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Date:	July 16, 2014
Title:	Justification of Individual Medical Exposures for Diagnosis: A HERCA Position Paper

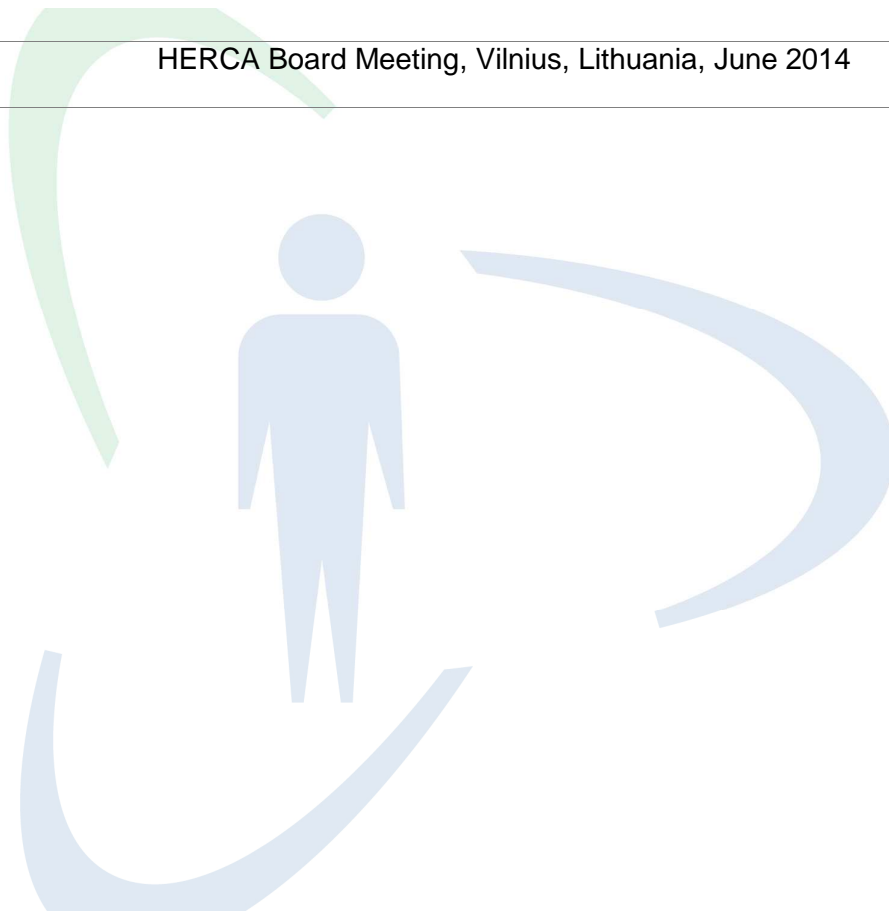
Summary:	<p>Improving the application of the justification principle in medical imaging is the responsibility of many stakeholders.</p> <p>This document is intended to provide clarity on the regulator's approach to the roles and responsibilities of the undertaking as well as a range of professionals involved in medical exposures. In doing so it considers the requirements of the new European Basic Safety Standards (BSS) Directive 2013/59/Euratom¹ and discusses a number of emerging challenges associated with efficient, effective and rapidly changing healthcare systems.</p> <p>In summary,</p> <ul style="list-style-type: none"> - the justification process should be completed prior to the exposure taking place and include consideration of the following: <ul style="list-style-type: none"> • adequate information regarding the clinical condition(s) of the patient, relevant to the imaging request -this must be available including known possible contraindications (eg pregnancy, breastfeeding) • the diagnostic question(s) to be addressed • where practicable, information, with regard to possible previous/concurrent examinations • the decision on the appropriate imaging procedure including the option of one that does not involve ionising radiation • traceability of the above to the referrer and practitioner, - the role of the regulator is to provide, through regulations and associated guidance, a clear and unambiguous regulatory
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framework including requirements for the justification process and accountability within local procedures - these will be subject to inspection,

- the role of the undertaking and the professionals involved is to demonstrate compliance with regulations through procedures and documentation associated with each individual exposure, showing beyond reasonable doubt that the elements of the justification process have been completed, and by whom, in accordance with the responsibilities laid down in procedures.

