SUBJECT/TITLE: Strengthening & Streamlining Generic Justification in Europe

Background (relevant SAMIRA project, other relevant EU projects, scientific or regulatory rationale)

Level II (generic) justification considers whether, in general, for a new or existing practice with a specified objective, the benefits outweigh the risks. In the medical context this includes exposures of both patients and asymptomatic individuals inside and outside of screening programmes. Furthermore, it explicitly includes the justification of screening programmes which involve exposures to ionising radiation. Article 19 of Council Directive 2013/59/EURATOM requires Member States (under Article 55 and Article 5) to ensure that new classes or types of practices resulting in exposure to ionising radiation are generically justified before being generally adopted. Furthermore, Member States may consider a review of existing classes or types of practices whenever there is new and important evidence about their efficacy or potential consequences, or new and important information about other techniques and technologies.

While there have been some projects focused on individual justification such as EU-JUST CT, there has been limited focus on how regulatory requirements around generic justification have been implemented and fulfilled across Member States. Variations in the transposition of these regulations and variation in the types of organisations or public bodies designated as competent authority is believed to have led to differing approaches to generic justification.

Furthermore, there has been little consideration of how generic justification fits within the lifecycle of radiopharmaceuticals and medical devices which emit ionising radiation. Regulation (EU) 2021/2282 on health technology assessment (HTAR) will apply from 12 January 2025 and aims to improve the availability of innovative technologies such as medicines and high-risk medical devices to EU patients. However, it has not been investigated how radiation protection will be considered in the clinical or non-clinical domains of the Core HTA Model at a European or national level respectively, nor have generic justification requirements been considered as part of the wider route to market and patient access which may lead to possible unforeseen delays.

This project will aim to further the implementation of generic justification and establish best practice recommendation.

Objectives

1. To recognise and map existing approaches to generic justification, and to put forth models of generic justifications. Worked examples of these different approaches (one of these to focus on radiopharmaceuticals) will be developed.
2. To identify and map common inputs/steps in the generic justification, HTA and medicines/medical devices authorisation/certification processes. Worked examples of the overlap and divergent inputs/steps in the generic justification, HTA and medicines/medical devices authorisation/certification processes (one of these to focus on radiopharmaceuticals) will be developed.
3. To produce a set of recommendations and advice on best practice conduct of generic justification, taking into account radiation protection, and how best to maximise effective and efficient use of resources in Europe.
4. To engage with and raise awareness of generic justification requirements amongst HTA agencies and medicines/medical device authorities following completion of objectives three and four.

Description of the project (overall description including methods, possible/needed partners, estimated length of a project)

This project has two main components planned over five years. The first component will focus on mapping approaches to generic justification and assessing the use of clinical evidence (and potential other EUnetHTA components and inputs) to inform justification decisions. This will require an understanding of the context, key stakeholders, existing policies and legislation at both a national and EU level. Although the methods have not yet been finalised, they will likely involve systematic searching, evidence synthesis and landscape analysis to identify, categorize, map and assess the various approaches to generic justification and the integration of clinical evidence within those approaches. A survey may also be conducted to supplement these findings. Collaboration with experts in evidence synthesis, EU medical device and medicines regulation, and radiation protection will be crucial. Partnerships with competent authorities and international networks for radiation protection will enhance the planning, development of methods and the execution of this work.

These results will feed into the second component of the project, where the inputs and processes for generic justification are mapped onto the inputs and processes for health technology assessment, the authorisation process for radiopharmaceuticals and the conformity assessment process for medical devices. Methods may include detailed process mapping or policy analysis methods to identify similarities and efficiencies so that we may quicken patient access while ensuring rigorous and comprehensive assessments still take place. In addition to the above stakeholders, involvement of HTAR HTA agencies will benefit all aspects of this component and may facilitate the translation of recommendations into policy changes. Best practice models of generic justification will be produced and accompanied by a set of recommendations.

It is anticipated that this work would take place over a five-year period, where each objective is completed and published sequentially, and the final year is dedicated to the establishment of recommendations. Engagement and dissemination will take place throughout the five-year period.

- Year 1: Protocol and project design
- Year 2: Mapping approaches to generic justification with worked examples.
- Year 3-4: Mapping inputs/steps in the generic justification, HTA and medicines/medical devices authorisation/certification processes with examples.
- Year 5: Finalising recommendations and proposed best practice models.

Expected outcomes (impact and sustainability)

While we are aware that there are different approaches taken in Member States to generic justification, it is not clear what these are, who uses what approach and how clinical evidence is used to inform decision making. Mapping the various approaches to generic justification across Member States will support information exchange and development of international recommendations and best practice. These recommendations may help improve patient safety from unjustified practices and improve the justification of radiological procedures for asymptomatic population screening. Furthermore, analysing these findings in the context of the wider assessment lifecycle for medical devices and medicinal products may help improve efficiency given the potential to reduce duplication of efforts across Member States.

Benefits of performing within a JA

A joint action will provide an efficient platform for competent authorities to work towards understanding the differing approaches to generic justification, supporting meaningful conversations on international best practice, and identify ways to facilitate reuse of information and reduce duplication of efforts. The involvement of competent authorities in a joint action will also facilitate the translation of findings directly into policy action.

