HERCA

HEADS OF THE EUROPEAN RADIOLOGICAL PROTECTION COMPETENT AUTHORITIES

HERCA Position Paper

Justification of New Types or Classes of Practices In the Medical Field

Report on the HERCA Multi-Stakeholder Workshop

(24 - 26 Oct. 2016, Montrouge, France)

November 2017

This document was approved by the Board of HERCA on 3 November 2017

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HERCA Key-Messages

The justification of new types of practices is a concept introduced by ICRP and updated in 2007[1]. The concept had been introduced in the Council Directive 97/43/Euratom and renewed in the Council Directive 2013/59/Euratom. In particular in the medical field – probably because of a real difficulty of applying this abstract concept in an operational way – the transposition of Art. 55.2 (a) Council Directive 2013/59/Euratom, referring to this, still poses some challenges to the Member States (MS), depending on the already existing system of radiation protection and healthcare. The HERCA Position Paper provides a kind of conceptual framework (see Chapter II) and its key-messages are:

- For HERCA, it is important to note that the fact that a procedure in medicine can be regarded as justified on ICRP level 2 (so called “generic justification”) does not necessarily mean that its application to a particular patient is justified on ICRP level 3 (so called “individual justification”). From a regulatory point of view this demonstrates that – although level 2 and level 3 justification are closely linked – they need separate consideration from a legal and operational point of view. A national regulatory framework has to ensure a well defined balance between the two levels to guarantee a high level of radiation protection for the patient, but also to avoid over-regulation in the field of medicine.
- Art. 19.4 explicitly makes reference to Art. 55 when medical exposures are involved and underlines that in this case, associated occupational and public exposures have to be taken into account, where relevant. For HERCA, these claims define important constraints to be considered with regard to the justification of new types of practices. This is in particular valid for the use of radiopharmaceuticals and X-Ray generators for interventional practices.
- Art. 55.2 (a) requires that *new types of practices involving medical exposure are justified in advance before being generally adopted*. HERCA believes that Art. 55.2 (a) underlines the claim that new types of practices have to be justified on a generic level, before these practices may be introduced as well established practices in the field of medicine.

[1] ICRP 2007, The 2007 Recommendations of the International Commission on Radiological Protection, ICRP Publication 103

- Art. 55.2 (c) requires that *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.* HERCA underlines that Art. 55.2 (c) does not provide a shortcut to healthcare, bypassing the need for justification on a generic level. Instead Art. 55.2 (c) is restricted to special circumstances with respect to an individual patient and requires a special individual justification.
- HERCA believes that the Principle of Justification – as generally stated in Art 55.1 Council Directive 2013/59/Euratom for the medical field – requires a demonstrated sufficient net benefit of medical exposures, which has to be based on an adequate level of evidence. Thus, the adequate way to integrate a new type of practice into healthcare requires some input from biomedical / clinical research.
- For HERCA, with respect to Art. 55.2 (a), a common understanding of the term *types of practices involving medical exposure* is required and necessitates some kind of categorisation. This categorisation has to be flexible, in order to cover different transposition approaches in the MS. Here, the granularity aspect will be key. HERCA believes that this effort alone is not the solution for the transposition of Art. 55.2 (a), but will be necessary to understand and to evaluate different transposition approaches, considered by MS.
- HERCA underlines that the adequate transposition of Art. 55.2 (a) requires a regulatory process to be established in each MS in one way or the other. Hereby, the requirements of Art. 77 Council Directive 2013/59/Euratom concerning traceability and transparency have to be met. Finally, HERCA, proposes a basic set of questions to be considered around the regulatory process:
    1. By what action shall the regulatory process be initiated for a new type of practice:
        - pro-actively by the competent authority;
        - re-actively by e.g. the undertaking within a notification / authorization process?
    2. By what measures shall the regulatory process be supported:
        - establishment of an expert panel (e.g. medical associations, manufacturers, radiation protection experts, etc) on a permanent base;
        - involvement of relevant stakeholders (e.g. medical associations, manufacturers, etc) on a case by case base;
        - involvement of existing structures in the field, such as HTA organisations;
        - development of approaches to weigh the impact of CE marking due to Medical Device Directive / Regulation?
    3. What shall the outcome of the regulatory process be:
        - pro-active approach: official statement of competent authority following publication of authoritative report (e.g. COMARE reports in UK);
        - re-active approach: approval with respect to notification / authorization processes (e.g. Luxembourg)?
- Art. 78.2 of the Council Directive 2013/59/Euratom requires that any undertaking acquiring medical radiological equipment is provided with adequate information on the risk assessment for patients, and on the available elements of the clinical evaluation and hereby, refers to the CE marking process, which includes that information on risk

and results on clinical evaluation have to be produced and transmitted to the notified body. HERCA encourages the manufacturers to organize the access to this information and is ready to collaborate in the definition of the information to be provided and in the development of an approach to facilitate a harmonized information documentation. In HERCA's view, it is an important result of the Multi-Stakeholder Workshop on Generic Justification of Medical Exposures using Ionising Radiation (24 - 26 October 2016, Montrouge, France), that COCIR and the Manufacturers explicitly showed their willingness to cooperate in this transfer of information from the medical device legal system to the radiation protection legal system.

1 Introduction

The new Council Directive 2013/59/Euratom was published in the Official Journal of the European Union on 17th January 2014. Member States (MS) have until the 6th February 2018 to complete the process of transposition into their national regulations.

In 2014, the Board of Heads (BoH) of HERCA, the Heads of the European Radiological protection Competent Authorities, approved an Action Plan in support of the transposition of the new Council Directive 2013/59/Euratom. The BoH underlined that – although HERCA has no statutory role in relation to the transposition of the Council Directive 2013/59/Euratom – HERCA can be a positive force in the transposition process by:

- acting as a platform to identify and discuss practical and technical regulatory problems and to exchange national approaches;
- exploring a common understanding of the new requirements and common approaches including guidance where this is appropriate and feasible;
- informing the transposition process by sharing regulatory experience and being a resource for Competent Authorities;
- acting as an interested stakeholder with the European Commission;
- adding significant value to the transposition process by focusing on areas with relevance to trans-boundary processes.

In relation to medical exposures, the Action Plan identified

- the justification of types or classes of practices (Articles 19 and 55.2 (a) and (c) Council Directive 2013/59/Euratom), whereby the focus is in particular on new types or classes of practices,

as key topic where HERCA could add value to the transposition process.

