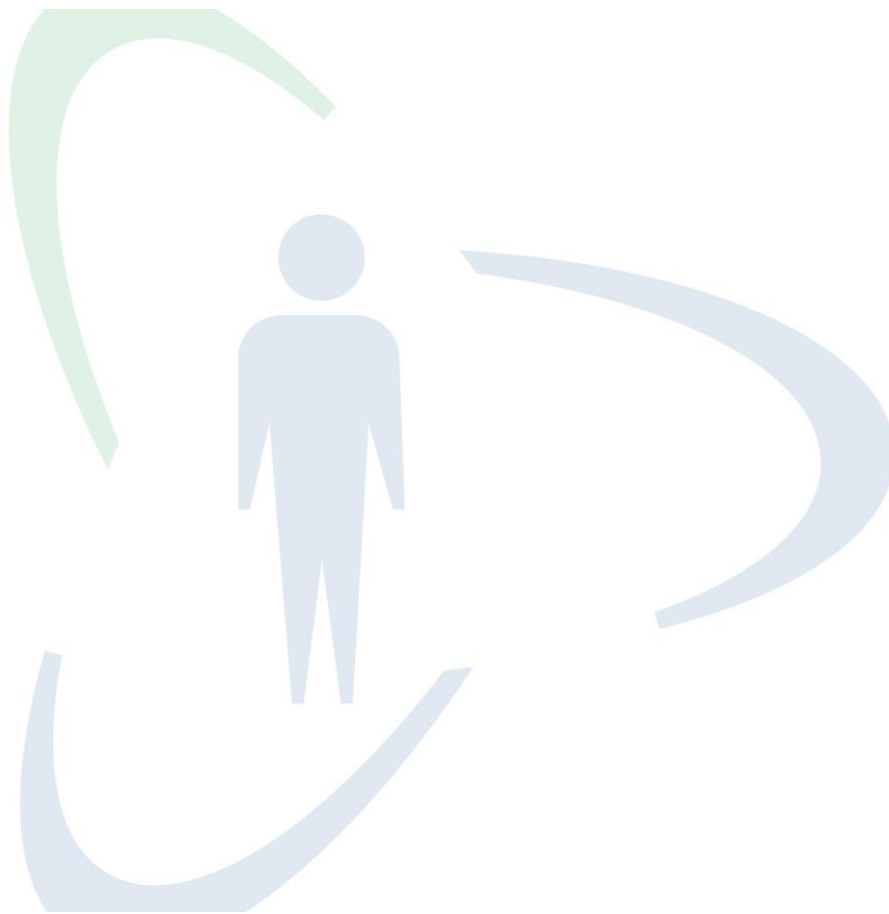




Heads of the European Radiological
protection Competent Authorities

**Addendum to HERCA Position Paper
Justification of Medical Exposures**
HERCA recommendations on the transposition
and implementation of BSS requirements
concerning the application of justification
principle for medical examinations using
ionising radiations

October 2014



The Addendum to the HERCA Position Paper on Justification of Medical Exposures “HERCA recommendations on the transposition and implementation of BSS requirements concerning the application of justification principle for medical examinations using ionising radiations” was approved by the Board of HERCA on 22 October 2014 on the occasion of the 14th HERCA meeting, in Stockholm, Sweden.

HERCA recommendations on the transposition and implementation of BSS requirements concerning the application of justification principle for medical examinations using ionising radiations

Justification of individual medical exposures for diagnosis is a key principle of radiation protection:

- for choosing the most appropriate examination to be performed for any given patient;
- for reducing or eliminating clinically unhelpful radiological / nuclear medicine examinations.

As part of the transposition process for Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionizing radiation (BSS), National Competent Authorities should assess the efficiency of national regulation introduced for the transposition of the justification requirements of the previous directive (Directive 97/43 Euratom) and, if needed, update this regulation taking into account chapter VII of the BSS, particularly articles 55 (justification), 57 (responsibilities) and 58 (procedures).

