The concepts of justification and optimisation and possible relation and relevance for the Healthcare Sector

This report covers patient radiation protection, and specifically the concepts of justification of medical exposures and optimisation of radiation protection. Justification and optimisation are explored using key references from a number of international bodies. The relation and relevance of these terms to quality and safety in healthcare are discussed. The goal is to give an overview of these concepts prior to commencing a full joint action. This report is exploratory and builds consensus for the PrISMA consortium. It does not aim to provide a comprehensive description of all relationships and interdependencies.

Introduction

Medical applications using ionising radiation are a fundamental and very beneficial part of European healthcare systems. Ionising radiation is used in numerous therapeutic and diagnostic procedures across a range of settings including oncology, nuclear medicine, radiology, dentistry and more. However, exposure to ionising radiation has potential risks. The World Health Organisation (WHO) draws attention to the fact that the use of ionising radiation in healthcare has potential radiation risks[1]. The probability of radiation adverse health effects, e.g. the risk of cancer later in life, is considered proportional to the radiation dose received[2]. There is an international consensus that careful consideration and management of these risks is essential and necessary in healthcare. The Basic Safety Standards Directive (BSSD)[3] governs radiation protection in Europe.

The International Commission on Radiological Protection (ICRP) has defined a system for radiation protection and issued recommendations to frame the management of radiation risks. This system of radiation protection is based on pillars for exposure of patients; the pillars are optimisation of protection and justification of exposure. The BSSD and radiation protection standards issued by the IAEA apply the recommendations from the ICRP at large. The terms "justification" and "optimisation" are commonly used in the field of radiation protection; however, their exact meaning can be subject to interpretation. Justification and optimisation are core values in the BSSD.

A framework of regulations, policies, and ethical standards shapes the governance of quality and safety in healthcare. While international organisations like the World Health Organization (WHO) provide guidelines, these frameworks vary across member states. Despite this variation, core concepts such as quality of care and patient safety are widely recognised within healthcare, though their definitions can be broad and open to interpretation. Additionally, there can be uncertainty regarding whether the justification of medical exposures and the optimisation of radiological protection are distinct aspects of healthcare and integral components of quality and safety standards.

[1] IARC monographs on the identification of carcinogenic hazards to humans, Volumes 1-136

2 ICRP, 2007. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann. ICRP 37 (2-4).

[3] Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union

The manufacturing and marketing of medical devices and pharmaceuticals have specific regulatory frameworks, Medical Devices Regulations (MDR)[4], pharma directive[5] and Clinical Trial Regulations[6]. The Health Technology Assessments Regulations (HTAR)[7] aims to improve the availability of innovative technologies in the area of healthcare and support safe and clinical effective use. These medical products (medical devices and pharmaceuticals) may rely on ionising radiation to achieve their intended purpose. Therefore, it is important to also include these regulatory frameworks in this overview.

1. The concepts of quality, safety and benefit-risk ratio in healthcare

Quality and safety are broad terms.

Commonly accepted definitions are:

"Quality in healthcare refers to the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge". [8]
and,
"Safety in healthcare is the avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of healthcare. It involves ensuring that the care provided does not cause harm to patients".[9]

The exact features of quality and safety activities will vary depending on the discipline and the practices being undertaken in that discipline. However, irrespective of the discipline, any practices which involve medical exposure to ionising radiation should consider both justification and optimisation activities as part of the management of quality and safety.

1.1 The concept of quality and safety in healthcare

It is the position of the PrISMA consortium that justification and optimisation are concepts which are closely related to quality and safety in healthcare. High quality healthcare has been previously described as having the following attributes (Table 1). In the table, links to justification and optimisation are given to illustrate this relationship.

[4] Regulation (EU) 2017/745 of the European parliament and of the council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
[5] Directive 2001/83/EC on the Community code relating to medicinal products for human use
[6] Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use
[7] Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU
[8] Institute of Medicine (IOM). *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academies Press; 2001.
[9] Institute of Medicine (IOM). *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academies Press; 1999.

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union

Table 1. The theoretical framework of quality in healthcare including the attributes, rational and link.

Attribute	Rationale	Link to radiation protection or HTA
Effectiveness:	Providing care processes and achieving outcomes as supported by scientific evidence. Treatments should be based on the best available evidence to achieve the best possible health outcomes.	HTA is linked to the concept of justification in healthcare. It evaluates the evidence supporting medical practices. The selection of medical equipment, tied to optimisation, is also tied to effectiveness, as appropriate tools are critical to achieving optimal patient outcomes.
Efficiency:	Making the best use of resources to achieve optimal health outcomes. This means avoiding waste, including waste of equipment, supplies, ideas, time and energy.	A procedure involving ionizing radiation may be deemed poorly justified if it is inefficient and results in a waste of resources. A non-optimized therapy can lead to ineffective treatment, resulting in inefficient use of resources, and consequently the medical exposure is not justified. In therapy, radiation dose planning, the optimisation process may reveal that the treatment should not be given because the intended health outcome will not be achieved.
Equity:	Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.	The equity aspects imply justified and optimized investigations and procedures for everyone.
Patient-Centeredness:	Providing care that is respectful of and responsive to individual patient preferences, needs, and values, ensuring that patient values guide all clinical decisions.	Effective communication of both the benefits and risks is essential for empowering patients and involving patients in their own care.
Timeliness:	Reducing waits and sometimes harmful delays for both those who receive and those who give care. Patients should receive timely care without unnecessary delays.	The availability of care is dependent on an efficient HTA process and justification process.
Safety:	Avoiding injuries to patients from the care that is intended to help them. Safety is a fundamental aspect of quality.	The use of ionising radiation poses potential health risks. Safety includes radiation protection in all aspects.

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union

In the table a link is indicated but not straight forward. Effectiveness and efficiency are included in the concept of optimisation of protection and justification of medical exposures. Timeliness could be linked to justification. If a number of imaging diagnostic and therapeutic procedures are not justified patients may not receive timely diagnostics or therapy because resources are restricted. The application of the attributes in healthcare has to be studied more in detail to give guidance on the link to justification or optimisation. The application is largely governed by national frameworks.

Safety can be further described with the following attributes, Table 2.

Table 2. The theoretical framework of safety including the attributes, rational and link.

Attribute	Rationale	Link to radiation protection or HTA
Preventing Errors:	Implementing systems and practices that reduce the risk of errors in diagnosis, treatment, and care processes. This includes medication errors, surgical errors, and diagnostic or therapeutic inaccuracies.	A clear attribute in radiation protection, the BSSD use the term unintended exposure.
Learning from Mistakes	Establishing a just culture where healthcare providers can report and learn from errors without fear of punishment. This helps in understanding the root causes of errors and preventing them in the future.	A clear attribute in radiation protection
Building a Safety Culture:	Promoting a culture where safety is a priority at all levels of the healthcare organisation. This involves training, policies, and leadership commitment to safety.	A clear attribute in radiation protection
Implementing Safety Protocols:	Using checklists, guidelines, and protocols to standardise care processes and reduce the risk of errors. For example, surgical safety checklists and hand hygiene protocols are crucial for preventing infections.	A clear attribute in radiation protection
Continuous Monitoring and Improvement:	Regularly assessing and improving safety measures through audits, feedback, and quality improvement initiatives. This helps in identifying potential safety issues and addressing them proactively.	A clear attribute in radiation protection

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union

All the attributes of safety are linked to the foundation of radiation protection but not necessarily restricted to the concepts of justification and optimisation of radiation protection. The conclusion is that radiation protection could be considered an integrated part in management of safety at the hospital level. The application is largely governed by national frameworks.