To further explore the transposition process of these articles, HERCA organised a *Multi-Stakeholder Workshop (MSW)* on *Generic Justification of Medical Exposures using Ionising Radiation* (24 - 26 October 2016, Montrouge, France). The objectives of the workshop were:

- to explore a common understanding of the new requirements;
- to exchange information on national approaches relating to the transposition and implementation of these new requirements;
- to collect the opinion of important European stakeholders, particularly the European medical societies and manufacturers;

In view of the MSW, the HERCA-Working Group *Medical Applications* (WGMA) prepared a discussion paper that was distributed to the participants of the MSW. The discussion paper presented the results of the investigations of WGMA on the transposition of Art. 55.2 (a), i.e. the justification of new types of practices in the field of medical exposures, and other articles around it, and thus, reflected the perspective of regulators. This needed to be extended and intensified by the input from relevant stakeholders in the field to ensure a broader view. It was the major objective of the discussion paper to facilitate this process at the MSW.

At the end of the MSW, the medical societies were invited to give written feedback on the discussion paper and to give written comments on the outcomes of the MSW. ESR followed this invitation and provided its feedback[2] in January 2017.

[2] ESR Feedback: HERCA WGMA Discussion Paper "Justification of Types or Classes of Practices Resulting in Medical Exposures", January 2017 (see *Chapter III / Appendix II*).

The aim of the current paper is:

- to provide HERCA's position on fundamental challenges in the transposition of Art. 55.2 (a) and (c) Council Directive 2013/59/Euratom (see Chapter II) and
- to present a report on the HERCA-MSW, including a set of conclusions, jointly developed by the participants at the end of the MSW (see Chapter III).

2 HERCA Position

2.1 General Considerations on the Principle of Justification

Justification is one of the three fundamental principles of radiation protection, along with optimisation and dose limitation. Medical exposures for patients require an application of these radiation protection principles that is - to some degree - different from that for other exposure categories, such as occupational or public exposures. In particular, in medical application of ionising radiation a key feature is the expectation of direct individual health benefit to the patient.

As a consequence, in medical exposures for patients, it is not appropriate to apply dose limits, since such limits may do more harm than good, while the principle of justification becomes a matter of primary importance. Its application requires – as claimed by Article 55.1 Council Directive 2013/59/Euratom – *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*.

The system of radiological protection that is used across Europe and worldwide is based on the recommendations of the International Commission for Radiation Protection (ICRP). The ICRP system differentiates between three levels of justification of a radiological practice in medicine[3]. In the field of medicine, the term 'practice' typically refers to the medical care that a practitioner provides to patients[4]. The first ICRP level of justification, the most general one, requires the judgement that *the use of radiation in medicine is generally accepted as doing more good than harm*. It is commonly taken for granted.

At the second ICRP level of justification, *a specified procedure with a specified objective is defined and justified. The aim is to judge whether the radiological procedure will improve the diagnosis or treatment, or will provide necessary information about the exposed individuals*. According to ICRP 103 (and 105), level 2 justification *is a matter for national and international professional bodies, in conjunction with national health and radiological protection authorities, and the corresponding international organisations*.

At the third level of justification, *the application of the procedure to an individual patient should be justified*. ICRP 103 (and 105) further claims that *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*. Typically, level 3 justification is in the responsibility of the practitioners involved.

For HERCA, it is important to note that the fact that a procedure in medicine can be regarded as justified on level 2 does not necessarily mean that its application to a particular patient is justified on level 3. From a regulatory point of view this demonstrates that – although level 2 and level 3 justification are closely linked – they need separate consideration. A national

[3] ICRP 2007, The 2007 Recommendations of the International Commission on Radiological Protection, ICRP Publication 103.

[4] ICRP 2007, Radiological Protection in Medicine, ICRP Publication 105.

regulatory framework has to ensure a well defined balance between the two levels to guarantee a high level of radiation protection for the patient in the medical use of ionising radiation, but also to avoid over-regulation in the field of medicine.

2.2 Legal Basis with Respect to Council Directive 2013/59/Euratom

In the new Council Directive 2013/59/Euratom, the concept of ICRP level 2 justification is addressed under Number 1 and 2 of 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. *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.*

Art. 19 differentiates between the justification of new and existing classes or types of practices and it applies to all categories of exposure situations, i.e. public, occupational and medical exposure situations. For the transposition of Council Directive 2013/59/Euratom, it is important to note that Art. 19.1 in particular claims that ***new** classes or types of practices … are justified **before being adopted***.

Special reference to medical exposures is made under Number 4 of Article 19:

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.*

Art. 19.4 in particular states that – for practices involving medical exposure – both a justification process on ICRP level 2 and 3 is required. In addition, Art. 19.4 explicitly makes reference to Art. 55 when medical exposures are involved and underlines that in this case, associated occupational and public exposures have to be taken into account, where relevant. For HERCA, these claims define important constraints to be considered for the transposition of Council Directive 2013/59/Euratom. This is in particular valid for the use of radiopharmaceuticals and X-Rays generators for interventional practices.

Art. 55 focusses on justification of medical exposures. In the following, the scope of the current paper will be focused on this article, when justification is addressed in the field of medicine. With respect to justification of new practices, Number 2 (a) and 2 (c) are of special interest:

a) *new types of practices involving medical exposure are justified in advance before being generally adopted;*
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.*

It is interesting to note that Art. 55.2 (a) uses the term *new types of practices,* while Art. 19.1 uses the somewhat broader term *new **classes or** types of practices*. In addition, Art. 55.2 (a) claims that *new types of practices … are justified **in advance** before being **generally** adopted*, while Art. 19.1 only uses the somewhat weaker wording *justified before being adopted*. It is somewhat unclear how relevant – in terms of wording with respect to the transposition of Council Directive 2013/59/Euratom – these inconsistencies between Art. 19 and Art. 55 are. HERCA is of the view that these differences are a consequence of the drafting process rather than a deliberate intention to provide a differentiation. In any case, HERCA believes that the wording in Art. 55.2 (a) underlines the claim that new types of

practices have to be justified on a generic level, before these practices may be introduced as well established practices in the field of medicine.

Art. 55.2 (c) offers the potential to justify a specific exposure on an individual basis, although the corresponding type of practice is not – yet – justified on a general level. But the scope of Art. 55.2 (c) is limited to *special circumstances* that have *to be evaluated on a case-by-case basis and documented.* It may be argued for example that the term *special circumstances* is closely related to the terms *off-label use of drugs* or *compassionate use of drugs*. Both cases refer to situations where a drug is provided to a patient – on humanitarian grounds – prior to a drug's receiving regulatory approval for a clinical indication[5]. The first case refers to an already established drug used for a new clinical indication. The second case refers to a newly developed drug. In line with this reasoning, HERCA underlines that Art. 55.2 (c) does not provide a shortcut to healthcare, bypassing the need for justification on a generic level. Instead, as outlined above, Art. 55.2 (c) is restricted to special circumstances with respect to an individual patient and requires a special individual justification.

Closely related to these considerations is the discussion about the interrelation between justification of new types of practices and justification of medical or biomedical research, i.e. between Art. 55.2 (a) and Art. 55.2 (e). HERCA believes that the Principle of Justification – as generally stated in Art 55.1 Council Directive 2013/59/Euratom for the medical field – requires a demonstrated sufficient net benefit of medical exposures, which has to be based on an adequate level of evidence. Thus, the adequate way to integrate a new type of practice into healthcare requires some input from biomedical / clinical research.

