note that this is even if <u>not one single</u> HEMS mission has taken place during the FDP prior to the alarm.

Should an alarm come in shortly (for example 1:30 to 1 hour) before overlap, the mission will have to be postponed until the new crew has commenced their FDP. Alternatively, three crews must be used for every 24-hour period to keep one HEMS operating base operational 24/7.

1:30 to 1 hour before the overlap is just an example. The period necessary to complete a mission is quite contextual and sufficient time is up for discussion, but the question needs to be addressed.

Furthermore, as mentioned in the comment to **CS FTL.3.205 Flight duty period (FDP)** — **HEMS, NPA p 35** above, prescribing breaks is not a practicable solution and the concept of breaks is very unclear, especially regarding how this should be planned.

An easier approach would be a concept comprising a maximum Duty Period with a maximum Flight Duty Period comprising "Passive time" and "Active time". This could look like the following example:

"Passive time" is all the time spent on a HEMS duty period that is not considered to be active time, relaxing, free of all duties except standing by to receive an alarm.

"Active time" is all the time spent pre- and post-flight activities, operation of the helicopter, HEMS missions, rapid response vehicle missions, training, checking, administrative work, meetings, attending a course, simulator, travel etc.

While passive time is the time the crew members are relaxing, the fatigue level is a direct consequence of the circadian rhythm and therefore it is of outmost importance, as far as practicable, to maintain a normal sleep pattern.

Passive time is calculated as 50% towards the total Flight Duty Time. Active time is calculated as 100% towards the total Flight Duty Time.

If reaching any Flight time or Active time limit, the crew member shall go off Active duty.

HEMS:



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 361 of 585

- Duties such as pre-flight inspection, fuel checks, equipment check, etc. shall be logged as active time;
- Active time is triggered by an alarm and is defined from time of alarm to minimum 1 hour after block-on time. If the time for post flight duties takes more than 1 hour, actual time shall be logged as active time.

Rapid response vehicle operation:

- Between 10:00 and 22:59, Active time is triggered by an alarm and is defined from time of alarm to the time the mission is completed and equipment etc. is resupplied and prepared and as a minimum 15 minutes; and
- Between 23:00 and 09:59, Active time is triggered by an alarm and is defined from time of alarm to minimum 1 hour after returning at the base. If the time for post mission duties takes more than 1-hour, actual time shall be logged as active time.

For HEMS and rapid response vehicle operation:

• If there are less than two hours between on-block and the time of a new alarm, the entire time between on-block and the time of a new alarm counts as Active time.

Other operations (pre-flight, ferry flight, test flight, training flight, etc.):

- Active time is triggered when reporting for duty or commencing preparations and ends minimum 30 minutes after block-on time;
- Related duties such as pre-flight inspection, fuel checks, equipment check, flights registration etc., are not counted separately. This is considered included in the minimum 30 minutes after block-on time; and
- If the time for post flight duties takes more than 30 minutes, actual time shall be logged as Active time.

With a system like this, perhaps a maximum Flight Duty Period of 16 hours could be introduced for a "day crew" with a maximum of 10 or 12 hours total active and passive time. For a "night crew", a maximum of 12 or even 14 hours maximum Flight Duty Period could be used with a maximum of 10 hours of total active time. This system would also allow for sufficient overlap in case of missions just prior to a crew/shift change.

response

Please see the answer to comment # 54

comment 596

comment by: NOLAS

"Unforeseen circumstances in flight operations — commander's discretion in HEMS under ORO.FTL.205(f)



(a) The maximum basic daily FDP may be increased for HEMS by up to 1 hour for singlepilot operation or by up to 2 hours for two-pilot operation."

Comment: Unforeseen circumstances would typically include only longer time at HEMS operating site or weather. Unforeseen should also should include catastrophic events.

response

Please see the answer to comment # 54

comment	597 comment by: NOLAS
	"(b) If on the final sector within the FDP the allowed increase under (a) is further exceeded because of unforeseen circumstances after take-off, the flight may continue to the planned destination or alternate aerodrome. If unforeseen circumstances occur just before take-off on the final sector, the allowed increase may only be exceeded to transport the patient."
	Comment: This is too restrictive. After delivering the patient, the crew should be allowed to return to the HEMS operating base (perhaps under the condition that there is suitable accommodation where the crew can rest). Otherwise, the consequence could be that the crew is stuck at a hospital without practical possibility to get rest. Furthermore, the helicopter will also be stuck at a hospital without crew to fly it. On most hospital landing sites, the helicopter would block the helipad for the duration of the stay (i.e. no other helicopters would be able to use the helipad) and in many circumstances also take occupy hospital security personnel. In addition, it is not necessary the case that the relieving crew have a practicable chance to travel from the HEMS operating base to the hospital where the helicopter is parked.
response	Please see the answer to comment # 54
comment	598 comment by: NOLAS
	"(c) If commander discretion is used in any HEMS operating base more than 10 % of the total FDP over a 3-month period, the schedule and crew resources of the HEMS operating base are reviewed and adapted.
	Comment: While sensible, the should be re-worked to make it easier to understand.
response	Please see the answer to comment # 54
comment	670 comment by: <i>Oya Vendée Hélicoptères</i>
	CS FTL.3.205 UNFORESEEN CIRCONSTANCES FOR HEMS under ORO FTL 205(f)
	ISSUE

**** * * *** TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 363 of 585 There are two CS FTL.3.205, which introduces complexity, uncertainty and may lead to misunderstanding.
OYA suggests adding precisions within the titles of the paragraph in order to quickly make the link with the ORO paragraph involved.
PROPOSAL Replace the title of this CS by: "CS FTL.3.205(f)"

response

Please see the answer to comment # 54

comment 671 comment by: Oya Vendée Hélicoptères CS FTL.3.205 UNFORESEEN CIRCONSTANCES FOR HEMS under ORO FTL 205(f) **ISSUE - FORCE MAJEURE** (Cf. comment #651) HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care services is a public service & a sovereign prerogative), with groupings of medical equipment and skills. HEMS in France is both operated by private operators and the State. State may charter private operators to operate HEMS operations on its behalf. Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved. Such a possibility shall remain for "Force majeure" and be introduced within the IR, in respect of the sovereignty of each Member State facing major health crisis. For example, in France, private operators of helicopters were chartered to ensure airlift rotations during recent Millas train disaster on December, the 14th of 2017. Besides, Helicopter Nuclear Response Team are partially delegated to a private operator. Therefore, OYA suggests adding a specific paragraph in this implementing rule allowing HEMS pilots to derogate from these requirements in case of Force Majeure as it is already the case in the Current French National Regulation. PROPOSAL For illustrative purposes, in France the following article is applied in case of « Force Majeure » : "Il peut être dérogé aux limitations mentionnées à la présente section dans les conditions suivantes : 1. Vols urgents, dont l'exécution immédiate est nécessaire : a) Pour prévenir des accidents imminents et organiser des mesures de sauvetage, ou pour réparer des accidents survenus soit au matériel, soit aux installations ; b) Pour assurer le dépannage des aéronefs. 2. Pour assurer l'achèvement d'une période de vol que des circonstances exceptionnelles n'auraient pas permis d'effectuer dans les limites préétablies.

3. Vols exécutés dans l'intérêt de la sûreté ou de la défense nationale ou d'un service public sur ordre du Gouvernement constatant la nécessité de la dérogation ; la limite est à fixer par le ministre chargé de l'aviation civile." (ref CAC D 422-12)

response

Please see the answer to comment # 54

comment	672 comment by: <i>Oya Vendée Hélicoptères</i>
	Attachments <u>#166</u> <u>#167</u>
	(Cf. attachment S2 illustrating this lack of commander's discretion issue)
	(a) ISSUE
	The paragraph (a) of this CS proposes a 1 hour commander's discretion for single-pilot + TCM HEMS operations. OYA wonders how this value has been chosen by the Agency since there is no justification within the RIA regarding this matter.
	Currently in France, the regulation allows a 2 hours commander's discretion, including for single-pilot + TCM HEMS operations, with no reported inherent safety issue through experience
	experience. This 2 hours commander's discretion is frequently used by single-pilot + TCM HEMS operations in case of emergency for the patient. In France, 3% ⁱ of flights saving lives would be impossible with a commander's discretion capped to 1 hour (cf. SNEH illustrative Table in attachment). To illustrate this issue, OYA attached a scenario taken from real HEMS operator planning where the commander's discretion (single-pilot + TCM) exceeds 1 hour (in that case, the commander's discretion is of 1h50).
	Safety record and experience show such an allowance demonstrates a high level of safety, with no accident occurrence when the commander's discretion exceeds 1 hour. For safety reasons, regulation already requires an additional crew member for HEMS, the TCM. Therefore, single-pilot HEMS operations are not PEQ1 operations but 1 single-pilot + 1 TCM contributing to the safety of the flight. As a consequence, commander's discretion should be of 2h for both two-pilots and 1 pilot + 1 TCM, as preexisting in France. Thus, OYA suggests a 2 hours commander's discretion for both 1 pilot +TCM and two-pilots operations.
	PROPOSAL Replace the content of the paragraph (a) by the following:
	"(a) The maximum basic daily FDP may be increased for HEMS by up to 2 hours."
response	Please see the answer to comment # 54
comment	673 comment by: <i>Oya Vendée Hélicoptères</i>
	(b) ISSUE



The paragraph (b) refers to 'sector'. However, the notion of 'sector' is not anymore defined for helicopters (Cf. ORO.FTL.105 (§24)). Therefore, OYA suggests replacing the term of sector by the notion of flight time.

(Cf. comment #643)

Besides, the wording 'alternate aerodrome' is used in the paragraph (b) but is not consistent with the activity of HEMS. Therefore, OYA suggests replacing this notion of alternate aerodrome by the notion of helipad or drop zone which better suits the activity of the HEMS.

PROPOSAL

Replace the paragraph (b) by the following:

"(b) If on the final flight time within the FDP the allowed increase under (a) is further exceeded because of unforeseen circumstances after take-off, the flight may continue to the planned destination or any other helipad or drop zone. If unforeseen circumstances occur just before take-off on the final flight time, the allowed increase may only be exceeded to transport *the patient*." (Cf. comment hereafter)

response

Please see the answer to comment # 54

comment 674

comment by: Oya Vendée Hélicoptères

(b)

involved).

ISSUE In the paragraph (b), the extension of the last flight time before take-off is limited to the case of the transportation of a patient. This is not consistent with the definition of HEMS, which encompasses the following HEMS payload (medical personnel, medical supplies such as equipment, blood, organs or drugs, ill or injured persons and other persons directly

Life threatening emergency of a flight is not only conditioned by a patient onboard. It can deal with all the HEMS payload defined in ORO.FTL.105 (§29): medical personnel, medical supplies such as equipment including the helicopter, blood, organs or drugs, ill or injured persons and other persons directly involved. Indeed, it may be urgent for the medical staff to come back to the hospital, to ensure the medical material is available for another operation, etc.

The extension of the last flight shall include all the content defined for HEMS payload, for the present or next HEMS operations requiring a quick return to the base without uselessly immobilizing critical material and staff, including the helicopter.

That is why OYA suggests replacing the term patient used in the paragraph (b) by the HEMS payload defined in this NPA in the ORO.FTL.105 (§29).

PROPOSAL

Replace the paragraph (b) by the following:

"(b) If on the final flight time within the FDP the allowed increase under (a) is further exceeded because of unforeseen circumstances after take-off, the flight may continue to the planned destination or any other helipad or drop zone. If unforeseen circumstances occur just before take-off on the final flight time, the allowed increase may only be exceeded to transport themedical personnel, medical supplies such as equipment including

**** * * * * * * the helicopter, blood, organs or drugs, ill or injured persons and other persons directly involved."

response

Please see the answer to comment # 54

comment	675 comment by: <i>Oya Vendée Hélicoptères</i>
	(c) ISSUE The paragraph (c) is redundant with the ORO.FTL.110 (k). Both says exactly the same thing. Therefore, in order to make the reading easier, OYA suggests not repeating the same ideas in different paragraphs of this NPA.
	PROPOSAL Suppress the paragraph (c) of this CS.
response	Please see the answer to comment # 54

comment	720 comment by: ÖAMTC Helicopter Air Rescue (Austria)
	CS FLT.3.205 (a) (c)
	[] is used in any HEMS operating base more than 10% of the total FDP []
	This 10% are probably meant for a base and not FDP, as the FDP would count for an individual person. The total flight duty period for three months for a base equals up to 1260h therefore 10% are 126,7h. As there is 1 additional hour only at commanders discretion allowed, this rule cannot apply in a single pilot operation within a 90-days period.
response	Please see the answer to comment # 54
comment	746 comment by: DRF-Luftrettung
	(I) As soon as the FDP is between 12 and 14 hours long a block of consecutive FDPs is limited to 4 days. The rest period preceding the first FDP is at least 36 hours including two local nights, the current system requires only 24 hours in advance. The rest period provided after completion of the series of consecutive FDPs is at least 60 hours including 3 local nights, the current system allows for 48 hours.



Question: Is travelling time in accordance with CS.FTL.3.200 (b) part of these 4 FDPs? If this is the case it will reduce the time on base of each pilot during times with more than 12 hours

FDP to 2-3 days. The use of reserve pilots for only 2 consecutive days would pose an economic

burden to the operator.

Question: What happens on 24h bases in case of a single exceedance of the 12 hour FDP? Will

the length of the duty block be automatically be shortened to 4 days instead of 7 as scheduled?

This would lead to an additional limit regarding these bases, because they will have to change

their current attractive 7 day blocks to 4 day blocks. This is expected to further reduce the attractivity of 24 h bases for pilots especially when they don't live close to their home base.

Split duty is not accounted for in this paragraph. Or is this paragraph not relevant for split duty?

Using split duty would allow for FDP of more than 14 hours. Currently there is no further regulation

provided for FDP of more than 14 hours.

response

Please see the answer to comment # 54

comment	747 comment by: <i>DRF-Luftrettung</i>
	Extension of max FDP by 2 hours (2-pilot crew), 1 hour (single pilot) only to finish either last
	flight or the last flight with patient. In addition use of this extension is limited to 10 % of all FDPs
	of the last 3 months. Compared to the current regulation, this is more limiting due to the exclusive
	use in relation to the last flight and the transport of the patient to a hospital.
	The use of the same numbering in two different CS paragraphs is puzzling – max FDP. Implementing this limit seems not reasonable because this can only happen in one mission. It
	can only occur during summer months (long days) and would only lead to changes during summer.
	To collect data for this statistic would pose additional work to the crews since they will have to
	produce the input. This additional work will be required exatly at that times, where the work load
	is already high namely at the end of long FDPs.
response	Please see the answer to comment # 54



comment	754 comment by: DRF-Luftrettung
	Standardized schedules should give for day and night pilots the same FDP at HEMS- bases with
	24 / 7 working times. This is not possible for the maximum FDP of 12 hours, because we need at least an overlapping period of 30 min for the pre-flight checks
	Solution: Alter the max. FDP between 1400 and 0629 to read 12:30! This allows for evenly spread schedules i.e.: Shift 1 from 0630 to 1900 Shift 2 from 1830 to 0700
response	Please see the answer to comment # 54
comment	755 comment by: DRF-Luftrettung
	As soon as the FDP is between 12 and 14 hours long a block of consecutive FDPs is limited to 4 days. The rest period preceding the first FDP is at least 36 hours including two local nights, the current system requires only 24 hours in advance. The rest period provided after completion of the series of consecutive FDPs is at least 60 hours including 3 local nights, the current system allows for 48 hours.
	Question: Is travelling time in accordance with CS.FTL.3.200 (b) part of these 4 FDPs? If this is the case it will reduce the time on base of each pilot during times with more than 12 hours FDP to 2-3 days. The use of reserve pilots for only 2 consecutive days would pose an economic burden to the operator.
	Question: What happens on 24h bases in case of a single exceedance of the 12 hour FDP? Will
	the length of the duty block be automatically be shortened to 4 days instead of 7 as scheduled?
	This would lead to an additional limit regarding these bases, because they will have to change
	their current attractive 7 day blocks to 4 day blocks. This is expected to further reduce the attractivity of 24 h bases for pilots especially when they don't live close to their home base. Split duty is not accounted for in this paragraph. Or is this paragraph not relevant for split duty?
	Using split duty would allow for FDP of more than 14 hours. Currently there is no further regulation provided for FDP of more than 14 hours.
response	Please see the answer to comment # 54

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

comment	786 comment by: AECA helicopteros.
	 d) The operator may assign a block of up to 4 consecutive FDPs of more than 12 hours, but less than 14 hours, if the following conditions are met: (1) the rest period preceding the first FDP is at least 36 hours including 2 local nights; and (2) the rest period provided after completion of the series of consecutive FDPs is at least 60 hours including 3 local nights.
	Question needing answer by regulation.
	This principle should be applied only in the case of 4 consecutive FDPs or also in the case of 2 or 3?
response	Please see the answer to comment # 54
comment	823 comment by: Babcock Mission Critical Services Limited
	We don't agree with : If on the final <i>sector</i> within the FDP
	Because : as per revised definition proposed page 10 of the NPA (ORO.FTL.105 (24)), "sector" is to be used only for aeroplanes, so it should not be used in a paragraph dedicated to HEMS to avoid any confusion with the applicability of some other paragraphs.
	We suggest the term "flight" is used, in place of "sector", in all requirements relating to helicopter operations. The meaning of the term "flight" is implied by the definition of "flight time" at ORO.FTL.105 Definitions:
	(13) 'flight time' means,, and for helicopters, the time from the moment a helicopter's rotor blades start turning until the moment the helicopter finally comes to rest at the end of the flight, and the rotor blades are stopped.
response	Please see the answer to comment # 54
comment	843 comment by: Yorkshire Air Ambulance
	This should include an exemption for exceptional circumstances in the national interests, or force majeure.
response	Please see the answer to comment # 54
comment	844 comment by: Yorkshire Air Ambulance



	Why is the aircraft not allowed to return to its HEMS operating base? This seems unduly prescriptive, and will introduce more problems for operators and crews regarding fatigue (ie. recovering flight crew by land transfers).
response	Please see the answer to comment # 54
comment	951 comment by: MBH SAMU
	CS FTL.3.205 UNFORESEEN CIRCONSTANCES FOR HEMS under ORO FTL 205(f)
	ISSUE
	There are two CS FTL.3.205, which introduces complexity, uncertainty and may lead to misunderstanding.
	MBH suggests adding precisions within the titles of the paragraph in order to quickly make the link with the ORO paragraph involved.
	PROPOSAL
	Replace the title of this CS by: "CS FTL.3.205(f)"
response	Please see the answer to comment # 54

comment	952 comment by: MBH SAMU
	CS FTL.3.205 UNFORESEEN CIRCONSTANCES FOR HEMS under ORO FTL 205(f)
	ISSUE - FORCE MAJEURE (Cf. comment #922)
	HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care services is a public service & a sovereign prerogative), with groupings of medical equipment and skills.
	HEMS in France is both operated by private operators and the State. State may charter private operators to operate HEMS operations on its behalf. Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved. Such a possibility shall remain for "Force majeure" and be introduced within the IR, in respect of the sovereignty of each Member State facing major health crisis.
	For example, in France, private operators of helicopters were chartered to ensure airlift rotations during recent Millas train disaster on December, the 14 th of 2017. Besides, Helicopter Nuclear Response Team are partially delegated to a private operator.
	Therefore, MBH suggests adding a specific paragraph in this implementing rule allowing HEMS pilots to derogate from these requirements in case of Force Majeure as it is already the case in the Current French National Regulation.

PROPOSAL

For illustrative purposes, in France the following article is applied in case of « Force Majeure » :

"Il peut être dérogé aux limitations mentionnées à la présente section dans les conditions suivantes :

1. Vols urgents, dont l'exécution immédiate est nécessaire :

a) Pour prévenir des accidents imminents et organiser des mesures de sauvetage, ou pour réparer des accidents survenus soit au matériel, soit aux installations ;

b) Pour assurer le dépannage des aéronefs.

2. Pour assurer l'achèvement d'une période de vol que des circonstances exceptionnelles n'auraient pas permis d'effectuer dans les limites préétablies.

3. Vols exécutés dans l'intérêt de la sûreté ou de la défense nationale ou d'un service public sur ordre du Gouvernement constatant la nécessité de la dérogation ; la limite est à fixer par le ministre chargé de l'aviation civile." (ref CAC D 422-12)

response

Please see the answer to comment # 54

comment 953

comment by: MBH SAMU

```
Attachments #168 #169
```

(Cf. attachment S2 illustrating this lack of commander's discretion issue)

(a)

ISSUE

The paragraph (a) of this CS proposes a 1 hour commander's discretion for single-pilot + TCM HEMS operations. MBH wonders how this value has been chosen by the Agency since there is no justification within the RIA regarding this matter.

Currently in France, the regulation allows a 2 hours commander's discretion, including for single-pilot + TCM HEMS operations, with no reported inherent safety issue through experience.

This 2 hours commander's discretion is frequently used by single-pilot + TCM HEMS operations in case of emergency for the patient. In France, 3% of flights saving lives would be impossible with a commander's discretion capped to 1 hour (cf. SNEH illustrative Table in attachment). To illustrate this issue, MBH attached a scenario taken from real HEMS operator planning where the commander's discretion (single-pilot + TCM) exceeds 1 hour (in that case, the commander's discretion is of 1h50).

Safety record and experience show such an allowance demonstrates a high level of safety, with no accident occurrence when the commander's discretion exceeds 1 hour.

For safety reasons, regulation already requires an additional crew member for HEMS, the TCM. Therefore, single-pilot HEMS operations are not PEQ1 operations but 1 single-pilot + 1 TCM contributing to the safety of the flight. As a consequence, commander's discretion should be of 2h for both two-pilots and 1 pilot + 1 TCM, as preexisting in France.

Thus, MBH suggests a 2 hours commander's discretion for both 1 pilot +TCM and two-pilots operations.

PROPOSAL



	Replace the content of the paragraph (a) by the following: "(a) The maximum basic daily FDP may be increased for HEMS by up to 2 hours."
response	Please see the answer to comment # 54
comment	954 comment by: <i>MBH SAMU</i>
	(b) ISSUE The paragraph (b) refers to 'sector'. However, the notion of 'sector' is not anymore defined for helicopters (Cf. ORO.FTL.105 (§24)). Therefore, MBH suggests replacing the term of sector by the notion of flight time. (Cf. comment #907)
	Besides, the wording 'alternate aerodrome' is used in the paragraph (b) but is not consistent with the activity of HEMS. Therefore, MBH suggests replacing this notion of alternate aerodrome by the notion of helipad or drop zone which better suits the activity of the HEMS.
	PROPOSAL Replace the paragraph (b) by the following:
	"(b) If on the final flight time within the FDP the allowed increase under (a) is further exceeded because of unforeseen circumstances after take-off, the flight may continue to the planned destination or any other helipad or drop zone. If unforeseen circumstances occur just before take-off on the final flight time, the allowed increase may only be exceeded to transport *the patient*." (Cf. comment hereafter)
response	Please see the answer to comment # 54
comment	955 comment by: MBH SAMU
	 (b) ISSUE In the paragraph (b), the extension of the last flight time before take-off is limited to the case of the transportation of a patient. This is not consistent with the definition of HEMS, which encompasses the following HEMS payload (medical personnel, medical supplies such as equipment, blood, organs or drugs, ill or injured persons and other persons directly involved). Life threatening emergency of a flight is not only conditioned by a patient onboard. It can deal with all the HEMS payload defined in ORO.FTL.105 (§29): medical personnel, medical supplies such as equipment including the helicopter, blood, organs or drugs, ill or injured persons and other persons directly involved. Indeed, it may be urgent for the medical staff to come back to the hospital, to ensure the medical material is available for another operation, etc.

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 373 of 585

The extension of the last flight shall include all the content defined for HEMS payload, for the present or next HEMS operations requiring a quick return to the base without uselessly immobilizing critical material and staff, including the helicopter.

That is why MBH suggests replacing the term patient used in the paragraph (b) by the HEMS payload defined in this NPA in the ORO.FTL.105 (§29).

PROPOSAL

Replace the paragraph (b) by the following:

"(b) If on the final flight time within the FDP the allowed increase under (a) is further exceeded because of unforeseen circumstances after take-off, the flight may continue to the planned destination or any other helipad or drop zone. If unforeseen circumstances occur just before take-off on the final flight time, the allowed increase may only be exceeded to transport themedical personnel, medical supplies such as equipment including the helicopter, blood, organs or drugs, ill or injured persons and other persons directly involved."

response

Please see the answer to comment # 54

comment	956 comment by: MBH SAMU
	(c) ISSUE The paragraph (c) is redundant with the ORO.FTL.110 (k). Both says exactly the same thing. Therefore, in order to make the reading easier, MBH suggests not repeating the same ideas in different paragraphs of this NPA.
	PROPOSAL Suppress the paragraph (c) of this CS.
response	Please see the answer to comment # 54

comment	991 comment by: AESA
	Point (a) allows increasing the maximum basic daily FDP up to 1 hour, but it doesn't allow to increase the maximum flight time. Is it correct?
response	Please see the answer to comment # 54
comment	1000 comment by: B. Wagner
	zu (a): eine zeitliche Beschränkung während eines Einsatzes ist nicht praxistauglich. Besser wäre eine Formulierung, die es der Besatzung erlaubt, einen bereits begonnenen Einsatz so

**** * * *** schnell wie möglich im Sinne des Patienten zu Ende zu fliegen.

zu (b):

Das Ziel sollte immer sein, den Hubschrauber zur Homebase zu überführen, da nur dort die Infrastruktur sowohl für den Schutz der Maschine als auch für die Ruhemöglichkeiten der Besatzung zur Verfügung stehen. Eine Übernachtung z.B. am Zielkrankenhaus hat eine Vielzahl von flugsicherheitsgefährdenden Auswirkungen, u.a. mangelhafte Absicherung der Maschine, Blockierung eines Nachtlandeplatzes für andere Maschinen, fehlende Ruhemöglichkeiten für die Crew (aus Erfahrung ist mit organisatorischem Aufwand von mehr als einer Stunde im Idealfall zu rechnen, bis die Besatzung tatsächlich eine Ruhemöglichkeit organisiert hat; in dünn besiedelten Regionen kann es deutlich länger dauern bis zu einem geeigneten Hotel o.ä.), Wettereinflüsse auf die im freien geparkte Maschine usw.

zu (c):

Dieser Punkt ist näher zu definieren. So ist nicht ersichtlich, wie diese 10% ermittelt werden sollen. Zusätzliche Daten zu ermitteln, um solche Statistiken zu füttern bedeutet immer Mehraufwand für die betroffenen Besatzungen. Dies ist speziell an den Tagen, an denen die Crews das erlaubte Limit im Dienst ausschöpfen nicht akzeptabel.

response

Please see the answer to comment # 54

comment	1013 comment by: Stephanie Selim
	(a)(b) Technical comment (commander's discretion, unforeseen circumstances) – <u>First comment:</u> The word « sector » is mentioned on b): should be replaced by « flight ».
response	Please see the answer to comment # 54

comment	1014 comment by: Stephanie Selim
	(a)(b)
	Technical comment (commander's discretion, unforeseen circumstances) –
	<u>Second comment</u> : We do not understand why, if « unforeseen circumstances occur just before take-off on the final sector, the allowed increase may <u>only be exceeded to transport</u> the patient ».
	Life threatening emergency of a flight is not only conditioned by a patient onboard. It can deal with all the HEMS payload defined in ORO.FTL.105 (§29): medical personnel, medical supplies
	If pilots cannot come back to the HEMS base with the helicopter and medical staff (but without patient on board), the helicopter won't be available for the next mission of the next pilot neither medical staff for another operation etc
	The extension of the last flight shall include all the content defined for HEMS payload, for the present or next HEMS operations requiring a quick return to the base without uselessly immobilizing critical material and staff, including the helicopter.
	This is why DGAC propose the following amendment: "If unforeseen circumstances occur just before take-off for the final flight sector, the allowed increase may only be exceeded

**** * * *. .*

	where immediate and rapid transportation is essential as defined in ORO.FTL.105 'EMS fight' to transport the patient."		
response	Please see the answer to comment # 54		
comment	1016 comment by: Stephanie Selim		
	(a)(b) Technical comment (commander's discretion, unforeseen circumstances) –		
	Third comment: Moreover, we ask for a 2 hours commander's discretion instead of 1, including for single-pilot. This 2 hours commander's discretion is frequently used by single-pilot in HEMS operations in France in case of emergency for the patient.		
	Moreover, regulation already requires for safety reason an additional crew member for single-pilot HEMS operations, the TCM. Therefore, single-pilot HEMS operations are not PEQ1operations but 1 single-pilot + 1 TCM contributing to the safety of the flight. As a consequence, commander's dicretion should be 2 hours for both two-pilots ans 1 pilot + 1 TCM.		
response	Please see the answer to comment # 54		
comment	1017 comment by: Stephanie Selim		
	(a)(b) Technical comment (commander's discretion, unforeseen circumstances) – <u>Fourth comment:</u> DGAC wonders if the words « alternate aerodrome » in (b) are appropriate for HEMS. We suggest « operating site ».		
response	Please see the answer to comment # 54		
comment	1018 comment by: Stephanie Selim		
	(c) Technical comment (commander's discretion, unforeseen circumstances) – We wonder if that requirement makes sense for HEMS operations which are unpredictable by definition. And we wonder why it is asked for 10 % of FDP in any 3 months. HEMS in France is characterized by a small number of flight hours, and statistics may be significantly modified by a very limited number of events. Moreover, since ORO.FTL.205(f)(4) and (5) should apply (refers to the technical comment on ORO.FTL.205(f)(7)), Authorities will be informed of recurrent important FDP or rest modifications. Therefore, we ask for the deletion of that point.		
response	Please see the answer to comment # 54		

comment | 1169

comment by: NHV Group

Attachment <u>**#170**</u>

Paragraph No: CS FTL.3.205 Flight duty period (FDP) - HEMS Subparagraph (d)

Comment: FOM should have freedom in defining number of consecutive FDP blocks taking into account pilot/TCM personal needs.

Justification: Block of 4 consecutive FDPs are inducing more interruption to the HEMS crews than blocks of 7 consecutive FDPs. Also, more frequent blocks of smaller number of consecutive FDPs are increasing the accumulation of commuting time and stress induced fatigue of pilots. Pilot mission familiarisation is less frequent with higher number of consecutive FDP blocks.

In particular NHV company case, limiting number of consecutive FDPs to 4 (from current 7) will have detrimental effects for the HEMS helicopter pilots, working in Northern France.

- NHV's HEMS helicopter pilots working in Northern France live in general in Southern part of France. The decrease of the duration of the shifts will lead to more travelling time from home to base station and vice versa. It will be a increase of 57% more travelling time.

- This increase of travelling time, together with the distance between home and work area, has a great impact on the private life of our HEMS helicopter pilots working in Northern France. The families can spend less time together.

- These pilots live in Southern France because of their human wellbeing. They feel integrated in this region, the families have their social environment over there, children are going to school/college and partners have their own career path to follow. Moving with their families to the North of France is in their opinion no option because of their wellbeing. - An increase of 57% travelling time on yearly basis (from ca. 41 travel days a year to ca. 72 days a year)

Evidence #1: HEMS crew members prefer longer stable periods as provided in blocks of 7 consecutive FDPs. "Company survey among its HEMS crew members."

Evidence #2: Results of the survey indicate that social and personal needs of pilots do have an effect, though indirectly, on pilots' perceptions of their flight performance. This effect is generally felt through deficits in concentration and energy that result from pilots' needs to resolve the conflict between personal requirements and professional demands. Work schedules impact this situation by the demands they place on pilot work time and the amount of off-duty time provided. If the schedule provides adequate rest, in addition to sufficient personal time to pursue individual interests, the conflict of personal and professional demands is minimized. If not, the pilots are caught on the horns of a major dilemma. The energy involved in resolving this may easily result in a lack of concentration at work, thus increasing one's personal accident liability and the potential for a fatal outcome. [Cauthorne, C. V., Fedorowicz, R. J. "Sociological impacts of work/rest schedules pilots, and their perceptions of performance" Hospital on Aviation, https://doi.org/10.1016/S0740-8315(86)80195-4]

Evidence #3: Distressing shifts are related to delayed sleep onset, workload is related to impaired sleep quality, and distressing shifts are positively related to perseverative cognition, perseverative cognition delayed sleep onset and mediated the association between distressing shifts and sleep onset latency. [Radstaak, M. et al "Work Stressors, Perseverative Cognition and Objective Sleep Quality: A Longitudinal Study among Dutch

Helicopter Emergency Medical Service (HEMS) Pilots" Journal of Occupational Health, https://doi.org/10.1539/joh.14-0118-OA]

Evidence #4: "An Investigation of Pilot Fatigue in Helicopter Emergency Medical Services" - This study found some evidence of a statistically significant positive relationship between HEMS pilot night shift respondent BFI (Brief Fatique Inventory) scores and experience as an HEMS pilot, while controlling for consecutive HEMS pilot night shifts and age. A 1-way analysis of variance suggested that the effect of experience as an HEMS pilot on HEMS pilot night shift respondent BFI scores was statistically significant. [Nix, S. "An Investigation of Pilot Fatigue in Helicopter Emergency Medical Services" Air Medical Journal, https://doi.org/10.1016/j.amj.2013.04.001]

Proposed text: (d) The operator may assign a block of up to 7 consecutive FDPs of more than 12 hours, but less than 14 hours, if the following conditions are met: (1) the rest period preceding the first FDP is at least 36 hours including 2 local nights; and (2) the rest period provided after completion of the series of consecutive FDPs is at least 60 hours including 3 local nights, or equal to the number of preceding duty days whichever is greatest.

response

Please see the answer to comment # 54

comment 1171

comment by: NHV Group

Paragraph No: CS FTL.3.205 Flight duty period (FDP) - HEMS

Unforeseen circumstances in flight operations — commander's discretion in HEMS under ORO.FTL.205(f)

Comment: Exceptional circumstances in HEMS missions might require pilot to either extend FDP or reduce rest period.

Justification: Proposition is to move commander's discretion into reducing the rest period or extending FDP, depending on medical complexity of ongoing HEMS mission.

Evidence #1: If on-duty rest on both day and night shifts is allowed, notable differences arose between on-duty work and rest patterns for pilots and medical team members. Shorter shifts limit on-duty rest. [Frakes, M. A., "Shift length and on-duty rest programs" patterns in rotor-wing air medical Air Medical Journal, https://doi.org/10.1016/j.amj.2004.08.027]

Proposed text: (a) The maximum daily rest period may be decreased for HEMS by up to 1 hour for single-pilot operation or by up to 2 hours for two-pilot operation, or FDP may be extended for HEMS by up to 1 hour for single-pilot operation or by up to 2 hours for twopilot operation.

response

Please see the answer to comment # 54

comment	1220	comment by: SAF
	CS FTL.3.205 UNFORESEEN CIRCONSTANCES FOR HEMS under ORO FTL	. 205(f)



There are two CS FTL.3.205, which introduces complexity, uncertainty and may lead to misunderstanding.

SAF suggests adding precisions within the titles of the paragraph in order to quickly make the link with the ORO paragraph involved.

PROPOSAL Replace the title of this CS by: "*CS FTL.3.205(f)*"

Please see the answer to comment # 54

response

comment	1221 comment by: SAF
	CS FTL.3.205 UNFORESEEN CIRCONSTANCES FOR HEMS under ORO FTL 205(f)
	ISSUE - FORCE MAJEURE
	(Cf. comment #1195)
	HEMS are deeply linked with national health, security and safety. HEMS depends on the organization of the French healthcare system (the permanence and continuity of care services is a public service & a sovereign prerogative), with groupings of medical equipment and skills.
	HEMS in France is both operated by private operators and the State.
	State may charter private operators to operate HEMS operations on its behalf.
	Current French regulation thus allows, by sovereign decision of the State, to grant derogation for HEMS operations as far as national health, security or safety is involved.
	Such a possibility shall remain for "Force majeure" and be introduced within the IR, in respect of the sovereignty of each Member State facing major health crisis.
	For example, in France, private operators of helicopters were chartered to ensure airlift rotations during recent Millas train disaster on December, the 14 th of 2017. Besides, Helicopter Nuclear Response Team are partially delegated to a private operator.
	Therefore, SAF suggests adding a specific paragraph in this implementing rule allowing HEMS pilots to derogate from these requirements in case of Force Majeure as it is already the case in the Current French National Regulation.
	PROPOSAL
	For illustrative purposes, in France the following article is applied in case of « Force Majeure » :



"Il peut être dérogé aux limitations mentionnées à la présente section dans les conditions suivantes :

1. Vols urgents, dont l'exécution immédiate est nécessaire :

a) Pour prévenir des accidents imminents et organiser des mesures de sauvetage, ou pour réparer des accidents survenus soit au matériel, soit aux installations ;

b) Pour assurer le dépannage des aéronefs.

2. Pour assurer l'achèvement d'une période de vol que des circonstances exceptionnelles n'auraient pas permis d'effectuer dans les limites préétablies.

3. Vols exécutés dans l'intérêt de la sûreté ou de la défense nationale ou d'un service public sur ordre du Gouvernement constatant la nécessité de la dérogation ; la limite est à fixer par le ministre chargé de l'aviation civile." (ref CAC D 422-12)

response

Please see the answer to comment # 54

comment	1222 comment by: SAF
	Attachments <u>#171</u> <u>#172</u>
	(Cf. attachment S2 illustrating this lack of commander's discretion issue)
	(a)
	ISSUE
	The paragraph (a) of this CS proposes a 1 hour commander's discretion for single-pilot + TCM HEMS operations. SAF wonders how this value has been chosen by the Agency since there is no justification within the RIA regarding this matter.
	Currently in France, the regulation allows a 2 hours commander's discretion, including for single-pilot + TCM HEMS operations, with no reported inherent safety issue through experience.
	This 2 hours commander's discretion is frequently used by single-pilot + TCM HEMS operations in case of emergency for the patient. In France, 3% ⁱ of flights saving lives would be impossible with a commander's discretion capped to 1 hour (cf. SNEH illustrative Table in attachment). To illustrate this issue, SAF attached a scenario taken from real HEMS operator planning where the commander's discretion (single-pilot + TCM) exceeds 1 hour (in that case, the commander's discretion is of 1h50).
	Safety record and experience show such an allowance demonstrates a high level of safety, with no accident occurrence when the commander's discretion exceeds 1 hour.

*** * * * * For safety reasons, regulation already requires an additional crew member for HEMS, the TCM. Therefore, single-pilot HEMS operations are not PEQ1 operations but 1 single-pilot + 1 TCM contributing to the safety of the flight. As a consequence, commander's discretion should be of 2h for both two-pilots and 1 pilot + 1 TCM, as preexisting in France.

Thus, SAF suggests a 2 hours commander's discretion for both 1 pilot +TCM and two-pilots operations.

PROPOSAL

Replace the content of the paragraph (a) by the following:

"(a) The maximum basic daily FDP may be increased for HEMS by up to 2 hours."

response

Please see the answer to comment # 54

comment 1223 comment by: SAF

(b)

ISSUE

The paragraph (b) refers to 'sector'. However, the notion of 'sector' is not anymore defined for helicopters (Cf. ORO.FTL.105 (§24)). Therefore, SAF suggests replacing the term of sector by the notion of flight time.

(Cf. comment #1184)

Besides, the wording 'alternate aerodrome' is used in the paragraph (b) but is not consistent with the activity of HEMS. Therefore, SAF suggests replacing this notion of alternate aerodrome by the notion of helipad or drop zone which better suits the activity of the HEMS.

PROPOSAL

Replace the paragraph (b) by the following:

"(b) If on the final flight time within the FDP the allowed increase under (a) is further exceeded because of unforeseen circumstances after take-off, the flight may continue to the planned destination or any other helipad or drop zone. If unforeseen circumstances occur just before take-off on the final flight time, the allowed increase may only be exceeded to transport *the patient*." (Cf. comment hereafter)

response

Please see the answer to comment # 54



comment 1224 comment by: SAF (b) ISSUE In the paragraph (b), the extension of the last flight time before take-off is limited to the case of the transportation of a patient. This is not consistent with the definition of HEMS, which encompasses the following HEMS payload (medical personnel, medical supplies such as equipment, blood, organs or drugs, ill or injured persons and other persons directly involved). Life threatening emergency of a flight is not only conditioned by a patient onboard. It can deal with all the HEMS payload defined in ORO.FTL.105 (§29): medical personnel, medical supplies such as equipment including the helicopter, blood, organs or drugs, ill or injured persons and other persons directly involved. Indeed, it may be urgent for the medical staff to come back to the hospital, to ensure the medical material is available for another operation, etc. The extension of the last flight shall include all the content defined for HEMS payload, for the present or next HEMS operations requiring a quick return to the base without uselessly immobilizing critical material and staff, including the helicopter. That is why SAF suggests replacing the term patient used in the paragraph (b) by the HEMS payload defined in this NPA in the ORO.FTL.105 (§29). PROPOSAL Replace the paragraph (b) by the following: "(b) If on the final flight time within the FDP the allowed increase under (a) is further exceeded because of unforeseen circumstances after take-off, the flight may continue to the planned destination or any other helipad or drop zone. If unforeseen circumstances occur just before take-off on the final flight time, the allowed increase may only be exceeded to transport themedical personnel, medical supplies such as equipment including the helicopter, blood, organs or drugs, ill or injured persons and other persons directly involved." response Please see the answer to comment # 54 comment 1225 comment by: SAF

gency of the European Unior

(c)

ISSUE

The paragraph (c) is redundant with the ORO.FTL.110 (k). Both says exactly the same thing. Therefore, in order to make the reading easier, SAF suggests not repeating the same ideas in different paragraphs of this NPA.

PROPOSAL

Suppress the paragraph (c) of this CS.

response

Please see the answer to comment # 54

comment | 1392

comment by: Swiss Air-Ambulance Rega

CS.FTL.3.205 (FDP)

Extension of the max. FDP by 2 hours (two-pilot crew), 1 hour (1 PiC) only for the completion of the last flight or for the flight with a patient. Moreover, the use of commander's discretion is limited to 10% of the entire FDP from the past 3 months. This passage cannot be compared to the previous one; it only applies to the completion of a flight or for taking the patient to hospital.

The same CS FDP name as for the max. is confusing. A limitation within 3 months is unrealistic, because the limit can be reached in just one mission. Furthermore, it could only occur in the summer and would then lead to duty plan changes just for this season. The evaluation of the 10% regulation would require the crews to perform extra work, which would have to be carried out precisely in times when the strain on the crews is at its highest level, that is, on long summer days.

CS.FTL.3.205(b) (FDP)

The text contains the word sector, which is not defined for HEMS. This probably means that crew will be tempted to turn down missions in the last hour of duty, because for a mission taking more more than one hour, crews will be condemned to remain on ground at the hospital. This could mean: Missions down are turned early; The mission might end in the field if no patient is to be transported; In case a patient has to be transported the hospital's landing site is blocked for at least another10 hours (affecting the capacity of the hospital and therefore affecting the health of thirdpatients); care Following multiple other effects because the helicopter cannot be protected against adverseweather conditions on most of the hospital landing sites; Crew would need to seek accommodation locally. i.e. all ends up at the wrong place and likely the crew is to become more fatigued then when returning to base

CS.FTL.3.205(c) (FDP)

This 10% are probably meant for a base and not FDP, as the FDP would count for an individual person. The total flight duty period for three months for a base equals up to 1267h therefore 10% are 126,7h. As there is 1 additional hour only at commanders discretion allowed, this rule cannot apply in a single pilot operation within a 90-days period. If something else is intended consider revising the text.

response	Please see the answer to comment # 54	
comment	1396 comment by: European Helicopter Association (EHA)	
	Deutscher Hubschrauber Verband / DHV (Germany)	
	Comment: The German FTL allows HEMS operator to apply for specific FTL schedules allowing FDP in single pilot operation of up to 15:30 hours on max. four consecutive days, according to NPA, this will not longer be possible.	
	Action requested: Please review and adjust accordingly.	
response	Please see the answer to comment # 54	
comment	1457 comment by: Association of Air Ambulances	
	This does not read logically. It should be amended to read: "(c) If the total of Commander's discretion used at any HEMS operating base is more th 10 % of the total FDP for a 3-month period, the future schedule of crew resource utilisation of that HEMS operating base is to be reviewed and amended."	
	CS FTL.3.205(b) permits the allowed increase to the FDP to be extended if the unforeseen circumstance (HEMS call) occurs just before take-off on the final sector, but only to transport the patient. If a medical decision is made not to transport the patient by air, this could result in a helicopter being stranded until a rested crew can arrive at the HEMS site to relieve the duty crew.	
	This should be amended to allow either the transport of the patient or an non-HEMS flight to the overnight base.	
	This contradicts ORO.FTL.105 (29) A sector flown to position an aircraft to the operating base before or after an EMS flight is considered part of that flight.	
response	Please see the answer to comment # 54	
comment	1470 comment by: Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)	
	Add a new condition:	
	After delivering the patient the crew should also be allowed to return to the HEMS base. Otherwise, the helicopter would risk blocking the helipad at the hospital.	



response

Please see the answer to comment # 54

1489 comment comment by: Finnish Transport Safety Agency In order to establish rolling 24 hour standby for HEMS, following amendments are proposed. **Proposal:** Add new paragraph CS FTL.3.208 after [second] CS FTL.3.205 as follows: CS FTL.3.208 Active duty period (ADP) in active standby — HEMS Unforeseen circumstances in flight operations — commander's discretion in HEMS under ORO.FTL.205(f) By way of derogation from CS FTL.3.205, the conditions to modify the limits on FT and ADP by the commander in the case of unforeseen circumstances in HEMS flight operations which occur during the active standby, comply with the following: (a) The maximum basic daily FT or ADP may be increased for HEMS by up to 1 hour for single-pilot operation or by up to 2 hours for two-pilot operation. (b) If on the final sector within the HEMS task the allowed increase under (a) is further exceeded because of unforeseen circumstances after take-off, the flight may continue to the planned destination or alternate aerodrome. If unforeseen circumstances occur just before take-off on the final sector, the allowed increase may only be exceeded to transport the patient. (c) If commander discretion is used in any HEMS operating base more than 10 % of the total ADP over a 3-month period, the schedule and crew resources of the HEMS operating base are reviewed and adapted. Please see the answer to comment # 54 response

CS FTL.3.210 p. 37

comment 7 comment by: TG Jede Veränderung, die für die Piloten erhöhte Reise-Belastung zur Folge hat ist zu vermeiden. Die langen Schichtfolgen ergeben überhaupt erst genug Erholung und verkürzen die Zeit auf der Straße für den großen Teil der HEMS-Piloten erheblich.

response

Please see the answer to comment # 54



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 385 of 585

Individual comments and responses - HEMS

comment	61 comment by: London's Air Ambulance
	First paragraph should be amended to read: "ORO.FTL.210(b) is not to exceed the following limits:"
response	Please see the answer to comment # 54
comment	121 comment by: UK CAA
	Page No: 37
	Paragraph No: CS FTL.3.210 Flight times and duty periods - HEMS
	Comment: As per UK CAA comment for page 13, the insertion of " either of the following limits" implies an either / or meaning so that only one of the limits need to be applied. This would be an incorrect application and generates potential confusion.
	Justification: The correct application of this requirement. Proposed Text: Delete "either of" in all of the alphabetical bullet points, leaving the text at "shall not exceed the following limits" or change "either" to "any".
response	Please see the answer to comment # 54
comment	185 comment by: ANSMUH
	CS FTL.3.210 Flight times and duty periods
Duty periods in HEMS operations under ORO.FTL.210(b) The total duty periods to which an individual crew member in HEMS operation assigned under ORO.FTL.210(b) does not exceed either of the following limits:	
	Refers to my comments regarding CS FTL 3.205
response	Please see the answer to comment # 54

omment	255 comment by: European Helicopter Association (EHA
	ADAC (Germany), DRF (Germany) and LAR (Luxembourg):
	a. 110 duty hours in 14 consecutive days
	b. 190 duty hours in 28 consecutive days
	Question: 1.i refers to max FDP of 14 hours. What would be the limit if this 14 hour limit
	was
	extended e.g. with commanders discretion or with split duty?
	1.vi refers to ORO.FTL.235(d) which is not part of the NPA documentation. It would be really
	helpful for interested parties to have a complete set of documents instead of a cloze wit empty
	spaces to be filled from different other documents.
	This paragraph introduces a setback compared to the current regulation where a maximum
	annual duty time in combination with 210 duty hours in consecutive 30 days was the limit. To
	avoid additional personnel and the ability of managing short notice illness of crews, the 14 days
	limit needs to be minimum 120 hours.
	Remark: It is not obvious how these limits are developed and what kind of data it is base on.
	Especially the 14 day/110 hour limit is too limiting and restricts the ability of crew planners to react
	to illness of crews on short notice.
esponse	Please see the answer to comment # 54

comment	287 co	mment by: European Helicopter Association (EHA)	
	ADAC (Germany), DRF (Germany) and LAR (Luxembourg):		
	CS FTL 3.210 (1)		
	TEXT: "110 duty hours in any consecutive days"		
	Problem: It is not possible to set up normal sched FDP, because this will give you 112 hour	ules(i.e. 4 days on, 4 days off) with 1400 hours s in 14 days	
	Solution: Increase the duty hours to 120 duty hou	irs in any 14 consecutive days	
response	Please see the answer to comment # 54		

**** ****

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.Page 387 of 585

comment	289	comment by: European Helicopter Association (EHA)	
	ADAC (Germany), DRF (Germany) and LAR (Luxembourg): CS FTL 3.210 (1) & (2)		
	TEXT: " (1) 110 duty hours; 14 hours FDP - rest period = 4 local nights" TEXT: " (2) 190 duty hours; 14 hours FDP - rest period = 3 local nights"		
	Problem:		
		ent rest periods; even in schedules based on 190 give two duty periods of 4 days with 14 hours FDP	
	Solution:		
	Set the rest period to 3 local nights		
response	Please see the answer to comment a	¥ 54	

comment	316	comment by: European Helicopter Association (EHA)	
	NORSK LUFTAMBULANSE AS (Norway):		
	Comment: (the same comment is placed on page 36 for CS FTL 3.205)		
	week in a 7 ON/14 OFF/7 ON/21 off f technical crew members. As our FRN conducted in a safe manner and we	hat have one crew on duty for 24/7 for one complete for flight crew members and 7 ON / 21 OFF for HEMS 1 and sicentific studies has shown, this is apparently ntend to seek an IFTSS. Having said that, having two 4 hour period is quite common pracice in Europe and acticable.	
	For HEMS operating base conducting	24/7 operations:	
	FTL.3.210 Flight times and duty period	CS FTL.3.205 Flight duty period (FDP) — HEMS and CS ods — HEMS, there is not enough overlap to ensure crews (a "day" and "night" crew) are used to cover	
	a maximum of 1 hour overlap in each	hours and 12 hours FDP limits respectively gives only end. This does not give enough time to dispatch on, that this is even if <u>not one single</u> HEMS mission has he alarm.	
		example 1:30 to 1 hour) before overlap, the mission new crew has commenced their FDP. Alternatively,	

**** **** three crews must be used for every 24-hour period to keep one HEMS operating base operational 24/7.

1:30 to 1 hour before the overlap is just an example. The period necessary to complete a mission is quite contextual and sufficient time is up for discussion, but the question needs to be addressed.

Furthermore, as mentioned in the comment to CS FTL.3.205 Flight duty period (FDP) -HEMS, NPA p 35 above, prescribing breaks is not a practicable solution and the concept of breaks is very unclear, especially regarding how this should be planned.