The PrISMA consortium want to emphasize that justification and optimisation should be an integral part of the quality and safety of healthcare.

The PriSMA consortium would like to point out that the definition of quality and safety of healthcare at the European level is given in a broad and undefined way and the national frameworks in member states must be taken into account to gain a more detailed understanding of the links and interdependencies.

1.2 The concept of benefit-risk ratio in healthcare

The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine[10] addresses the equitable access to healthcare. The Oviedo Convention states: Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality. However, the terms "appropriate quality", or “benefit/risk” are not further defined. A comparison with concepts of justification and optimisation and the concept of benefit/risk in the health legislation on the European level is therefore not evident and is not further discussed.

However, in the pharma legislation benefit-risk ratio is a central concept. When applying quality and safety to pharmaceuticals under development, they are usually discussed in terms of benefit vs risk for the intended patients. A new drug can only be approved for marketing, or for use in a clinical trial, if the expected benefits on a population level outweigh the identified and potential risks for the individuals receiving the drug. This is a concept similar to justification. Of note, the term “quality” in the pharmaceutical sphere usually refers specifically to pharmaceutical quality (chemical purity, reliable manufacturing processes, quality assurance processes, etc.).

Justification and optimisation principles are applied for pharmaceutical or medical devices available on the market, i.e. in the use of the pharmaceutical or devices. The information gained in the clinical trials, authorisation and production is important when using the products. The hospitals need the information included in the product information. In the process of justification on a national level, the institutions, agencies or authorities are also dependent on adequate information.

The benefit to society has to take into account whether the new device or drug also performs better than existing alternatives, introduces additional risk to staff or the environment and includes also economic considerations. These issues may be considered in the HTA processes at different levels. However, the knowledge gained in the marketing process may be a valuable input to the HTA, optimisation and justification.

The PrISMA consortium would like to state that the benefit-risk ratio according to pharmaceutical legislation is narrower scope compared to the use in radiation protection in general and for justification of pharmaceutical use in particular. Resulting in further assessment of this concept.

[10] CETS 164 - Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (coe.int). A convention by the European Commission, Oviedo, 4.IV.1997

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union

2. The concept of justification and appropriateness as used in the context of radiation protection

The PrISMA consortium recognises that while the Basic Safety Standards Directive (BSSD) provides for instances where justification is required, the exact meaning and wider concept of justification in medical exposures to ionising radiation can be less clear at times. Several relevant definitions and texts provide further insight into what justification is and how it should be applied at a national level and in clinical practice (Appendix 1).

Firstly, it should be noted that that there are three levels of justification as set out by the International Commission on Radiation Protection (ICRP) publications 103[11] and 105[12].

- Level I: Justification in general
- Level II: Generic justification (justification of specific procedures with a specific objective)
- Level III: Individual justification

The regulatory requirements of the BSSD also take into account a hierarchical structure of justification. It is for these reason that some justification requirements are at a national or regional level (with respect to Article 5, 19, 55(2) and 77, for example) and others relate to the practitioner and the individual person under their care (Article 57 and 62, for example). However, in both scenarios it is advisable to refer to Article 55 (1) when carrying out justification, as this is the legal basis for justification decisions in Europe:

"Medical exposure shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct benefits to health of an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation."

As per Part 3 of the International Atomic Agency's (IAEA's) General Safety Requirements (GSR)[13], level I justification can be taken for granted in medicine (i.e. it is widely accepted that the use of radiation in medicine does more good than harm). ICRP 103, ICRP 105 and Part 3 of the IAEA's GSR do not offer any contradictory statements to the above. ICRP 105 also provides further examples and insight into how the justification decision may vary between countries for reasons such as available resources or the incidence and prevalence of a given condition. With respect to level II justification, ICRP 105 agrees that occupational and public exposure should be taken into account. Both the ICRP and IAEA agree that the competent authority/health authority should seek the input of professional bodies in the level II justification process of a given diagnostic or therapeutic procedure.

ICRP 105 states that justification "is a matter for national and international professional bodies, in conjunction with national health and radiological protection authorities". In the BSSD it is the responsibility of the Member State to ensure that new classes and types (or at times existing classes and types) of practices are justified, and hence this function may be assigned to an independent competent authority. This approach is closer to that set out in Part 3 of the IAEA's GSR under 3.16 and 3.156. How Member States carry

[11] ICRP, 2007. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann. ICRP 37 (2-4).
12 ICRP, 2007. Radiological Protection in Medicine. ICRP Publication 105. Ann. ICRP 37 (6).
[13] IAEA, 2014, Radiation Protection and safety of radiation sources: International basic safety standards, general safety requirements, IAEA SAFETY STANDARDS SERIES No. GSR Part 3

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union

out this justification process, and their interaction with professional bodies and wider stakeholders, is beyond the scope of this report.

In contrast, responsibility for level III justification lies with the practitioner and the referrer in advance of the exposure. The ICRP describe this as "the application of the procedure to an individual patient should be justified". Justification assessments should be undertaken in advance of the exposure and should be carried out by the practitioner in consultation with the referrer, however the legal responsibility for justification lies with the undertaking performing the radiological procedure. The best course of action may vary between individuals due to different characteristics. Hence, just because an exposure is justified for one patient with a given condition does not mean it is necessarily justified for another patient with the same condition. The justification is at an individual person level or on a generic level. However, practitioners should ensure that level II justification is first in place before considering level III justification.
ICRP 105 (67) outlines that before any exposure, it should be checked that the information is not already available to avoid unnecessary exposures. It places particular emphasis on procedures with higher doses, where the justification is increasingly important. It should take account of all the available information such as patient characteristics, alternative procedures and so forth. It is for this reason that referral criteria and patient categories are important in individual justification, especially regarding efficiency of services as outlined in ICRP 105 and Part 3 of the IAEA's GSR.

PrISMA consortium would also like to highlight confusion around the term 'appropriate' or 'appropriateness' with respect to justification. The word appropriate is sometimes used in place of justification or may instead be specific to 'the appropriateness of the referral' or appropriate imaging or treatment decision for a specific clinical condition. We urge caution when using this term as its exact meaning can be unclear. As outlined in Part 3 of the IAEA's GSR appropriateness could be seen as a proxy for individual justification, but the referral or referral guidelines may not take into account other factors such as local availability, urgency of the procedure or those specific to the patient which may affect the individual justification decision. Requirement 37 point 3.158 of Part 3 of the IAEA's GSR explains that while national or international referral guidelines should be considered, they are not the sole basis for justification (see Article 55 (1) of the BSSD above).