SUBJECT/TITLE: Individual justification of medical CT procedures

Background (relevant SAMIRA project, other relevant EU projects, scientific or regulatory rationale)
Use of ionising radiation is associated with increased risk of cancer. To ensure that only necessary examinations are carried out, the European Basic Standard Directive, BSSD, states that all individual medical exposure shall be justified (Art. 55), meaning that the net benefit of the examination must exceed the associated risks. Furthermore, the referrer and the practitioner are involved in the justification process of individual medical exposures (Art. 57). The BSSD assign the clinical responsibility of medical exposure to the medical practitioner, which includes the responsibility for the justification process. Findings from the EU JUST-CT project have recently indicated that many CT examinations in Europe are unjustified or inappropriate. Unjustified examinations have strong influence on healthcare systems, public health economy, resources and waiting times, in addition to exposing individuals to unnecessary radiation. The main suggestions from EU JUST-CT are to ensure availability of imaging referral guidelines in clinical decision support systems, improvement of the quality of the referrals, performing regular audits of justification and providing education and training on justification and clinical audits. This project aims to act on those suggestions, further describe patterns of potentially unjustified exposures, describe the impact of these potentially unjustified exposures on the wider health system, and identify more specific corrective actions to reduce potentially unjustified CT examinations.
Objectives
1. To identify the proportion of potentially unjustified CT examinations 2. To identify waiting times for non-emergency CT examinations 3. To identify the costs associated with the potentially unjustified CT examination 4. To identify underlying causes and implement corrective interventions to reduce the number of potentially unjustified CT-examinations
Description of the project (overall description including methods, possible/needed partners, estimated length of a project)
The methodology established in the EU JUST-CT pilot study for retrospectively auditing referrals and CT-examinations will be adapted for use in this project, lasting 4-5 years. Participating countries can choose the referral guidelines they prefer, for instance iGuide, iRefer, or own national guidelines if they exist. Building on the findings of EU JUST-CT, this project also seeks to identify waiting times for non-emergency examinations and the costs associated with the unnecessary ones. An initial part of this project will be to develop the methods for those additional aspects and identify what outcomes can and cannot be compared between participating countries. In line with the recommendations from EU JUST-CT related to regularly performing such audits, all MS can participate, even if they already have performed such an audit. Countries which have already performed a clinical audit on level III justification of CT examinations will bring an additional perspective to issues such as over-diagnosis, the inappropriate use of health resources, and the development of methods for this project. Repetition of such audit will also be an effective tool to demonstrate effect of interventions and hopefully a reduction in the number of potentially unjustified exams can be shown, due to increased awareness based on previous audit results. The second part of the project seeks to identify the underlaying causes and find actions that can help reduce the number of potentially unjustified CT-examinations and help evaluate these effects in terms of waiting lists and costs. Actions identified may be at local (hospital, referrer etc), national or on European level. While not part of this project, repeating the audit could give the possibility to evaluate action taken in the nation for reducing the number of potentially unjustified examinations. This project is focusing on CT examinations, but the methodology can be used on other modalities like MRI and other X-ray-examinations as well. There is the possibility to broaden the scope of this project to look at other imaging modalities perhaps a small scale, even if it is not part of the main project. Ideally, the project would have contributions from the following agencies: Radiation protection authorities, health authorities, hospitals, professional societies, health technology assessment bodies.
Expected outcomes (impact and sustainability)
This project would help countries estimate the proportion of potentially unjustified exposures and identify the impact on costs and resources associated with those. The results from the audit can be used to identify the corrective interventions to be put in place for reducing this proportion. Reducing the numbers of unjustified examinations, will release resources (appointments, personnel, costs) that can be used in a more appropriate way and reduce unnecessary radiation exposure. This project can also be used as a pilot within each country

to establish a system for regularly performing such audits. Conducting such a project, will also increase awareness on the justification process and the importance of high-quality referrals.
Benefits of performing within a JA
Doing this as a JA will establish a baseline which countries can compare their results to and help identify what costs are associated with these potentially unjustified examinations. It will also help facilitate the translation of findings into policy and action. Good initiatives could be shared throughout Europe, with the intention of reducing exposure of the European population, enabling better use of the resources and reducing the waiting time for patients.

A Roadmap to Optimisation of Radionuclide Therapy

Background (relevant SAMIRA project, other relevant EU projects, scientific or regulatory rationale)

The development of new therapeutic radiopharmaceuticals (tRPhs) is increasing rapidly. There is therefore a high unmet need to work towards legislative, regulatory and scientific clarity on the marketing, assessment and use of tRPhs in Europe. This project aims to address these issues through a series of fixed term collaborative networks, each one involving the stakeholders with the remit to address each identified issue.

Achieving co-ordinated and coherent regulation of radiopharmaceuticals has been challenging due to the different regulatory frameworks that apply. The SIMPLERAD project recently assessed the gaps between the BSSD and pharma legislation regarding therapeutic radiopharmaceuticals and identified 10 items and recommended actions “to advance the coherent implementation of the European legal requirements with respect to therapeutic nuclear medicine”. Eight of these items require coordinated action by European and/or national regulatory bodies in collaboration with the professions involved in nuclear medicine. These 8 items can be grouped into three main areas of work: the implementation of dosimetry-based treatment optimisation, radioactive waste management and patient release criteria.

Furthermore, a new proposal for EU pharmaceutical legislation is currently under review. This creates an opportunity for coherence and collaboration on narrowing the gaps between the BSSD and pharma legislation.

The new Health Technology Assessment Regulation ((EU) 2021/2282, “HTAR”) will soon require joint clinical assessments between member states of new radiopharmaceuticals. However, there are concerns that some of the requirements of the BSSD are not adequately considered in these processes. Reimbursement of dosimetry-based treatment optimisation also needs to be considered in the HTA-evaluation on the national level. These aspects will be further developed in the project “Strengthening and Streamlining Generic Justification in Europe”.

Objectives

1. To carry out a coordinated effort to address the recommended actions from the SIMPLERAD project that require action by European and/or national regulatory bodies in collaboration with the professions.
2. To ensure regular communication and alignment between regulators and stakeholders involved in therapeutic nuclear medicine to progressively reach a more coherent implementation of the applicable legislation, including dosimetry-based treatment optimisation, waste management and patient release criteria.

Description of the project (overall description including methods, possible/needed partners, estimated length of a project)

Methods: Create working groups on three levels of action, each to address the issues specific to its remit. Periodic meetings between the participants of the three levels to ensure coherence..

A. **European authority level (**DG SANTE + DG ENER + EMA (+ DG RTD?))– a) address regulatory issues and ensure harmonised legislations, b) consider specific grant programmes for research and training, c) consider creating an EMA Committee for tRPhs, d) resolve possible gaps in HTAR implementation with regard to tRPhs, as identified in the project Generic Justification.
B. **National authority level (NCAs for pharmaceuticals, radiation protection and HTA)** – a) regulator mutual training program on tRPhs and dosimetry-based treatment optimisation, relevant legislation and procedures; b) tRPh-specific HTA/Authorisation meetings; c) clinical audits on tRPhs and dosimetry; d) waste management; e) release criteria.
C. **Professions (universities + hospitals + professional societies)** – create a network of Centres of Excellence for a) education & training according to mutually agreed core curricula for involved professions, b) develop infrastructure for efficient clinical trials with state-of-the-art dosimetry for industry and academia, c) set up clinical data registry for dosimetry data and treatment outcomes, d) develop stepwise guidance on the process of setting up a theranostics unit

Estimated duration: 5 years

Partners: As specified above (point A-C) + pharmaceutical industry involved in the development of tRPs.