An easier approach would be a concept comprising a maximum Duty Period with a maximum Flight Duty Period comprising "Passive time" and "Active time". This could look like the following example:

"Passive time" is all the time spent on a HEMS duty period that is not considered to be active time, relaxing, free of all duties except standing by to receive an alarm.

"Active time" is all the time spent pre- and post-flight activities, operation of the helicopter, HEMS missions, rapid response vehicle missions, training, checking, administrative work, meetings, attending a course, simulator, travel etc.

While passive time is the time the crew members are relaxing, the fatigue level is a direct consequence of the circadian rhythm and therefore it is of outmost importance, as far as practicable, to maintain a normal sleep pattern.

Passive time is calculated as 50% towards the total Flight Duty Time. Active time is calculated as 100% towards the total Flight Duty Time.

If reaching any Flight time or Active time limit, the crew member shall go off Active duty.

HEMS:

- Duties such as pre-flight inspection, fuel checks, equipment check, etc. shall be logged as active time;
- Active time is triggered by an alarm and is defined from time of alarm to minimum 1 hour after block-on time. If the time for post flight duties takes more than 1 hour, actual time shall be logged as active time.

Rapid response vehicle operation:

Between 10:00 and 22:59, Active time is triggered by an alarm and is defined from time of alarm to the time the mission is completed and equipment etc. is resupplied and prepared and as a minimum 15 minutes; and

	• Between 23:00 and 09:59, Active time is triggered by an alarm and is defined from time of alarm to minimum 1 hour after returning at the base. If the time for post mission duties takes more than 1-hour, actual time shall be logged as active time.
	For HEMS and rapid response vehicle operation:
	 If there are less than two hours between on-block and the time of a new alarm, the entire time between on-block and the time of a new alarm counts as Active time.
	Other operations (pre-flight, ferry flight, test flight, training flight, etc.):
	 Active time is triggered when reporting for duty or commencing preparations and ends minimum 30 minutes after block-on time; Related duties such as pre-flight inspection, fuel checks, equipment check, flights registration etc., are not counted separately. This is considered included in the minimum 30 minutes after block-on time; and If the time for post flight duties takes more than 30 minutes, actual time shall be logged as Active time.
	With a system like this, perhaps a maximum Flight Duty Period of 16 hours could be introduced for a "day crew" with a maximum of 10 or 12 hours total active and passive time. For a "night crew", a maximum of 12 or even 14 hours maximum Flight Duty Period could be used with a maximum of 10 hours of total active time. This system would also allow for sufficient overlap in case of missions just prior to a crew/shift change.
response	Please see the answer to comment # 54
comment	343 comment by: European Helicopter Association (EHA)
Comment	FNAM (France) #1
	 ISSUE In general, and in this paragraph, it is not explicit whether: All the CS.FTL.3 requirements shall be applicable "in block" The CS requirements should apply depending on what is said in the implementing rule Cherry-picking is allowed Indeed, two options seem to be presented, one described in ORO.FTL.210 (a) and another in CS.3.210.

In that way, the CS is a substitution of the IR, which is not the aim and the statute of a CS. The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #18.1, #24, #25, #39, #40) Therefore, the FNAM suggests listing the two options in the CS.FTL.3.210 instead of having one described in the IR and one in the CS. PROPOSAL List the two options in the CS.FTL.3.210 instead of having one described in the IR and one in the CS. Cf. consolidated proposal of writing at the end of below additional comments #2 (1)(i)ISSUE The paragraph (1)(i) of this CS says that the maximum daily FDP does not exceed 14 hours. It is redundant with the provisions of the CS FTL.3.205 (a) Table 1 and (b) Table 2. Indeed, in these tables, the maximum FDP is 14 hours. Besides, the HEMS operators do not have any option to apply FDP requirements described in the CS. Therefore, the reference to the specific CS FTL.3.205(a) and (b) is not consistent, it is not useful to repeat it in this paragraph since it will be applied anyway. The actual writing may lead to misunderstanding. That is why, the FNAM suggests withdrawing the paragraph (1)(i) of this CS. PROPOSAL Withdraw the paragraph (1)(i) of this CS. Cf. consolidated proposal of writing at the end of below additional comments #3 (1)(ii)ISSUE Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since flight times are unpredictable and cannot be scheduled within a FDP, the same has to be applied for breaks. Besides the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour. For Single-pilot + TCM operations As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, the opportunity for a break lasting between 2h and 1h is warranted. Indeed, given the following aspects (Table 1 and 2 of this CS): • Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours for break with



a maximum Total Flight Time with autopilot = 7 hours which means at least 5 to 7 no-flown hours • Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours for break with a maximum Total Flight Time without autopilot = 5 hours which means at least 7 to 9 noflown hours There is always a room for such a break lasting between 2h and 1h in a suitable accommodation at HEMS operating base. For Two-pilots operations As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, the opportunity for a 1h hour break is warranted. Indeed, given the following aspects (Table 1 of this CS): Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time with autopilot = 9 hours which means at least 3 to 5 no-flown hours Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time without autopilot = 7 hours which means at least 5 to 7 noflown hours. There is always a room for such a 1h break in a suitable accommodation at HEMS operating base. Such a break may be monitored ex-post by the operator SMS, under the principle of the fatigue risk management. Therefore, under the above risk analysis and under a monitoring following the principles of a fatigue risk management, the FNAM suggests writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the operation. (Cf. comments #28.4.1 and #28.4.2) PROPOSAL Replace this paragraph of the NPA by the following: *(ii) The operator ensures ex-post at least one break of minimum 60 consecutive minutes* within each FDP at the HEMS operating base at times that ensure likelihood of sleep. This break can be monitored ex-post by the operator SMS, under the principle of the fatigue risk management." But in fact CS.FTL.3.210(1)(ii) is strictly the same as CS.FTL.3.205(a)(2) and CS.FTL.3(b)(2). Those provisions already apply in all cases. (Cf. comment #28.4.1 and #28.4.2) Therefore, it is not consistent nor useful to repeat them in this paragraph since it will be applied anyway. The actual writing may lead to misunderstanding. That is why, the FNAM suggests withdrawing the paragraph (1)(ii) of this CS.

Withdraw the paragraph (1)(ii) of this CS.



Cf. consolidated proposal of writing at the end of below additional comments #4 (1)(iii) and (iv) ISSUE (1)(iii) and (iv) The paragraph (1)(iii) and (iv) of this CS is redundant with the provisions of the CS FTL.3.205 (a)(2) and (b)(3). It is therefore not consistent nor useful to repeat these dispositions in those paragraphs since it will be applied anyway. The actual writing may lead to misunderstanding. That is why, the FNAM suggests withdrawing the paragraph (1)(iii) and (iv) of this CS. PROPOSAL Withdraw the paragraph (1)(iii) and (iv) of this CS. #5 (1)(v)ISSUE The paragraph (1)(v) of this CS says the operator provides suitable accommodation for crew members at the HEMS operating base for the purpose of breaks. It is redundant with the provisions of the CS FTL.3.205 (a)(1) and (b)(2). Besides, the HEMS operators do not have any option to apply FDP requirements described in the CS. Therefore, it is not consistent nor useful to repeat it in this paragraph since it will be applied anyway. The actual writing may lead to misunderstanding. That is why, the FNAM suggests withdrawing the paragraph (1)(v) of this CS. PROPOSAL Withdraw the paragraph (1)(v) of this CS. #6 (1)(vi) ISSUE The FNAM wonders why the minimum recurrent extended recovery rest period following a reduced rest period is increased to include 4 local nights since no analysis has been made in the RIA. Besides. there is not such a requirement is for non-HEMS CAT operations. The FNAM underlines the French regulation historically proposes several rostering cycles for HEMS operations that are currently used with an excellent safety track record demonstrated by experience: 7 days ON / 7 days OFF with a limitation of 14 hours of duties for 24 hours 5 days ON / 2 days OFF with a limitation of 12 hours of duties for 24 hours • 12 days ON / 6 days OFF with a limitation of 12 hours of duties for 24 hours Therefore, most hospitals / HEMS organizations have a contractual engagement with the National Health Authority over a rolling 24 hours period: 12 hours of HEMS operative availability and 12 hours OFF. According to the Agency requirement on the pre-flight and post-flight minimum times (Cf. #28.5), an



HEMS organization will yet roster cycle with a FDP of 12h30 and a Duty Period of 12h45 to ensure they follow their engagement with hospitals. Thus, all HEMS operators will have to schedule: • More than 12h FDP for each and every vacation Reduced rest of more than 10h amongst a 11h15 available time for rest according to CS.FTL.3.235 to reengage at the same time the day after under the principles of a FRM. More than 12 hours FDP does not appear more tiring than less than 12 hours FDP: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes *i.e* 50 minutes back and force for 1 mission in Francei). Reduced rest does not appear over tiring, as balanced to the nature of the FDP and flight time: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes *i.e.* 50 minutes back and force for 1 mission in Francei). Moreover, such a reduced rest is used under the principles of a FRM, that shall provide all other mitigation measures as necessary. Furthermore, no demonstration nor RIA is given to justify this value, while the current rostering in France on this subject for HEMS operations has no reported inherent safety issue through experience. The FNAM suggests keeping the standard extended recovery rest period of 3 local nights including when reduced rest occurs, under the principles of a FRM, unless a sound RIA and/or a scientific study justify the necessity of 4 local nights. (Cf. comment #36.1 et #36.2) PROPOSAL Replace the paragraph (1)(vi) by the following: "(1)(vi) the minimum recurrent extended recovery rest period required under ORO.FTL.235(d) shall be increased to include 4 local nights or 3 local nights under the principles of a FRM." CONSOLIDATED PROPOSAL of #1, #2, #3, #4, #5 and #6 Replace the whole CS by the following: CS FTL.3.210: "The total duty periods to which an individual crew member may be assigned in HEMS operation shall not exceed either of the following limits: **OPTION 1:** (1) 60 duty hours in any 7 consecutive days; (2) 110 duty hours in any 14 consecutive days; and (3) 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period. OR

**** * * ***

n agency of the European Unior

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

OPTION 2:
(1) 110 duty hours in any 14 consecutive days, on the condition that:
ii. the minimum recurrent extended recovery rest period required under ORO.FTL.235(d) shall be
increased to include 4 local nights or 3 local nights under the principles of a FRM.
(2) 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period."

response

Please see the answer to comment # 54

comment	369	comment by: European Helicopter Association (EHA)
	вна (ик)	
	"CS FTL 3.210 Flight times and duty periods — HEMS (1) (ii)"	
	Comment: Whatever the length of the individu	al FDP?
response	Please see the answer to comment #	<mark>‡ 54</mark> .

comment	388 comment by: Joachim J. Janezic (Institute for Austrian and International Aviation law)
	To CS FTL.3.210(1)(ii) and (iii): These two requirements are in fact redundant.
response	Please see the answer to comment # 54

comment	400	comment by: European Helicopter Association (EHA)		
	OEATMC (Austria):			
	CS FTL.3.210 Flight times and duty p	eriods — HEMS		
	Duty periods in HEMS operations under ORO.FTL.210(b)			
	The total duty periods to which an i assigned	ndividual crew member in HEMS operations may be		
	under ORO.FTL.210(b) does not exce	ed either of the following limits:		
	(1) 110 duty hours in any 14 consecu	tive days, on the condition that:		
	i. the maximum daily FDP specified in and	n CS FTL.3.205(a) or (b) does not exceed 14 hours;		
	(2) 190 duty hours in any 28 consecutive that	tive days, spread as evenly as practicable throughout		

**** * * *** TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 395 of 585 period.

COMMENT(S)

Apparently this is calculated ONLY for a 5-days ON/ 5-days OFF roster with 12 hour FDPs. If an

organization needs a 4-days ON/4-days OFF roster with up to 14 hour FDPs it is not manageable with

110 hours in 14 days! It would require at least 115 hours in 14 days being the multiple of 4 times 14

and additional 3h of reserve. Following this line of thoughts, 190 hours in paragraph (2) is also not

the multiple 14 times 14 and should be raised to 200 hours.

An evaluation of third party damages of over 36.000 missions (108.000 flights) in the period of 2016

and 2017 concluded two peaks, one on Thursday which represents the starting day in our duty roster

and one Saturday. Interestingly enough shows Wednesday (the last day of the 7 days roster) the

lowest risk for damages. This correlates with a study made by employer's mutual insurance associations in Germany and Switzerland (SUVA and BGW) which prove a high peak on the first day

of duty. This NPA's duty roster would almost double this count!

response

Please see the answer to comment # 54

comment 427 comment by: UFH French Helicopters Association #1 ISSUE general, and in this paragraph, it is not explicit whether: In All CS.FTL.3 requirements shall be applicable "in block" the The CS requirements should apply depending on what is said in the implementing rule Cherry-picking allowed is Indeed, two options seem to be presented, one described in ORO.FTL.210 (a) and another CS.3.210. in In that way, the CS is a substitution of the IR, which is not the aim and the statute of a CS. The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #18.1, #25, #39, #40) #24, Therefore, we suggest listing the two options in the CS.FTL.3.210 instead of having one described the IR CS. in and one in the PROPOSAL List the two options in the CS.FTL.3.210 instead of having one described in the IR and one



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 396 of 585

in the	CS.
Cf. consolidated proposal of writing at the end of below additional comments	
#2	
(1)(i)	
ISSUE	
The paragraph (1)(i) of this CS says that the maximum daily FDP does not exceed 14 hou It	is
redundant with the provisions of the CS FTL.3.205 (a) Table 1 and (b) Table 2. Indeed these Tab	
the maximum FDP is 14 hours. Besides, the HEMS operators do not have any option apply	n to FDP
requirements described in the CS. Therefore, the reference to the specific CS FTL.3.205 and (b)	5(a) is
not consistent, it is not useful to repeat it in this paragraph since it will be applied anyw	-
writing may lead to misunderstanding. That is why, FNAM suggests withdrawing	
of this	CS.
PROPOSAL	
Withdraw the paragraph (1)(i) of this CS.	
(1)(ii) ISSUE	
Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Si	nce
flight times	are
unpredictable and cannot be scheduled within a FDP, the same has to be applied	for
breaks. Besi	
the wording "break" should be rethought to make it easy to understand that this perio	ime
a allowed for physiological needs, which is different from a rest period free of all duties	
at least	1
hour.	
For Single-pilot + TCM operati	
As a mitigation, it is obvious that due to the very low average reported flight time in HEI	MS,
the opportunity for a break lasting between 2h and 1h is warrant	hot
	CS):
• Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours	•
break	vith
a maximum Total Flight Time with autopilot = 7 hours which means at least 5 to 7 no-flo	wn
hours	~
 Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours break 	tor vith
a maximum Total Flight Time without autopilot = 5 hours which means at least 7 to 9	-
flown	
hours	
There is always a room for such a break lasting between 2h and 1h in a suita	ble
accommodation	at
HEMSoperatingbaForTwo-pilotsoperati	ase.



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, the for 1h hour break opportunity is warranted. а Indeed, given the following aspects (Table 1 of this CS): Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time with autopilot = 9 hours which means at least 3 to 5 no-flown hours Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time without autopilot = 7 hours which means at least 5 to 7 noflown hours There is always a room for such a 1h break in a suitable accommodation at HEMS operating base. Such a break may be monitored ex-post by the operator SMS, under the principles of the fatigue risk management. Therefore, under the above risk analysis and under a monitoring following the principles of fatigue risk management, we suggest writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the operation. (Cf. #28.4.1 #28.4.2) comments and PROPOSAL Replace this of the NPA by the following: paragraph "(ii) The operator ensures ex-post at least one break of minimum 60 consecutive minutes within each FDP at the HEMS operating base at times that ensure likelihood of sleep. This break can be monitored ex-post by the operator SMS, under the principle of the fatigue risk management." But in fact CS.FTL.3.210(1)(ii) is strictly the same as CS.FTL.3.205(a)(2) and CS.FTL.3(b)(2). Those provisions already apply in all cases. (Cf. comment #28.4.1 and #28.4.2) Therefore, it is not consistent nor useful to repeat them in this paragraph since it will be applied anyway. The actual writing may lead to misunderstanding. That is why, FNAM suggests withdrawing the CS. paragraph (1)(ii)of this Withdraw the (1)(ii)this CS. paragraph of #4 (1)(iii)and (iv) ISSUE (1)(iii) and (iv) The paragraph (1)(iii) and (iv) of this CS is redundant with the provisions of the CS FTL.3.205 (a)(2) and (b)(3). It is therefore not consistent nor useful to repeat these dispositions those in paragraphs since it will be applied anyway. The actual writing may lead to That misunderstanding. is



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

Page 399 of 585

why, FNAM suggests withdrawing the paragraph (1)(iii) and (iv) of this CS. PROPOSAL Withdraw the paragraph (1)(iii) and (iv) of this CS. #5 (1)(v)ISSUE The paragraph (1)(v) of this CS says the operator provides suitable accommodation for crew members at the HEMS operating base for the purpose of breaks. It is redundant with the provisions of the CS FTL.3.205 (a)(1) and (b)(2). Besides, the HEMS operators do not have any option to apply FDP requirements described in the CS. Therefore, it is not consistent nor useful to repeat it in this paragraph since it will be applied anyway. The actual writing may lead to misunderstanding. That is why, we suggest withdrawing the paragraph (1)(v) of this CS. PROPOSAL Withdraw the paragraph (1)(v) of this CS. #6 (1)(vi) ISSUE French stakeholders wonder why the minimum recurrent extended recovery rest period following reduced rest period is increased to include 4 local nights since no analysis has been made in the RIA. Besides, there is not such а requirement is for non-HEMS CAT operations. We underlines the French regulation historically proposes several rostering cycles for HEMS operations that are currently used with an excellent safety track record demonstrated by experience: • 7 days ON / 7 days OFF with a limitation of 14 hours of duties for 24 hours • 5 days ON / 2 days OFF with a limitation of 12 hours of duties for 24 hours • 12 days ON / 6 days OFF with a limitation of 12 hours of duties for 24 hours Therefore, most hospitals / HEMS organizations have a contractual engagement with the National Health Authority over a rolling 24 hours period: 12 hours of HEMS operative availability and 12 hours OFF. (Cf. attachments S1, S2, S3 and S4 illustrating the 12h operational readiness issue) According to the Agency requirement on the pre-flight and post-flight minimum times (Cf. #28.5), an HEMS organization will yet roster cycles with a FDP of 12h30 and a Duty Period of 12h45 to ensure they follow their engagement with hospitals. Thus, all HEMS operators will have to schedule: ٠ More than 12h FDP for each and every shift Reduced rest of more than 10h amongst a 11h15 available time for rest according to CS.FTL.3.235 to reengage at the same time the day after under the principles of a FRM. More than 12 hours FDP does not appear more tiring than less than 12 hours FDP: they are spent

gency of the European Unior

in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for French operators i.e 50 minutes back and forth for 1 mission in Francei). Reduced rest does not appear over tiring, as balanced to the nature of the FDP and flight time: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for SNEH i.e 50 minutes back and forth for 1 mission in Francei). Moreover, such a reduced rest is used under the principles of a FRM, that shall provide all other mitigation measures as necessary. Furthermore, no demonstration nor RIA is given to justify this value, while the current rostering in France on this subject for HEMS operations has no reported inherent safety issue through experience. We suggest keeping the standard extended recovery rest period of 3 local nights including when reduced rest occurs, under the principles of a FRM, unless a further developed RIA and/or scientific а study justify the necessity of 4 local nights. #36.2) (Cf. comment #36.1 et PROPOSAL Replace the paragraph (1)(vi) by the following: "(1)(vi) the minimum recurrent extended recovery rest period required under ORO.FTL.235(d) shall be increased to include 4 local nights or 3 local nights under the principles of a FRM." CONSOLIDATED PROPOSAL of #1. #2. #3, #4. #5 and #6 Replace the whole CS by the following: FTL.3.210: CS "The total duty periods to which an individual crew member may be assigned in HEMS operation shall following limits: not exceed any of the OPTION 1: (1) 60 duty 7 consecutive hours in any days; 14 (2) 110 duty hours in any consecutive davs; and (3) 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period. OR OPTION 2: (1) 110 duty hours in any 14 consecutive days, on the condition that: ii. the minimum recurrent extended recovery rest period required under ORO.FTL.235(d) shall he

increased to include 4 local nights or 3 local nights under the principles of a FRM.



	(2) 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period."
response	Please see the answer to comment # 54
comment	496 comment by: FNAM/SNEH
	ISSUE In general, and in this paragraph, it is not explicit whether:
	 All the CS.FTL.3 requirements shall be applicable "in block" The CS requirements should apply depending on what is said in the implementing rule Cherry-picking is allowed
	Indeed, two options seem to be presented, one described in ORO.FTL.210 (a) and another in CS.3.210. In that way, the CS is a substitution of the IR, which is not the aim and the statute of a CS. The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #473, #477, #478, #510, #511)
	Therefore, FNAM and SNEH suggest listing the two options in the CS.FTL.3.210 instead of having one described in the IR and one in the CS.
	PROPOSAL List the two options in the CS.FTL.3.210 instead of having one described in the IR and one in the CS. Cf. consolidated proposal of writing at the end of below additional comments
response	Please see the answer to comment # 54
comment	497 comment by: FNAM/SNEH
	(1)(i) ISSUE The paragraph (1)(i) of this CS says that the maximum daily FDP does not exceed 14 hours. It is redundant with the provisions of the CS FTL.3.205 (a) Table 1 and (b) Table 2. Indeed, in these Tables, the maximum FDP is 14 hours. Besides, the HEMS operators do not have any option to apply FDP requirements described in the CS. Therefore, the reference to the specific CS FTL.3.205(a) and (b) is not consistent, it is not useful to repeat it in this paragraph since it will be applied anyway. The actual writing may lead to misunderstanding. That is why, FNAM and SNEH suggest withdrawing the paragraph (1)(i) of this CS.

PROPOSAL Withdraw the paragraph (1)(i) of this CS.



Cf. consolidated proposal of writing at the end of below additional comments

response

Please see the answer to comment # 54

comment 498 comment by: FNAM/SNEH Attachments #173 #174 #175 #176 (Cf. attachments S1, S2, S3 and S4 illustrating break issue) (1)(ii)ISSUE Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since flight times are unpredictable and cannot be scheduled within a FDP, the same has to be applied for breaks. Besides the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour. For Single-pilot + TCM operations As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, the opportunity for a break lasting between 2h and 1h is warranted. Indeed, given the following aspects (Table 2 of this CS): Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours for break with a maximum Total Flight Time with autopilot = 7 hours which means at least 5 to 7 no-flown hours Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours for break with a maximum Total Flight Time without autopilot = 5 hours which means at least 7 to 9 no-flown hours There is always a room for such a break lasting between 2h and 1h in a suitable accommodation at HEMS operating base. For Two-pilots operations As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, the opportunity for a 1h hour break is warranted. Indeed, given the following aspects (Table 1 of this CS): Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time with autopilot = 9 hours which means at least 3 to 5 no-flown hours Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours • for break with a maximum Total Flight Time without autopilot = 7 hours which means at least 5 to 7 no-flown hours

**** * * ***

There is always a room for such a 1h break in a suitable accommodation at HEMS operating base. Such a break may be monitored *ex-post* by the operator SMS, under the principles of the fatigue risk management. Therefore, under the above risk analysis and under a monitoring following the principles of a fatigue risk management, FNAM and SNEH suggest writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the operation. (Cf. comments #484 and #485) PROPOSAL Replace this paragraph of the NPA by the following: (ii) The operator ensures ex-post at least one break of minimum 60 consecutive minutes within each FDP at the HEMS operating base at times that ensure likelihood of sleep. This break can be monitored ex-post by the operator SMS, under the principle of the fatigue risk management." But in fact CS.FTL.3.210(1)(ii) is strictly the same as CS.FTL.3.205(a)(2) and CS.FTL.3(b)(2). Those provisions already apply in all cases. (Cf. comment #484 and #485) Therefore, it is not consistent nor useful to repeat them in this paragraph since it will be applied anyway. The actual writing may lead to misunderstanding. That is why, FNAM and SNEH suggest withdrawing the paragraph (1)(ii) of this CS. Withdraw the paragraph (1)(ii) of this CS. Cf. consolidated proposal of writing at the end of below additional comments response Please see the answer to comment # 54 comment by: FNAM/SNEH comment 499

ISSUE

(1)(iii) and (iv)

(1)(iii) and (iv) The paragraph (1)(iii) and (iv) of this CS is redundant with the provisions of the CS FTL.3.205 (a)(2) and (b)(3). It is therefore not consistent nor useful to repeat these dispositions in those paragraphs since it will be applied anyway. The actual writing may lead to misunderstanding. That is why, FNAM and SNEH suggest withdrawing the paragraph (1)(iii) and (iv) of this CS.

PROPOSAL Withdraw the paragraph (1)(iii) and (iv) of this CS.

response

Please see the answer to comment # 54

comment	500	comment by: FNAM/SNEH
	(1)(v) ISSUE	



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 403 of 585 The paragraph (1)(v) of this CS says the operator provides suitable accommodation for crew members at the HEMS operating base for the purpose of breaks. It is redundant with the provisions of the CS FTL.3.205 (a)(1) and (b)(2). Besides, the HEMS operators do not have any option to apply FDP requirements described in the CS. Therefore, it is not consistent nor useful to repeat it in this paragraph since it will be applied anyway. The actual writing may lead to misunderstanding. That is why, FNAM and SNEH suggest withdrawing the paragraph (1)(v) of this CS.

PROPOSAL

Withdraw the paragraph (1)(v) of this CS.

Please see the answer to comment # 54

response

comment

comment by: FNAM/SNEH

Attachments #177 #178 #179 #180

(1)(vi)

501

ISSUE

FNAM and SNEH wonder why the minimum recurrent extended recovery rest period following a reduced rest period is increased to include 4 local nights since no analysis has been made in the RIA. Besides, there is not such a requirement is for non-HEMS CAT operations.

FNAM and SNEH underline the French regulation historically proposes several rostering cycles for HEMS operations that are currently used with an excellent safety track record demonstrated by experience:

- 7 days ON / 7 days OFF with a limitation of 14 hours of duties for 24 hours
- 5 days ON / 2 days OFF with a limitation of 12 hours of duties for 24 hours
- 12 days ON / 6 days OFF with a limitation of 12 hours of duties for 24 hours

Therefore, most hospitals / HEMS organizations have a contractual engagement with the National Health Authority over a rolling 24 hours period: 12 hours of HEMS operative availability and 12 hours OFF. (Cf. attachments S1, S2, S3 and S4 illustrating the 12h operational readiness issue)

According to the Agency requirement on the pre-flight and post-flight minimum times (Cf. #486), an HEMS organization will yet roster cycles with a FDP of 12h30 and a Duty Period of 12h45 to ensure they follow their engagement with hospitals. Thus, all HEMS operators will have to schedule:

- More than 12h FDP for each and every shift
- Reduced rest of more than 10h amongst a 11h15 available time for rest according to CS.FTL.3.235 to reengage at the same time the day after under the principles of



a FRM. More than 12 hours FDP does not appear more tiring than less than 12 hours FDP: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for SNEH *i.e* 50 minutes back and forth for 1 mission in Franceⁱ).

Reduced rest does not appear over tiring, as balanced to the nature of the FDP and flight time: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for SNEH *i.e* 50 minutes back and forth for 1 mission in Franceⁱ). Moreover, such a reduced rest is used under the principles of a FRM, that shall provide all other mitigation measures as necessary.

Furthermore, no demonstration nor RIA is given to justify this value, while the current rostering in France on this subject for HEMS operations has no reported inherent safety issue through experience.

FNAM and SNEH suggest keeping the standard extended recovery rest period of 3 local nights including when reduced rest occurs, under the principles of a FRM, unless a further developed RIA and/or a scientific study justify the necessity of 4 local nights. (Cf. comment #507 et #508)

PROPOSAL

Replace the paragraph (1)(vi) by the following:

"(1)(vi) the minimum recurrent extended recovery rest period required under ORO.FTL.235(d) shall be increased to include 4 local nights or 3 local nights under the principles of a FRM."

CONSOLIDATED PROPOSAL of #496, #497, #498, #499, #500 and #501 Replace the whole CS by the following: CS FTL.3.210:

"The total duty periods to which an individual crew member may be assigned in HEMS operation shall not exceed any of the following limits:

OPTION 1:

- 1. 60 duty hours in any 7 consecutive days;
- 2. 110 duty hours in any 14 consecutive days; and
- 3. 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period.

OR

OPTION 2:



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

1. 110 duty hours in any 14 consecutive days, on the condition that: 1. the minimum recurrent extended recovery rest period required under ORO.FTL.235(d) shall be increased to include 4 local nights or 3 local nights under the principles of a FRM. 2. 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period." response Please see the answer to comment # 54 comment 534 comment by: ADAC Luftrettung gGmbH (1) 110 duty hours in 14 consecutive days (2) 190 duty hours in 28 consecutive days Question: 1.i refers to max FDP of 14 hours. What would be the limit if this 14 hour limit was extended e.g. with commanders discretion or with split duty? 1.vi refers to ORO.FTL.235(d) which is not part of the NPA documentation. It would be really helpful for interested parties to have a complete set of documents instead of a cloze with empty spaces to be filled from different other documents. This paragraph introduces a setback compared to the current regulation where a maximum annual duty time in combination with 210 duty hours in consecutive 30 days was the limit. To avoid additional personnel and the ability of managing short notice illness of crews, the 14 days limit needs to be minimum 120 hours.

Remark: It is not obvious how these limits are developed and what kind of data it is based on. Especially the 14 day/110 hour limit is too limiting and restricts the ability of crew planners to react to illness of crews on short notice.

response

Please see the answer to comment # 54

comment555comment by: Rüdiger Neua.Limit 110 Stunden Arbeitszeit innerhalb 14 aufeinanderfolgenden Tagen
b.Limit 190 Stunden Arbeitszeit innerhalb 28 aufeinanderfolgenden TagenFragestellung: Bei 1.i. bezieht man sich auf eine maximale FDP von 14 Stunden. Würde mit
dem Kommandantenentscheid oder Split duty die 14 Stunden Marke überschritten, was
wäre dann das Limit?
Bei 1.vi. bezieht man sich auf ORO.FTL.235 (d), dieser ist in den NPA Unterlagen nicht zu
finden. Man sollte einen Entwurf mit allen notwendigen Bezugsquellen veröffentlichen
und nicht mit einem Lückentext, bei dem man im Gesetzes Wust sich seine Quellen suchen
muss.



Eine deutliche Verschlechterung der bisherigen Regelung in der die Jahresarbeitszeit geregelt war und eine maximale Flugdienstzeit von 210 Stunden innerhalb von 30 Tagen. Um einen vernünftigen Dienstplan zu gewährleisten muss das 14-Tage-Limit 120h betragen, damit ein Ausfallmanagement gewährleistet werden kann.

Anmerkung: auch hier stellt sich die Frage, aufgrund welcher Datengrundlage diese Stunden festgelegt wurden. Insbesondere die 110h innerhalb von 14 Tagen sind zu knapp bemessen. Um kurzfristige Ausfälle (z.B. Krankheit) auffangen zu können, ist dieser Stundensatz auf 120h zu erhöhen.

response

Please see the answer to comment # 54

comment	676 c	comment by: Oya Vendée Hélicoptères
	ISSUE In general, and in this paragraph, it is not explicit wl	hether:
	 All the CS.FTL.3 requirements shall be applie The CS requirements should apply depending rule Cherry-picking is allowed 	
	Indeed, two options seem to be presented, one des in CS.3.210. In that way, the CS is a substitution of statute of a CS. The complexity of this proposal ma wrong application of the regulation. (Cf. comments	f the IR, which is not the aim and the ay lead to misunderstanding and thus
	Therefore, OYA suggests listing the two options in t described in the IR and one in the CS.	the CS.FTL.3.210 instead of having one
	PROPOSAL List the two options in the CS.FTL.3.210 instead of h in the CS. Cf. consolidated proposal of writing at the end of be	-
response	Please see the answer to comment # 54	
comment	677 c	comment by: Oya Vendée Hélicoptères
	(1)(i)	

ISSUE

The paragraph (1)(i) of this CS says that the maximum daily FDP does not exceed 14 hours. It is redundant with the provisions of the CS FTL.3.205 (a) Table 1 and (b) Table 2. Indeed, in these Tables, the maximum FDP is 14 hours. Besides, the HEMS operators do not have any option to apply FDP requirements described in the CS. Therefore, the reference to the

**** **** specific CS FTL.3.205(a) and (b) is not consistent, it is not useful to repeat it in this
paragraph since it will be applied anyway. The actual writing may lead to
misunderstanding. That is why, OYA suggests withdrawing the paragraph (1)(i) of this CS.PROPOSAL
Withdraw the paragraph (1)(i) of this CS.
Cf. consolidated proposal of writing at the end of below additional commentsresponsePlease see the answer to comment # 54

nent	678 comment by: Oya Vendée Hélicoptères
	Attachments <u>#181</u> <u>#182</u> <u>#183</u> <u>#184</u>
	(Cf. attachments S1, S2, S3 and S4 illustrating break issue) (1)(ii)
	ISSUE Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since flight times are unpredictable and cannot be scheduled within a FDP, the same has to be applied for breaks. Besides the wording "break" should be rethought to make it easy to
	understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour.
	<u>For Single-pilot + TCM operations</u> As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, the opportunity for a break lasting between 2h and 1h is warranted. Indeed, given the following aspects (Table 2 of this CS):
	 Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours for break with a maximum Total Flight Time with autopilot = 7 hours which means at least 5 to 7 no-flown hours Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours
	for break with a maximum Total Flight Time without autopilot = 5 hours which means at least 7 to 9 no-flown hours
	There is always a room for such a break lasting between 2h and 1h in a suitable accommodation at HEMS operating base.
	For Two-pilots operations
	As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, the opportunity for a 1h hour break is warranted. Indeed, given the following aspects (Table 1 of this CS):

- Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time with autopilot = 9 hours which means at least 3 to 5 no-flown hours
- Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time without autopilot = 7 hours which means at least 5 to 7 no-flown hours

There is always a room for such a 1h break in a suitable accommodation at HEMS operating base.

Such a break may be monitored *ex-post* by the operator SMS, under the principles of the fatigue risk management.

Therefore, under the above risk analysis and under a monitoring following the principles of a fatigue risk management, OYA suggests writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the operation.

(Cf. comments #664 and #665)

PROPOSAL

Replace this paragraph of the NPA by the following:

"(ii) The operator ensures ex-post at least one break of minimum 60 consecutive minutes within each FDP at the HEMS operating base at times that ensure likelihood of sleep. This break can be monitored ex-post by the operator SMS, under the principle of the fatigue risk management."

But in fact CS.FTL.3.210(1)(ii) is strictly the same as CS.FTL.3.205(a)(2) and CS.FTL.3(b)(2). Those provisions already apply in all cases. (Cf. comment #664 and #665)

Therefore, it is not consistent nor useful to repeat them in this paragraph since it will be applied anyway. The actual writing may lead to misunderstanding. That is why, OYA suggests withdrawing the paragraph (1)(ii) of this CS.

Withdraw the paragraph (1)(ii) of this CS.

Cf. consolidated proposal of writing at the end of below additional comments

response

Please see the answer to comment # 54

comment 679

comment by: Oya Vendée Hélicoptères

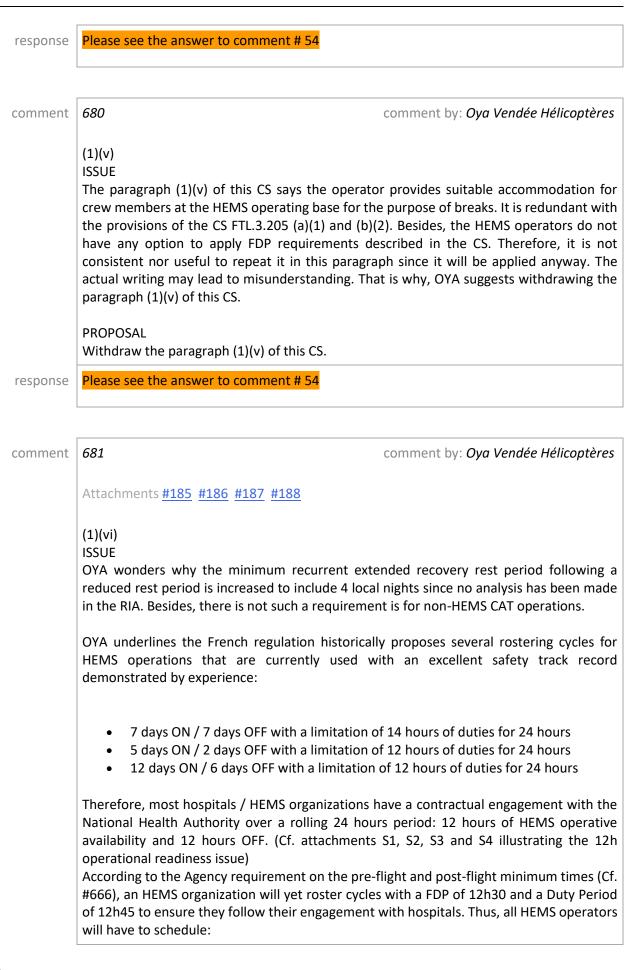
(1)(iii) and (iv)

ISSUE

(1)(iii) and (iv) The paragraph (1)(iii) and (iv) of this CS is redundant with the provisions of the CS FTL.3.205 (a)(2) and (b)(3). It is therefore not consistent nor useful to repeat these dispositions in those paragraphs since it will be applied anyway. The actual writing may lead to misunderstanding. That is why, OYA suggests withdrawing the paragraph (1)(iii) and (iv) of this CS.

PROPOSAL Withdraw the paragraph (1)(iii) and (iv) of this CS.

**** * * ***



- More than 12h FDP for each and every shift
- Reduced rest of more than 10h amongst a 11h15 available time for rest according to CS.FTL.3.235 to reengage at the same time the day after under the principles of a FRM. More than 12 hours FDP does not appear more tiring than less than 12 hours FDP: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for OYA *i.e* 50 minutes back and forth for 1 mission in France¹).

Reduced rest does not appear over tiring, as balanced to the nature of the FDP and flight time: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for OYA *i.e* 50 minutes back and forth for 1 mission in Franceⁱ). Moreover, such a reduced rest is used under the principles of a FRM, that shall provide all other mitigation measures as necessary.

Furthermore, no demonstration nor RIA is given to justify this value, while the current rostering in France on this subject for HEMS operations has no reported inherent safety issue through experience.

OYA suggests keeping the standard extended recovery rest period of 3 local nights including when reduced rest occurs, under the principles of a FRM, unless a further developed RIA and/or a scientific study justify the necessity of 4 local nights. (Cf. comment #686 et #687)

PROPOSAL

Replace the paragraph (1)(vi) by the following:

"(1)(vi) the minimum recurrent extended recovery rest period required under ORO.FTL.235(d) shall be increased to include 4 local nights or 3 local nights under the principles of a FRM."

CONSOLIDATED PROPOSAL of #676, #677, #678, #679, #680 and #681 Replace the whole CS by the following: CS FTL.3.210:

"The total duty periods to which an individual crew member may be assigned in HEMS operation shall not exceed any of the following limits:

OPTION 1:

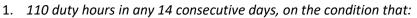
- 1. 60 duty hours in any 7 consecutive days;
- 2. 110 duty hours in any 14 consecutive days; and
- 3. 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period.

OR

OPTION 2:

**** * * ***

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.



- 1. the minimum recurrent extended recovery rest period required under ORO.FTL.235(d) shall be increased to include 4 local nights or 3 local nights under the principles of a FRM.
- 2. 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period."

response

Please see the answer to comment # 54

comment	722	comment by: ÖAMTC Helicopter Air Rescue (Austria)
	CS FLT.3.210 (1) and	(2)
	needs a 4/4 days rost the multiple of 4 tim	culated for a 5/4 roster (5 days duty / 4 days off). If an organization for it is not manageable with 110h. It requires at least 115 hours being hes 14 and additional 3h of reserve. Following this line of thoughts,) are also not the multiple 14 times 14.
response	Please see the answe	e <mark>r to comment # 54</mark>
comment	724	comment by: ÖAMTC Helicopter Air Rescue (Austria)
	CS FLT.3.210 (1) and	(2)
	[] 110 duty hours in	n any 14 consecutive days []
	4 off) are not possibl question about who Applying this to a rea and TCMs by 40%. T pilots cannot be brou	an airline but is not suitable for a HEMS operation. Rosters 4/4 (4 on / e due to traveling/positioning but 4/5 rosters (4 on / 5 off) leave the is doing the 5th days duty. I duty roster in a HEMS operation it would increase the need for pilots this human resource is not available on the market and even young aght to the required experience. At the same time the proficiency level op by the same percentage.
response	Please see the answe	er to comment # 54
comment	748	comment by: DRF-Luftrettung
	Question: 1.i refers t was	o max FDP of 14 hours. What would be the limit if this 14 hour limit

extended e.g. with commanders discretion or with split duty?



1.vi refers to ORO.FTL.235(d) which is not part of the NPA documentation. It would be really helpful for interested parties to have a complete set of documents instead of a cloze with

empty spaces to be filled from different other documents.

This paragraph introduces a setback compared to the current regulation where a maximum annual duty time in combination with 210 duty hours in consecutive 30 days was the limit. To

avoid additional personnel and the ability of managing short notice illness of crews, the 14 days

limit needs to be minimum 120 hours.

Remark: It is not obvious how these limits are developed and what kind of data it is based on.

Especially the 14 day/110 hour limit is too limiting and restricts the ability of crew planners to react

to illness of crews on short notice.

Please see the answer to comment # 54

response

comment	757 comment by: DRF-Luftrettung
	TEXT: "110 duty hours in any consecutive days"
	Problem: It is not possible to set up normal schedules(i.e. 4 days on, 4 days off) with 1400 hours FDP, because this will give you 112 hours in 14 days
	Solution: Increase the duty hours to 120 duty hours in any 14 consecutive days
response	Please see the answer to comment # 54
comment	758 comment by: DRF-Luftrettung
	TEXT: " (1) 110 duty hours; 14 hours FDP - rest period = 4 local nights"

Problem:

We do not see the reason for different rest periods; even in schedules based on 190 hours duty, it may be necessary, to give two duty periods of 4 days with 14 hours FDP shortly one after the other

Solution: Set the rest period to 3 local nights



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 413 of 585

TEXT: " (2) 190 duty hours; 14 hours FDP - rest period = 3 local nights"

response	Please see the answer to comment # 54
comment	822 comment by: Babcock Mission Critical Services Limited
	The reduction to 190 hours in 28 days restricts only a 4/4 roster. All other variations are permitted (1/1,2/2,3/3,5/5) 4/4 is an existing safe working model consisting of a block of 4 days on 4 days off, maintaining below 60 hours in 7 days. But with the problem of achieving 190 hours in 28 days.
	We request that the 190 hour limit is increased to 200 hours (as per current UK policy) to accommodate the existing safe 4/4 working model.
response	Please see the answer to comment # 54
comment	958 comment by: MBH SAMU
	ISSUE In general, and in this paragraph, it is not explicit whether:
	 All the CS.FTL.3 requirements shall be applicable "in block" The CS requirements should apply depending on what is said in the implementing rule Cherry-picking is allowed
	Indeed, two options seem to be presented, one described in ORO.FTL.210 (a) and another in CS.3.210. In that way, the CS is a substitution of the IR, which is not the aim and the statute of a CS. The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #926, #932, #933, #975, #977)
	Therefore, MBH suggests listing the two options in the CS.FTL.3.210 instead of having one described in the IR and one in the CS.
	PROPOSAL List the two options in the CS.FTL.3.210 instead of having one described in the IR and one in the CS.
	Cf. consolidated proposal of writing at the end of below additional comments
response	Please see the answer to comment # 54



comment 959

comment by: MBH SAMU

(1)(i) ISSUE

The paragraph (1)(i) of this CS says that the maximum daily FDP does not exceed 14 hours. It is redundant with the provisions of the CS FTL.3.205 (a) Table 1 and (b) Table 2. Indeed, in these Tables, the maximum FDP is 14 hours. Besides, the HEMS operators do not have any option to apply FDP requirements described in the CS. Therefore, the reference to the specific CS FTL.3.205(a) and (b) is not consistent, it is not useful to repeat it in this paragraph since it will be applied anyway. The actual writing may lead to misunderstanding. That is why, MBH suggests withdrawing the paragraph (1)(i) of this CS.

PROPOSAL

Withdraw the paragraph (1)(i) of this CS. Cf. consolidated proposal of writing at the end of below additional comments

response

Please see the answer to comment # 54

comment 960 comment by: MBH SAMU Attachments #189 #190 #191 #192 (Cf. attachments S1, S2, S3 and S4 illustrating break issue) (1)(ii)ISSUE Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since flight times are unpredictable and cannot be scheduled within a FDP, the same has to be applied for breaks. Besides the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour. For Single-pilot + TCM operations As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, the opportunity for a break lasting between 2h and 1h is warranted. Indeed, given the following aspects (Table 2 of this CS): Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours • for break with a maximum Total Flight Time with autopilot = 7 hours which means at least 5 to 7 no-flown hours Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours for break with a maximum Total Flight Time without autopilot = 5 hours which means at least 7 to 9 no-flown hours There is always a room for such a break lasting between 2h and 1h in a suitable accommodation at HEMS operating base.



For Two-pilots operations As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, the opportunity for a 1h hour break is warranted. Indeed, given the following aspects (Table 1 of this CS): Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time with autopilot = 9 hours which means at least 3 to 5 no-flown hours Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time without autopilot = 7 hours which means at least 5 to 7 no-flown hours There is always a room for such a 1h break in a suitable accommodation at HEMS operating base. Such a break may be monitored *ex-post* by the operator SMS, under the principles of the fatigue risk management. Therefore, under the above risk analysis and under a monitoring following the principles of a fatigue risk management, MBH suggests writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the operation. (Cf. comments #940 and #941) PROPOSAL Replace this paragraph of the NPA by the following: (ii) The operator ensures ex-post at least one break of minimum 60 consecutive minutes within each FDP at the HEMS operating base at times that ensure likelihood of sleep. This break can be monitored ex-post by the operator SMS, under the principle of the fatigue risk management." But in fact CS.FTL.3.210(1)(ii) is strictly the same as CS.FTL.3.205(a)(2) and CS.FTL.3(b)(2). Those provisions already apply in all cases. (Cf. comment #940 and #941) Therefore, it is not consistent nor useful to repeat them in this paragraph since it will be applied anyway. The actual writing may lead to misunderstanding. That is why, MBH suggests withdrawing the paragraph (1)(ii) of this CS. Withdraw the paragraph (1)(ii) of this CS. Cf. consolidated proposal of writing at the end of below additional comments Please see the answer to comment # 54

comment	t 962 comm	nent by: <i>MBH SAMU</i>
	 (1)(iii) and (iv) ISSUE (1)(iii) and (iv) The paragraph (1)(iii) and (iv) of this CS is redundant w the CS FTL.3.205 (a)(2) and (b)(3). It is therefore not consistent nor use 	•



response

dispositions in those paragraphs since it will be applied anyway. The actual writing may lead to misunderstanding. That is why, MBH suggests withdrawing the paragraph (1)(iii) and (iv) of this CS.

PROPOSAL Withdraw the paragraph (1)(iii) and (iv) of this CS.

response

Please see the answer to comment # 54

comment	964 comment by: MBH SAMU
	(1)(v) ISSUE The paragraph (1)(v) of this CS says the operator provides suitable accommodation for crew members at the HEMS operating base for the purpose of breaks. It is redundant with the provisions of the CS FTL.3.205 (a)(1) and (b)(2). Besides, the HEMS operators do not have any option to apply FDP requirements described in the CS. Therefore, it is not consistent nor useful to repeat it in this paragraph since it will be applied anyway. The actual writing may lead to misunderstanding. That is why, MBH suggests withdrawing the paragraph (1)(v) of this CS.
	PROPOSAL Withdraw the paragraph (1)(v) of this CS.
response	Please see the answer to comment # 54
comment	965 comment by: MBH SAMU
	Attachments <u>#193</u> <u>#194</u> <u>#195</u> <u>#196</u>
	(1)(vi) ISSUE MBH wonders why the minimum recurrent extended recovery rest period following a reduced rest period is increased to include 4 local nights since no analysis has been made in the RIA. Besides, there is not such a requirement is for non-HEMS CAT operations.
	MBH underlines the French regulation historically proposes several rostering cycles for HEMS operations that are currently used with an excellent safety track record demonstrated by experience:
	 7 days ON / 7 days OFF with a limitation of 14 hours of duties for 24 hours 5 days ON / 2 days OFF with a limitation of 12 hours of duties for 24 hours 12 days ON / 6 days OFF with a limitation of 12 hours of duties for 24 hours



Therefore, most hospitals / HEMS organizations have a contractual engagement with the National Health Authority over a rolling 24 hours period: 12 hours of HEMS operative availability and 12 hours OFF. (Cf. attachments S1, S2, S3 and S4 illustrating the 12h operational readiness issue)

According to the Agency requirement on the pre-flight and post-flight minimum times (Cf. #944), an HEMS organization will yet roster cycles with a FDP of 12h30 and a Duty Period of 12h45 to ensure they follow their engagement with hospitals. Thus, all HEMS operators will have to schedule:

- More than 12h FDP for each and every shift
- Reduced rest of more than 10h amongst a 11h15 available time for rest according to CS.FTL.3.235 to reengage at the same time the day after under the principles of a FRM. More than 12 hours FDP does not appear more tiring than less than 12 hours FDP: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for MBH *i.e* 50 minutes back and forth for 1 mission in Franceⁱ).

Reduced rest does not appear over tiring, as balanced to the nature of the FDP and flight time: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for MBH *i.e* 50 minutes back and forth for 1 mission in Franceⁱ). Moreover, such a reduced rest is used under the principles of a FRM, that shall provide all other mitigation measures as necessary.

Furthermore, no demonstration nor RIA is given to justify this value, while the current rostering in France on this subject for HEMS operations has no reported inherent safety issue through experience.

MBH suggests keeping the standard extended recovery rest period of 3 local nights including when reduced rest occurs, under the principles of a FRM, unless a further developed RIA and/or a scientific study justify the necessity of 4 local nights. (Cf. comment #971 et #973)

PROPOSAL

Replace the paragraph (1)(vi) by the following:

"(1)(vi) the minimum recurrent extended recovery rest period required under ORO.FTL.235(d) shall be increased to include 4 local nights or 3 local nights under the principles of a FRM."

