HERCA position paper

HERCA Working group on Medical Applications

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HERCA's view on patient radiation protection in medicine

November 2023

- Approved by the HERCA Board of Heads on the 23rd of November 2023 -

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A Position Paper from the Heads of the European Radiological Protection Competent Authorities

Summary

The use of patient contact shielding is somewhat diverse. Practices vary from one member state to another and even within one country or within an institution. This situation can lead to great uncertainty for staff but also for patients who may experience different practices. Due to technological developments being more effective and efficient in the reduction of dose, patient protection devices in X-ray diagnostics is nowadays only recommended in exceptional cases. The purpose of this statement is to help to harmonize the use of contact shielding within the European countries by giving a general recommendation to the national radiation protection authorities on how a decision-making process concerning the use of patient contact shielding should be implemented in all radiological facilities. The appropriate use of contact shielding is best determined by the professionals (mainly the practitioners and the medical physics expert); regulating it in detail by the national authority should be avoided. In analogy to the 3 levels of the justification process, HERCA recommends to the member states a 3 level decision-making process for the use of patient contact shielding to be implemented in all radiological facilities.

This HERCA position statement is meant as a recommendation to the national competent regulatory authorities of the member states.

Introduction

There are many different roles, duties and responsibilities within the radiology community. It is therefore important to define the role of the radiation protection competent authorities as regulators and supervisory and monitoring authorities. What tasks should the authority perform and what should other organisations and associations do? The role of the authority depends on the regulations in place in each member state and also on the level of radiation protection competence in radiological facilities. Therefore, differences can be seen from one country to another. However, all European radiation protection legislation is based on ICRPs

recommendations[1] and the latest European radiation protection directive[2] and on its transposition into national law; these also form the basis for the authorities' guidance and supervision.

Practices vary from one member state to another and even within one country there can be differences. This situation can be confusing and leads to great uncertainty for practitioners and especially for patients who directly experience different practices.

A modern regulatory body must be willing to adopt changes and ensure that their roles and tasks are up to date and follow the technological development in health care. It is not the role of the regulatory body to regulate the optimisation process in detail, instead it should encourage and promote the undertaking to set-up an integral quality management system, which includes the optimisation process. The responsibility for radiation safety and radiation protection lies on the undertaking. The regulatory body can act as an adviser and should be active in communicating radiation risk.

Optimisation of protection when applying a radiological procedure is a complex task. Reasons for this include a large number of different radiological practices, the rapid development of technology, and psychological factors such as patients' fears. Related decisions, including the decision about the use of contact shielding, should be made by the practitioner and the medical physics expert in a radiological facility as part of the optimisation process that must be applied to all radiological procedures. The responsibility for adequate implementation of the optimisation process lies with the undertaking of the radiological facility and should consider other techniques like collimating of the x-ray field, PA-projections, compression, automatic exposure control, , adjusting additional filtration, use of the optimum grid etc.

The purpose of this statement is to harmonize the use of contact shielding within the European countries by giving a general recommendation to the national authorities on how a decision-making process related to the use of patient contact shielding should be implemented in radiological facilities.

Position Statement on the use of contact shielding

Discussions regarding the use of patient contact shielding, e.g., lead aprons and shields, thyroid or gonadal protection continue at a national and international level. The main international organisations and associations have recently produced new or updated guidelines on when different types of contact shielding should be and conversely when contact shielding should not be used (see list in literature section below).

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

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

The Council Directive 2013/59/EURATOM has identified relevant aspects of optimisation principles to consider including:

- the selection of equipment, the consistent production of adequate diagnostic information, the practical aspects of medical radiological procedures, quality assurance, and the assessment and evaluation of patient doses or the verification of administered activities, taking into account economic and societal factors.
- the use of written protocols for every type of standard medical radiological procedure are established for each equipment for relevant categories of patients. The written protocols are part of the quality management system of the medical facility.
- the involvement of the practitioner, the medical physics expert and those entitled to carry out practical aspects of medical radiological procedures in the optimisation process and in the development and implementation of the written protocols.

A good integral quality management system is essential for good radiation protection regardless of where the examination takes place or who performs it. This quality management system must in particular contain the procedures for justification and optimisation and regulate the responsibilities. In analogy to the 3 levels in the justification process HERCA proposes considering these optimisation processes at 3 levels, as described below:

Level 1: Overarching optimisation principles

All doses due to medical exposure for radio diagnostic, interventional radiology, planning, guiding and verification purposes are kept as low as reasonably achievable consistent with obtaining the required medical information, taking into account economic and societal factors. The use of contact shielding in radiology for some indications may be useful and constitutes a radiation protection measure to limit the irradiated volume in the same way as e.g. actively collimating the x-ray field to reduce the overall integral radiation dose to the patient.