3. The concept of optimisation of protection as used in the context of radiation protection

The PrISMA consortium has reviewed and analysed international reference literature and the BSSD with regard to optimisation. A summary of international guidance and recommendations is included in Appendix 2. Questions remain about the precise definition and broader concept of optimisation in radiation protection for medical exposures. These areas require further clarification and guidance to ensure effective implementation in national regulations and clinical practice.

Several international references offer definitions, descriptions, and clarifications that provide deeper insights into what optimisation of radiation protection entails and how it should be applied at the national level and in clinical practice (see Appendix 2). The following points highlight key aspects that the PrISMA consortium wishes to emphasise.

Firstly, the definitions provided in the BSSD differ distinctly between public and occupational exposures compared to those for patients. While there should be specific dose limits and dose constraints for public and occupational exposures, they do not apply to patients. This underscores the importance of applying the optimisation principle specifically for patient protection, ensuring proper radiation safety and the effective use of other tools such as diagnostic reference levels in diagnostics, interventional radiology and nuclear medicine or to minimise the dose to organs at risk in the treatment planning process.

Secondly, it should be noted that two levels of optimisation as set out by the International Commission on Radiation Protection (ICRP) publication 105.

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union

Level I: the design, appropriate selection, and construction of equipment and installations

Level II: the day-to-day methods of working (i.e. the working procedures).

It is important to note that while the BSSD does not directly address the design and construction of equipment, it does state that "*optimisation includes the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical radiological procedures, quality assurance, and the assessment and evaluation of patient doses or the verification of administered activities, taking into account economic and societal factors*" (BSSD Article 56.4). This implies that considerations for radiation protection should be integrated into the early stages of equipment design and construction.

The PrISMA consortium emphasises that Level II includes crucial steps such as establishing methods and protocols for specific medical purposes, along with staff training and documentation. Additionally, IAEA GRS part 3, 2.12 underscores the importance of optimising each medical exposure. That is, for each patient. However, the subject of individual optimisation has not been developed in any detail in ICRP references. To highlight this, the introduction of a Level III optimisation could be considered, focusing on each individual examination or treatment. Such an addition may be helpful.

Thirdly, all international references emphasise the ALARA principle as a key concept, as outlined by the ICRP: *The optimisation of radiological protection means keeping the doses 'as low as reasonably achievable, economic and societal factors being taken into account'*. The ICRP provides a comprehensive approach to optimisation of patient protection in diagnostic imaging, interventional radiology, as well as imaging used for planning, guidance, and verification purposes, focusing on managing radiation doses to align with the medical purpose. The BSSD similarly mandates that radiation doses should be kept as low as reasonably achievable, taking into account current technical knowledge as well as economic and societal factors. In the case of radiotherapy, it is the radiation dose to the non-target volumes and tissues that shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.

A prerequisite in this context is that the required diagnostic or therapeutic result is achieved. Ensuring the medical outcome is integrated into the optimisation principle and this is clearly stated in the BSSD. As an example, in medical imaging, the radiation dose cannot be reduced to a level where the necessary medical information is compromised. Additionally, to optimise radiation protection, the desired medical outcome must be clearly defined and, ideally, quantified and included into the optimisation process.

Fourthly, international references clearly describe the balance between radiation exposure and medical purpose in the context of optimisation. The BSSD further clarifies that this applies to both diagnostic and therapeutic applications. It emphasises that medical information is a key component of optimisation in medical imaging. For therapeutic purposes, the BSSD mandates that doses to non-target volumes and tissues should be as low as reasonably achievable, while still being consistent with the intended radiotherapeutic purpose (i.e. sufficient dose to the target volumes for achieving a therapeutic effect). The latter requires individual planning of the exposure.

The PrISMA consortium concludes that the international references and the BSSD are generally consistent. According to the BSSD, optimisation must be an integral part of clinical practice for both diagnostic and therapeutic procedures.

The PrISMA consortium emphasises the need to clearly define the medical purpose for different applications. For example, in diagnostic imaging, it is crucial to specify the medical information needed from the examination.

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union

4. Examples of the application of justification and optimisation in the clinic

This section describes activities carried out in the hospitals and the link to justification and optimisation. The activities are described as a process in Figure 1. The relation to development of medical products (medical devices and pharmaceuticals) is included in the figure for clarity, highlighting the connection between the legalisation of MDR and PHARMA on the one hand and BSSD's on the other. In between are the health technology assessments placed. That is, MDR and PHARMA has main goal to put products on the marked, and BSSD take into account the use of the products. HTA/HTAR is one of the processes to ensure safe and effective implementation of new methods.

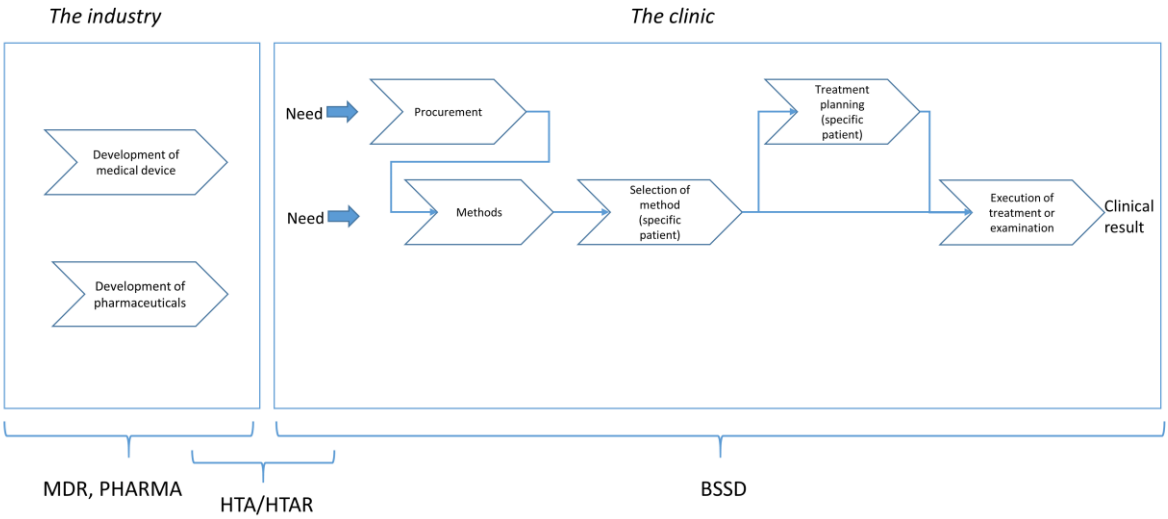

Figure 1. The clinical process starting from a medical need to the clinical result (i.e. the medical images or treatment). Including the relations to development of medical products.