CONSOLIDATED PROPOSAL of #958, #959, #960, #962, #964, and #965 Replace the whole CS by the following: CS FTL.3.210: "The total duty periods to which an individual crew member may be assigned in HEMS

OPTION 1:

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

operation shall not exceed any of the following limits:

1. 60 duty hours in any 7 consecutive days; 2. 110 duty hours in any 14 consecutive days; and 3. 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period. OR **OPTION 2:** 1. 110 duty hours in any 14 consecutive days, on the condition that: 1. the minimum recurrent extended recovery rest period required under ORO.FTL.235(d) shall be increased to include 4 local nights or 3 local nights under the principles of a FRM. 2. 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period." Please see the answer to comment # 54

response

comment	994 comment by: AESA
	Is it mandatory accomplishing with both, (1) and (2)? According the text, it seems that only
	is mandatory to accomplish with one of them.
	About point (1), what happen if not all the conditions from i to vi are accomplished? In that
	case could the pilot flight more than 110 hours in 14 consecutive days?
	Additionally, some of the conditions i to vi are included in the rules. For example, condition
	"i. the maximum daily FDP specified in CS FTL.3.205(a) or (b) does not exceed 14 hours".
	The tables specified in CS FTL.3.205(a) or (b) doesn't allow more than 14 hours in any case.
	About point (2), would be acceptable, for example, 120 duty hours in first 14 days and 70
	hours in second 14 days if it is not practicable more spreading throughout the 28 days?
response	Please see the answer to comment # 54
comment	1002 comment by: B. Wagner

Uneindeutig formuliert: müssen beide Unterpunkte (1) und (2) gleichzeitig erfüllt sein oder nur einer von beiden ("either ... or")

zu (1):



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 419 of 585

An agency of the European Union

i. was passiert bei Überschreitung der 14h durch Commanders descretion oder split duty? Eine solche Überschreitung ist gemäß der entsprechenden Artikel im vorliegenden Entwurf möglich, die Folgen sind jedoch nicht definiert.

ii. die vorgeplante Pause ist im Luftrettungsdienst nicht möglich, da weder Einsätze noch daraus resultierende Pausen im Vorhinein bekannt und planbar sind.

response

Please see the answer to comment # 54

comment	1226 comment by: SAF
	ISSUE
	In general, and in this paragraph, it is not explicit whether:
	 All the CS.FTL.3 requirements shall be applicable "in block" The CS requirements should apply depending on what is said in the implementing rule Cherry-picking is allowed
	Indeed, two options seem to be presented, one described in ORO.FTL.210 (a) and another in CS.3.210. In that way, the CS is a substitution of the IR, which is not the aim and the statute of a CS. The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #1199, #1205, #1208, #1239, #1240)
	Therefore, SAF suggests listing the two options in the CS.FTL.3.210 instead of having one described in the IR and one in the CS.
	PROPOSAL
	List the two options in the CS.FTL.3.210 instead of having one described in the IR and one in the CS.
	Cf. consolidated proposal of writing at the end of below additional comments
response	Please see the answer to comment # 54
comment	1227 comment by: SAF

(1)(i)

ISSUE

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 420 of 585

The paragraph (1)(i) of this CS says that the maximum daily FDP does not exceed 14 hours. It is redundant with the provisions of the CS FTL.3.205 (a) Table 1 and (b) Table 2. Indeed, in these Tables, the maximum FDP is 14 hours. Besides, the HEMS operators do not have any option to apply FDP requirements described in the CS. Therefore, the reference to the specific CS FTL.3.205(a) and (b) is not consistent, it is not useful to repeat it in this paragraph since it will be applied anyway. The actual writing may lead to misunderstanding. That is why, SAF suggests withdrawing the paragraph (1)(i) of this CS.

PROPOSAL

Withdraw the paragraph (1)(i) of this CS.

Please see the answer to comment # 54

Cf. consolidated proposal of writing at the end of below additional comments

response

comment	1228 comment by: SAF		
	Attachments <u>#197</u> <u>#198</u> <u>#199</u> <u>#200</u>		
	(Cf. attachments S1, S2, S3 and S4 illustrating break issue)		
	(1)(ii)		
ISSUE			
	Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS flight times are unpredictable and cannot be scheduled within a FDP, the same ha applied for breaks. Besides the wording "break" should be rethought to make it e understand that this period is a time allowed for physiological needs, which is diffrom a rest period free of all duties, of at least 1 hour.		
	For Single-pilot + TCM operations		
	As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, the opportunity for a break lasting between 2h and 1h is warranted.		
	Indeed, given the following aspects (Table 2 of this CS):		
	 Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours for break with a maximum Total Flight Time with autopilot = 7 hours which means at least 5 to 7 no-flown hours Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours for break with a maximum Total Flight Time without autopilot = 5 hours which means at least 7 to 9 no-flown hours 		

** T

There is always a room for such a break lasting between 2h and 1h in a suitable accommodation at HEMS operating base.

For Two-pilots operations

As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, the opportunity for a 1h hour break is warranted.

Indeed, given the following aspects (Table 1 of this CS):

- Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time with autopilot = 9 hours which means at least 3 to 5 no-flown hours
- Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time without autopilot = 7 hours which means at least 5 to 7 no-flown hours

There is always a room for such a 1h break in a suitable accommodation at HEMS operating base.

Such a break may be monitored *ex-post* by the operator SMS, under the principles of the fatigue risk management.

Therefore, under the above risk analysis and under a monitoring following the principles of a fatigue risk management, SAF suggests writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the operation.

(Cf. comments #1214 and #1215)

PROPOSAL

Replace this paragraph of the NPA by the following:

"(ii) The operator ensures ex-post at least one break of minimum 60 consecutive minutes within each FDP at the HEMS operating base at times that ensure likelihood of sleep. This break can be monitored ex-post by the operator SMS, under the principle of the fatigue risk management."

But in fact CS.FTL.3.210(1)(ii) is strictly the same as CS.FTL.3.205(a)(2) and CS.FTL.3(b)(2). Those provisions already apply in all cases. (Cf. comment #1214 and #1215)

Therefore, it is not consistent nor useful to repeat them in this paragraph since it will be applied anyway. The actual writing may lead to misunderstanding. That is why, SAF suggests withdrawing the paragraph (1)(ii) of this CS.

Withdraw the paragraph (1)(ii) of this CS.

Cf. consolidated proposal of writing at the end of below additional comments

Individual comments and responses - HEMS

response	Please see the answer to comment # 54	

comment	1229 comment by: SAF	
	(1)(iii) and (iv)	
ISSUE		
	(1)(iii) and (iv) The paragraph (1)(iii) and (iv) of this CS is redundant with the provisio the CS FTL.3.205 (a)(2) and (b)(3). It is therefore not consistent nor useful to repeat t dispositions in those paragraphs since it will be applied anyway. The actual writing lead to misunderstanding. That is why, SAF suggests withdrawing the paragraph (1)(iii (iv) of this CS.	
	PROPOSAL Withdraw the paragraph (1)(iii) and (iv) of this CS.	
response	Please see the answer to comment # 54	

comment	1230 comment by: SAF
	(1)(v)
	ISSUE
	The paragraph (1)(v) of this CS says the operator provides suitable accommodation for crew members at the HEMS operating base for the purpose of breaks. It is redundant with the provisions of the CS FTL.3.205 (a)(1) and (b)(2). Besides, the HEMS operators do not have any option to apply FDP requirements described in the CS. Therefore, it is not consistent nor useful to repeat it in this paragraph since it will be applied anyway. The actual writing may lead to misunderstanding. That is why, SAF suggests withdrawing the paragraph (1)(v) of this CS.
	Withdraw the paragraph (1)(v) of this CS.
response	Please see the answer to comment # 54
comment	1231 comment by: SAF

Attachments <u>#201</u> <u>#202</u> <u>#203</u> <u>#204</u>

**** * * ***

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.Page 423 of 585

(1)(vi)

ISSUE

SAF wonders why the minimum recurrent extended recovery rest period following a reduced rest period is increased to include 4 local nights since no analysis has been made in the RIA. Besides, there is not such a requirement is for non-HEMS CAT operations.

SAF underlines the French regulation historically proposes several rostering cycles for HEMS operations that are currently used with an excellent safety track record demonstrated by experience:

- 7 days ON / 7 days OFF with a limitation of 14 hours of duties for 24 hours
- 5 days ON / 2 days OFF with a limitation of 12 hours of duties for 24 hours
- 12 days ON / 6 days OFF with a limitation of 12 hours of duties for 24 hours

Therefore, most hospitals / HEMS organizations have a contractual engagement with the National Health Authority over a rolling 24 hours period: 12 hours of HEMS operative availability and 12 hours OFF. (Cf. attachments S1, S2, S3 and S4 illustrating the 12h operational readiness issue)

According to the Agency requirement on the pre-flight and post-flight minimum times (Cf. #1216), an HEMS organization will yet roster cycles with a FDP of 12h30 and a Duty Period of 12h45 to ensure they follow their engagement with hospitals. Thus, all HEMS operators will have to schedule:

- More than 12h FDP for each and every shift
- Reduced rest of more than 10h amongst a 11h15 available time for rest according to CS.FTL.3.235 to reengage at the same time the day after under the principles of a FRM. More than 12 hours FDP does not appear more tiring than less than 12 hours FDP: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for SAF *i.e* 50 minutes back and forth for 1 mission in Franceⁱ).

Reduced rest does not appear over tiring, as balanced to the nature of the FDP and flight time: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for SAF *i.e* 50 minutes back and forth for 1 mission in Franceⁱ).

Moreover, such a reduced rest is used under the principles of a FRM, that shall provide all other mitigation measures as necessary.

**** * * * * * * Furthermore, no demonstration nor RIA is given to justify this value, while the current rostering in France on this subject for HEMS operations has no reported inherent safety issue through experience.

SAF suggests keeping the standard extended recovery rest period of 3 local nights including when reduced rest occurs, under the principles of a FRM, unless a further developed RIA and/or a scientific study justify the necessity of 4 local nights.

(Cf. comment #1236 et #1237)

PROPOSAL

Replace the paragraph (1)(vi) by the following:

"(1)(vi) the minimum recurrent extended recovery rest period required under ORO.FTL.235(d) shall be increased to include 4 local nights or 3 local nights under the principles of a FRM."

CONSOLIDATED PROPOSAL of #1226, #1227, #1228, #1229, #1230 and #1231

Replace the whole CS by the following:

CS FTL.3.210:

"The total duty periods to which an individual crew member may be assigned in HEMS operation shall not exceed any of the following limits:

OPTION 1:

- 1. 60 duty hours in any 7 consecutive days;
- 2. 110 duty hours in any 14 consecutive days; and
- 3. 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period.

OR

OPTION 2:

- 1. 110 duty hours in any 14 consecutive days, on the condition that:
 - 1. the minimum recurrent extended recovery rest period required under ORO.FTL.235(d) shall be increased to include 4 local nights or 3 local nights under the principles of a FRM.
- 2. 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period."

response

Please see the answer to comment # 54

**** * * *** comment 1278 comment by: Hélicoptères de France #1 ISSUE In general, and in this paragraph, it is not explicit whether: All the CS.FTL.3 requirements shall be applicable "in block" • The CS requirements should apply depending on what is said in the implementing rule Cherry-picking is allowed Indeed, two options seem to be presented, one described in ORO.FTL.210 (a) and another in CS.3.210. In that way, the CS is a substitution of the IR, which is not the aim and the statute of a CS. The complexity of this proposal may lead to misunderstanding and thus wrong application of the regulation. (Cf. comments #18.1, #24, #25, #39, #40) Therefore, HDF suggests listing the two options in the CS.FTL.3.210 instead of having one described in the IR and one in the CS. PROPOSAL List the two options in the CS.FTL.3.210 instead of having one described in the IR and one in the CS. Cf. consolidated proposal of writing at the end of below additional comments #2 (1)(i)ISSUE The paragraph (1)(i) of this CS says that the maximum daily FDP does not exceed 14 hours. It is redundant with the provisions of the CS FTL.3.205 (a) Table 1 and (b) Table 2. Indeed, in these Tables, the maximum FDP is 14 hours. Besides, the HEMS operators do not have any option to apply FDP requirements described in the CS. Therefore, the reference to the specific CS FTL.3.205(a) and (b) is not consistent, it is not useful to repeat it in this paragraph since it will be applied anyway. The actual writing may lead to misunderstanding. That is why, HDF suggests withdrawing the paragraph (1)(i) of this CS. PROPOSAL Withdraw the paragraph (1)(i) of this CS. Cf. consolidated proposal of writing at the end of below additional comments #3 (Cf. attachments S1, S2, S3 and S4 illustrating break issue) (1)(ii)ISSUE Flight times in HEMS are unpredictable inside a given FDP, by definition of HEMS. Since flight times are unpredictable and cannot be scheduled within a FDP, the same has to be applied for breaks. Besides



the wording "break" should be rethought to make it easy to understand that this period is a time allowed for physiological needs, which is different from a rest period free of all duties, of at least 1 hour. For Single-pilot + TCM operations As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, the opportunity for a break lasting between 2h and 1h is warranted. Indeed, given the following aspects (Table 2 of this CS): Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours for break with a maximum Total Flight Time with autopilot = 7 hours which means at least 5 to 7 no-flown hours • Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 10 hours for break with a maximum Total Flight Time without autopilot = 5 hours which means at least 7 to 9 noflown hours There is always a room for such a break lasting between 2h and 1h in a suitable accommodation at HEMS operating base. For Two-pilots operations As a mitigation, it is obvious that due to the very low average reported flight time in HEMS, the opportunity for a 1h hour break is warranted. Indeed, given the following aspects (Table 1 of this CS): • Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time with autopilot = 9 hours which means at least 3 to 5 no-flown hours Maximum FDP = Ranged between 14 hours and 12 hours and threshold at 12 hours for break with a maximum Total Flight Time without autopilot = 7 hours which means at least 5 to 7 noflown hours There is always a room for such a 1h break in a suitable accommodation at HEMS operating base. Such a break may be monitored ex-post by the operator SMS, under the principles of the fatigue risk management. Therefore, under the above risk analysis and under a monitoring following the principles of a fatigue risk management, HDF suggests writing clearly in the regulation that in HEMS, breaks do not have to be scheduled before the operation. (Cf. comments #28.4.1 and #28.4.2)

PROPOSAL



Replace this paragraph of the NPA by the following: "(ii) The operator ensures ex-post at least one break of minimum 60 consecutive minutes within each FDP at the HEMS operating base at times that ensure likelihood of sleep. This break can be monitored ex-post by the operator SMS, under the principle of the fatigue risk management." But in fact CS.FTL.3.210(1)(ii) is strictly the same as CS.FTL.3.205(a)(2) and CS.FTL.3(b)(2). Those provisions already apply in all cases. (Cf. comment #28.4.1 and #28.4.2) Therefore, it is not consistent nor useful to repeat them in this paragraph since it will be applied anyway. The actual writing may lead to misunderstanding. That is why, HDF suggests withdrawing the paragraph (1)(ii) of this CS. Withdraw the paragraph (1)(ii) of this CS. Cf. consolidated proposal of writing at the end of below additional comments #4 (1)(iii) and (iv) The paragraph (1)(v) of this CS says the operator provides suitable accommodation for crew members at the HEMS operating base for the purpose of breaks. It is redundant with the provisions of the CS FTL.3.205 (a)(1) and (b)(2). Besides, the HEMS operators do not have any option to apply FDP requirements described in the CS. Therefore, it is not consistent nor useful to repeat it in this paragraph since it will be applied anyway. The actual writing may lead to misunderstanding. That is why, HDF suggests withdrawing the paragraph (1)(v) of this CS. PROPOSAL Withdraw the paragraph (1)(v) of this CS. #6 (1)(vi) ISSUE HDF wonders why the minimum recurrent extended recovery rest period following a reduced rest period is increased to include 4 local nights since no analysis has been made in the RIA. Besides, there is not such a requirement is for non-HEMS CAT operations. HDF underlines the French regulation historically proposes several rostering cycles for HEMS operations that are currently used with an excellent safety track record demonstrated by experience: 7 days ON / 7 days OFF with a limitation of 14 hours of duties for 24 hours 5 days ON / 2 days OFF with a limitation of 12 hours of duties for 24 hours 12 days ON / 6 days OFF with a limitation of 12 hours of duties for 24 hours Therefore, most hospitals / HEMS organizations have a contractual engagement with the National

Health Authority over a rolling 24 hours period: 12 hours of HEMS operative availability and 12 hours

**** * * **** OFF. (Cf. attachments S1, S2, S3 and S4 illustrating the 12h operational readiness issue) According to the Agency requirement on the pre-flight and post-flight minimum times (Cf. #28.5), an

HEMS organization will yet roster cycles with a FDP of 12h30 and a Duty Period of 12h45 to ensure they

follow their engagement with hospitals. Thus, all HEMS operators will have to schedule: • More than 12h FDP for each and every shift

• Reduced rest of more than 10h amongst a 11h15 available time for rest according to CS.FTL.3.235 to reengage at the same time the day after under the principles of a FRM. More

than 12 hours FDP does not appear more tiring than less than 12 hours FDP: they are spent in

ISSUE

(1)(iii) and (iv) The paragraph (1)(iii) and (iv) of this CS is redundant with the provisions of the CS

FTL.3.205 (a)(2) and (b)(3). It is therefore not consistent nor useful to repeat these dispositions in those

paragraphs since it will be applied anyway. The actual writing may lead to misunderstanding. That is

why, HDF suggests withdrawing the paragraph (1)(iii) and (iv) of this CS.

PROPOSAL

Withdraw the paragraph (1)(iii) and (iv) of this CS.

#5

(1)(v)

ISSUE

The paragraph (1)(v) of this CS says the operator provides suitable accommodation for crew members

at the HEMS operating base for the purpose of breaks. It is redundant with the provisions of the CS

FTL.3.205 (a)(1) and (b)(2). Besides, the HEMS operators do not have any option to apply FDP

requirements described in the CS. Therefore, it is not consistent nor useful to repeat it in this paragraph

since it will be applied anyway. The actual writing may lead to misunderstanding. That is why, HDF suggests withdrawing the paragraph HDF underlines the French regulation historically proposes several rostering cycles for

HEMS operations that are currently used with an excellent safety track record demonstrated by

experience:

• 7 days ON / 7 days OFF with a limitation of 14 hours of duties for 24 hours

• 5 days ON / 2 days OFF with a limitation of 12 hours of duties for 24 hours

• 12 days ON / 6 days OFF with a limitation of 12 hours of duties for 24 hours

Therefore, most hospitals / HEMS organizations have a contractual engagement with the National

Health Authority over a rolling 24 hours period: 12 hours of HEMS operative availability and 12 hours

OFF. (Cf. attachments S1, S2, S3 and S4 illustrating the 12h operational readiness issue)



According to the Agency requirement on the pre-flight and post-flight minimum times (Cf. #28.5), an HEMS organization will yet roster cycles with a FDP of 12h30 and a Duty Period of 12h45 to ensure they follow their engagement with hospitals. Thus, all HEMS operators will have to schedule: More than 12h FDP for each and every shift • Reduced rest of more than 10h amongst a 11h15 available time for rest according to CS.FTL.3.235 to reengage at the same time the day after under the principles of a FRM. More than 12 hours FDP does not appear more tiring than less than 12 hours FDP: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are verv low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for SNEH i.e 50 minutes back and forth for 1 mission in Francei). Reduced rest does not appear over tiring, as balanced to the nature of the FDP and flight time: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for SNEH i.e 50 minutes back and forth for 1 mission in Francei). Moreover, such a reduced rest is used under the principles of a FRM, that shall provide all other mitigation measures as necessary. Furthermore, no demonstration nor RIA is given to justify this value, while the current rostering in France on this subject for HEMS operations has no reported inherent safety issue through experience. HDF suggests keeping the standard extended recovery rest period of 3 local nights including when reduced rest occurs, under the principles of a FRM, unless a further developed RIA and/or a scientific study justify the necessity of 4 local nights. (Cf. comment #36.1 et #36.2) PROPOSAL Replace the paragraph (1)(vi) by the following: "(1)(vi) the minimum recurrent extended recovery rest period required under ORO.FTL.235(d) shall be

increased to include 4 local nights or 3 local nights under the principles of a FRM."

CONSOLIDATED PROPOSAL of #1, #2, #3, #4, #5 and #6

Replace the whole CS by the following:

CS FTL.3.210:

"The total duty periods to which an individual crew member may be assigned in HEMS operation shall

not exceed any of the following limits:

OPTION 1:

60 duty hours in any 7 consecutive days;



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. (2) 110 duty hours in any 14 consecutive days; and NPA 2017-17 | HEMS Comments | FNAM & SNEH 41/57
(3) 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period. OR
OPTION 2:
(1) 110 duty hours in any 14 consecutive days, on the condition that:
ii. the minimum recurrent extended recovery rest period required under ORO.FTL.235(d) shall be increased to include 4 local nights or 3 local nights under the principles of a FRM.
(2) 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period."

response

Please see the answer to comment # 54

comment 1307 comment by: Elilombarda CS FTL.3.210 Flight times and duty periods — HEMS See comment to CS FTL.3.205 Flight duty period (FDP) — HEMS for rationale. If the operator elects to plan rosters of 10/10 and up to 14/14, provided that an equal number of subsequent days of extended rest period is assigned to the crew, the point (a) cannot be applicable. Maximum duty time in 28 consecutive days, as in point (b), shall remain. The concept of prolonged duty periods followed by equal number of rest days period is not compatible with the sentence "spread as evenly as practicable throughout that period". Suggested NPA amendment CS FTL.3.210 Flight times and duty periods — HEMS Duty periods in HEMS operations under ORO.FTL.210(b) The total duty periods to which an individual crew member in HEMS operations may be assigned under ORO.FTL.210(b) does not exceed either of the following limits: 110 duty hours in any 14 consecutive days, on the condition that: the maximum daily FDP specified in CS FTL.3.205(a) or (b) does not exceed 14 hours; the operator ensures at least one break of minimum 60 consecutive minutes within each FDP at the HEMS operating base at times that ensure likelihood of sleep; for each FDP of more than 12 hours, the total break time constitutes 50 % of the time above 12 hours; the time for breaks excludes the necessary time for post- and pre-flight duties;



the operator provides suitable accommodation for crew members at the HEMS operating base for the purpose of breaks;

the minimum recurrent extended recovery rest period required under ORO.FTL.235(d) shall be increased to include 4 local nights.

190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period.

(3) in case of a block of more than 10 consecutive FDP, followed by an equal number of days of extended recovery rest period, point (a) is not applicable.

response

Please see the answer to comment # 54

comment	1324 comment by: SAS
	The English used in this paragraph does not appear to be correct. By saying 'does not exceed either' it is stating that you must comply with both of them (and therefore, in part (1)ii) stating that every HEMS shift must have a break of minimum 60 minutes, regardless of the length of FDP). We believe the intention of the paragraph is to ensure that duty periods <i>comply</i> with either of the limits; (1) must not exceed 110 duty hours (2) must not exceed 190 duty hours
response	Please see the answer to comment # 54

comment	1341	comment by: European Cockpit Association	
	in the case of unforeseen the reporting time, or at the comment:	the limits on flight duty, duty and rest periods by the commander circumstances in HEMS flight operations which occur at or after the end of the FDP, comply with the following: roach; this is a major achievement/improvement against fatigue	
response	Please see the answer to comment # 54		
comment	1346	comment by: European Cockpit Association	
	Commented text:		

CS FTL.3.210 Flight times and duty periods — HEMS

**** * * ***

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.Page 432 of 585

(1) 110 duty hours in any 14 consecutive days, on the condition that:

ECA Comment: This limit is not useful for the majority of HEMS operations in Europe, we suggest this to be GM

response

Please see the answer to comment # 54

comment	1347	comment by: European Cockpit Association
	Commented text: <i>i. the maximum daily FDP specified</i>	in CS FTL.3.205(a) or (b) does not exceed 14 hours;
	facilities; it is against the logic, that	is more relaxant than in flight rest, even in class 1 with in-flight-rest, the FDP can be extended to 16 ufficient breaks in suitable accomodation are
response	Please see the answer to comment	: # 54

comment	1348 comn	nent by: European Cockpit Association
	Commented text: <i>ii. the operator ensures at least one break of minimu</i> <i>FDP at the HEMS operating base at times that ensur</i>	
	ECA Comment: The break time to be used for extension, can consist used to extend duty/FDP has to be longer than one not assure required rest and recreation.	
response	Please see the answer to comment # 54	
comment	1349 comn	nent by: European Cockpit Association
	Commented text: iii. for each FDP of more than 12 hours, the total bre above 12 hours;	eak time constitutes 50 % of the time
	ECA Comment: We believe that, a 10 hour (single pilot) an a 12 hou	ır (dual pilot) operation per day is safe

We believe that, a 10 hour (single pilot) an a 12 hour (dual pilot) operation per day is safe from the fatigue perspective - as long as sufficient break times are available, this time can be prolonged, by the amount of break time (>than 1 hour breaks) - we suggest a clearer, easier approach: Max. FDP is (up to - depending on reporting time) 10 hours single Pilot

**** ****

	and 12 hours dual pilot. The FDP can be extended by the amount of break times of more than one hour breaks up to 16 hours (corresponding to in-flight-rest limit)		
response	Please see the answer to comment # 54		
comment	1350	comment by: European Cockpit Association	
	Commented text: <i>iv. the time for breaks excludes the necessary</i>	time for post- and pre-flight duties;	
	ECA Comment: absolute condition for above		
response	Please see the answer to comment # 54		
comment	1351	comment by: European Cockpit Association	
	Commented text: v. the operator provides suitable accommodat base for the purpose of breaks	tion for crew members at the HEMS operating	
	ECA Comment: absolute condition for above		
response	Please see the answer to comment # 54		
comment	1352	comment by: European Cockpit Association	
	Commented text; vi. the minimum recurrent extended recover; shall be increased to include 4 local nights.	v rest period required under ORO.FTL.235(d)	
	ECA Comment: not supported		
response	Please see the answer to comment # 54		
	1		
comment	1353	comment by: European Cockpit Association	

Commented text: (2) 190 duty hours in any 28 consecutive days, spread as evenly as practicable throughout that period.



Plea

ECA Comment.	ECA Comment:	
--------------	--------------	--

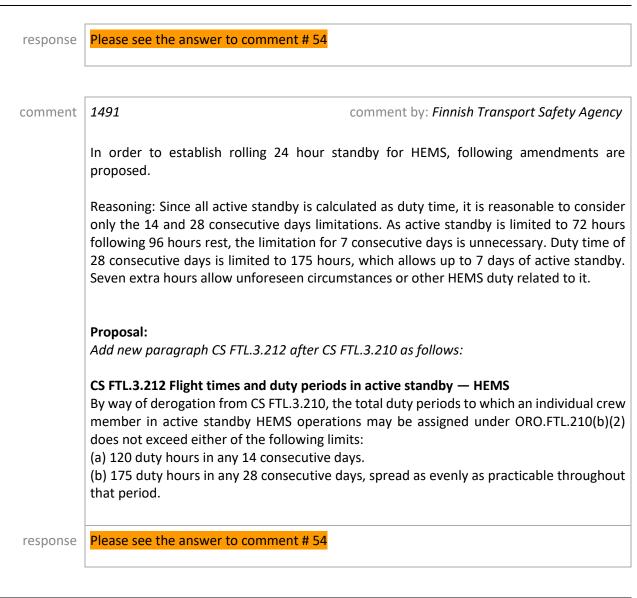
It is necessary to take this number into the IR.

response

se	see	the	answer	to	comment # 54	

comment	1397 comment by: Swiss Air-Ambulance Rega
	a. Limit 110 duty hours in any 14 consecutive days b. Limit 190 duty hours in any 28 consecutive days Question: Para. 1.i. refers to a maximum FDP of 14 hours. If the 14-hour mark was exceeded at the commander's discretion or through split duty, what would be the limit then?
	Para. 1.vi. refers to ORO.FTL.235 (d), which is not found in the NPA documents. A draft with all the necessary reference sources should be published, not a text full of gaps, which leaves you to search for sources in the regulatory mess.
	A clear worsening of the previous regulation that established the annual working hours and a maximum flight duty period of 210 hours within 30 days.
	To ensure a reasonable duty plan, the 14-day limit must amount to 120 hours, so that absences can be managed reliably. Please note: here too, the question is raised as to what data these hours are based on. In particular, 110 hours within 14 days are assessed as too few. To be able to compensate for last-minute absences (e.g. illness), this must be increased to 120 hours.
	Apparently this is calculated ONLY for a 5-days ON/ 5-days OFF roster with 12 hour FDPs. If an organization needs a 4-days ON/4-days OFF roster with up to 14 hour FDPs it is not manageable with 110 hours in 14 days! It would require at least 115 hours in 14 days being the multiple of 4 times 14 and additional 3h of reserve. Following this line of thoughts, 190 hours in paragraph (2) is also not the multiple 14 times 14 and should be raised to 200 hours.
	An evaluation of third party damages of over 36.000 missions (108.000 flights) in the period of 2016 and 2017 concluded two peaks, one on Thursday which represents the starting day in our duty roster and one Saturday. Interestingly enough shows Wednesday (the last day of the 7 days roster) the lowest risk for damages. This correlates with a study made by employer's mutual insurance associations in Germany and Switzerland (SUVA and BGW) which prove a high peak on the first day of duty. This NPA's duty roster would almost double this count!
response	Please see the answer to comment # 54
comment	1458 comment by: Association of Air Ambulances

First paragraph should be amended to read: "...ORO.FTL.210(b) is not to exceed the following limits:"



CS FTL.3.220

p. 37

comment 177

comment by: Marc Rothenhäusler

Anstatt Spilt Duty einzuführen, wäre eine Möglichkeit Hems folgendermaßen zu gestallten. Pausen größer 1h auf der Station unterbrechen die Flugdienstzeit.

Maximale Dienstzeit beträgt 15:30h mit entsprechenden Pausen.

Flugdienstzeit 10h darf jedoch wie bisher auch auf 12h "Kommandantenentscheid" ausgeweitet werden zur Versorgung von Patienten.

Die Anzahl der Tage einer Dienstperiode im Sommer (Dienstzeit größer 14h) auf 3 Tage in Folge zu verkürzen mit 24h Ruhezeit vor der Dienstperiode und 48h Ruhezeit nach einer Periode.

Eine Einschränkung der Dienstzeit sowie Flugdienstzeit würde zu einem Schichtdienst im Sommer führen, der vor allem für die Bestzungen ein größerer Stress wäre und mehr

**** * * *** Arbeitstage mit sich ziehen würde wie Ruhezeiten und freie Tage. Viele Kollegen wohnen nicht stationsnah sondern pendeln. Viele ca 70% haben Anfahrtswege von über einer Stunde was bedeutet, dass man weniger Freizeit und Ruhezeit hat. Sowie ist es ein enormer Einschnitt in die Work-life-Balance von uns Piloten.

Ein Schichtbetrieb wird zu einer Ausweitung der Einsatzzeit führen, was bedeutet dass morgens um 5 Einsatzbereitschaft gewährleistet werden muss. Was bedeutet, dass selbst Piloten die in der Nähe der Station um 3 Uhr aufstehen müssen um pünktlich den Frühdienst aufnehmen zu können. Gegen 14:30Uhr endet dann der Dienst. Der Spätdienst übernimmt gegen 14:30 Uhr und endet um 23 Uhr. Der Biorythmus wird dadurch völlig verschoben. Die Anzahl der Diensttage wird enorm zunehmen, was die Lebensqualität herabsetzt.

response

Please see the answer to comment # 54

comment 186 comment by: ANSMUH This concept is difficult to understand in France. The pilot is assigned in his/her operating base for a standby (H12, or H14), and must be available for each mission. If this concept of split duty is validated it will have a strong impact on the HEMS business in France, without gain of security (No accident since 1987 in France), and with a strong economic impact for the operators and hospitals. This concept is still modeled on the practices of aircraft. It is not usable in HEMS. **Proposal:** CS FTL.3.220 Split duty -HEMS The following applies in the case of split duty with one or more breaks on the ground in HEMS operations: (a) A break on the ground at the HEMS operating base is at least 60 consecutive minutes, if taken in a suitable accommodation, or at least 2 consecutive hours, if taken in accommodation. (b) If not taken at the HEMS operating base, the break on the ground has a minimum duration of 3 consecutive hours. (c) For any break of 6 hours or more or for a break that encroaches the window of circadian low (WOCL), suitable accommodation is provided; (d) Time allowed for post- and pre-flight duties and travelling is excluded from each break; the minimum total time for post- and pre-flight duties and travelling is 30 minutes or 15 minutes if at a HEMS operating base; the operator shall specify the actual times in its operations manual; (e) An operator may extend the basic maximum daily FDP specified in CS FTL.3.205 by up to 50 % of the combined duration of all breaks on the ground, with the exception of the time exceeding 6 hours or encroaching the WOCL if spent in other than suitable accommodation. Please see the answer to comment # 54 response

**** * * ***

comment	234 comment by: Federal Office of Civil Aviation (FOCA), Switzerland
	<i>Comment FOCA</i> : (b)a suitable accommodation has to be available.
response	Please see the answer to comment # 54
comment	256 comment by: European Helicopter Association (EHA)
	ADAC (Germany), DRF (Germany) and LAR (Luxembourg): (a) and (b)
	Breaks can be taken into account for split duty, when they are of the following length: >60 minutes
	when taken at home base, >2 hours in a place with accommodation or >3 hours in other places.
	(e) May EDD can be automoded by EQ % of the dynation of the breaks
	Max FDP can be extended by 50 % of the duration of the breaks. Question: Is this contradicting the max FDP of 14 hours as defined in above paragraphs?
	Remark: possible extensions by using split duty are well meant but not practicable.
	Calculation of
	possible FDP is complex due to all available options and must be made during the day on
	base
	taking into account all breaks of that day. Breaks can't be planned in advance when the HEMS
	base is part of the national rescue system where availability times are defined and need
	to be
	covered by the base.
	To simplify this paragraph, we suggest to cancel the calculation of breaks and allow to
	stop
	counting FDP when breaks are longer than 60 minutes.
	Proposal text:
	CS FTL 3.220 Interruption FDP
	a. For HEMS operations only breaks of more than 60 minutes at the home base count as
	break. These breaks will interrupt FDP. b. Max FDP according table 1 and 2 remain valid
	c. Max duty time per day is limited to 16 h
	For example: Report for duty 06:30, max FDP 12:30h, three times break of 1 hour each,
	15:30 h HEMS availability.
response	Please see the answer to comment # 54
comment	344 comment by: European Helicopter Association (EHA)

comment by: European Helicopter Association (EHA)

FNAM (France)



#1 (d) MINIMUM TIME FOR DUTIES PERFORMED BY THE PILOTS BEFORE AND AFTER FLIGHTS AND TRAVELLING TIME (d) ISSUE The FNAM agrees a minimum time shall be taken to ensure the safety of the flight: Before the 1st flight of the crew, by preparing the aircraft, and • After each flight, by reporting flight and aircraft information. Due to the life-threatening emergency operation in HEMS, these times shall be as short as possible to maximize operational availability and response time. In that way, in France, the contractual time for the National Health Authorities between the launch of an HEMS flight and the effective take-off is 7 minutes. Indeed, when a patient needs essential life-saving measures, after 30 minutes, there are almost no chance to save the life of the patient. Thus, the first patient of a FDP will have no chance of survival due to the EASA proposition of having a minimum time for duties performed by the pilots after and before flights and travelling of 30 minutes. Moreover, French numbers underlines that 7% i of the HEMS take-off preformed within the first 30 minutes of the FDP. Whatever the number of life that would not have been saved during these 30 minutes, no loss would be politically and socially acceptable. To align the values with the initial preflight time and proportionate pre-flight time before any take-off from the HEMS operating base proposed in FNAM's comment #28.5, the FNAM suggests reducing this 30 minutes value to a 15 minutes period to take into account the time for duties performed by the pilots after and before flights and travelling time if not at the HEMS operating base. This reduction from 30 minutes to this current value of 15 minutes for duties performed by the pilots after and before flights and travelling will not impact the level of safety, otherwise a sound **RIA** based on experience and safety records on this subject would be appreciated. Moreover, due to multiple flight times inside a unique FDP, the FNAM underlines that the definition of post flight duty is non-consistent with the usual definition of post-flight: Which starts at the end (of the last FT) of the FDP Assuming the FDP ends with the last FT Though for HEMS operations FT are unpredictable and scheduled FDP may end long after the last effective FT For French HEMS services, the suitable accommodation is nearby the helicopter, hence, there is no need for traveling time.



With the same philosophy, the proposed requirement of having a minimum time for duties performed by the pilots after and before flights of 15 minutes at the HEMS operating base will reduce the chance of survival by 8 minutes for the next patient in case of close consecutive missions. According to French experiences, the effective time for preparing a new flight is 7 minutes. This reduction from 15 minutes to this current value of 7 minutes for duties performed by the pilots after and before flights at the HEMS operating base will not impact the level of safety, otherwise a sound RIA based on experience and safety records on this subject would be appreciated. On the other hand, the FNAM agrees these requirements do not apply for the Technical Crew Member since TCM function does not include the flight preparation. (Cf. comment #44) Besides, for HEMS operations, the definition implicitly given (but never written) to postflight seems not to be in accordance with the usual acceptance of a post-flight as given in the IR for the CAT operations other than HEMS: post-flight is a time after the last FT of a FDP, outside the FDP. CS.FTL.3.205(a)(3) and (b)(4) only defines "post-flight" when returning to the HEMS operating base. Therefore, the FNAM suggests suppressing the post flight duties as written and to refer to the definition stated in the proposal of comment #28.5 to CS.FTL.3.205(a)(3) and (b)(4). (Cf. comment #28.5) PROPOSAL Replace the paragraph (d) by the following: "(d) Time allowed for the duties performed by the pilots after and before flights and travelling is excluded from each break; such a minimum total time for the pilots is 15 minutes or 7 minutes at a HEMS operating base; the operator shall specify the actual times in its operations manual; a shorter time may be specified for the TCM, but not less than the actual travelling time;" Please see the answer to comment # 54 428 comment by: UFH French Helicopters Association

#1 (d) MINIMUM TIME FOR DUTIES PERFORMED BY THE PILOTS BEFORE AND AFTER FLIGHTS AND TRAVELLING TIME

ISSUE UFH agrees a minimum time shall be taken to ensure the safety of the flight: • Before the 1st flight of the crew, by preparing the aircraft, and



response

comment

 After each flight, by reporting flight and aircraft information Due to the life-threatening emergency operation in HEMS, these times shall be as short as possible to maximize operational availability and response time. In that way, in France, the contractual time for the National Health Authorities between the launch of a HEMS flight and the effective take-off is 7 minutes. Indeed, when a patient needs essential life-saving measures, after 30 minutes, there are almost no chance to save the life of the patient. Thus, the first patient of a FDP will have no chance of survival due to EASA proposition of having a minimum time for duties performed by the pilots after and before flights and travelling of 30 minutes. Moreover, French numbers underlines that 7% i of the HEMS take-off preformed within the first 30 minutes of the FDP. (Cf. SNEH illustrative Table in attachment) Whatever the number of life that would not have been saved during these 30 minutes, no loss would be politically and socially acceptable. To align the values with the initial preflight time and proportionate pre-flight time before any take-off from the HEMS operating base proposed in our comment #28.5, we suggest reducing this 30 minutes value to a 15 minutes period to take into account the time for duties performed by the pilots after and before flights and travelling time if not at the HEMS operating base. This reduction from 30 minutes to this current value of 15 minutes for duties performed by the pilots after and before flights and travelling will not impact the level of safety, otherwise it would be beneficial to further develop the RIA basing it on experience and safety records on this subject. Besides, this proposal does not affect the cammander's prerogatives since he remains the one to make the final decision regarding the take-off time. Moreover, due to multiple flight times inside a unique FDP, we underline that the definition of post flight duty is non-consistent with the usual definition of post-flight: • Which starts at the end (of the last FT) of the FDP Assuming the FDP ends with the last FT Though for HEMS operations FT are unpredictable and scheduled FDP may end long after the last effective FT For French HEMS services, the suitable accommodation is nearby the helicopter, hence, there is no need for traveling time. With the same philosophy, the proposed requirement of having a minimum time for duties performed by the pilots after and before flights of 15 minutes at the HEMS operating base will reduce the chance

**** * * *** of survival by 8 minutes for the next patient in case of close consecutive missions. According to French experience, the effective time for preparing a new flight is 7 minutes. This reduction from 15 minutes to this current value of 7 minutes for duties performed by the pilots

after and before flights at the HEMS operating base will not impact the level of safety, otherwise it

would be beneficial to further develop the RIA basing it on experience and safety records on this

subject.

(Cf. attachments S2 and S3 illustrating this issue of 15 min inoperative readiness) On the other hand, we agree these requirements do not apply for the Technical Crew Member

since TCM function does not include the flight preparation.

(Cf. comment #44)

Besides, for HEMS operations, the definition implicitly given (but never written) to postflight seems

not to be in accordance with the usual acceptance of a post-flight as given in the IR for the CAT

operations other than HEMS: post-flight is a time after the last FT of a FDP, outside of the FDP.

response

Please see the answer to comment # 54

comment	502	comment by: FNAM/SNEH
	Attachments <u>#205</u> <u>#206</u> <u>#207</u> <u>#208</u> <u>#209</u>	
	(d) MINIMUM TIME FOR DUTIES PERFORMED BY TI FLIGHTS AND TRAVELLING TIME	HE PILOTS BEFORE AND AFTER
	(Cf. attachments S1, S2, S3 and S4 illustrating pre and po (d)	st flight issues)
	ISSUE FNAM and SNEH agree a minimum time shall be taken to	o ensure the safety of the flight:
	 Before the 1st flight of the crew, by preparing the After each flight, by reporting flight and aircraft in 	
	Due to the life-threatening emergency operation in HEM possible to maximize operational availability and response contractual time for the National Health Authorities betwand the effective take-off is 7 minutes. Indeed, when a preasures, after 30 minutes, there are almost no chance Thus, the first patient of a FDP will have no chance of su having a minimum time forduties performed by the pitravelling of 30 minutes.	se time. In that way, in France, the ween the launch of a HEMS flight patient needs essential life-saving se to save the life of the patient. arvival due to EASA proposition of



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 442 of 585 Moreover, French numbers underlines that 7%ⁱ of the HEMS take-off preformed within the first 30 minutes of the FDP. (Cf. SNEH illustrative Table in attachment) Whatever the number of life that would not have been saved during these 30 minutes no

Whatever the number of life that would not have been saved during these 30 minutes, no loss would be politically and socially acceptable.

To align the values with the initial preflight time and proportionate pre-flight time before any take-off from the HEMS operating base proposed in FNAM and SNEH's comment #486, FNAM and SNEH suggest suppressing this 30 minutes value and to add that *"a sufficient time is determined by the operator and specified in the operating manual"* to take into account the time for duties performed by the pilots after and before flights and travelling time if not at the HEMS operating base.

Besides, this proposal does not affect the commander's prerogatives since he remains the one to make the final decision regarding the take-off time.

Moreover, due to multiple flight times inside a unique FDP, FNAM and SNEH underline that the definition of post flight duty is non-consistent with the usual definition of post-flight:

- Which starts at the end (of the last FT) of the FDP
- Assuming the FDP ends with the last FT
- Though for HEMS operations FT are unpredictable and scheduled FDP may end long after the last effective FT

For French HEMS services, the suitable accommodation is nearby the helicopter, hence, there is no need for traveling time.

With the same philosophy, the proposed requirement of having a minimum time for duties performed by the pilots after and before flights of 15 minutes at the HEMS operating base will reduce the chance of survival by 8 minutes for the next patient in case of close consecutive missions.

(Cf. attachments S2 and S3 illustrating this issue of 15 min inoperative readiness)

On the other hand, FNAM and SNEH agree these requirements do not apply for the Technical Crew Member since TCM function does not include the flight preparation. (Cf. comment #513)

Besides, for HEMS operations, the definition implicitly given (but never written) to postflight seems not to be in accordance with the usual acceptance of a post-flight as given in the IR for the CAT operations other than HEMS: post-flight is a time after the last FT of a FDP, outside of the FDP.

CS.FTL.3.205(a)(3) and (b)(4) only defines "post-flight" when returning to the HEMS operating base. Therefore, FNAM and SNEH suggest suppressing the post flight duties as written and to refer to the definition stated in the proposal of comment #486to CS.FTL.3.205(a)(3) and (b)(4). (Cf. comment #486)



	PROPOSAL Replace the paragraph (d) by the following: "(d) Time allowed for the duties performed by the pilots after and before flights and travelling is excluded from each break; such a minimum total time is determined by the operator and specified in the operating manual; a shorter time may be specified for the TCM, but not less than the actual travelling time;"
response	Please see the answer to comment # 54
comment	<i>comment by: ADAC Luftrettung gGmbH</i>
	Question: Can breaks be taken into account for split duty, when they are of the following length: >60 minutes when taken at home base, >2 hours in a place with accommodation or >3 hours in other places?
	Max FDP can be extended by 50 % of the duration of the breaks. Question: Is this contradicting the max FDP of 14 hours as defined in above paragraphs?
	Remark: possible extensions by using split duty are well meant but not practicable. Calculation of possible FDP is complex due to all available options and must be made during the day on base taking into account all breaks of that day. Breaks can't be planned in advance when the HEMS base is part of the national rescue system where availability times are defined and need to be covered by the base. To simplify this paragraph, we suggest to cancel the calculation of breaks and allow to stop counting FDP when breaks are longer than 60 minutes.
	Proposal text:
	 CS FTL 3.220 Interruption FDP a. For HEMS operations only breaks of more than 60 minutes at the home base count as break. These breaks will interrupt FDP. b. Max FDP according table 1 and 2 remain valid c. Max duty time per day is limited to 16 h For example: Report for duty 06:30, max FDP 12:30h, three times break of 1 hour each, à 15:30h HEMS availability
response	Please see the answer to comment # 54
commont	EEC commont by Büdiger Neu

comment 556

comment by: Rüdiger Neu



Fragestellung: Gilt bei Split duty eine Zeit von > 60 Minuten an der Station, > 2 Stunden an einem Ort mit einer Unterkunft oder einem anderen Ort wenn > 3 Stunden, als Pause?

Die max. FDP kann um 50% der Pausen verlängert werden. Dieser Punkt ist der wichtigste bei unseren Planungen und unserem weiteren Vorgehen. Da mit diesem Passus die max. Flugdienstzeit (FDP) deutlich über das heutige Maß angehoben werden kann. Der Wermutstropfen kommt jedoch später bei den verlängerten Ruhezeiten und beim Standby.

Fragestellung: Steht dies im Widerspruch zu den oftmals beschriebenen max. 14 Stunden FDP, da nun doch die max. FDP verlängert werden kann?

Anmerkung: die möglichen Erleichterungen durch die Anwendung von split duty sind gut gemeint, aber nicht praktikabel. Die Berechnung der möglichen Zeiten ist zu kompliziert, als dass dies in der Praxis von den Besatzungsmitgliedern auf den Stationen umgesetzt werden kann. Hinzu kommt, dass die Pausen aufgrund der Einbindung in den öffentlichrechtlichen Rettungsdienst nicht in Voraus planbar sind. Zur Erleichterung wird angeregt, die komplizierte Berechnung zu streichen und stattdessen einen Passus einzupflegen, dass Pausen zwischen einzelnen Einsätzen, die mindestens 60 zusammenhängende Minuten dauern, die FDP unterbrechen.

Alternative für HEMS anstelle split duty:

CS FTL.3.220 Interruption FDP

a. Für HEMS Operation gelten nur die Pausen >1h auf der Station mit entsprechender Unterkunft. Diese Pausen führen zu einer Unterbrechung der FDP

- b. Die max. FDP gem. Table 1 und Table 2 haben Bestand
- c. Die Dienstzeit pro Tag wird auf 16h limitiert

Beispiel: Dienstbeginn 06:30, max. FDP 12:30h, drei Mal eine Stunde Pause, ergeben einen möglichen Einsatztag mit 15:30h Dienstzeit

response

Please see the answer to comment # 54

comment	682	comment by: Oya Vendée Hélicoptères
	Attachments <u>#210</u> <u>#211</u> <u>#212</u> <u>#213</u> <u>#214</u>	
	 (d) MINIMUM TIME FOR DUTIES PERFORMED FLIGHTS AND TRAVELLING TIME (Cf. attachments S1, S2, S3 and S4 illustrating pre (d) ISSUE OYA agrees a minimum time shall be taken to ensure 	and post flight issues)
	• Before the 1 st flight of the crew, by prepa	ring the aircraft, and



• After each flight, by reporting flight and aircraft information

Due to the life-threatening emergency operation in HEMS, these times shall be as short as possible to maximize operational availability and response time. In that way, in France, the contractual time for the National Health Authorities between the launch of a HEMS flight and the effective take-off is 7 minutes. Indeed, when a patient needs essential life-saving measures, after 30 minutes, there are almost no chance to save the life of the patient. Thus, the first patient of a FDP will have no chance of survival due to EASA proposition of having a minimum time forduties performed by the pilots after and before flights and travelling of 30 minutes.

Moreover, French numbers underlines that 7%ⁱ of the HEMS take-off preformed within the first 30 minutes of the FDP. (Cf. SNEH illustrative Table in attachment)

Whatever the number of life that would not have been saved during these 30 minutes, no loss would be politically and socially acceptable.

To align the values with the initial preflight time and proportionate pre-flight time before any take-off from the HEMS operating base proposed in OYA's comment #666, OYA suggests suppressing this 30 minutes value and to add that *"a sufficient time is determined by the operator and specified in the operating manual"* to take into account the time for duties performed by the pilots after and before flights and travelling time if not at the HEMS operating base.

Besides, this proposal does not affect the commander's prerogatives since he remains the one to make the final decision regarding the take-off time.

Moreover, due to multiple flight times inside a unique FDP, OYA underlines that the definition of post flight duty is non-consistent with the usual definition of post-flight:

- Which starts at the end (of the last FT) of the FDP
- Assuming the FDP ends with the last FT
- Though for HEMS operations FT are unpredictable and scheduled FDP may end long after the last effective FT

For French HEMS services, the suitable accommodation is nearby the helicopter, hence, there is no need for traveling time.

With the same philosophy, the proposed requirement of having a minimum time for duties performed by the pilots after and before flights of 15 minutes at the HEMS operating base will reduce the chance of survival by 8 minutes for the next patient in case of close consecutive missions.

(Cf. attachments S2 and S3 illustrating this issue of 15 min inoperative readiness)

On the other hand, OYA agrees these requirements do not apply for the Technical Crew Member since TCM function does not include the flight preparation. (Cf. comment #692)

Besides, for HEMS operations, the definition implicitly given (but never written) to postflight seems not to be in accordance with the usual acceptance of a post-flight as given in the IR for the CAT operations other than HEMS: post-flight is a time after the last FT of a FDP, outside of the FDP.

CS.FTL.3.205(a)(3) and (b)(4) only defines "post-flight" when returning to the HEMS operating base. Therefore, OYA suggests suppressing the post flight duties as written and to refer to the definition stated in the proposal of comment #666 to CS.FTL.3.205(a)(3) and (b)(4).

(Cf. comment #666)

PROPOSAL Replace the paragraph (d) by the following:

"(d) Time allowed for the duties performed by the pilots after and before flights and travelling is excluded from each break; such a minimum total time is determined by the operator and specified in the operating manual; a shorter time may be specified for the TCM, but not less than the actual travelling time;"

response

Please see the answer to comment # 54

comment	725 comment by: ADAC
	Pausen sind grundsätzlich nie planbar oder vorhersehbar, daher ist diese Regelung praxisfremd.
response	Please see the answer to comment # 54
comment	726 comment by: ADAC
	Aufgrund welcher Erfahrung/welchen Vorfalls/welcher Studie wird eine solche Regel erstellt ? HEMS Operation bietet genug Pausen, und wenn nicht kann der Kapitän diese jederzeit einfordern - unabhängig fest vorgegebener Zeiten sondern nach dem eigenen Befinden. Dies ist praxisrelevant, keine Vorgaben die die verschiedenen Biorhythmen und Pausenanforderungen verschiedener Piloten nicht erüllen können.
response	Please see the answer to comment # 54
comment	749 comment by: DRF-Luftrettung
	Max FDP can be extended by 50 % of the duration of the breaks.
	Question: Is this contradicting the max FDP of 14 hours as defined in above paragraphs?