Expected outcomes (impact and sustainability)

The root cause of many of the issues identified in the SIMPLERAD project is lack of awareness and ownership of the regulations, procedures and requirements on each "side" of the regulation of tRPhs. This situation may continue and be further complicated by the new HTAR and pharma directive if appropriate action is not taken. By creating working groups that are competent to address the specific issues on each level, we aim to identify solutions and close these gaps. The duration of the project ensures not only that there is sufficient time to solve diverse and complex problems, but also that the habit of communication and collaboration is established. The latter is the key to a sustainable effect of the project, while the former ensures the immediate impact.

Benefits of performing within a JA

One of the main identified hurdles to implementing the BSSD in therapeutic nuclear medicine is a lack of mutual understanding and communication between the regulated and regulating bodies involved – health care providers, radiation protection authorities, medicines authorities and health authorities – both nationally and on a European level. An important step forward would be to achieve coherence *within* each member state with regard to applying both radiation protection, pharma legislation and HTAR to tRPhs. An even greater achievement would be to have a core of coherence *between* member states. Without such coherence, the clinical development of new and effective tRPhs is hampered, Furthermore, the tRPs which do reach the market will not have the necessary data for optimisation and individual treatment planning.

Abbreviations

tRPh: therapeutic radiopharmaceutical **RNT**: radionuclide therapy **HTA**: health technology assessment **E&T**: Education & training **EMA**: European Medicines Agency **EANM**: European Association of Nuclear Medicine **EFOMP**: European Federation of Organisations for Medical Physics **NCA**: national competent authority **NM**: Nuclear medicine **RTD:** Directorate General for Research and Innovation

References

Reform of the EU pharmaceutical legislation

Health Technology Assessment Regulation 2021/2282

HTA CG Scientific specifications of medicinal products subject to joint clinical assessments

PrISMA

Preparatory activities for
Implementation of quality and
Safety of
Medical Ionizing radiation
Applications

SUBJECT/TITLE: Optimisation of Radiation Protection in Paediatric Imaging

Background (relevant SAMIRA project, other relevant EU projects, scientific or regulatory rationale)

Appropriate medical radiological equipment, practical techniques and ancillary equipment must be used in medical exposure of children, as required in the Article 61 of BSSD. Moreover, all doses due to medical exposure for radiodiagnostic purposes have to be kept as low as reasonably achievable consistent with obtaining the required medical information (Article 56). Establishment, regular review, and use of diagnostic reference levels* for radiodiagnostic examinations, and the availability of guidance for this purpose are necessary for optimization of protection (Article 56). A number of EU actions have been taken on DRLs (RP 109, RP180, RP 185 and RP195). All reports highlight the importance of establishing DRLs for high-dose medical examinations of patients more sensitive to radiation, especially children. The EU Radiation Protection No 185, established by the project PiDRL, contains basic recommendations on how to establish and to use DRLs for paediatric x-ray examinations and procedures. DRLs are key optimisation tools: whenever DRLs are consistently exceeded, appropriate local reviews should be undertaken, and appropriate corrective actions taken.

Objectives

1. **Establish Practical Guidelines:**
   - Develop and disseminate comprehensive guidelines to promote the adoption of principles and best practices for optimisation of paediatric radiation protection across healthcare settings.
   - Facilitate collaboration among a multidisciplinary group of experts (paediatric radiologists, radiographers, medical physicists, and regulatory authorities) to create practical guidance aimed at optimizing X-ray examinations (including X-ray, CT, and fluoroscopy) for paediatric patients.
2. **Continuous Training Development:**
   - Design and implement ongoing training programs for radiologists, radiographers, and technologists focused on best practices in paediatric radiology, encompassing radiation exposure risks, safety protocols, and the effective use of protective equipment.
3. **Identify Diagnostic and Interventional Procedures and to establish DRLs:**
   - Conduct a comprehensive review to identify specific diagnostic and interventional radiology and nuclear medicine procedures to update and extend the DRLs established in the PiDRL project.
   - Collaborate with relevant stakeholders to develop and implement European Diagnostic Reference Levels for selected paediatric imaging procedures, ensuring they reflect current best practices and technological advancements.
4. **Promote Effective Use of Paediatric DRLs:**
   - Enhance awareness and application of paediatric reference levels in clinical practice to ensure they are effectively utilized for optimizing radiation protection in paediatric imaging.

These objectives aim to create a structured approach to improving paediatric radiation protection and ensure the quality and safety of young patients undergoing imaging procedures. Moreover, follow-up of patients to undergo repeated imaging procedures will be enhanced.

Description of the project (overall description including methods, possible/needed partners, estimated length of a project)

Preliminary project scheduling: Total estimated length of project is 5 years.

1. Development of Practical Optimization Guidelines (Years 1-3):

- This phase focuses on creating comprehensive guidelines for practical optimization methods in paediatric imaging. The guidelines will be designed to enhance the quality and safety of imaging practices, ensuring that paediatric patients receive the best care possible.

2. Establishment of Diagnostic Reference Levels (DRLs) for Paediatric Imaging (Years 1-3):

- Conduct a feasibility study to include hospitals with low paediatric patient volumes in the implementation of DRLs, ensuring that all facilities, regardless of size, can benefit from these standards.
- Analyze the current status of established paediatric DRLs across Europe to identify gaps and opportunities for improvement.
- Identify the most pertinent examinations or procedures for DRL implementation based on their frequency and the associated patient dose, prioritizing those that will have the greatest impact on safety.

- Gather comprehensive data on paediatric examinations and procedures, including dose indicators, administered activities, and parameters that assess patient size. This data will inform the establishment of appropriate DRLs.
- Develop and implement national DRLs, and as appropriate, standardized European paediatric DRLs for selected imaging procedures, enhancing the consistency of radiation protection across healthcare settings.

3. Training on Optimization and Use of DRLs (Years 3-5):

- Provide training programs focused on optimization techniques and the effective use of DRLs. This will include recorded webinars and presentations that cover various dose reduction strategies and emphasize the importance of minimizing radiation exposure for children. The training aims to empower healthcare professionals with the knowledge and tools necessary to implement best practices in paediatric imaging.

Expected outcomes (impact and sustainability)

The aim is to establish comprehensive practical guidelines and create additional training materials for optimizing X-ray examinations and procedures in paediatric imaging. This will include online publications, video clips, and other resources aimed at harmonizing radiation protection for paediatric patients and promoting best practices. We intend to reach all facilities that image children, including those outside paediatric hospitals, ensuring a wide impact on the quality of care.

