HERCA

Heads of the European Radiological protection Competent Authorities

HERCA Action Plan

HERCA Action Plan in relation to the transposition and implementation of Directive 2013/59/Euratom (Euratom BSS)

October 2014

The HERCA Action Plan in relation to the transposition and implementation of Directive 2013/59/Euratom (Euratom BSS) was approved by the Board of HERCA on the occasion of its 14th meeting in Stockholm, Sweden, on 21-22 October 2014.

Content

Content 3
Executive Summary 5
1. Introduction 7
2. New Basic Safety Standards Directive - Context 7
3. HERCA Action Plan in relation to the transposition and implementation of Directive 2013/59/Euratom (Euratom BSS) 8
3.1. Role for HERCA in the Transposition of the BSS 8
3.2. Agreed Actions for HERCA in relation to the transposition of the BSS 8
3.3. Coordination between HERCA and the EC in relation to BSS Transposition Activities 14
References 15
List of acronyms 16
Authors 18

Executive Summary

On 5 December 2013, the Council of the European Union adopted Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.[1] Member States have to transpose the new Basic Safety Standards Directive (BSS Directive) into their national legal systems by 6 February 2018 at the latest.

At the 13th meeting of the Board of HERCA (BoH) in Vilnius in June 2014, a proposal to establish a special Task Force (TF) to make proposals in relation to HERCA activities in support of the transposition and implementation of the new Euratom BSS Directive was agreed. The BSS-TF was established, commenced its work on the basis of a 'non-questionnaire' and a discussion document. It met on one occasion on 7 October 2014and agreed an action plan for consideration by the BoH. The agreed action plan proposal was approved by the BoH on the occasion of its 14th meeting in Stockholm, on 21-22 October 2014.

The approved Action Plan covers the following areas:

- Identification of HERCA's role in the transposition of the new Euratom BSS;
- Definition of actions for HERCA in relation to the transposition of the BSS;
- Coordination between HERCA and the EC in relation to BSS transposition activities.

The Actions identified relate to several subject areas: Emergency preparedness and response; Medical exposures; Radon; Non-medical imaging exposures; RPE/RPO; General exchange of information.

HERCA is a voluntary association, in which the Heads of European Radiological Protection Competent Authorities work together in order to identify common issues and propose practical solutions for these issues. It has no statutory role in relation to the transposition of the Euratom BSS. However, additional work by HERCA can support the transposition process as indicated in the Action Plan. Uniform transposition or implementation in the Member States is not an objective of HERCA activities. Clearly it will remain a matter for individual Member States as to the extent to which they avail of HERCA's work in transposing the BSS into their national regulations.

[1] 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 (OJ L 13, 17.1.2014, p. 1).

1. Introduction

At its 12th meeting in Berlin in November 2013, the HERCA Board expressed its desire to explore what role it might usefully play in the transposition and implementation of the Euratom BSS as it impacts Member States as binding obligations. At its 13th meeting in Vilnius in May 2014, the Board considered and agreed a proposal to establish a special Task Force (TF) with the following mandate to:

- define the role of HERCA in terms of the transposition and implementation of the BSS;
- identify the topics within the BSS where additional work by HERCA would add value;
- identify what actions would be required by HERCA to deliver that added value;
- develop a coordination plan to ensure the avoidance of duplication of effort with other actors such as the European Commission and
- propose an action plan for consideration by HERCA at its meeting in October 2014 taking all of these matters into account.

It was proposed that the composition of the TF should be kept to a 'manageable size' and in order to ensure internal coordination, the chairs of the existing working groups should be involved in this TF. The TF should also include at least one member from the European Commission to facilitate effective coordination and to try to avoid any unnecessary duplication. The TF presented a proposal for an Action Plan at the 14th HERCA meeting in Stockholm in October 2014 which was approved.

