



Mandate and Action Plan for 2022-2025

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I. MANDATE

1. Introduction

The HERCA WG on Medical Applications (later called WG MA in this document) is interested in all radiation protection issues concerning medical applications of ionising radiation for diagnosis-, therapy- and research-purposes. This includes medical exposures (patient, carers and comforters, biomedical research), occupational exposure and public exposures. The focus of the WG MA is on developing common understanding and approaches, where possible, regarding the

implementation of radiation protection regulations in Europe, including those related to new medical applications and requirements.

2. Mission

The HERCA WG MA shall:

2.1 Enhance common understanding and approaches, where possible, regarding the implementation of the radiation protection regulations on medical applications, focusing on justification and optimisation by:

- a. Sharing among regulatory bodies examples of good practice in implementing the radiation protection regulations on medical applications.
- b. Enhancing the exchange of knowledge on the technical and scientific aspects of radiation protection of new medical applications.
- c. Preparing position papers and guidance for implementing radiation protection principles and regulations on medical applications.
- d. Highlighting and reporting through HERCA, needs for developing European guidance and providing advice on implementing and amending existing directives, from the perspective of regulators.

2.2 Engage in stakeholder involvement on radiation protection issues by:

- a. Enhancing the exchange of information on best available radiation protection practices between regulatory bodies and other relevant competent authorities, professional bodies and organisations, professionals, manufacturers and suppliers and patient organizations.
- b. Enhancing the exchange of scientific and technical knowledge and experience, between stakeholder's representatives and regulatory bodies.
- c. Coordinating efforts under the umbrella of HERCA to maximize impact in stakeholder involvement.

2.3 Give advice on radiation protection issues in medical practice by:

- a. Active participation in EU projects (either as member of the advisory board, steering committee or as participants of these projects).
- b. Critical evaluation of these projects in order not to duplicate previous work (by WG MA or professional bodies).

3. Organization

3.1 The organization of the WG MA consists of:

- members, which have to be nominated officially by their national authority.
- a chair and a co-chair for two years proposed by the WG MA members and approved by the BoH of HERCA.

Normally, the co-chair will become the next chair after a period of two years. However, exceptions are possible after approval of the WG MA and the BoH.

The term of a new chair and co-chair starts after the autumn BoH meeting.

- a secretary.
 - a core group, consisting of the chair, the co-chair, the secretary, the immediate past chair and the leaders of the work packages (WP) and task forces (TF). The core group will strengthen its work by organizing video meetings and teleconferences. The core group will prepare the meetings of the WG MA and discuss ad hoc topics.
 - Work packages and task forces of WG MA that execute proposed actions, are led by a Work Package/Task Force leader, who is chosen among the members of the WG MA, and composed of collaborators, also members of WG MA. In specific cases and as required, external experts and/or observers may be invited to participate in dealing with the subject matters of the work packages.
 - ad hoc invited experts.
 - invited observers from international organizations WHO, IAEA, EC participate in WG MA's meetings, depending on the topics to be discussed; additionally, the working group could invite an ad-hoc representative of an organisation (e.g., FDA, NCRP).
- 3.2 The WG MA will meet in plenary twice a year. The core group will meet on invitation of the chair as necessary, preferably by video and teleconferences. The members of work package groups will meet according to the current needs. The exchange of information in WG MA will be facilitated by use of the HERCA web page and by e-mail. Further communication and dissemination of information in WG MA will be arranged to increase interaction among the members of the working group.
- 3.3 The HERCA WG MA maintains contacts with the "Medical Exposures" Working Party of the Article 31 group of experts in which it has a representative, and with WHO and IAEA. Furthermore the WG MA shall establish contacts with other relevant groups to collaborate and to avoid duplication of efforts.
- 3.4 The actions of the WG MA on medical applications will be carried out in work packages or task forces. Each of the work package/task force groups will define their work in an action plan, which will be submitted to the WG MA plenary meetings for discussions and further to the HERCA BoH for approval. The WG MA can nominate responsible members for preparation of a task or for acting as a contact person between the WG MA and a stakeholder group.