Approval:

HERCA Board Meeting, Vilnius, Lithuania, June 2014



Justification of Individual Medical Exposures for Diagnosis: A HERCA Position Paper

Introduction

In diagnostic medical imaging, justification is considered by many as the most important of the fundamental principles of radiation protection, HERCA has identified better understanding and application of the justification process as one of its priorities.

The scope of this document is limited to the justification of individual medical exposures, often considered as level 3 justification within the framework proposed by ICRP². It is intended primarily to clarify regulators' views on the roles and responsibilities of the undertaking as well as clinical professionals with regard to these exposures. At a secondary level, the document considers challenges to implementation and compliance as well as the importance of other contributing requirements. These include education, training and the availability and communication of information required to ensure that the justification process is conducted in accordance with the requirements of the new BSS Directive and the expected standards of healthcare.

Its publication during the transposition period for the Directive is intended to help clarify the expected approaches to adoption of the principles and concepts provided by the Directive. It is acknowledged however, that adoption by Member States into specific national regulations will result in variations, taking advantage of the flexibility of the Directive. In this way, local legislation will reflect the needs of the healthcare systems in place, but within the framework provided by the Directive.

HERCA is fully aware of other initiatives outside Europe, in particular the IAEA "triple A" scheme and the 2012 IAEA/WHO "Bonn Call for Action"³. The approach outlined in this HERCA document is consistent with these initiatives, as HERCA understands them, as much as compliance with the Euratom BSS Directive allows.

General concept

Within this position statement, HERCA's prime objective is to provide clarity on the regulator's approach to the roles of the undertaking and a range of professionals with regard to the justification process. The new BSS Directive is directed at Member States and is essentially goal setting rather than being overly prescriptive. It provides a range of requirements and outlines responsibilities, but allows for some flexibility for national authorities to reflect local healthcare systems and structures. Because of this flexibility, there is a danger that responsibilities might be confused, shared or neglected. The challenge for national regulatory authorities will be to create unambiguous clarity as to who exactly is responsible for what.

The justification process includes a number of sequential and parallel events from initial presentation of the patient to the authorisation for an exposure to take place. It is possible to

consider these as separate components of a whole and to assign clear functions and responsibilities for every step identified.

Ideally, these functions and responsibilities should be assigned to the persons best placed to carry them out. This requires appropriate and agreed empowerment to those involved throughout the process and this will be underpinned by education and training of the holders of these responsibilities.

Depending on national arrangements, some of the decisions regarding the practical implementation of the justification process could be passed on to more decentralised authorities, such as regional authorities, hospital management, licensed departments or practices, or radiological practitioners. This will allow different approaches for different scenarios or healthcare settings. However in every case, the local solution must fit into the national framework provided by regulation. Local processes must define clearly procedures for justification, including responsibilities as well as the scope of application, as dictated by local circumstances and availability.

At the level of the departments and practices where imaging procedures are carried out, the justification process must be an explicit item within the quality assurance programme. It should be subject to regulatory inspection and to peer review and audit. As the justification process will be a clear component of any regulatory system addressing individual medical exposures, it will be subject to inspection by the Regulatory Authority. The Regulatory Authority will need to ensure compliance with national regulation and with any local procedures that determine responsibilities and processes for different scenarios. To ensure compliance, the undertaking should clarify within procedures all aspects of its justification process and control should be provided through quality assurance programmes.

Performance can also be monitored through audit processes. The European Commission has provided guidance on audit and it is a requirement of the BSS Directive that clinical audit is carried out in accordance with national procedures. The Directive does not explicitly state that audit of the justification process is required, but its importance is such that audit of elements of the justification process might be reasonably expected by Regulatory Authorities.

Elements of the Justification Process and Associated Responsibilities

The essential requirement in justification is that the benefit of the exposure outweighs the associated potential detriment. This principle can be applied whether the benefit is intended for the individual, as in a diagnostic exposure, or for society, such as when normal healthy volunteers are exposed as part of research.

For an exposure to be appropriately justified, consideration should be given to the individual characteristics of the patient, to previous diagnostic information and to the value of a specific exposure to answer the clinical question that has been posed.

Regulators expect that these elements are all addressed in procedures describing the justification process and that there is a clear and unambiguous responsibility placed on

someone to undertake these parts of the justification process. In addition, these activities must be carried out prior to the exposure taking place.