4.1 A schematic description of the process and the constituent sub-processes

The process of procurement

New types of procedures involving medical exposure sometimes involve new devices or radiopharmaceuticals. These procedures should be justified in advance before being generally adopted into clinical practice (justification level II). The clinic needs to get advice from national HTA evaluations or conduct its own evaluations. The clinic's ability to handle the new products also needs to be evaluated. In this process, the specificities of the equipment such as the ability to adjust exposure to the patients, collect radiation dose and other relevant technical parameters need to be considered. This also applies to therapeutic radiopharmaceuticals where equipment for dose-planning purposes may need to be included. The prerequisites for optimisation of radiation protection should be included in the procurement process.

- Reference to BSSD art 55 2a and art 56 4

The process of development on methods and routines to be used in the clinic

Even if no new medical products are needed, new methods are developed using existing products. Before a specific method is adopted it should be generically justified for the intended use (level II justification), compare the process for procurement. The clinics need to clearly state internal guidelines for clinical indications and prerequisites for the method – both diagnostic and therapeutic. In the development of how the procedure should be performed – both from a technical and medical point of view - optimisation of radiation protection should be considered and included in the processes. The processes also need to ensure

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union

that an adequate medical result is gained. This means, e.g. in medical imaging, that the technical parameters should be adjusted to get sufficient medical information while minimising the radiation dose. For diagnostics this also means determining e.g. the number of projections and scans, and the use of contrast media as well as the volume of exposure. Conditions for adapting the exposure to the patients are determined in the development of procedures. This also links to diagnostic reference levels as a tool in the optimisation process. In the therapeutic setting, the corresponding process would be to ensure that the ionising radiation is delivered in such a way that it ensures a high likelihood of efficacy while minimising the radiation dose to normal tissues and organs, and that the delivered radiation doses can be correctly verified.

- Reference to BSSD art 56 1 and art. 58 1a

The process for justifying a diagnostic examination for a patient

The appropriate medical imaging modality and examination method should be chosen for each patient depending on the clinical indications and questions defined and addressed in the referral. The quality of the referral, i.e. that sufficient information is given in the referral, is thus important at this stage. The patient record is also sometimes important as a supplementary source of information. The use of national referral guidance, including clinical support systems could be of great value. The resulting examinations should contain information that is helpful for the further treatment of the patient.

- Reference to BSSD art 55 2b

The process of selection of patients for radiation therapy (external, brachy or radiopharmaceuticals)

The appropriate therapy for a patient is the one that is likely to be effective without an unacceptable risk of toxicity. For instance, patients with a very short, expected survival are unlikely to benefit from certain therapies, and therefore the medical exposure may not be justified (justification level III), even if a method is generically justified (justification level II). Likewise, a patient with risk of organ dysfunction due to co-morbidities or prior therapies may have a high risk of severe toxicity, and the exposure can therefore not be justified (unless the expected benefit outweighs the risk).

- Reference to BSSD art 55 2b

The process of target volume definition and dose planning for radiation therapy (external, brachy or radiopharmaceuticals)

Radiation therapy should include defining target site and planning of radiation dose to target site and organs at risk. At the individual level this includes delivering an adequate absorbed dose to tumour lesions while minimising the radiation dose to surrounding organs at risk. This approach minimises the probability of acute and late side effects to some extent. The planning stage encompasses patient immobilization, pre-therapy imaging for target definition, structures delineation, positioning, and dose planning. For radiopharmaceutical therapy, the treatment is dependent on the individual patient´s biodistribution and pharmacokinetics. Therefore, image-based dosimetry may be conducted to investigate the individual patient´s dose distribution and the activity administered may be adjusted so that an adequate absorbed dose to tumour lesions is ensured, while avoiding an unacceptable dose to organs at risk. In the planning process it may be concluded that the planned therapeutic goal cannot be reached for a specific patient due to a number of causes, i.e. the treatment for the patient is not justified (justification level III).

- Reference to BSSD art 56 1

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union

The process of performing the diagnostic examination

Before the examinations, the patient's identity must be checked and that the examination is justified according to the hospital guidance. For certain examinations and specific patients, it must be asked if the patient is pregnant. If there is uncertainty, possible pregnancy should be tested. An assessment is made as to whether it is justified to carry out the examination and thereby expose the foetus to ionising radiation.

The exposure should be adapted to the individual patient and the clinical indication, i.e. optimisation. This is done by choosing an appropriate protocol and positioning the patient properly. The exposed volume and level of exposure should also be adapted to the patient. In nuclear medicine, the exposure is linked to the administered activity of the radiopharmaceutical and the amount of activity may be adjusted according to weight as suggested for children in the posology for different diagnostic pharmaceuticals. The quality of the radiological report is crucial and determines, together with appropriate image information, whether the examination has value for the patient or if the patient safety is compromised. The outcome in medical imaging should meet the medical goal.

- Reference to BSSD art. 56 1, art. 55 2b, 2c and art. 62 2

The process of delivering a radiation treatment

The identity of the patient is validated. In the case of external radiotherapy, and whenever applicable, it is necessary to ensure that the planning system data is correctly transferred to the treatment unit. In image-guided radiotherapy, imaging is used to verify that the patient is positioned as it was planned. Post-treatment imaging can be used to verify treatment outcomes using various imaging techniques. In nuclear medicine therapy, imaging may also be employed to confirm the radiation dose delivered to the patient.

- Reference to BSSD art. 56 1, art. 55 2b, 2c and art. 62 2

4.2 Some prerequisites for a functioning process

Leadership and available resources

Awareness of the concept of motivation and optimization among leaders and ensuring that resources are available and appropriate decisions concerning radiation protection are made in the organisation.

Education and training

Prerequisites for all of the above scenarios is appropriate education and training for all staff involved in the clinical process.

Quality assurance programme:

BSSD requires that a quality assurance programme to be in place. That is, the process described above should be part of such a programme.

Clinical Audit should be part of this programme (including patient dose or administered activity assessment). Clinical audit is a systematic examination or review of all medical radiological (all medical applications involving ionizing radiation) procedures which seeks to:

- Improve the quality of patient care
- Allow for identifying critical issues and taking corrective actions
- Promote the effective use of resources
- Enhance the provision and organization of clinical serviced
- Further professional education and training

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union

The quality assurance programme should be part of the managing system[14]

The PrISMA consortium want to emphasise that justification and optimisation should be integrated into the clinical process and evaluated in clinical audits.

5. The regulation on health technology assessments regulation (HTAR) and the Basic Safety Standards Directive (BSSD)

Regulation 2021/2282 on health technology assessments (HTAR) will apply from 12 January 2025 and will involve implementation for different technologies according to a defined implementation plan from January 2025 onwards. This regulation will aim to improve the availability of innovative health technologies, such as medicinal products and medical devices, to EU patients. It also aims to ensure the efficient use of resources and strengthen the quality of HTA across the Union. It should be clarified that only radiopharmaceuticals will be included in the HTAR. Medical devices that use ionizing radiation will not be included in these evaluations.