**** ****

 TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.
 Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.
 Page 447 of 585

Remark: possible extensions by using split duty are well meant but not practicable. Calculation of possible FDP is complex due to all available options and must be made during the day on base taking into account all breaks of that day. Breaks can't be planned in advance when the HEMS base is part of the national rescue system where availability times are defined and need to be

covered by the base.

To simplify this paragraph, we suggest to cancel the calculation of breaks and allow to stop counting FDP when breaks are longer than 60 minutes.

response

Please see the answer to comment # 54

comment 966 comment by: MBH SAMU Attachments #215 #216 #217 #218 #219 (d) MINIMUM TIME FOR DUTIES PERFORMED BY THE PILOTS BEFORE AND AFTER FLIGHTS AND TRAVELLING TIME (Cf. attachments S1, S2, S3 and S4 illustrating pre and post flight issues) (d) ISSUE MBH agrees a minimum time shall be taken to ensure the safety of the flight: Before the 1st flight of the crew, by preparing the aircraft, and After each flight, by reporting flight and aircraft information Due to the life-threatening emergency operation in HEMS, these times shall be as short as possible to maximize operational availability and response time. In that way, in France, the contractual time for the National Health Authorities between the launch of a HEMS flight and the effective take-off is 7 minutes. Indeed, when a patient needs essential life-saving measures, after 30 minutes, there are almost no chance to save the life of the patient. Thus, the first patient of a FDP will have no chance of survival due to EASA proposition of having a minimum time forduties performed by the pilots after and before flights and travelling of 30 minutes. Moreover, French numbers underlines that 7%ⁱ of the HEMS take-off preformed within the first 30 minutes of the FDP. (Cf. SNEH illustrative Table in attachment) Whatever the number of life that would not have been saved during these 30 minutes, no loss would be politically and socially acceptable. To align the values with the initial preflight time and proportionate pre-flight time before any take-off from the HEMS operating base proposed in MBH's comment #644, MBH suggests suppressing this 30 minutes value and to add that "a sufficient time is determined" by the operator and specified in the operating manual" to take into account the time for

duties performed by the pilots after and before flights and travelling time if not at the HEMS operating base.

Besides, this proposal does not affect the commander's prerogatives since he remains the one to make the final decision regarding the take-off time.

Moreover, due to multiple flight times inside a unique FDP, MBH underlines that the definition of post flight duty is non-consistent with the usual definition of post-flight:

- Which starts at the end (of the last FT) of the FDP
- Assuming the FDP ends with the last FT
- Though for HEMS operations FT are unpredictable and scheduled FDP may end long after the last effective FT

For French HEMS services, the suitable accommodation is nearby the helicopter, hence, there is no need for traveling time.

With the same philosophy, the proposed requirement of having a minimum time for duties performed by the pilots after and before flights of 15 minutes at the HEMS operating base will reduce the chance of survival by 8 minutes for the next patient in case of close consecutive missions.

(Cf. attachments S2 and S3 illustrating this issue of 15 min inoperative readiness)

On the other hand, MBH agrees these requirements do not apply for the Technical Crew Member since TCM function does not include the flight preparation. (Cf. comment #979)

Besides, for HEMS operations, the definition implicitly given (but never written) to postflight seems not to be in accordance with the usual acceptance of a post-flight as given in the IR for the CAT operations other than HEMS: post-flight is a time after the last FT of a FDP, outside of the FDP.

CS.FTL.3.205(a)(3) and (b)(4) only defines "post-flight" when returning to the HEMS operating base. Therefore, MBH suggests suppressing the post flight duties as written and to refer to the definition stated in the proposal of comment #944 to CS.FTL.3.205(a)(3) and (b)(4).

(Cf. comment #944)

PROPOSAL Replace the paragraph (d) by the following:

"(d) Time allowed for the duties performed by the pilots after and before flights and travelling is excluded from each break; such a minimum total time is determined by the operator and specified in the operating manual; a shorter time may be specified for the TCM, but not less than the actual travelling time;"

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

response	Please see the answer to comment # 54
comment	995 comment by: AESA
	Are the breaks considered in CS FTL.3.220 split duty for extending the basic máximum daily FDP independent to break included in CS FTL.3.205 (a)(1) when FDP is over 12 hours? In other words, if the operator plans a FDP of 13 hours with breaks along de FDP including one of 60 min like prescribed in CS FTL.3.205(a)(1) because the FDP is over 12 hours, could it be used this break of 60 min to extend 30 min more the FDP?
response	Please see the answer to comment # 54
comment	1015 comment by: <i>B. Wagner</i>
	Das Konzept von Split duty entstammt wahrscheinlich der FTL Regelungen für Fixed wing operations. Eine Übertragung auf den HEMS Flugbetrieb ohne eine komplette inhaltliche Überarbeitung ist wenig sinnvoll. Grundsätzlich befindet sich die Besatzung während ihrer Bereitschaftszeit auf der Station, die in der Regel als "suitable accommodation" betrachtet werden kann. Damit sollten alle Zeiten auf Station, die nicht Flugzeit oder Nachbereitung eines Einsatzes sind, als Pause gerechnet werden dürfen. Die Idee hinter diesem Punkt liesse sich einfacher regeln, indem man FDP als die Zeit definiert, in der ein Einsatz durchgeführt, vor- oder nachbereitet wird oder andere Stationsarbeiten erledigt werden und der Rest der Bereitschaftszeit zählt nur zur Dienstzeit. Dann reicht die Definition von max FDP und max DP pro Tag aus und der Abschnitt split duty kann ersatzlos entfallen.
response	Please see the answer to comment # 54
comment	1232 comment by: SAF
	Attachments <u>#220</u> <u>#221</u> <u>#222</u> <u>#223</u> <u>#224</u>
	(d) MINIMUM TIME FOR DUTIES PERFORMED BY THE PILOTS BEFORE AND AFTER FLIGHTS AND TRAVELLING TIME
	(Cf. attachments S1, S2, S3 and S4 illustrating pre and post flight issues)
	(d)
	ISSUE
	SAF agrees a minimum time shall be taken to ensure the safety of the flight:

**** ****

- Before the 1st flight of the crew, by preparing the aircraft, and
- After each flight, by reporting flight and aircraft information

Due to the life-threatening emergency operation in HEMS, these times shall be as short as possible to maximize operational availability and response time. In that way, in France, the contractual time for the National Health Authorities between the launch of a HEMS flight and the effective take-off is 7 minutes. Indeed, when a patient needs essential life-saving measures, after 30 minutes, there are almost no chance to save the life of the patient. Thus, the first patient of a FDP will have no chance of survival due to EASA proposition of having a minimum time forduties performed by the pilots after and before flights and travelling of 30 minutes.

Moreover, French numbers underlines that 7%ⁱ of the HEMS take-off preformed within the first 30 minutes of the FDP. (Cf. SNEH illustrative Table in attachment)

Whatever the number of life that would not have been saved during these 30 minutes, no loss would be politically and socially acceptable.

To align the values with the initial preflight time and proportionate pre-flight time before any take-off from the HEMS operating base proposed in SAF's comment #666, SAF suggests suppressing this 30 minutes value and to add that *"a sufficient time is determined by the operator and specified in the operating manual"* to take into account the time for duties performed by the pilots after and before flights and travelling time if not at the HEMS operating base.

Besides, this proposal does not affect the commander's prerogatives since he remains the one to make the final decision regarding the take-off time.

Moreover, due to multiple flight times inside a unique FDP, SAF underlines that the definition of post flight duty is non-consistent with the usual definition of post-flight:

- Which starts at the end (of the last FT) of the FDP
- Assuming the FDP ends with the last FT
- Though for HEMS operations FT are unpredictable and scheduled FDP may end long after the last effective FT

For French HEMS services, the suitable accommodation is nearby the helicopter, hence, there is no need for traveling time.

With the same philosophy, the proposed requirement of having a minimum time for duties performed by the pilots after and before flights of 15 minutes at the HEMS operating base will reduce the chance of survival by 8 minutes for the next patient in case of close consecutive missions.

(Cf. attachments S2 and S3 illustrating this issue of 15 min inoperative readiness)



An agency of the European Union

On the other hand, SAF agrees these requirements do not apply for the Technical Crew Member since TCM function does not include the flight preparation.

(Cf. comment #1242)

Besides, for HEMS operations, the definition implicitly given (but never written) to postflight seems not to be in accordance with the usual acceptance of a post-flight as given in the IR for the CAT operations other than HEMS: post-flight is a time after the last FT of a FDP, outside of the FDP.

CS.FTL.3.205(a)(3) and (b)(4) only defines "post-flight" when returning to the HEMS operating base. Therefore, SAF suggests suppressing the post flight duties as written and to refer to the definition stated in the proposal of comment #1216 to CS.FTL.3.205(a)(3) and (b)(4).

(Cf. comment #1216)

PROPOSAL

Replace the paragraph (d) by the following:

"(d) Time allowed for the duties performed by the pilots after and before flights and travelling is excluded from each break; such a minimum total time is determined by the operator and specified in the operating manual; a shorter time may be specified for the TCM, but not less than the actual travelling time;"

response

Please see the answer to comment # 54

comment	1280 comment by: <i>Hélicoptères de France</i>
	#1 (d) MINIMUM TIME FOR DUTIES PERFORMED BY THE PILOTS BEFORE AND AFTER FLIGHTS AND TRAVELLING TIME
	(Cf. attachments S1, S2, S3 and S4 illustrating pre and post flight issues) (d) ISSUE
	HDF agrees a minimum time shall be taken to ensure the safety of the flight:Before the 1st flight of the crew, by preparing the aircraft, and
	• After each flight, by reporting flight and aircraft information Due to the life-threatening emergency operation in HEMS, these times shall be as short as possible to
	maximize operational availability and response time. In that way, in France, the contractual time for
	the National Health Authorities between the launch of a HEMS flight and the effective take- off is 7
	minutes. Indeed, when a patient needs essential life-saving measures, after 30 minutes, there are
	almost no chance to save the life of the patient. Thus, the first patient of a FDP will have no chance of



survival due to EASA proposition of having a minimum time for duties performed by the pilots after and before flights and travelling of 30 minutes. Moreover, French numbers underlines that 7% i of the HEMS take-off preformed within the first 30 minutes of the FDP. (Cf. SNEH illustrative Table in attachment) Whatever the number of life that would not have been saved during these 30 minutes, no loss would be politically and socially acceptable. To align the values with the initial preflight time and proportionate pre-flight time before any take-off from the HEMS operating base proposed in HDF's comment #28.5, HDF suggests suppressing this 30 minutes value and to add that "a sufficient time is determined by the operator and specified in the operating manual" to take into account the time for duties performed by the pilots after and before flights and travelling time if not at the HEMS operating base. Besides, this proposal does not affect the commander's prerogatives since he remains the one to make the final decision regarding the take-off time. Moreover, due to multiple flight times inside a unique FDP, HDF underlines that the definition of post flight duty is non-consistent with the usual definition of post-flight: • Which starts at the end (of the last FT) of the FDP Assuming the FDP ends with the last FT Though for HEMS operations FT are unpredictable and scheduled FDP may end long after the last effective FT For French HEMS services, the suitable accommodation is nearby the helicopter, hence, there is no need for traveling time. With the same philosophy, the proposed requirement of having a minimum time for duties performed by the pilots after and before flights of 15 minutes at the HEMS operating base will reduce the chance of survival by 8 minutes for the next patient in case of close consecutive missions. (Cf. attachments S2 and S3 illustrating this issue of 15 min inoperative readiness) On the other hand, HDF agrees these requirements do not apply for the Technical Crew Member since TCM function does not include the flight preparation. (Cf. comment #44) Besides, for HEMS operations, the definition implicitly given (but never written) to postflight seems not to be in accordance with the usual acceptance of a post-flight as given in the IR for the CAT operations other than HEMS: post-flight is a time after the last FT of a FDP, outside of the FDP. CS.FTL.3.205(a)(3) and (b)(4) only defines "post-flight" when returning to the HEMS operating base. Therefore, HDF suggests suppressing the post flight duties as written and to refer to the definition stated in the proposal of comment #28.5 to CS.FTL.3.205(a)(3) and (b)(4).

(Cf. comment #28.5)



PROPOSAL Replace the paragraph (d) by the following: "(d) Time allowed for the duties performed by the pilots after and before flights and travelling is excluded from each break; such a minimum total time is determined by the operator and specified in the operating manual; a shorter time may be specified for the TCM, but not less than the actual travelling time;"

response

Please see the answer to comment # 54

comment	1354	comment by: European Cockpit Association
	Commented text:	
	CS FTL.3.220	
	The following applies HEMS operations:	in the case of split duty with one or more breaks on the ground in
	ECA Comment:	
	There is a need to cla hour cannot be consid point: Split Duty canno	rify that being on alertness, with a notification time of less than 1 dered as a break for the use of split duty. Urgent need to clarify this ot be combined with rest periods at the base to extend FDP - similar lit duty cannot be combined with in-flight rest" - which is similar
response	Please see the answer	to comment # 54
comment	1355	comment by: European Cockpit Association
	Commented text:	
		e HEMS operating base, the break on the ground has a minimum tive hours.
	ECA Comment:	
		able if at least accomodation is provided
response	Please see the answer	to comment # 54
comment	1399	comment by: Swiss Air-Ambulance Rega
	<u>CS.FTL.3.220(a)(b)</u>	
		uty, a period of > 60 minutes at the base, > 2 hours at a place with for $r > 3$ hours in another place is considered a break
	Surgoie accommodati	on, or 2.5 hours in another blace is considered a break.

CS.FTL.3.220(e)



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 454 of 585 The max. FDP can be extended by 50% of the breaks. This point is the most important one in our plans and our further action. This is because as a result of this passage the max. flight duty period (FDP) can be increased much above today's period. However, the "bitter pill" comes later in the form of the extended rest times and standby.

Question: Does this contradict the frequently described max. 14-hour FDP, because the FDP be extended after all? max. can now Please note: The potential simplifications through the application of split duty are wellintentioned, but not practical. The calculation of the possible times is too complicated, as this has to be implementable in practice by crew members at bases. In addition, the breaks cannot be planned in advance due to the integration in the public emergency services. To make things easier, it is suggested to take out the complicated calculation and instead incorporate a passage stating that breaks between individual missions that last at least 60 consecutive minutes interrupt the FDP.

Proposed amendment:

FDP CS FTL.3.220 Interruption a. Only breaks >1 hour at the base with suitable accommodation apply to HEMS operations. These breaks FDP. interrupt the FDPs 2 b. The max. acc. to Table 1 and Table are maintained. c. The duty period per day is limited to 16 hours. Example: Start of duty 6:30 a.m., max. FDP 12.5 hours, three one-hour breaks result in a possible duty day of 15.5 hours.

response

Please see the answer to comment # 54

comment	1493 comment by: Finnish Transport Safety Agency
	In order to establish rolling 24 hour standby for HEMS, following amendments are proposed.
	Proposal: Amend CS FTL.3.220 as follows:
	CS FTL.3.220 Split duty in continuous standby — HEMS
	(f) Split duty may not be used during active standby.
response	Please see the answer to comment # 54

GM1 CS FTL.3.220(b)

p. 37-38



ment 345	comment by: European Helicopter Association (EHA)
FNAM (Frar	ce)
ISSUE	
(Cf. comme	nt #31)
Taking into proposed to	account comment and proposal for CS.FTL.3.220(b), this referring GM is be
amended to	reflect the above suggested modifications.
It would al travelling ti	so clarify misunderstanding that this GM precising "Post-, pre-flight duty, nes
and operation but differer	onal pre-flight duties" for the sake of Split duty may have on the same terms t
notions use PROPOSAL	d in CS.FTL.3.205(a)(3) and (b)(4).
Replace the	content of this GM by the following:
"Duties per	ormed by the pilots after and before flights and travelling
The operate	r should specify:
	ved for duties performed by the pilots after and before flights;
• Travelling from	times for the crews; operational pre-flight duties before each flight taking-off
the HEMS o	perating base and travelling times for HEMS
taking into landing site	account the aircraft type, the type of operation and the condition of the airport,
or HEMS op	erating base, as applicable."
nse Please see t	he answer to comment # 54

comment	503comment by: FNAM/SNEH
	ISSUE (Cf. comment #502) Taking into account comment and proposal for CS.FTL.3.220(b), this referring GM is proposed to be amended to reflect the above suggested modifications. It would also clarify misunderstanding if this GM precising " <i>Post-, pre-flight duty and</i> <i>travelling times</i> " for the sake of split duty reuses the same terms (although the notions are different) used in CS.FTL.3.205(a)(3) and (b)(4). <i>i.e</i> "and operational pre-flight duties".
	PROPOSAL Replace the content of this GM by the following:
	"Duties performed by the pilots after and before flights and travelling
	The operator should specify:
	• Time allowed for duties performed by the pilots after and before flights;



Travelling times for the crews; operational pre-flight duties before each flight taking-off from the HEMS operating base and travelling times for HEMS
 taking into account the aircraft type, the type of operation and the condition of the airport, landing site or HEMS operating base, as applicable."
 response

comment	683 comment by: Oya Vendée Hélicoptères
	ISSUE (Cf. comment #682) Taking into account comment and proposal for CS.FTL.3.220(b), this referring GM is proposed to be amended to reflect the above suggested modifications. It would also clarify misunderstanding if this GM precising " <i>Post-, pre-flight duty and</i> <i>travelling times</i> " for the sake of split duty reuses the same terms (although the notions are different) used in CS.FTL.3.205(a)(3) and (b)(4). <i>i.e</i> "and operational pre-flight duties".
	PROPOSAL Replace the content of this GM by the following:
	"Duties performed by the pilots after and before flights and travelling
	The operator should specify:
	 Time allowed for duties performed by the pilots after and before flights; Travelling times for the crews; operational pre-flight duties before each flight taking-off from the HEMS operating base and travelling times for HEMS
	taking into account the aircraft type, the type of operation and the condition of the airport, landing site or HEMS operating base, as applicable."
response	Please see the answer to comment # 54
comment	968 comment by: MBH SAMU
	ISSUE (Cf. comment #966) Taking into account comment and proposal for CS.FTL.3.220(b), this referring GM is proposed to be amended to reflect the above suggested modifications.

It would also clarify misunderstanding if this GM precising "*Post-, pre-flight duty and travelling times*" for the sake of split duty reuses the same terms (although the notions are different) used in CS.FTL.3.205(a)(3) and (b)(4).*i.e "and operational pre-flight duties"*.

**** * * *** PROPOSAL Replace the content of this GM by the following:

"Duties performed by the pilots after and before flights and travelling

The operator should specify:

- Time allowed for duties performed by the pilots after and before flights;
- Travelling times for the crews; operational pre-flight duties before each flight taking-off from the HEMS operating base and travelling times for HEMS

taking into account the aircraft type, the type of operation and the condition of the airport, landing site or HEMS operating base, as applicable."

response

Please see the answer to comment # 54

comment1020comment by: B. WagnerDieser Absatz widerspricht der Zielsetzung, die Regelungen europaweit zu harmonisieren.
Wenn jeder Operator für sich diese Zeiten definieren kann, wird es zu Unterschieden
kommen, die sich bei der Bewerbung auf ausgeschriebene Stationen als Wettbewerbsvor-
oder nachteil erweisen können.
Feste Vorgaben, die für alle verbindlich sind, sollten in GM vorgegeben werden.
Abweichungen in begründeten Ausnahmefällen könnten trotzdem erlaubt werden, wenn
sie von der EASA für die jeweilige Station und nicht für einen bestimmten Operator
genehmigt werden.responsePlease see the answer to comment # 54

comment1233comment by: SAFISSUEISSUE(Cf. comment #1232)Taking into account comment and proposal for CS.FTL.3.220(b), this referring GM is
proposed to be amended to reflect the above suggested modifications.It would also clarify misunderstanding if this GM precising "Post-, pre-flight duty and
travelling times" for the sake of split duty reuses the same terms (although the notions are
different) used in CS.FTL.3.205(a)(3) and (b)(4).*i.e* "and operational pre-flight duties".

PROPOSAL Replace the content of this GM by the following: "Duties performed by the pilots after and before flights and travelling

The operator should specify:

- Time allowed for duties performed by the pilots after and before flights;
- Travelling times for the crews; operational pre-flight duties before each flight taking-off from the HEMS operating base and travelling times for HEMS taking into account the aircraft type, the type of operation and the condition of the airport, landing site or HEMS operating base, as applicable."

response

Please see the answer to comment # 54

CS FTL.3.225

p. 38

comment	62 comment by: London's Air Ambulance
	First paragraph contains the word 'may'. This implies that the paragraph is GM not IR, therefore optional. This is clearly not the intention. The wording of the paragraph needs to be amended to reflect the intention.
response	Please see the answer to comment # 54
comment	187 comment by: ANSMUH
	It is felt that the "standby" section of the CS for HEMS operations is not sufficiently defined and articulated. As presently defined in the NPA, the operator is allowed to use the standby tool in order to systematically assign rosters at the operating base with long periods of standby without counting those as full duty periods, in case no flight is requested during the daily shift. As a result, the personnel could undergo long periods at the operator's disposal with little time counted as duty. This is particularly true in operating bases where the actual number of assigned missions are low and there can be a consistent part of the day without flights. In particular, night shifts are likely to end with few mission assignments. If the operator defines the shift as 2 hours for bureaucratic paperwork (20:00-22:00) and 10 hours of standby for take-off within 30 minutes from call (22:00-08:00), in case of no flight requests the pilot will end up with a 12-hours availability in an operative environment (inside the operating base), but with only 2 hours of recorded duty time.



This kind of roster can became a regular everyday planning, permitting continuous personnel availability with very little duty period, thus influencing the duty, rest and recurrent extended recovery rest periods. This will also influence the count of the 2000 hours of working time as per Council Directive 2000/79/EC.

We consider the standby as duty. The crew not being at rest is considered active, so this standby must be deducted from duty. See proposal ORO FTL 225.

In France the crew is in standby at the HEMS operating base for 12 or 14 hours. During these 12 or 14 hours of standby the crew is limited of flying hours per day, month and year independently the time which he is assigned to a mission.

It is then up to the crew to accept or not a mission depending on the time of release, without exceeding the maximum of 14 hours of duty per day.

This is not the time of the beginning of a flight assignment which determines the duty time.

If this proposal is applied it is likely to have strong social movements in France.

We refuse this proposal. The maximum standby duration should be 14 hours as HEMS PFD which includes standby, post and pre-flight duties, fligths, and all type of duties.

Proposal:

CS FTL.3.225 Standby and duties at the HEMS operating base.

The limits on flight duty, duty and rest periods in HEMS operations may be modified in accordance with the following:

Standby at the HEMS operating base is defined as a standby with whenever, due to operative and logistic requirements, the crew is required to remain at the operating base during the standby period. Standby at the HEMS operating base should count in full as duty period:

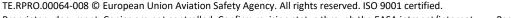
(a) When a standby at the HEMS operating base does not lead to the assignment of a FDP, standby at the HEMS operating base is followed by a rest period as specified in ORO.FTL.235.

(b) Standby at the HEMS operating base should count in full as FDP.

(a) The maximum duration of standby duty is 16 hours.

(b) Standby is followed by a rest period in accordance with ORO.FTL.235. In case of consecutive standby duties not leading to an assignment of FDP, the applicable minimum rest period may be reduced to 8 hours, if the response time specified by the operator is 60 minutes or more.

(c) Standby ceases when the crew member reports at the designated reporting point.



(d) If standby ceases within the first 6 hours of standby, the maximum FDP counts from reporting;

(e) If standby ceases after the first 6 hours, the maximum FDP is reduced by the amount of standby time exceeding 6 hours except in case of split duty; or (f) Time on standby duty is not counted for the reduction of the maximum allowable FDP in the following cases:

 (1) if the standby starts between 23:00 and 07:00 and the crew member is not contacted by the operator during that period;

- (2) if the assigned FDP includes a break on the ground; and

(3) the response time established by the operator allows the crew member to arrive from his/her place of rest to the designated reporting point within a reasonable time. (g) The response time is the time between the communication of a duty assignment and the reporting time and is reflected in the operator's flight time specification scheme.

response

Please see the answer to comment # 54

comment257comment by: European Helicopter Association (EHA)ADAC (Germany), DRF (Germany) and LAR (Luxembourg):
(a)
Limit 16 hours.
This means max allowable day with split duty is also limited to 16 hours?responsePlease see the answer to comment # 54

comment	346	comment by: European Helicopter Association (EHA)
	FNAM (France)	
	#1	
	AGREEMENT	
	The FNAM globally agrees with these	e standby modalities.
	Nevertheless, the 8-hour sleep opp depending on the	portunity should have the flexibility to be adapted
	local conditions on rhythm of life.	
	For instance, for some overseas ter time and	ritories have not the same alignment between local
	effective sunrise / sunset. Thus an a time, does not	3-hour sleep opportunity between 23h and 7h, local
		ed circadian rhythm, expressed in local time.
	(1) Allow to change 23:00 and 7:00 effective	to another 8-hour sleep opportunity, adapted to the
	acclimatized circadian rhythm, expression 21:00	essed in local time (eg 0:00 to 8:00, 22:00 to 6:00, or
	to 5:00 depending of the area of wor	ld considered)



response

Please see the answer to comment # 54

comment	401 comment by: European Helicopter Association (EHA)
	OEATMC (Austria):
	CS FTL.3.225 Standby and duties at the HEMS operating base
	[] (b) Standby is followed by a rest period in accordance with ORO.FTL.235. In case of
	consecutive standby duties not leading to an assignment of FDP, the applicable minimum rest period
	may be reduced to 8 hours, if the response time specified by the operator is 60 minutes or more.
	COMMENT(S)
	This was apparently as well taken from scheduled fixed wing operations and does in no means apply
	to HEMS operations. The spirit of HEMS implies a quick response; therefore a response time of one
	hour surprises us.
	CS FTL.3.230 Reserve — HEMS []
	(f) Minimum notification time for any duty is 10 hours that may include the 8-hour sleep opportunity under (e).
	COMMENT(S)
	Assuming a sick leave of a pilot in the morning - this rule prohibits the reserve pilot to fill the gap
	within 10h. Even if it is the home base and the reserve pilot is living a couple minutes away. With this
	rule it is basically not possible to continue service if someone gets sick throughout the day. This
	endangers the health of sick or injured people!
response	Please see the answer to comment # 54
comment	504 comment by: FNAM/SNEH
	AGREEMENT FNAM and SNEH globally agree with these standby modalities. Nevertheless, the 8-hour sleep opportunity should have the flexibility to be adapted depending on the local conditions on rhythm of life.



For instance, some overseas territories have not the same alignment between local time and effective sunrise / sunset. Thus an 8-hour sleep opportunity between 23h and 7h, local time, does not always correspond to the acclimatized circadian rhythm, expressed in local time.

PROPOSAL

Allow to change 23:00 and 7:00 to another 8-hour sleep opportunity, adapted to the effective acclimatized circadian rhythm, expressed in local time (eg 0:00 to 8:00, 22:00 to 6:00, or 21:00 to 5:00 depending of the area of world considered)

response

Please see the answer to comment # 54

comment	536comment by: ADAC Luftrettung gGmbH
	Limit 16 hours.
	Question: Does this mean, that the max allowable day with split duty is also limited to 16 hours?
response	Please see the answer to comment # 54
comment	557 comment by: <i>Rüdiger Neu</i>
	Limit sind 16 Stunden. Fragestellung: Kann bei Split duty der Arbeitstag nur max. 16 Stunden betragen, da die Besatzung sich sonst im Standby befindet?
response	Please see the answer to comment # 54
comment	684 comment by: <i>Oya Vendée Hélicoptères</i>
	AGREEMENT OYA globally agrees with these standby modalities. Nevertheless, the 8-hour sleep opportunity should have the flexibility to be adapted depending on the local conditions on rhythm of life. For instance, some overseas territories have not the same alignment between local time and effective sunrise / sunset. Thus an 8-hour sleep opportunity between 23h and 7h, local time, does not always correspond to the acclimatized circadian rhythm, expressed in local time. PROPOSAL Allow to change 23:00 and 7:00 to another 8-hour sleep opportunity, adapted to the effective acclimatized circadian rhythm, expressed in local time (eg 0:00 to 8:00, 22:00 to 6:00, or 21:00 to 5:00 depending of the area of world considered)



response	Please see the answer to comment # 54
comment	727 comment by: ÖAMTC Helicopter Air Rescue (Austria)
	CS FLT.3.225 (b)
	[] if the response time specified by the operator is 60 minutes or more []
	This was apparently as well taken from scheduled fixed wing operations and does in no
	means apply to HEMS operations. The spirit of HEMS implies a quick response; therefore a
	response time of one hour surprises us.
response	Please see the answer to comment # 54
I	
comment	787 comment by: AECA helicopteros.
comment	787 comment by: AECA hericopteros.
	Standby and duties at the HEMS operating base
	(a) The maximum duration of standby duty is 16 hours. Which criteria apply in the event
	that the standby period takes place at pilot's home? Can in this case be extended up to 24
	hours ?.
	There are no regulation for HEMS in case of Satnd by in any place other than operating base.
response	Please see the answer to comment # 54
comment	969 comment by: MBH SAMU
	AGREEMENT
	MBH globally agrees with these standby modalities.
	Nevertheless, the 8-hour sleep opportunity should have the flexibility to be adapted
	depending on the local conditions on rhythm of life.
	For instance, some overseas territories have not the same alignment between local time and effective sunrise / sunset. Thus an 8-hour sleep opportunity between 23h and 7h, local
	time, does not always correspond to the acclimatized circadian rhythm, expressed in local
	time.
	PROPOSAL
	Allow to change 23:00 and 7:00 to another 8-hour sleep opportunity, adapted to the
	effective acclimatized circadian rhythm, expressed in local time (eg 0:00 to 8:00, 22:00 to 6:00, or 21:00 to 5:00 depending of the area of world considered)

response

Please see the answer to comment # 54

**** * * ****

comment	997 comment by: AESA
	Title seems to be wrong; point only includes standby, so the title should be "CS FTL.3.225 Standby". It would be consistent with CS 1 and CS 2.
	In the body, it should be included different requirements for standby in HEMS operating base and for other than HEMS operating base, following the scheme used in CS 1 and CS 2.
	Requirements included (a) to (g) seems to be for standby in other than HEMS operating base, but rationale says that it is an adaptation from CS 1 airport standby. For example, response time is a concept from other than airport standby in CS 1.
response	Please see the answer to comment # 54
comment	1028 comment by: B. Wagner
	Auch hier gibt es zuviele mögliche Anwendungen, die zu unterschiedlicher Berechnung der
	maximal möglichen FDP führen. Das ist nicht praktikabel. Dieser Abschnitt ist in Deutschland dennoch akzeptabel, da dieses Dienstmodell derzeit keine Anwendung findet.
response	Please see the answer to comment # 54
comment	1172 comment by: NHV Group
	Paragraph No: CS FTL.3.225 Standby and duties at the HEMS operating base
	Comment: Response time is not taken into account when assessing impact of stress induced fatigue on flight crews during FDP and/or FT.
	Justification: Response time should reflect adversity level of current or forecasted meteo
	conditions & flight rules applicable to the mission planned to be flown. Rationale: prescriptive short response times after rest period during night duty can be critical to the
	pilot's ability to make necessary accommodation in the cockpit.
	Proposed text: (g) The response time is the time between the communication of a duty assignment and the rotor-start time and is reflected in the operator's flight time
	specification scheme as a minimum response time allowing safety checks being performed by the pilot before take-off.
response	Please see the answer to comment # 54
comment	1234 comment by: SAF
	,
	AGREEMENT

**** * * *** SAF globally agrees with these standby modalities.

Nevertheless, the 8-hour sleep opportunity should have the flexibility to be adapted depending on the local conditions on rhythm of life.

For instance, some overseas territories have not the same alignment between local time and effective sunrise / sunset. Thus an 8-hour sleep opportunity between 23h and 7h, local time, does not always correspond to the acclimatized circadian rhythm, expressed in local time.

PROPOSAL

Allow to change 23:00 and 7:00 to another 8-hour sleep opportunity, adapted to the effective acclimatized circadian rhythm, expressed in local time (eg 0:00 to 8:00, 22:00 to 6:00, or 21:00 to 5:00 depending of the area of world considered)

response

Please see the answer to comment # 54

comment 1282 comment by: Hélicoptères de France #1 AGREEMENT HDF globally agrees with these standby modalities. Nevertheless, the 8-hour sleep opportunity should have the flexibility to be adapted depending on the local conditions on rhythm of life. For instance, some overseas territories have not the same alignment between local time and effective sunrise / sunset. Thus an 8-hour sleep opportunity between 23h and 7h, local time, does not always correspond to the acclimatized circadian rhythm, expressed in local time. PROPOSAL (1) Allow to change 23:00 and 7:00 to another 8-hour sleep opportunity, adapted to the effective acclimatized circadian rhythm, expressed in local time (eg 0:00 to 8:00, 22:00 to 6:00, or 21:00 to 5:00 depending of the area of world considered) Please see the answer to comment # 54 response

comment | 1317

comment by: Elilombarda

CS FTL.3.225 Standby and duties in at the HEMS operations operating base

The limits on flight duty, duty and rest periods in HEMS operations are modified in accordance with the following:



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 466 of 585

Standby at the HEMS operating base

Standby at the HEMS operating base is defined as a standby with a response time of less than 90 minutes or whenever, due to operative and logistic requirements, the crew is required to remain at the operating base during the standby period. Standby at the HEMS operating base should count in full as flight duty period (FDP).

When a standby at the HEMS operating base does not lead to the assignment of a FDP, standby at the HEMS operating base is followed by a rest period as specified in ORO.FTL.235.

If an assigned FDP starts during standby at the HEMS operating base, the following applies:

the FDP counts from the start of the FDP. The maximum FDP is reduced by any time spent on standby in excess of 4 hours;

the maximum combined duration of standby at the HEMS operating base and assigned FDP as specified in ORO.FTL.205(b) is 16 hours.

Standby other than standby at the HEMS operating base:

The maximum duration of standby other than airport standby is 16 hours;

Standby other than standby at the HEMS operating base is followed by a rest period in accordance with ORO.FTL.235. In case of consecutive standby duties not leading to an assignment of FDP, the applicable minimum rest period may be reduced to 8 hours, if the response time specified by the operator is 60 minutes or more.

the operator's standby procedures are designed to avoid that the combination of standby and FDP leads to more than 18 consecutive hours awake time;

Time spent on standby other than at the HEMS operating base counts as duty time for the purpose of CS.FTL.3.210, as follows:

25 % for standby duty with a response time of 120 minutes or more;

50 % for standby duty with a response time between 119 and 90 minutes;

100 % for standby duty with a response time of less than 90 minutes.

standby ceases when the crew member reports at the designated reporting point;

if standby ceases within the first 6 hours, the maximum FDP counts from reporting;

if standby ceases after the first 6 hours, the maximum FDP is reduced by the amount of standby time exceeding 6 hours;

if the FDP is extended due to split duty according to CS FTL.3.220, the 6 hours of points (6) and (7) are extended to 8 hours;

Time on standby duty is not counted for the reduction of the maximum allowable FDP in the following cases:

if the standby starts between 23:00 and 07:00 and the crew member is not contacted by the operator during that period;

if the assigned FDP includes a break on the ground; and

the response time established by the operator allows the crew member to arrive from his/her place of rest to the designated reporting point within a reasonable time.

IMPACT ANALYSIS

Before suggested changes:

<u>SAFETY</u>

OPERATOR – IMPROVED – Due to lack of regulation in HEMS standby, the operator may consider the crew in standby, with a reduced response time down to 30 minutes or 5 minutes, until a mission assignment, thus reducing the count of the crew's duty time and related limits over the 14 and 30 days.

CREWS – NEGATIVE – The count of the duty time and related rest and extended rest periods could be defined by the operator and possibly reduced.

<u>LOGISTIC</u>

OPERATOR – IMPROVED – In case the operator elects to partially count the standby at HEMS operating base as duty time, the total crews' duty time will be reduced. CREWS – NEGATIVE – The crew is available to the operator's needs with reduced count of duty time.

ECONOMIC

OPERATOR – NEUTRAL - It depends on the personal or collective contracts. CREWS – NEUTRAL – It depends on the personal or collective contracts.

After suggested changes:

SAFETY

OPERATOR – NEUTRAL – Basically, it will not change today's assets. CREWS – NEUTRAL – Basically, it will not change today's assets.

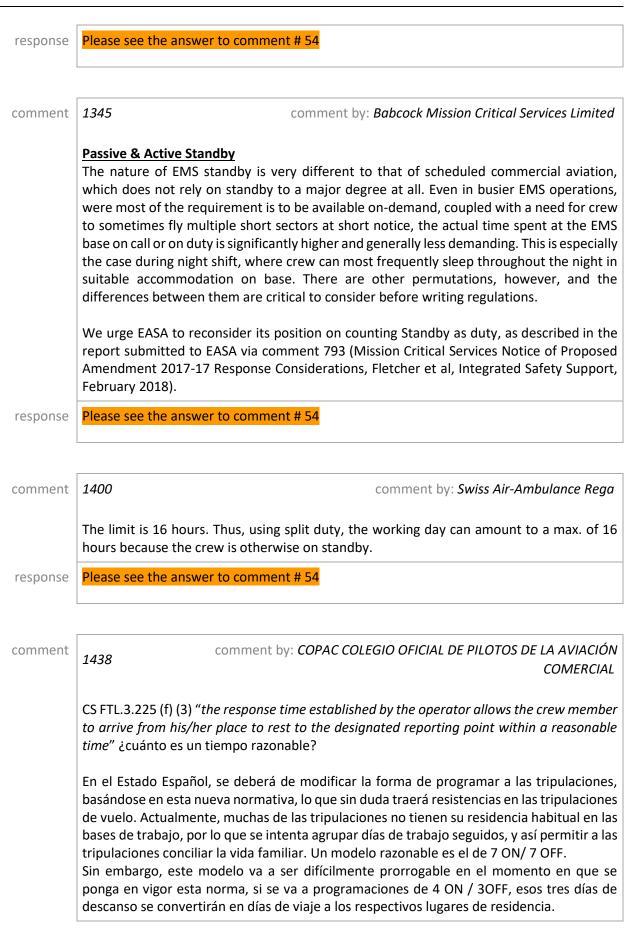
LOGISTIC

OPERATOR – NEUTRAL – Basically, it will not change today's assets. CREWS – NEUTRAL – Basically, it will not change today's assets.

ECONOMIC

OPERATOR – NEUTRAL - It depends on the personal or collective contracts. CREWS – NEUTRAL – It depends on the personal or collective contracts.





** TE

	Uno de los motivos por los que no se mudan los tripulantes de vuelo junto a sus familias, es la falta de estabilidad laboral en este sector, castigado por concursos públicos que se asignan con muy poco tiempo hasta el momento en el que se inicia la operación, además de duraciones relativamente cortas que no dan ninguna garantía de futuro.
response	Please see the answer to comment # 54
comment	1459 comment by: Association of Air Ambulances
	First paragraph contains the word 'may'. This implies that the paragraph is GM not IR, therefore optional. This is clearly not the intention. The wording of the paragraph needs to be amended to reflect the intention.
response	Please see the answer to comment # 54
comment	1495 comment by: Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)
	If EASA prefers to go forward with regulations according to Option 1 or 2, the Swedish Transport Agency has the following proposal: CS FTL.3.225 Standby and duties at the HEMS operating base (a) The maximum duration of standby duty is 16 hours Should be changed to 24 hours per day during a maximum of 7 consecutive days to be followed by a minimum of 7 day's rest. Note: ORO.FTL.235 Rest Periods should be changed in line with this proposal.
response	Please see the answer to comment # 54
comment	1496 comment by: Finnish Transport Safety Agency
	In order to establish rolling 24 hour standby for HEMS, following amendments are proposed.
	Proposal: Add new paragraph CS FTL.3.227 after CS FTL.3.225 as follows:
	CS FTL.3.227 IDP and ADP in active standby -HEMS By way of derogation from CS FTL.3.225, the limits on flight duty, duty and rest periods in active standby HEMS operations may be modified in accordance with the following: (a) The maximum rostered duration of active standby is 72 hours.

**** * * ***

p. 38-39

(b) For active standby in HEMS, the ADP is counted as starting when an alarm is received, or when air operator requires crew to start other tasks than flying. ADP is counted ending 30 minutes after the flight has ended, or when all duties related to the flight or to other tasks that have been carried out, whichever occurs later.

(c) For active standby in HEMS, if the time between two ADPs is less than 1 hour, this time shall be counted as ADP.

response

Please see the answer to comment # 54

CS FTL.3.230

comment 8 comment by: TG Mir ist nicht klar, ob Sie sich unsere Bereitschaftspläne angesehen haben und deren praktische Anwendung untersucht. Alle Piloten sind ausnahmslos einverstanden und sehen die persönlichen Vorteile des bestehenden Systems. Please see the answer to comment # 54 response comment 188 comment by: ANSMUH For airplanes, the same home base is shared by several crews, so in case of personnel unavailability, crews from the same home base can replace the colleagues. They regularly use the airport standby and the reserve personnel from the same home base to face operating problems. HEMS operating bases will have just the strict number of required crews to be rostered, because the other crews will have different rosters and home bases. In case of crew's unavailability a crew with the same home base is not automatically available. This proposal is modeled on what is done for aiplanes. It would be difficult to apply it to the French HEMS and other european country, especially for day/night bases. if this proposal is applied, it risks having a strong social movement in France. **Proposal:** CS FTL.3.230 Reserve HEMS The operator, when assigning duties to a crew member on reserve as provided for by ORO.FTL.230, complies with the following: (a) A crew member may be assigned to a maximum of 21 days on reserve per calendar year.



(b) Any FDP or standby duty, assigned after the reserve, counts from the reporting time.

(c) Reserve times count for 50% of duty period do not count as duty period for the purpose of ORO.FTL.210(a) or (b) and ORO.FTL.235.

(d) The operator specifies a number of consecutive reserve days within the limits of ORO.FTL.235(d).

(e) To protect an 8-hour sleep opportunity in accordance with fatigue management principles, the operator rosters/pre-notifies for each reserve day a period of 8 hours during which a crew member on reserve cannot be contacted by the operator.

(f) Minimum notification time for any duty is 10 hours that may include the 8-hour sleep opportunity under (e). (g) Reserve time does not count as recurrent extended recovery rest.

response

Please see the answer to comment # 54

comment	258	comment by: European Helicopter Association (EHA)
	ADAC (Germany), DRF (Germany) and	LAR (Luxembourg):
	(a) max 21 days/year (b) FDP Counts from reporting time	
	Question: Definition of reporting time the activation from reserve?	e? Does it start with arrival at base or with receiving
	(c) The operator needs to define an 8 be contacted	hour period during reserve when the pilot must not
	(d) Reserve time doesn't count for ex	tended recurrent rest
	This can be accepted because if the p	ilot is not activated during reserve time he
	doesn't need additional time for rest	afterwards.
response	Please see the answer to comment #	<mark>54</mark>

comment292comment by: European Helicopter Association (EHA)ADAC (Germany), DRF (Germany) and LAR (Luxembourg):CS FTL 3.230Problem:Pilots in HEMS Service are on reserve, in case another pilot gets ill. Being 2 weeks at
home in reserve without beeing activated has no impact on cumulative fatique. Being
called all standard regulations apply. If there is a large distance to the HEMS base, he has
to perform a 10 hour rest before starting service and because his travel counts as FDP, he
can only perform 3 day shift.

**** * * * * * * We do not see any impact on cumulative fatique, if a pilot has more than 21 days in reserve

Solution: Maximum of 4 periods with 7 days on reserve

response

Please see the answer to comment # 54

comment	347 comment by: European Helicopter Association (EHA)
	FNAM (France)
	ISSUE
	#1
	(a)
	Réserve limitée à 21 jours, est-ce problématique ? => A discuter avec le SNEH.
	#2
	REMARK
	(f)
	Due to the life-threatening mission and unexpected missions, the response time in the case of HEMS
	operation shall be really short to ensure, for example, the essential life-saving measures
	are offered to
	the patient as fast as possible.
	However, the EASA proposal allows a maximum notification time of 10 hours when the
	pilot is in
	reserve.
	In that way, the use of "reserve" for HEMS operation seems <i>de facto</i> limited to non-urgen
	duties; for
	instance, to ensure a "reserve" crew can replaces an ill / not available crew at anothe
	operating base.
response	Please see the answer to comment # 54

In practice this will mean an operator (whose aim it will be to continue the HEMS operation as quick as possible) needs a standby crew on every station to replace an ill/not available pilot as 10 hours will be way too long to use the reserve pilot. Suggest to change this to less reaction time when notified in the morning (after 0700) and 8 hours if notified after 2200

response

Please see the answer to comment # 54

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

comment 430 comment by: UFH French Helicopters Association REMARK (f) Due to the life-threatening mission and unexpected missions, the response time in the case HEMS of operation shall be really short to ensure, for example, the essential life-saving measures offered are to the patient possible. as fast as However, EASA proposal allows a maximum notification time of 10 hours when the pilot is reserve. in In that way, the use of "reserve" for HEMS operation seems de facto limited to non-urgent

duties; instance, to ensure a "reserve" crew can replaces an ill / not available crew at another operating base.

response

Please see the answer to comment # 54

comment	505	comment by: FNAM/SNEH
	REMARK	
	(f)	
		xpected missions, the response time in the case
	-	ensure, for example, the essential life-saving
	measures are offered to the patient as fast	
		notification time of 10 hours when the pilot is
	in reserve.	r notification time of 10 hours when the phot is
		operation seems <i>de facto</i> limited to non-urgent
	•	crew can replaces an ill / not available crew at
		trew can replaces an in 7 not available crew at
	another operating base.	
response	Please see the answer to comment # 54	
I		
	L	
comment	537	comment by: ADAC Luftrettung gGmbH

- (a) max 21 days/year
- (b) FDP Counts from reporting time

Question: Definition of reporting time? Does it start with arrival at base or with receiving the activation from reserve?

(c) The operator needs to define an 8 hour period during reserve when the pilot must not be contacted

(d) Reserve time doesn't count for extended recurrent rest

This can be accepted because if the pilot is not activated during reserve time he doesn't need additional time for rest afterwards.



Please see the answer to comment # 54 response comment 558 comment by: Rüdiger Neu (a) Max. 21 Tage/Jahr FDP in der Bereitschaft zählt ab der Reporting time (b) Fragestellung: Wie ist die Reporting Time definiert, ist es der Zeitpunkt des Erhalts des Auftrags, Zeitpunkt Beginn des Auftrags (FDP / Standby)? (e) Das Unternehmen muss 8 Stunden innerhalb der Bereitschaft definieren, in der das Besatzungsmitglied nicht kontaktiert werden darf. (g) Bereitschaftszeit zählt nicht zur verlängerten Ruhezeit Dies ist akzeptabel, da wenn ein Pilot in der Bereitschaft nicht gerufen wird im Anschluss noch eine zusätzliche Phase, die Ruhezeit von bis zu 36 Stunden (unter den Voraussetzungen von CS FTL.3.205 (d) einhalten müsste. Please see the answer to comment # 54 response

comment	685	comment by: Oya Vendée Hélicoptères
	REMARK (f) Due to the life-threatening	mission and unexpected missions, the response time in the case
		e really short to ensure, for example, the essential life-saving e patient as fast as possible.
		llows a maximum notification time of 10 hours when the pilot is
		serve" for HEMS operation seems <i>de facto</i> limited to non-urgent sure a "reserve" crew can replaces an ill / not available crew at
response	Please see the answer to co	omment # 54
comment	728	comment by: ÖAMTC Helicopter Air Rescue (Austria)
	CS FLT.3.230 (f)	
	[] minimum notification t	ime for any duty is 10 hours[]
	-	pilot on a HEMS duty in the morning - this rule prohibits the within 10h. Even though if it is the home base and the reserve

reserve pilot to fill the gap within 10h. Even though if it is the home base and the reserve pilot is living within a couple minutes. With this rule it is basically not possible to continue service if someone gets sick throughout the day. This endangers the health of sick or injured people!

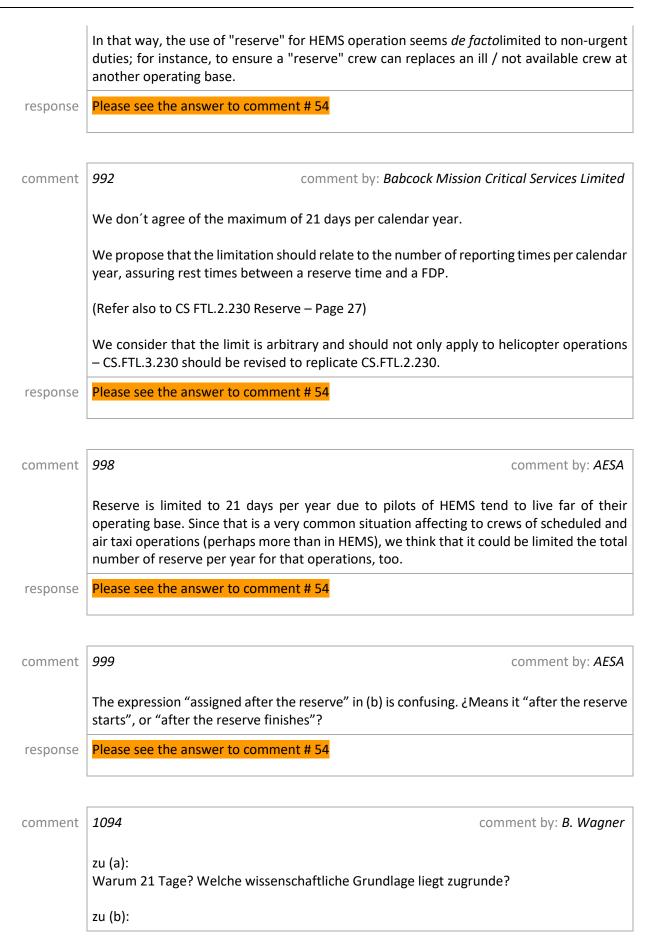
**<u>*</u> T

Individual comments and responses — HEMS response Please see the answer to comment # 54 comment 759 comment by: DRF-Luftrettung Problem: Pilots in HEMS Service are on reserve, in case another pilot gets ill. Being 2 weeks at home in reserve without being activated has no impact on cumulative fatique. Being called all standard regulations apply. If there is a large distance to the HEMS base, he has to perform a 10 hour rest before starting service and because his travel counts as FDP, he can only perform 3 day shift. We do not see any impact on cumulative fatique, if a pilot has more than 21 days in reserve Solution: Delete this limitation Please see the answer to comment # 54 response comment 789 comment by: AECA helicopteros. The operator, when assigning duties to a crew member on reserve as provided for by ORO.FTL.230, complies with the following: (a) A crew member may be assigned to a maximum of 21 days on reserve per calendar year. Proposal.- Delete (a) Justification.-For a small operator having, for example, 2 helicopters and 10 pilots can not cover one year of reserve, they would have 155 days a year without coverage.. The number of reserves that can be programmed should be left to the discretion of the operator.

response

Please see the answer to comment # 54

comment 970 comment by: MBH SAMU REMARK (f) Due to the life-threatening mission and unexpected missions, the response time in the case of HEMS operation shall be really short to ensure, for example, the essential life-saving measures are offered to the patient as fast as possible. However, EASA proposal allows a maximum notification time of 10 hours when the pilot is in reserve.