2. New Basic Safety Standards Directive - Context

Since the first Basic Safety Standards Directive was adopted in 1959, it has been updated in 1962, 1966, 1976, 1980, 1984 and 1996 taking account of advances in scientific knowledge on the effects of ionising radiation in line with the recommendations of ICRP and on the basis of operational experience. Medical exposures have been included in specific legislation since 1984. Areas where specific radiation protection challenges were identified are covered in three "associated directives" – the High-Activity Sealed Radioactive Sources (HASS) Directive, the Outside Workers Directive and the Public Information Directive.

In relation to the consolidation of the European radiation protection legal framework, the new Euratom BSS Directive consolidates (and repeals) the following:

- Basic Safety Standards, Directive 96/29/Euratom;
- Medical Exposures, Directive 97/43/Euratom;
- Public Information, Directive 89/618/Euratom;
- Outside Workers, Directive 90/641/Euratom;
- Control of High-activity Sealed Radioactive Sources and Orphan Sources, Directive 2003/122/Euratom;

Provisions of Commission Recommendation 90/143/Euratom (concerning radon) have also been incorporated.

The new BSS Directive, Council Directive 2013/59/Euratom, was published in the Official Journal of the European Union on 17th January 2014 and entered into force on 6 February 2014. Member States have to transpose the Directive into their national legal systems by 6 February 2018 at the latest.

3. HERCA Action Plan in relation to the transposition and implementation of Directive 2013/59/Euratom (Euratom BSS)

3.1. Role for HERCA in the Transposition of the BSS

- Acting as a platform to identify and discuss practical and technical regulatory problems, to exchange national approaches and to inform about anticipated studies and their results relating to the implementation of the BSS;
- Exploring a common understanding of the new requirements and common approaches including guidance where this is appropriate and feasible;
- Informing the transposition process by sharing regulatory experience and being a resource for Competent Authorities;
- Acting as an interested stakeholder with the European Commission to ensure that the voice of European radiation protection authorities is heard in the development of radiation protection policy and guidance in relation to the BSS;
- Adding significant value to the transposition and implementation of the BSS by focusing on areas with relevance to trans-boundary processes.

3.2. Agreed Actions for HERCA in relation to the transposition of the BSS

HERCA BSS Action #1

Thematic Area:	Emergency Preparedness
Issue Identified:	International Cooperation (Article 99).
Action Identified:	Elaboration of a guidance document for bilateral agreements.
Expected Outcome:	The report "HERCA-Approach for a better cross-border coordination of protective actions during the response in the early phase of a nuclear accident; development and practical testing" can be used for the transposition of Art. 99. The proposed guidance will assist the implementation of those provisions.
Timing:	The document to be used for the **transposition** is published already on www.herca.org The proposed guidance to assist **implementation** is tentatively scheduled for autumn 2015. .
Action Owner:	HERCA WGE

HERCA BSS Action #2

Thematic Area:	Emergency Preparedness
Issue Identified:	Emergency workers (Articles: 4 (31), 17 and 53).
Action Identified:	Exploring the possibilities of a common understanding of the provisions related to emergency workers.
Expected Outcome:	▪ Establish examples of people or functions normally considered as emergency worker; ▪ Defining the need for a common understanding for adequate and regularly updated training; ▪ Defining the need for shared approaches concerning individual protection.
Timing:	May 2015
Action Owner:	HERCA WGE

HERCA BSS Action #3

Thematic Area:	Emergency Preparedness
Issue Identified:	Reference levels for public exposures in an emergency situation (Articles: 4 (84); 7).
Action Identified:	Development of a common understanding of the concept of reference levels concerning EP&R (emergency phase).
Expected Outcome:	▪ Review of the different national interpretations of the concept; ▪ For planning: - Review how MS use the concept to optimise strategies for emergency management; - Justification for the setting of a reference value between 20 to 100 mSv (acute or annual) for emergency exposure situations; - Possible approaches concerning the criteria for individual protective actions in relation to a global reference level; ▪ For the response: - Guidance on how to optimise during the response.
Timing:	Tentatively spring 2016, with possibly some earlier intermediate results.
Action Owner:	HERCA WGE