By raising awareness among the public and healthcare professionals about best practices in paediatric imaging and the importance of radiation protection for children, we aim to foster a culture of safety and responsibility. This increased awareness will lead to more informed decisions and practices in paediatric care.

While to primary focus is in developing national DRLs, data will be used, as appropriate, to develop and implement updated and new European DRLs to promote harmonization and emphasize the optimization of radiation protection in paediatric imaging procedures. This initiative will not only enhance safety but also ensure sustainable practices across healthcare settings, leading to long-term improvements in patient outcomes.

Benefits of performing within a JA

Partnering with various professional groups will enhance the outcomes and acceptance of results. This collaboration will also reduce duplication of efforts and promote harmonization in the protection of paediatric patients. Involving regulatory bodies in a joint initiative will facilitate the translation of findings into actionable regulations and encourage the adoption of DRLs.

The limited number of paediatric studies conducted annually in each country hinders the optimization of paediatric imaging and highlights the need for additional training. By collectively analysing data, we can significantly enhance the effectiveness of optimization efforts.

*****"diagnostic reference levels" means dose levels in medical radiodiagnostic or interventional radiology practices, or, in the case of radio-pharmaceuticals, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment (Definition in the BSSD).

SUBJECT/TITLE: Optimisation of radiation protection in interventional radiology

Background (relevant SAMIRA project, other relevant EU projects, scientific or regulatory rationale)

Interventional radiology is evolving and there is an increasing demand for these services. These procedures are usually associated with relatively high doses to patients and potentially high doses to staff. The contribution of interventional radiology to population level effective dose is increasing. Therefore, there is a need to optimize radiation protection of patients, which also has impact on exposure of workers.

Appropriate medical radiological equipment, practical techniques and ancillary equipment must be used in medical exposure involving high doses to the patient under Article 61 of BSSD. Under Article 56, doses due to medical exposure for imaging purposes have to be kept as low as reasonably achievable consistent with obtaining the required medical information. Establishment, regular review and use of diagnostic reference levels for interventional procedures, and the availability of guidance to do this is necessary for optimization of protection. Optimization of patient exposures also helps reduce occupational exposure in interventional radiology.

The MEDIRAD project (2017-2022) has investigated staff protection in interventional procedures. EURADOS has carried out multiple projects related to occupational exposure monitoring and patient skin dose determination. The TRAMEXI project aims to improve the calibration accuracy of interventional radiology x-ray devices, and the project will end in May 2026. SAMIRA Equipment study on dose displays and a specified project on criteria for acceptability of devices (from the grounds of RP 162). This project focuses on implementation of recommendations from these projects.

Objectives

1. Up-to-date information on radiation protection in interventional radiology in Europe.
2. Promoting good practices in optimization of occupational exposure.
3. Training personnel in interventional radiology and cardiology with a multi-professional perspective.
4. Gathering information how patients that have received high dose during an interventional procedure are monitored after the procedure and promoting good practices.

Description of the project (overall description including methods, possible/needed partners, estimated length of a project)

The overall duration of the project would be 5 years. The description of the project would be as follows:

1) Evaluation of the status of protection in interventional radiology (including cardiology) by surveying and conducting inspections/audits. The evaluations can be conducted by authorities or professionals/auditors, as most convenient for the country. Years 1-2.
2) Emphasizing optimization of radiation protection in interventional radiology with practical guidance by multidisciplinary group of experts in interventional radiology (including cardiology) and dissemination of good practices in European countries. Years 3-4.
3) Developing and conducting continuous training for radiologists and other physicians conducting interventional procedures, radiographers, and technologists on best practices including the information on radiation exposure risks, safety protocols, and the use of protective equipment. Years 4-5.
4) Enhancing the effective use of reference levels in interventional radiology. Years 4-5.

Expected outcomes (impact and sustainability)

The primary aim is the improved quality and safety of patients and staff, when best practices are adopted and implemented in daily practice throughout Europe. The aim is also to produce practical

guidance and training material for optimization of radiation protection in interventional radiology. These guidelines could be used also as standards for clinical auditing.
Benefits of performing within a JA
The project allows for the gathering of best practices all over the Europe from professionals and authorities. Work is conducted in co-operation between authorities, professional societies and hospitals. Moreover, a joint action allows for a multi-professional approach that combines both clinical professionals and authorities and other parties such as professional organizations and auditors.

SUBJECT/TITLE: Optimisation in image guided radiotherapy (IGRT)

Background (relevant SAMIRA project, other relevant EU projects, scientific or regulatory rationale)

As the precision in radiotherapy treatment is increasing and treatment becomes steadily more personalised, the amount of radiological imaging used during the treatment course has also increased. To reduce the dose contribution to the patient outside the target volumes, and especially to organs at risk, it is important that protocols and imaging regimes are optimised, in line with requirements in the Council Directive 2013/59/Euratom (BSSD) Article 56. It is, nevertheless, important to stress that a sufficient image quality, which allows identification of key anatomical structures for positioning verification prior to treatment, should not be compromised. The project will take other work related to IGRT into account, like iViolin, European Radiation Dosimetry Group (EURADOS) WG 12, Task group 2.2, European Society for Radiotherapy and Oncology (ESTRO), and ICRP Task group 116.

Objectives

1. Identify typical image guidance protocols for different anatomical regions
2. Identify dose reduction strategies which also ensure adequate image quality
3. Investigate the possibilities to report dose indicators for every individual exposure
4. Identify good examples of optimisation work done in IGRT, including quality assurance procedures
5. Develop guidelines for optimisation of IGRT
6. A feasibility study to explore the possibility to establish an optimisation concept, similar to diagnostic reference levels (DRLs), also for imaging in radiotherapy

Description of the project (overall description including methods, possible/needed partners, estimated length of a project)

The main aim of this project is to promote optimisation of imaging protocols and routines associated with image-guided radiotherapy (IGRT) in order to reduce dose contributions from patient imaging, while maintaining sufficient quality to ensure correct treatment delivery.

