HERCA

Heads of the European Radiological protection Competent Authorities

Interations with other regulations

The HERCA WGMA's view

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Overview HERCA WGMA

Ongoing Work Packages, Task Force and Platform

a) WP Inspection

b) WP Nuclear medicine

c) WP New Technologies

d) TF Patient protection

e) TF Non-medical Imaging

f) Platform on information sharing

MEDICAL APPLICATIONS

Structural Work Package

a) Awareness in medical exposures

EU-BSS directive requirements on use of medical equipment

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 use of medical equipment

Article 56 Optimisation

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.

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 -Directive and -Regulation on use of pharmaceuticals

EUROPEAN
COMMISSION

Brussels, 26.4.2023
COM(2023) 192 final

2023/0132 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/E(

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006

EU -Directive and -Regulation on use of pharmaceuticals

Pre-ambule pharma Directive

(19) This Directive should be without prejudice to the **provisions of Council Directive 2013/59/Euratom**, including with respect to justification and optimisation of protection of patients and other individuals subject to medical exposure to ionising radiation.

In the case of **radiopharmaceuticals used for therapy**, marketing authorisations, posology and administration rules have to notably **respect that Directive's requirements that exposures of target volumes are to be individually planned, and their delivery appropriately verified** taking into account that doses to non-target volumes and tissues are to be as low as reasonably achievable and consistent with the intended therapeutic purpose of the exposure.

- Not in articles Directive

EU -Directive and -Regulation on use of pharmaceuticals

Pharma Directive

Article 28 on adapted frameworks due to the characteristics or methods inherent to the medicinal product

- Radiopharmaceutical development by non-commercial entities/small scale preparations, not compliant with industrial GMP (statement EANM)

→ Specific standards for radiopharmaceuticals?

EU-BSS directive requirements on use of medical equipment – *HERCA WGMA experience*

Article 58 Procedures

Member States shall ensure that:
(a) written protocols for every type of standard medical radiological procedure are established for each equipment for relevant categories of patients;
(b) information relating to patient exposure forms part of the report of the medical radiological procedure

HERCA WGMA WP Equipment:

- Standardisation of DAP units
  - Gycm2 for interventional radiology
  - mGycm2 for general radiography
  - Contact with IEC/EFOMP

→IEC standards

EU-BSS directive requirements on use of medical equipment

Article 60 Equipment
Article 61 Special practices

- Quality assurance programmes
- Assessment of dose or verification of administered activity
- Relevant parameters for assessing the patient dose
- Transfer of information
- Special attention to interventional radiology and NM

Article 78 Information on equipment

- Adequate information about its potential radiological hazards and its proper use, testing and maintenance
- Adequate information on the risk assessment for patients