HERCA BSS Action #4

Thematic Area:	Medical Exposures
Issue Identified:	Medical Equipment (Articles 60 and 58(b)) New detailed provisions relating to medical equipment: information to practitioners about quantities of radiation and parameters for assessing radiation dose, transferring data to the record of the examination etc.
Action Identified:	A special focus group session within HERCA MA which may inform EC Medical Exposure Workshop and/or stimulate development of a new HERCA Work Package.
Expected Outcome:	A common understanding and sharing of approaches to transposition and implementation.
Timing:	Q1 2015 onwards (Q4 2015 EC Workshop).
Action Owner:	WG MA

HERCA BSS Action #5

Thematic Area:	Medical Exposures
Issue Identified:	Level II Justification.(Articles 19, 55.2(a),(c) and (h)) New requirements for consideration of occupational and public exposure when considering justification of medical exposure. Consideration of timely justification processes for new applications to prevent or restrict types of practices before they become available e.g. hand-held dental x-ray sets, individual health assessment etc.
Action Identified:	A special focus group session within HERCA WG MA which may inform EC Medical Exposure Workshop and/or stimulate development of a new HERCA Work Package.
Expected Outcome:	A common understanding and sharing of approaches to transposition and implementation.
Timing:	Q1 2015 onwards (Q4 2015 EC Workshop).
Action Owner:	WG MA

HERCA BSS Action #6

Thematic Area:	Medical Exposures
Issue Identified:	Education and Training (Article 18). Additional requirements relating to continuing education on medical radiological practice and radiation protection for a range of staff involved in medical exposures.
Action Identified:	A special focus group session within HERCA WG MA which may inform EC Medical Exposure Workshop and/or stimulate development of a new HERCA Work Package.
Expected Outcome:	A common understanding and sharing of approaches to transposition and implementation.
Timing:	Q1 2015 onwards (Q4 2015 EC Workshop).
Action Owner:	WG MA

HERCA BSS Action #7

Thematic Area:	Medical Exposures
Issue Identified:	Notification of significant events (Articles 63 and 96). New requirements relating to reporting to the competent authority of significant events arising from accidental or unintended medical exposures and associated requirements on the undertaking relating to clinically significant events
Action Identified:	A new HERCA Work Package (agreed by BoHs April 2014) which may also inform EC Medical Exposure Workshop.
Expected Outcome:	A common understanding of options and difficulties and sharing of approaches to transposition and implementation.
Timing:	Q1 2015 onwards.
Action Owner:	WG MA

HERCA BSS Action #8

Thematic Area:	Medical Exposures
Issue Identified:	Notification of significant events involving underexposures (primarily in radiotherapy) (Articles 63 and 96). New requirements relating to reporting to the competent authority of significant events arising from accidental or unintended medical exposures may involve incidents where the patient(s) receive less dose than intended. The inclusion of these within transposing regulations is in keeping with the spirit of the Directive but may be outside the overarching scope of the Directive when considered within the context of the Directive (and Treaty) intentions.
Action Identified:	A subset of new HERCA Work Package (agreed by BoHs April 2014) which may inform EC Medical Exposure Workshop.
Expected Outcome:	A common understanding of options and difficulties and sharing of approaches to transposition and implementation.
Timing:	Q1 2015 and onwards (Q4 2015 EC Workshop).
Action Owner:	WG MA

HERCA BSS Action #9

Thematic Area:	Non-Medical Imaging Exposures
Issue Identified:	Non-medical imaging exposures (Article 22). New requirements relating to imaging of persons for purposes other than diagnosis, treatment or research using medical radiological equipment and other techniques, introducing flexibility regarding dose limits and constraints and requiring cross-sector discussion.
Action Identified:	Not yet identified but would clearly benefit from some consideration with existing working groups (Medical and Justification) – chairs to consider further.
Expected Outcome:	A common understanding of options and difficulties and sharing of approaches to transposition and implementation, across a range of sectors.
Timing:	Q3 2015 if HERCA WG MA addresses this and Q4 2015 if taken up initially within EC Medical Exposure Workshop.
Action Owner:	HERCA WGs