4. Scope and Methodology

The WG MA intends to:

- 4.1 Enhance the best available practices of radiation regulatory bodies to support the implementation of justification and optimization and safe practice in the medical field. These activities will be based on international and European initiatives on the one hand, and on field observations, including reported incidents and accidents, on the other. The scope will be:
- a. medical radiological imaging: radiography, fluoroscopy, computed tomography, interventional radiology, nuclear medicine (including hybrid imaging like PET-CT) and emerging technologies. Special focus will be on applications characterized by high(er) delivered doses and/or when sensitive patient subgroups are implicated, on the increase of collective dose, on worrisome individual doses to some subgroups of patients and also on exposure of asymptomatic individuals in health care;
 - b. Radiotherapeutic applications: external beam therapy, brachytherapy and metabolic therapy including planning and verification.
A special focus will be on prevention of accidents and unintended exposures in modern radiation therapy and radionuclide therapy;
 - c. research uses of ionizing radiation in medicine;
 - d. dose limits and dose constraints;
 - e. other types of practice as appropriate (e.g., non-medical imaging using medical radiological equipment)
- 4.2 Engage in stakeholder involvement (relevant organisations and bodies for patients, medical and technical staff, medical physicists, manufacturers of radiological devices etc).
- 4.3 Provide advice on radiation protection issues in medical practice by participation in relevant EU projects.
- 4.4 As previously, HERCA WG MA will continue to speak and present (when invited) at important international conferences to inform the wider community of its activities.

II. MAJOR ACHIEVEMENTS FOR THE PERIOD 2018-2021

Position papers/Reports

2019 October: HERCA Position paper on 'Clinical audit in medical radiological practices'
<https://www.herca.org/download/4739/>

2021 March: HERCA Internal Final Report from the Work package Equipment
<https://www.herca.org/herca-report-on-equipment/>

2021 March: HERCA Public Final Report from the Work package Equipment
<https://www.herca.org/download/4758/>

2021 March: HERCA Position paper on Proton therapy for competent authority use
<https://www.herca.org/documents/>

2021 June: HERCA Resume of Position paper on 'Proton therapy'
<https://www.herca.org/download/4761/>

2021 June: Addendum to the HERCA position paper on Clinical Audit
<https://www.herca.org/documents/>

2021 June: HERCA Internal Report from the Work package Awareness

Workshops and Multi-stakeholder meetings

2018 November 6-8: MedInspector Workshop 'How to inspect Justification and Optimization in Nuclear Medicine' (Stockholm, Sweden)

Agenda, presentations and conclusions: <https://www.herca.org/medinspector-workshop-2018/>

Common action at European level

2019 November 8: HERCA Awareness campaign 'Getting the right image for my patient'
<https://www.herca.org/getting-the-right-image-for-my-patient-2/>

Presentations and Publications

Presentations (oral and poster) at a range of important international radiation protection and medical conferences.

Articles were published in the EFOMP journal on the awareness campaign of 2019 and on the work carried out by the WP Equipment on DAP harmonization.

III. ACTION PLAN FOR 2022-2025

1. Orientation and topics of interest

The main areas of interest of the WG MA are:

- Inspection skills
- Nuclear medicine
- Clinical audit
- Radiation therapy
- Justification
- Optimization of imaging
- Interventional radiology
- Unintended and accidental exposures
- Involvement of medical physics experts

Since the transposition of the 2013/59/Euratom directive, laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation (EU BSSD), in February 2018 in the national legislation of the respective HERCA member states, the WG MA focused its work mainly on issues related to the practical implementation of the EU BSSD directive. This included the development of a stakeholder/HERCA platform for discussion through the organization of several workshops and multi stakeholders meetings, and the publication of position papers.

For the 2022 – 2025 period, the WG MA plans to focus its work on further questions related to the implementation of the EU BSSD Directive with special attention towards sharing information between the member states and dissemination of information in the member states.

The involvement of stakeholders will continue to be part of the WGMA method of working as done in the previous 2018-2021 period.

The WG MA has identified the need for further work on:

- Patient protection, including patient shielding
- Non-medical imaging: legal framework, including justification
- Interventional radiology: medical and occupational exposures
- Optimization of imaging
- New technologies, including digital breast tomosynthesis (and its role in screening), artificial intelligence (reconstruction, operator assistance, image evaluation, justification, ...)
- Medical radioactive waste
- Paediatric imaging
- Communication of risk

These topics will be considered as information sharing topics or in new work packages and/or task forces to be created and approved.

The WG MA also will focus on its **advisory role** in the 2022-2025 period. This will be done by the active participation in EU projects, either as participants, in advisory boards or steering committees, on topics related to our mandate. It should be noted that WG MA members who participate in the EU projects do not participate in general as simple observers. They participate actively not only by giving their expert opinion on project outcomes but also by actively participating in meetings and workshops with presentations and in the development of project documents.