Was ist die "reporting time"? Ankunft auf der jeweiligen Station oder Erhalt der Aktivierung?

zu (f):

nicht praktikabel. Sollte ein Pilot aus gesundheitlichen Gründen kurzfristig ersetzt werden, muss ich 10h vorher den Ersatz informieren? Dies wird in der Praxis zu Ausfällen in der vertraglich geforderten Bereitschaftszeit führen und eine Versorgungslücke für Patienten generieren.

zu (g):

Wenn in der Reserve keine Aktivierung erfolgt ist, hat der Besatzungsangehörige effektiv ausreichend Gelegenheit zur Ruhe. Deshalb ist diese geforderte Einschränkung nicht logisch.

response

Please see the answer to comment # 54

comment	1173 comment by: NHV Group
	 Paragraph No: CS FTL.3.230 Reserve — HEMS Comment: Limiting the maximum number of days assigned to reserve, is related to the proposed limitation of maximum number of 4 consecutive FDP blocks, which in turn negatively affects quality of life for HEMS crew members is. Final effect of related limitation in number of consecutive FDPs induces more frequent exchange of reserve periods, and as such should be addressed. Justification: In case of the following work schedule: block of 7 consecutive FDP + block of 7 consecutive FDP + block of 14 days off-duty (in the last 7 days of off-duty block, flight crew is reserve flight crew), flight crews appreciate less frequent exchange of on-duty/off-duty periods, increasing their quality of life and flight performance. Evidence #1: Company survey among its HEMS crew members. Proposed text: (a) A crew member may be assigned to a maximum of 42 days on reserve per calendar year.
response	Please see the answer to comment # 54
comment	1235 comment by: SAF
	REMARK
	(f)

Due to the life-threatening mission and unexpected missions, the response time in the case of HEMS operation shall be really short to ensure, for example, the essential life-saving measures are offered to the patient as fast as possible.

However, EASA proposal allows a maximum notification time of 10 hours when the pilot is in reserve.

**** ****

In that way, the use of "reserve" for HEMS operation seems *de factolimited* to non-urgent duties; for instance, to ensure a "reserve" crew can replaces an ill / not available crew at another operating base. Please see the answer to comment # 54 response 1283 comment comment by: Hélicoptères de France #1 REMARK (f) Due to the life-threatening mission and unexpected missions, the response time in the case of HEMS operation shall be really short to ensure, for example, the essential life-saving measures are offered to the patient as fast as possible. However, EASA proposal allows a maximum notification time of 10 hours when the pilot is in reserve. In that way, the use of "reserve" for HEMS operation seems de facto limited to non-urgent duties; for instance, to ensure a "reserve" crew can replaces an ill / not available crew at another operating base. response Please see the answer to comment # 54 comment 1402 comment by: Swiss Air-Ambulance Rega

	(a) (b) FDP Question: How the start of an	is the rep	•	e defin	-	21 from point whe	the en an assi	reporting	ys/year time eceived,
	(e) The operat member canno (g) Reserve This is accepta phase after that requirements of	ot be conta time ble, beca at, which	acted. does use if a pi would ha	no [:] lot on	t count reserve is r	as not called,	extende there w	ed rest ill be an ad	time ditional
response	Please see the	answer to	o commen	<mark>t # 54</mark>					

F

comment 1497

comment by: Finnish Transport Safety Agency

In order to establish rolling 24 hour standby for HEMS, following amendments are proposed.

Reasoning: When active standby is used, relief crew is required as a mitigating measure. The details of the system will be required in the operations manual. The intention is that relief crew is ready to be notified when the operator notices that duty times of the crew in active standby threaten to be exceeded. With this requirement the pressure on active crew would be decreased. It must be kept in mind that HEMS is a life-saving activity, and the pressure it creates for the crew should be taken into account.

Proposal:

Add new paragraph CS FTL.3.232 after CS FTL.3.230 as follows:

CS FTL.3.232 Relief crew — HEMS

(a) active standby can only be used if a system for alarming relief crew is described in operations manual.

(b) the operator, when assigning duties to a relief crew member to back-up crew in active standby in HEMS operations, and as provided for by ORO.FTL.230, complies with the following:

(1) a crew member may be assigned to a maximum of 21 days on as a relief crew member per calendar year.

(2) the ADP of relief crew starts from alarm to HEMS base and ends 30 minutes after the flight has ended, or when all duties related to the flight or to other tasks that have been carried out, whichever occurs later.

response

Please see the answer to comment # 54

GM1 CS.FTL.3.230(d)

p. 39

comment	63 comment by: London's Air Ambulance
	The use of the words "surrounding days" is poor use of English. You cannot 'surround' a sleep pattern with 'days'. Consider amending to read: "crew members should be able to maintain an established sleep pattern."
response	Please see the answer to comment # 54
comment	1284 comment by: <i>Hélicoptères de France</i>
	#1 GENERAL AGREEMENT TO CS.FTL.3.235

**** * * * * * * TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 480 of 585 HDF thanks EASA for allowing flexibility to use reduced rest. HDF underlines the French regulation historically proposes several rostering cycles for HEMS operations that are currently used with an excellent safety track record demonstrated by experience: 7 days ON / 7 days OFF with a limitation of 14 hours of duties for 24 hours • 5 days ON / 2 days OFF with a limitation of 12 hours of duties for 24 hours 12 days ON / 6 days OFF with a limitation of 12 hours of duties for 24 hours Therefore, most hospitals / HEMS organizations have a contractual engagement with the National Health Authority over a rolling 24 hours period: 12 hours of HEMS operative availability and 12 hours OFF. Cf. attachments S1, S2, S3 and S4 illustrating the reduced rest and the 12h operational readiness issues According to the Agency requirement on the pre-flight and post-flight minimum times, an HEMS organization will yet roster cycles with a FDP of 12h30 and a Duty Period of 12h45 to ensure they follow their engagement with hospitals. Thus, all HEMS operators will have to schedule: More than 12h FDP for each and every shift Reduced rest of more than 10h amongst a 11h15 available time for rest according to CS.FTL.3.235 to reengage at the same time the day after, under the principles of a FRM. More than 12 hours FDP does not appear more tiring than less than 12 hours FDP: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for SNEH i.e 50 minutes back and forth for 1 mission in Francei). (Cf. comment #30.6) #2 (a)(3) ISSUE HDF wonders why the minimum recurrent extended recovery rest period following a reduced rest period is increased to include 4 local nights since no analysis has been made in the RIA. Besides, there is not such a requirement is for non-HEMS CAT operations.

Reduced rest does not appear over tiring, as balanced to the nature of the FDP and flight time: they

are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are

very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for SNEH i.e

50 minutes back and forth for 1 mission in Francei).

Moreover, reduced rest is used under the principles of a FRM, that shall provide all other mitigation

measures as necessary.



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

Furthermore, no demonstration nor RIA is given to justify this value, while the current rostering in France on this subject for HEMS operations has not reported inherent safety issue through experience. Therefore, HDF suggests keeping the standard extended recovery rest period of 3 local nights including when reduced rest occurs, under the principles of a FRM, unless a further developed RIA and/or a scientific study justify the necessity of 4 local nights. (Cf. comment #30.6) **PROPOSAL:** Replace the paragraph (3) by the following: "(3) The recurrent extended recovery rest following a reduced rest period is increased to include 3 local nights." #3 (b)(2) AGREEMENT HDF agrees to require the use of a FRM for using reduced rest and points out again to EASA the necessity to allow flexibility to use reduced rest. Nevertheless, as the majority of HEMS operators are SME, HDF suggests proportionating the measure and using reduced rest under the principles of a FRM. PROPOSAL Replace the paragraph (a)(3) by the following: "(3) Reduced rest is used under the principles of a FRM." Please see the answer to comment # 54 response

	· · · · · · · · · · · · · · · · · · ·	
comment	1356	comment by: European Cockpit Association
	Commented text:	
	Fatigue management principles means, in	the context of a rostered 8-hour sleep
	opportunity, that crew members should be all surrounding days.	le to maintain a consistent sleep pattern with
	ECA Comment:	
		ictions below 12hrs. The min rest period may
		een two extended recovery rests; if the WOCL
	. ,	I to an 8 hour sleep opportunity taking any
		e time between two extended recovery rests. aken at the operation base with suitable
	accommodation. (This is in line with the reco	
response	Please see the answer to comment # 54	



comment1460comment by: Association of Air AmbulancesThe use of the words "surrounding days" is poor use of English. You cannot 'surround' a
sleep pattern with 'days'. Consider amending to read:
"…crew members should be able to maintain an established sleep pattern."responsePlease see the answer to comment # 54

FTL.3.235	p. 3
comment	9 comment by: To
	Eine festgelegte Zeit von 10h "Rest" erhöht keineswegs die Erholung. Die nötige Zeit häng ausschließlich von der tatsächlichen Belastung der Crew ab. Das REGA Modell - "Flieg und Ruhe wie Du es benötigst" schafft den besten Fatigue-Schutz.
response	Please see the answer to comment # 54
comment	259 comment by: European Helicopter Association (EHA
response	ADAC (Germany), DRF (Germany) and LAR (Luxembourg): (a) Rest period can be reduced to 10 hours (currently in Germany 8:30h, based on a scientificstudy from DLR 1996). As soon as rest period is reduced a FRM is required. If res periodis reduced, extended recurrent recovery rest is required afterwards including 4 nights(currently 3 nights and 48 hours). Reduced rest is defined as rest of less than the FDP infront, min. 12 hours at home base or 10 hours at other bases. (b) When changing from night duty to day duty, at least one night free of duty needs to beplanned. After more than 4 night duties, early start (05:00 – 05:59) or late landing (23:00-01:59) recurrent recovery rest period needs to include 3 nights. We need to insist on a further reduction of possible rest periods to allow for thecontinuation of the current duty roster. Experience from our own operation with 08:30hours rest and Austrian schedules with 08:00 hours rest and flight safety statistics fromthe past missing any fatigue related accident in HEMS should allow for a reduction of restperiod times. In addition, results from the ongoing DLR study will probably show, that there is no major risk in reducing rest periods according to the implemented and provenregulations already in place in Germany for some years. The implementation of FRMseems to be unnecessary as well. Please see the answer to comment # 54
comment	348 comment by: European Helicopter Association (EHA

**** * * ***

FNAM (France)

#1

GENERAL AGREEMENT TO CS.FTL.3.235

The FNAM thanks the EASA for allowing flexibility to use reduced rest.

The FNAM underlines the French regulation historically proposes several rostering cycles for HEMS

operations that are currently used with an excellent safety track record demonstrated by experience:

• 7 days ON / 7 days OFF with a limitation of 14 hours of duties for 24 hours

• 5 days ON / 2 days OFF with a limitation of 12 hours of duties for 24 hours

• 12 days ON / 6 days OFF with a limitation of 12 hours of duties for 24 hours

Therefore, most hospitals / HEMS organizations have a contractual engagement with the NationalHealth Authority over a rolling 24 hours period: 12 hours of HEMS operative availability and 12 hoursOFF. According to the Agency requirement on the pre-flight and post-flight minimum times, an HEMS organization will yet roster cycle with a FDP of 12h30 and a Duty Period of 12h45 to ensure they follow their engagement with hospitals. Thus, all HEMS operators will have to schedule:

• More than 12h FDP for each and every vacation

• Reduced rest of more than 10h amongst a 11h15 available time for rest according to CS.FTL.3.235 to reengage at the same time the day after, under the principles of a FRM. Morethan 12 hours FDP does not appear more tiring than less than 12 hours FDP: they are spent ina suitable accommodation at the HEMS operating base, and the effective flight time are verylow (average of total flight time of 1h30 per FDP with an average leg of 25 minutes *i.e* 50 minutes back and force for 1 mission in Francei).

(Cf. comment #30.6)

#2

(a)(3)

ISSUE

The FNAM wonders why the minimum recurrent extended recovery rest period following a reduced rest period is increased to include 4 local nights since no analysis has been made in the RIA. Besides, there is not such a requirement is for non-HEMS CAT operations.

Reduced rest does not appear over tiring, as balanced to the nature of the FDP and flight time: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes *i.e* 50 minutes back and force for 1 mission in Francei).

Moreover, reduced rest is used under the principles of a FRM, that shall provide all other mitigation measures as necessary.

Furthermore, no demonstration nor RIA is given to justify this value, while the current rostering in France on this subject for HEMS operations has no reported inherent safety issue through experience.

Therefore, the FNAM suggests keeping the standard extended recovery rest period of 3 local nights including when reduced rest occurs, under the principles of a FRM, unless a sound RIA and/or a scientific study justify the necessity of 4 local nights.

(Cf. comment #30.6)

PROPOSAL:

Replace the paragraph (3) by the following:

"(3) The recurrent extended recovery rest following a reduced rest period is increased to include 3 local nights."

#3

(b)(2)



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

* Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 484 of 585

AGREEMENT

The FNAM agrees to require the use of a FRM for using reduced rest and points out again to the EASA the necessity to allow flexibility to use reduced rest. Nevertheless, as the majority of HEMS operators are SME, the FNAM suggests proportionating the measure and using reduced rest under the principles of a FRM. PROPOSAL

Replace the paragraph (a)(3) by the following: "(3) Reduced rest is used under the principles of a FRM."

response

Please see the answer to comment # 54

comment	370	comment by: European Helicopter Association (EHA)
	BHA (UK)	
	"CS FTL.3.235 Rest periods — HEMS (a)(1)"	
		TL scheme, there is no mention of how an operator ovides some useful guidance, but this is not reflected
response	Please see the answer to comment	¥ 54

comment	402	comment by: European Helicopter Association (EHA)
	OEATMC (Austria):	
		s complies with the following: be reduced to 10 hours, only if taken at the HEMS nmodation provided by the operator.
	COMMENT(S) The pilot living in vicinity of the base home within a couple of minutes?	has to stay on the base? Even thought he would be at
response	Please see the answer to comment a	<mark># 54</mark>
comment	410	comment by: ANWB MAA

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

As some people live close by and to fulfill the requirement of 8 hours sleep suggest to change in 8 hours rest excluding travelling

response

Please see the answer to comment # 54

comment 432

comment by: UFH French Helicopters Association

Allowing flexibility to use reduced rest is most appreciated.

The French regulation historically proposes several rostering cycles for HEMS operations that are currently used with an excellent safety track record demonstrated by experience:

• 7 days ON / 7 days OFF with a limitation of 14 hours of duties for 24 hours

• 5 days ON / 2 days OFF with a limitation of 12 hours of duties for 24 hours

• 12 days ON / 6 days OFF with a limitation of 12 hours of duties for 24 hours

Therefore, most hospitals / HEMS organizations have a contractual engagement with the National Health Authority over a rolling 24 hours period: 12 hours of HEMS operative availability and 12 hours OFF.

Cf. attachments S1, S2, S3 and S4 illustrating the reduced rest and the 12h operational readiness issues According to the Agency requirement on the pre-flight and post-flight minimum times, an HEMS organization will yet roster cycles with a FDP of 12h30 and a Duty Period of 12h45 to ensure they follow their engagement with hospitals. Thus, all HEMS operators will have to schedule:

• More than 12h FDP for each and every shift

• Reduced rest of more than 10h amongst a 11h15 available time for rest according to CS.FTL.3.235 to reengage at the same time the day after, under the principles of a FRM. More than 12 hours FDP does not appear more tiring than less than 12 hours FDP: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for SNEH i.e 50 minutes back and forth for 1 mission in Francei).

#2

(a)(3) ISSUE

We wonder why the minimum recurrent extended recovery rest period following a reduced rest period is increased to include 4 local nights since no analysis has been made in the RIA. Besides, there is not such a requirement is for non-HEMS CAT operations. Reduced rest does not appear over tiring, as balanced to the nature of the FDP and flight time: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for SNEH i.e 50 minutes back and forth for 1 mission in Francei).

Moreover, reduced rest is used under the principles of a FRM, that shall provide all other mitigation measures as necessary.

Furthermore, no demonstration nor RIA is given to justify this value, while the current



rostering in France on this subject for HEMS operations has not reported inherent safety issue through experience.

Therefore, UFH suggests keeping the standard extended recovery rest period of 3 local nights including when reduced rest occurs, under the principles of a FRM, unless a further developed RIA and/or a scientific study justify the necessity of 4 local nights. (Cf. comment #30.6)

PROPOSAL:

Replace the paragraph (3) by the following:

"(3) The recurrent extended recovery rest following a reduced rest period is increased to include 3 local nights."

#3

(b)(2)

AGREEMENT

We agree to require the use of a FRM for using reduced rest and points out again to EASA the necessity to allow flexibility to use reduced rest. Nevertheless, as the majority of HEMS operators are SME, we agree with FNAM proposal to suggests proportionating the measure and using reduced rest under the principles of a FRM. PROPOSAL

Replace the paragraph (a)(3) by the following:

"(3) Reduced rest is used under the principles of a FRM."

response

Please see the answer to comment # 54

comment 507

comment by: FNAM/SNEH

Attachments #225 #226 #227 #228

GENERAL AGREEMENT TO CS.FTL.3.235

FNAM and SNEH thank EASA for allowing flexibility to use reduced rest.

FNAM and SNEH underline the French regulation historically proposes several rostering cycles for HEMS operations that are currently used with an excellent safety track record demonstrated by experience:

- 7 days ON / 7 days OFF with a limitation of 14 hours of duties for 24 hours
- 5 days ON / 2 days OFF with a limitation of 12 hours of duties for 24 hours
- 12 days ON / 6 days OFF with a limitation of 12 hours of duties for 24 hours



Therefore, most hospitals / HEMS organizations have a contractual engagement with the National Health Authority over a rolling 24 hours period: 12 hours of HEMS operative availability and 12 hours OFF.

Cf. attachments S1, S2, S3 and S4 illustrating the reduced rest and the 12h operational readiness issues

According to the Agency requirement on the pre-flight and post-flight minimum times, an HEMS organization will yet roster cycles with a FDP of 12h30 and a Duty Period of 12h45 to ensure they follow their engagement with hospitals. Thus, all HEMS operators will have to schedule:

- More than 12h FDP for each and every shift
- Reduced rest of more than 10h amongst a 11h15 available time for rest according to CS.FTL.3.235 to reengage at the same time the day after, under the principles of a FRM. More than 12 hours FDP does not appear more tiring than less than 12 hours FDP: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for SNEH *i.e* 50 minutes back and forth for 1 mission in Franceⁱ).

(Cf. comment #501)

response

Please see the answer to comment # 54

508 comment comment by: FNAM/SNEH (a)(3) ISSUE FNAM and SNEH wonder why the minimum recurrent extended recovery rest period following a reduced rest period is increased to include 4 local nights since no analysis has been made in the RIA. Besides, there is not such a requirement is for non-HEMS CAT operations. Reduced rest does not appear over tiring, as balanced to the nature of the FDP and flight time: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for SNEH *i.e* 50 minutes back and forth for 1 mission in Franceⁱ). Moreover, reduced rest is used under the principles of a FRM, that shall provide all other mitigation measures as necessary. Furthermore, no demonstration nor RIA is given to justify this value, while the current rostering in France on this subject for HEMS operations has not reported inherent safety issue through experience. Therefore, FNAM and SNEH suggest keeping the standard extended recovery rest period of 3 local nights including when reduced rest occurs, under the principles of a FRM, unless a further developed RIA and/or a scientific study justify the necessity of 4 local nights. (Cf. comment #501)

**** * * ***

	PROPOSAL: Replace the paragraph (3) by the following: "(3) The recurrent extended recovery rest following a reduced rest period is increased to include 3 local nights."
response	Please see the answer to comment # 54
comment	509 comment by: FNAM/SNEH
	 (b)(2) AGREEMENT FNAM and SNEH agree to require the use of a FRM for using reduced rest and points out again to EASA the necessity to allow flexibility to use reduced rest. Nevertheless, as the majority of HEMS operators are SME, FNAM and SNEH suggest proportionating the measure and using reduced rest under the principles of a FRM. PROPOSAL Replace the paragraph (a)(3) by the following:
	"(3) Reduced rest is used under the principles of a FRM."

response

Please see the answer to comment # 54

comment 538 comment by: ADAC Luftrettung gGmbH a) Rest period can be reduced to 10 hours (currently in Germany 8:30h, based on a scientific study from DLR 1996). As soon as rest period is reduced a FRM is required. If rest period is reduced, extended recurrent recovery rest is required afterwards including 4 nights (currently 3 nights and 48 hours). Reduced rest is defined as rest of less than the FDP in front, min. 12 hours at home base or 10 hours at other bases. (b) When changing from night duty to day duty, at least one night free of duty needs to be planned. After more than 4 night duties, early start (05:00 – 05:59) or late landing (23:00 -01:59) recurrent recovery rest period needs to include 3 nights. We need to insist on a further reduction of possible rest periods to allow for the continuation of the current duty roster. Experience from our own operation with 08:30 hours rest and Austrian schedules with 08:00 hours rest and flight safety statistics from the past missing any fatigue related accident in HEMS should allow for a reduction of rest period times. In addition, results from the ongoing DLR study will probably show, that there is no major risk in reducing rest periods according to the implemented and proven regulations already in place in Germany for some years. The implementation of FRM seems to be unnecessary as well. Please see the answer to comment # 54 response



comment 559

comment by: Rüdiger Neu

(a) Ruhezeit darf auf 10 Stunden reduziert werden (bisher 8:30 Stunden). Sobald man die Ruhezeit reduziert wird ein FRM benötigt. Wird eine Ruhezeit reduziert, muss eine verlängerte Ruhezeit im Anschluss an die Dienstperiode von 4 Nächten (bisher 48 Stunden und 3 Nächte) eingehalten werden. Von einer reduzierten Ruhezeit spricht man, sobald diese kleiner ist als die vorangegangene FDP, min. 12 Stunden an der Heimatstation oder 10 Stunden an einer fremden Station.

(b) Beim Übergang von Nacht- zu Tagdienst muss mindestens eine Nacht eingeplant werden. Bei mehr als 4 Nachtdiensten oder frühem Start (05:00 -05:59 Uhr) oder später Landung (23:00 – 01:59) muss die verlängerte Ruhezeit drei Nächte enthalten.

Hier muss auf eine weitergehende Verkürzung der Ruhezeit gedrängt werden, damit ein Dienstmodell analog heute weiterhin möglich bleibt. Die Erfahrung aus unserem Flugbetrieb mit min. 8:30 Stunden und den Österreichern mit 8:00 Stunden Ruhezeit, sowie die fehlenden Flugunfälle in der Vergangenheit bezüglich Fatigue, sollten eine weitergehende Reduzierung belegen. Hier werden auch unser Studienergebnis weitere Erkenntnisse bringen und belegen, dass eine Reduzierung der Ruhezeit, wie sie in Deutschland seit Jahrzehnten praktiziert wird, keinen Einfluss auf die Sicherheit hat. Die Einführung eines FRM muss damit hier obsolet sein.

response

Please see the answer to comment # 54

comment 686 comment by: Oya Vendée Hélicoptères Attachments #229 #230 #231 #232 **GENERAL AGREEMENT TO CS.FTL.3.235** OYA thanks EASA for allowing flexibility to use reduced rest. OYA underlines the French regulation historically proposes several rostering cycles for HEMS operations that are currently used with an excellent safety track record demonstrated by experience: 7 days ON / 7 days OFF with a limitation of 14 hours of duties for 24 hours • 5 days ON / 2 days OFF with a limitation of 12 hours of duties for 24 hours 12 days ON / 6 days OFF with a limitation of 12 hours of duties for 24 hours Therefore, most hospitals / HEMS organizations have a contractual engagement with the National Health Authority over a rolling 24 hours period: 12 hours of HEMS operative availability and 12 hours OFF.

TE.RPI

Cf. attachments S1, S2, S3 and S4 illustrating the reduced rest and the 12h operational readiness issues

According to the Agency requirement on the pre-flight and post-flight minimum times, an HEMS organization will yet roster cycles with a FDP of 12h30 and a Duty Period of 12h45 to ensure they follow their engagement with hospitals. Thus, all HEMS operators will have to schedule:

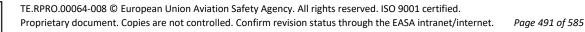
- More than 12h FDP for each and every shift
- Reduced rest of more than 10h amongst a 11h15 available time for rest according to CS.FTL.3.235 to reengage at the same time the day after, under the principles of a FRM. More than 12 hours FDP does not appear more tiring than less than 12 hours FDP: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for OYA *i.e* 50 minutes back and forth for 1 mission in Franceⁱ).

(Cf. comment #681)

response

Please see the answer to comment # 54

comment	687 comment by: <i>Oya Vendée Hélicoptères</i>
	(a)(3) ISSUE OYA wonders why the minimum recurrent extended recovery rest period following a reduced rest period is increased to include 4 local nights since no analysis has been made in the RIA. Besides, there is not such a requirement is for non-HEMS CAT operations. Reduced rest does not appear over tiring, as balanced to the nature of the FDP and flight time: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for OYA <i>i.e</i> 50 minutes back and forth for 1 mission in France ⁱ). Moreover, reduced rest is used under the principles of a FRM, that shall provide all other mitigation measures as necessary.
	Furthermore, no demonstration nor RIA is given to justify this value, while the current rostering in France on this subject for HEMS operations has not reported inherent safety issue through experience.
	Therefore, OYA suggests keeping the standard extended recovery rest period of 3 local nights including when reduced rest occurs, under the principles of a FRM, unless a further developed RIA and/or a scientific study justify the necessity of 4 local nights. (Cf. comment #681)
	PROPOSAL: Replace the paragraph (3) by the following:



	<i>"(3)</i> The recurrent extended recovery rest following a reduced rest period is increased to include 3 local nights."
response	Please see the answer to comment # 54
comment	688 comment by: <i>Oya Vendée Hélicoptères</i>
	(b)(2) AGREEMENT OYA agrees to require the use of a FRM for using reduced rest and points out again to EASA the necessity to allow flexibility to use reduced rest. Nevertheless, as the majority of HEMS operators are SME, OYA suggests proportionating the measure and using reduced rest under the principles of a FRM.
	PROPOSAL Replace the paragraph (a)(3) by the following: "(3) Reduced rest is used under the principles of a FRM."
response	Please see the answer to comment # 54

comment	730	comment by: ÖAMTC Helicopter Air Rescue (Austria)
	CS FLT.3.235	
	(a) [] only if taken <u>at the HEMS</u> operat	ing base []
	The pilot living in vicinity of the base home within a couple of minutes?	has to stay on the base? Even thought he would be at
		a normal HEMS schedule, you won't be able to work sary and to many restrictions which make a applicable
response	Please see the answer to comment #	! 54

comment	750 comment by: DRF-Luftrettung
	We need to insist on a further reduction of possible rest periods to allow for the continuation of the current duty roster. Experience from our own operation with 08:30 hours rest and Austrian schedules with 08:00 hours rest and flight safety statistics from the past missing any fatigue related accident in HEMS should allow for a reduction of rest period times. In addition, results from the ongoing DLR study will probably show, that there is no major risk in reducing rest periods according to the implemented and proven

**** * * ** *

	regulations already in place in Germany for some years. The implementation of FRM seems to be unnecessary as well.
response	Please see the answer to comment # 54
comment	824 comment by: Babcock Mission Critical Services Limited
	Clarification required on rest period at HEMS base.
	Nearby suitable and more appropriate accommodation needs to be defined within a distance/time of an operating base.
	Revise as follows:
	CS FTL.3.235 Rest periods — HEMS
	(a) Reduced rest in HEMS operations complies with the following:
	(1) The minimum rest period may be reduced to 10 hours, only if taken at suitable accommodation designated by the operator.
	(2)
response	Please see the answer to comment # 54
comment	845 comment by: Yorkshire Air Ambulance
	Mandating rest periods is useful but, throughout the FTL scheme, there is no mention of how an operator should manage Days Off. CAP371 provides some useful guidance, but this is not reflected by the NPA.
response	Please see the answer to comment # 54
comment	971 comment by: <i>MBH SAMU</i>
	Attachments <u>#233</u> <u>#234</u> <u>#235</u> <u>#236</u>
	GENERAL AGREEMENT TO CS.FTL.3.235
	MBH thanks EASA for allowing flexibility to use reduced rest.

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

**** * * ***

MBH underlines the French regulation historically proposes several rostering cycles for HEMS operations that are currently used with an excellent safety track record demonstrated by experience: 7 days ON / 7 days OFF with a limitation of 14 hours of duties for 24 hours 5 days ON / 2 days OFF with a limitation of 12 hours of duties for 24 hours 12 days ON / 6 days OFF with a limitation of 12 hours of duties for 24 hours Therefore, most hospitals / HEMS organizations have a contractual engagement with the National Health Authority over a rolling 24 hours period: 12 hours of HEMS operative availability and 12 hours OFF. Cf. attachments S1, S2, S3 and S4 illustrating the reduced rest and the 12h operational readiness issues According to the Agency requirement on the pre-flight and post-flight minimum times, an HEMS organization will yet roster cycles with a FDP of 12h30 and a Duty Period of 12h45 to ensure they follow their engagement with hospitals. Thus, all HEMS operators will have to schedule: More than 12h FDP for each and every shift Reduced rest of more than 10h amongst a 11h15 available time for rest according to CS.FTL.3.235 to reengage at the same time the day after, under the principles of a FRM. More than 12 hours FDP does not appear more tiring than less than 12 hours FDP: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for MBH *i.e* 50 minutes back and forth for 1 mission in Franceⁱ). (Cf. comment #965) Please see the answer to comment # 54 response comment 973 comment by: MBH SAMU (a)(3) ISSUE

MBH wonders why the minimum recurrent extended recovery rest period following a reduced rest period is increased to include 4 local nights since no analysis has been made in the RIA. Besides, there is not such a requirement is for non-HEMS CAT operations. Reduced rest does not appear over tiring, as balanced to the nature of the FDP and flight time: they are spent in a suitable accommodation at the HEMS operating base, and the

**** *...* effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for MBH *i.e* 50 minutes back and forth for 1 mission in Franceⁱ). Moreover, reduced rest is used under the principles of a FRM, that shall provide all other mitigation measures as necessary.

Furthermore, no demonstration nor RIA is given to justify this value, while the current rostering in France on this subject for HEMS operations has not reported inherent safety issue through experience.

Therefore, MBH suggests keeping the standard extended recovery rest period of 3 local nights including when reduced rest occurs, under the principles of a FRM, unless a further developed RIA and/or a scientific study justify the necessity of 4 local nights. (Cf. comment #965)

PROPOSAL: Replace the paragraph (3) by the following:

"(3) The recurrent extended recovery rest following a reduced rest period is increased to include 3 local nights."

response

Please see the answer to comment # 54

comment	974 comment by: <i>MBH SAMU</i>
	(b)(2) AGREEMENT MBH agrees to require the use of a FRM for using reduced rest and points out again to EASA the necessity to allow flexibility to use reduced rest. Nevertheless, as the majority of HEMS operators are SME, MBH suggests proportionating the measure and using reduced rest under the principles of a FRM.
	PROPOSAL Replace the paragraph (a)(3) by the following: <i>"(3) Reduced rest is used under the principles of a FRM."</i>
response	Please see the answer to comment # 54

comment | 1113

comment by: B. Wagner

zu (a) (1):

die Erfahrung mit bestehenden Systemen zeigt, dass für eine begrenzte Anzahl aufeinanderfolgender Tage eine Reduzierung der Ruhezeit auch auf acht Stunden ohne Probleme machbar ist. Speziell wenn die Crew adäquate Ruhemöglichkeiten auf der Station oder in der direkten Umgebung hat, reichen acht Stunden aus, um effektiv sieben Stunden am Stück und planbar zu schlafen, was für einen Erwachsenen als durchaus realistischer und ausreichender Wert betrachtet werden kann. Diese Annahme basiert auf

**** * * **** jahrelanger praktischer Erfahrung und hat sich auch ohne Nachweis durch eine Studie bewährt.

zu (a) (2):

FRM ist eine zusätzliche Bürde für die Unternehmen. Besser wäre es, die Prinzipien eines FRM anzuwenden ohne den administrativen Aufwand der Implementierung eines solchen Systems auf jedes Unternehmen zu übertragen. Kleine Unternehmen haben keine Kapazitäten, dieses Erfordernis umzusetzen.

zu (b) (2):

Auch hier wird wieder ein hoher organisatorischer Aufwand gefordert, um die speziellen Fälle festzustellen und die Planung entsprechend anzupassen. Das führt eher zu Störungen in der Dienstplanung und damit Einbussen in der planbaren Freizeit und fördert dadurch das Risiko von Fatigue. Dies widerspricht der eigentlichen Zielsetzung des Entwurfs.

response

Please see the answer to comment # 54

comment	1174 comment by: NHV Group
	Paragraph No: CS FTL.3.235 Rest periods — HEMS Comment: To be aligned with change of provisions given under comments in CS FTL.3.205 Flight duty period (FDP) - HEMS <i>Unforeseen circumstances in flight operations</i> — <i>commander's discretion in HEMS under ORO.FTL.205(f)</i> , commander's discretion should allow reduction of the rest period instead of increase of the FDP as proposed in the NPA. Justification:
	Proposed text: 1) The minimum rest period may be reduced to 8 hours, only if taken at the HEMS operating base with a suitable accommodation provided by the operator.
response	Please see the answer to comment # 54

comment	1236 comment by: SAF
	Attachments <u>#237</u> <u>#238</u> <u>#239</u> <u>#240</u>
	GENERAL AGREEMENT TO CS.FTL.3.235
	SAF thanks EASA for allowing flexibility to use reduced rest.
	SAF underlines the French regulation historically proposes several rostering cycles for HEMS operations that are currently used with an excellent safety track record demonstrated by experience:
	 7 days ON / 7 days OFF with a limitation of 14 hours of duties for 24 hours 5 days ON / 2 days OFF with a limitation of 12 hours of duties for 24 hours



• 12 days ON / 6 days OFF with a limitation of 12 hours of duties for 24 hours

Therefore, most hospitals / HEMS organizations have a contractual engagement with the National Health Authority over a rolling 24 hours period: 12 hours of HEMS operative availability and 12 hours OFF.

Cf. attachments S1, S2, S3 and S4 illustrating the reduced rest and the 12h operational readiness issues

According to the Agency requirement on the pre-flight and post-flight minimum times, an HEMS organization will yet roster cycles with a FDP of 12h30 and a Duty Period of 12h45 to ensure they follow their engagement with hospitals. Thus, all HEMS operators will have to schedule:

- More than 12h FDP for each and every shift
- Reduced rest of more than 10h amongst a 11h15 available time for rest according to CS.FTL.3.235 to reengage at the same time the day after, under the principles of a FRM. More than 12 hours FDP does not appear more tiring than less than 12 hours FDP: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for SAF *i.e* 50 minutes back and forth for 1 mission in Franceⁱ).

(Cf. comment #1231)

response Please see the answer to comment # 54

comment	1237 comment by: SAF
	(2)(2)
	(a)(3)
	ISSUE
	SAF wonders why the minimum recurrent extended recovery rest period following a reduced rest period is increased to include 4 local nights since no analysis has been made in the RIA. Besides, there is not such a requirement is for non-HEMS CAT operations.
	Reduced rest does not appear over tiring, as balanced to the nature of the FDP and flight time: they are spent in a suitable accommodation at the HEMS operating base, and the effective flight time are very low (average of total flight time of 1h30 per FDP with an average leg of 25 minutes for SAF <i>i.e</i> 50 minutes back and forth for 1 mission in France ⁱ).

Moreover, reduced rest is used under the principles of a FRM, that shall provide all other mitigation measures as necessary.

*** * * *** Furthermore, no demonstration nor RIA is given to justify this value, while the current rostering in France on this subject for HEMS operations has not reported inherent safety issue through experience.

Therefore, SAF suggests keeping the standard extended recovery rest period of 3 local nights including when reduced rest occurs, under the principles of a FRM, unless a further developed RIA and/or a scientific study justify the necessity of 4 local nights.

(Cf. comment #1231)

PROPOSAL: Replace the paragraph (3) by the following: "(3) The recurrent extended recovery rest following a reduced rest period is increased to include 3 local nights."

response

Please see the answer to comment # 54

comment	1238 comment by: SAF
	(b)(2)
	AGREEMENT
	SAF agrees to require the use of a FRM for using reduced rest and points out again to EASA the necessity to allow flexibility to use reduced rest. Nevertheless, as the majority of HEMS operators are SME, SAF suggests proportionating the measure and using reduced rest under the principles of a FRM.
	PROPOSAL
	Replace the paragraph (a)(3) by the following:
	"(3) Reduced rest is used under the principles of a FRM."
response	Please see the answer to comment # 54

comment | 1312

comment by: Elilombarda

CS FTL.3.235 Rest periods — HEMS

See comment to CS FTL.3.205 Flight duty period (FDP) — HEMS for rationale.

It is suggested to allow rosters of 7/7 and up to 14/14, maintaining an equal number of extended rest period days as the preceding FDP block days. During the rest period, the crew can be tasked to perform training, checking and duties in a non-operative environment (not for an operative shift) as per the operator's necessities, provided that adequate rest is granted after the end of the preceding shift and before the beginning of

the subsequent shift. All training, checking and duties shall be counted as duty time for the maximum duty time in the 14 and 28 days.

Point (a)(3) has been increased to "84 hours including 4 local nighs" which correspond to 3 full days of continuous rest after a shift. 2 full days, as indicated in the NPA are not enough for a complete rest after a full shift.

Suggested NPA amendment

CS FTL.3.235 Rest periods — HEMS Recurrent extended recovery rest periods

The minimum recurrent extended recovery rest period should be at least of the same number of days and nights as the preceding duty or FDP period.

The operator may assign duties, training and checking to a crew during the recurrent extended recovery rest period, provided that:

the assigned duties are not in an operative context;

the rest period preceding the first FDP is at least 36 hours including 2 local nights;

the rest period provided after completion of the series of consecutive FDPs is at least 84 hours including 4 local nights; and

all the assigned duties, training and checking are counted as duty time for the duty time limits defined in 'CS FTL.3.210 Flight times and duty periods — HEMS'.

Reduced rest in HEMS operations complies with the following:

The minimum rest period may be reduced to 10 hours, only if taken at the HEMS operating base with a suitable accommodation provided by the operator.

Reduced rest is used under FRM.

The recurrent extended recovery rest following a reduced rest period is increased to include 4 local nights.

Disruptive schedules

When a transition from a late finish/night duty to an early start is planned at home base, the rest period between the 2 FDPs, includes 1 local night.

For a crew member performing 4 or more night duties, early starts or late finishes between 2 extended recovery rest periods as defined by ORO.FTL.235(d), the second extended recovery rest period is extended to include 3 local nights.'

IMPACT ANALYSIS ON DUTY PERIOD, FLIGHT DUTY PERIOD and REST PERIODS

Before suggested changes:



comment by: Swiss Air-Ambulance Rega

<u>SAFETY</u>

OPERATOR – NEGATIVE – In case the operator shall guarantee an uninterrupted HEMS service during the day (most of present contracts), he must organise for a substitute crew during brakes.

CREWS – NEGATIVE – In case of 4/4 rosters the crew may not be able to rest at his residence and family place. If the crew's local accommodation is at the HEMS operating base, he will not be able to use that accommodation due to the presence of the duty crew.

ECONOMIC

OPERATOR – IMPROVED – The operator shall not organise for a substitute crew during brakes.

CREWS – IMPROVED – If the crew's residence and family place is away from the operating base, the crew shall not manage for a local accommodation during extended rest periods.

ECONOMIC

OPERATOR – IMPROVED – The operator shall not renegotiate the HEMS contracts or provide for a substitute crew for breaks.

CREWS – IMPROVED – The crew will reduce the travel and the local accommodation expenses.

response

comment

1403

Please see the answer to comment # 54

(a) The rest period may be reduced to 10 hours (8.5 hours until now). Once the rest period is reduced, FRM is needed. If a rest period is reduced, an extended rest period of 4 nights (48 hours and 3 nights until now) must be observed after the duty period. A rest time is reduced once it is shorter than the preceding FDP, min. 12 hours at the home base or 10

hours at another base.

(b) In the event of transition from night duty to day duty, at least one night must be planned in between. In the event of more than 4 nights of duty or an early start (5:00–5:59 a.m.) or late landing (11:00 p.m.–1:59 a.m.), the extended rest time must include three nights. Here, it is necessary to insist on a further reduction of the rest time so that a duty model similar to today's continues to be possible. The experience gained from flight operations in Germany with min. 8.5 hours and in Austria with 8 hours of rest time, as well as the absence of aircraft accidents in the past resulting from fatigue should serve as evidence for a further reduction. Here, the ADAC and DRF study results will provide further information as well and demonstrate that a reduction in rest time, as practised in Germany for decades, has no impact on safety.

response

Please see the answer to comment # 54



comment 1498 comment by: Finnish Transport Safety Agency In order to establish rolling 24 hour standby for HEMS, following amendments are proposed. Reasoning: Proposed rest periods are more restrictive than in the NPA for HEMS. This mitigates fatigue between the two active standby periods. **Proposal:** Add new paragraph CS FTL.3.237 after CS FTL.3.235 as follows: CS FTL.3.237 Rest periods in active standby — HEMS By way of derogation from CS FTL.3.235, the minimum rest periods in active standby are established in accordance with Table 1: Table 1 Active standby - HEMS Minimum rest period after active standby 48:00 24:00 48:00 72:00 72:00 96:00 Please see the answer to comment # 54 response

Rationale for CS-FTL.3

р. 39-41

comment	10 comment by: TG
	zu 39.: Die erforderlich Schlafmenge ist äusserst individuell - mir reichen 5h pro Tag vollkommen aus und ich bin mit 54J. kerngesund. Das Prinzip "Melde dich zur Erholung ab wenn erforderlich auch vor dem Ende des regulären Dienstes" ist effektiver. Ich habe das bereits mehrfach angewandt - der Operator ist zufrieden damit. Das erhöht die Sicherheit wirklich.
response	Please see the answer to comment # 54
comment	371 comment by: European Helicopter Association (EHA)

**** * * ***

BHA (UK)

"(38)...

CS FTL.3.230 is an adaptation of the CS-FTL.1 Reserve provisions, but for clarity includes some elements from the definition and the GM. The prescriptive limit of 21 days of reserve per crew member and per calendar year is based on the comparison of existing practices and the consensus of the rulemaking group. In the HEMS operating environment it is often found that crew members have considerable commuting distances between their residence and the HEMS operating base. "

Comment:

Seems to be a very arbitrary limit - why 21 days and not 28?

"(39)..

CS FTL.3.235 establishes reduced rest provisions that are tailored to the HEMS environment. The reduced rest periods in HEMS operations are provided on the HEMS operating base. That means, crew members do not spend any time on travelling between the HEMS operating base and the place of rest. Therefore, the minimum rest period at the HEMS operating base is set to 10 hours. This allows for an 8-hour sleep opportunity. The FDP following a reduced rest period does need to be reduced because the workload in HEMS is limited by limiting the number of flight hours per FDP and by prescribing a protected break(s) during the FDP. "

Comment:

This paragraph suggests that breaks for HEMS FDPS have been introduced as mitigation for reduced rest. The two elements should be kept separate.

response

Please see the answer to comment # 54

comment	411 comment by: ANWB MAA
	Ad 38. It states "often found" - often found but doesn't meet countries that have just short commuting distances
response	Please see the answer to comment # 54

comment 732

comment by: ÖAMTC Helicopter Air Rescue (Austria)

34. CS FTL.3.205:

34. On and off duty times are interconnected in a roster. Less on duties create less off duties in a specific period. This leads to a significant higher travel activity. Applied to our operation we had the experience that this might lead up to 2,7 times of the time used for traveling. Therefore this diverts possible free time into travel activities of the pilots (as well as spending more time on the road).

**** * **** response Please see the answer to comment # 54

233 comment by: ÖAMTC Helicopter Air Rescue (Austria)		
34 CS FTL.3.205: [] the maximum flight time for the maximum daytime FDP is limited to 7 hours with autopilot and 5 hours without autopilot[]		
4. We appreciate considering autopilot systems as a support for the flight crew. But in iew of the fact that AP systems create a complex work environment we do not understand hat not using the AP reduces average flight time up to 2 hours per day (This reduction hight not have a scientific background and seems not to be an evidenced based approach)		
Please see the answer to comment # 54		
comment by: Yorkshire Air Ambulance		
Seems to be a very arbitrary limit - why 21 days and not 28?		
Please see the answer to comment # 54		
comment by: Yorkshire Air Ambulance		
This paragraph suggests that breaks for HEMS FDPS have been introduced as mitigation for reduced rest. The two elements should be kept separate.		
lease see the answer to comment # 54		

Id. CRD table of comments, responses and resulting text – Impact Assessment (HEMS)

comment	262 c	omment by: European Helicopter Association (EHA)	
	The contents have already been doubt Even associations have shown failures have not been taken into regard by EA	tions and tables are not explained to interested parties and social impact on	

**** * * ***

This NPA when being transferred into regulation without change will lead to a requirement of additional pilots. In Germany there is not enough qualified personnel available on short notice and the training and qualification of available pilots will cost a large amount of money and take several years. The rise in costs could in the worst case even lead to a total collapse of the system implemented in Germany with unpredictable social impact concerning jobs of crew and reduction of quality in the rescue system. The impact assessment (IA) to NPA 2017-17 did not evaluate the impact of the proposed response FTL requirements for HEMS on Member States' health care and social systems from a macroeconomic perspective. Regulation (EU) No 965/2012, in general, and the FTL requirements, in particular, do not regulate social aspects, although enhanced safety requirements may result in social benefits for individuals. From a safety perspective, the IA estimated that the potential safety benefit for HEMS operators would be limited. Recognising the importance of HEMS operations for the European communities as well as the diversity in HEMS systems established in the Member States, EASA decided to separate the HEMS proposal from further rulemaking process under RMT.0492 & RMT.0493. A future common FTL framework in the domain of HEMS that provides for flexibility and continuation of existing safe practices, will likely be established under RMT.0494 FTL rules for helicopter commercial operations. Feedback from stakeholders indicates that while there is no unanimous support for RMT.0494, there is enough strong support from a significant number of stakeholders to recommend keeping the rulemaking task in the EPAS. It should be noted, however, that the analysis of fatigue-related safety events demonstrates that a direct link between fatigue, FTL and safety events is very often not evident. Fatigue cannot easily be isolated from other (human) factors that influence crew performance. Also, the investigation of fatigue can vary considerably depending on the background, expertise and focus of the safety investigator(s) involved. There is no agreed definition of a 'fatigue-related safety occurrence'. It is well known that the current system of investigation of aviation occurrences is not particularly apt to identifying *pilot fatique* as an immediate contributing factor. Member States' national regulations applicable to HEMS are in most cases the result of a political compromise. Some of these regulations may be lacking contemporary scientific understanding of human performance limitations and of sleep science. For example, transient and cumulative fatigue and its impact on circadian rhythm may not be very well addressed. On the other side, national regulations do not increase compliance costs and are, therefore, preferred by operators.

comment | 435

comment by: UFH French Helicopters Association

The impact of the implementation of European FTL regulation for HEMS in France goes beyond the French operators. It is a complete change of the whole French Health care system which might be necessary. Thus, it would be appreciated if the RIA addresses the



impacts on the national policy for emergency access to care and the Government Health policy, etc.

Many lifesavings would be impossible with the time being organization.

As a consequence, 3 options emerge and are listed here below, ranked according to their level of relevance for Frenc stakeholders

OPTION A or option 0 of the RIA

This option, whose choice relies on the Member States (MS) or EASA's decision, corresponds to the option 0 described in the RIA: no policy change. Safety impact, social impact and economic impact are neutral or having a little impact. The solution 0 is the proper answer to a one size fits all model which is not applicable to the industry. The FTL shall stay in the hand of the local authority. The wellfunctioning current national FTL schemes are enforced since years, no excessive fatigue has been demonstrated and the current national system provides French operators with satisfaction. Besides, in the EMS safety risk assessment of this NPA, it is written that "Even with the caveats about underreporting of fatigue as a causal factor it would appear from the occurrence data that the controls that have been in place to manage fatigue in European EMS have generally been effective. Compared to the social benefits from EMS operations in terms of patient safety and health (see below), the overall safety balance (flight safety v patient safety) is very positive". FNAM strongly asks this option to be considered by EASA and the Member States : "no change in the existing situation; HEMS continue to be regulated under MS national rules".

OPTION B

This option consists in a total revamp of the NPA 2017-17 for HEMS. we ask for a completely new proposal, distinguishing the HEMS from AEMS and Air Taxi as no operational comparison can be made between the fundamentals of these different activities and respecting the following principles:

• Basing an alternative proposal on:

o 14h Standby / 10h Rest with a commander's discretion applicable in case of unforeseen circumstances

o short-time operational readiness for ready-to-go EMS take-off

o rostering of 7 days ON / 7 days OFF

o flight time limitations to be discussed within this frame FNAM and SNEH ask for this option to be considered in the Comment Response Document (CRD) with the elaboration of a sound RIA. Moreover, FNAM, SNEH and UFH would be happy to offer its expertise to discuss and study this subject with EASA policy officers. Besides, for clarity reasons, this would imply to separate, regarding the FTL scope, the HEMS from CAT, Air Taxi and AEMS operations.

OPTION C

If these 2 first options are not retained, We asks for this proposed NPA to be amended and reviewed as stated in the following comments. The proposed requirements, as it is, will lead to amend Health National regulations and it will request more crew, more constraints, more costs with a low added safety value as stated in the RIA. The main proposals are laid down here below:

• The "Flight time" (instead of "sector" whose definition is now restricted to aeroplanes) in all the requirements should not be scheduled as they cannot be in real life

**** * * * *

	 The travelling time between multiple HEMS operating bases of the home base should be increased a minima to 120 minutes (instead of 60 minutes) and in case of change of home base, the ERRP after starting duty (and not the one prior to starting duty) should be increased to allow the continuity of the operations The duration of pre-flight, post-flight or inter-flights should be reduced to 15 minutes to take into account the helicopter checks at the beginning of the FDP (in France, 7%) of flights saving lives would be impossible with a 30 minutes preflight, and then 7 minutes before each take-off from the HEMS operating base. No limitations on the number of consecutive FDP lasting more than 12h should be madebetween 2 extended recovery rest periods For single-pilot + 1 TCM operations, in the case of a FDP lasting more than 10h, the break should be unscheduled and the operator should ensure ex-post that the break requirement has been fulfilled for pilots as they cannot be in real life The commander's discretion prior to take-off under unforeseen circumstances needs to be extended to all the EMS payload and not only limited to the patient and extended up to 2 hours for 1 pilot + 1 TCM operations (in France, 3%) of flights saving lives would be impossible with a commander's discretion capped to 1 hour, cf. SNEH illustrative Table in attachment) The limitations of the maximum values for continuous FT need to be increased by at least 1 hour The limitations of the maximum values for total flight time within a FDP need to be increased by at least 1 hour The 10% allowance between scheduled and actual FDP is not appropriate with the HEMS operations and needs to be suppressed The standby needs to be reviewed else it will never be used
	The 3 options all respect the general FTL philosophy and the learnings of fatigue impact assessments. This proposal would increase by 20% the French State budget allocated for the HEMS activity which is not affordable according to the French State. Since the objective of this regulation is not flight safety but the harmonization of the different national regulations regarding HEMS, the text should not have the opposite effect leading to less level playing field. If the proposed dispositions are inapplicable, there may be non-binding opt-in / opt-out system possibilities (through the newly proposed Article 8 of this NPA). Misunderstanding or interpretation of National level of a far too complex regulation for small operators might also lead to lower level playing field.
response	Please refer to the answer to comment #262.
comment	517 comment by: FNAM/SNEH

Attachments <u>#253</u> <u>#254</u> <u>#255</u> <u>#256</u> <u>#257</u>

The impact study presented in this chapter 4 makes it clear that the national provisions already enforced are effective to manage the risk of fatigue.