First, a systematic literature review will provide an overview of recommended IGRT protocols for different anatomical regions and the typical imaging regimes associated with these. Dose reduction strategies that maintain the image quality required for precise treatment delivery will then be identified, in addition to investigate what image quality criteria to use. In addition, the project will explore the potential for manufacturers to report dose indicators for kV-CBCT acquisitions, as it is done for CT scanners, in accordance with BSSD requirements, allowing dose monitoring of each individual exposure. Good examples of work done by different clinics in the field of IGRT optimisation will be explored. This part of the project will also try to identify barriers and challenges that limit the possibilities of IGRT optimisation. Guidelines on how to work with IGRT optimisation in the clinic will be defined. Diagnostic reference levels (DRLs) is an important tool for optimisation in diagnostic imaging. Due to the increased use of imaging in radiotherapy, there has been suggestions in the radiation protection community, to implement this concept as an optimisation tool also for imaging in radiotherapy. This project will do a feasibility study, where it will be investigated whether this concept (or similar) is transferrable to radiotherapy imaging as a tool in the optimisation process of imaging protocols.

In addition to the radiation protection authorities, this project needs involvement of clinical personnel and professional societies. The manufacturers are also important stakeholders since they are the premise suppliers for the possibilities of the equipment. To be able to get the full overview and sufficient attention to the actual contribution of the dose from imaging to the patient, a long-term goal is to raise awareness of the manufacturers to include imaging dose into the treatment planning systems.

Expected outcomes (impact and sustainability)

The project will address the issues related to the increasing use of image guidance during the radiation treatment course. While these images are critical for the precise delivery of the treatment dose to the patient, they also contribute significantly to the dose outside the target volumes. Previous work has shown that optimisation of imaging protocols and imaging regimes in IGRT has been done to a limited extent, with clinics very often using the standard protocols from the manufacturers. An important outcome of this project will be to

provide access to clinics of guidelines on how to perform IGRT optimization. Examples of good optimisation projects from hospitals will be included to inspire other to carry out similar projects. The main goal of the optimisation work will be to reduce the imaging dose to the patient, without compromising the accuracy in the verification of patient anatomy prior to treatment. Such a project will promote the necessity of performing dose optimisation also in the field of imaging in radiotherapy as well as the importance to minimize the dose to healthy tissue and thereby reducing the risk of late effects due to the radiation outside the treatment volume.
7¾ ¾
Collaboration through a JA will facilitate a joint and harmonised initiative, raising awareness to the dose contributions resulting from patient verification images. Good examples of optimisation work can be collected and shared among all the European countries and hospitals. This can provide valuable input to other hospitals, increasing the level of requirement implementation regarding dose optimisation. By having the support of a JA, a stronger influence on the manufacturers can be achieved, in order to work towards the same goal: lower dose contribution from IGRT ensuring precise treatment.

SUBJECT/TITLE: Diagnostic reference levels in NM, CT, IR and radiography procedures of adult patients

Background (relevant SAMIRA project, other relevant EU projects, scientific or regulatory rationale)

Diagnostic reference level (DRL) in medical imaging was introduced as an optimisation tool in the medical exposure of patients for diagnostic and interventional procedures by ICRP. It is used to indicate if, in routine conditions, the dose to the patient or the radiopharmaceuticals activity administered for some medical imaging procedure is unusually high or unusually low for that procedure. EU BSSD, Art 56(2) require the establishment, regular review and use of diagnostic reference levels for radiodiagnostic examinations, having regard to the recommended European diagnostic reference levels (EDRLs) where available, and where appropriate, for interventional radiology procedures.

The EUCLID project (RP195) made a great first step in setting a list of 10 clinical indications for CT and a list of four procedures in interventional radiology (IR) for which DRLs are considered as needed. EDRLs were established based on survey in 19 hospitals. It is also stated that in IR, the definition and use of complexity of the procedure looked to be challenging, and there is a need to cover a wider spectrum of clinical indications. For radiography, the impact of digital devices was not reflected because the EUCLID report was only based on the literature review and on previous studies such as EU project Dose Datamed. The EUCLID workshop also clearly showed the need to move ahead towards the development of DRLs in the fields of cardiac procedures and nuclear medicine, where the lack of DRLs, as well as absence of the use of those that have been established, became evident. Additionally, Working Group on DRLs of SGQS recommend that DRLs for nuclear medicine should be calculated using weight-based administered activities for adult patients. Nuclear medicine DRLs should be based on quality assured measured administrative activity to patients and not on nominal values. The provision for hybrid imaging and the CT component for the different medical purposes (attenuation correction, localisation and direct diagnosis respectively) should be incorporated into nuclear medicine DRLs.

Rapid evolvement of equipment and methods that allows emerging new procedures and change of radiation dose due to new developments, seeks for the establishment of up-to-date DRLs repeatedly. Nevertheless, differences in equipment and practice between countries, but also between different levels of hospitals, limit the relevance of EDRLs, so data analysis should encompass these differences and possible solutions including use of regional, national, or local DRLs in case of converging practices.

Additionally, Working Group on Diagnostic Reference Levels of SGSQ highlights that Member States, authorities, and healthcare institutions differ in the level of implementation of DRLs and face differing challenges in establishing or developing an effective infrastructure to enable the establishment, use and review of DRLs.

Objectives

1. To review the status of DRLs and advances in concept of DRLs in NM, CT, IR and radiography (including mammography and digital breast tomosynthesis) procedures with special emphasis on DRLs based on clinical indication in CT, use of complexity of the IR procedure and use of weight based administered activities in NM procedures in scientific literature
2. To decide which examinations in NM, CT, IR and radiography should have DRLs
3. To establish DRLs in CT based on clinical indication through a European survey
4. To establish DRLs in IR procedures through a European survey, considering possibility of use of complexity of the IR procedure
5. To establish DRLs in radiography procedures through a European survey
6. To establish DRLs in diagnostic NM procedures through a European survey considering possibility of use weight based administered activity
7. To give guidelines for better integration of established DRLs into clinical practice

8. To train all relevant stakeholders in establishment, use and review of DRLs (to enable better understanding between relevant stakeholders that should result in better implementation of DRL process)

Description of the project (overall description including methods, possible/needed partners, estimated length of a project)

Project should last 5 years. Relevant stakeholders for project implementation are regulatory bodies and relevant professional societies. These stakeholders can participate in part of the project (some modality can be omitted). Project should also include large number of hospitals to assure representativeness for data collection.