The WG MA members will also participate actively in IAEA technical meetings when required. Until now, the WG MA has focused its work mainly on radiology (individual justification, CT manufacturers, inspections, and awareness) and nuclear medicine, and to a lesser extent on interventional radiology and radiation therapy.

2. Working Group Chairpersons and Secretariat

For the period 2022-2023 the WG MA will be chaired by Barbara Godthelp (ANVS, The Netherlands) and co-chaired by Katrien Van Slambrouck (FANC, Belgium). The WG MA secretariat will be fulfilled by Karen Fuller (HSE, UK).

3. Work packages and task forces

The WG MA will conduct its work in work packages and task forces. Each work package or task force defines its goals and milestones in its own action plan.

Work packages for the considered time period as agreed by the BoH:

Work package "Inspection" – Action: Radiotherapy

WP Coordinator	Eva G. Friberg (Norway)
Chair of action	Philipp Trueb (Switzerland)
WP members	Petr Papirnik (Czech Republic), Sampsa Kaijaluoto (Finland), Richard Elek (Hungary), Torsten Cederlund (Sweden), Dejan Zontar (Slovenia), Herbert Michalczak (Germany), Rachael Ward (United Kingdom)

Work package "Clinical audit"

WP Coordinator	Rachael Ward (United Kingdom)
WP Members	Alexandra Schreiner (Luxembourg), Maria Kalathaki (Greece), Hanne Waltenburg (Denmark), Ritva Bly (Finland), Eva Friberg (Norway), Carine Galli Marxer (Switzerland), Marleen Vandecapelle (Belgium), Petr Papirnik (Czech Republic)

Work package "Nuclear Medicine"

WP Coordinator	Ritva Bly (Finland)
WP Members	Nicolas Stritt (Switzerland), Sampsa Kaijaluoto (Finland), Veronika Stedrova (Czech Republic), Herbert Michalczac (Germany), Barbara Godthelp (Netherlands), Karen Fuller (United Kingdom), Torsten Cederlund (Sweden), Marleen Vandecapelle (Belgium), Richárd Elek (Hungary)

The action plan of this work package can be found in annex I.

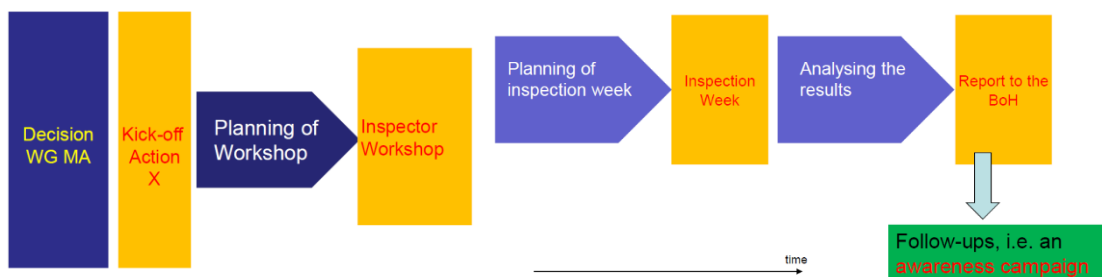
Proposal for structural tasks for 2022-2025

Work package "Inspection" (permanent since 2018)

WP Coordination	Eva G. Friberg (Norway), Co-chair: Collette O'Connor (Ireland)
WP Core group	WP Chair and co-chair together with "chair of action"

The action plan of this work package can be found in annex II.

The WP "Inspection" serves a structural role in our new action plan 2022-2025. An inspector workshop can be organized with support of this structural WP "Inspection", after which a European Action week can be organized that will focus on inspection dedicated to the workshop topic. This approach is demonstrated in the figure below.



Work package "Awareness in medical exposures"

WP Coordination	Maria Kalathaki (Greece) and Hanne Waltenburg (Denmark)
WP Core group	WP Chair and co-chair together with “chair of action”, when appropriate

The “Awareness in medical exposures” work package will serve a more structural role in our new action plan 2022-2025. The “Awareness” WP can support other topical WP when questions arise, for example after European Action weeks.

Information sharing platform

PL Coordination	PL-coordinator: Katrien Van Slambrouck (Belgium), PL-co-coordinator Aurélie Isambert (France)
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The WG MA has identified a need for more structural information sharing and dissemination of information.

1. Exchange of information within the WG MA

Organisation of the special focus sessions with the aim of information sharing and to stimulate discussion between the HERCA member states.

These are topical sessions based on the topics in point 2 and other issues raised by the working group.

For some of the topics external experts or organisations will be invited. Therefore, the liaison with COCIR will be maintained within this group.