**** * * *** The summary tables for HEMS highlight that the effects of the proposed regulation (options 1 & 2 of the RIA) are questionable and that they would be likely to cause a loss of crew knowledge. FNAM and SNEH agree with this analysis.

Cf. comment 464

Cf. comment 457 and 521

The impact of the implementation of European FTL regulation for HEMS in France goes beyond the French operators. It is a complete change of the whole French Health care system which might be necessary. Thus, it would be appreciated if the RIA addresses the impacts on the national policy for emergency access to care and the Government Health policy, etc.

Many lifesavings would be impossible with the time being organization. (Cf. attachments S1, S2, S3 and S4)

As a consequence, 3 options emerge and are listed here below, ranked according to their level of relevance for FNAM and SNEH:

OPTION A or option 0 of the RIA

This option, whose choice relies on the Member States (MS) or EASA's decision, corresponds to the option 0 described in the RIA: no policy change. Safety impact, social impact and economic impact are neutral or having a little impact. The solution 0 is the proper answer to a one size fits all model which is not applicable to the industry. The FTL shall stay in the hand of the local authority. The well-functioning current national FTL schemes are enforced for years, no excessive fatigue has been demonstrated and the current national system provides French operators with satisfaction. Besides, in the EMS safety risk assessment of this NPA, it is written that *"Even with the caveats about underreporting of fatigue as a causal factor it would appear from the occurrence data that the controls that have been in place to manage fatigue in European EMS have generally been effective. Compared to the social benefits from EMS operations in terms of patient safety and health (see below), the overall safety balance (flight safety v patient safety) is very positive". FNAM and SNEH strongly ask this option to be considered by EASA and the Member States : <i>"no change in the existing situation; HEMS continue to be regulated under MS national rules".*

OPTION B

This option consists in a total revamp of the NPA 2017-17 for HEMS. FNAM and SNEH ask for a completely new proposal, distinguishing the HEMS from AEMS and Air Taxi as no operational comparison can be made between the fundamentals of these different activities and respecting the following principles:

- Basing an alternative proposal on:
 - 14h Standby / 10h Rest with a commander's discretion applicable in case of unforeseen circumstances
 - o short-time operational readiness for ready-to-go EMS take-off
 - rostering of 7 days ON / 7 days OFF

o flight time limitations to be discussed within this frame

FNAM and SNEH ask for this option to be considered in the Comment Response Document (CRD) with the elaboration of a sound RIA. Moreover, FNAM and SNEH would be happy to offer its expertise to discuss and study this subject with EASA policy officers. Besides, for clarity reasons, this would imply to separate, regarding the FTL scope, the HEMS from CAT, Air Taxi and AEMS operations.

OPTION C

If these 2 first options are not retained, FNAM and SNEH ask for this proposed NPA to be amended and reviewed as stated in the following comments. The proposed requirements, as it is, will lead to amend Health National regulations and it will request more crew, more constraints, more costs with a low added safety value as stated in the RIA. The main proposals are laid down here below:

- The "Flight time" (instead of "sector" whose definition is now restricted to aeroplanes) in all the requirements should not be scheduled as they cannot be in real life
- The travelling time between multiple HEMS operating bases of the home base should be increased *a minima* to 120 minutes (instead of 60 minutes) and in case of change of home base, the ERRP after starting duty (and not the one prior to starting duty) should be increased to allow the continuity of the operations
- The duration of pre-flight, post-flight or inter-flights should be suppressed and replaced by "a sufficient time determined by the operator and specified in the operating manual" (in France, 7%ⁱ of flights saving lives would be impossible with a 30 minutes preflight, cf. SNEH illustrative Table in attachment) No limitations on the number of consecutive FDP lasting more than 12h should be made between 2 extended recovery rest periods
- For single-pilot + 1 TCM operations, in the case of a FDP lasting more than 10h, the break should be unscheduled and the operator should ensure ex-post that the break requirement has been fulfilled for pilots as they cannot be in real life
- The commander's discretion prior to take-off under unforeseen circumstances needs to be extended to all the EMS payload and not only limited to the patient and extended up to 2 hours for 1 pilot + 1 TCM operations (in France, 3%ⁱ of flights saving lives would be impossible with a commander's discretion capped to 1 hour, cf. SNEH illustrative Table in attachment)
- The limitations of the maximum values for continuous FT need to be increased by at least 1 hour
- The limitations of the maximum values for total flight time within a FDP need to be increased by at least 1 hour
- The 10% allowance between scheduled and actual FDP is not appropriate with the HEMS operations and needs to be suppressed

• The standby needs to be reviewed else it will never be used

The 3 options all respect the general FTL philosophy and the learnings of fatigue impact assessments. This proposal would increase by 20% the French State budget allocated for the HEMS activity which is not affordable according to the French State.

Since the objective of this regulation is not flight safety but the harmonization of the different national regulations regarding HEMS, the text should not have the opposite effect leading to less level playing field. If the proposed dispositions are inapplicable, there may be non-binding opt-in / opt-out system possibilities (through the newly proposed Article 8 of this NPA). Misunderstanding or interpretation of National level of a far too complex regulation for small operators might also lead to lower level playing field.

response

Please refer to the answer to comment #262.

comment	542comment by: ADAC Luftrettung gGmbH
	The contents have already been doubted and partially contradicted during RMT phase. Even associations have shown failures during the assessment, nevertheless these inputs have not been taken into regard by EASA.
	Time calculations and tables are not explained to interested parties and social impact on crews is not mentioned and accounted for at all.
	This NPA when being transferred into regulation without change will lead to a requirement of additional pilots. In Germany there is not enough qualified personnel available on short notice and the training and qualification of available pilots will cost a large amount of money and take several years. The rise in costs could in the worst case even lead to a total collapse of the system implemented in Germany with unpredictable social impact concerning jobs of crew and reduction of quality in the rescue system.
response	Please refer to the answer to comment #262.

comment	<i>563</i> comment by: <i>Rüdiger Neu</i>
	Die Inhalte des Assessment wurden schon in der RMT-Phase teilweise wiederlegt und angezweifelt. Sogar Verbände haben auf Fehler im Assessment hingewiesen, dennoch wurde dies von der EASA ignoriert.
	Die Kalkulationen und Tabellen sind für den Laien nicht nachvollziehbar, außerdem wird der soziale Aspekt der Betroffenen Besatzungsmitglieder nicht ernsthaft beleuchtet. Erkennbar ist, dass die Anzahl der benötigten Besatzungsmitglieder bei einer Umsetzung dieser NPA sehr stark ansteigen würde. Ob genügend qualifiziertes Personal zu Verfügung stehen würde ist zu bezweifeln, entsprechendes Personal auszubilden und zu qualifizieren würde mehrere Jahre in Anspruch nehmen. Außerdem würden die Kosten enorm steigen, was in letzter Konsequenz, wenn dies nicht mehr bezahlt werden würde, zum Kollaps des
_	HEMS System führen könnte. Please refer to the answer to comment #262.

comment 696 comment by: Oya Vendée Hélicoptères Attachments #258 #259 #260 #261 #262 The impact study presented in this chapter 4 makes it clear that the national provisions already enforced are effective to manage the risk of fatigue. The summary tables for HEMS highlight that the effects of the proposed regulation (options 1 & 2 of the RIA) are questionable and that they would be likely to cause a loss of crew knowledge. OYA agrees with this analysis. Cf. comment 644 *** Cf. comment 637 and 700 The impact of the implementation of European FTL regulation for HEMS in France goes beyond the French operators. It is a complete change of the whole French Health care system which might be necessary. Thus, it would be appreciated if the RIA addresses the impacts on the national policy for emergency access to care and the Government Health policy, etc. Many lifesavings would be impossible with the time being organization. (Cf. attachments S1, S2, S3 and S4) As a consequence, 3 options emerge and are listed here below, ranked according to their level of relevance for OYA: # OPTION A or option 0 of the RIA This option, whose choice relies on the Member States (MS) or EASA's decision, corresponds to the option 0 described in the RIA: no policy change. Safety impact, social impact and economic impact are neutral or having a little impact. The solution 0 is the proper answer to a one size fits all model which is not applicable to the industry. The FTL shall stay in the hand of the local authority. The well-functioning current national FTL schemes are enforced for years, no excessive fatigue has been demonstrated and the current national system provides French operators with satisfaction. Besides, in the EMS safety risk assessment of this NPA, it is written that "Even with the caveats about underreporting of fatigue as a causal factor it would appear from the occurrence data that the controls that have been in place to manage fatigue in European EMS have generally been effective. Compared to the social benefits from EMS operations in terms of patient safety and health (see below), the overall safety balance (flight safety v patient safety) is very positive". OYA strongly asks this option to be considered by EASA and the Member States : "no change in the existing situation; HEMS continue to be regulated under MS national rules". **# OPTION B** This option consists in a total revamp of the NPA 2017-17 for HEMS. OYA asks for a completely new proposal, distinguishing the HEMS from AEMS and Air Taxi as no operational comparison can be made between the fundamentals of these different

activities and respecting the following principles:

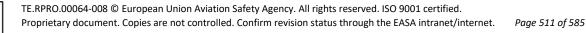
- Basing an alternative proposal on:
 - 14h Standby / 10h Rest with a commander's discretion applicable in case of unforeseen circumstances
 - o short-time operational readiness for ready-to-go EMS take-off
 - rostering of 7 days ON / 7 days OFF
 - flight time limitations to be discussed within this frame

OYA asks for this option to be considered in the Comment Response Document (CRD) with the elaboration of a sound RIA. Moreover, OYA would be happy to offer its expertise to discuss and study this subject with EASA policy officers. Besides, for clarity reasons, this would imply to separate, regarding the FTL scope, the HEMS from CAT, Air Taxi and AEMS operations.

OPTION C

If these 2 first options are not retained, OYA asks for this proposed NPA to be amended and reviewed as stated in the following comments. The proposed requirements, as it is, will lead to amend Health National regulations and it will request more crew, more constraints, more costs with a low added safety value as stated in the RIA. The main proposals are laid down here below:

- The "Flight time" (instead of "sector" whose definition is now restricted to aeroplanes) in all the requirements should not be scheduled as they cannot be in real life
- The travelling time between multiple HEMS operating bases of the home base should be increased *a minima* to 120 minutes (instead of 60 minutes) and in case of change of home base, the ERRP after starting duty (and not the one prior to starting duty) should be increased to allow the continuity of the operations
- The duration of pre-flight, post-flight or inter-flights should be suppressed and replaced by "a sufficient time determined by the operator and specified in the operating manual" (in France, 7%ⁱ of flights saving lives would be impossible with a 30 minutes preflight, cf. SNEH illustrative Table in attachment) No limitations on the number of consecutive FDP lasting more than 12h should be made between 2 extended recovery rest periods
- For single-pilot + 1 TCM operations, in the case of a FDP lasting more than 10h, the break should be unscheduled and the operator should ensure ex-post that the break requirement has been fulfilled for pilots as they cannot be in real life
- The commander's discretion prior to take-off under unforeseen circumstances needs to be extended to all the EMS payload and not only limited to the patient and extended up to 2 hours for 1 pilot + 1 TCM operations (in France, 3%ⁱ of flights saving lives would be impossible with a commander's discretion capped to 1 hour, cf. SNEH illustrative Table in attachment)
- The limitations of the maximum values for continuous FT need to be increased by at least 1 hour
- The limitations of the maximum values for total flight time within a FDP need to be increased by at least 1 hour
- The 10% allowance between scheduled and actual FDP is not appropriate with the HEMS operations and needs to be suppressed



• The standby needs to be reviewed else it will never be used

The 3 options all respect the general FTL philosophy and the learnings of fatigue impact assessments. This proposal would increase by 20% the French State budget allocated for the HEMS activity which is not affordable according to the French State.

Since the objective of this regulation is not flight safety but the harmonization of the different national regulations regarding HEMS, the text should not have the opposite effect leading to less level playing field. If the proposed dispositions are inapplicable, there may be non-binding opt-in / opt-out system possibilities (through the newly proposed Article 8 of this NPA). Misunderstanding or interpretation of National level of a far too complex regulation for small operators might also lead to lower level playing field.

response

Please refer to the answer to comment #262.

comment	985 comment by: MBH SAMU
	Attachments <u>#263</u> <u>#264</u> <u>#265</u> <u>#266</u> <u>#267</u>
	The impact study presented in this chapter 4 makes it clear that the national provisions already enforced are effective to manage the risk of fatigue. The summary tables for HEMS highlight that the effects of the proposed regulation (options 1 & 2 of the RIA) are questionable and that they would be likely to cause a loss of crew knowledge. MBH agrees with this analysis.
	Cf. comment 913

	Cf. comment 1006 and 989
	The impact of the implementation of European FTL regulation for HEMS in France goes beyond the French operators. It is a complete change of the whole French Health care system which might be necessary. Thus, it would be appreciated if the RIA addresses the impacts on the national policy for emergency access to care and the Government Health policy, etc.
	Many lifesavings would be impossible with the time being organization. (Cf. attachments S1, S2, S3 and S4)
	As a consequence, 3 options emerge and are listed here below, ranked according to their level of relevance for MBH:
	# OPTION A or option 0 of the RIA This option, whose choice relies on the Member States (MS) or EASA's decision, corresponds to the option 0 described in the RIA: no policy change. Safety impact, social impact and economic impact are neutral or having a little impact. The solution 0 is the proper answer to a one size fits all model which is not applicable to the industry. The FTL



shall stay in the hand of the local authority. The well-functioning current national FTL schemes are enforced for years, no excessive fatigue has been demonstrated and the current national system provides French operators with satisfaction. Besides, in the EMS safety risk assessment of this NPA, it is written that *"Even with the caveats about under-reporting of fatigue as a causal factor it would appear from the occurrence data that the controls that have been in place to manage fatigue in European EMS have generally been effective. Compared to the social benefits from EMS operations in terms of patient safety and health (see below), the overall safety balance (flight safety v patient safety) is very positive". MBH strongly asks this option to be considered by EASA and the Member States : "no change in the existing situation; HEMS continue to be regulated under MS national rules".*

OPTION B

This option consists in a total revamp of the NPA 2017-17 for HEMS. MBH asks for a completely new proposal, distinguishing the HEMS from AEMS and Air Taxi as no operational comparison can be made between the fundamentals of these different activities and respecting the following principles:

- Basing an alternative proposal on:
 - 14h Standby / 10h Rest with a commander's discretion applicable in case of unforeseen circumstances
 - o short-time operational readiness for ready-to-go EMS take-off
 - rostering of 7 days ON / 7 days OFF
 - flight time limitations to be discussed within this frame

MBH asks for this option to be considered in the Comment Response Document (CRD) with the elaboration of a sound RIA. Moreover, MBH would be happy to offer its expertise to discuss and study this subject with EASA policy officers. Besides, for clarity reasons, this would imply to separate, regarding the FTL scope, the HEMS from CAT, Air Taxi and AEMS operations.

OPTION C

If these 2 first options are not retained, MBH asks for this proposed NPA to be amended and reviewed as stated in the following comments. The proposed requirements, as it is, will lead to amend Health National regulations and it will request more crew, more constraints, more costs with a low added safety value as stated in the RIA. The main proposals are laid down here below:

- The "Flight time" (instead of "sector" whose definition is now restricted to aeroplanes) in all the requirements should not be scheduled as they cannot be in real life
- The travelling time between multiple HEMS operating bases of the home base should be increased *a minima* to 120 minutes (instead of 60 minutes) and in case of change of home base, the ERRP after starting duty (and not the one prior to starting duty) should be increased to allow the continuity of the operations
- The duration of pre-flight, post-flight or inter-flights should be suppressed and replaced by "a sufficient time determined by the operator and specified in the operating manual" (in France, 7%ⁱ of flights saving lives would be impossible with

a 30 minutes preflight, cf. SNEH illustrative Table in attachment) No limitations on the number of consecutive FDP lasting more than 12h should be made between 2 extended recovery rest periods For single-pilot + 1 TCM operations, in the case of a FDP lasting more than 10h, the break should be unscheduled and the operator should ensure ex-post that the break requirement has been fulfilled for pilots as they cannot be in real life The commander's discretion prior to take-off under unforeseen circumstances needs to be extended to all the EMS payload and not only limited to the patient and extended up to 2 hours for 1 pilot + 1 TCM operations (in France, 3%ⁱ of flights saving lives would be impossible with a commander's discretion capped to 1 hour, cf. SNEH illustrative Table in attachment) The limitations of the maximum values for continuous FT need to be increased by at least 1 hour The limitations of the maximum values for total flight time within a FDP need to be increased by at least 1 hour The 10% allowance between scheduled and actual FDP is not appropriate with the HEMS operations and needs to be suppressed The standby needs to be reviewed else it will never be used The 3 options all respect the general FTL philosophy and the learnings of fatigue impact assessments. This proposal would increase by 20% the French State budget allocated for the HEMS activity which is not affordable according to the French State. Since the objective of this regulation is not flight safety but the harmonization of the different national regulations regarding HEMS, the text should not have the opposite effect leading to less level playing field. If the proposed dispositions are inapplicable, there may be non-binding opt-in / opt-out system possibilities (through the newly proposed Article 8 of this NPA). Misunderstanding or interpretation of National level of a far too complex regulation for small operators might also lead to lower level playing field. Please refer to the answer to comment #262. response

comment 1022

comment by: European Cockpit Association

The European HEMS operating patterns are highly diversified (not only between countries, but also within countries) and have been developed and matured over a long period of time. The diversified operating patterns are necessary to perform safe and affordable HEMS operations in very different operating environments and in accordance with different requirements. Harmonizing and standardizing to a degree proposed by the NPA 2017_17, might be a wrong way to go unless the harmonization and standardization is at a framework level where the actual details are left up to the national authorities.

We fear that the NPA, as far as the HEMS operations are concerned, has been based on insufficient data, an incomplete pre-RIA report by DNV and very few relevant scientific publications concerning fatigue in HEMS. Such approach risks failing to cover all aspects of risk of fatigue in all European HEMS operations.

**** * * *...* We furthermore fear that the new FTL requirements for HEMS as envisioned in the NPA, will not meet the requirements of most operators and to continue their operation in the usual manner, the operators will apply for individual schemes and use the Regulation (EC) No 216/2008 Article 14-6 or 22-2 flexibility provision (e.g. applying for an Individual Flight Time Specification Scheme (i.e. Option 1 – Flexible approach).

Therefore, while we agree with the principles of the objective of the NPA 2017-17, we believe that harmonization and standardization will not be achieved by the approach presented in this draft.

response

Please refer to the answer to comment #262.

comment	1090 comment by: Stephanie Selim
	HEMS operations :
	DGAC would like the requirement of a "suitable accommodation" in HEMS to be assessed. Indeed, in France, hospitals provide individual rooms for HEMS pilots and TCM in the hospital which fulfil almost all requirements of a "suitable accommodation" but not the totality of them, mainly device for regulating temperature. Providing "suitable accommodation" for HEMS pilots and TCM would be a supplementary cost which should be assessed with a costs-benefits analysis.
response	Please refer to the answer to comment #262.

comment	1246 comment by: SAF
	Attachments <u>#268</u> <u>#269</u> <u>#270</u> <u>#271</u> <u>#272</u>
	The impact study presented in this chapter 4 makes it clear that the national provisions already enforced are effective to manage the risk of fatigue.
	The summary tables for HEMS highlight that the effects of the proposed regulation (options 1 & 2 of the RIA) are questionable and that they would be likely to cause a loss of crew knowledge. SAF agrees with this analysis.
	Cf. comment 1185

	Cf. comment 1178 and 1250
	The impact of the implementation of European FTL regulation for HEMS in France goes beyond the French operators. It is a complete change of the whole French Health care system which might be necessary. Thus, it would be appreciated if the RIA addresses the

impacts on the national policy for emergency access to care and the Government Health policy, etc.

Many lifesavings would be impossible with the time being organization.

(Cf. attachments S1, S2, S3 and S4)

As a consequence, 3 options emerge and are listed here below, ranked according to their level of relevance for SAF:

OPTION A or option 0 of the RIA

This option, whose choice relies on the Member States (MS) or EASA's decision, corresponds to the option 0 described in the RIA: no policy change. Safety impact, social impact and economic impact are neutral or having a little impact. The solution 0 is the proper answer to a one size fits all model which is not applicable to the industry. The FTL shall stay in the hand of the local authority. The well-functioning current national FTL schemes are enforced for years, no excessive fatigue has been demonstrated and the current national system provides French operators with satisfaction. Besides, in the EMS safety risk assessment of this NPA, it is written that *"Even with the caveats about underreporting of fatigue as a causal factor it would appear from the occurrence data that the controls that have been in place to manage fatigue in European EMS have generally been effective. Compared to the social benefits from EMS operations in terms of patient safety and health (see below), the overall safety balance (flight safety v patient safety) is very positive". SAF strongly asks this option to be considered by EASA and the Member States : "no change in the existing situation; HEMS continue to be regulated under MS national rules".*

OPTION B

This option consists in a total revamp of the NPA 2017-17 for HEMS. SAF asks for a completely new proposal, distinguishing the HEMS from AEMS and Air Taxi as no operational comparison can be made between the fundamentals of these different activities and respecting the following principles:

- Basing an alternative proposal on:
 - 14h Standby / 10h Rest with a commander's discretion applicable in case of unforeseen circumstances
 - o short-time operational readiness for ready-to-go EMS take-off
 - rostering of 7 days ON / 7 days OFF
 - o flight time limitations to be discussed within this frame

SAF asks for this option to be considered in the Comment Response Document (CRD) with the elaboration of a sound RIA. Moreover, SAF would be happy to offer its expertise to discuss and study this subject with EASA policy officers. Besides, for clarity reasons, this would imply to separate, regarding the FTL scope, the HEMS from CAT, Air Taxi and AEMS operations.

****, TE**.F

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

OPTION C

If these 2 first options are not retained, SAF asks for this proposed NPA to be amended and reviewed as stated in the following comments. The proposed requirements, as it is, will lead to amend Health National regulations and it will request more crew, more constraints, more costs with a low added safety value as stated in the RIA. The main proposals are laid down here below:

- The "Flight time" (instead of "sector" whose definition is now restricted to aeroplanes) in all the requirements should not be scheduled as they cannot be in real life
- The travelling time between multiple HEMS operating bases of the home base should be increased *a minima* to 120 minutes (instead of 60 minutes) and in case of change of home base, the ERRP after starting duty (and not the one prior to starting duty) should be increased to allow the continuity of the operations
- The duration of pre-flight, post-flight or inter-flights should be suppressed and replaced by "a sufficient time determined by the operator and specified in the operating manual" (in France, 7%ⁱ of flights saving lives would be impossible with a 30 minutes preflight, cf. SNEH illustrative Table in attachment) No limitations on the number of consecutive FDP lasting more than 12h should be made between 2 extended recovery rest periods
- For single-pilot + 1 TCM operations, in the case of a FDP lasting more than 10h, the break should be unscheduled and the operator should ensure ex-post that the break requirement has been fulfilled for pilots as they cannot be in real life
- The commander's discretion prior to take-off under unforeseen circumstances needs to be extended to all the EMS payload and not only limited to the patient and extended up to 2 hours for 1 pilot + 1 TCM operations (in France, 3%ⁱ of flights saving lives would be impossible with a commander's discretion capped to 1 hour, cf. SNEH illustrative Table in attachment)
- The limitations of the maximum values for continuous FT need to be increased by at least 1 hour
- The limitations of the maximum values for total flight time within a FDP need to be increased by at least 1 hour
- The 10% allowance between scheduled and actual FDP is not appropriate with the HEMS operations and needs to be suppressed
- The standby needs to be reviewed else it will never be used

The 3 options all respect the general FTL philosophy and the learnings of fatigue impact assessments. This proposal would increase by 20% the French State budget allocated for the HEMS activity which is not affordable according to the French State.

Since the objective of this regulation is not flight safety but the harmonization of the different national regulations regarding HEMS, the text should not have the opposite effect leading to less level playing field. If the proposed dispositions are inapplicable, there may be non-binding opt-in / opt-out system possibilities (through the newly proposed Article 8

of this NPA). Misunderstanding or interpretation of National level of a far too complex regulation for small operators might also lead to lower level playing field. Please refer to the answer to comment #262. response comment 1294 comment by: Hélicoptères de France The impact study presented in this chapter 4 makes it clear that the national provisions already enforced are effective to manage the risk of fatigue. The summary tables for HEMS highlight that the effects of the proposed regulation (options 1 & 2 of the RIA) are questionable and that they would be likely to cause a loss of crew knowledge. HDF agrees with this analysis. Cf. comment 7 *** Cf. comment 1 and 64 The impact of the implementation of European FTL regulation for HEMS in France goes beyond the French operators. It is a complete change of the whole French Health care system which might be necessary. Thus, it would be appreciated if the RIA addresses the impacts on the national policy for emergency access to care and the Government Health policy, etc. Many lifesavings would be impossible with the time being organization. (Cf. attachments S1, S2, S3 and S4) As a consequence, 3 options emerge and are listed here below, ranked according to their level of relevance for HDF: # OPTION A or option 0 of the RIA This option, whose choice relies on the Member States (MS) or EASA's decision, corresponds to the option 0 described in the RIA: no policy change. Safety impact, social impact and economic impact are neutral or having a little impact. The solution 0 is the proper answer to a one size fits all model which is not applicable to the industry. The FTL shall stay in the hand of the local authority. The wellfunctioning current national FTL schemes are enforced since years, no excessive fatigue has been demonstrated and the current national system provides French operators with satisfaction. Besides, in the EMS safety risk assessment of this NPA, it is written that "Even with the caveats about underreporting of fatigue as a causal factor it would appear from the occurrence data that the controls that have been in place to manage fatigue in European EMS have generally been effective. Compared to the

social benefits from EMS operations in terms of patient safety and health (see below), the overall safety

balance (flight safety v patient safety) is very positive". HDF strongly asks this option to be considered by EASA and the Member States : "no change in the existing situation; HEMS continue to

be regulated under MS national rules".

OPTION B

This option consists in a total revamp of the NPA 2017-17 for HEMS. HDF asks for a completely new proposal, distinguishing the HEMS from AEMS and Air Taxi as no operational

comparison can be made between the fundamentals of these different activities and respecting the

following principles:

• Basing an alternative proposal on:

o 14h Standby / 10h Rest with a commander's discretion applicable in case of unforeseen circumstances

o short-time operational readiness for ready-to-go EMS take-off

o rostering of 7 days ON / 7 days OFF

o flight time limitations to be discussed within this frame

HDF asks for this option to be considered in the Comment Response Document (CRD) with the elaboration of a sound RIA. Moreover, HDF would be happy to offer its expertise to discuss and study this subject with EASA policy officers. Besides, for clarity reasons, this would imply

to separate, regarding the FTL scope, the HEMS from CAT, Air Taxi and AEMS operations.

OPTION C

If these 2 first options are not retained, HDF asks for this proposed NPA to be amended and

reviewed as stated in the following comments. The proposed requirements, as it is, will lead to amend

Health National regulations and it will request more crew, more constraints, more costs with a low

added safety value as stated in the RIA. The main proposals are laid down here below:

• The "Flight time" (instead of "sector" whose definition is now restricted to aeroplanes) in all

the requirements should not be scheduled as they cannot be in real life

• The travelling time between multiple HEMS operating bases of the home base should be increased a minima to 120 minutes (instead of 60 minutes) and in case of change of home base, the ERRP after starting duty (and not the one prior to starting duty) should be increased

to allow the continuity of the operations

• The duration of pre-flight, post-flight or inter-flights should be suppressed and replaced by "a

sufficient time determined by the operator and specified in the operating manual" (in France,

7%i of flights saving lives would be impossible with a 30 minutes preflight, cf. SNEH illustrative

Table in attachment) No limitations on the number of consecutive FDP lasting more than 12h



should be made between 2 extended recovery rest periods

• For single-pilot + 1 TCM operations, in the case of a FDP lasting more than 10h, the break should be unscheduled and the operator should ensure ex-post that the break requirement has been fulfilled for pilots as they cannot be in real life

• The commander's discretion prior to take-off under unforeseen circumstances needs to be

extended to all the EMS payload and not only limited to the patient and extended up to 2 hours for 1 pilot + 1 TCM operations (in France, 3%i of flights saving lives would be impossible

with a commander's discretion capped to 1 hour, cf. SNEH illustrative Table in attachment)
The limitations of the maximum values for continuous FT need to be increased by at least

1

hour

• The limitations of the maximum values for total flight time within a FDP need to be increased

by at least 1 hour

• The 10% allowance between scheduled and actual FDP is not appropriate with the HEMS operations and needs to be suppressed

• The standby needs to be reviewed else it will never be used

The 3 options all respect the general FTL philosophy and the learnings of fatigue impact assessments.

This proposal would increase by 20% the French State budget allocated for the HEMS activity which is

not affordable according to the French State.

Since the objective of this regulation is not flight safety but the harmonization of the different national

regulations regarding HEMS, the text should not have the opposite effect leading to less level playing

field. If the proposed dispositions are inapplicable, there may be non-binding opt-in / opt-out system

possibilities (through the newly proposed Article 8 of this NPA). Misunderstanding or interpretation of

National level of a far too complex regulation for small operators might also lead to lower level playing

response

field.

Please refer to the answer to comment #262.

comment 1408

comment by: Swiss Air-Ambulance Rega

The content of the assessment was already partially refuted and questioned in the RMT phase. Even associations pointed out errors in the assessment, but EASA ignored this.

The calculations and tables are not comprehensible for laypersons, and moreover, the social aspect of the affected crew members is not seriously addressed.

It is apparent that the number of required crew members would increase significantly if

**** * * *** this NPA were to be implemented. It is doubtful whether there would be enough qualified personnel, and it would take several years to train appropriate personnel and ensure that they had the right qualifications. Moreover, the costs would increase enormously, which could ultimately lead to the collapse of the HEMS system, if it can no longer be paid for.

response

Please refer to the answer to comment #262.

4. IA - 4.1. What is the issue

p. 47-53

comment | 12

comment by: TG

4.1.4.: Daten seit 1971 sind irrelevant. Es hat sich viel getan in Sachen Training (CRM, Simulatoren etc.) und der Qualität und Leistung der eingesetzten Hubschrauber, sodass Jahrzehnte alte Vorgänge nicht in Betracht gezogen werden dürfen.

Bei Unfällen ist der Faktor Fatigue immer nur "possibly contributary". Das kann er auch dann sein, wenn die Crew aus anderen als dienstlichen Gründen "unfit to fly" ist. Wieviele Stunden darf ein Pilot arbeiten, der private aber realistische Zusatzbelastungen (Scheidung, krankes Kind, Geldsorgen etc.) hat? Ab wann Müdigkeit oder Arbeitsbelastung nicht mehr durch verändertes Verhalten kompensiert werden kann wird nicht erfasst. Tagesformabhängig wird jeder Pilot die richtige Enscheidung ob und wie er den Flug durchführt treffen müssen.

Die HEMS-Arbeit ist viel zu komplex um sie durch Formen und Zahlen sicherer machen zu können. Je komplizierter die Regelwerke werden, desto mehr Kapazitäten gehen dadurch verloren, herauszufinden ob ein Flug z.B. aus FTL-Gründen überhaupt noch angetreten werden darf. Das ist jetzt noch beherrschbar, wird aber mit dem vorliegenden Entwurf ein Desaster.

response

Please refer to the answer to comment #262.

comment	179 comment by: Marc Rothenhäusler
	Mehrere Verbände haben auf Fehler im Assessment hingedeutet, welche von der EASA ignoriert wurden. Soziale Aspekte und die Work-Life-Balance der Crewmitglieder werden in keinster Weise
	berücksichtigt. Die Forderungen die von Seiten der EASA vorgesehen sind, würden einen enormen Anstieg und Bedarf an Personal bedeuten! Qualifiziertes Personal in der Menge zu bekommen und bzw. auszubilden würde Jahre dauern. Des Weiteren würde es zu einem enormen Kostenanstieg führen was zu bezweifeln ist, dass dies die Krankenkassen tragen würden. Mit der Gefahr, dass die Luftrettung und HEMS zum Erliegen bringen könnte!
response	Please refer to the answer to comment #262.

comment	373 comment by: European Helicopter Association (EHA)
	BHA (UK)
	"Page 49: Shared cost model – some EMS operators share aircraft, pilots and facilities with other organisations. Examples include the UK's Wiltshire and Sussex Air Ambulance services which part share their helicopter operations with the Police. "
	<i>Comment:</i> This information is no longer correct and should be removed.
	"Page 49: Whether medical staff are included within the overall personnel costs of an EMS operator or whether they are outside funded within health care services; "
	<i>Comment:</i> This is predominantly the UK model, but is not adequately addressed by this NPA.
response	Please refer to the answer to comment #262.

comment	374 comment by: European Helicopter Association (EHA)
	BHA (UK)
	Page 52 4.1.4.1. 'EMS operations have certain higher risk characteristics relative to other aircraft operations such as time pressures to reach and transport patients and flights made at short notice with potentially challenging topographical features and weather conditions. In addition there are aspects of flight time limitations and rest provisions that could lead to fatigue and increased risk, e.g. requirements to extend a duty period to respond to an emergency.'
	<i>Comment:</i> Agreed, yet this NPA impacts negatively on existing FTLs that have been tested over many years and approved by national authorities.
	"One event from 2005 in the UK (described in Appendix I) reveals the potential difficulty of pilots on home standby managing their rest so that they do not become excessively fatigued when they are called out, particularly at night. Another occurrence was also related to a pilot remaining awake all day before a helicopter nighttime shift. "
	<i>Comment:</i> Regulations can only provide the facility for crews to rest, but are unable to mandate that pilots actually take it.



	"-EC-IBA, Spain, 2012-08-02, fatal accident, 2 fatalities, aircraft crashed on approach in heavy fog condition: 'The ultimate cause of the accident could not be determined. [] The contributing factors were: [] the fatigue built up over"
	Comment: Both F/W, and one of them occurring in thick fog.
response	Please refer to the answer to comment #262.

392 comment comment by: European Helicopter Association (EHA) NORSK LUFTAMBULANSE AS (Norway): "EMS operations have certain higher risk characteristics relative to other aircraft operations such as time pressures to reach and transport patients and flights made at short notice with potentially challenging topographical features and weather conditions. In addition there are aspects of flight time limitations and rest provisions that could lead to fatigue and increased risk, e.g. requirements to extend a duty period to respond to an emergency."" **Comment:** This is true, however, EASA has acknowledged, and it is also indicated in this NPA, that there are no indications that the existing FTL requirements for HEMS under National authority approvals, poses a flight safety problem. The only goal is merely to harmonize and standardize. It seems like the only way of doing so is to use specified numbers, robust regulation with a huge safety buffer to protect against all possible risk for fatigue. While the new EMS FTL requirements won't only be too conservative for many HEMS operators and in many cases be detrimental to the safety of the operations, it will also have a negative impact on social aspects for the patients, the public, the crew members and the "customers" (the patients). The European HEMS operating patterns are highly diversified (not only between countries, but also within countries, and have been developed and matured over a long period of time. The diversified operating patterns are necessary to perform safe and affordable HEMS operations in very different operating environments and in accordance with different customer requirements. By following the regulation in this NPA, there will be increased level of fatigue for many crew members and a lower level of flight-recency. Furthermore, finding suitably experienced crew member will be a significant challenge for many operators "- F-GXES, French Antilles, 2012-05-05, fatal accident, 4 fatalities, aircraft crashed in sea shortly after take-off: 'The causes of the accident cannot be determined with any certainty. However, the almost permanent standby status used in single-pilot operations and the underlying risk of fatigue can be considered a contributing factor.' - EC-IBA, Spain, 2012-08-02, fatal accident, 2 fatalities, aircraft crashed on approach in heavy fog condition: 'The ultimate cause of the accident could not be determined. [...] The contributing factors were: [...] the fatigue built up over the course of working at a time when they should have been sleeping after an unplanned duty period.' "

Comment: These are FW accidents and while fatigue was an issue, neither of these are apparently relevant for (a well-managed) HEMS operation.

response Plea

Please refer to the answer to comment #262.

comment 412

comment by: ANWB MAA

As the HEMS operation are highly effected by local circumstances (commuting distances, duration average flight, remote areas, number of missions a day) it would be more feasible and make more sense to have a national FTL that will be applicable to all HEMS operators operating in that specific country. This FTL should be a performance based FTL (see option 1 next page)

response Please refer to the answer to comment #262.

comment	436 comment by: UFH French Helicopters Association
	The well-functioning current national FTL schemes are enforced since years, no excessive fatigue has
	been demonstrated and the current national system provides French operators with satisfaction.
	Besides, in the EMS safety risk assessment of this NPA, it is written that "Even with the caveats about
	under-reporting of fatigue as a causal factor it would appear from the occurrence data that the controls
	that have been in place to manage fatigue in European EMS have generally been effective.
	Compared to the social benefits from EMS operations in terms of patient safety and health (see below), the overall
	safety balance (flight safety v patient safety) is very positive". The proposed requirements, as it is, will lead to amend Health National regulations and it
	will request more staff, more constraints, more costs without any safety added value. Indeed, HEMS
	pilots are scarce resources in France, and this NPA would lead to hire 120 additional pilots and 120
	additional
	TCM in order to offer the same quality of HEMS activity in France. This represents an additional cost of
	20% for the whole French HEMS State Budget. It is likely that such a massive recruitment would not be
	achievable and would thus result in a significant reduction in the quality of the French Healthcare
	system. We thinks it would be beneficial to further develop the economic, social, emergency access to care
	and national health policy impacts in addition to the flight safety impact. For illustrative purposes, in France, during recent Millas train disaster on December, the

**** * * ***

	14th of 2017, it would have been neither politically nor socially acceptable if the airlift performed under a public service delegation was not implemented to take care of the victims because of an inadequate European regulation. The slightest loss of life chance of survival of a patient is unacceptable. Hence, UFH would like national impacts regarding healthcare organization to be considered by the Agency.
response	Please refer to the answer to comment #262.
comment	518 comment by: FNAM/SNEH
	The well-functioning current national FTL schemes are enforced for years, no excessive fatigue has been demonstrated and the current national system provides French operators with satisfaction. Besides, in the EMS safety risk assessment of this NPA, it is written that <i>"Even with the caveats about under-reporting of fatigue as a causal factor it would appear from the occurrence data that the controls that have been in place to manage fatigue in European EMS have generally been effective. Compared to the social benefits from EMS operations in terms of patient safety and health (see below), the overall safety balance (flight safety v patient safety) is very positive".</i>
	The proposed requirements, as it is, will lead to amend Health National regulations and it will request more staff, more constraints, more costs without any safety added value. Indeed, HEMS pilots are scarce resources in France, and this NPA would lead to hire 120 additional pilots and 120 additional TCM in order to offer the same quality of HEMS activity in France. This represents an additional cost of 20% for the whole French HEMS State Budget. It is likely that such a massive recruitment would not be achievable and would thus result in a significant reduction in the quality of the French Healthcare system. FNAM and SNEH think it would be beneficial to further develop the economic, social, emergency access to care and national health policy impacts in addition to the flight safety impact.
	For illustrative purposes, in France, during recent Millas train disaster on December, the 14 th of 2017, it would have been neither politically nor socially acceptable if the airlift performed under a public service delegation was not implemented to take care of the victims because of an inadequate European regulation. The slightest loss of life chance of survival of a patient is unacceptable.
	Hence, FNAM and SNEH would like national impacts regarding healthcare organization to be considered by the Agency.
response	Please refer to the answer to comment #262.
comment	601 comment by: NOLAS



4.1.4.1 EMS Safety risk assessment (DNV assessment)

"'EMS operations have certain higher risk characteristics relative to other aircraft operations such as time pressures to reach and transport patients and flights made at short notice with potentially challenging topographical features and weather conditions. In addition there are aspects of flight time limitations and rest provisions that could lead to fatigue and increased risk, e.g. requirements to extend a duty period to respond to an emergency."

Comment: This is true, however, EASA has acknowledged, and it is also indicated in this NPA, that there are no indications that the existing FTL requirements for HEMS under National authority approvals, poses a flight safety problem. The only goal is merely to harmonize and standardize. It seems like the only way of doing so is to use specified numbers, robust regulation with a huge safety buffer to protect against all possible risk for fatigue. While the new EMS FTL requirements won't only be too conservative for many HEMS operators and in many cases be detrimental to the safety of the operations, it will also have a negative impact on social aspects for the patients, the public, the crew members and the "customers" (the patients). The European HEMS operating patterns are highly diversified (not only between countries, but also within countries, and have been developed and matured over a long period of time. The diversified operating patterns are necessary to perform safe and affordable HEMS operations in very different operating environments and in accordance with different customer requirements. By following the regulation in this NPA, there will be increased level of fatigue for many crew members and a lower level of flight-recency. Furthermore, finding suitably experienced crew member will be a significant challenge for many operators.

response Ple

Please refer to the answer to comment #262.

comment	602 comment by: NOLAS
	 "— F-GXES, French Antilles, 2012-05-05, fatal accident, 4 fatalities, aircraft crashed in sea shortly after take-off: 'The causes of the accident cannot be determined with any certainty. However, the almost permanent standby status used in single-pilot operations and the underlying risk of fatigue can be considered a contributing factor.' — EC-IBA, Spain, 2012-08-02, fatal accident, 2 fatalities, aircraft crashed on approach in heavy fog condition: 'The ultimate cause of the accident could not be determined. [] The contributing factors were: [] the fatigue built up over the course of working at a time when they should have been sleeping after an unplanned duty period.' " Comment: These are FW accidents and while fatigue was an issue, neither of these are apparently relevant for (a well-managed) HEMS operation.
response	Please refer to the answer to comment #262.
comment	697 comment by: <i>Oya Vendée Hélicoptères</i>
	The well-functioning current national FTL schemes are enforced for years, no excessive

fatigue has been demonstrated and the current national system provides French operators

**** * * * * * * with satisfaction. Besides, in the EMS safety risk assessment of this NPA, it is written that "Even with the caveats about under-reporting of fatigue as a causal factor it would appear from the occurrence data that the controls that have been in place to manage fatigue in European EMS have generally been effective. Compared to the social benefits from EMS operations in terms of patient safety and health (see below), the overall safety balance (flight safety v patient safety) is very positive".

The proposed requirements, as it is, will lead to amend Health National regulations and it will request more staff, more constraints, more costs without any safety added value. Indeed, HEMS pilots are scarce resources in France, and this NPA would lead to hire 120 additional pilots and 120 additional TCM in order to offer the same quality of HEMS activity in France. This represents an additional cost of 20% for the whole French HEMS State Budget. It is likely that such a massive recruitment would not be achievable and would thus result in a significant reduction in the quality of the French Healthcare system. OYA thinks it would be beneficial to further develop the economic, social, emergency access to care and national health policy impacts in addition to the flight safety impact.

For illustrative purposes, in France, during recent Millas train disaster on December, the 14th of 2017, it would have been neither politically nor socially acceptable if the airlift performed under a public service delegation was not implemented to take care of the victims because of an inadequate European regulation. The slightest loss of life chance of survival of a patient is unacceptable.

Hence, OYA would like national impacts regarding healthcare organization to be considered by the Agency.

response

Please refer to the answer to comment #262.

comment	850 comment by: Yorkshire Air Ambulance
	TCMs in the UK HEMS industry are predominantly funded by the NHS, but this consideration is not adequately addressed by the NPA.
response	Please refer to the answer to comment #262.
comment	852 comment by: Yorkshire Air Ambulance
	Agree with para 1, yet this NPA impacts negatively on existing FTLs that have been tested over many years and approved by national authorities.
response	Please refer to the answer to comment #262.

comment 853

comment by: Yorkshire Air Ambulance

**** * * *** TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 527 of 585

	Regulations can only provide the facility for crews to rest, but are unable to mandate that pilots actually take it.
response	EASA is not a low enforcement body.
comment	854 comment by: Yorkshire Air Ambulance
	Of the two incidents described, both are F/W, and one of them occurred in thick fog - hardly relevant to day VFR HEMS.
response	Please refer to the answer to comment #262.
comment	986 comment by: MBH SAMU
	The well-functioning current national FTL schemes are enforced for years, no excessive fatigue has been demonstrated and the current national system provides French operators with satisfaction. Besides, in the EMS safety risk assessment of this NPA, it is written that <i>"Even with the caveats about under-reporting of fatigue as a causal factor it would appear from the occurrence data that the controls that have been in place to manage fatigue in European EMS have generally been effective. Compared to the social benefits from EMS operations in terms of patient safety and health (see below), the overall safety balance (flight safety v patient safety) is very positive".</i>
	The proposed requirements, as it is, will lead to amend Health National regulations and it will request more staff, more constraints, more costs without any safety added value. Indeed, HEMS pilots are scarce resources in France, and this NPA would lead to hire 120 additional pilots and 120 additional TCM in order to offer the same quality of HEMS activity in France. This represents an additional cost of 20% for the whole French HEMS State Budget. It is likely that such a massive recruitment would not be achievable and would thus result in a significant reduction in the quality of the French Healthcare system. MBH thinks it would be beneficial to further develop the economic, social, emergency access to care and national health policy impacts in addition to the flight safety impact. For illustrative purposes, in France, during recent Millas train disaster on December, the 14 th of 2017, it would have been neither politically nor socially acceptable if the airlift performed under a public service delegation was not implemented to take care of the victims because of an inadequate European regulation. The slightest loss of life chance of survival of a patient is unacceptable.
	considered by the Agency.
response	Please refer to the answer to comment #262.



comment | 1155

comment by: FNAM

Attachment #273

The well-functioning current French FTL schemes are enforced for years, no excessive fatigue has been demonstrated and the current national system provides French operators with satisfaction. Besides, in the EMS safety risk assessment of this NPA, it is written that *"Even with the caveats about under-reporting of fatigue as a causal factor it would appear from the occurrence data that the controls that have been in place to manage fatigue in European EMS have generally been effective. Compared to the social benefits from EMS operations in terms of patient safety and health (see below), the overall safety balance (flight safety v patient safety) is very positive".*

Thus, it will request more staff, more constraints, more costs without any safety added value. Indeed, pilots are scarce resources in France, and this NPA would lead to hire additional pilots to offer the same quality of AEMS activity in France. It is likely that such a massive recruitment would not be achievable and would thus result in a significant reduction in the quality of the French AEMS system.

FNAM and EBAA France think it would be beneficial to further develop the economic, social, emergency access to care as well as impacts on:

- Graft and organ transportations linked to the national Health care system
- Other emergency transportations linked to insurance needs and their organization

For illustrative purposes, for typical AEMS missions, it would have been neither politically nor socially acceptable if the rescue of French tourists in Morocco and Spain was not performed because of an inadequate European regulation. The slightest loss of life chance of survival of a patient is unacceptable (Cf. Annex 3).

response Please refer to the answer to comment #262.

comment | 1247

comment by: SAF

The well-functioning current national FTL schemes are enforced for years, no excessive fatigue has been demonstrated and the current national system provides French operators with satisfaction. Besides, in the EMS safety risk assessment of this NPA, it is written that *"Even with the caveats about under-reporting of fatigue as a causal factor it would appear from the occurrence data that the controls that have been in place to manage fatigue in European EMS have generally been effective. Compared to the social benefits from EMS operations in terms of patient safety and health (see below), the overall safety balance (flight safety v patient safety) is very positive".*

The proposed requirements, as it is, will lead to amend Health National regulations and it will request more staff, more constraints, more costs without any safety added value. Indeed, HEMS pilots are scarce resources in France, and this NPA would lead to hire

**** * * *** 120 additional pilots and 120 additional TCM in order to offer the same quality of HEMS activity in France. This represents an additional cost of 20% for the whole French HEMS State Budget. It is likely that such a massive recruitment would not be achievable and would thus result in a significant reduction in the quality of the French Healthcare system.

SAF thinks it would be beneficial to further develop the economic, social, emergency access to care and national health policy impacts in addition to the flight safety impact.

For illustrative purposes, in France, during recent Millas train disaster on December, the 14th of 2017, it would have been neither politically nor socially acceptable if the airlift performed under a public service delegation was not implemented to take care of the victims because of an inadequate European regulation. The slightest loss of life chance of survival of a patient is unacceptable.

Hence, SAF would like national impacts regarding healthcare organization to be considered by the Agency.

response

Please refer to the answer to comment #262.

comment	1295comment by: Hélicoptères de France
	The well-functioning current national FTL schemes are enforced since years, no excessive
	fatigue has been demonstrated and the current national system provides French operators with
	satisfaction. Besides, in the EMS safety risk assessment of this NPA, it is written that "Even with the
	caveats about under-reporting of fatigue as a causal factor it would appear from the occurrence data that
	the controls that have been in place to manage fatigue in European EMS have generally been effective.
	Compared to the social benefits from EMS operations in terms of patient safety and health (see
	below), the overall safety balance (flight safety v patient safety) is very positive".
	The proposed requirements, as it is, will lead to amend Health National regulations and it will request
	more staff, more constraints, more costs without any safety added value. Indeed, HEMS pilots are
	scarce resources in France, and this NPA would lead to hire 120 additional pilots and 120
	additional TCM in order to offer the same quality of HEMS activity in France. This represents an
	additional cost of 20% for the whole French HEMS State Budget. It is likely that such a massive recruitment
	would not be achievable and would thus result in a significant reduction in the quality of the French
	Healthcare system.
	HDF thinks it would be beneficial to further develop the economic, social, emergency access



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

to care and national health policy impacts in addition to the flight safety impact. For illustrative purposes, in France, during recent Millas train disaster on December, the 14th of 2017, it would have been neither politically nor socially acceptable if the airlift performed under a public service delegation was not implemented to take care of the victims because of an inadequate European regulation. The slightest loss of life chance of survival of a patient is unacceptable. Hence, HDF would like national impacts regarding healthcare organization to be considered by the Agency.

response Ple

4. IA - 4.3. How it could be achieved - optionsp. 53-58

comment	13 comment by: TG
	Option "0" ist die Einzige - gepaart mit der Motivation der Betreiber die Überstunden radikal zu reduzieren. Ist ein Dienstplan wie er heute existiert wirklich durchführbar, kann der Pilot sich im Privatleben auch bei ggf. kurzen Pausen hervorragend regenerieren. Jede Veränderung hin zu häufigeren Anreisen an den Arbeitsort zerstört ein funktionierendes Konstrukt. 80% der Kollegen können mit Einführung von Tag-Schichtdienst bis zu 100 Tage weniger zu Hause sein - das zerstört Familien! (Auch das wird ein Flugsicherheitsrisiko!)
response	Please refer to the answer to comment #262.

comment	320	comment by: European Helicopter Association (EHA)
	NORSK LUFTAMBULANSE AS (Norway	y):
	Table 6	
	Option 1 – Flexible approach wou demonstrate a safe operation. Option 2 – Fully prescriptive approac pertaining to the risk of fatigue. Actu could be nullified due to the extra am	vork quite well for most Member States. uld have the benefit of forcing the operators to h would have a "Positive low benefits" for safety <u>only</u> ually, for many operators/member states the benefits ount of commuting that would be experienced. Other e introduced (lack of recency, insufficient experience,

An agency of the European Union

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

EASA has acknowledged, and it is also indicated in this NPA, that there are no indications that the existing FTL requirements for HEMS under National authority approvals, poses a flight safety problem. The only goal is merely to harmonize and standardize. It seems like the only way of doing so is to use specified numbers, robust regulation with a huge safety buffer to protect against all possible risk for fatigue. While the new EMS FTL requirements won't only be too conservative for many HEMS operators and in many cases be detrimental to the safety of the operations, it will also have a negative impact on social aspects for the patients, the public, the crew members and the "customers" (the patients). The European HEMS operating patterns are highly diversified (not only between countries, but also within countries, and have been developed and matured over a long period of time. The diversified operating patterns are necessary to perform safe and affordable HEMS operations in very different operating environments and in accordance with different customer requirements. By following the regulation in this NPA, there will be increased level of fatigue for many crew members and a lower level of flight-recency. Furthermore, finding suitably experienced crew member (including HEMS technical crew members) will be a significant challenge for many operators.