2.3 Regulatory Requirements for the Transposition of Council Directive 2013/59/Euratom

As a starting point for considering regulatory requirements for the transposition of Art. 55.2 (a) Council Directive 2013/59/Euratom and articles around it, a common understanding of the term *types of practices involving medical exposure* needs to be developed. For HERCA, this effort alone is not the solution for the transposition of these articles, but will be necessary to understand and to evaluate different transposition approaches, considered by MS.

In the field of medicine, the term *type of practice* refers to both the device or radiopharmaceutical to be used and the objective to be achieved by using the device or radiopharmaceutical, i.e. the clinical indication. In addition, the term *type of practice* may have to be considered in a broader sense as compared to the term *practice* and thus necessitates some kind of categorization.

HERCA is of the view that this categorization has to be flexible, in order to cover different transposition approaches in the MS. Here, the granularity aspect will be key. In the MS, there already exist transposition approaches with both quite a rough granularity (e.g. UK) and quite a fine granularity (e.g. Luxembourg). These examples (see Attachment / Plenary Sessions 1 – 5) indicate how important the granularity aspect is to understand and evaluate the consequences of these approaches - in particular with respect to the resources, which have to be allocated for the different approaches. These are important lessons to be learned from existing approaches, which may help other MS in their transposition efforts.

In a next step, it has to be considered that the adequate transposition of Art. 55.2 (a) requires a regulatory process to be established in each MS in one way or the other. Hereby, HERCA underlines that the requirements of Art. 77 Council Directive 2013/59/Euratom concerning traceability and transparency have to be met.

[5] http://www.cancer.org/treatment/treatmentsandsideeffects/clinicaltrials/compassionate-drug-use
http://www.fda.gov/ForPatients/Other/OffLabel/default.htm

Finally, for HERCA, a basic set of questions around the regulatory process needs to be considered:

(1) By what action shall the regulatory process be initiated for a new types of practices:

- pro-actively by the competent authority;
- re-actively by e.g. the undertaking within a notification / authorization process?

(2) By what measures shall the regulatory process be supported:

- establishment of an expert panel (e.g. medical associations, manufacturers, radiation protection expert, etc.) on a permanent base;
- involvement of relevant stakeholders (e.g. medical associations, manufacturers, etc.) on a case by case base;
- involvement of existing structures in the field, such as HTA organisations;
- development of approaches to weigh the impact of CE marking due to Medical Device Directive / Regulation?

(3) What shall the outcome of the regulatory process be:

- pro-active approach: official statement of competent authority following publication of authoritative report (e.g. COMARE reports in UK);
- re-active approach: approval with respect to notification / authorization processes (e.g. Luxembourg)?

2.4 Interrelation between Council Directive 2013/59/Euratom and Medical Device Regulation

Basically, a medical device (MD), placed on the market or put into service, shall meet the general safety and performance requirements which apply to it (set Annex I of the Medical Device Regulation[6], including specific requirements for MD using Ionizing Radiation). Devices considered to be in conformity with the requirements of this regulation shall bear the CE marking[7].

Nevertheless, the use of MD (bearing the CE marking) will continue to be submitted to the regulatory control defined by national regulation for the implementation of the Council Directive 2013/59/Euratom. Particularly, an authorization process (registration or licence), already in place, is mandatory for the use of MD, and the justification principle applies to relevant medical practices (see Chapter III and IV above). On the basis of this principle, from a legal point of view, a MS may not allow the use of a MD put on the market, considering for instance that the risk for patient is too high in comparison with the expected benefit, or taking

[6] Proposal for a Regulation of the European Parliament and of the Council on Medical Devices, Brussels, 15 June 2016

[7] In some more detail: CE marking means *a marking by which the manufacturer indicates that the device is in conformity with the applicable requirements set out in this Regulation,* i.e. the Medical Device Regulation, *and other applicable Union harmonisation legislation providing for its affixing* (see: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices, 15.06.2016). The Medical Device Regulation in particular claims that *this Regulation should include requirements regarding the design and manufacture of medical devices emitting ionizing radiation without affecting the application of Council Directive 2013/59/Euratom*. A potential source of concern is that the CE marking process is embedded in the legal system provided by the Medical Device Regulation, which is not fully transparent from outside.

into account *"information about other techniques and technologies"* (Art.19.2 Council Directive 2013/59/Euratom).

However, the flexibility introduced by Art. 55.2 (a) Council Directive 2013/59/Euratom (*new types of practices involving medical exposure are justified in advance before being generally adopted*) offers the potential to manage possible conflicts between the two legal systems. For example, following an approach currently discussed in France, a new MD placed on the market and utilizing a new technology, may be used subject to specific conditions during a transition period (experimental use, research, …), and the justification may be assessed at the end, on the basis of available clinical data collected during this period. This example demonstrates the importance of the exchange of clinical and risk data, to ensure consistency between both legal systems.

Taking into account that, on the one hand, Art. 78.2 Council Directive 2013/59/Euratom requires that *any undertaking acquiring medical radiological equipment is provided with adequate information on the risk assessment for patients, and on the available elements of the clinical evaluation* and, on the other hand, that information on risk and results on clinical evaluation have to be produced and transmitted to notified body in the frame of the CE marking process, the issues from a radiation protection perspective are:

(1) Could the information held by the manufacturer about the risk assessment and the clinical evaluation, being provided to obtain the CE marking, be made available for the application of the Art. 78.2 Council Directive 2013/59/Euratom? In accordance of this directive, this information shall have to be addressed to the undertaking (user), but not to the competent authority, but a specific provision on this point in the national regulation always seems possible (i.e. link with the authorization procedure provided for in the Directive).

(2) Could this information be made available in the frame of the justification process related to a new class of medical practice - but also in the review of the justification of an existing class of practice? It is not provided in the directive but a specific requirement in national regulation seems also possible.

Consequently, considering that this information held by manufacturers could be very useful for the assessment of the justification of a practice, particularly in the case of practice utilizing a new technology, and should be made available in the frame of the justification process, HERCA encourages the manufacturer to organize the access to this information and is ready to collaborate in the definition of the information to be provided and in the development of an approach to facilitate a *harmonized information documentation*. In HERCA's view, it is an important result of the MSW, that COCIR and the Manufacturers explicitly showed their willingness to cooperate in this transfer of information from the MD legal system to the RP legal system.