Depending on the situation, these responsibilities might be assigned to different individuals, but in each case, responsibilities should remain clear. For example, for routine referrals, the family doctor may be best placed to provide information about the individual characteristics of the patient and in this case the responsibility as referrer is clear. The justification of the procedure will be made in the imaging department, often by the radiologist or nuclear medicine specialist who will take on the role of practitioner. In other situations, the family doctor might refer a patient to another specialists (eg a cardiologist), who undertakes an additional examination of the patient and decides that a specific radiological procedure is justified. In this case, the cardiologist acts as referrer and practitioner.

As stated previously, the justification process should be completed prior to the exposure taking place. In daily routine under the conditions provided by a specific healthcare system, the radiologist or nuclear medicine specialist may not be able to consider every request for an imaging procedure. In such cases, the undertaking must develop procedures to ensure that the requirements around the justification process are still fulfilled but these must be within the framework allowed by national legislation. If this states that the referring clinician might be responsible to some degree for justification, then it would be possible for the local procedures to reflect this, but the situations for which these apply must be agreed and the associated responsibility clear. For a specific set of examinations defined in local procedures, the regulator may define even further going legal systems, including other specified competent healthcare professionals. In any case, the professional justifying the individual medical exposure must be adequately trained to ensure the standard of care is equivalent to that provided by a radiologist or nuclear medicine specialist.

Some legal systems allow delegation of tasks to professionals capable of undertaking them. However, responsibility itself cannot be delegated. The regulator will need to know the procedures for delegation of tasks, but the professionals assigned the responsibility for justification must be aware that they retain this responsibility. Increasingly, in some countries with role development of non-medical healthcare professionals, this delegation of tasks will become unnecessary. The relative scopes of practice and associated responsibilities of non-medical healthcare professionals, radiologists and nuclear medicine specialists will be based on education, training and competence rather than professional title alone.

It may not be possible to address each of the elements of the justification process in every case – in emergency situations, accessing previous diagnostic information may not be practicable in the time frame available to ensure appropriate care for the patient. If this is the case, this should be included within procedures outlining the requirements and responsibilities associated with the justification process. Whatever the scenario, the roles of the professionals within the justification process should be clear and the responsibilities outlined should be undertaken.

- In summary, the justification process should include consideration of the following:
 - adequate information regarding the clinical condition(s) of the patient, relevant to the imaging request -this must be available including known possible contraindications (eg pregnancy, breastfeeding),

- the diagnostic question(s) to be addressed,
 - where practicable, information, with regard to possible previous/concurrent examinations,
 - the decision on the appropriate imaging procedure including the option of one that does not involve ionising radiation,
 - traceability of the above to the referrer and practitioner,
- the role of the regulator is to provide, through regulations and associated guidance, a clear and unambiguous regulatory framework including requirements for the justification process and accountability within local procedures - these will be subject to inspection,
- the role of the undertaking and the professionals involved is to demonstrate compliance with regulations through procedures and documentation associated with each individual exposure, showing beyond reasonable doubt that the elements of the justification process have been completed, and by whom, in accordance with the responsibilities laid down in procedures.

Aids to the Justification Process

Referral Guidelines

The new BSS Directive continues to recognise the importance of referral guidelines and the importance of making these available to referrers. These guidelines have been in place for many years and in Europe they have an established role in helping to guide the referrer to make a request consistent with the best possibility of answering the clinical question associated with the clinical presentation of a patient.

HERCA welcomes further international and/or European initiatives aimed at the development and updating of the evidence base for referral guidelines, which should be applicable throughout Europe and beyond. It recognizes the difficulties associated with producing up to date guidelines and accepts that where a robust evidence base is lacking and guidelines need to be based on expert opinion, consensus should be sought by a multidisciplinary and cross-border approaches that put first the interest of patients.

The latest Directive has emphasized the importance of referral guidelines, by requiring that these are available to referrers. Comprehensive transposition will require Member States to include this requirement in national regulations and to check this as part of inspection processes designed to demonstrate compliance.

It is accepted that initiatives to increase use of guidelines may result in their inclusion within e-referral or computerized decision support (CDS) systems but as stated previously by HERCA⁴ these systems do not alter the legal responsibilities assigned to the referrer or the practitioner, as stated in national regulations. In themselves, they cannot replace or remove the responsibilities associated with the justification process – the family doctor still needs to assess the patient and the practitioner, perhaps in conjunction with the referrer as defined by national regulations, still has to take responsibility for justification of the medical exposure.

