Objectives of publications of the HERCA Working Group on Medical Applications in the transposition of the Euratom Directive 2013/59 in the medical field

Poster No.: ESI-0096
Congress: EuroSafe Imaging 2019
Type: EuroSafe Imaging
Authors: B. C. Godthelp\textsuperscript{1}, K. Van Slambrouck\textsuperscript{2}; \textsuperscript{1}Authority Nuclear Safety and Radiation Protection (ANVS) Heads of the European Radiological Protection Competent Authorities (HERCA) - Working Group on Medical Applications The Hague/NL, \textsuperscript{2}Federal Agency for Nuclear Control (FANC) - Heads of the European Radiological Protection Competent Authorities (HERCA) - Working Group on Medical Applications Brussels/BE

Keywords: Nuclear medicine conventional, CT, Nuclear medicine, Radioprotection / Radiation dose, Action 13 - Stakeholder engagement and collaboration, Action 11 - Dialogue with industry, Action 3 - Image quality assessment based on clinical indications, Equipment, Technical aspects, Safety, Occupational / Environmental hazards, Radiotherapy techniques, Quality assurance

DOI: 10.26044/esi2019/ESI-0096

This PDF document has been automatically generated from a digital poster submitted online, and is meant for personal use only. Copyright restrictions might apply. Certain materials like for example videos - or multimedia files other than images in general, are not included in this PDF.
Background/introduction

Council Directive 2013/59/EURATOM lays down the basic safety standards for the protection against the dangers arising from exposure to ionising radiation. This includes the protection of workers, public and environment as well as protection of patients. All EC member states were obliged to bring into force the laws, regulations and administrative provisions that are necessary to comply with this Directive by 6 February 2018.

Heads of the European Radiological Protection Competent Authorities (HERCA) is a voluntary association in which the Heads of Radiation Protection Authorities work together in order to identify common issues and propose practical solutions for these issues. HERCA is working on topics generally covered by provisions of the EURATOM Treaty. The programme of work of HERCA is based on common interest in significant regulatory issues. HERCA brings together 56 radiation protection Authorities from 33 European countries.

Current fields of activity of HERCA include Medical Applications, Emergency Preparedness and Response, Veterinary applications, Research and Industrial Sources and Practices, Radon, NORM and Building Materials, and Education and Training.

HERCA activities on medical applications are under the responsibility of the Working Group on Medical Applications (WGMA). This HERCA working group is interested in all radiation protection issues concerning medical applications of ionising radiation for diagnosis, therapy and research, including patients and occupational exposures.

The WGMA focusses on:

• Enhancing common understanding and approaches, where possible, regarding the implementation of the radiation protection regulation, such as the council Directive 2013/59/EURATOM, on medical applications.
• Engaging in stakeholder involvement on radiation protection issues by:
  • enhancing the information exchange on best available radiation protection practices between regulatory bodies and other relevant competent authorities, professional bodies and organisations, professionals, manufacturers and suppliers and patient organisations.
  • Enhancing the exchange of scientific and technical knowledge and of experience, between stakeholders' representatives and regulatory bodies.
• Co-coordinating national efforts under the umbrella of HERCA to maximize impact in stakeholder involvement.

Since the publication of council Directive 2013/59/EURATOM, the WGMA has focused its work mainly on issues related to the directive transposition including development of a stakeholder/HERCA platform for discussion through the organization of several workshops and multi-stakeholders meetings, and the publication of position papers.
Description of activity and work performed

During the transposition period, the WGMA has been working on the following topics:

- Individual justification in radiology (article 55.2 (b) of 2013/59/EURATOM)
- Generic justification (article 55.2 (a) of 2013/59/EURATOM)
- Accidental or unintended exposures (article 63 of 2013/59/EURATOM)
- Inspection by the competent authorities
- Optimised use of CT scanners
- Non-medical imaging
- Clinical audit
- Medical Equipment (article 78 (2) of 2013/59/EURATOM)

Individual justification in radiology

A HERCA Position paper "Justification of Individual Medical Exposures for Diagnosis" has been published in October 2014. A multi-stakeholder meeting has been organised in 2014 and the work has been presented as a poster on ECR in 2015.

A MedInspector workshop has been organised in 2015 on "How to inspect justification and optimisation in diagnostic radiology" for inspectors from competent authorities from all over Europe. The goal was to exchange practises and experiences on how to inspect justification and optimization. During the workshop, recommendations and good practices on practical aspects have been identified.