3 Report on the HERCA Multi-Stakeholder Workshop on Generic Justification of Medical Exposures using Ionising Radiation

The justification of new types of practices is a concept introduced by ICRP and updated in 2007[8]. The concept had been introduced in the Council Directive 97/43/Euratom and renewed in the Council Directive 2013/59/Euratom. In particular in the medical field – probably because of a real difficulty of applying this abstract concept in an operational way –

[8] ICRP 2007, The 2007 Recommendations of the International Commission on Radiological Protection, ICRP Publication 103

the transposition of Art. 55.2 (a) Council Directive 2013/59/Euratom, referring to this, still poses some challenges to the MS.

In view of the MSW, the WGMA identified and explored potential approaches, which are discussed in the MS with respect to the transposition of Art. 55.2 (a) and other articles around it. From this work, relevant questions emerged which were discussed with relevant stakeholders at the MSW. To facilitate these discussions, five specific plenary sessions with case-studies referring to existing or planned regulatory practices in MS were scheduled at the MSW (see Appendix I: Plenary Sessions 1 - 5). The questions addressed included:

How can Health Technology Assessment (HTA)[9] contribute to the justification process of new types of practices (Plenary Session 1)?

- What are potential weak points of the HTA approach?
- How could these weak points be strengthened within HTA by Radiation Protection Authorities on a MS level / on a European level - by HERCA?

How can CE Marking contribute to the justification process of new types of practices (Plenary Session 2)?

- May CE marking according to the Medical Device Regulation serve as indication for justification of new types of practices due to the Council Directive 2013/59/Euratom?
- In this case, what is the potential impact of Art 78.2 Council Directive 2013/59/Euratom10?
- How to handle new radiopharmaceuticals by this approach?

Does the regulator have to define a "Standard Medical practice List", by which all ICRP level 2 justified types of practice are addressed, referring to the device, the radiopharmaceutical and the clinical indication and using a classification scheme of the different "types of medical practices" (Plenary Session 3)?

- How can this approach contribute to the justification process of new types of practices?
- What is the impact of granularity in this approach?
- What role may referral guidelines play in this approach?

Shall the regulator link the justification process of new types of practices to the

[9] **Health technology assessment (HTA)** *is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value* (see: http://www.eunethta.eu/about-us/faq#t287n73).
The term "health technology" comprises a wide range of meanings, such as diagnostic and treatment methods, pharmaceuticals, rehabilitation and prevention methods, organisational and supportive systems within which health care is provided. The examples show that the scope of the term "health technology" extends far beyond the use of ionizing radiation in medicine. Furthermore, HTA organisations on a national and EU level usually perform assessments following their own list of priorities.

[10] Art 78.2 Council Directive 2013/59/Euratom claims: *Member States shall ensure that any undertaking acquiring medical radiological equipment is provided with adequate information on the risk assessment for patients, and on the available elements of the clinical evaluation*.

authorization[11] process (Plenary Session 4)?

- How to ensure – by this approach – an adequate execution of Art. 55.2 (a) in a MS with respect to the claim that new types of practices involving medical exposure are justified in advance before being generally adopted?
- How to ensure – by this approach – a harmonized execution of Art. 55.2 (a) in a MS?

What further approaches exist in MS for the transposition of Art. 55.2 (a) Council Directive 2013/59/Euratom and other articles around it (Plenary Session 5)?

In a further plenary session, the interrelation between Art. 55.2 (a) Council Directive 2013/59/Euratom addressing new types of practices and Art. 55.2 (e) Council Directive 2013/59/Euratom addressing medical or biomedical research was discussed (see Appendix I: Plenary Session 6).

Based on Plenary Sessions 1 - 6, the HERCA-WGMA and the stakeholders participating in the workshop worked together to produce a set of conclusions, which summarizes the discussions in the plenary sessions and reflects some general considerations concerning the justification of new types of practices.

The following conclusions were agreed:

- A new type of practice is considered to be justified in general, when the practice is – in principle – appropriate to the application in medicine, taking into account benefit and risk.
- The key question is: what is a type of practice and in particular[12], what is a new type of practice? Reflecting the term “type” reveals that some kind of categorization is needed, which implies some discussion on categorization and granularity issues. Furthermore, the distinction between a fundamentally new type of practice and the variation of a well-established type of practice could provide guidance and could lead to a graded approach. In line with this kind of reasoning, a rough granularity may be sufficient for the variation of a well-established device with an established clinical indication. However, it was also reflected that for a well-established device with a new clinical indication, such as any kind of population screening or individual health assessment, a fine granularity may be necessary. A fine granularity may also be necessary for a newly developed device, in particular if it also offers a new clinical indication.

[11] The term "authorisation" means *the registration or licensing of a practice* (see: Art. 2.7 Council Directive 2013/59/Euratom). The term "licence" means *permission granted in a document by the competent authority to carry out a practice in accordance with specific conditions laid down in that document* (see: Art. 2.47 Council Directive 2013/59/Euratom). The term "registration" means *permission granted in a document by the competent authority, or granted by national legislation, through a simplified procedure, to carry out a practice in accordance with conditions laid down in national legislation or specified by a competent authority for this type or class of practice* (see: Art. 2.86 Council Directive 2013/59/Euratom). Further provisions are given by Art. 27 – 29 Council Directive 2013/59/Euratom.
A characteristic feature of this approach is that the justification process due to Art. 55.2 (a) is typically initiated by the undertaking when applying for a registration or licence for a new practice, is thus embedded in the registration or licensing process for this new practice, and does not refer to a new type of practice to be justified in advance before being generally adopted, but to a new practice to be permitted on a case-by-case basis.

[12] See Chapter II.3

- It is further important to understand that the intended approach to transpose Art. 55.2 (a) Council Directive 2013/59/Euratom needs to be flexible and simple enough to ensure appropriate benefit to the patient when considering technical progress, but also that the intended approach has to take into account the risk aspect.
- For a MS to transpose Art. 55.2 (a) Council Directive 2013/59/Euratom it is helpful to be aware of decisions and approaches in other MS.
- An important impact factor to be taken into account is the system of radiation protection implemented in a MS and its interrelation with the healthcare system in the MS. Reimbursement of practice and/or allocation of resources are important driving forces in the healthcare system that could be helpful for radiation protection as well. Furthermore, if a type of practice is justified in general, it may not necessarily be established in healthcare (Health Authority) – e.g. due to financial limitations in the healthcare system.
- Concerns addressed in particular by Medical Associations and Manufacturers were:
    - Care should be taken that the transposition of Art. 55.2 (a) Council Directive 2013/59/Euratom does not unduly delay the adoption of new types of practices in a MS and thus, does not slow down progress in medicine.
    - Steps towards harmonization on the European level – as far as any possible – would be highly appreciated.