HERCA BSS Action #10

Thematic Area:	Radon
Issue Identified:	How Member States transpose the radon requirements may be influenced by the new ICRP dose coefficients and sharing of experiences would be valuable in that context.
Action Identified:	A seminar on the transposition approach of the radon requirements.
Expected Outcome:	An exchange of views that might assist Member States in their transposition of these requirements.
Timing:	Q3 2015
Action Owner:	Switzerland

HERCA BSS Action #11

Thematic Area:	RPE/RPO
Issue Identified:	The need for developing guidance on the implementation of RPE and RPO.
Action Identified:	Development of criteria/guidelines for the implementation of RPE and RPO by HERCA TF E&T (making use of ENETRAP I, II, III results where appropriate).
Expected Outcome:	Guidance on the implementation of RPE and RPO respecting diversity in implementation of the BSS.
Timing:	2015
Action Owner:	HERCA TF E&T

HERCA BSS Action #12

Thematic Area:	General Exchange of Information
Issue Identified:	Member States are at different stages in their transposition process including the commissioning of specific studies, workshops and research in different thematic areas. Sharing this information would benefit HERCA members.
Action Identified:	Establish a dedicated page on the HERCA website dedicated to BSS transposition providing for a record of: National Activities; Regional Activities; Research/Survey.
Expected Outcome:	A dedicated web page on HERCA website.
Timing:	Q1 2015
Action Owner:	Secretariat / Member States

3.3. Coordination between HERCA and the EC in relation to BSS Transposition Activities

Effective coordination will be achieved by:

- Updates provided at BoHs meetings;
- Liaison between HERCA Chair and EC hierarchy;
- Participation by EC, where appropriate in HERCA WG activities and actions on BSS issues;
- Informal channels of communication between experts;
- Chair may reactive BSS-TF to review progress and coordination needs where necessary.

References

[1] 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.

[2] Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources (EU HASS Directive).

[3] Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas.

[4] Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency.

[5] Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation (Basic Safety Standards).

[6] Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom.

[7] Commission Recommendation 90/143/Euratom of 21 February 1990 on the protection of the public against indoor exposure to radon.

List of acronyms

BoH	Board of HERCA
BSS	Basic Safety Standards
BSS-TF	HERCA Task Force on the Euratom BSS
EC	European Commission
EP&R	Emergency Preparedness and Response
EU	European Union
Euratom	European Atomic Energy Community (EAEC or Euratom)
HASS	High-Activity Sealed Radioactive Sources
HERCA	Heads of the European Radiological protection Competent Authorities
HERCA TF E&T	HERCA Task Force on Education and Training
HERCA WG MA	HERCA Working Group on Medical Applications
HERCA WGE	HERCA Working Group on Emergencies
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
Q1, Q2, Q3, Q4	Quarter 1, 2, 3, 4 of the year
RPE	Radiation Protection Expert
RPO	Radiation Protection Officer

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The authors participated actively in the Task Force between July and October 2014. During this period, the TF was chaired by **Dr Tom Ryan (EPA/ORP, IE).**

ASN – Autorité de Sûreté Nucléaire; **BfS** – Bundesamt für Strahlenschutz**; BMUB** – Bundesministerium fur Umwelt, Naturschutz, Bau und Reaktorsicherheit; **EEAE** – Greek Atomic Energy Commission; **EC** – European Commission; **ENSI** - Swiss Federal Nuclear Safety Inspectorate; **EPA/ORP** – Environmental Protection Agency / Office of Radiological Protection of Ireland**; FANC/AFCN** – Federal agency for nuclear control; **FOPH** – Federal office of Public Health of Switzerland; **HSE** – Health and Safety Executive UK; **Minez** - Ministerie van Economische Zaken; **MS** – Ministère de la santé du Luxembourg; **NRPA** – Norwegian Radiation Protection Authority;- Public Health England; **SIS -** Danish Institute of Radiation Protection**; SSM** - Swedish Radiation Safety Authority; **STUK** - Radiation and Nuclear Safety Authority.

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