In practice and in most circumstances, referral guidelines, if developed correctly and updated and adapted to local circumstances, will indicate the appropriate examination. They can be used as an essential tool in safe and efficient referral processes. There will always be cases where they do not and in such cases the Directive gives the freedom to justify alternative exposures, or in some cases to defer or refuse an examination. In such cases the decision should be documented.

HERCA recognizes that internationally, the same or similar evidence which forms the basis for referral guidelines has been used to produce appropriateness criteria. There are subtle differences between the two. Referral guidelines, as the term suggests are intended to help referrers rather than radiologists or nuclear medicine specialists etc. Guidelines are usually considered as providing an indication, while criteria are often interpreted as a standards against which something can be assessed. Within this context, the European Directives' intentions are to provide referring clinicians with information to help inform their thinking and requests for medical exposures, rather than to offer criteria against which such requests can be judged. It should always be possible for the final decision on justification, performed by the clinical radiological specialist, to be inconsistent with the referrer's request - which is essentially a request for a clinical opinion. In contrast, if a referrer's request is consistent with national appropriateness criteria, the clinical radiological specialist may be less inclined or find it more difficult to disagree. This difficulty could be compounded if specific appropriateness criteria were to be adopted within a healthcare system, through legislation, insurance systems etc.

Education and Training

Education and training, and the resulting competence and skill of healthcare professionals underpins safe and efficient delivery of all healthcare and this applies to the justification process as well.

The amount and type of training received by referrers and practitioners with regard to the justification process and its components will vary. Radiologists and nuclear medicine specialists are experts in their field and will be expected to keep up to date with developments in imaging and their application. Many radiographers have vast experience of imaging procedures and their value. The same may be true for specialists in other areas, such as cardiologists or dentists, but this will be in a more restricted scope of practice. The family doctor cannot be expected to have the same level of knowledge of imaging techniques, but may have greater knowledge of symptoms and overall management of symptoms and disease, compared with the radiologist if not the specialist. This knowledge, supported by education and training, will form the basis for allocating the roles of referrer and practitioner.

Whatever the role, the healthcare professional will need to understand their responsibilities within the legal framework provided for medical exposures and to be able to use the tools and services available to them.

All healthcare professionals should be able to discuss with patients, elements of imaging and the justification process commensurate with their activities and responsibilities. This will include, to varying degrees, some understanding of radiation protection matters and the relative risks compared to the potential risk of the symptoms or disease to be investigated, as well as practical aspects of the examination such as preparation and the examination itself. The training required to perform these activities will be outlined in national regulations and is supported by a range of guidance from professional bodies and international organizations.

Audit

Clinical audit is a requirement of the BSS Directive, although no detail is provided on the essential factors to be audited or how it should be done. Further detail on clinical audit has been provided however in guidance published by the European Commission⁵. Auditing the effectiveness of the justification process and within it the consistency between advice provided in referral guidelines and the exposures finally provided, can provide valuable information, although it is accepted this can be time consuming and resource intensive. HERCA supports such activities, even if they are not specified in the regulatory requirements of Member States, but accepts that non-agreement between guidelines and final examinations does not automatically mean that justification was inappropriate.

Inspection

Inspection is a significant tool available to the regulator and is required by the BSS Directive. Increasingly, the focus of inspection has moved from enforcement to assessment of compliance and inspections offer opportunities for organizations to improve their processes.

As part of inspection, undertakings can expect the regulator to inspect compliance with requirements around the justification process. The detail of these inspections will vary depending on the culture within the Member State and the competence of the inspector. At the very least, the regulator will be able to verify compliance with elements of the process, such as identification of the referrer and practitioner and their ability and entitlement to act in this capacity, their input into the process, recording of clinical information and an unambiguous allocation of responsibilities in accordance with regulatory requirements. In some cases, the regulator may be competent to discuss the validity of justification of an individual exposure, but the ability to do so should be accepted also on a legal basis.

Conclusion

Appropriate justification processes offer the most effective method to achieve dose reduction in medical imaging, for the individual and for the exposed population. The responsibility for appropriate justification at the individual level rests with clinical professionals. To assist with this task, HERCA is committed to providing clarity regarding the regulatory frameworks within which these professionals conduct their clinical practice and to working together with professional bodies and organizations in order to provide a safe environment for the medical exposures of patients.

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