After the workshop, a European Action Week "Inspection of justification in radiology" has been organised in 2016 with 18 participating countries using a common template for their inspections. An analysis has been performed on a European level and was presented at the "International Conference on Radiation Protection in Medicine: Achieving Change in Practice (2017)".

Currently the WGMA is working on an awareness campaign regarding this subject.

Generic Justification and Accidental or unintended exposures
A multi-stakeholder workshop has been organised in October 2016 both on Generic Justification and on Accidental or unintended exposures with 44 participants amongst which 12 participants from European and international stakeholder organisations.

On both subjects a position paper has been published. All information presented during the workshop is also freely available on the HERCA website.

HERCA WGMA has been a forum for discussion of many topics, in addition to the already mentioned topics non-medical imaging, clinical audit and medical equipment requirements have been discussed.

Clinical audits

Clinical audit has been the subject of many internal discussions and exchanges with several professional organisations (ESR, EANM, ESTRO) have taken place. A document summarising these discussions is currently under preparation.

Medical Equipment

In relation to medical equipment the WGMA has started regular exchanges with the manufacturers of medical devices through COCIR, in first instance in the context of the optimised use of CT devices. In the context of the implementation article 63 and 78 (2) of 2013/59/EURATOM the WGMA has started discussions with the manufacturers, this work is ongoing.

Inspection by the competent authorities

The first topic for inspection the WGMA has worked on has been diagnostic radiology starting with a workshop for HERCA inspectors in November 2016. In November 2018, a second workshop has been organized on nuclear medicine. In 2019, HERCA WGMA will continue to work on nuclear medicine issues and also on radiation therapy (including proton therapy) regarding patient and occupational exposures.
Conclusion and recommendations

Since 2010, the WGMA has organized more than 5 multi stakeholder workshops, 2 inspector workshops, 1 common action week on inspection of justification in radiology, and has published 10 position papers. The WGMA provides through these position papers tools to assist the proper transposition and implementation of these EU Directive-requirements. This included the individual justification as well as justification of new types or classes of practices and the accidental and unintended exposures. All HERCA papers are freely available on the HERCA website: www.herca.org.

Over the last years "transposition" of the EU-directive was the most important issue for the HERCA Member States. In the next years "implementation" of the EU-directive will be the most important issue.

In the coming years (2019-2021), the WGMA will assess the major changes which have occurred since the Directive transposition and the possible difficulties on selected topics such as generic justification, questions related to medical equipment (especially Art 78 of the BSS Directive), and clinical audits.

HERCA WGMA will continue to be a platform for the member states for sharing information on these topics among radiation protection authorities but also with the professional societies and the manufacturers.
Personal/organisational information

HERCA as an organization

The Heads of the European Radiological protection Competent Authorities (HERCA) was founded in 2007 on the initiative of the French Autorité de sûreté nucléaire (ASN). It is a voluntary association in which the heads of the Radiation Protection Authorities work together in order to identify common interests in significant regulatory issues and provides practical solutions for these issues. The uniqueness of HERCA is that it is composed of the heads of organizations that either have decision-making capacity or significant influence on policy and decisions within their countries. HERCA brings together 56 radiation protection authorities from 33 European countries (Figure 1). The present chairman of HERCA is Mrs. Karla Petrova, deputy chairman for radiation protection, state office for nuclear safety, Czech Republic. The structure of HERCA is illustrated in Figure 2.

HERCA Working Group on Medical Applications (WGMA)

The HERCA Working Group on Medical Applications (WGMA) covers all radiation protection issues concerning the medical applications of ionizing radiation for diagnosis and treatment. Its activities are conducted as work packages and include discussions, surveys, hosting stakeholder meetings and publishing position papers on key issues.

For more information about HERCA, please visit our website www.herca.org.
Fig. 1: HERCA Member States

**Fig. 2:** HERCA Organisation

References


2017 November: HERCA report: CT manufactures Stakeholder Involvement

http://herca.org/docstats/CT%20manfacturer%20involvement.pdf

2017 November: HERCA position paper on the Justification of New Types or Classes of Practices In the Medical Field


2017 June : HERCA Position Paper Accidental and Unintended Medical Exposures

http://www.herca.org/docstats/HERCA%20position%20paper%20AUE%20%28May%202017%29.pdf

2014 Oct and 2016 Feb (addendum) : HERCA CT Position paper The process of CT dose optimization through education and training and the role of the manufacturers