"It has to be noted that the scope of the HEMS rules exclude the remote bases that are open on a 24-hour basis. This decision has been taken after an analysis of the potential high negative economic impacts which could, as a side effect, reduce the availability of such remote bases and limit the availability of emergency medical services. For the future more research needs to be done in order to assess the fatigue risks in remote basis."

Comment: This is highly agreeable and relevant for operation serving remote areas, where also the mission rate is low. However, here it is important to emphasize that it is not always the location of the HEMS operating base that is relevant, but the actual area served. For example, a helicopter can be based in a city, while serving exclusively remote areas. Also, the wording "ineffective" should perhaps be reviewed as most medical personnel or operators could argue that the majority of road transport could be "ineffective" as compared to helicopter transport.

response Please refer to the answer to comment #262.

413 comment by: ANWB MAA
Why has the economic impact been accepted for those bases as they are there as well for the none remote bases?
Please refer to the answer to comment #262.
437 comment by: UFH French Helicopters Association

We fully agrees that the scope of the HEMS rules shall exclude the remote bases. It is obvious that remote bases cannot be submitted to these limitations, else it will imply less service for

**** * * ***

	the public inducing social tensions if the number of pilots stays the same; or loss of practical experience if additional pilots are recruited.
response	Please refer to the answer to comment #262.
comment	519 comment by: FNAM/SNEH
	FNAM and SNEH fully agree that the scope of the HEMS rules shall exclude the remote bases. It is obvious that remote bases cannot be submitted to these limitations, else it will imply less service for the public inducing social tensions if the number of pilots stays the same; or loss of practical experience if additional pilots are recruited. However, FNAM and SNEH wonder why only remote bases open on a 24 hours basis are excluded from the scope. Indeed, some remote bases are open on a 12 hours basis due to weather conditions for instance. Hence, FNAM and SNEH suggest that all remote bases shall be excluded from the scope of the HEMS rules. Besides, there is no definition of what is meant by "remote bases". Does it only mean offshore bases, as quoted in the Norway case study, or is the definition broader? Therefore, FNAM and SNEH ask for a precise and clear definition of a "remote base".
response	Please refer to the answer to comment #262.
comment	603 comment by: NOLAS
	 Table 6: Selected policy options HEMS Comment: Option 0 – No policy change would work quite well for most Member States. Option 1 – Flexible approach would have the benefit of forcing the operators to demonstrate a safe operation. Option 2 – Fully prescriptive approach would have a "Positive low benefits" for safety <u>only</u> pertaining to the risk of fatigue. Actually, for many operators/member states the benefits could be nullified due to the extra amount of commuting that would be experienced. Other negative flight safety factors would be introduced (lack of recency, insufficient experience, etc.). EASA has acknowledged, and it is also indicated in this NPA, that there are no indications
	that the existing FTL requirements for HEMS under National authority approvals, poses a flight safety problem. The only goal is merely to harmonize and standardize. It seems like the only way of doing so is to use specified numbers, robust regulation with a huge safety buffer to protect against all possible risk for fatigue. While the new EMS FTL requirements won't only be too conservative for many HEMS operators and in many cases be detrimental to the safety of the operations, it will also have a negative impact on social aspects for the patients, the public, the crew members and the "customers" (the patients). The European HEMS operating patterns are highly diversified (not only between countries, but also within countries, and have been developed and matured over a long period of time. The

**** * * ****

	diversified operating patterns are necessary to perform <u>safe</u> and affordable HEMS operations in very different operating environments and in accordance with different customer requirements. By following the regulation in this NPA, there will be increased level of fatigue for many crew members and a lower level of flight-recency. Furthermore, finding suitably experienced crew member (including HEMS technical crew members) will be a significant challenge for many operators.
response	Please refer to the answer to comment #262.
comment	604 comment by: <i>NOLAS</i>
	Table 6: Selected policy options HEMS "It has to be noted that the scope of the HEMS rules exclude the remote bases that are open on a 24-hour basis. This decision has been taken after an analysis of the potential high negative economic impacts which could, as a side effect, reduce the availability of such remote bases and limit the availability of emergency medical services. For the future more research needs to be done in order to assess the fatigue risks in remote basis."
	Comment: This is highly agreeable and relevant for operation serving remote areas, where also the mission rate is low. However, here it is important to emphasize that it is not always the location of the HEMS operating base that is relevant, but the actual area served. For example, a helicopter can be based in a city, while serving exclusively remote areas. Also, the wording "ineffective" should perhaps be reviewed as most medical personnel or operators could argue that the majority of road transport could be "ineffective" as compared to helicopter transport.
response	Please refer to the answer to comment #262.

698 comment by: Oya Vendée Hélicoptères
OYA fully agrees that the scope of the HEMS rules shall exclude the remote bases. It is obvious that remote bases cannot be submitted to these limitations, else it will imply less service for the public inducing social tensions if the number of pilots stays the same; or loss of practical experience if additional pilots are recruited. However, OYA wonders why only remote bases open on a 24 hours basis are excluded from the scope. Indeed, some remote bases are open on a 12 hours basis due to weather conditions for instance. Hence, OYA suggests that all remote bases shall be excluded from the scope of the HEMS rules. Besides, there is no definition of what is meant by "remote bases". Does it only mean offshore bases, as quoted in the Norway case study, or is the definition broader? Therefore, OYA asks for a precise and clear definition of a "remote base".
Please refer to the answer to comment #262.

comment 851

comment by: Atlantic Airways Helicopter department



We agree on the decision, described in paragraph 4.3. To exclude remote bases with 24 hour per day shifts from the further development of the FTL. Along with the financial impact, of implementing the new FTL system for remote bases, the actual HEMS flight time, which normally is low at remote bases, would have to be shared into even smaller numbers between the pilots. The impact on the actual flying ability will, in the long term, reduce crewmembers ability to perform their task. Thereby it becomes a safety issue and training alone does not fully solve the problem. Please refer to the answer to comment #262. response 987 comment comment by: MBH SAMU MBH fully agrees that the scope of the HEMS rules shall exclude the remote bases. It is obvious that remote bases cannot be submitted to these limitations, else it will imply less service for the public inducing social tensions if the number of pilots stays the same; or loss of practical experience if additional pilots are recruited. However, MBH wonders why only remote bases open on a 24 hours basis are excluded from the scope. Indeed, some remote bases are open on a 12 hours basis due to weather conditions for instance. Hence, MBH suggests that all remote bases shall be excluded from the scope of the HEMS rules. Besides, there is no definition of what is meant by "remote bases". Does it only mean offshore bases, as quoted in the Norway case study, or is the definition broader? Therefore, MBH asks for a precise and clear definition of a "remote base". response Please refer to the answer to comment #262. comment 1248 comment by: SAF SAF fully agrees that the scope of the HEMS rules shall exclude the remote bases. It is obvious that remote bases cannot be submitted to these limitations, else it will imply less service for the public inducing social tensions if the number of pilots stays the same; or loss of practical experience if additional pilots are recruited. However, SAF wonders why only remote bases open on a 24 hours basis are excluded from the scope. Indeed, some remote bases are open on a 12 hours basis due to weather conditions for instance. Hence, SAF suggests that all remote bases shall be excluded from the scope of the HEMS rules. Besides, there is no definition of what is meant by "remote bases". Does it only mean offshore bases, as quoted in the Norway case study, or is the definition broader? Therefore, SAF asks for a precise and clear definition of a "remote base". Please refer to the answer to comment #262. response

comment 1296

comment by: Hélicoptères de France



HDF fully agrees that the scope of the HEMS rules shall exclude the remote bases. It is obvious that remote bases cannot be submitted to these limitations, else it will imply less service for

the public inducing social tensions if the number of pilots stays the same; or loss of practical experience

if additional pilots are recruited. However, HDF wonderes why only remote bases open on a

24 hours basis are excluded from the scope. Indeed, some remote bases are open on a 12 hours basis

due to weather conditions for instance. Hence, HDF suggests that all remote bases shall be excluded from the scope of the HEMS rules.

Besides, there is no definition of what is meant by "remote bases". Does it only mean offshore bases,

as quoted in the Norway case study, or is the definition broader? Therefore, HDF asks for a precise and clear definition of a "remote base".

Please refer to the answer to comment #262.

response

4. IA - 4.4. What are the impacts

p. 58-67

comment	14 comment by: TG
	 Bei genauer Betrachtung jedes einzelnen Impacts wird deutlich, dass das Beibehalten des derzeitigen Systems bei gleichzeitiger Reduzierung der Überstunden das Mittel der Wahl ist. Piloten sind mündige Bürger und zumindest die Marktführer zwingen ihre Angestellten nicht in die Überlastung. Dafür sorgen Arbeitsverträge und Betriebsvereinbarungen. Wenn diese Kultur angegriffen wird, führt die unausweichliche Destabilisierung zu Risiken, die wir noch nicht abschätzen können. 4.4.4.3.: Der Aufwand ist nicht nur teuer, er erreicht auch das Gegenteil vom heeren Ziel, der Erhöhung der Flugsicherheit.
response	Please refer to the answer to comment #262.
comment	26 comment by: Johannes Brantz
	Loss of experience
	As FTL might increase the demand for pilots the risk that is seen in the analysis is that this will lower the flight time per pilot. The minimum requirement for a HEMS captain is 1000 flight hours experience. This experience level is high enough to ensure that currency is not lost if FTL should reduce the flight time per pilot.



Individual comments and responses - HEMS

response

Please refer to the answer to comment #262.

comment	217 comment by: ANSMUH
	What will be the impacts in France ?
	4.4.1 Security impacts: For more than 20 years (last HEMS crash in France. July 4, 1997) there no has been accident. Since July 18, 2003, Annex 2 of the collective convention regulates HEMS activity in France, limits duty to 3 modes of operation to 12 hours duty, 14 hours duty, and 24 hours (divided by 2 with 2 crews making 12 hours duty), flight hours limitations, etc
	The application of this FTL 3, in our opinion, will not improve security in France. No change in the existing situation; HEMS continue to be regulated under MS national rules.
	4.4.3 Social impact: The mode of operation currently regulated by Annex 2 of the collective convention does not allow to exceed 14 hours of duty. Most pilots are not living near her/his operating base. Currently, the permanence does not exceed 7 days, which allows pilots to stay away from their home base without strong family impact.
	No change in the existing situation; HEMS continue to be regulated under MS national rules.
	4.4.4 Economic impact:The application of this FTL 3 will involve additional costs for French State without HEMS gain, such as the constraints of a requirement of a minimum break of 1 hour. These constraint will be a cut of the public service and personal assistance.We require no change in the existing situation; HEMS continue to be regulated under MS national rules.
response	Please refer to the answer to comment #262.
comment	265 comment by: European Helicopter Association (EHA)
	ADAC (Germany), DRF (Germany) and LAR (Luxembourg):

Safety Impact Regarding the flexible Approach in comparison to the safety impact the EASA expects a positive low benefit. We do not agree with the manner, in which this conclusion was argued. The Attachment II stated in the period of 1971 to 2012 only three accidents, where fatigue was found as contributing factor. According to the EASA statement this is about 1.3% of all EMS occurrences from the ICAO ADFREP database. We have to question the data from the ADREP Database, because the EASA didn't explain, if the 395 EMS related accidents where based on a worldwide search or on a query only for the EU region. The number looks quite high compared to the data from the German federal bureau of aircraft accident investigation (BFU). In the period from 1989 to 2007 there have been only 14 fatal accidents related to HEMS operation in Germany. As stated in the beginning, German HEMS makes up nearly 40% of all HEMS Missions flown in the EASA member states. Therefore we consider the database as not relevant for the EASA kind of argumentation. Furthermore, if we compare the 3 accidents with the number of sectors flown in these 40 years (estimated more than 8 Mill), it is very clear, that fatigue is not a factor, where the safety of HEMS missions is jeopardized. Additionally the NPA states, that the current situation would remain acceptable, if HEMS operations were conducted predominantly in the Member State that issued the AOC. From the German side of view, there are isolated cross border missions, but these starts and ends always in the member state issuing the AOC. As shown in the beginning, HEMS is mainly government founded and assists the ground based national rescue system. We do not see the point in the argumentation of the EASA that this situation will change in the near future in terms of number of HEMS bases to be established across Europe and the number of services to he available cross-border. Also the next EASA statement regarding the safety aspects cannot be followed from our side of view. "Discrepancies between national FTL regimes might make it difficult for operators to conduct HEMS outside their principal home base". Our Opinion is that discrepancies between FTL regimes within the scope of the operators

due to



individual flight time schedules make it impossible to establish common rules for tenders and to give national ministries the chance to compare, which operator will have the best safety policy regarding fatigue. All together, we came to the conclusion, that the new proposals will not enhance the flight safety and fatigue management and that the EASA conclusion has to be rethought with appropriate studies and the safety records from HEMS Missions in the last decade. The EASA itself made some presumptions like to consider, that option 1 may provide some low positive benefits. Within the scope of this highly difficult theme, considerations should not be used to argue about changing an existing, functioning and safe System of national flight time limitations. This is also more important, while the EASA will keep normal CAT Operations (i.e. passenger transport with one pilot) within the national scope. For Germany this means, that with single pilot CAT the existing rules stay in place, while in HEMS operations with 2 pilots or one pilot and HEMS-TC way more restrictive rules apply. Ridiculous! Social Impact Regarding the flexible Approach in comparison to the social impact the EASA expects a neutral result. In fact, we estimate a negative outcome. In summer 2017 the ADAC and the DRF started scientific study with the German center of aeronautics and space (DLR). Unfortunately the scientific outcome will not be published by the DLR before the midst of march. From the point of view from the participating pilots we can already tell, that no one was fond working in a system with 2 shifts for rescue helicopters during the day time. Working in the rescue service will soon become unattractive, which leads to reduced safety due to the fact, that experienced pilots will join other services. The impact of the NPA is mainly, that the operators have to recruit and employ more pilots. The European market for experienced HEMS Pilots is more or less nonexistent. We are afraid, that this will lead to deterioration in flight safety. Assuming that there are not enough trained pilots, the operator have to reduce their common working schedule, which will lead to deterioration in the provision of the HEMS operating hours.



Furthermore this will have immediate effect to the number of HEMS missions, treated persons and patients transported. Thinking of need for relocation or more travelling time due to the FTL changes, also the work/life balance will deteriorate together with the social acceptance of the HEMS Business and the Crews involved. The DNR Study "Preliminary Analysis of Potential Regulatory Impacts – EMS" comes to the conclusion that these task where relevant regarding possible social impacts. Being objective we cannot go conform to the EASA expectation of a neutral result. Instead we think that the social impact has to be downgraded. **Economic Impact** The EASA rule making group itself came to the conclusion, that the economic impact of option 1 the flexible approach to a new regulation – has to be classified as medium negative. Here we cannot follow the argumentation in total. The difference between the fully prescriptive and the flexible approach is based on the fact, that in option 1 the operator will have the opportunity to set up individual flight time schemes as where in option 2 the operators stick to the new regulations and recruit new pilots. Option 2 is considered as highly negative. To avoid these highly negative impacts we assume, that nearly every HEMS operator will set up individual flight time schedules / schemes. The operators have to set up scientific based studies with a medical expertise. Due to the fact, that some operators have multiple HEMS operating bases with 24/7 h or bases only during daytime and these bases differs sometimes totally in the amount of flight times, duty times and mission complexity and also the daily missions flown, each base has to be evaluated separately. Worst case will be 360 individually based flight time schemes. According to regulation/EU) 216-2008 Article 22 Chapter (2) (c) the EASA has only 1 month for the assessment. The EASA estimates in the first year 11 derogations with about 800 hours for the evaluation. These figures do not match the current evaluations with up to 800 hours a single complex derogation flight time scheme. We do not see the EASA capable of handling the derogations in the given time frames of the basic regulation. The case study of the EASA came to the conclusion, to employ a forth pilot during the summer season. They did not mention how this will fit into the regulations in cause 5 of the Council



Directive 1999/70/EC of 28 June 1999 concerning the framework agreement on fixedterm work. To prevent abuse arising from the use of successive fixed-term employment contracts or

relationships, the member states did set up regulations regarding:

(a) Objective reasons justifying the renewal of such contracts;

(b) the maximum total duration of successive fixed-term employment contracts;

(c) the number of renewals of such contracts.

In Germany this means, if a pilot more is employed more than two times, he will automatically

become a fixed-term employer.

The impacts of these multiple short term employments have not been considered by the EASA.

We therefore consider even the flexible approach (option 1) as highly negative.

response

Please refer to the answer to comment #262.

comment	322	comment by: European Helicopter Association (EHA)
	NORSK LUFTAMBULANSE AS (Norwa	ау):
	4.4.1.1. Comment: Same as comment for Ta	able 6: Selected policy options HEMS, NPA p 54.
response	Please refer to the answer to comm	ent #262.

comment	323 comment by: European Helicopter Association (EHA)
	NORSK LUFTAMBULANSE AS (Norway):
	Comment: The social impact for the patients, that are negatively affected by many of the elements in this NPA, is lacking completely and should be addressed.
response	Please refer to the answer to comment #262.

comment	324	comment by: European Helicopter Association (EHA)
	NORSK LUFTAMBULANSE AS (Norwa	ау):
	"Fully prescriptive approach"	
	Comment: While the specific exampare absolutely correct.	ple of offshore Norway is a bit dated, the conclusions
	1	

**** **** TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

"1) Impacts only for HEMS operators. They would address the impacts by either: a) recruiting additional pilots;

b) increasing the working time of pilots;

c) increase of service cost, or "

Comment: The impact in points a) through b) need to include HEMS technical crew members.

"2) in order to continue their current way of operations, the number of derogation would increase which would require an additional work for operators, competent authorities, DG MOVE and EASA."

Comment: This is correct. As most HEMS operations seem to be performed at an adequate level of safety pertaining to fatigue, most HEMS operators will most probably pursue an Individual Flight Time Specification Scheme.

response

Please refer to the answer to comment #262.

comment	375 со	mment by: European Helicopter Association (EHA)
	BHA (UK)	
	"4.4.3 Social Impact"	
		ven to the key social purpose of HEMS - saving life. introduced Europe-wide, patients will undoubtedly
	"Option 2 — Fully prescriptive approach	n (1)(b)"
	Comment: No mention or consideration given of th	ne impact of this NPA on TCMs.
	"Option 2 — Fully prescriptive approach	n (2)
	Comment: This is absolutely true, which is why EAS by industry before it becomes an Opinio	A should make sure the HEMS FTL has been agreed on.
	Option 1 impact. Experience shows th	nger negative impact for EASA workload than the at processing a request for derogation from FTL uming than the assessment of a deviation from

Comment:
I suspect Option 2 will result in a massive increase in applications for FRMS deviations.responsePlease refer to the answer to comment #262.

comment	438	comment by: UFH French Helicopters Association
	to manage the risk o arising from the pro would be likely to ca	ety impact that the national provisions already enforced are effective of fatigue. Besides, the possible improvements regarding safety posed regulation (options 1 & 2 of the RIA) are questionable and suse a loss of crew knowledge.
	Considering the econ negative impacts:	nomic impact, options 1 & 2 of the RIA will induce medium and highly
		nal pilots whereas no qualified crews are available on the market
	• Reducing the total experience and the l	amount of flight hours flown for a given pilot, thus reducing their evel of safety
	• Changing the Fren accepted by pilots a	ch rostering organization which is efficient as regards safety and well nd their unions
	has been, in the past	ocial risks and disruption of the emergency medical services which t, proven to be politically and socially unacceptable and would have a complete change of the whole French Health care system that
	Hence, the option 0 Safety impact, social The option 0 is the p	- no policy change is the option retained by FNAM, SNEH and UFH. I impact and economic impact are neutral or having a little impact. Proper answer to a one size fits all model which is not applicable to L shall stay in the hand of the local authority. We strongly ask this
	option to be conside situation; HEMS con was not to be retain	ered by EASA and the Member States: "no change in the existing tinue to be regulated under MS national rules". If this option ed 2 other options that might be considered have been decribed (cf. ne comments 1, 59 and 64).
response	Please refer to the a	nswer to comment #262.
	L	
comment	520	comment by: FNAM/SNEH

It is stated in the safety impact that the national provisions already enforced are effective to manage the risk of fatigue.

Besides, the possible improvements regarding safety arising from the proposed regulation (options 1 & 2 of the RIA) are questionable and would be likely to cause a loss of crew knowledge.

Considering the economic impact, options 1 & 2 of the RIA will induce medium and highly negative impacts:



- Recruiting additional pilots whereas no qualified crews are available on the market
- Reducing the total amount of flight hours flown for a given pilot, thus reducing their experience and the level of safety
- Changing the French rostering organization which is efficient as regards safety and well accepted by pilots and their unions

This would induce social risks and disruption of the emergency medical services which has been, in the past, proven to be politically and socially unacceptable and would have broader effects (it is a complete change of the whole French Health care system that might be necessary).

Hence, the option 0 - no policy change is the option retained by FNAM and SNEH. Safety impact, social impact and economic impact are neutral or having a little impact. The option 0 is the proper answer to a one size fits all model which is not applicable to the industry. The FTL shall stay in the hand of the local authority. FNAM and SNEH strongly ask this option to be considered by EASA and the Member States: "*no change in the existing situation; HEMS continue to be regulated under MS national rules*". If this option was not to be retained FNAM and SNEH described 2 other options that might be considered (cf. options B and C of the comments 457, 517 and 521).

response

Please refer to the answer to comment #262.

comment	579 comment by: Cat Aviation AG
	Option 0 states "a negative social impact" is to be expected if no change and all remains status quo under Subpart Q. We would disagree with this point, as historically no negative social impact for the majority of operators' crew exist. To the contrary, if we start to limit freedom of hotel location selection and self-driving transport mode to crews, this has a higher negative social impact. Unhappy crew might have a negative impact on safety.
response	Please refer to the answer to comment #262.
comment	605 comment by: NOLAS
	4.4.1.1 HEMS Comment: Same as comment for Table 6: Selected policy options HEMS, NPA p 54.
response	Please refer to the answer to comment #262.
comment	606 comment by: NOLAS
	4.4.3. Social impact

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 544 of 585

Comment: The social impact for the patients, that are negatively affected by many of the elements in this NPA, is lacking completely and should be addressed. Please refer to the answer to comment #262. response comment 607 comment by: NOLAS **Option 2** — Fully prescriptive approach **Comment:** While the specific example of offshore Norway is a bit dated, the conclusions are absolutely correct. Please refer to the answer to comment #262. response comment 608 comment by: NOLAS **Option 2** — Fully prescriptive approach "1) Impacts only for HEMS operators. They would address the impacts by either: a) recruiting additional pilots; b) increasing the working time of pilots; c) increase of service cost, or " Comment: The impact in points a) through b) need to include HEMS technical crew members. Please refer to the answer to comment #262. response comment 609 comment by: NOLAS **Option 2** — Fully prescriptive approach "2) in order to continue their current way of operations, the number of derogation would increase which would require an additional work for operators, competent authorities, DG MOVE and EASA." **Comment:** This is correct. As most HEMS operations seem to be performed at an adequate

Individual Flight Time Specification Scheme.

response Please refer to the answer to comment #262.

comment	699	comment by: Oya Vendée Hélicoptères
	It is stated in the safety impact that the national p to manage the risk of fatigue.	provisions already enforced are effective

level of safety pertaining to fatigue, most HEMS operators will most probably pursue an

**** * * *** Besides, the possible improvements regarding safety arising from the proposed regulation (options 1 & 2 of the RIA) are questionable and would be likely to cause a loss of crew knowledge.

Considering the economic impact, options 1 & 2 of the RIA will induce medium and highly negative impacts:

- Recruiting additional pilots whereas no qualified crews are available on the market
- Reducing the total amount of flight hours flown for a given pilot, thus reducing • their experience and the level of safety
- Changing the French rostering organization which is efficient as regards safety and • well accepted by pilots and their unions

This would induce social risks and disruption of the emergency medical services which has been, in the past, proven to be politically and socially unacceptable and would have broader effects (it is a complete change of the whole French Health care system that might be necessary).

Hence, the option 0 - no policy change is the option retained by OYA. Safety impact, social impact and economic impact are neutral or having a little impact. The option 0 is the proper answer to a one size fits all model which is not applicable to the industry. The FTL shall stay in the hand of the local authority. OYA strongly asks this option to be considered by EASA and the Member States: "no change in the existing situation; HEMS continue to be regulated under MS national rules". If this option was not to be retained OYA described 2 other options that might be considered (cf. options B and C of the comments 637, 696 and 700).

response

Please refer to the answer to comment #262.

comment	714	comment by: ÖAMTC Helicopter Air Rescue (Austria)
comment	714	comment by. OAMTE Hencopter Air Rescue (Austriu)
	Option 1 - flexible approach	
	[] allows implementing an i	ndividual flight time scheme for each operator []
	the impression that a rather is possible. Actually a detaile	h EASA on the 5 th of Dec 2017 ÖAMTC Air Rescue was given quick adoption of an individual flight time limitation scheme ed look at the rules shows that only parts of the certification nd major portions of the NPA which affect operations cannot
response	Please refer to the answer to	comment #262.
	L	
comment	762	comment by: DRF-Luftrettung

Safety Impact

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Regarding the flexible Approach in comparison to the safety impact the EASA expects a positive low benefit.

We do not agree with the manner, in which this conclusion was argued. The Attachment II stated in the period of 1971 to 2012 only three accidents, where fatigue was found as contributing factor. According to the EASA statement this is about 1.3% of all EMS occurrences from the ICAO ADFREP database.

We have to question the data from the ADREP Database, because the EASA didn't explain, if the 395 EMS related accidents where based on a world wide search or on a query only for the EU region.

The number looks quite high compared to the data from the German federal bureau of aircraft accident investigation (BFU). In the period from 1989 to 2007 there have been only 14 fatal accidents related to HEMS operation in Germany. As stated in the beginning, German HEMS makes up nearly 40% of all HEMS Missions flown in the EASA member states. Therefore we consider the database as not relevant for the EASA kind of argumentation.

Furthermore, if we compare the 3 accidents with the number of sectors flown in these 40 years (estimated more than 8 Mill), it is very clear, that fatigue is not a factor, where the safety of HEMS missions is jeopardized.

Additionally the NPA states, that the current situation would remain acceptable, if HEMS operations were conducted predominantly in the Member State that issued the AOC.

From the German side of view, there are isolated cross border missions, but these starts and ends always in the member state issuing the AOC. As shown in the beginning, HEMS is mainly government founded and assists the ground based national rescue system. We do not see the point in the argumentation of the EASA that this situation will change in the near future in terms of number of HEMS bases to be established across Europe and the number of services to be available cross-border.

Also the next EASA statement regarding the safety aspects cannot be followed from our side of view. "Discrepancies between national FTL regimes might make it difficult for operators to conduct HEMS outside their principal home base."

Our Opinion is that discrepancies between FTL regimes within the scope of the operators due to individual flight time schedules make it impossible to establish common rules for tenders and to give national ministries the chance to compare, which operator will have the best safety policy regarding fatigue.

All together we came to the conclusion, that the new proposals will not enhance the flight safety and fatigue management and that the EASA conclusion has to be rethought with appropriate studies and the safety records from HEMS Missions in the last decade. The EASA itself made some presumptions like to consider, that option 1 may provide some low positive benefits. Within the scope of this highly difficult theme, considerations should not be used to argue about changing an existing, functioning and safe System of national flight time limitations.

This is also more important, while the EASA will keep normal CAT Operations (i.E. passenger transport with one pilot) within the national scope. For germany this means, that with single pilot CAT the existing rules stay in place, while in HEMS operations with 2 pilots or one pilot and HEMS-TC way more restrictive rules apply. Ridiculous!



response Please refer to the answer to comment #262. 763 comment comment by: DRF-Luftrettung Social Impact Regarding the flexible Approach in comparison to the social impact the EASA expects a neutral result. In fact, we estimate a negative outcome. In Summer 2017 the ADAC and the DRF started a scientific study with the German center of aeronautics and space (DLR). Unfortunately the scientific outcome will not be published by the DLR before the midst of march. From the point of view from the participating pilots we can already tell, that no one was fond working in a system with 2 shifts for rescue helicopters during the day time. Working in the rescue service will soon become unattractive, which leads to reduced safety due to the fact, that experienced pilots will join other services. The impact of the NPA is mainly, that the operators have to recruit and employ more pilots. The European market for experienced HEMS Pilots is more or less nonexistent. We are afraid, that this will lead to deterioration in flight safety. Assuming that there are not enough trained pilots, the operator have to reduce there common working schedule, which will lead to a deteoration in the provision of the HEMS operating hours. Furthermore this will have immediate effect to the number of HEMS missions, treated persons and patients transported. Thinking of need for relocation or more travelling time due to the FTL changes, also the work/life balance will deteriorate together with the social acceptance of the HEMS Business and the Crews involved. The DNR Study "Preliminary Analysis of Potential Regulatory Impacts – EMS" comes to the conclusion, that these task where relevant regarding possible social impacts. Being objective we cannot go conform with the EASA expectation of a neutral result. Instead we think, that the social impact has to be downgraded Please refer to the answer to comment #262. response comment 764 comment by: DRF-Luftrettung

EConomic Impacts

The EASA rule making group itself came to the conclusion, that the economical impact of option 1 - the flexible approach to a new regulation - has to be classified as medium negative.

Here we cannot follow the argumentation in total. The difference between the fully prescriptive and the flexible approach is based on the fact, that in option 1 the operator

**** **** will have the opportunity to set up individual flight time schemes as where in option 2 the operators stick to the new regulations and recruit new pilots.

Option 2 is considered as highly negative.

To avoid these highly negative impacts we assume, that nearly every HEMS operator will set up individual flight time schedules / schemes. The operators have to set up scientific based studies with a medical expertise. Due to the fact, that some operators have multiple HEMS operating bases with 24/7 h or bases only during daytime and these bases differs sometimes totally in the amount of flight times, duty times and mission complexity and also the daily missions flown, each base has to be evaluated separately.

Worst case will be 360 individually based flight time schemes. According to regulation/EU) 216-2008 Article 22 Chapter (2)(c) the EASA has only 1 month for the assessment. The EASA estimates in the first year 11 derogations with about 800 hours for the evaluation. These figures do not match the current evaluations with up to 800 hours a single complex derogation flight time scheme.

We do not see the EASA capable of handling the derogations in the given time frames of the basic regulation.

The case study of the EASA came to the conclusion, to employ a forth pilot during the summer season. They did not mention, how this will fit into the regulations in cause 5 of the Council Directive 1999/70/EC of 28 June 1999 concerning the framework agreement on fixed-term work.

To prevent abuse arising from the use of successive fixed-term employment contracts or relationships, the member states did set up regulations regarding:

(a) objective reasons justifying the renewal of such contracts;(b) the maximum total duration of successive fixed-term employment contracts;(c) the number of renewals of such contracts.

In Germany this means, if a pilot more is employed more than two times, he will automatically become a fixed-term employer.

The impacts of these multiple short term employments have not been considered by the EASA.

We therefore consider even the flexible approach (option 1) as highly negative.

response

Please refer to the answer to comment #262.

comment	855 comment by: Yorkshire Air Ambulance
	There appears to be no consideration given to the key social purpose of HEMS - saving life. If some of the measures in this NPA are introduced Europe-wide, patients will undoubtedly suffer.
response	Please refer to the answer to comment #262.



Individual comments and responses - HEMS

comment	856 comment by: Yorkshire Air Ambulance
	No mention or consideration given of the impact of this NPA on TCMs.
response	Please refer to the answer to comment #262.
comment	857 comment by: Yorkshire Air Ambulance
	Para 2 is absolutely true, which is why EASA should make sure the HEMS FTL has been agreed by industry before it becomes an Opinion.
response	Please refer to the answer to comment #262.
comment	858 comment by: Yorkshire Air Ambulance
	Option 2 will result in a massive increase in applications for FRMS deviations.
response	Please refer to the answer to comment #262.
comment	988 comment by: MBH SAMU
	It is stated in the safety impact that the national provisions already enforced are effective to manage the risk of fatigue. Besides, the possible improvements regarding safety arising from the proposed regulation (options 1 & 2 of the RIA) are questionable and would be likely to cause a loss of crew knowledge. Considering the economic impact, options 1 & 2 of the RIA will induce medium and highly negative impacts:
	 Recruiting additional pilots whereas no qualified crews are available on the market Reducing the total amount of flight hours flown for a given pilot, thus reducing their experience and the level of safety Changing the French rostering organization which is efficient as regards safety and well accepted by pilots and their unions
	This would induce social risks and disruption of the emergency medical services which has been, in the past, proven to be politically and socially unacceptable and would have broader effects (it is a complete change of the whole French Health care system that might be necessary).
	Hence, the option 0 - no policy change is the option retained by MBH. Safety impact, social impact and economic impact are neutral or having a little impact. The option 0 is the proper answer to a one size fits all model which is not applicable to the industry. The FTL shall stay in the hand of the local authority. MBH strongly asks this option to be considered by EASA

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.Page 550 of 585

**** * * *** and the Member States: "no change in the existing situation; HEMS continue to be
regulated under MS national rules". If this option was not to be retained MBH described 2
other options that might be considered (cf. options B and C of the comments 1006, 985
and 989).responsePlease refer to the answer to comment #262.comment1110commentcomment by: Rabbit-Air Ltd
Unlike Subpart Q this regulation increases likelyhood of "negative social impact". Small
operators loose flexibility, complex tables make it almost impossible to grant customer's
plans, crews are more restricted in different ways. This could result in turning down
business because flexibility is lost, resulting in staff reduction.responsePlease refer to the answer to comment #262.

comment	1156 comment by: FNAM
	4. IA - 4.4.1 What are the impacts
	CAT operations and AEMS missions cannot be compared mostly due to the unpredictable character of the activity. Plus, AEMS operations are based on life threatening missions with defined travel through precise sectors which require short time reactions (notification, load, unload, etc.). Although CAT operations rely on clients/passengers transportation, with no emergency flights. In CAT operation, the flights are planned with a precise flight plan. In AEMS, the most important need is to ensure a flexible commander's discretion. Indeed, it is not rare that the Flight Duty Period needs to be exceeded due to unforeseen circumstances during an emergency mission. Thus, distinguishing AEMS and CAT operations in 2 separate regulatory texts seems more suitable as no operational comparison can be made between the fundamentals of these different activities.
response	Please refer to the answer to comment #262.
comment	1157comment by: FNAM
	Attachment <u>#274</u>

It is stated in the safety impact that the national provisions already enforced are effective to manage the risk of fatigue.



Besides, the possible improvements regarding safety arising from the proposed regulation (options 1 & 2 of the RIA) are questionable and would be likely to cause a loss of crew knowledge considering the new standby requirement (Cf. Annex 5). Considering the economic impact, options 1 & 2 of the RIA will induce medium and highly negative impacts:

- Recruiting additional pilots whereas no qualified crews are available on the market
- Reducing the total amount of flight hours flown for a given pilot, thus reducing their experience and the level of safety
- Changing the French rostering organization which is efficient as regards safety and well accepted by pilots and their union

This would induce social risks and disruption of the emergency services which have been, in the past, proven to be politically and socially unacceptable and would have broader effects. The option 0 is the proper answer to a one size fits all model which is not applicable to the industry. FNAM and EBAA France strongly ask this option to be considered by EASA and the Member States: *"no change in the existing situation; {...} AEMS continue to be regulated under Subpart Q plus national rules".*

response

Please refer to the answer to comment #262.

comment 1249 comment by: SAF It is stated in the safety impact that the national provisions already enforced are effective to manage the risk of fatigue. Besides, the possible improvements regarding safety arising from the proposed regulation (options 1 & 2 of the RIA) are questionable and would be likely to cause a loss of crew knowledge. Considering the economic impact, options 1 & 2 of the RIA will induce medium and highly negative impacts: Recruiting additional pilots whereas no qualified crews are available on the market Reducing the total amount of flight hours flown for a given pilot, thus reducing • their experience and the level of safety Changing the French rostering organization which is efficient as regards safety and well accepted by pilots and their unions This would induce social risks and disruption of the emergency medical services which has been, in the past, proven to be politically and socially unacceptable and would have broader effects (it is a complete change of the whole French Health care system that might be necessary). Hence, the option 0 - no policy change is the option retained by SAF. Safety impact, social

Hence, the option 0 - no policy change is the option retained by SAF. Safety impact, social impact and economic impact are neutral or having a little impact. The option 0 is the proper

** TE

answer to a one size fits all model which is not applicable to the industry. The FTL shall stay in the hand of the local authority. SAF strongly asks this option to be considered by EASA and the Member States: "*no change in the existing situation; HEMS continue to be regulated under MS national rules*". If this option was not to be retained SAF described 2 other options that might be considered (cf. options B and C of the comments 1178, 1246 and 1250).

response

Please refer to the answer to comment #262.

comment	1298 comment by: Hélicoptères de France
	It is stated in the safety impact that the national provisions already enforced are effective to manage the risk of fatigue. Besides, the possible improvements regarding safety arising from the proposed regulation (options 1
	& 2 of the RIA) are questionable and would be likely to cause a loss of crew knowledge.
response	Please refer to the answer to comment #262.

comment	1485 comment by: GBAA
	 4.4.4.2 Option 0: What more effictive operations at certain times of the day do you refer to? The 3 hours in the morning of option 1 while the rest of the day is curtailed? Option 1: What do mean by flexible approach? Spending 2,000 working hours equals at least 200,000 Euros to maybe get some exemptions which are rejected later on? The rules will be taken as is with hardly any possibility to deviate. You as EASA might have the idea of having some options and flexibility, but the authorities just want to be compliant. Nothing else! Plus, every operation needs to apply for it <u>individually</u>! This will be loss of millions of Euro! Option 2: What is the negative impact? All options are described with rules which needs to be compliant with unless you spend hundreds of thousands Euro.
response	Please refer to the answer to comment #262.

4. IA - 4.5. Conclusion

p. 67-68



comment	158 comment by: Air-Glaciers (pf)
	According to NPA 2017-17 page 67 article 4.5 conclusion. The option 0 - no policy change is the option choosen by the company. Safety impact, Social impact and Economic Impact are neutral or having a little impact. The solution 0 is the proper answer to a one size fit all model which is not applicable to the industry. The FTL shall stay in the hand of the local authority.
response	Please refer to the answer to comment #262.

comment	263 comment by: European Helicopter Association (EHA)
	ADAC (Germany), DRF (Germany) and LAR (Luxembourg): 4.5.1. Comparison of options Risk analysis is not made from an objective and neutral point of view and would not withstand a
	closer research. The results are optimized concerning the requirements of the basic rule. This regulation shall be implemented to increase flight safety but in the same paragraph, it is
	mentioned that side effects like missing experience could even lead to a decrease. The regulation contradicts itself.
response	Please refer to the answer to comment #262.

comment	279 co	mment by: European Helicopter Association (EHA)
	SHA (Switzerland)	
	change is the option choosen by the as Economic Impact are neutral or having	cle 4.5 conclusion. The option 0 - no policy sociation. Safety impact, Social impact and a little impact. The solution 0 is the proper n is not applicable to the indistry. The FTL shall
response	Please refer to the answer to comment	#262.

**** * * ***

comment	439 comment by: UFH French Helicopters Association
	The impact of the implementation of European FTL regulation for HEMS in France goes the
	French operators. It is a complete change of the whole French Health care system which might be
	necessary. Thus, it would be appreciated if the RIA addresses the impacts on the national policy for
	emergency access to care and the Government Health policy, etc. Many lifesavings would be impossible with the time being organization.
	As a consequence, 3 options emerge and are listed here below, ranked according to their level of relevance :
	# OPTION A or option 0 of the RIA
	This option, whose choice relies on the Member States (MS) or EASA's decision, corresponds to the
	option 0 described in the RIA: no policy change. Safety impact, social impact and economic impact are
	neutral or having a little impact. The solution 0 is the proper answer to a one size fits all model which
	is not applicable to the industry. The FTL shall stay in the hand of the local authority. The wellfunctioning
	current national FTL schemes are enforced since years, no excessive fatigue has been demonstrated and the current national system provides French operators with satisfaction. Besides, in the EMS safety risk assessment of this NPA, it is written that "Even with the caveats about
	underreporting of fatigue as a causal factor it would appear from the occurrence data that the controls
	that have been in place to manage fatigue in European EMS have generally been effective.
	Compared to the social benefits from EMS operations in terms of patient safety and health (see below), the overall safety
	balance (flight safety v patient safety) is very positive". UFH strongly asks this option to be considered
	by EASA and the Member States : "no change in the existing situation; HEMS continue to be regulated
	under MS national rules".
	# OPTION B
	This option consists in a total revamp of the NPA 2017-17 for HEMS. We ask for a completely new proposal, distinguishing the HEMS from AEMS and Air Taxi as no operational comparison
	between the fundamentals of these different activities and respecting the following principles:

Individual comments and responses — HEMS

Basing alternative proposal an on: o 14h Standby / 10h Rest with a commander's discretion applicable in case of unforeseen circumstances 0 short-time operational readiness for ready-to-go EMS take-off rostering of 7 ON 7 davs OFF 0 davs flight time limitations to be discussed within this frame 0 FNAM and SNEH ask for this option to be considered in the Comment Response Document (CRD) with the elaboration of a sound RIA. Moreover, FNAM, UFH and SNEH would be happy to offer expertise its to discuss and study this subject with EASA policy officers. Besides, for clarity reasons, this would imply to separate, regarding the FTL scope, the HEMS from CAT, Air Taxi and AEMS operations. **# OPTION C** If these 2 first options are not retained, French stakeholders will ask for this proposed NPA be amended and reviewed to as stated in the following comments. The proposed requirements, as it is, will lead to amend Health National regulations and it will request more crew, more constraints, more costs with a low added safety value as stated in the RIA. The main proposals are laid down here below: The "Flight time" (instead of "sector" whose definition is now restricted to aeroplanes) all in the requirements should not be scheduled as they cannot be in real life • The travelling time between multiple HEMS operating bases of the home base should be increased a minima to 120 minutes (instead of 60 minutes) and in case of change of home base, the ERRP after starting duty (and not the one prior to starting duty) should be increased allow to the continuity of the operations The duration of pre-flight, post-flight or inter-flights should be reduced to 15 minutes to take into account the helicopter checks at the beginning of the FDP (in France, 7%i of flights saving lives would be impossible with a 30 minutes preflight, cf. SNEH illustrative Table in attachment) and then 7 minutes before each take-off from the HEMS operating base No limitations on the number of consecutive FDP lasting more than 12h should be made 2 between extended recovery rest periods • For single-pilot + 1 TCM operations, in the case of a FDP lasting more than 10h, the break should be unscheduled and the operator should ensure ex-post that the break requirement has been fulfilled for pilots as they cannot be in real life The commander's discretion prior to take-off under unforeseen circumstances needs to be extended to all the EMS payload and not only limited to the patient and extended up to 2 hours for 1 pilot + 1 TCM operations (in France, 3%i of flights saving lives would be impossible with a commander's discretion capped to 1 hour, cf. SNEH illustrative Table in attachment) The limitations of the maximum values for continuous FT need to be increased by at least 1

**** * * *** hour

	 The limitations of the maximum values for total flight time within a FDP need to be increased
	by at least 1 hour
	• The 10% allowance between scheduled and actual FDP is not appropriate with the HEMS
	operations and needs to be suppressed
	• The standby needs to be reviewed else it will never be used
	• The standby needs to be reviewed else it will never be used
	This proposal would increase by 20% the French State budget allocated for the HEMS activity which is
	not affordable according to the French State.
	Since the objective of this regulation is not flight safety but the harmonization of the different national
	regulations regarding HEMS, the text should not have the opposite effect leading to less
	level playing
	field. If the proposed dispositions are inapplicable, there may be non-binding opt-in / opt- out system
	possibilities (through the newly proposed Article 8 of this NPA). Misunderstanding or
	interpretation of
	National level of a far too complex regulation for small operators might also lead to lower
	level playing
	field.
	To conclude, FNAM, UFH and SNEH ask EASA for considering all the impacts (economic,
	social, emergency access to
	care, national health policy impacts in addition to the flight safety impact) to identify the preferred
	option, keeping in mind that the option C would lead to significant changes of the original text.
response	Please refer to the answer to comment #262.

comment 521

comment by: FNAM/SNEH

Attachments <u>#275</u> <u>#276</u> <u>#277</u> <u>#278</u> <u>#279</u>

Cf. comment 457 and 517

The impact of the implementation of European FTL regulation for HEMS in France goes beyond the French operators. It is a complete change of the whole French Health care system which might be necessary. Thus, it would be appreciated if the RIA addresses the impacts on the national policy for emergency access to care and the Government Health policy, etc.

Many lifesavings would be impossible with the time being organization. (Cf. attachments S1, S2, S3 and S4)

As a consequence, 3 options emerge and are listed here below, ranked according to their level of relevance for FNAM and SNEH:



OPTION A or option 0 of the RIA

This option, whose choice relies on the Member States (MS) or EASA's decision, corresponds to the option 0 described in the RIA: no policy change. Safety impact, social impact and economic impact are neutral or having a little impact. The solution 0 is the proper answer to a one size fits all model which is not applicable to the industry. The FTL shall stay in the hand of the local authority. The well-functioning current national FTL schemes are enforced for years, no excessive fatigue has been demonstrated and the current national system provides French operators with satisfaction. Besides, in the EMS safety risk assessment of this NPA, it is written that *"Even with the caveats about underreporting of fatigue as a causal factor it would appear from the occurrence data that the controls that have been in place to manage fatigue in European EMS have generally been effective. Compared to the social benefits from EMS operations in terms of patient safety and health (see below), the overall safety balance (flight safety v patient safety) is very positive". FNAM and SNEH strongly ask this option to be considered by EASA and the Member States : <i>"no change in the existing situation; HEMS continue to be regulated under MS national rules"*.

OPTION B

This option consists in a total revamp of the NPA 2017-17 for HEMS. FNAM and SNEH ask for a completely new proposal, distinguishing the HEMS from AEMS and Air Taxi as no operational comparison can be made between the fundamentals of these different activities and respecting the following principles:

- Basing an alternative proposal on:
 - 14h Standby / 10h Rest with a commander's discretion applicable in case of unforeseen circumstances
 - o short-time operational readiness for ready-to-go EMS take-off
 - rostering of 7 days ON / 7 days OFF
 - o flight time limitations to be discussed within this frame

FNAM and SNEH ask for this option to be considered in the Comment Response Document (CRD) with the elaboration of a sound RIA. Moreover, FNAM and SNEH would be happy to offer its expertise to discuss and study this subject with EASA policy officers. Besides, for clarity reasons, this would imply to separate, regarding the FTL scope, the HEMS from CAT, Air Taxi and AEMS operations.

OPTION C

If these 2 first options are not retained, FNAM and SNEH ask for this proposed NPA to be amended and reviewed as stated in the following comments. The proposed requirements, as it is, will lead to amend Health National regulations and it will request more crew, more constraints, more costs with a low added safety value as stated in the RIA. The main proposals are laid down here below:

 The "Flight time" (instead of "sector" whose definition is now restricted to aeroplanes) in all the requirements should not be scheduled as they cannot be in real life



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

- The travelling time between multiple HEMS operating bases of the home base should be increased *a minima* to 120 minutes (instead of 60 minutes) and in case of change of home base, the ERRP after starting duty (and not the one prior to starting duty) should be increased to allow the continuity of the operations
- The duration of pre-flight, post-flight or inter-flights should be suppressed and replaced by "a sufficient time determined by the operator and specified in the operating manual" (in France, 7%ⁱ of flights saving lives would be impossible with a 30 minutes preflight, cf. SNEH illustrative Table in attachment) No limitations on the number of consecutive FDP lasting more than 12h should be made between 2 extended recovery rest periods
- For single-pilot + 1 TCM operations, in the case of a FDP lasting more than 10h, the break should be unscheduled and the operator should ensure ex-post that the break requirement has been fulfilled for pilots as they cannot be in real life
- The commander's discretion prior to take-off under unforeseen circumstances needs to be extended to all the EMS payload and not only limited to the patient and extended up to 2 hours for 1 pilot + 1 TCM operations (in France, 3%ⁱ of flights saving lives would be impossible with a commander's discretion capped to 1 hour, cf. SNEH illustrative Table in attachment)
- The limitations of the maximum values for continuous FT need to be increased by at least 1 hour
- The limitations of the maximum values for total flight time within a FDP need to be increased by at least 1 hour
- The 10% allowance between scheduled and actual FDP is not appropriate with the HEMS operations and needs to be suppressed
- The standby needs to be reviewed else it will never be used

The 3 options all respect the general FTL philosophy and the learnings of fatigue impact assessments.

This proposal would increase by 20% the French State budget allocated for the HEMS activity which is not affordable according to the French State.

Since the objective of this regulation is not flight safety but the harmonization of the different national regulations regarding HEMS, the text should not have the opposite effect leading to less level playing field. If the proposed dispositions are inapplicable, there may be non-binding opt-in / opt-out system possibilities (through the newly proposed Article 8 of this NPA). Misunderstanding or interpretation of National level of a far too complex regulation for small operators might also lead to lower level playing field.

To conclude, FNAM and SNEH ask EASA for considering all the impacts (economic, social, emergency access to care, national health policy impacts in addition to the flight safety impact) to identify the preferred option, keeping in mind that the option C would lead to significant changes of the original text.

response

Please refer to the answer to comment #262.

comment 543

comment by: ADAC Luftrettung gGmbH



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 559 of 585 Risk analysis is not made from an objective and neutral point of view and would not withstand a closer research. The results are optimized concerning the requirements of the basic rule.

This regulation shall be implemented to increase flight safety but in the same paragraph, it is mentioned that side effects like missing experience could even lead to a decrease. The regulation contradicts itself.

Comment to safety Impact

Regarding the flexible Approach in comparison to the safety impact the EASA expects a positive low benefit.

We do not agree with the manner, in which this conclusion was argued. The Attachment II stated in the period of 1971 to 2012 only three accidents, where fatigue was found as contributing factor. According to the EASA statement this is about 1.3% of all EMS occurrences from the ICAO ADFREP database.

We have to question the data from the ADREP Database, because the EASA didn't explain, if the 395 EMS related accidents where based on a worldwide search or on a query only for the EU region.

The number looks quite high compared to the data from the German federal bureau of aircraft accident investigation (BFU). In the period from 1989 to 2007 there have been only 14 fatal accidents related to HEMS operation in Germany. As stated in the beginning, German HEMS makes up nearly 40% of all HEMS Missions flown in the EASA member states. Therefore we consider the database as not relevant for the EASA kind of argumentation.

Furthermore, if we compare the 3 accidents with the number of sectors flown in these 40 years (estimated more than 8 Mill), it is very clear, that fatigue is not a factor, where the safety of HEMS missions is jeopardized.

Additionally the NPA states, that the current situation would remain acceptable, if HEMS operations were conducted predominantly in the Member State that issued the AOC.

