

ALARA in medical applications of ionizing radiation

The HERCA workgroup on medical applications experience

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HERCA

- **Heads of Radiation Protection Authorities (HERCA):** voluntary association
- Working on topics generally covered by EURATOM Treaty
- Work program: based on common interest in significant regulatory issues

Participation

32 countries
(the 28 EU MS + Iceland, Norway, Switzerland and Serbia)

56 organisations
(RPA + TSO), + 330 nominations

Observers
EC, IAEA, WHO, US FDA, OECD/NEA



HERCA Structure & Functioning

Board
Managerial Level

Technical Secretariat

Terms of Reference
& HERCA Policies

Chairmanship

Jean-Luc Lachaume ASN,
France (since 2023)

Working Groups (WG)

Emergencies

Medical Applications

Veterinary Applications

Research & Industrial Sources & Practices

Education & Training

Natural Radiation Sources - NEW

Networks (NT)

Dose Passbook/Outside workers

Collective medical doses

Task Forces (TF)

Workshops (WS)

Overview HERCA WGMA

Ongoing Work Packages, Task Force and Platform

- a) WP Inspection
- b) WP Clinical audit
- c) WP Nuclear medicine**
- d) WP New Technologies**
- e) TF Patient protection
- f) TF Non-medical Imaging
- g) Platform on information sharing



MEDICAL
APPLICATIONS

Structural Work Package

- a) Awareness in medical exposures

EU-BSS directive requirements on ALARA in medical applications

17.1.2014

EN

Official Journal of the European Union

L 13/1

II

(Non-legislative acts)

DIRECTIVES

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

EU-BSS directive requirements on ALARA in medical applications

Considerations

14) New scientific information on tissue reactions calls for the optimisation principle to be applied to equivalent doses as well, where appropriate, in order to keep doses **as low as reasonably achievable**. This Directive should also follow new ICRP guidance on the limit for equivalent dose for the lens of the eye in occupational exposure.

Article 5 General principles of radiation protection

Member States shall establish legal requirements and an appropriate regime of regulatory control which, for all exposure situations, reflect a system of radiation protection based on the **principles of justification, optimisation and dose limitation**:

(a) **Justification**: Decisions introducing *a practice shall be justified in the sense that such decisions shall be taken with the intent to ensure that the individual or societal benefit resulting from the practice outweighs the health detriment that it may cause.*

EU-BSS directive requirements on ALARA in medical applications

Article 5 General principles of radiation protection cont'd

(b) **Optimisation**: Radiation protection of individuals shall be optimised with the aim of keeping the **magnitude of individual doses**, the **likelihood of exposure** and the **number of individuals** exposed **as low as reasonably achievable** taking into account the *current state of technical knowledge and economic and societal factors*.

The optimisation of the protection of individuals subject to **medical exposure** shall apply to the **magnitude of individual doses** and be **consistent with the medical purpose of the exposure**

EU-BSS directive requirements on ALARA in medical applications

Article 5 General principles of radiation protection cont'd

(c) **Dose limitation**: In planned exposure situations, the *sum of doses to an individual shall not exceed the dose limits* laid down for occupational exposure or public exposure. **Dose limits shall not apply to medical exposures.**

EU-BSS directive requirements on ALARA in medical applications

Article 56 Optimisation

1. MS shall ensure that **all doses due to medical exposure are kept as low as reasonably achievable** *consistent with obtaining the required medical information, taking into account economic and societal factors.*

For all medical exposure of patients for **radiotherapeutic purposes**, **exposures of target volumes** shall be **individually planned** and **verified** taking into account that **doses to non-target volumes and tissues shall be as low as reasonably achievable**

2. Member States shall ensure the establishment, regular review and **use of diagnostic reference levels** for radiodiagnostic examinations, and where appropriate, for interventional radiology procedures, and the availability of guidance for this purpose

EU-BSS directive requirements on ALARA in medical applications

Article 56 Optimisation cont'd

4. Member States shall ensure that the **optimisation includes the selection of equipment**, the consistent production of adequate diagnostic information or therapeutic outcomes, 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.

EU-BSS directive requirements on ALARA in medical applications

Article 56 Optimisation cont'd

5. Member States shall ensure that:

- (a) **dose constraints** are established for the exposure of **carers and comforters**, where appropriate;
- (b) **appropriate guidance** is established for the exposure of **carers and comforters**.

6. Member States shall ensure that in the case of a patient undergoing **treatment or diagnosis with radionuclides**, the practitioner or the undertaking, as specified by Member States, provides the patient or their representative with **information on the risks of ionising radiation** and **appropriate instructions** with a view to restricting doses to persons in contact with the patient as far as reasonably achievable



PAPER • OPEN ACCESS

Radiation safety of current European practices of therapeutic nuclear medicine: survey results from 20 HERCA countries

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View the [article online](#) for updates and enhancements.

