EU-BSSD Workshop

Madrid 20-24 MAY 2024

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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

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Articles 31 and 32 thereof,

Having regard to the proposal from the European Commission, drawn up after having obtained the opinion of a group of persons appointed by the Scientific and Technical Committee from among scientific experts in the Member States, and after having consulted the European Economic and Social Committee,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the European Economic and Social Committee,

Whereas:

(1) Point (b) of Article 2 of the Euratom Treaty provides for the establishment of uniform safety standards to protect the health of workers and of the general public. Article 30 of the Euratom Treaty defines "basic standards" for the protection of the health of workers and the general public against the dangers arising from ionising radiations.

(3) Directive 96/29/Euratom establishes the basic safety standards. The provisions of that Directive apply to normal and emergency situations and have been supplemented by more specific legislation.

(4) Council Directive 97/43/Euratom (1), Council Directive 89/618/Euratom (2), Council Directive 90/641/Euratom (3) and Council Directive 2003/122/Euratom (4) cover different specific aspects complementary to Directive 96/29/Euratom.

(5) As recognised by the Court of Justice of the European Union in its case-law, the tasks imposed on the Community by point (b) of Article 2 of the Euratom Treaty to lay down uniform safety standards to protect the health of workers and the general public does not preclude, unless explicitly stated in the standards, a Member State from providing for more stringent measures of protection. As this Directive provides for minimum rules, Member States should be free to adopt or maintain more stringent measures in the subject-matter covered by this Directive, without prejudice to the free movement of goods and services in the internal market as defined by the case-law of the Court of Justice.

(6) The Group of Experts appointed by the Scientific and Technical Committee has advised that the basic safety

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1. Introduction

The purpose was to organise a workshop in 2024 aimed at:

1. Identify any gaps and ambiguities, in the European BSS as well as in international BSS that need to be addressed

2. Identify difficulties encountered in the process of implementation

3. Any other areas identified in the process of implementation that merit specific attention

4. Prepare a summary report to the HERCA BoH

2. Organization team

✓ The organization of the Workshop has been worked out by a Task Group made of:

- Mika Markkanen (STUK - Finland)
- Carole Rouse (ASN - France)
- Goli-Schabnam Akbarian (BMUV-Germany)
- Carol Robinson (DSA - Norway)
- Åsa Wiklund (SSM - Sweden)
- Isabel Villanueva (CSN - Spain)
- Katrien van Slambrouck (WGMA)
- Inmaculada Simón (CSN – Spain)
- Peter Görts (ANVS - Netherlands)
- Heloisa Fonseca (APA - Portugal)
- Economides Sotiris (EEAE- Greece)
- Marie-Lorraine Alberico (ASN – France)
- Mª Luisa Tormo (CSN – Spain)
- Javier Zarzuela (SCN – Spain) Chair

✓ The Task Group met by VC 3 times in 2023 and 5 times in 2024

3. Some figures

- ✓ Sessions 11
- ✓ Presentations 25

- ✓ Audience
  - 142 Registered (86 in person, 58 online)
  - 23 Countries
  - 6 International agencies, stakeholders (EC, IAEA, ICRP, NEA, EFOMP, SEFM)
  - All sessions attended by 50-65 persons, present, and 30-40, online
  - The total number of persons that have attended at least one session have been 80, in person, and 58, online
  - All sessions have received many questions, a demonstration of the audience interest

4. Workshop opening

Juan Carlos Lentijo – CSN Chair

Jean-Luc Lachaume – HERCA Chair

5. Summary of sessions

S1 Dosimetry

Session leader *Isabel Villanueva* (CSN - Spain)

Presentations

- Dose Coefficients- Internal Exposures – *Mª Antonia Lopez* (ICRP Committee 2)
- Key challenges in external dosimetry – *Eleftheria Carinou* (EEAE - Greece)

Main insights, remarks

✓ Difficulties to make legally binding the use of the Occupational Intakes of Radionuclides (OIR) Data Viewer electronic annex of ICRP Publication 131 including the new dose coefficients for internal exposures.

✓ Multiple commercial software packages are available, it is needed to validate them by comparison or benchmarking.

✓ Need to make case studies for emergencies of internal doses, depending on the radioisotope, type of exposure (inhalation, ingestion or injection) and the chemical form of the material.