Some definitions stated therein:

... ***"health technology assessment' or 'HTA' means a multidisciplinary process that summarises information about the medical, patient and social aspects and the economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner";***

In comparison to the marketing authorisation process for new drugs, HTA can cover both clinical and non-clinical aspects of a health technology, depending on the healthcare system. The Union's co-funded joint actions on HTA (EUnetHTA Joint Actions) have identified nine domains by reference to which health technologies are assessed. Of these nine domains, four are clinical and five are non-clinical. The four clinical domains of assessment concern the identification of a health problem and current health technology, the examination of the technical characteristics of the health technology under assessment, its relative safety, and its relative clinical effectiveness. The five non-clinical assessment domains concern cost and economic evaluation of health technologies, and its ethical, organisational, social and legal aspects. Hence, the HTA process can be resource-intensive for a number of stakeholders and there is a recognised needed for joint clinical assessments. HTAR focus on the clinical assessment related to the patient, BSSD require that the clinical assessment also cover radiation protection issues for staff, the public and the environment.

... "*joint clinical assessment' of a health technology means the scientific compilation and the description of a comparative analysis of the available clinical evidence on a health technology in comparison with one or more other health technologies or existing procedures, in accordance with an assessment scope agreed pursuant to this Regulation, and based on the scientific aspects of the clinical domains of HTA of the description of the health problem addressed by the health technology and the current use of other health technologies addressing that health problem, the description and technical characterization of the health technology, the relative clinical effectiveness, and the relative safety of the health technology*"

Joint clinical assessments will be performed for some, but not all, technologies. While the clinical assessments would occur at a European level for these technologies, the non-clinical assessments will continue to occur at a national level. Professionals working in radiation protection (such as medical physicist experts) are important experts to be included in these assessments or consultations. Competent authorities for radiation protection are important stakeholders in implementing HTAR. Many aspects of radiation

[14] IAEA, 2016 Leadership and management for safety, General safety requirements, IAEA SAFETY STANDARDS SERIES No. GSR Part 2

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union

protection form important considerations in both the authorisation of radiopharmaceuticals and the wider evaluation of health technologies that involve ionising radiation. It is thought that there is at present little awareness among the HTA-bodies (at national and European level) of the BSSD and the requirements related to radiation protection and, in particular, generic justification. Radiation protection authorities and networks such as HERCA are not included in the established governance structure of the HTAR or the common Joint Clinical Assessments (JCA) and Joint Scientific Consultations (JSC) that is regulated through HTAR.

PrISMA consortium would like to highlight that these joint assessments may not significantly enhance access for EU patients if the generic justification is not also adequately considered within the entire lifecycle of these products. Failing to do so will results in delayed access to radiopharmaceuticals and devices which involve ionising radiation, which is contrary to the intention of HTAR. Furthermore, including radiation protection considerations in HTAs at all levels (European, national and local) is crucial in ensuring that the clinical and non-clinical aspects of the technology are adequately captured and inform the decision-making process.

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union

Appendix 1: Definitions of Justification and Appropriateness

1.1 Collection of definitions and application from the council directive 2013/59/EURATOM

The BSSD includes justification in the following articles:

In the introduction section (26): “In the medical area, important technological and scientific developments have led to a notable increase in the exposure of patients. In this respect, this Directive should emphasise the need for j**ustification of medical exposure**, including the exposure of asymptomatic individuals and should strengthen the requirements concerning information to be provided to patients, the recording and reporting of doses from medical procedures, the use of diagnostic reference levels and the availability of dose-indicating devices. It should be noted that according to the World Health Organisation the concept of health is understood to cover the physical, mental and social well-being of an individual and not merely the absence of disease or infirmity.”

In the introduction section (52): Pursuant to Article 106a(3) of the Euratom Treaty, the legislation adopted on the basis of the provisions of the Treaty on European Union and of the Treaty on the Functioning of the European Union should not derogate from the provisions of this Directive, and consequently **the justification and optimisation principles** should apply notably for medical devices and construction products covered by CE marking.

Article 4 (48) "medical exposure" means exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health, as well as exposure incurred by carers and comforters.

Article 5 (a) General principles of radiation protection
Justification: Decisions introducing a practice shall be justified in the sense that such decisions shall be taken with the intent to ensure that the individual or societal benefit resulting from the practice outweighs the health detriment that it may cause. Decisions introducing or altering an exposure pathway for existing and emergency exposure situations shall be justified in the sense that they should do more good than harm.

Article 19

1. Member States shall ensure that new classes or types of practices resulting in exposure to ionising radiation are justified before being adopted.

2. justification of practices. Member States shall consider a review of existing classes or types of practices with regard to their **justification** whenever there is new and important evidence about their efficacy or potential consequences or new and important information about other techniques and technologies.
4. Practices involving medical exposure shall be **justified** both as a class or type of practice, taking into account medical and, where relevant, associated occupational and public exposures, and at the level of each individual medical exposure as specified in Article 55.

Article 55

1. Medical exposure shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct benefits to health of an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union

2. Member States shall ensure that the principle defined in paragraph 1 is applied and in particular that: (a) new types of practices involving medical exposure are justified in advance before being generally adopted; (b) all individual medical exposures are justified in advance taking into account the specific objectives of the exposure and the characteristics of the individual involved. (c) if a type of practice involving medical exposure is not justified in general, a specific individual exposure of this type can be justified, where appropriate, in special circumstances, to be evaluated on a case-by-case basis and documented. d) the referrer and the practitioner, as specified by Member States, seek, where practicable, to obtain previous diagnostic information or medical records relevant to the planned exposure and consider these data to avoid unnecessary exposure. (e) medical exposure for medical or biomedical research are examined by an ethics committee, set up in accordance with national procedures and/or by the competent authority; f) specific justification for medical radiological procedures to be performed as part of a health screening programme are carried out by the competent authority in conjunction with appropriate medical scientific societies or relevant bodies. (g) the exposure of carers and comforters show a sufficient net benefit, taking into account the direct health benefits to a patient, the possible benefits to the carer / comforter and the detriment that the exposure might cause. (h) any medical radiological procedure on an asymptomatic individual, to be performed for the early detection of disease, is part of a health screening programme, or requires specific documented justification for that individual by the practitioner, in consultation with the referrer, following guidelines from relevant medical scientific societies and the competent authority. Special attention shall be given to the provision of information to the individual subject to medical exposure, as required by point (d) of Article 57(1).

Article 57

(c) the referrer and the practitioner are involved, as specified by Member States, in **the justification process** of individual medical exposures;

Article 62

2. If pregnancy cannot be ruled out and depending on the medical radiological procedure, in particular if abdominal and pelvic regions are involved, special attention shall be given to the justification, particularly the urgency, and to the optimisation, taking into account both the expectant individual and the unborn child.