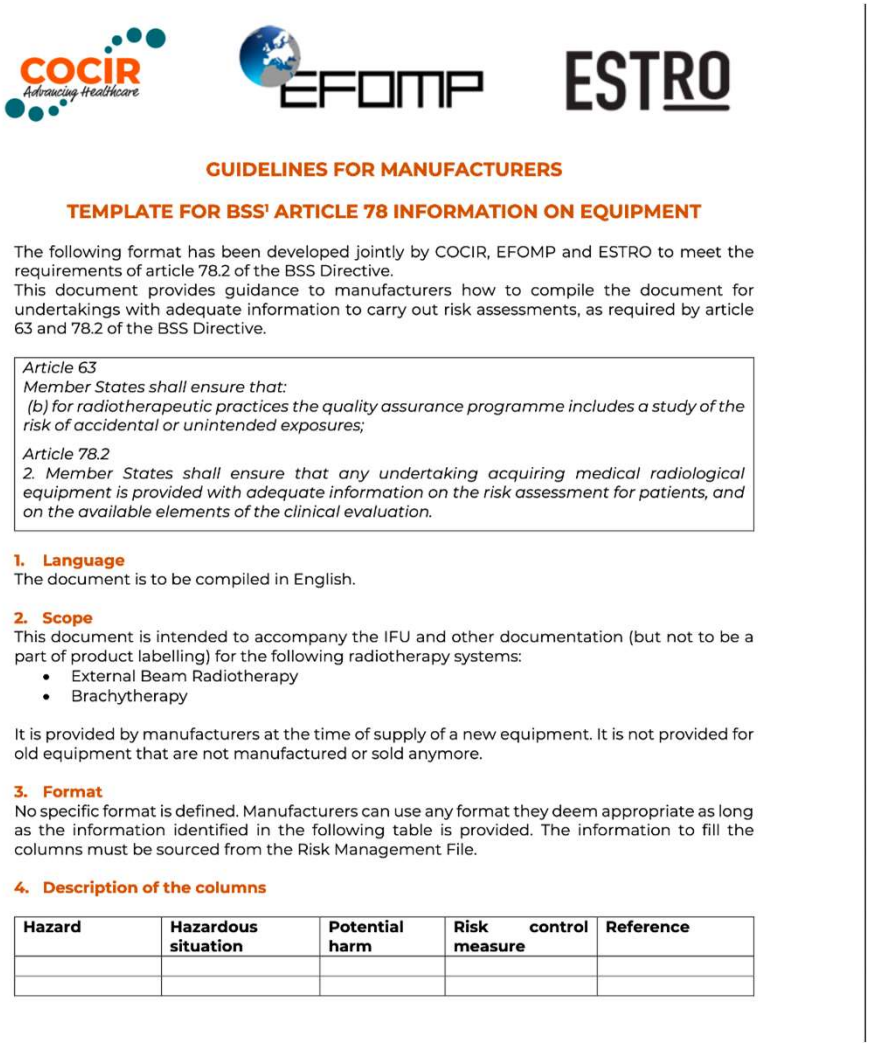
HERCA report on equipment

Implementation Article 78 Information on equipment

- Interaction between HERCA WGMA WP equipment with COCIR
- Publication of Guidelines for manufacturers together with ESTRO and EFOMP: COCIR: TEMPLATE FOR BSS ARTICLE 78 INFORMATION ON EQUIPMENT

HERCA
HEADS OF THE EUROPEAN RADIOLOGICAL PROTECTION COMPETENT AUTHORITIES

HERCA Working group on
Medical Applications
-
HERCA report on Equipment



COCIR Advancing Healthcare · EFOMP · ESTRO

GUIDELINES FOR MANUFACTURERS

TEMPLATE FOR BSS' ARTICLE 78 INFORMATION ON EQUIPMENT

The following format has been developed jointly by COCIR, EFOMP and ESTRO to meet the requirements of article 78.2 of the BSS Directive.
This document provides guidance to manufacturers how to compile the document for undertakings with adequate information to carry out risk assessments, as required by article 63 and 78.2 of the BSS Directive.

Article 63
Member States shall ensure that:
(b) for radiotherapeutic practices the quality assurance programme includes a study of the risk of accidental or unintended exposures;

Article 78.2
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.

1. Language
The document is to be compiled in English.

2. Scope
This document is intended to accompany the IFU and other documentation (but not to be a part of product labelling) for the following radiotherapy systems:
- External Beam Radiotherapy
- Brachytherapy

It is provided by manufacturers at the time of supply of a new equipment. It is not provided for old equipment that are not manufactured or sold anymore.

3. Format
No specific format is defined. Manufacturers can use any format they deem appropriate as long as the information identified in the following table is provided. The information to fill the columns must be sourced from the Risk Management File.

4. Description of the columns

Hazard	Hazardous situation	Potential harm	Risk control measure	Reference

Other regulations: Medical devices regulation (MDR)

Preambule MDR (17) This Regulation should include requirements regarding the design and manufacture of devices emitting ionizing radiation without affecting the application of Council Directive 2013/59/Euratom (6) which pursues other objectives.

Preambule MDR (18) This Regulation should include requirements for devices' design, safety and performance characteristics which are developed in such a way as to prevent occupational injuries, including protection from radiation.

Article 14 Construction of devices and interaction with their environment

14.2 Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible: b) risks connected with reasonably foreseeable external influences or environmental conditions, such as ....radiation associated with diagnostic or therapeutic procedures

Article 16 Protection against radiation

16.4 Devices intended to emit ionizing radiation shall be designed and manufactured taking into account the requirements of the *Directive 2013/59/Euratom* laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.

Classification rules

→ Challenges with hybrid equipment

EU-BSS directive implementation:
Challenges with other regulations

Equipment/Nuclear medicine

- **Article 56.1 Individually planned target volumes**
  - Large differences in 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 with HERCA and EANM on possibilities of dosimetry tools, EANM might support hospitals to implement new regulations based on the Article 56.1

- **Article 61.1 quality assurance programmes, assessment of dose, verification of administered activity**
  - Finding partners to be able to enhance the implementation of the EU-BSS directive and optimize radiation protection in health care
    → Field of radiology: fruitful collaboration with COCIR
    → Comparable collaboration in field of nuclear medicine: NMEU.

  - **Challenge with *GDPR*** (Regulation 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data): data collection and sharing data BSSD

EU-BSS directive implementation:
Challenges with other regulations

REACH autorisation lead:
European Chemicals Agency's (ECHA) recommendation to include lead metal in the REACH Authorisation

Consequences radiation protection:
- lead shielding
- Manufacturing of radionuclides: packaging

EU-BSS directive implementation:
Challenges with other regulations

Conclusions

- The technical requirements of the BSSD regarding the equipment are not a huge challenge for the HERCA MS
- The challenge is to use the data in the hospitals efficiently
- We see a need for efficient data handling systems including dose data management systems (interaction with GDPR)

- (Overlapping) **other regulations** of relevance
  - Pharma Directive and regulation
  - MDR
  - REACH authorization lead
  - IAEA TRANSC new guideline and values for the shipping of class 7 radioactive materials: type B containers for some radiopharmaceuticals

Questions