From the German side of view, there are isolated cross border missions, but these starts and ends always in the member state issuing the AOC. As shown in the beginning, HEMS is mainly government founded and assists the ground based national rescue system. We do not see the point in the argumentation of the EASA that this situation will change in the near future in terms of number of HEMS bases to be established across Europe and the number of services to be available cross-border.

Also the next EASA statement regarding the safety aspects cannot be followed from our side of view. "Discrepancies between national FTL regimes might make it difficult for operators to conduct HEMS outside their principal home base".

Our Opinion is that discrepancies between FTL regimes within the scope of the operators due to individual flight time schedules make it impossible to establish common rules for tenders and to give national ministries the chance to compare, which operator will have the best safety policy regarding fatigue.

All together, we came to the conclusion, that the new proposals will not enhance the flight safety and fatigue management and that the EASA conclusion has to be rethought with appropriate studies and the safety records from HEMS Missions in the last decade. The EASA itself made some presumptions like to consider, that option 1 may provide some low positive benefits. Within the scope of this highly difficult theme, considerations should not be used to argue about changing an existing, functioning and safe System of national flight time limitations.

**** * * **** This is also more important, while the EASA will keep normal CAT Operations (i.e. passenger transport with one pilot) within the national scope. For Germany this means, that with single pilot CAT the existing rules stay in place, while in HEMS operations with 2 pilots or one pilot and HEMS-TC way more restrictive rules apply. Ridiculous!

Comment to social impact

Regarding the flexible Approach in comparison to the social impact the EASA expects a neutral result.

In fact, we estimate a negative outcome. In summer 2017 the ADAC and the DRF started a scientific study with the German center of aeronautics and space (DLR). Unfortunately the scientific outcome will not be published by the DLR before the midst of march. From the point of view from the participating pilots we can already tell, that no one was fond working in a system with 2 shifts for rescue helicopters during the day time.

Working in the rescue service will soon become unattractive, which leads to reduced safety due to the fact, that experienced pilots will join other services.

The impact of the NPA is mainly, that the operators have to recruit and employ more pilots. The European market for experienced HEMS Pilots is more or less nonexistent. We are afraid, that this will lead to deterioration in flight safety.

Assuming that there are not enough trained pilots, the operator have to reduce their common working schedule, which will lead to deterioration in the provision of the HEMS operating hours. Furthermore this will have immediate effect to the number of HEMS missions, treated persons and patients transported.

Thinking of need for relocation or more travelling time due to the FTL changes, also the work/life balance will deteriorate together with the social acceptance of the HEMS Business and the Crews involved.

The DNR Study "Preliminary Analysis of Potential Regulatory Impacts – EMS" comes to the conclusion that these task where relevant regarding possible social impacts.

Being objective we cannot go conform to the EASA expectation of a neutral result. Instead we think that the social impact has to be downgraded

Comment to economic impact

The EASA rule making group itself came to the conclusion, that the economic impact of option 1 - the flexible approach to a new regulation - has to be classified as medium negative.

Here we cannot follow the argumentation in total. The difference between the fully prescriptive and the flexible approach is based on the fact, that in option 1 the operator will have the opportunity to set up individual flight time schemes as where in option 2 the operators stick to the new regulations and recruit new pilots.

Option 2 is considered as highly negative.

To avoid these highly negative impacts we assume, that nearly every HEMS operator will set up individual flight time schedules / schemes. The operators have to set up scientific based studies with a medical expertise. Due to the fact, that some operators have multiple HEMS operating bases with 24/7 h or bases only during daytime and these bases differs sometimes totally in the amount of flight times, duty times and mission complexity and also the daily missions flown, each base has to be evaluated separately.

Worst case will be 360 individually based flight time schemes. According to regulation/EU) 216-2008 Article 22 Chapter (2) (c) the EASA has only 1 month for the assessment.

The EASA estimates in the first year 11 derogations with about 800 hours for the evaluation. These figures do not match the current evaluations with up to 800 hours a single complex derogation flight time scheme.

We do not see the EASA capable of handling the derogations in the given time frames of the basic regulation.

The case study of the EASA came to the conclusion, to employ a forth pilot during the summer season. They did not mention how this will fit into the regulations in cause 5 of the Council Directive 1999/70/EC of 28 June 1999 concerning the framework agreement on fixed-term work.

To prevent abuse arising from the use of successive fixed-term employment contracts or relationships, the member states did set up regulations regarding:

(a) Objective reasons justifying the renewal of such contracts;(b) the maximum total duration of successive fixed-term employment contracts;(c) the number of renewals of such contracts.

In Germany this means, if a pilot more is employed more than two times, he will automatically become a fixed-term employer.

The impacts of these multiple short term employments have not been considered by the EASA.

We therefore consider even the flexible approach (option 1) as highly negative.

response

Please refer to the answer to comment #262.

comment	564	comment by: <i>Rüdiger Neu</i>
	Die Risikoanalysen wurden subjektiv bewertet u standhalten. In Bezug auf das Grundregelwerk, ist o Das Regelwerk dient einer Erhöhung der Flugsicher dass das Regelwerk auf Grund fehlender Erfahrung Dies ist ein Widerspruch in sich!	die Bewertung geschönt. heit, jedoch wird die Aussage getroffen,
	Die neue Regelung hätte vielleicht nur neutrale schere und massive Auswirkungen auf das Soziale u	
	Eine der Auswirkungen wäre wohl der Schichte Reisezeiten bei den Piloten führen. Das Resulta Erholung. Somit läuft dies auch dem urspünglichen	t wäre deutlich weniger Zeit für die
response	Please refer to the answer to comment #262.	
comment	700	comment by: Oya Vendée Hélicoptères

Attachments <u>#280</u> <u>#281</u> <u>#282</u> <u>#283</u> <u>#284</u>

Cf. comment 637 and 696



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 562 of 585 The impact of the implementation of European FTL regulation for HEMS in France goes beyond the French operators. It is a complete change of the whole French Health care system which might be necessary. Thus, it would be appreciated if the RIA addresses the impacts on the national policy for emergency access to care and the Government Health policy, etc.

Many lifesavings would be impossible with the time being organization. (Cf. attachments S1, S2, S3 and S4)

As a consequence, 3 options emerge and are listed here below, ranked according to their level of relevance for OYA:

OPTION A or option 0 of the RIA

This option, whose choice relies on the Member States (MS) or EASA's decision, corresponds to the option 0 described in the RIA: no policy change. Safety impact, social impact and economic impact are neutral or having a little impact. The solution 0 is the proper answer to a one size fits all model which is not applicable to the industry. The FTL shall stay in the hand of the local authority. The well-functioning current national FTL schemes are enforced for years, no excessive fatigue has been demonstrated and the current national system provides French operators with satisfaction. Besides, in the EMS safety risk assessment of this NPA, it is written that *"Even with the caveats about underreporting of fatigue as a causal factor it would appear from the occurrence data that the controls that have been in place to manage fatigue in European EMS have generally been effective. Compared to the social benefits from EMS operations in terms of patient safety and health (see below), the overall safety balance (flight safety v patient safety) is very positive". OYA strongly asks this option to be considered by EASA and the Member States : "no change in the existing situation; HEMS continue to be regulated under MS national rules".*

OPTION B

This option consists in a total revamp of the NPA 2017-17 for HEMS. OYA asks for a completely new proposal, distinguishing the HEMS from AEMS and Air Taxi as no operational comparison can be made between the fundamentals of these different activities and respecting the following principles:

- Basing an alternative proposal on:
 - 14h Standby / 10h Rest with a commander's discretion applicable in case of unforeseen circumstances
 - short-time operational readiness for ready-to-go EMS take-off
 - rostering of 7 days ON / 7 days OFF
 - o flight time limitations to be discussed within this frame

OYA asks for this option to be considered in the Comment Response Document (CRD) with the elaboration of a sound RIA. Moreover, OYA would be happy to offer its expertise to discuss and study this subject with EASA policy officers. Besides, for clarity reasons, this would imply to separate, regarding the FTL scope, the HEMS from CAT, Air Taxi and AEMS operations.

OPTION C

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 563 of 585 If these 2 first options are not retained, OYA asks for this proposed NPA to be amended and reviewed as stated in the following comments. The proposed requirements, as it is, will lead to amend Health National regulations and it will request more crew, more constraints, more costs with a low added safety value as stated in the RIA. The main proposals are laid down here below:

- The "Flight time" (instead of "sector" whose definition is now restricted to aeroplanes) in all the requirements should not be scheduled as they cannot be in real life
- The travelling time between multiple HEMS operating bases of the home base should be increased *a minima* to 120 minutes (instead of 60 minutes) and in case of change of home base, the ERRP after starting duty (and not the one prior to starting duty) should be increased to allow the continuity of the operations
- The duration of pre-flight, post-flight or inter-flights should be suppressed and replaced by "a sufficient time determined by the operator and specified in the operating manual" (in France, 7%ⁱ of flights saving lives would be impossible with a 30 minutes preflight, cf. SNEH illustrative Table in attachment) No limitations on the number of consecutive FDP lasting more than 12h should be made between 2 extended recovery rest periods
- For single-pilot + 1 TCM operations, in the case of a FDP lasting more than 10h, the break should be unscheduled and the operator should ensure ex-post that the break requirement has been fulfilled for pilots as they cannot be in real life
- The commander's discretion prior to take-off under unforeseen circumstances needs to be extended to all the EMS payload and not only limited to the patient and extended up to 2 hours for 1 pilot + 1 TCM operations (in France, 3%ⁱ of flights saving lives would be impossible with a commander's discretion capped to 1 hour, cf. SNEH illustrative Table in attachment)
- The limitations of the maximum values for continuous FT need to be increased by at least 1 hour
- The limitations of the maximum values for total flight time within a FDP need to be increased by at least 1 hour
- The 10% allowance between scheduled and actual FDP is not appropriate with the HEMS operations and needs to be suppressed
- The standby needs to be reviewed else it will never be used

The 3 options all respect the general FTL philosophy and the learnings of fatigue impact assessments.

This proposal would increase by 20% the French State budget allocated for the HEMS activity which is not affordable according to the French State.

Since the objective of this regulation is not flight safety but the harmonization of the different national regulations regarding HEMS, the text should not have the opposite effect leading to less level playing field. If the proposed dispositions are inapplicable, there may be non-binding opt-in / opt-out system possibilities (through the newly proposed Article 8 of this NPA). Misunderstanding or interpretation of National level of a far too complex regulation for small operators might also lead to lower level playing field.

**** ****

To conclude, OYA asks EASA for considering all the impacts (economic, social, emergency access to care, national health policy impacts in addition to the flight safety impact) to identify the preferred option, keeping in mind that the option C would lead to significant changes of the original text. Please refer to the answer to comment #262. response 765 comment comment by: DRF-Luftrettung Comparing the EASA conclusion Safety Impact Social impact Economical impact Option 1 Positive low benefit neutral Medium negative With our conclusion (see comments 762, 763, 764) Safety Impact Social impact **Economical impact** Option 1 neutral Medium negative Highly negative we really have to question, if the NPA 2017-17 is appropriate to enhance the safety of **HEMS** operations. We would like the EASA to think about FTL from the operators and pilots view of sight. With the support of the competent operators, EASA should conduct a continuous monitoring over a period of minimum 5 years about the present provisions concerning flight and duty time limitations and rest requirements to get a updated evidence based judgement of the safety of the existing flight time regulations. Please refer to the answer to comment #262. response comment 989 comment by: MBH SAMU Attachments #285 #286 #287 #288 #289 Cf. comments 1006 and 985 The impact of the implementation of European FTL regulation for HEMS in France goes beyond the French operators. It is a complete change of the whole French Health care system which might be necessary. Thus, it would be appreciated if the RIA addresses the



impacts on the national policy for emergency access to care and the Government Health policy, etc.

Many lifesavings would be impossible with the time being organization. (Cf. attachments S1, S2, S3 and S4)

As a consequence, 3 options emerge and are listed here below, ranked according to their level of relevance for MBH:

OPTION A or option 0 of the RIA

This option, whose choice relies on the Member States (MS) or EASA's decision, corresponds to the option 0 described in the RIA: no policy change. Safety impact, social impact and economic impact are neutral or having a little impact. The solution 0 is the proper answer to a one size fits all model which is not applicable to the industry. The FTL shall stay in the hand of the local authority. The well-functioning current national FTL schemes are enforced for years, no excessive fatigue has been demonstrated and the current national system provides French operators with satisfaction. Besides, in the EMS safety risk assessment of this NPA, it is written that *"Even with the caveats about underreporting of fatigue as a causal factor it would appear from the occurrence data that the controls that have been in place to manage fatigue in European EMS have generally been effective. Compared to the social benefits from EMS operations in terms of patient safety and health (see below), the overall safety balance (flight safety v patient safety) is very positive". MBH strongly asks this option to be considered by EASA and the Member States : "no change in the existing situation; HEMS continue to be regulated under MS national rules".*

OPTION B

This option consists in a total revamp of the NPA 2017-17 for HEMS. MBH asks for a completely new proposal, distinguishing the HEMS from AEMS and Air Taxi as no operational comparison can be made between the fundamentals of these different activities and respecting the following principles:

- Basing an alternative proposal on:
 - 14h Standby / 10h Rest with a commander's discretion applicable in case of unforeseen circumstances
 - \circ $\;$ short-time operational readiness for ready-to-go EMS take-off $\;$
 - rostering of 7 days ON / 7 days OFF
 - flight time limitations to be discussed within this frame

MBH asks for this option to be considered in the Comment Response Document (CRD) with the elaboration of a sound RIA. Moreover, MBH would be happy to offer its expertise to discuss and study this subject with EASA policy officers. Besides, for clarity reasons, this would imply to separate, regarding the FTL scope, the HEMS from CAT, Air Taxi and AEMS operations.

OPTION C

If these 2 first options are not retained, MBH asks for this proposed NPA to be amended and reviewed as stated in the following comments. The proposed requirements, as it is, will lead to amend Health National regulations and it will request more crew, more

**** **** constraints, more costs with a low added safety value as stated in the RIA. The main proposals are laid down here below:

- The "Flight time" (instead of "sector" whose definition is now restricted to aeroplanes) in all the requirements should not be scheduled as they cannot be in real life
- The travelling time between multiple HEMS operating bases of the home base should be increased *a minima* to 120 minutes (instead of 60 minutes) and in case of change of home base, the ERRP after starting duty (and not the one prior to starting duty) should be increased to allow the continuity of the operations
- The duration of pre-flight, post-flight or inter-flights should be suppressed and replaced by "a sufficient time determined by the operator and specified in the operating manual" (in France, 7%ⁱ of flights saving lives would be impossible with a 30 minutes preflight, cf. SNEH illustrative Table in attachment) No limitations on the number of consecutive FDP lasting more than 12h should be made between 2 extended recovery rest periods
- For single-pilot + 1 TCM operations, in the case of a FDP lasting more than 10h, the break should be unscheduled and the operator should ensure ex-post that the break requirement has been fulfilled for pilots as they cannot be in real life
- The commander's discretion prior to take-off under unforeseen circumstances needs to be extended to all the EMS payload and not only limited to the patient and extended up to 2 hours for 1 pilot + 1 TCM operations (in France, 3%ⁱ of flights saving lives would be impossible with a commander's discretion capped to 1 hour, cf. SNEH illustrative Table in attachment)
- The limitations of the maximum values for continuous FT need to be increased by at least 1 hour
- The limitations of the maximum values for total flight time within a FDP need to be increased by at least 1 hour
- The 10% allowance between scheduled and actual FDP is not appropriate with the HEMS operations and needs to be suppressed
- The standby needs to be reviewed else it will never be used

The 3 options all respect the general FTL philosophy and the learnings of fatigue impact assessments.

This proposal would increase by 20% the French State budget allocated for the HEMS activity which is not affordable according to the French State.

Since the objective of this regulation is not flight safety but the harmonization of the different national regulations regarding HEMS, the text should not have the opposite effect leading to less level playing field. If the proposed dispositions are inapplicable, there may be non-binding opt-in / opt-out system possibilities (through the newly proposed Article 8 of this NPA). Misunderstanding or interpretation of National level of a far too complex regulation for small operators might also lead to lower level playing field.

To conclude, MBH asks EASA for considering all the impacts (economic, social, emergency access to care, national health policy impacts in addition to the flight safety impact) to

identify the preferred option, keeping in mind that the option C would lead to significant changes of the original text.

response

Please refer to the answer to comment #262.

comment1108comment by: Rabbit-Air LtdThe Corporate Aviation having an AOC is not taken into consideration at all. This issue was
mentioned since a long time ago without success. Any additional restriction on the already
restricted FTL limitations would give further signals to change into NCC operation.responseYour comments is not clear.

comment	1160comment by: FNAM
	Attachments <u>#290</u> <u>#291</u> <u>#292</u> <u>#293</u> <u>#294</u>
	FNAM and EBAA France agree with option 0 described in the RIA. This option, whose choice relies on the Member States (MS) or the EASA's decision, corresponds to the option 0 described in the RIA : no policy change. Safety impact, social impact and economic impact are neutral or having a little impact. The option 0 seems the proper action since a one size fits all model is not applicable to the industry. The well-functioning current national FTL schemes are enforced for years, no excessive fatigue has been demonstrated and more specifically, the current national system provides French operators and their crews with satisfaction. As a consequence, any changes in the FTL schemes in AEMS may take benefit from considering the experience of the existing system and organization instead of creating from scratch a brand new system but inadequate and inefficient.
	If the Option 0 is not retained by EASA, FNAM and EBAA France ask for this proposed NPA to be amended and reviewed as stated in the following comments distinguishing AEMS, HEMS and Air Taxi. Indeed, a completely new proposal, distinguishing the AEMS from HEMS and Air Taxi is needed as no operational comparison can be made between the fundamentals of these different activities. FNAM and EBAA France insist above all in protecting the amplitude for the Flight Duty Period and the long reserve with short notification time which are necessary to allow emergency missions. In that way, FNAM and EBAA France ask to have new European dispositions that would allow:
	 18 hours maximum FDP with 4 sectors with 3 pilots (augmented crew) (Cf. Annex 2) 14 hours maximum FDP with 4 sectors with 2 pilots (non-augmented crew) (Cf. Annex 3) A standby definition allowing up to 24 hours of operational readiness (Cf. Annex 5) The possibility to have several consecutive standby provided no flights/activities are performed meanwhile on standby (Cf. Annex 5)

• 2h of commander's discretion with non-augmented crew & 3h with augmented crew, which are the same requirements than for CAT operations (Cf. Annex 4)

FNAM and EBAA France ask for this option to be considered in the Comment Response Document (CRD) with the elaboration of a sound RIA. These elements of our proposals for NPA 2017-17 for AEMS form an integrated whole: there are each and all interrelated and interdependent. Moreover, FNAM and EBAA France would be happy to offer its expertise to discuss and study this subject with EASA policy officers. Besides, for clarity reasons, this would imply to separate, regarding the FTL scope, the AEMS from CAT, Air Taxi and HEMS operations.

Thus, FNAM and EBAA France hereby:

- Proposes dispositions limited to AEMS
- Agrees and adopts for Air Taxi, the EBAA comments published in CRD

However, since the Air Taxi and AEMS requirements are deeply linked (Cf. Annex 1), the Air Taxi dispositions need to be adapted taking into account the AEMS proposals. Thus, FNAM and EBAA France propose changes for AEMS requirements in this Comment Respond Document which have implied to also comment marginally Air Taxi proposals.

response

Please refer to the answer to comment #262.

comment	1250 comme	ent by: SAF
	Attachments <u>#295</u> <u>#296</u> <u>#297</u> <u>#298</u> <u>#299</u>	
	Cf. comments 1178 and 1246	
	The impact of the implementation of European FTL regulation for HEMS in F beyond the French operators. It is a complete change of the whole French I system which might be necessary. Thus, it would be appreciated if the RIA ad impacts on the national policy for emergency access to care and the Governm policy, etc.	Health care dresses the
	Many lifesavings would be impossible with the time being organization.	
	(Cf. attachments S1, S2, S3 and S4)	
	As a consequence, 3 options emerge and are listed here below, ranked accord level of relevance for SAF:	ing to their
	# OPTION A or option 0 of the RIA	
	This option, whose choice relies on the Member States (MS) or EASA' corresponds to the option 0 described in the RIA: no policy change. Safety im	



impact and economic impact are neutral or having a little impact. The solution 0 is the proper answer to a one size fits all model which is not applicable to the industry. The FTL shall stay in the hand of the local authority. The well-functioning current national FTL schemes are enforced for years, no excessive fatigue has been demonstrated and the current national system provides French operators with satisfaction. Besides, in the EMS safety risk assessment of this NPA, it is written that *"Even with the caveats about underreporting of fatigue as a causal factor it would appear from the occurrence data that the controls that have been in place to manage fatigue in European EMS have generally been effective. Compared to the social benefits from EMS operations in terms of patient safety and health (see below), the overall safety balance (flight safety v patient safety) is very positive". SAF strongly asks this option to be considered by EASA and the Member States : "no change in the existing situation; HEMS continue to be regulated under MS national rules".*

OPTION B

This option consists in a total revamp of the NPA 2017-17 for HEMS. SAF asks for a completely new proposal, distinguishing the HEMS from AEMS and Air Taxi as no operational comparison can be made between the fundamentals of these different activities and respecting the following principles:

- Basing an alternative proposal on:
 - 14h Standby / 10h Rest with a commander's discretion applicable in case of unforeseen circumstances
 - o short-time operational readiness for ready-to-go EMS take-off
 - rostering of 7 days ON / 7 days OFF
 - \circ ~ flight time limitations to be discussed within this frame

SAF asks for this option to be considered in the Comment Response Document (CRD) with the elaboration of a sound RIA. Moreover, SAF would be happy to offer its expertise to discuss and study this subject with EASA policy officers. Besides, for clarity reasons, this would imply to separate, regarding the FTL scope, the HEMS from CAT, Air Taxi and AEMS operations.

OPTION C

If these 2 first options are not retained, SAF asks for this proposed NPA to be amended and reviewed as stated in the following comments. The proposed requirements, as it is, will lead to amend Health National regulations and it will request more crew, more constraints, more costs with a low added safety value as stated in the RIA. The main proposals are laid down here below:

- The "Flight time" (instead of "sector" whose definition is now restricted to aeroplanes) in all the requirements should not be scheduled as they cannot be in real life
- The travelling time between multiple HEMS operating bases of the home base should be increased *a minima* to 120 minutes (instead of 60 minutes) and in case

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

of change of home base, the ERRP after starting duty (and not the one prior to starting duty) should be increased to allow the continuity of the operations

- The duration of pre-flight, post-flight or inter-flights should be suppressed and replaced by "a sufficient time determined by the operator and specified in the operating manual" (in France, 7%ⁱ of flights saving lives would be impossible with a 30 minutes preflight, cf. SNEH illustrative Table in attachment) No limitations on the number of consecutive FDP lasting more than 12h should be made between 2 extended recovery rest periods
- For single-pilot + 1 TCM operations, in the case of a FDP lasting more than 10h, the break should be unscheduled and the operator should ensure ex-post that the break requirement has been fulfilled for pilots as they cannot be in real life
- The commander's discretion prior to take-off under unforeseen circumstances needs to be extended to all the EMS payload and not only limited to the patient and extended up to 2 hours for 1 pilot + 1 TCM operations (in France, 3%ⁱ of flights saving lives would be impossible with a commander's discretion capped to 1 hour, cf. SNEH illustrative Table in attachment)
- The limitations of the maximum values for continuous FT need to be increased by at least 1 hour
- The limitations of the maximum values for total flight time within a FDP need to be increased by at least 1 hour
- The 10% allowance between scheduled and actual FDP is not appropriate with the HEMS operations and needs to be suppressed
- The standby needs to be reviewed else it will never be used

The 3 options all respect the general FTL philosophy and the learnings of fatigue impact assessments.

This proposal would increase by 20% the French State budget allocated for the HEMS activity which is not affordable according to the French State.

Since the objective of this regulation is not flight safety but the harmonization of the different national regulations regarding HEMS, the text should not have the opposite effect leading to less level playing field. If the proposed dispositions are inapplicable, there may be non-binding opt-in / opt-out system possibilities (through the newly proposed Article 8 of this NPA). Misunderstanding or interpretation of National level of a far too complex regulation for small operators might also lead to lower level playing field.

To conclude, SAF asks EASA for considering all the impacts (economic, social, emergency access to care, national health policy impacts in addition to the flight safety impact) to identify the preferred option, keeping in mind that the option C would lead to significant changes of the original text.

response

Please refer to the answer to comment #262.

comment 1299

comment by: Hélicoptères de France



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 571 of 585

Cf. comment 1 and 59

The impact of the implementation of European FTL regulation for HEMS in France goes beyond the French operators. It is a complete change of the whole French Health care system which might be necessary. Thus, it would be appreciated if the RIA addresses the impacts on the national policy for emergency access to care and the Government Health policy, etc.

Many lifesavings would be impossible with the time being organization.

(Cf. attachments S1, S2, S3 and S4)

As a consequence, 3 options emerge and are listed here below, ranked according to their level of relevance for HDF:

OPTION A or option 0 of the RIA

This option, whose choice relies on the Member States (MS) or EASA's decision, corresponds to the option 0 described in the RIA: no policy change. Safety impact, social impact and economic impact are neutral or having a little impact. The solution 0 is the proper answer to a one size fits all model which is not applicable to the industry. The FTL shall stay in the hand of the local authority. The wellfunctioning current national FTL schemes are enforced since years, no excessive fatigue has been demonstrated and the current national system provides French operators with satisfaction. Besides, in the EMS safety risk assessment of this NPA, it is written that "Even with the caveats about underreporting of fatigue as a causal factor it would appear from the occurrence data that the controls that have been in place to manage fatigue in European EMS have generally been effective. Compared to the social benefits from EMS operations in terms of patient safety and health (see below), the overall safety balance (flight safety v patient safety) is very positive". HDF strongly asks this option to be considered by EASA and the Member States : "no change in the existing situation; HEMS continue to be regulated under MS national rules".

OPTION B

This option consists in a total revamp of the NPA 2017-17 for HEMS. HDF asks for a completely new proposal, distinguishing the HEMS from AEMS and Air Taxi as no operational comparison can be made between the fundamentals of these different activities and respecting the following principles:

• Basing an alternative proposal on:

o 14h Standby / 10h Rest with a commander's discretion applicable in case of unforeseen circumstances

o short-time operational readiness for ready-to-go EMS take-off

o rostering of 7 days ON / 7 days OFF

o flight time limitations to be discussed within this frame HDF asks for this option to be considered in the Comment Response Document (CRD) with the elaboration of a sound RIA. Moreover, HDF would be happy to offer its expertise to discuss and study this subject with EASA policy officers. Besides, for clarity reasons, this would imply to separate, regarding the FTL scope, the HEMS from CAT, Air Taxi and AEMS operations.

OPTION C

If these 2 first options are not retained, HDF asks for this proposed NPA to be amended and reviewed as stated in the following comments. The proposed requirements, as it is, will lead to amend Health National regulations and it will request more crew, more constraints, more costs with a low added safety value as stated in the RIA. The main proposals are laid down here below:

**** * * *+.+* • The "Flight time" (instead of "sector" whose definition is now restricted to aeroplanes) in all the requirements should not be scheduled as they cannot be in real life

• The travelling time between multiple HEMS operating bases of the home base should be increased a minima to 120 minutes (instead of 60 minutes) and in case of change of home base, the ERRP after starting duty (and not the one prior to starting duty) should be increased to allow the continuity of the operations

• The duration of pre-flight, post-flight or inter-flights should be suppressed and replaced by "a sufficient time determined by the operator and specified in the operating manual" (in France, 7% of flights saving lives would be impossible with a 30 minutes preflight, cf. SNEH illustrative Table in attachment) No limitations on the number of consecutive FDP lasting more than 12h should be made between 2 extended recovery rest periods

• For single-pilot + 1 TCM operations, in the case of a FDP lasting more than 10h, the break should be unscheduled and the operator should ensure ex-post that the break requirement has been fulfilled for pilots as they cannot be in real life

• The commander's discretion prior to take-off under unforeseen circumstances needs to be extended to all the EMS payload and not only limited to the patient and extended up to 2 hours for 1 pilot + 1 TCM operations (in France, 3%i of flights saving lives would be impossible with a commander's discretion capped to 1 hour, cf. SNEH illustrative Table in attachment)

• The limitations of the maximum values for continuous FT need to be increased by at least 1 hour

• The limitations of the maximum values for total flight time within a FDP need to be increased by at least 1 hour

• The 10% allowance between scheduled and actual FDP is not appropriate with the HEMS operations and needs to be suppressed

• The standby needs to be reviewed else it will never be used ***

The 3 options all respect the general FTL philosophy and the learnings of fatigue impact assessments.

This proposal would increase by 20% the French State budget allocated for the HEMS activity which is not affordable according to the French State.

Since the objective of this regulation is not flight safety but the harmonization of the different national regulations regarding HEMS, the text should not have the opposite effect leading to less level playing field. If the proposed dispositions are inapplicable, there may be non-binding opt-in / opt-out system possibilities (through the newly proposed Article 8 of this NPA). Misunderstanding or interpretation of National level of a far too complex regulation for small operators might also lead to lower level playing field.

To conclude, HDF asks EASA for considering all the impacts (economic, social, emergency access to care, national health policy impacts in addition to the flight safety impact) to identify the preferred option, keeping in mind that the option C would lead to significant changes of the original text.

response

Please refer to the answer to comment #262.

comment | 1409

comment by: Swiss Air-Ambulance Rega

The risk analyses are assessed subjectively and would not withstand scrutiny. With regard to the basic policy, the assessment is sugar-coated.



The purpose of the policy is to increase flight safety, but it is stated that the policy could lead to a higher risk due to the lack of experience. This is a contradiction in itself. response Please refer to the answer to comment #262. comment 1479 comment by: GBAA In Germany and Austria, the option 1 reduces the guaranteed days off. In these two countries, you will get at least 96 days off without duty and at least 28 days of vacation. I haven't seen something like this in option 1; just 6 days per month and nothing else. Why is the social impact then negative with option 0 and positive with option 1? It is acutally vice versa! Please refer to the answer to comment #262. response comment comment by: Swedish Transport Agency, Civil Aviation Department 1484 (Transportstyrelsen, Luftfartsavdelningen) The Swedish Transport Agency recommends to follow the EASA Option 0 since there are only minor safety benefits described in the Impact Assessment. Option 1 and 2 will lead to increased cost for HEMS operators that must employ additional crew. This will have a negative impact on the cost of the health care system. Furthermore the HEMS pilots will get less flight hours per year when the total amount of flight hours per base are shared by more crew members. Less flight hours cannot be improved by additional training. The Swedish Transport Agency suggests that EASA initiate a scientific fatigue study on HEMS crew members. Sweden may be able to contribute with a study taking into consideration the specific conditions for HEMS operations in those Member States, which are less densely populated compared with central EU. Until result has been obtained from scientific fatigue studies, it would be better to postpone Flight Time Limitations regulation for HEMS operations. If EASA prefers to go forward with regulations according to Option 1 or 2, the Swedish Transport Agency has the following proposal: CS FTL.3.225 Standby and duties at the HEMS operating base (a) The maximum duration of standby duty is 16 hours Should be changed to 24 hours per day during a maximum of 7 consecutive days to be followed by a minimum of 7 day's rest. Note: ORO.FTL.235 Rest Periods should be changed in line with this proposal. response Please refer to the answer to comment #262.

comment 1501

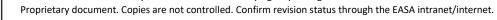
comment by: SBAA Swiss Business Aviation Association / Helene Niedhart

**** **** The Swiss Business Aviation Association (SBAA) is asked to provide its overall conclusion on the proposed rules, as stated in the current NPA. As an organization with the goal of protecting our members' interests, we cannot support the notion that the rules, as designed in the current NPA will produce a benefit for operators engaged in ATXO. The reason the NPA fails to fulfill the expectaions of our industry stems from the fact that the proposed rules were drafted without taking into account the basic constraints, economic mechanisms and operational peculiarities under which our industry operates. Whereas our association unconditionally welcomes the enhancement of the general safety-level in aviation, the NPA clearly fails in delivering on this unquestioned goal. Instead, the NPA pursues - even without intention - a rather prescriptive approach, leading to unbearable burdens on the operators, were the new rules to be enacted as laid out in the NPA. A gross weakness of the NPA is also the fact that there is no estimate on the impact of the proposed rules on the member states. This renders the regulatory impact assessment of the NPA inconclusive, or at least ambiguous. As a bottom line, our association rejects, in spite of the good intention to increase overall safety, the NPA in its current form and content. Finally, we generally question the gains in aviation safety by producing rules that are complex. Our notion is the opposite: More paperwork leads to less safety.

response

Please refer to the answer to comment #262.

A - 4.5. Con	p.
comment	79 comment by: Bjoern Glo
	As Flight Ops director of a target demonstration company, certified under SPO and operating a CMPA (14xLearjet 35/36) from a military base, I wonder, if it is possible to g some special consideration in following aspects: - Local days:
	Our pilots in generell depart from home base and land at home base after a sortie duration between 2 - 4 hrs. The normal FDT is max 6 hrs within the time frame betwee 0800 local til 1600 local. They return home like a normal worker. Could a day like that be considered a Local Day?
	 Rest time: Deployment to a German fighter base for night flight target demonstration. Pilots leave the Hotel to attend the preflight briefing at around 1800l.
	After the mission we attend the debriefing and be back at the hotel by 0200 local. No standby or other duties. Starting briefing again at 1800l and so on.
	The pilots taking breakfast at the hotel at 1000l and wold like to redeploy to the home base with less than 10 hrs rest time (max 1 hrs flighttime), totally relaxed and awake. Could there be spaciel considerations?
response	Noted.



comment	90	comment by: AIR ZERMATT AG
	Conclusion: In the opinion of the industry the implementation wou excessive rise of the overall HEMS operating costs and the the risk of lower salaries. Therefore, the industry su implementation of the EASA FTL and supports the option page 67 article 4.5 and alternatively gives the suggestions	e danger of social tension due to ggests to deny the <u>mandatory</u> o of the NPA 2017-17 stated on
	Suggestion from the industry:	
	 Due to different operating structures (state vs organizations), different tasks & responsibilities different geographical environment within the lapproach does not work and it should be left to the FTL (closeness to operators, practical knowledge has a FTL regulation in place since 1990, which hefficient in regards to safety and quality; For cross border operations, member states shagreements. 	s defined by the state and the EASA territory, a one-size-fits-all ne national authorities to regulate of operations). E.g. Switzerland has proven itself as effective and
response	Please refer to the answer to comment #262.	
comment	157	commont by Air Classers (of)
comment		comment by: <i>Air-Glaciers (pf)</i>
	I find this document not clear and not user friendly mixin HEMS, sectors, etc I wish to have a dedicated documen regulation does not take into account our actual FDTL sc comments several time about them. If this is accepted w regulation and it will request more personal, more const value. The actual FDTL schemes that we apply are in place operators with satisfaction. I am therefore in favor of no keep our national sytems in place. There shall be Opt-in a binding system. A one size fit all model is again not the se errors from the past done by the agency (Single engine, I	ht for helicopter. The proposed hemes and we had delivered we will have to amend such traints, without any added ces since years and provide our t accepting such regulation and system possibilities but no olution and we shall avoid the
response	Please refer to the answer to comment #262.	
comment	544 comme	ent by: ADAC Luftrettung gGmbH

**** * * ***

	Comparin	g the EASA conc	lusion	
	-	Cofoty Incoget	Cosial impos	
	Option 1	Safety Impact Positive low ber		t Economic impact Medium negative
	with our o	conclusion		
		Safety Impact S	ocial impact	Economic impact
	Option 1	neutral N	Aedium negative	Highly negative
oonse	Please ref	er to the answer	r to comment #26	2.
ment	739			comment by: Captain M Alcaid
	a (1)	o problem for	this type of aviat	ion is data collection. There are man

response Please refer to the answer to comment #262.

4. IA - 4.6. Monitoring and evaluationp. 68

comment124comment by: UK CAAPage No: 68Paragraph No: 4.6 Monitoring and evaluationComment: The intent of the monitoring and evaluation of the regulations is supported.
However, NAA's will need more active support from EASA to be able to deliver the data
required.



Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 577 of 585

Also, this list of information would be relevant to all Subpart FTL operations and we believe EASA should consider the wider application of this type of data collection.

It is strongly recommended that EASA should consider developing a clear communication plan and supportive activities and guidance to enable this requirement to be successful.

Justification: To ensure consistency of data from all NAA's, EASA will need to run workshops, provide standardised templates and guidance to enable the operators and NAA's to provide the information requested. If EASA does not actively support the NAA's, the data it receives will be extremely variable and inconsistent across countries. This could generate a misleading picture of the application and impact of the regulations.

response

Accepted. As in the case of FTL in the area of scheduled and charter operations, EASA will organise workshops, provide standardised templates and guidance to enable the operators and NAA's to implement the rules.

5. Proposed actions to support implementation

p. 69

comment	376	comment by: European Helicopter Association (EHA)
	BHA (UK)	
	п	
	 A dedicated workshop with st when all comments have been pr 	akeholders in Cologne after the consultation of the NPA ocessed. "
	Comment: Very much welcomed.	
response	Noted	
comment	522	comment by: <i>FNAM/SNEH</i>
	FNAM for and on behalf of SNEH workshop.	would be happy to send representatives to this dedicated
response	Noted	
comment	701	comment by: Oya Vendée Hélicoptères

TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified.

Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet. Page 578 of 585

	OYA represented by SNEH would be happy to send representatives to this dedicated workshop.
response	Noted
comment	738 comment by: Captain M Alcaide GVI
	I think that such a relevant issue should be more publicized. Most pilots I know don't ever know what an NPA is I obviously will try to attend/assist/participate as much as I can.
response	Noted
comment	859 comment by: Yorkshire Air Ambulance
	Both the BHA and EHA would be happy to send representatives.
response	Noted
comment	990 comment by: MBH SAMU
	MBH represented by SNEH would be happy to send representatives to this dedicated workshop.
response	Noted
comment	1251 comment by: SAF
	SAF represented by SNEH would be happy to send representatives to this dedicated workshop.
response	Noted
6. References	p. 70

comment	125	comment by: UK CAA
	Page No: 70	

**** * * *** Paragraph No: 6.3, Other reference documents

Comment: The UK CAA has no comments on the following reference documents:

- Data Collection and Comparative Assessment of Existing National FTL provisions for EMS
- Preliminary Analysis of Impacts from Future Potential FTL Regulatory Changes for EMS
- Preliminary Analysis of Impacts from Future Potential FTL Regulatory Changes for Air Taxi and Single Pilot Operations
- Scientific Study commissioned by EBAA and ECA
- Report on the Assessment of proposed FTL tables for Air Taxi and Emergency Medical Services Operations

response Noted

comment	266	comment by: European Helicopter Association (EHA)
	ADAC (Germany), DR Studies and Best Prac	F (Germany) and LAR (Luxembourg): ctices
	Europe-wide basis fo	e of this proposal is to establish an improved and proportionate r regulating flight and duty times and rest periods for HEMS, based ge and established best practices.
		very critically the scientific studies and knowledges which have beer
	based but relate to tr	e NPA we find some references to studies, which are not aviation ruck drivers, oil rig workers and railroad drivers which examine
	more.	ground based transportation companies, automobile factories and
	HEMS service. Worki	e field, where the data is not appropriate to be compared with the ng as employer in a factory always means, that from beginning of e end there are no extended break times more than the national is.
	Looking at the tables state clear, that altho	in Attachment 1 – data collection of EMS FTL provisions we have to bugh the daily duty period may be up to 16 hours, the flight duty much lesser value. In practice this means, that if the HEMS Crew has
	to fly multiple missio service before the du	ns a day, the flight duty time increases and the crew has to quit the ity period is expired. On the other hand are flights at the end of the e, when the crew had some hours rest in between.
	Fatigue in the HEMS	Operation is therefore minimized due to early ends or several break ot be compared with scientific studies in other branches.
	We would like to p	ooint out one more mentioned study, where data collection and the actual fatigue based evidences.



The	EASA takes the Study of Goodes from 2003 (Journal of safety research 2003) and
	tes, that working hours more than 12 hours a day have a more than 5 time larger risk
	atigue related incidents.
	odes did not compare EMS but commercial American air traffic and used the so called
	square to combine two totally different sets of statistic. His first set was the accident
	tistic from 1978 to 1999 with 55 accidents. His second setup was a set of the working
	urs from 10 aircraft carriers taken in one month in 1999.
	conclusion was, that 5% of human factor accidents where related to pilots working
	re than 13 hours. The ratio taken from the working hours showed him, that in this
	cific one month period only 1% of the pilots worked more than 13 hours.
	nbining these both ratios he concluded, that the risk is more than 5 times higher than
	the working shifts with less than 13 hours working time.
	king at this study, you can read that Goodes is only writing about human error idents, not fatigue related accidents. For human errors CRM is the relevant tool not
	. We cannot see the reason, why the EASA takes statistics with values as old as nearly
	years, to set up scenarios of fatigue related problems.
	he list of the scientific studies we missed the only study for fatigue related flight time
	itations of helicopter pilots in the HEMS services from the German center of
	onautics and space (DLR), which came 1996 to the conclusion, that a duty period up to
	30 hrs. are a reasonable compromise between the demands of the rescue service and
	ht safety. The study end with the sentence, that It could be used as a basis for
har	monization at European level.
This	s study was not used in the preparation of the NPA and we have heard rumors, that
the	results of the study where too old to be transferred to the modern demands of the
HEN	MS Service. If this statement of the task group is verified, we have to ask about all the
	studies (see Attachment 2 of the NPA) from the early 1990 to 2000 and why these
	e been used to create a scenario of safety risks in the field of HEMS Services all tough
	y do not cover HEMS Operations.
	ase remember, that since 1996 the German HEMS Operators have flown most likely
	re than 1.600.000 HEMS Missions with about 4.000.000 sectors without any fatigue
	ated incident or accident.
	think that this fact is decisive to think about the German regulations as basis for a
nev	v harmonized EASA wide flight time specification.
Plea	ase refer to the answer to comment #262.

comment 545

response

comment by: ADAC Luftrettung gGmbH

Studies and best practice

The specific objective of this proposal is to establish an improved and proportionate Europe-wide basis for regulating flight and duty times and rest periods for HEMS, based on scientific knowledge and established best practices.

We have to question very critically the scientific studies and knowledges which have been used. In attachment 2 of the NPA we find some references to studies, which are not aviation based but relate to truck drivers, oil rig workers and railroad drivers which examine fatigue in the field of ground based transportation companies, automobile factories and more.

Here we see one large field, where the data is not appropriate to be compared with the HEMS service. Working as employer in a factory always means, that from beginning of the

shift until the late end there are no extended break times more than the national labor time regulations.

Looking at the tables in Attachment 1 – data collection of EMS FTL provisions we have to state clear, that although the daily duty period may be up to 16 hours, the flight duty period is limited to a much lesser value. In practice this means, that if the HEMS Crew has to fly multiple missions a day, the flight duty time increases and the crew has to quit the service before the duty period is expired. On the other hand are flights at the end of the duty day only possible, when the crew had some hours rest in between.

Fatigue in the HEMS Operation is therefore minimized due to early ends or several breaks in between and cannot be compared with scientific studies in other branches.

We would like to point out one more mentioned study, where data collection and conclusion do not fit the actual fatigue based evidences.

The EASA takes the Study of Goodes from 2003 (Journal of safety research 2003) and states, that working hours more than 12 hours a day have a more than 5 time larger risk of fatigue related incidents.

Goodes did not compare EMS but commercial American air traffic and used the so called Chi square to combine two totally different sets of statistic. His first set was the accident statistic from 1978 to 1999 with 55 accidents. His second setup was a set of the working hours from 10 aircraft carriers taken in one month in 1999.

His conclusion was, that 5% of human factor accidents where related to pilots working more than 13 hours. The ratio taken from the working hours showed him, that in this specific one month period only 1% of the pilots worked more than 13 hours.

Combining these both ratios he concluded, that the risk is more than 5 times higher than for the working shifts with less than 13 hours working time.

Looking at this study, you can read that Goodes is only writing about human error accidents, not fatigue related accidents. For human errors CRM is the relevant tool not FTL. We cannot see the reason, why the EASA takes statistics with values as old as nearly 40 years, to set up scenarios of fatigue related problems.

In the list of the scientific studies we missed the only study for fatigue related flight time limitations of helicopter pilots in the HEMS services from the German center of aeronautics and space (DLR), which came 1996 to the conclusion, that a duty period up to 15:30 hrs. are a reasonable compromise between the demands of the rescue service and flight safety. The study end with the sentence, that It could be used as a basis for harmonization at European level.

This study was not used in the preparation of the NPA and we have heard rumors, that the results of the study where too old to be transferred to the modern demands of the HEMS Service. If this statement of the task group is verified, we have to ask about all the old studies (see Attachment 2 of the NPA) from the early 1990 to 2000 and why these have been used to create a scenario of safety risks in the field of HEMS Services all tough they do not cover HEMS Operations.

Please remember, that since 1996 the German HEMS Operators have flown most likely more than 1.600.000 HEMS Missions with about 4.000.000 sectors without any fatigue related incident or accident.

We think that this fact is decisive to think about the German regulations as basis for a new harmonized EASA wide flight time specification or on national solutions by the NAA.

Noted response



TE.RPRO.00064-008 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

comment	566 comment by: <i>Rüdiger Neu</i>
	Die wissentschaftlichen Quellen sind teilweise veraltet und haben keinen konkreten Bezug zur Fliegerei, Geschweige zur HEMS. Die vorhandenen Studien (DLR 1996) wurden von der EASA nicht akzeptiert, da sie zu alt sei, jedoch nutzt die EASA Studien von 1999.
	Auch die Werte für Blockzeuten etc. können nicht fundiert nachgewiesen werden.
response	Please refer to the answer to comment #262.

comment	1521 comment by: Air Ambulance Services of Norwa	
	Comments on NPA 2017-17	
	General The Air Ambulance Services of Norway (Luftambulansetjenesten HF, shortened LAT HF) the government agency responsible for all air ambulance (AEMS and HEMS) in Norwa The service is funded by the Government.	
	LAT HF signs contracts valid for 6-11 years with civilian AOC-holders to operate our HEMS-bases and 7 AEMS-bases. They are all on 24/7 duty, and perform about 20 000 a ambulance- and HEMS missions per year.	
	Norway has today one of the most modern and advanced air ambulance services in the world. With the new contracts starting in 2018 (HEMS) and 2019 (AEMS) we will have brain new aircraft (9) and helicopters (17) with the highest safety standards available, combine with requirements regarding flight crew training, fatigue risk management system simulators, dispatch services and all aspects of the service that well exceeds the EASA an national legislation demands.	
	The service is well functioning and regarded as very safe at today's level, and this was al the conclusion in a national study of 2014 which compared safety and risks in different parts of Norwegian domestic helicopter operations. The HEMS service was described to at the same high safety level as offshore helicopter operations in Norway (Bye, R.J., Seljel J., Heide; B., Lillehammer, G. Aasprang, B., Antonsen, S. Vinnem, J.E., Bø, B. (201 Sikkerhetststudie innlandshelikopter - <i>Hovedrapport</i> . [Safety study inland helicopters main report]). Our AEMS service is based on the present EASA regulations. Our comments to the NPA a	
	primarily based on the suggested changes to the HEMS regulations, which are regulate on a national level today.	
	Intended harmonization EASA has described the extreme variety of HEMS services performed in their memb states (mix of day and night services, IFR, NVG, single/two pilot operations, SAR and so of LAT HF finds that a continued legislation by the national aviation authority is the best w	



to ensure a safe and proper HEMS operation in each member state. This will also cover the specific needs of each country as the HEMS service is an integrated part of the national specialist health service, as it is in Norway.

If an EASA FTL is imposed for HEMS services, it will end up with almost all operators applying for an Individual Flight Time Specification Scheme (IFTSS), based on their Fatigue Risk Management Systems. This will, contrary to the intentions of the NPA, not lead to a level playing field. It will favor the operators in service in i.e. Norway, as they can participate in the next tender process offering a number of crews based on their IFTSS. It will be almost impossible for other contenders to compete with, as they have no such IFTSS and probably must offer a much higher number of crews. This will favour operators that are well established in future competitions in an unfair way. This undermines the idea behind the EU-wide rules for public procurement and the rules of competition.

The HEMS operation in Norway is a national service, and less than 0.5 % of the HEMS missions performed per year are to neighboring countries.

LAT HF considers that the best way to ensure a level playing field will be to continue to have a national HEMS regulation. This will ensure that all operators can participate in future tender processes based on the public and known national regulations (as opposed to competing with the present operators who probably have an IFTSS, unwilling to share all the details).

Intended increase in safety

The HEMS service is characterized by a low number of flight hours per crew per year. In Norway the average crew member has about 200 flight hours per year. This is considered low from a flight safety aspect, given the extreme variety of missions and qualifications the crews are required to hold). Today the crews can, based on national legislation, count a 24- hour duty on base as less than 24 hours (on average 16 hours) towards the annual 2000 hour limit. If the NPA is passed this will no longer be possible, and can cause a need to increase the number of crews by as much as 44 % to meet the requirements in the NPA. This will end up in the same number of flight hours divided by a substantially higher number of crews, ending up in a critically low number of flight hours per crew per year.

The fixed wing air ambulance operation in Norway produces about 10 000 flight hours a year distributed on 9 aircraft. A high number of the flights are into short fields, with steep approaches during night time in the winter. The national authorities require the operator to give the crew special training and recency to operate into these special category airfields. With current flight time limitation it is hard for the operator to keep the crew current at all times. With the proposed limitations more pilots will be needed to deliver 24/7 service. This will lead to less flying per pilot, decreased regularity and in the end decreased level of safety.

LAT HF finds the suggested change to be the largest identified risk towards flight safety in our service today. If the NPA is passed, we strongly suggest that operators will be granted an IFTSS (based on their FRMS) that allows them to continue with 24-hour duty periods, but counting as less than 24 hours towards the annual 2000 hour limit.

<u>Costs</u>

As described above; the suggested FTL can end up in a need for up to 44 % more crews. Next to the helicopters, the crews are the most expensive part of the service (salaries, training and pensions). The number of missions will not increase by the increase of crews. LAT HF will need to buy more helicopters, fly several thousand training hours in helicopters



and simulators to partly compensate for the drop in annual flight hours per crew. Without going into detail; - the potential increase in costs for the Norwegian service could be more than 10 million Euro per year.

Summary

The NPA states that the "proposed changes are expected to improve safety..... and ensure harmonisation across the EU", furthermore to "ensure a level playing field and improved safety".

In the NPA EMS Safety Risk Assessment (4.1.4.1) it is acknowledged that fatigue is at a very low occurrence, and that *"the controls that have been in place to manage fatigue in European EMS have generally been effective"*.

The NPA describes the safety, social and economic impacts of the suggested FTL (based on option 0, 1 and 2). LAT HF would emphasize the major safety risk an increase in crews could cause, in addition to a tremendous increase in costs.

Based on the:

- reduced ability for operators to participate on a level playing field,
- flight safety risks associated with the need for more crews and
- substantial increase in costs

The Air Ambulance Services of Norway (LAT HF) can only recommend Option 0 for HEMS (No policy change). The other options will lead to one or more of the consequences listed above, without any positive effects to our service.

Kind regards, Øyvind Juell Managing director (CEO)

response

Please refer to the answer to comment #262.