1. Review of existing NDRLs (set in regulations) in NM, CT, IR and radiography procedures (1st year)
9. Review on DRLs and advances in DRL concept after the RP195 of DRLs in NM, CT, IR and radiography procedures with special emphasis on DRLs based on clinical indication in CT, use of complexity of the IR procedure and use of weight based administered activities in NM procedures in scientific literature (1st year)
2. Determining the list of diagnostic NM, CT, IR and radiography procedures that should have DRLs based on 1 and 2 (1st year)
3. Creating the representative network of hospitals to collect the data considering possible differences between countries, but also between different levels of hospitals (1st year)
4. Collecting the data for establishment of NDRLs (2nd year)
5. Analysis of the data needed for NDRL establishment (including possible differences in equipment between countries and between different levels of hospitals, use of regional, national and local DRLs, use of dose management systems, how image quality (IQ) is included and all other relevant data). Analyze how different types of data can be handled in a quality-assured systematic and rational manner with e.g. DMS systems. All data needed to establish DRL and use DRL should be included. Investigate how IQ and equipment features can be included in the system of DRL. (1st to 4th year)
6. Establishment of national and, where possible, regional or European DRLs considering differences found in the previous point (3rd year)
7. Produce guidelines or better integration of established DRLs into clinical practice considering analysis from point 5 of this description (2nd, 3rd and 4th year)
8. Produce training materials for establishing or developing an effective infrastructure to enable the establishment, use and review of DRLs considering analysis from point 5 of this description (2nd, 3rd and 4th year)
9. Produce materials to promote DRLs as a tool for optimisation imaging and guidelines produced in point 9 (3rd and 4th year)
10. Organize joint trainings in establishment, use and review of DRLs for all relevant stakeholders (to enable better understanding between relevant stakeholders that should result in better implementation of DRL process in MSs) (3rd, 4th and 5th year)

Expected outcomes (impact and sustainability)

The expected outcome of this project is update of list of diagnostic and interventional procedures that needs national DRLs in NM, IR, CT and radiography. Due to rapid evolvement of medical imaging equipment and methods, establishment and use of DRLs is cyclical process that needs constant updates. Besides the national DRL values, the analysis of all other relevant data that could influence establishment, use and review of DRLs can point to the direction of improvement of DRL concept. E.g., the concept of EDRL as regional DRL is of limited value because of possibly large differences in radiological equipment and practice between regions, different levels of hospitals, etc. This project should analyse these differences and give guidelines that will help in harmonizing the use of DRL process in the EU MSs. A practical guidance and training material for establishment, use and review of DRLs will be produced for all relevant stakeholders to improve implementation of project results. This will strengthen radiation protection of patients undergoing these procedures through improved optimisation of procedures.

Benefits of performing within a JA

A joint action will provide a platform for all relevant stakeholders in medical imaging to cooperate in advancing the optimisation process in NM, IR, CT and radiography procedures. Joint action will increase level of understanding between stakeholders increasing level of implementation of the

project results. This will result with guidelines on DRLs establishment and utilization that should give raise to harmonization of DRL use in optimization of radiological practices. The involvement of regulatory bodies in a joint action will facilitate translation of findings in regulations and harmonization through all EU MSs.

SUBJECT/TITLE: Radiation protection during pregnancy related to medical exposure

Background (relevant SAMIRA project, other relevant EU projects, scientific or regulatory rationale)

Pregnant patients are undergoing radiodiagnostic and therapeutic radiological procedures placing the unborn child at an increased risk due to the use of ionising radiation. EU BSSD requires that when the pregnant patient undergoes medical exposure, special attention should be given to the justification and optimization of the procedure, considering both, the expectant individual and the unborn child.

The ICRP84 and EC100 guidelines on pregnancy and medical radiation are more than 20 years old and, in some parts, obsolete. To optimize radiation protection in medical applications within this highly sensitive group of patients, it is of great importance to include advanced technologies and methods to generate scientifically based findings for guidelines and recommendations. E.g., recent work conducted within the EURADOS in the field of fetal dosimetry in patients undergoing radiotherapy (RT) shows that new technologies, such as proton therapy, enable a safe and optimal treatment during pregnancy with clear benefits for both the mother and the child. European PIANOFORTE SONORA research project focuses on improving the accuracy of fetal doses estimation in diagnostic and interventional radiology and RT to optimize process. Nevertheless, it does not include fetal dosimetry in nuclear medicine procedures. EURADOS research on management of pregnant patients showed that national or hospital guidelines on the management of pregnant patients undergoing diagnostic and interventional radiology procedures are used in clinics. However, it has been sown that the guidelines differ considerably.

It is necessary to update the information that were in EC RP100 guidelines on radiation protection during pregnancy in medicine to help in harmonizing practices all over Europe to reduce the harmful effect of ionizing radiation due to occupational and medical exposure.

Objectives

1. To update information in existing European guidelines on radiation protection during pregnancy in medicine related to medical exposure for all relevant stakeholders. It should also include examples of best practices, the information on radiation exposure risks, safety protocols, the use of protective equipment and risk/benefit communication to the pregnant or potentially pregnant patients and workers
2. To develop training materials on radiation protection during pregnancy in medicine related to medical exposure for all relevant stakeholders. It should also include examples of best practices, the information on radiation exposure risks, safety protocols, the use of protective equipment and risk/benefit communication to the pregnant or potentially pregnant patients
3. To train all relevant stakeholders on use of guidelines on radiation protection during pregnancy in medicine related to medical exposure (to enable better understanding between relevant stakeholders that should result in better implementation guidelines)
4. To initiate awareness campaign to decrease the fear due to lack of knowledge for all relevant stakeholders

Description of the project (overall description including methods, possible/needed partners, estimated length of a project)

Project should last 4 years. Relevant stakeholders are relevant professional societies (radiologists, radiotherapists, nuclear medicine specialists, gynaecologists, medical physicists, radiation technologists), health authority, radiation protection authority, patients, referral doctors, universities.

1. Review on the status of radiation protection during pregnancy in medicine due to medical exposure using regulations, guidelines and scientific literature review (optional is to use surveys or interviews among all relevant stakeholders if some data are missing or need to be clarified) (1st year)

2. Based on review, organize workshops that include different groups of relevant stakeholders to compare practices, identify problems, gaps, solutions and harmonize the approach (2nd year)
3. Produce document on update information given in European guidelines for radiation protection during pregnancy in medicine due to medical exposure (2nd, 3rd year)
4. Produce training materials for radiation protection during pregnancy in medicine due to medical exposure (3rd, 4th year)
5. Organize joint trainings in radiation protection during pregnancy in medicine due to medical exposure for all relevant stakeholders (to enable better understanding between relevant stakeholders that should result in better implementation guidelines in MSs) (3rd, 4th year)
6. Initiate awareness campaign to decrease the fear due to lack of knowledge for all relevant stakeholders using different means for dissemination of project results. This should include awareness of universities and health professional schools for the importance of including information on radiation and pregnancy in undergraduate curricula.