3. In the case of a breastfeeding individual, in nuclear medicine, depending on the medical radiological procedure, special attention shall be given to the justification, particularly the urgency, and to the optimisation, taking into account both the individual and the child.

Article 77

Member States shall ensure that information in relation to **the justification of classes or types of practices**, the regulation of radiation sources and of radiation protection is made available to undertakings, workers, members of the public, as well as patients and other individuals subject to medical exposure. This obligation includes ensuring that the competent authority provides information within its fields of competence. Information shall be made available in accordance with national legislation and international obligations, provided that this does not jeopardise other interests such as, inter alia, security, recognised in national legislation or international obligations.

ANNEX IV Justification of new classes or types of practices involving consumer products as referred to in Article 20.

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union

A. Any undertaking intending to manufacture or import into a Member State consumer products for which the intended use is likely to lead to a new class or type of practice, shall provide the competent authority of this Member State with all relevant information, as to the:

(1) intended use of the product;
(2) technical characteristics of the product;
(3) in the case of products containing radioactive substances, information as to their means of fixation;
(4) dose rates at relevant distances for the use of the product, including dose rates at a distance of 0,1 m from any accessible surface;
(5) expected doses to regular users of the product.

B. The competent authority shall examine that information and in particular assess whether:
(1) the performance of the consumer product justifies its intended use;
(2) the design is adequate in order to minimise exposures in normal use and the likelihood and consequences of misuse or accidental exposures, or whether there should be conditions imposed on the technical and physical characteristics of the product;
(3) the product is adequately designed to meet the exemption criteria, and, where applicable, is of an approved type and does not necessitate specific precautions for disposal when no longer in use;(4) the product is appropriately labelled and suitable documentation is provided to the consumer with instructions for proper use and disposal.

1.2 Collection of definitions and application from the International Commission on Radiological Protection (ICRP)

ICRP 105 recommendations on medical exposures.

(35) The principle of justification: any decision that alters the existing radiation exposure situation (e.g. by introducing a new radiation source or by reducing existing exposure) should do more good than harm. This means that by introducing a new radiation source, by reducing existing exposure, or by reducing the risk of potential exposure, one should achieve sufficient individual or societal benefit to offset the detriment it causes.

(57) In principle, the decision to adopt or continue any human activity involves a review of the benefits and disadvantages of the possible options. This review usually provides a number of alternative procedures that will do more good than harm. The more elaborate process of judging which of these options is the 'best' (e.g. choosing between the use of X-ays or ultrasound) is still necessary and is more complex. The harm, more strictly the detriment, to be considered is not confined to that associated with the radiation; it includes other detriments and the economic and societal costs of the practice. Often, the radiation detriment will be only a small part of the total. For these reasons, the Commission limits its use of the term 'justification' to the first of the above stages (i.e. it requires only that the net benefit be positive). Searching for the best available option is usually a task beyond the responsibility of radiological protection organisations.

(60) There are three levels of justification of a radiological practice in medicine.

At the first and most general level, the proper use of radiation in medicine is accepted as doing more good than harm to society. This general level of justification is now taken for granted, and is not discussed here further.

At the second level, a specified procedure with a specified objective is defined and justified (e.g. chest x rays for patients showing relevant symptoms, or a group of individuals at risk for a condition that can be detected

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union

and treated). The aim of the second level of justification is to judge whether the radiological procedure will improve the diagnosis or treatment, or will provide necessary information about the exposed individuals.

At the third level, the application of the procedure to an individual patient should be justified (i.e. the particular application should be judged to do more good than harm to the individual patient). Hence all individual medical exposures should be justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved.

8.1. Justification of a defined radiological procedure (Level 2)

(62) The justification of a radiological procedure is a matter for national and international professional bodies, in conjunction with national health and radiological protection authorities, and the corresponding international organisations. The total benefits from a medical procedure include not only the direct health benefits to the patient, but also the benefits to the patient's family and to society.
(63) It should be noted that the justification of a medical procedure does not necessarily lead to the same choice of the best procedure in all situations. For example, chest fluoroscopy for the diagnosis of serious pulmonary conditions may do more good than harm, but chest radiography is likely to be the procedure of choice in a country with substantial resources, because the ratio of good to harm would be larger. However, fluoroscopy may be the procedure chosen in developing countries with fewer resources, if it would still produce a net benefit and if no better alternatives were available.
(64) In a similar manner, the justification for routine radiological screening for some types of cancer will depend on the national incidence and on the availability of effective treatment for detected cases. National variations are to be expected.
(65) Although the main exposures in medicine are to patients, the exposures to staff and to members of the public who are not connected with the procedures should be considered. The possibility of accidental or unintended exposures should also be considered. The decisions should be reviewed from time to time, as more information becomes available about the risks and effectiveness of the existing procedure and about new procedures.
(66) The justification of diagnostic investigations for which the benefit to the patient is not the primary objective needs special consideration. In the use of radiography for insurance purposes, the primary benefit usually accrues to the insurer, but there may be some economic benefit for the individual examined. Examinations ordered by physicians as a defence against malpractice claims may only have marginal advantages for the individual patient.

8.2. Justification of a procedure for an individual patient (Level 3)

(67) Justification of individual exposures should include checking that the required information is not already available. Usually, no additional justification is needed for the application of a simple diagnostic procedure to an individual patient with the symptoms or indications for which the procedure has already been justified in general. For high-dose examinations, such as complex diagnostic and interventional procedures, individual justification by the practitioner is particularly important. The evaluation should take account of all the available information. This includes the details of the proposed procedure and of alternative procedures, the characteristics of the individual patient, the expected dose to the patient, and the availability of information on previous or expected examinations or treatment. It will often be possible to speed up the procedure by defining referral criteria and patient categories in advance.

1.3 The International Atomic Energy Agency (IAEA)

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union

IAEA General safety requirements part 3. (No. GSR Part 3).

Fundamental safety principles: Principle 4: Justification of facilities and activities
Facilities and activities that give rise to radiation risks must yield an overall benefit.

1.14. The application of the justification principle to medical exposures requires a special approach. As an overarching justification of medical exposures, it is accepted that the use of radiation in medicine does more good than harm. However, at the next level, there is a need for generic justification, to be carried out by the health authority in conjunction with appropriate professional bodies, of a given radiological procedure. This applies to the justification of new technologies and techniques as they evolve. For the final level of justification, the application of the radiological procedure to a given individual has to be considered. The specific objectives of the exposure, the clinical circumstances and the characteristics of the individual involved have to be taken into account by means of referral guidelines developed by professional bodies and the health authority.

1.16. As is the case with justification, the application of the optimization principle to the medical exposure of patients, and to that of volunteers as part of a programme of biomedical research, requires a special approach. Too low a radiation dose could be as bad as too high a radiation dose, in that the consequence could be that a cancer is not cured or the images obtained are not of suitable diagnostic quality. It is of paramount importance that the medical exposure leads to the required outcome.

3.16. The government or the regulatory body, as appropriate, shall ensure that provision 20 is made for the justification of any type of practice 21 and for review of the justification, as necessary, and shall ensure that only justified practices are authorized.