2. Dissemination of information

Organisation of WG MA webinars to disseminate the work published in position papers, statements, public information reports etc.

Proposal for new Work Packages and Task forces in 2022-2025

Task force "Patient protection"

TF Coordination	Rachael Ward (UK) and Philipp Trueb (Switzerland)
TF members	<i>To be determined</i>

This task force will focus on the protection and safety of patients including patient shielding and other ways to protect the patient during imaging procedures. The task force will pay special attention to the role of the different stakeholders and communication with them.

Other work packages or task forces

Other possible work packages/task forces need further consideration. The topics under point 2 will first be treated as an information sharing topic upon which the WG MA can express a wish to further work on that specific topic and hence a proposal will be made for the BoH.

The task force Proton Therapy has finalized its job but can be reactivated if development of new technologies requires modification of the practical document

IV. CURRENT NOMINATED PERSONS

- Hanne Waltenburg: Responsible for keeping contacts to HERCA countries to get information on published national surveys of collective effective doses and updated diagnostic reference levels. Responsible also for encouraging countries to participate in international surveys on collective effective doses.
- Alexandra Karoussou-Schreiner has been nominated as the HERCA WG MA observer with the Working Party “Medical Exposures” of the Article 31 group of experts.
- Alexandra Karoussou-Schreiner has been nominated as a member of the ESR standards and clinical audit subcommittee.
- Sarah Peters has been the nominated person for our collaboration with IEC.
- Katrien Van Slambrouck has been nominated as member of the advisory board of the EURAMED Rocc-n-roll project
- Alexandra Karoussou-Schreiner has been nominated as a member of the MEDIRAD stakeholder forum.
- Rachael Ward has been nominated as member of the advisory board of the Quadrant project.

ANNEX I (note: AIPES has meanwhile changed its name to NMEU = Nuclear Medicine Europe)**Action Plan****HERCA WGMA
WP on Nuclear Medicine****Author:** R. Bly**Scope and Objectives**

The previous work of the WGMA has been focusing on radiology and only release of I-131 therapy patients was dealt in a specified WP in the early years of HERCA. The number of nuclear medicine procedures is increasing because of new techniques of hybrid imaging (PET-CT and SPECT-CT) and new radionuclides for therapy. Hybrid imaging procedures are high dose diagnostic procedures and therapeutic use of radiation is always a concern of radiation safety.

Objectives of the WP on Nuclear Medicine are:

- to improve inspection knowledge and skills on nuclear medicine with a special focus on optimization;
- to strengthen implementation of the BSS Directive on the field of nuclear medicine;
- to improve optimization in practice by continuing the collaboration with EANM;
- to improve optimization in practice by establishing co-operation with other relevant bodies such as AIPES (Association of Imaging Producers & Equipment Suppliers).

Actions**1. Inspection weeks on optimization in nuclear medicine**

HERCA WGMA has good experience on previous Action Week on justification in radiology. The similar methodology would be used to carry out on Action Weeks on optimization in nuclear medicine. Work sheets for inspections would be developed in the WP and inspections would be carried out during a few weeks at a specified time frame. The conclusions of the week would be published preferably in an international conference to increase awareness of the need for optimization of medical exposure in nuclear medicine.

2. Self-commitment of manufacturers for optimization in nuclear medicine

HERCA should actively seek cooperation with AIPES (Association of Imaging Producers & Equipment Suppliers) to emphasize importance of optimization of medical exposures and the need for dosimetry software and training on them to be part of the package of therapy radionuclides. The methodology to be used in this action would be, as previously with COCIR, to establish a self commitment by AIPES. Based on previous experience, it might take a couple of years to achieve the goals in the self-commitment, but there should be some mile stones and follow-up meetings to strengthen the work. More detailed plan would be introduced to HERCA for approval after the first meeting with AIPES. The results of the fulfilled self-commitment would be published jointly with AIPES. Moreover, a press conference at an EANM Conference might be possible to disseminate the results.