HERCA believes that the transposition of the directive 2013/59 Euratom offers a unique opportunity to implement in the national regulations procedures addressing the justification process¹. So, Regulators should ensure that the process of justification follows written formal procedures in each imaging department which should clearly define the responsibilities assigned to each individual (referring clinician, radiologist/nuclear medicine physician and other professionals including technologists).

HERCA suggests that the written formal procedure describing the process of justification could be a requirement of a quality management system dedicated to radiological examination, including the quality assurance programme on equipment, as mentioned in article 60.c of the BSS. In practice, such a procedure could address the following issues.

¹ HERCA Position Paper on the Justification of Individual Medical Exposures for Diagnosis published in July 2014 - http://www.herca.org/herca_news.asp?newsID=33

1. Referral guidelines

“Referral guidelines”, as referred in article 58.c of the BSS, should be an integral part of the referral process and thus of a comprehensive justification process. These guidelines, already required by regulations as the result of the transposition of directive 97/43 Euratom, developed and updated by the learned societies, are available in Europe in different languages (English, French, German...). To facilitate the practical use of these guidelines, HERCA recommends that they are made available particularly to the “referrer”², by promoting tools such as internet accessibility with smart phones.

2. Request of examination

The request of an examination by the referrer should contain sufficient clinical information, and the clinical question to be answered in order to provide the practitioner³ with the information needed to justify the proper examination with the right views (article 55.2b and d of the BSS). The referrer, moreover, should be properly identified and sign the request. According to HERCA, this could be made mandatory and clinical audits and inspections can check that the requests provide all the components required to fulfill the justification principle.

3. Report of the examination

Ideally, in addition to the information related to patient exposure, in particular the physical parameters of the examination which allow the dose delivered to be estimated, the report of an examination should include the relevant clinical information, related to justification, given by the referrer (article 58.b of the BSS).

HERCA encourages Member States to make this mandatory. Thus clinical audits and inspections can check that the reports of medical examination are fully addressing the original clinical question, which is a key part of the justification principle.

HERCA notes that the BSS contains specific requirements regarding new medical radiological equipment (article 60.3.e). HERCA strongly recommends that the new medical regulation on medical devices, in preparation at European level, includes these specific requirements from BSS in order that new equipment that will be put on the market, under CE marking, complies with these technical rules.

4. Computerized decision support systems

HERCA encourages the development of Computerized Decision Support Systems as an efficient way to help the implementation of the justification principle. If needed, HERCA will support any European initiative involving national competent authorities and professional bodies such as learned societies.

² Referrer (definition 85 of the BSS): a medical doctor, dentist or other health professional who is in entitled to refer individuals for medical radiological procedures to a practitioner, in accordance with national requirements.

³ Practitioner (definition 66 of the BSS): a medical doctor, dentist or other health professional who is in entitled to take clinical responsibility for an individual medical exposure, in accordance with national requirements.