Expected outcomes (impact and sustainability)

The project will result in an update of information given in European guidelines on radiation protection during pregnancy in medicine due to medical exposure. This will strengthen the radiation protection within this highly sensitive group of patients. Fetal dose and associated risk data will be considered and debated between all stakeholders to increase the quality of existing guidelines and to harmonize them in EU MSs. A training material and awareness campaign in radiation protection during pregnancy in medicine due to medical exposure for all relevant stakeholders will be produced to improve implementation of project results.

Benefits of performing within a JA

A joint action will provide a platform for all relevant stakeholders in use of radiation in medical applications to cooperate in updating information on radiation protection during pregnancy in medicine to enable harmonizing guidelines across EU MSs. Joint action will increase level of understanding between stakeholders increasing level of implementation of the project results. The involvement of regulatory bodies in a joint action will facilitate harmonization of practice and translation of findings in regulations.

SUBJECT/TITLE: Strengthening the implementation of incident learning systems

Background (relevant SAMIRA project, other relevant EU projects, scientific or regulatory rationale)

The European project MARLIN (Medical Application Reporting of Incidents Learning and Improvement Network) focuses on enhancing the safety of medical radiological practices, by establishing a robust incident reporting and learning system. MARLIN advocates a structured framework for reporting, recording, analysis, learning and dissemination, feedback, redesign and audit. These elements are already partially available at platforms like SAFRON (IAEA) or ROSEIS (ESTRO). It aligns with the Council Directive 2013/59/Euratom (BSSD), which mandates MS to ensure that healthcare organizations implement systems for reporting radiation incidents and share lessons learned to improve safety. It requires that significant incidents are reported to national authorities and that appropriate measures are taken to address deficiencies, ultimately promoting a safer environment for both patients and healthcare workers. Incident learning systems in the clinical setting can be considered a cyclical process aimed at continual strengthening of safety through a promotion of a culture of active learning and continuous quality improvement.

Objectives

1. Enhancing Incident Learning Systems (ILS) in radiological practices
2. Education and Training on Safety Culture to promote learning from incidents and continuous quality improvement.

Description of the project (overall description including methods, possible/needed partners, estimated length of a project)

This project aims to create and strengthen national infrastructures and processes for reporting radiation related incidents across the EU, in line with MARLIN recommendations, while also fostering a learning culture where lessons from incidents can be shared and applied to improve patient safety in radiological practices. The project will build on existing ILS systems, emphasizing the continuous feedback loop where incident data leads to learning, which in turn drives actionable improvements in patient safety. Another core objective would be to establish comprehensive education and training programs for students and healthcare professionals addressing radiation protection standards, proactive safety measures and incident response skills. This would include both creating adequate curricula for graduate programs and continuous professional development programs, ensuring that healthcare workers are equipped with the necessary skills to minimize radiation risks and respond effectively to any incidents.

Methods:

- Organize workshops, webinars, and site visits for countries with developing systems, allowing them to learn directly from countries with robust incident reporting and learning systems.
- Provide flexible templates and guidelines that encourage not just reporting but in-depth analysis and sharing of lessons learned from radiation incidents. Countries can adopt or adapt these tools based on their technical capacities and existing healthcare practices.
- Provide guidance on analysing and investigating events and performing proactive risk assessment and multiple safety checks along the organisational processes.
- Create detailed case studies and toolkits based on the experiences of countries with mature systems.
- Work with national medical and educational institutions to create training curricula that reflect local regulatory requirements and practices related to incident learning systems

Partners: IAEA, National health and radiation protection competent authorities, scientific and professional societies (ESR, EANM, ESTRO, EFRS), medical physicists and radiography/radiation therapy associations, hospitals and universities.

Estimated length: 5 years, by focusing on local and national practices and cross-country collaboration, the proposed methods will help each country develop effective and tailored incident reporting and learning systems while benefiting from existing good practices across Europe.

Expected outcomes (impact and sustainability)

Achievement of higher levels of compliance with BSSD. As national systems evolve, they will not only capture and report incidents but also ensure that these incidents serve as critical learning opportunities, helping

healthcare systems to become more resilient. By embedding learning into the fabric of incident reporting, countries will be better equipped to align with EU radiation safety goals while protecting public health.
Benefits of performing within a JA
A JA provides a structured framework not only to promote the alignment of national systems while respecting each country's specific needs, but also promoting cross-border learning and the sharing of best practices This collaboration will help ensure that incident learning leads to actionable insights that are implemented EU-wide, building a foundation for long-term learning networks and enhancing radiation safety beyond the project's lifetime

SUBJECT/TITLE: Effective implementation of clinical audits

Background (relevant SAMIRA project, other relevant EU projects, scientific or regulatory rationale)

The Commission Recommendation 2024/1112/Euratom on clinical audits of medical radiological practices, adopted on April 18, 2024, builds on the framework established by Council Directive 2013/59/Euratom (BSSD) and results from collaborative efforts among key European stakeholders, including the SAMIRA Steering Group, HERCA, and the QuADRANT project. It promotes further measures for enhancing the quality and safety of radiological practices across Europe and outlines the implementation of robust clinical audit systems in radiology, radiotherapy, and nuclear medicine, reinforcing the need for continuous assessment and improvement in these fields.