3.155. Medical exposures shall be justified by weighing the diagnostic or therapeutic benefits43 that they are expected to yield against the radiation detriment that they might cause, with account taken of the benefits and the risks of available alternative techniques that do not involve medical exposure.

Requirement 37: Justification of medical exposures
3.156. Generic justification of a radiological procedure shall be carried out by the health authority in conjunction with appropriate professional bodies, and shall be reviewed from time to time, with account taken of advances in knowledge and technological developments.

3.157. The justification of medical exposure for an individual patient shall be carried out by means of consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, with account taken, in particular for patients who are pregnant or breast-feeding or are paediatric, of:

(a) The appropriateness of the request; (b) The urgency of the radiological procedure;
(c) The characteristics of the medical exposure; (d) The characteristics of the individual patient;
(e) Relevant information from the patient's previous radiological procedures.

3.158. Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure.

3.159. Justification for radiological procedures to be performed as part of a health screening programme for asymptomatic populations shall be carried out by the health authority in conjunction with appropriate professional bodies.

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union

3.160. Any radiological procedure on an asymptomatic individual that is intended to be performed for the early detection of disease, but not as part of an approved health screening programme, shall require specific justification for that individual by the radiological medical practitioner and the referring medical practitioner, in accordance with the guidelines of relevant professional bodies or the health authority. As part of this process, the individual shall be informed in advance of the expected benefits, risks and limitations of the radiological procedure.

3.176. Registrants and licensees shall ensure that there are procedures in place for ascertaining the pregnancy status of a female patient of reproductive capacity before the performance of any radiological procedure that could result in a significant dose to the embryo or fetus, so that this information can be considered in the justification for the radiological procedure (paras 3.155 and 3.156) and in the optimization of protection and safety (para. 3.166).

3.177. Registrants and licensees shall ensure that there are arrangements in place for establishing that a female patient is not currently breast-feeding before the performance of any radiological procedure involving the administration of a radiopharmaceutical that could result in a significant dose to a breastfed infant, so that this information can be considered in the justification for the radiological procedure (paras 3.155 and 3.157) and in the optimization of protection and safety (para. 3.166).

Definitions. Justification
1. The process of determining for a planned exposure situation whether a practice is, overall, beneficial; i.e. whether the expected benefits to individuals and to society from introducing or continuing the practice outweigh the harm (including radiation detriment) resulting from the practice.

1.4. Appropriateness of an examination

Appropriateness in the context of radiation protection has been used with regard to justification of level 3. in medical imaging. European guidelines were derived and adopted in Radiation protection 118 Referral Guidelines for Imaging. These guidelines included clinical/diagnostic problems (indication) and guided the referrer of which investigation that should be applied. The European guidelines was based on the concept derived by the American College of Radiology, and “Appropriateness criteria for imaging and treatment decisions” and the Royal College of Radiologists “Making the best use of a department of clinical radiology: Guidelines for Doctors.” The possible investigations using for example computed tomography for a clinical problem using a classification of evidence levels for the investigation and advice if an investigation using the modality is indicated. The European guidelines are now outdated. Both the American College of Radiology and the Royal College of Radiologists have updated the guidelines. The Royal College of Radiologists has published the iRefer guidelines (iRefer) since 1989. The European Society of Radiologists has developed a similar concept and has published iGuide.

Appropriateness could be seen as a proxy for justification on level 3 for medical imaging. The guidelines do not take into account specifically costs or local availably of medical imaging. The criteria could be of practical use and support the communication between the practitioner and the referrer.

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union

Appendix 2: Definitions of Optimisation

2.1 Collection of definitions and application from the council directive 2013/59/EURATOM

The BSSD includes optimisation in the following articles:

(52) Pursuant to Article 106a(3) of the Euratom Treaty, the legislation adopted on the basis of the provisions of the Treaty on European Union and of the Treaty on the Functioning of the European Union should not derogate from the provisions of this Directive, and consequently the justification and optimisation principles should apply notably for medical devices and construction products covered by CE marking.

Article 5

b) Optimisation: Radiation protection of individuals subject to public or occupational exposure shall be optimised with the likelihood of exposure and the number of individuals exposed as low as reasonably achievable taking into account the current state of technical knowledge and economic and societal factors. The optimisation of the protection of individuals subject to medical exposure shall apply to the magnitude of individual doses and be consistent with the medical purpose of the exposure, as described in Article 56. This principle shall be applied not only in terms of effective dose but also, where appropriate, in terms of equivalent doses, as a precautionary measure to allow for uncertainties as to health detriment below the threshold for tissue reactions.

Article 6

1. Member States shall ensure that, where appropriate, dose constraints are established for the purpose of prospective optimisation of protection:

(a) for occupational exposure, the dose constraint shall be established as an operational tool for optimisation by the undertaking under the general supervision of the competent authority. In the case of outside workers the dose constraint shall be established in cooperation between the employer and the undertaking.
(b) for public exposure, the dose constraint shall be set for the individual dose that members of the public receive from the planned operation of a specified radiation source. The competent authority shall ensure that the constraints are consistent with the dose limit for the sum of doses to the same individual from all authorised practices.
(c) for medical exposure, dose constraints shall apply only with regard to the protection of carers and comforters and volunteers participating in medical or biomedical research.

2. Dose constraints shall be established in terms of individual effective or equivalent doses over a defined appropriate time period.

Article 29

3. A licence shall include, as appropriate, specific conditions and reference to requirements in national legislation so as to ensure that the elements of the licence are legally enforceable, and impose appropriate restrictions on the operational limits and conditions of operation. National legislation or the specific conditions shall also require, when appropriate, the formal and documented implementation of the principle of optimisation.

Article 32 Operational protection of exposed workers

Member States shall ensure that the operational protection of exposed workers is based, in accordance with the relevant provisions of this Directive, on:

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union

(b) optimisation of radiation protection in all working conditions, including occupational exposures as a consequence of practices involving medical exposures;

Article 56

1. Member States shall ensure that all doses due to medical exposure for radiodiagnostic, interventional radiology, planning, guiding and verification purposes are kept as low as reasonably achievable consistent with obtaining the required medical information, taking into account economic and societal factors.

For all medical exposure of patients for radiotherapeutic purposes, exposures of target volumes shall be individually planned and their delivery appropriately verified taking into account that doses to non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.

2. Member States shall ensure the establishment, regular review and use of diagnostic reference levels for radiodiagnostic examinations, having regard to the recommended European diagnostic reference levels where available, and where appropriate, for interventional radiology procedures, and the availability of guidance for this purpose.

4. Member States shall ensure that the optimisation includes the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical radiological procedures, quality assurance, and the assessment and evaluation of patient doses or the verification of administered activities, taking into account economic and societal factors.