- CE marking cannot replace generic justification, but could be a source for information, in particular with respect to clinical evaluation and risk assessment, which could be helpful for the justification process on a generic level. Hereby, Art. 78.2 Council Directive 2013/59/Euratom addressing the information transfer from the legal system of Medical Devices Regulation to the legal system of Basic Safety Standards Directive is essential. COCIR / Manufacturers are willing to cooperate in this transfer of information.
- Approaches based on health technology assessment (HTA), a standard medical practice list, the authorization process, as well as other approaches discussed within the MSW, seem to be feasible with respect to the transposition of Art. 55.2 (a) Council Directive 2013/59/Euratom. They all have their pros and cons. It is essential to take into account the characteristics of the individual MS. Finally, the involvement of relevant stakeholders is key in the process of generic justification of new types of practices to enhance credibility.
- Art. 55.2 (c) Council Directive 2013/59/Euratom addressing a type of practice that is not yet justified in general does not provide a shortcut to healthcare, bypassing the need for justification on a generic level. Instead, Art. 55.2 (c) is restricted to special circumstances with respect to an individual patient and requires a special individual justification. Similar approaches are used in *off-label* or *compassionate* use of drugs.
- Last, but not least, it was concluded that any system that is adopted by a MS has to work in practice.

Appendix I: Summary of Plenary Sessions 1 – 6 of the HERCA Multi-Stakeholder Workshop (24-26 October 2016)

In *Appendix I*, a summary of Plenary Sessions 1 – 6 of the MSW is provided:

Plenary Session 1: How can Health Technology Assessment (HTA) contribute to the justification process of new types of practices?

In an introductory presentation important information on the Health Technology Assessment (HTA) was provided. It was outlined that HTA is a systematic evaluation of available knowledge on safety and clinical effect of the method combined with an evaluation of cost-effectiveness as well as ethical, social, organizational and juridical aspects. HTA is a tool for decision-making in the introduction of new health technologies and practices with the main goal to ensure they are safe, cost-effective and associated with evidence-based clinical effect. HTA is also the tool for an evidence-based decision to phase-out practices that are no longer safe, clinically effective or cost-effective. This decision-making process has to be transparent, unbiased and based on proper stakeholder involvement.

HTA can contribute to the generic justification process by integrating the radiation detriment into already established procedures for HTA based decision-making. The main advantage with this approach is that radiation protection and the concept of generic justification is evaluated as an integrated part of the total HTA performed and not handled in a separate and isolated system. It is important to include experts with sufficient competence in radiation protection to ensure that the radiation detriment is properly addressed in these assessments. However, the integration of generic justification in HTA is not straightforward and may not be feasible in all countries.

Case-Study on Nordic Countries:

Some Nordic Member States have identified the implementation of generic justification into already established HTA systems as one possible approach to transpose Art. 55.2 (a) Council Directive 2013/59/Euratom into national legislation. A close cooperation between the national radiation protection authority and relevant national bodies, preferably competent HTA bodies, is required to succeed with the HTA approach. Integration of generic justification in HTA was outlined in a case-study from Norway. The Nordic radiation protection authorities have recently published a *Nordic Position Statement on Justification of New Types of Practices involving Medical Exposures*, which recommend the integration of generic justification into established methods for assessments of new health technologies. Further information on how HTA and similar methods can strengthen the generic justification process is given in this statement. [13]

Discussion:

In the discussion some concerns related to this approach were identified:

- The main concern was related to the time frame related to an HTA, and it was emphasized that the assessment must not delay the introduction of new methods or hinder innovations. In particular ESR uttered this concern and underlined, that HTA seems to be slow, complex, expensive and not cost-effective for diagnostic imaging tests at least. In addition, the concern was raised that HTA organisations may prioritise drugs over equipment and application.

[13] http://www.nrpa.no/dav/94777f951e.pdf

- Another concern was related to the possibilities of different conclusions in different countries. A harmonization among the European countries was welcomed among the manufacturer and medical professional societies.
- It was also mentioned that cost-effectiveness in healthcare is the main driving force for HTA, that radiation protection issues are not generally addressed in HTA, that HTA bodies normally have their own agenda for prioritizing HTA and that HTA are resource demanding.

Nevertheless, it was stressed, that HTA could – in particular - play a role in evaluating the cost-benefit-ratio with respect to screening projects, such as breast cancer screening, where additional aspects like finances, availability or regulatory aspects are essential.

It was further concluded that available resources to perform HTA may be a challenge for countries that want to adapt the HTA-approach. It is unrealistic for any country to have enough resources to perform comprehensive HTA assessments for all new health technologies, and the use of less resource demanding assessments like Mini-HTA and Rapid-HTA should be investigated. To make the best use of available resources in the long run, evaluation of evidence (safety and clinical effect) should preferably be carried out through European or international cooperation while the evaluation of the consequences associated with the decision to implement the method (cost-effectiveness and budget) should be made nationally. Most European countries have national or regional competent HTA bodies and most of them are member of the European HTA platform, EUnetHTA. This platform is responsible for European cooperation on HTA production and different tools for HTAs, including a core model for the production of HTAs, has been developed. A possible role of EUnetHTA and HERCA in solving issues related to resources and harmonizing of generic justification within the HTA-approach was raised.

Plenary Session 2: How can CE Marking contribute to the justification process of new types of practices?

In the introductory presentations of the session, the question was addressed, whether there is a possible conflict between Council Directive 2013/59/Euratom and Medical Device Directive / Regulation from a legal point of view. It was underlined, that in this case the Council Directive 2013/59/Euratom – being a *lex specialis* - could override the Medical Device Directive / Regulation, but no practical example is known at present.

Another point was the different terminology used in both legal systems. It was well accepted that the letter received from EC on 22.07.2016 was very useful to clarify this point. In particular, it was concluded that, even if the meaning of the terms “risk assessment” and “clinical evaluation” may not be fully consistent in both legal systems, the provision of this information collected under CE marking may be helpful for the justification of new types of practices. The challenge will be to make these data available easily and in a harmonised way for the justification of new types of practices.

Discussion:

The feedback from manufacturers was very supportive. CE marking can contribute to the generic justification process. Particularly, IEC and ISO standards requirements include quantitative information about radiation protection or risk management, and the MDD Guidance MEDDEV 2.7/1[14] give detailed requirements on how to perform an appropriate clinical evaluation. COCIR outlines that information on risk assessment and clinical

[14] GUIDELINES ON MEDICAL DEVICES, CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC (June 2016), EUROPEAN COMMISSION

evaluation can be made available; nevertheless, manufacturers estimate that identifying relevant information may be difficult: *information is there but will need to be agreed*.

In this context, it was underlined by regulators and medical associations that for newly developed devices the display of dose parameters as well as instructions and phantoms for acceptance testing is often insufficient or missing. The question was raised, whether and to what extent quality assurance issues including quality control should be addressed before a newly developed device is authorized and new practices related to that device are justified in general. There was no controversy about the statement that quality assurance, generic justification and authorization needs strongly to be connected.