Radiation safety of current European practices of therapeutic nuclear medicine

- Survey results from 20/32 HERCA countries (WP NM)

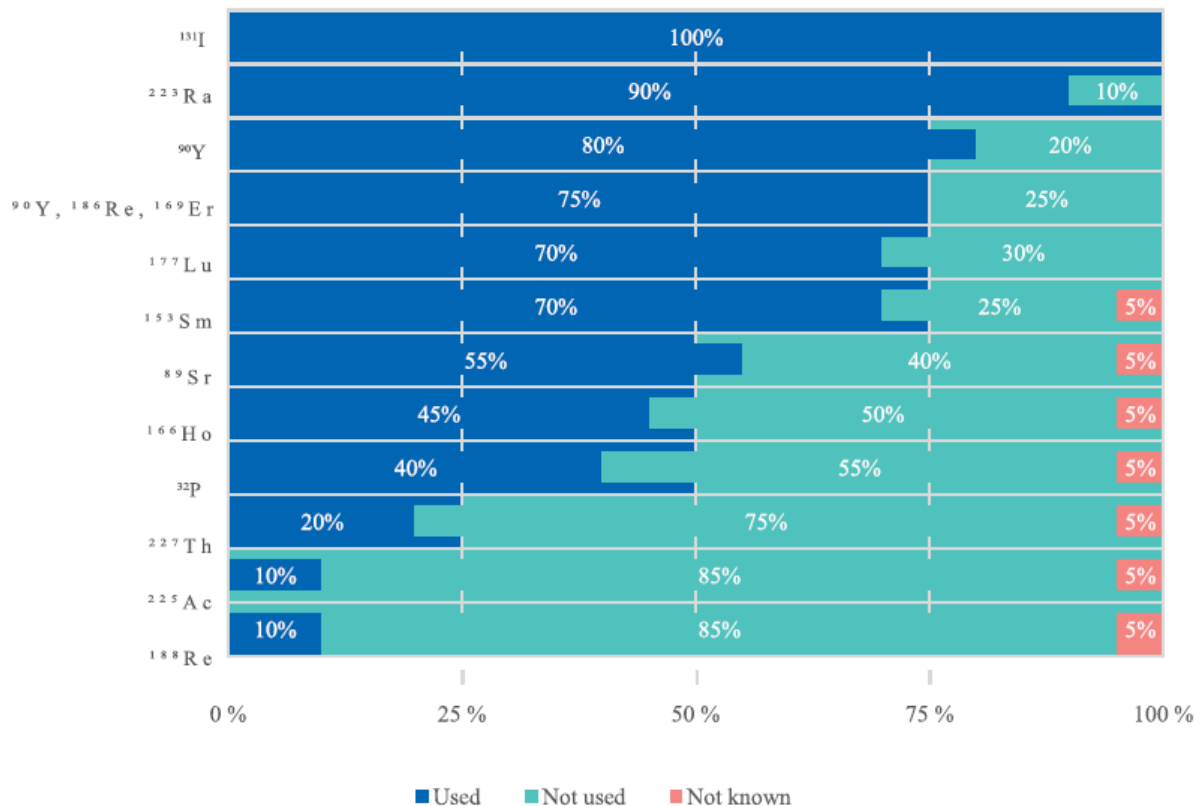


Figure 1. Therapeutic use of radionuclides in 20 European countries per radionuclide licensed by a radiation protection authority.



Radiation safety of current European practices of therapeutic nuclear medicine

- Justification of new radiopharmaceuticals
 - Regulatory requirements in 85% of responders
- Individual treatment planning and –verification
 - For all radionuclide therapies in 55%, some therapies in 30%, not required in 15 % of responders
 - Dosimetry in 85% of the responders (^{90}Y -labelled microspheres, ^{131}I , ^{166}Ho -labelled microspheres, ^{177}Lu -labelled PSMA)
 - Verification required in 45 % of the responders, by measurements in 45% of responders

Radiation safety of current European practices of therapeutic nuclear medicine

- Radiation protection instructions
 - Instructions for patients in 19/20 responders
 - Instructions deceased recently treated patients in 70 %, cremation in 65 % responders
 - Release criteria in all responders
 - Patient release card (HERCA)

Medical Treatment Card

The under named patient has undergone a medical treatment with a radioactive substance. This person left the treatment unit after verification according to International safety standards. Radiation safety can therefore be guaranteed, provided the instructions given to the person are observed.

Patient ID	Radioactive substance :
Full name:	Isotope:
Address:	Time of administration DD/MM/YYYY
	Activity administrated : MBq

National authority address and logo

This card should be carried at all times until dd/mm/yyyy

In case of emergency

Information about this patient can be given by :

Contact	:	X
Institution	:	Y
Phone number	:	000000000000000
Email	:	

HERCA
Heads of the European Radiological protection Competent Authorities

Card developed by:

This card should be carried at all times until dd/mm/yyyy

2011



EU-BSS directive requirements on ALARA in medical applications

Article 78 Information on equipment

1. Member States shall ensure that any undertaking acquiring equipment containing radioactive sources or a radiation generator is provided with **adequate information about its potential radiological hazards** and its **proper use, testing and maintenance**, and with a demonstration that the **design permits to restrict exposures to a level which is as low as reasonably achievable**.
2. Member States shall ensure that any undertaking acquiring medical radiological equipment is provided with **adequate information on the risk assessment for patients**, and on the available elements of the clinical evaluation.

HERCA Working group on
Medical Applications
-
HERCA report on Equipment

January 2021

Questions