Level 2: Optimisation of protection – the methodology

It is the undertaking's responsibility to ensure that the radiation protection is optimized and that written protocols are in place and known. The written protocols for all standard medical radiological procedures shall include information regarding optimisation of radiation protection, including the application of patient contact shielding when appropriate. All relevant staff including practitioners and the medical physics experts must contribute to the written protocols. Specific detail on the additional education that can be used to manage an anxious patient should be included in these protocols.

Level 3: Optimisation of protection – application for individual patients' examinations

Those who carry out the medical radiological procedures should follow the written protocols. Exceptions can be made in individual cases following approval by the practitioner with advice from the medical physics expert if appropriate. The reason for not following the protocol must then be documented in the medical record.

The use of patient protection devices in X-ray diagnostics has changed considerably with protective devices only recommended in exceptional cases due to new knowledge and other techniques being more effective and efficient in the reduction of dose, like collimating of the x-ray field, PA-projections, compression, automatic exposure control, adjusting additional

filtration or use of the optimum grid etc. Whether to use patient contact shielding or not depends on the X-ray device and imaging techniques applied in each radiological facility, along with the education and training on the use of shielding. The appropriate use of contact shielding is best determined by the professionals (mainly the practitioners and the medical physics expert); regulating it in detail by the national authority should be avoided. The appropriate use of contact shielding should be stated in the written protocols of the radiological facility and put into practice by healthcare staff carrying out the medical radiological procedure. When written protocols are prepared by practitioners, medical physics experts and persons entitled to carry out practical aspects of medical radiological procedures, up to date national and/or international guidelines should be taken into consideration as they will provide an important input. The written protocols should be regularly reviewed and updated as new evidence becomes available and the use of these protocols should be included in clinical audits.

It is important to take into account the rapid technological developments in healthcare and the fact that new applications and new radiological procedures and techniques may be introduced where shielding may-be warranted.

Inspection:

At inspections and during other monitoring activities, the radiation protection authority's role is to make sure that written protocols are in place and that they are being implemented into practice. Noncompliance should lead to measures that aim to improve the practice (adapted behaviour and a revision of the quality management system). The authority also plays an important role in investigating, benchmarking and disseminating good practices between radiological facilities.

Communication:

Generally, the radiation protection authority should not interfere with the process as long as it is in line with the radiation protection principles.

Until new evidence becomes available, HERCA believes that radiation protection regulatory authorities should support implementation of the current guidelines regarding contact shielding. In some countries the international recommendations may represent a considerable change from the actual practice and subsequently their implementation may cause concern among some patients. It may thus be beneficial if regulatory authorities support implementation of the existing guidelines through adequate communication strategies, preferably in cooperation with the relevant professional bodies and the education and training institutions.

Conclusion and Key Message

The use of patient protection devices in X-ray diagnostics has changed considerably with protective devices only recommended in exceptional cases due to new knowledge and techniques being more effective and efficient in the reduction of dose.

1. The role of the regulatory body is to promote radiation protection, encourage the undertakings to set-up an integral quality management system to ensure optimization of all procedures in light of technological advances and to support staff in making decisions about patient contact shielding.
2. HERCA recommends to member states a decision-making process to be implemented in radiological facilities to identify when the use of patient contact shielding is beneficial. It is based on 3 levels:

    Level 1: Overarching optimisation principles

    Level 2: Optimisation of protection – the methodology

    Level 3: Optimisation of protection – application for individual patients' examinations

Until new evidence becomes available regulatory authorities should support the implementation of these guidelines through adequate communication strategies, preferably in cooperation with the relevant professional bodies and the education and training institutions. Communication with the general public is also warranted.

Further work is required which may include leaflet and/or web campaigns, information for patients in waiting or changing rooms and similar, but should also be reflected in the direct communication with concerned patients who may contact the regulatory authority.

Literature

The list includes national and international guidelines, but is not exhaustive.

- European consensus on patient contact shielding", Physica Medica 96 (2022) p. 198–203 Hiles P, Gilligan P, Damilakis J, Briers E, Candela-Juan C, Faj D, Foley S, Frija G, Granta C, de las Heras Gala H, Pauwels R, Sans Merce M, Simantirakis G, Vano E (2022) European consensus on patient contact shielding, Physica Medica Vol 96(2022), pg 198-203
- Guidance on using shielding on patients for diagnostic radiology applications, British Institute of Radiology, www.bir.org.uk, Published March 2020
- Use of patient contact shielding in the diagnostic application of X-rays in humans, German Commission on Radiological Protection SSK, www.ssk.de, Published September 2022
- American Association of Physicists in Medicine (2019) PS 8-A – AAPM Position Statement on the Use of Patient Gonadal and Foetal Shielding , April 2-3, 2019 AAPM Board of Directors Meeting Minutes *[Available from http://aapm.org/org/policies]*
- ICRP, 2013 Radiological protection in paediatric diagnostic and interventional radiology. ICRP Publication 121. Ann. ICRP 42(2).
- ICRP, 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann. ICRP 37 (2-4).
- IAEA, Radiation Protection and Safety in Medical Uses of Ionizing Radiation. Specific Safety Guide No. SSG-46, 2018