In summary, it was concluded that CE marking cannot replace generic justification. Nevertheless, it could be a source for information within the process of generic justification. Hereby, the transposition of Article 78 Council Directive 2013/59/Euratom, and particularly of Article 78.2 explicitly addressing information on ”risk assessment” and “clinical evaluation” produced by the manufacturer within CE marking process, is pivotal. COCIR and the Manufacturers explicitly showed their willingness to cooperate in this transfer of information from the MD legal system to the RP legal system.

Plenary Session 3: Does the regulator have to define a “Standard Medical practice List”, by which all ICRP level 2 justified types of practice are addressed, referring to the device, the radiopharmaceutical and the clinical indication and using a classification scheme of the different “types of medical practices”?

In this session the UK presented a case-study on the approach of using a “Standard Medical practice List”.

Case-Study on UK:

In the case-study the UK regulations on justification of practices involving ionising radiation (2004) were presented. It should be noted, that these regulations apply to all practices of ionising radiation, medical as well as other types of practices. They provide a defined process with consultation, and address new practices, review of existing practices and determination of new practices.

Part of the regulation is a list of the existing practices which are already justified, and they are described through three components: purpose, classes or types of practice and the governmental department responsible for the justification. Within the medical field six purposes were identified, with associated classes or type of practice (shown in parenthesis):

- Diagnosis – medical (Radiography, fluoroscopy, CT, in-vivo nuclear medicine, in-vitro nuclear medicine)
- Treatment – medical (Interventional radiology, in-vivo nuclear medicine, teletherapy, brachytherapy, radiography and fluoroscopy (for planning purposes), CT, neutron activation)
- Occupational health screening (Radiography, in-vivo nuclear medicine)
- Health screening (Radiography, in-vivo nuclear medicine)
- Medical and biomedical research (Radiography, fluoroscopy, interventional radiology, CT, in-vivo nuclear medicine, in-vitro nuclear medicine, teletherapy, brachytherapy, neutron activation)
- Medico-legal procedures (Radiography, fluoroscopy, interventional radiography, CT, in-vivo nuclear medicine).

The UK Department of Health is the lead department for all of these.

Discussion:

It was commented from the EU commission representative that this approach is important, but further steps in the process are needed to ensure ICRP level 2 justification. It was elaborated from the UK representative, that this approach is not the only part of the justification process; it is complemented by HTA and other processes.

ESR was also critical about the approach and underlined that the clinical setting cannot be addressed in a fixed and rigid way, but needs to be looked at on a case-by-case basis. ESR further pointed out that this fine level of granularity will only be provided by referral guidelines, requiring a very specialised level of knowledge. This level of expertise might not be available at the radiation protection authority.

In contrast, EANM welcomed the simplicity of the approach and EFRS was in favour of this approach as well. They noted that referral guidelines are not level 2 justification. COCIR and the Manufacturers pointed to the advantages of a harmonised European approach.

In summary, it was noted that this type of process is driven mainly by radiation protections issues, and it is important to also consider clinical benefits as well as other types of risks, for instance overdiagnosis and overtreatment in the case of screening.

Plenary Session 4: Shall the regulator link the justification process of new types of practices to the authorization process?

In this session Luxembourg and the Nordic countries presented two case studies. Switzerland presented the potential problems and limitations related to linking the justification process of new types of practices to the authorisation process.

Case-Study on Luxembourg:

It was pointed out that Luxembourg is a small country with one straightforward public healthcare system. The justification process of new types of practices is linked to the authorisation process. The Ministry of health gives an authorisation for the installation and use of each and every radiological installation and radionuclide. The undertaking has to submit a demand for the new practice, which will allow for the establishment of the justification of the new practice. Specific regulations detail the information/documents to be submitted to the Ministry of Health.

The submitted file is forwarded to national and/or international experts for advice. If the beneficial effects of a new practice are not yet completely known the authorisation can be given for a defined period of time and under certain specified conditions.

Information to be provided by the undertaking include:

- description of the new practice,
- referral guidelines,
- radiation protection measures and security,
- written procedures,
- quality assurance program,
- quantification of no of acts to be done,
- quantification of the advantages for the patient and society,
- estimation of the risk for the professionals exposed, the patient and the patients entourage,
- names and signatures of the persons responsible for putting the into practice the new practice,
- proposal for a methodology for the evaluation of the benefits for the patients after 1 year.

If the authorisation of this new practice already exists in another EU country, documents recognising this practice for the EU country can be submitted.

In the authorisation of a new practice, conditions will be set concerning:

- education and training,
- QA,
- referral guidelines,
- others.

In order for this type of authorisation process to be able to function, Art. 78 Council Directive 2013/59/Euratom is very important.

Case-Study on Nordic Countries:

A new type of practice can either be related to an existing type of equipment or radionuclide, which can be difficult to identify, or can be related to a new type of equipment or radionuclide, which is easier to identify. Some examples of new practices which have been discussed in the Nordic Working Group on Medical Applications were presented. Based on the discussions, similar requirements have been introduced across the Nordic countries, adapted to the different legal structures in the individual countries.

Thus, in general, licenses are not required for ordinary dental applications, but for hand held dental equipment a license is required in several Nordic countries. As part of the application process to obtain this license, special reasons justifying the use of a hand held dental equipment instead of a mounted one have to be provided. Accepted reasons for this can be the use on elderly, disabled or psychiatric patients. The doses to the personnel must be assessed and monitored and extra documentation is required. Another example is the radiopharmaceutical Xofigo (Ra-223). Before licenses were issued, it had to be approved for patient treatment by the national medicines agencies. In addition, a risk assessment regarding staff exposures was part of the licensing procedure.

Considerations from Switzerland on Problems and Limitations of the Approach:

In order to link the justification of new practices to the authorisation process, a list of medical practices considered to be justified in general needs to be established. The questions raised concerning this list are:

- In what detail or granularity should the list be formulated?
- Should it be static or dynamic?
- Who will be responsible for it:
  - holder of authorisation?
  - medical staff?

How to deal with new practices? When generic justification is to be considered, there are typically no clinical trials done yet and no sufficient evidence given. How to control these new practices is another issue raised. Possible solutions would be insurance control, health authority control and clinical audits. However the problems in all three cases are huge.

Discussion:

The first question discussed was:

- How to ensure – by this approach – an adequate execution of Art. 55.2(a) Council Directive 2013/59/Euratom in the MS with respect to the claim that new types of practices involving medical exposure are justified in advance before being generally adopted?

The case study of Luxembourg shows that it is possible for new types of practices to be justified in advance before being generally adopted. In this process all the stakeholders

involved are made responsible for the new practice. The authorisation is given with strict conditions that have to be respected. However, it cannot be neglected that this process requires a lot of time and effort on behalf of the competent authority.

The next question discussed was:

- How to ensure – by this approach- a harmonised execution of Art.55.2 (a) in a MS?

In a small country such as Luxembourg where there is only one competent authority the execution of Art. 55.2 (a) can be harmonised. However, in a big country with a number of competent authorities it is more complicated. For this process to work, an excellent communication between competent authorities would have to be put into place. The competent authorities would have to collaborate together in the process of authorising a new practice.