Objectives

1. Establishment of clinical audits networks and national infrastructure for effective implementation of clinical audits, including setting up national training programmes for auditors and, inspectors
2. Establishment of a European platform to share information on clinical audits, such as clinical audit guidelines, standards for good medical radiological procedures, audit outcomes and other reference documents, making full use of digital technology
3. Enable and support for the successful implementation of clinical audit by means of cross border collaborations on pilot audits

Description of the project (overall description including methods, possible/needed partners, estimated length of a project)

Description: This project aims to establish or expand national and regional networks of clinical audits in radiology, radiotherapy, and nuclear medicine across Europe. The focus is on standardizing audit procedures, training of healthcare professionals to become auditors (including setting up harmonized training programmes), and promoting that countries develop clinical audit systems/programs in compliance with the BSSD and the European Commission Recommendation 2024/1112/Euratom. A second aim is to enhance cross-border collaboration among MS. It will focus on creating a framework for the exchange of safety protocols, compare and benchmark audit findings at national and, as far as possible, at Community level

Methods:

- Develop a European discussion forum to help creating national framework and infrastructure for clinical audits, tailored to radiology, radiotherapy, and nuclear medicine. Develop guidance taking into account gaps and best practices identified from the QuADRANT project (2 years)
- Review, design and implementation of specialized training programs for auditors and healthcare professionals, including physicians, medical physicists, and radiographers. Raise awareness of universities and health professional schools for the importance of including clinical audit topics in undergraduate curricula. Provide guidance on how to set up efficient training programs (2 years).
- Conduct pilot audits in selected countries to refine methodologies, identify key topics to be audited, compare and benchmark findings (for instance, percentage of compliance in particular areas), and identify areas for improvement before expanding the methodologies nationally or regionally (1 year).

Partners: National health and radiation protection competent authorities, scientific and professional societies, hospitals and universities

Estimated length: 5 years, allowing for the initial setup, pilot phases, and full implementation across participating countries

Expected outcomes (impact and sustainability)

Achievement of higher levels of effectiveness and efficiency concerning clinical auditing. Establishing national and regional clinical audit frameworks will create a self-sustaining system for continuous quality improvement. National frameworks should include regular assessment of the implementation of clinical audits by the competent inspection authorities, which also will contribute to the quality cycle. With ongoing training and standardized audit procedures, these networks will remain operational and adaptive, ensuring that healthcare institutions regularly update and refine their radiological practices based on audit feedback and analysis. Cross-border collaboration will enable continuous knowledge exchange, making it easier for countries to share best practices, innovations, and policy developments. This sustainability will be reinforced by shared audit tools, training programs, and joint policy recommendations.

Benefits of performing within a JA
A JA facilitates the pooling of knowledge, skills, and expertise from different countries. MS can leverage each other's strengths, making it easier to address complex challenges like clinical audit methodologies, key topics to be audited, audit training programs. A JA enables MS to develop and implement standardized benchmarks for clinical audits. This promotes uniformity in safety protocols, ensuring that all EU citizens benefit from the same high level of care, regardless of location. A JA provides a platform for the rapid dissemination and adoption of best practices, allowing countries to share audit tools, and helping to develop national audit structures including all types of healthcare professionals.

SUBJECT/TITLE: Revisiting European clinical image quality criteria for x-ray imaging supporting clinical optimisation

Background

The optimisation of radiation protection in medical imaging requires that radiological procedures provide diagnostic information of sufficient quality. To ensure this, it is essential to assess image quality using established imaging quality criteria as part of the optimization process. This approach is particularly relevant in contexts such as Diagnostic Reference Levels (DRLs).

The European Commission developed a series of guidelines defining clinical quality criteria for X-ray imaging, addressing both computed tomography and diagnostic radiography for adults and children (ref). These guidelines emerged from a collaborative European initiative involving professionals and regulatory bodies across the continent. Although these guidelines are now outdated due to advancements in imaging technology and changes in radiation dose standards, they established a critical foundation in specifying image quality criteria. Specifically, these criteria focused on the visualisation of anatomical structures and accurate reproduction of key diagnostic features within images. The guidelines intended for these criteria to be used in clinical image evaluations. They have been adopted in some research projects, occasionally with minor modifications. This evaluation process relies on subjective assessments made by human observers.

The digital nature of medical imaging facilitates the analysis of large volumes of data quickly and efficiently, with potential support from advanced technologies, including artificial intelligence (ref). This project aims to build upon prior work and the established European image quality criteria investigating the usefulness of prior methods developed, e.g.in the iViolin project (ref) which advanced the evaluation of physical image quality parameters in clinical images.

Objectives

1. Evaluate the European clinical image criteria and other image criteria used in clinical studies.
2. Re-establish European image criteria for key examinations and technology.
3. Explore the possibility of including objective European image criteria that can be assessed using automated systems based on the established clinical image criteria.

Description of the project

The aim of this project is to update and expand imaging criteria for critical X-ray examinations to support clinical assessments of image quality. The project will begin with an in-depth review of current practices in the use of image criteria, resulting in a report on their current application and evaluation methodologies (Year 1). The subsequent phase will involve selecting specific X-ray examinations, such as lung cancer screening, and revising or developing tailored imaging criteria for these applications. This phase will include a pilot study to validate the criteria, using clinical images sourced from at least three countries and using common evaluation method (Years 2–3). In parallel, the project will explore objective assessment methods through digital image evaluations, leveraging recent advancements. For instance, this approach has been applied in chest imaging, where factors such as lung inclusion at image boundaries, patient alignment, and inspiration depth were assessed automatically (ref). (Years 1–4). Throughout the project, a range of outreach activities will be conducted, engaging stakeholder platforms and presenting findings at conferences.

Expected outcomes (impact and sustainability)

A set of European imaging criteria, developed through collaboration across clinical and regulatory levels, will be made available for clinical application. Both subjective and objective assessment methods will be included, ensuring relevance and adaptability for different healthcare settings both now and in the future. The outcome will provide defined and widely accepted image quality standards that support the optimisation process in medical imaging. These imaging criteria will serve as key quality indicators for medical imaging, forming an important element in clinical quality assurance. Additionally, they will facilitate compliance with broader requirements, such as clinical audits, and support in the establishment and application of Diagnostic Reference Levels (DRLs).

Benefits of performing within a JA

A JA will facilitate an efficient platform for professionals together with competent authorities to work towards an efficient optimisation process addressing a key item for quality and safety in medical imaging – clinical image quality. The involvement of competent authorities will also facilitate the transposing of findings directly into national guidelines. The involvement of European professional societies will facilitate acceptance among clinicians.

References:

European guidelines on quality criteria for computed tomography (2000)
European guidelines on quality criteria for diagnostic radiographic images (1996)
European guidelines on quality criteria for diagnostic radiographic images in paediatrics (1996)
Nousiainen K. et al. Automating chest radiograph imaging quality control. Physica Medica 83 (2021) 138–145
Jorg T. et al. Implementing verifiable oncological imaging by quality assurance and optimization (i-Violin), Radiologie (published on-line 30 October 2024) https://doi.org/10.1007/s00117-024-01389-8