Article 57

1 (b) the practitioner, the medical physics expert and those entitled to carry out practical aspects of medical radiological procedures are involved, as specified by Member States, in the optimisation process;

Article 62

2. If pregnancy cannot be ruled out and depending on the medical radiological procedure, in particular if abdominal and pelvic regions are involved, special attention shall be given to the justification, particularly the urgency, and to the optimisation, taking into account both the expectant individual and the unborn child.

3. In the case of a breastfeeding individual, in nuclear medicine, depending on the medical radiological procedure, special attention shall be given to the justification, particularly the urgency, and to the optimisation, taking into account both the individual and the child.

Article 83 Medical physics expert

2. Member States shall ensure that depending on the medical radiological practice, the medical physics expert takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure, give advice on medical radiological equipment, and contribute in particular to the following:

(a) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels

1.2 Collection of definitions and application from the International Commission on Radiological Protection (ICRP 103 and 105)

“Optimisation of protection for patients is also unique. In the first place, radiation therapy is entirely different from anything else in that the dose to a human being is intentional and its potentially cell-killing

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union

properties the very purpose of the treatment. In such cases, optimisation becomes an exercise in minimising doses (and/or their deleterious effects) to surrounding tissues without compromising the pre-determined and intentionally lethal dose and effect to the target volume."

"In optimisation of protection of the patient in diagnostic procedures, again the same person gets the benefit and suffers the risk, and again individual restrictions on patient dose could be counterproductive to the medical purpose of the procedure. Therefore, source-related individual dose constraints are not relevant. Instead, Diagnostic Reference Levels (DRLs) for a particular procedure, which apply to groups of similar patients rather than individuals, are used to ensure that doses do not deviate significantly from those achieved at peer departments for that procedure unless there is a known, relevant, and acceptable reason for the deviation. This is in contrast to the Commission's usual balancing of utilitarian protection policies based on collective doses against deontological safeguards using dose constraints for the individual."

(35) The principle of optimisation of protection: the likelihood of incurring exposures, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors. This means that the level of protection should be the best under the prevailing circumstances, maximising the margin of benefit over harm. In order to avoid severely inequitable outcomes of this optimisation procedure, there should be restrictions on the doses or risks to the individuals from a particular source (dose or risk constraints and reference levels).

9.1. General approach

(68) The optimisation of radiological protection for patients in medicine is usually applied at two levels: (1) the design, appropriate selection, and construction of equipment and installations; and (2) the day-to-day methods of working (i.e. the working procedures). The basic aim of this optimisation of protection is to adjust the protection measures for a source of radiation in such a way that the net benefit is maximised.

(69) The concepts involved can be set out in simple terms, but their practical application can range from simple common sense to complex quantitative processes. In selecting the provision for protection in relation to a source, there is always a choice of options. The choice of protection option directly alters the level of exposure of the patient, the staff, and sometimes the public. However, the choice also alters the scale of resources applied to protection. These resources may be reflected directly in financial costs, but they may also involve less easily quantified societal costs such as other health risks to staff.

(70) The optimisation of radiological protection means keeping the doses 'as low as reasonably achievable, economic and societal factors being taken into account', and is best described as management of the radiation dose to the patient to be commensurate with the medical purpose.

1.3 Collection of definitions and application from the International Atomic Energy Agency (IAEA)

Definition

optimization of protection and safety: The process of determining what level of protection and safety would result in the magnitude of individual doses, the number of individuals (workers and members of the public) subject to exposure and the likelihood of exposure being "as low as reasonably achievable, economic and social factors being taken into account" (ALARA). For medical exposures of patients, the optimization of protection and safety is the management of the radiation dose to the patient commensurate with the medical purpose.

Principle 5: Optimization of protection

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union

Protection must be optimized to provide the highest level of safety that can reasonably be achieved.

1.15. The optimization of protection and safety, when applied to the exposure of workers and members of the public, and carers and comforters of patients undergoing radiological procedures, is a process for ensuring that the likelihood and magnitude of exposures and the number of individuals exposed are as low as reasonably achievable, with economic, societal and environmental factors taken into account. This means that the level of protection would be the best possible under the prevailing circumstances. Optimization is a prospective and iterative process that requires both qualitative and quantitative judgements to be made.

1.16. As is the case with justification, the application of the optimization principle to the medical exposure of patients, and to that of volunteers as part of a programme of biomedical research, requires a special approach. Too low a radiation dose could be as bad as too high a radiation dose, in that the consequence could be that a cancer is not cured or the images obtained are not of suitable diagnostic quality. It is of paramount importance that the medical exposure leads to the required outcome.

1.17. For planned exposure situations, exposures and risks are subject to control to ensure that the specified dose limits for occupational exposure and those for public exposure are not exceeded, and optimization is applied to attain the desired level of protection and safety.

1.22. Dose constraints and reference levels are used for optimization of protection and safety, the intended outcome of which is that all exposures are controlled to levels that are as low as reasonably achievable, economic, societal and environmental factors being taken into account.

1.30. Dose constraints are used in optimization of protection and safety for carers and comforters and for volunteers subject to exposure as part of a programme of biomedical research. Dose constraints are not applicable to the exposure of patients in radiological procedures for the purposes of medical diagnosis or treatment.

2.10. For all exposure situations, each party with responsibilities for protection and safety shall ensure, when relevant requirements apply to that party, that protection and safety is optimized. Protection and safety is optimized' means that optimization of protection and safety has been applied and the result of that process has been implemented.

2.11. For planned exposure situations other than for medical exposure, each party with responsibilities for protection and safety shall ensure that, when relevant requirements apply to that party, specified dose limits are not exceeded.

2.12. The application of the requirements for the system of protection and safety shall be commensurate with the radiation risks associated with the exposure situation.

Requirement 38: Optimization of protection and safety

Registrants and licensees and radiological medical practitioners shall ensure that protection and safety is optimized for each medical exposure.

3.162. In addition to ensuring that the responsibilities stated in para. 3.49 are discharged, as applicable, registrants and licensees, in cooperation with suppliers, shall ensure that medical radiological equipment and software that could influence the delivery of medical exposure are used only if they conform to the applicable standards of the International Electrotechnical Commission and the International Organization for Standardization or to national standards adopted by the regulatory body.

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union

3.176. Registrants and licensees shall ensure that there are procedures in place for ascertaining the pregnancy status of a female patient of reproductive capacity before the performance of any radiological procedure that could result in a significant dose to the embryo or foetus, so that this information can be considered in the justification for the radiological procedure (paras 3.155 and 3.156) and in the optimization of protection and safety (para. 3.166).

3.177. Registrants and licensees shall ensure that there are arrangements in place for establishing that a female patient is not currently breast-feeding before the performance of any radiological procedure involving the administration of a radiopharmaceutical that could result in a significant dose to a breastfed infant, so that this information can be considered in the justification for the radiological procedure (paras 3.155 and 3.157) and in the optimization of protection and safety (para. 3.166).

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Health and Digital Executive Agency (HaDEA)/ Neither the European Union nor the granting authority can be held responsible for them.

Co-funded by the European Union