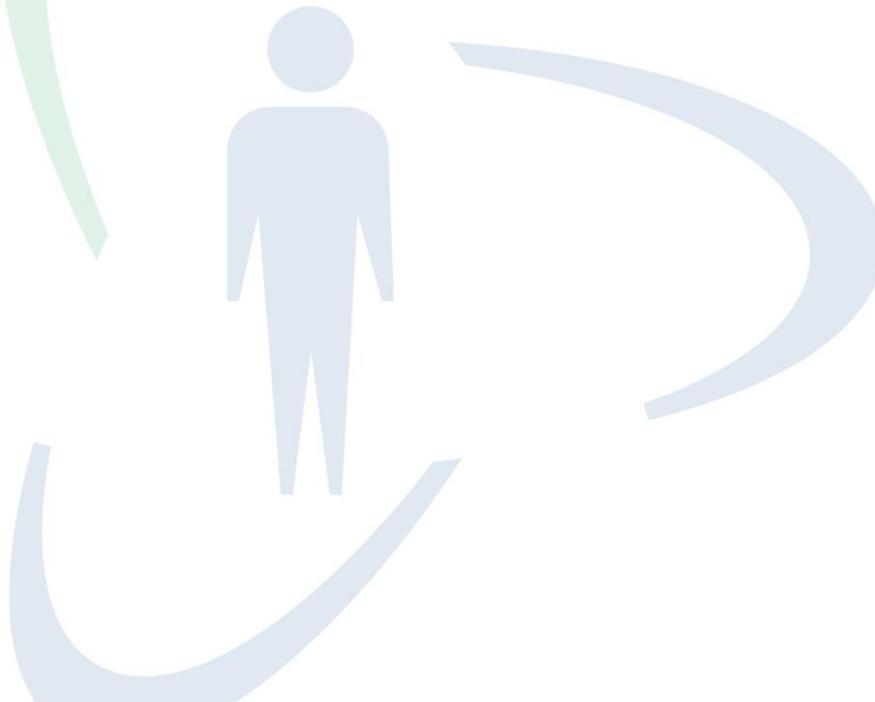
5. Education and training

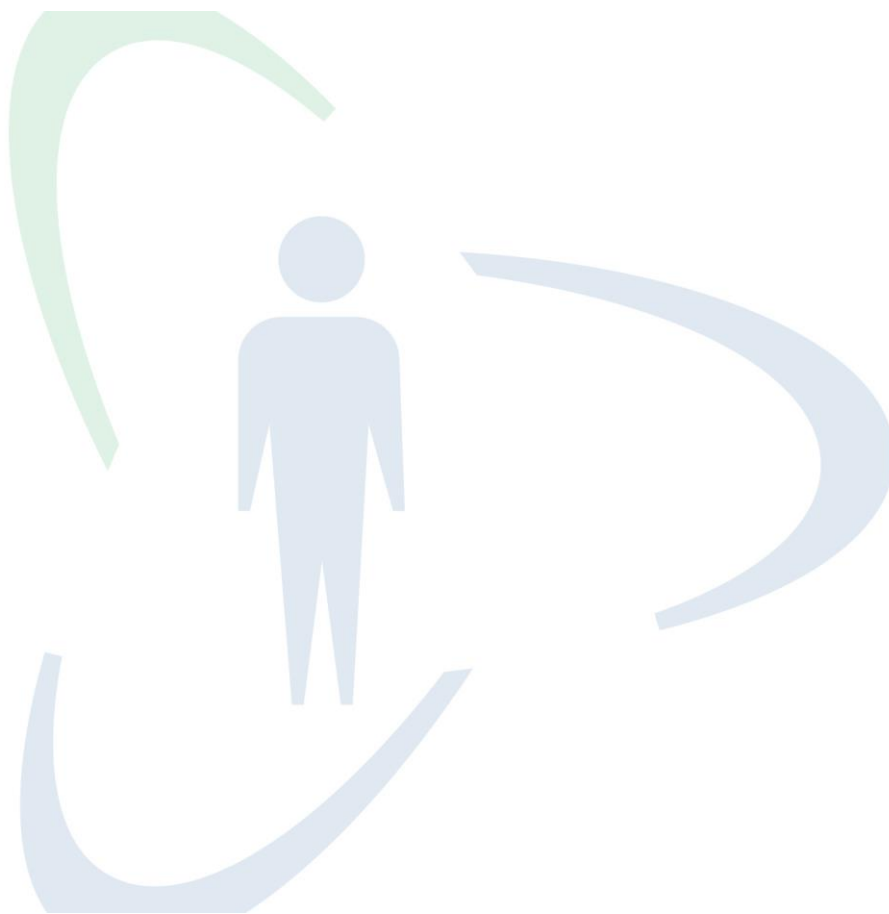
Education and training, and the resulting competence and skill of healthcare professionals underpins safe and efficient delivery of all healthcare and this applies to the justification process as well (see article 14.1 and article 18 of the BSS).

6. Self-reporting of justification deviations

HERCA considers that the internal reporting and analysis of justification of examinations which involve deviations from the referral guidelines or inappropriate requests, through the use of a dedicated learning tool that is available to all those involved in the justification process, would be an efficient way to promote feedback.

The reporting of justification deviations could also be a requirement of the quality management system, in addition to a system for the record keeping and analysis of events involving or potentially involving unintended medical exposure due to radiological examination. Both could be checked during inspection and clinical audits.





Heads of the European Radiological
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HERCA Technical Secretariat:

secretariat@herca.org