Plenary Session 5: What further approaches exist in MS for the transposition of Art. 55.2 (a) Council Directive 2013/59/Euratom and other articles around it?

In this session, two approaches on how to implement the transposition of Art. 55.2 Council Directive 2013/59/Euratom were presented by France and the Czech Republic.

Case-Study on France:

The presentation proposed a complementary "approach" for the implementation of Article 55.2 (a) Council Directive 2013/59/Euratom. Hereby, in particular two questions were addressed:

- How to deal with the justification of new types of practices concerning both examinations (i.e. medical imaging) and treatments (i.e. therapy) - with or without a new technology?
- How to avoid administrative burden before the implementation of a new technology, in particular with respect to a new radiopharmaceutical?

The proposal is based – among others - on the following points :

- A "**watch**" should be organized on new technics and on new examinations or treatments. For this purpose, a **strong collaboration** between medical societies, expert bodies and regulators at national level would be necessary.
- The **key-stakeholders** from a radiation protection point of view (patient, occupational and public exposure) have to be identified as well as the needs in terms of research funding.
- The current text of the decree under preparation in France gives the possibility (depending on the stakes) to issue a **regulatory decision** to support the implementation of a new technic/examination/treatment, **during a transitory period**:
    - to collect data related to benefit/risk,
    - to state specific radiation protection rules, if needed.
- At the end of the transitory period, the evaluation of "justification" should be done by an **expert committee**.
- In parallel, the **updating of national guidelines** should be carried on.

Case-Study on Czech Republic:

The Czech approach considers that:

- when a type of practice is not – yet – justified in general according to Art. 55.2 (a), it has to be handled under the provisions of bio-medical research according to Art. 55.2 (e),
- in order to progress from the status of research according to Art. 55.2 (e) to the status of generally accepted type of practice according to Art. 55.2 (a), the research should be officially completed by a report agreed by the Ministry,
- the regulatory process has to be initiated, in particular for new types of practices, re-actively by e.g. undertakings - not within a notification / authorization process, but within the HTA process,
- care should be given on the HTA process to ensure the full understanding and consideration given to the risks related to ionizing radiation by the HTA agencies; herby cooperation should be organised between RP competent authority and HTA agency and Ministry of Health,
- the justification process should be linked with the reimbursement process,
- CE Marking should be closely connected to the justification process of new types of practices.

Discussion:

Following these presentations, the ESR's representative indicated that the proposed French approach seems feasible and transparent. Furthermore, it has been stressed that the involvement of stakeholders (experts/ scientific societies) is key in the process of generic justification to enhance credibility.

Plenary Session 6: Justification of New Types of Practices versus Biomedical Research?

In an introductory presentation, it was outlined that the *Principle of Justification* – as stated in Art 55.1 EU-BSS Directive for the medical field in general – requires that *medical exposures shall show a sufficient net benefit.* To evaluate this "*sufficient net benefit"*, an adequate benefit versus risk analysis is essential, which should be based on an adequate level of evidence. Thus, the *Principle of Justification* is closely linked to the level of evidence. In line with this kind of reasoning, it was then concluded that the adequate way from a new type of practice to the healthcare scenario requires an element of biomedical / clinical research. Otherwise, how else could the benefit versus risk analysis adequately be accomplished? But, there are shortcuts that directly lead to healthcare, without the detour on biomedical / clinical research. Based on these considerations, two questions were raised: (1) When a new type of practice is not – yet – justified in general according to Art. 55.2 (a), is it then to be handled under the provisions of bio-medical research according to Art. 55.2 (e)? and (2) How to progress from the status of research according to Art. 55.2 (e) to the status of a generally accepted new type of practice according to Art. 55.2 (a)?

In the second part of the introductory presentation, Art. 55.2 (c) Council Directive 2013/59/Euratom has been addressed. It claims that – 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. The term "special circumstances" is closely related to the terms "off-label use of drugs" or "compassionate use of drugs". Both cases refer to situations where a drug is provided to a patient – on humanitarian grounds – prior to a drug's receiving regulatory approval for a clinical indication. From this two further questions emerge: (3) How broad is the scope of application of Art. 55.2 (c)? and (4) Does Art. 55.2 (c) establish a further way to the healthcare scenario, i.e. to the individual application of medical exposures, which is not a shortcut, but a way consistent with the EU-BSS Directive?

Case-Study on France: New Radiopharmaceuticals

The case-study on France focused on the justification process for new radiopharmaceuticals, in particular the unsealed source therapy. The key-messages were:

- The process involves several institutions and agencies such as radiation protection authority (ASN), medical device / pharmaceutical authority (ANSM), ethics committees, healthcare authority, etc. Thus, exchange of data and information between institutions and agencies involved is essential.
- Occupational and public exposures have to be taken into account. But the direct impact on the justification process as well as on the licensing process has to be investigated.
- Proposal of new French system will enhance justification.

Case study on Switzerland: New Medical Devices

The case-study focused on the framework given in Switzerland for clinical research on new medical devices. The key-messages were:

- Ethics committee judge benefit versus risk, but health authority and radiation protection authority are also involved in justification process.
- Regulation through Radiation Protection Act and Human Research Act.
- Estimated doses involved help define process – e.g. for effective doses < 5mSv radiation protection authority is not involved; for higher doses radiation protection authority is involved.
- In all clinical trials involving ionising radiation it is investigated whether the use of ionizing radiation is the primary purpose of the trial (i.e. primary use) or whether it is only used to assess important clinical parameters such as the regression of a tumor under a new therapy (i.e. adjunct use).
- Dose limits and constraints for special groups of volunteers (healthy, diseased) may be imposed relating to research, as well as claims concerning QA.

Discussion:

In their oral feedback, the medical associations and manufacturers focused in particular on the requirements imposed by Art. 55.2 (e) Council Directive 2013/59/Euratom on biomedical research and underlined that a graded approach is essential. Hereby, the primary purpose of the research is important: is the purpose of research to evaluate the impact of radiation itself or is it to monitor e.g. the impact of drugs by using radiation – among others – as a tool? Furthermore, doses should be considered relative to the inclusion criteria: are diseased volunteers (=patients) involved, who may benefit from the use of radiation, or normal healthy volunteers, who will not benefit from the use of radiation. The medical associations and manufacturers also stressed the need to bring ethical and radiation protection factors together, to ensure a comprehensive and well-balanced approach. Finally, they expresses their concerns that the development of better products may be inhibited when the transposition of Art. 55.2 (a) and (e) Council Directive 2013/59/Euratom into national legislations impose too many restrictions on the adoption of a new type of practice into healthcare.