3. Position Paper on Implementation of new issues in BSSD in nuclear medicine

Transposition and implementation of the following Articles of the BSS Directive should be surveyed and further discussed in the HERCA WG MA:

- Article 56.1. "For all medical exposure of patients for radiotherapeutic purposes, exposures of target volumes shall be individually planned and their delivery appropriately verified taking into account that doses to non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure."
 - Large differences were identified in the practices among hospitals in Europe: a few perform dosimetry, software is more in test use under development or there is a lack of evidence regarding the use of them.
 - Co-operation between HERCA and EANM might increase awareness of HERCA inspectors on possibilities of dosimetry tools and EANM might support hospitals to implement new regulations based on the Article 56.1.
 - HERCA might co-operate with AIPES (Association of Imaging Producers & Equipment Suppliers) to emphasize the need for dosimetry software to be part of the package of therapy radionuclides.
- Article 58 d) i) "in radiotherapeutic practices other than standardised therapeutic nuclear medicine practices, a medical physics expert shall be closely involved;"
 - Large differences were identified in interpretation of the Article.
 - HERCA statement on implementation of the Article might support national practices.
- Article 61.1 "Member States shall ensure that appropriate medical radiological equipment, practical techniques and ancillary equipment is used in medical exposure... Special attention shall be given to quality assurance programmes and the assessment of dose or verification of administered activity for these practices."
 - HERCA might co-operate with AIPES (Association of Imaging Producers & Equipment Suppliers) as previously with COCIR to emphasize optimization of medical exposures.

A HERCA Position Paper would be published based on the work carried out in the WP. The Position Paper would focus on implementation of new issues in BSSD on nuclear medicine to conclude the current situation and to disseminate good practices and information on available methodologies for dosimetry of new therapeutic radionuclides.

ANNEX II (the workpackage's action plan mentioned spring 2022 as possible date for the next inspector workshop, due to the evaluation of the pandemic situation, this will not be possible and will rather be 2023)



Action Plan 2022-2025

HERCA WGMA WP Inspection

Author: Eva G. Friberg

Background

HERCA WGMA has identified that regulatory bodies have an important role in promoting and ensuring that justification and optimization is properly implemented for medical exposure. To be able to take on this responsibility, inspectors need to have sufficient clinical competence. The WP Inspection competence of authorities was created around 2011 with a focus on increasing the clinical competence of inspectors working at regulatory authorities within the field of medical exposure. Three actions were performed during the first Action Plan period:

- 1) a survey on clinical competence of inspectors among the member states (2012)
- 2) clinical training courses for inspectors in UK (2012-2014)
- 3) 1st HERCA Inspection Workshop on radiology (2015).

After the first Action Plan period, the focus of the WP has changed. In the following period, a European Action Week on inspection of justification in radiology (2016) and the 2nd HERCA Inspection Workshop on NM (2018) were performed.

The future of the WP Inspection Competence of authorities was discussed at the WGMA meeting in Athens in September 2018. It was agreed that the WP should continue on a more permanent basis with its main purpose to organise Workshops, Inspection Weeks and other identified actions related to inspections. The BoH approved this proposal at the Paris meeting in October 2018. As a consequence, the WP has changed its name to WP Inspection. The mandate and Action Plan will continuously be updated for a 3 year period based on discussions and conclusions made by the WGMA.

Scope and Objectives

WP Inspection will focus on organizing identified HERCA actions related to inspections of medical exposure, like Inspection Workshops, European Action Weeks on inspections, etc. The objective of these actions will be to increase awareness and to identify the needs in different topics related to inspections of medical exposure. Results from the actions will give input to existing WPs or identify the need for special Task Force groups or the creation of new WPs to address the identified issues.

Organization of the WP

The WP Inspection will be organized on a permanent basis and lead by a chair and co-chair to ensure continuity of the WP and to ensure that experience from previous actions is taken into account in the planning of new actions. For each new action to be performed, new WP members with relevant knowledge and competence related to that specific action will be identified. One of these members will take on the role as chair of the planned action ("chair of action"). To ensure progress and to facilitate discussions there will be a "core group" containing the permanent chair, co-chair and "chair of action". WP Inspection will have close cooperation with other existing WPs working in the relevant field, if any.

Chair: Eva G. Friberg (Norway)

Co-chair: Collette O'Connor (Ireland)

Constitution of "Core-group": WP Chair and co-chair together with "chair of action"



Action Plan on WP Inspection

Identified actions

The WP is still planning to organize the Inspection Workshop on radiotherapy that was planned for the autumn of 2020. The WS was postponed due to the covid-19 pandemic, but hopefully it will be possible to organize in spring 2022.

The Action Plan will not contain a list of identified actions. New actions will be identified during future WGMA meetings. It is important that the WP is flexible and that actions to be performed are within an agreed topic and time frame discussed and approved during future WGMA meetings.

HERCA actions to be performed need to be approved by the WGMA and the BoH and an Action Description Plan must be prepared for each action. This plan must at a minimum cover: the action to be performed, the associated WP-members, the chair of action, time-frame, budget and hosting country (if any).