One focus of the general discussion was Art. 55.2 (c) Council Directive 2013/59/Euratom addressing a type of practice that is not yet justified in general. There was a strong agreement that – in this case – Art. 55.2 (c) does not provide a shortcut to healthcare, bypassing the need for justification on a generic level. Instead, Art. 55.2 (c) is restricted to special circumstances with respect to an individual patient and requires a special individual

justification. Explicitly, Art. 55.2 (c) does not cover the application of a new type of practice to a group of patients. If this is the case, the application then has to be handled under the provisions of biomedical research according to Art. 55.2 (e) Council Directive 2013/59/Euratom.

Another focus was translation from research to generic justification for a new type of practice. It was agreed that an adequate process needs to be developed which properly links both spheres and which ensures a high level of transparency as well as communication – particularly with regard to data availability if it has direct impact on radiation protection issues. Hereby, both occupational and public exposures have to be considered and problems thrown up by research have to be reflected in later justification processes.

Appendix II:

ESR Feedback

HERCA WGMA Discussion Paper
Justification of Types or Classes of Practices Resulting in Medical Exposures
January 2017

The ESR is pleased to offer its opinion to the HERCA discussion paper and to highlight in particular the viewpoints from the practical clinical perspective.
The ESR would like to emphasise that any approach in regard to the transposition and implementation of the justification requirements in the new BSS Directive needs to be practicable and implementable without jeopardising patient safety or the pace of technological innovation. Thus taking into account the clinical setting and current scenarios of the medical device industry is considered crucial.
Additionally, the justification process of EURATOM Directive 97/43 has not been successfully implemented for several reasons: In particular cultural aspects and healthcare systems organisation were not considered and also the disconnection between the regulators and healthcare organisations across Europe needs to be pointed out and might have been an explanation for this unsuccessful implementation.
Finally, quality and safety are overarching concepts, which are not and should not be limited to the radiation protection field only. Surprisingly, the current European Commission DG Sante approach to quality and safety is not really focusing on radiation protection, thus illustrating the above mentioned disconnection.
Finally, the ESR regrets that new tools such as Clinical Decision Support are not considered.
The ESR is very much concerned by above facts and also because the current approach envisaged by HERCA does not seem to consider the lessons learnt from the implementation issues related to EURATOM Directive 97/43.

In the following, the ESR provides its viewpoints to the individual questions raised in the HERCA discussion paper. In general, the questions raised in the HERCA discussion paper appear to be of marginal importance, as they look very far from the core of the problem.

How broad is the scope of application of Art 55.2 (c)?
If types of practices in 55.2(c) are not justified in general, their use may be interpreted like an off-label use of drugs. In this case the scope is narrow and always needs an individual level III justification and documentation.
If types of practices are new, as mentioned in 55.2(a) and have to be justified in advance, the scope should be wide enough with a rough granularity to avoid delayed application in medicine by a regulatory process.
Definition of new practices should clearly separate between

a) ***modified use of existing techniques, not requiring an advanced justification***
b) ***introduction of completely new technical practices***

Examples for a) are introduction of iterative reconstruction or dual energy techniques in CT, or the introduction of Cone Beam CT (CBCT) with dedicated scanners or as add on in angiography devices. Modified use of existing techniques should be justified at level II.

Examples for b) could be imaging with X-ray backscatter techniques or phase contrast imaging. Before completely new technical practices are generally justified, they could be used under 55.2(e) in research projects.

By what action shall the regulatory process be initiated, in particular for new types of practices?
The ESR considers reactively being the more reasonable approach. Pro-active would imply that competent authorities are fully up to date on all new scientific developments of new practices. This could perhaps be expected from scientific organizations.

By what measures can / must the regulatory process be supported:

- establishment of an expert panel (e.g. medical associations, manufacturers, etc) on a permanent base;
- involvement of relevant stakeholders (e.g. medical associations, manufacturers, etc) on a case by case base;
- involvement of existing structures in the field such as HTA organisations;
- impact of CE marking due to Medical Device Directive / Regulation?

As we do not consider a proactive approach relevant, we can only support bullet 2.

What shall the outcome of the regulatory process be:

- pro-active approach: official statement of competent authority following publication of authoritative report (e.g. COMARE reports in UK);
- re-active approach: approval with respect to notification / authorization processes (e.g. Luxembourg)?

The ESR considers a re-active approach more flexible and faster than a pro-active competent authority statement.

Interrelation MDR and BSS Directive
Could the information held by the manufacturer about the risk assessment and the clinical evaluation, being provided to obtain the CE marking, be made available for the application of Art. 78.2 Directive 2013/59/Euratom?

As all equipment, emitting ionizing radiation for medical use should either be licensed or at least be notified to competent authorities it would be desirable to provide all the listed information for CE marking also to the competent authority for first time market authorisation.

Could this information be available in the frame of the justification process related to a new class of medical practice, i.e. Art. 55.2 (a) Directive 2013/59/Euratom?

Although agreeing that the manufacturers should make available the data from the CE mark application process as background information, the ESR would like to underline that CE marking is not a clinical evaluation process.
The ESR emphasises that the medical question is most important in this process and

not the medical system itself.

Role of HTA in justification process
How can Health Technology Assessment (HTA) contribute to the justification process of new types of practices?

HTA is slow, complex, expensive and not cost-effective for diagnostic imaging tests. HTA should rather be used in a cost effectiveness perspective of different diagnostic strategies. It should, however not be used as a regulatory tool.
HTA may play a role in screening projects, like breast cancer screening, where additional aspects like finances, availability or regulatory aspects play a role.

How can CE Marking contribute to the justification process of new types of practices?

The ESR is of the opinion that CE marking can not at all contribute and should not be used to serve as a clinical evaluation of any medical device. Many CE labelled modalities are brought into the market without any justification process. Furthermore local authorities are often faced (for licensing a practice) with the problem that display of dose parameters is insufficient and instructions and phantoms for acceptance testing and quality control are missing.

Does the regulator have to define a "Standard Medical practice List", by which all ICRP level 2 justified types of practice are addressed, referring to the device, the radiopharmaceutical and the clinical indication and using a classification scheme of the different "types of medical practices"

The ESR is strongly against regulators setting up a list of justified criteria. Referral criteria are probably the best solution to provide such a list. A separate list by regulators may lead to confusion and conflicting information. In addition, the clinical setting, which is in essence of utmost importance and needs to be looked at on a case-by-case basis, cannot be addressed in a fixed and rigid way.

Shall the regulator link the justification process of new types of practices to the authorisation process?

The ESR is of the opinion that the regulator should not link the justification process of new types of practices to the authorisation process, as the authorisation process has a completely different purpose.

Justification of New Types of Practices versus Biomedical Research
When a type of practice is not – yet – justified in general according to Art. 55.2 (a), is it then to be handled under the provisions of bio-medical research according to Art. 55.2 (e)?

Yes, if the practice is part of a research programme and approved by an ethics committee.

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Contact: secretariat@herca.org