✓ Regarding new dose limit to lens of eye:

- The main sector affected is interventional procedures.
- Difficulties on the practical implementation for monitoring occupational exposures.
- Importance of training, raising competence and awareness of personal in the most impacted sectors,

5. Summary of sessions

S2 Emergencies

Session leader *Åsa Wiklund (SSM - Sweden)*

Presentations

- HERCA and the HERCA-WENRA Approach Instruments to meet article 99 (International Cooperation) – Alfredo Mozas (CSN - Spain)
- Implementation of the requirements for "Emergency Workers" – Gareth Thomas (ONR – UK)

Main insights, remarks

✓ The HWA has shown to be a useful tool when implementing the Article 99 of the Directive 2013/59 and should be considered a unique and joint achievement by HERCA and WENRA.

✓ It has been emphasized the need to make exercises of application of the HERCA-WENRA approach among neighbouring countries

✓ Emergency workers: need clear definition as the concept vary very much, and to define the training needed for such workers depending on their duties

5. Summary of sessions

S3 Justification

Session leader Åsa Wiklund (SSM - Sweden)

Presentations

- Experiences in applying the general principle of justification – Mika Markkanen (STUK - Finland)
- Justification: Non-medical imaging – Katrien van Slambrouck (FANC – Belgium)
- Justifications of Practices for non-medical Imaging purposes – Tasks of WG RISP – Stefan Büchi (Suva – Switzerland)

Main insights, remarks

- ✓ Most countries have identified justified and non-justified practices and the new practices pass a process of justification before being authorized
- ✓ The principles of justification, optimisation and limitation should be applied in a linear process
- ✓ The audience advocated that justification is an extremely important principle which takes ethical and societal values into account and it should remain as one of the three pillars of RP
- ✓ Justification of non-medical imaging is a complex, constantly evolving, includes issues such as insurance matters, immigration, examinations of top-athletes including adolescents, drug trafficking, security screening. Issues that have strong interests behind and, eventually its own regulation that may override RP concerns Cooperation between WGMA and WGRISP is necessary, and should continue

5. Summary of sessions

S4 Justification - Medical

Session leader Katrien van Slambrouck (FANC- Belgium)

Presentations

- New technologies: What "intelligence" do we need? – Katrien van Slambrouck (FANC- Belgium)
- Metabolic radionuclide therapy: blessing for patient, curse for regulator? - Barbara Godthelp (ANVS - Netherlands)

Main insights, remarks

✓ Big challenge for regulators to guarantee a proper justification for all applications in a sector with an overwhelming number of innovations: difficult balance between rigor in the justification process and benefit for the patients

✓ Artificial Intelligence is an up-and-coming technique in terms of benefits for the patient, but it is often a black box with software that can still train itself after installation: regulators need skills in the matter

✓ HERCA can play an important role in sharing information amongst its members to avoid duplicating work

✓ There is another important role for European and national regulatory bodies to ensure that interfaces between regulations cover existing gaps or grey zones e.g. on premarket assessments.

5. Summary of sessions


S5 Existing Exposures

Session leader *Inmaculada Simón* (CSN - Spain)

Presentations

- Reference levels at existing exposure situations – Jelena Popic (DSA - Norway)
- Regulation of Indoor Gamma Radiation from Building Materials– Frans van de Put (ANVS – Netherlands)

Main insights, remarks

- ✓ The optimization is a case-by-case process that takes into account factors other than radiological ones, for a huge variety of exposure situations and conditions, e.g., legacy sites, post emergency sites
- ✓ As for reference levels, it was discussed what are the conditions for an existing exposure situation to warrant no further consideration of optimization;
- ✓ What would be the conditions to continue implementing remedial actions even below the reference levels, when to stop? Consideration of factors such as technology, cost of remediation, and others site-specific are needed.
- ✓ Communication to public and involving different relevant stakeholder groups is recognized as of high importance for the optimization process and application of Reference levels at most of existing exposure sites
- ✓ As for exposure to gamma radiation from building materials it is considered the need for more harmonization of European approach in order to favor free trade within an internal market.
- ✓ Control of materials coming from third countries into the European Union is an issue not well solved so far

5. Summary of sessions

S6 NORM

Session leader Peter Görts (ANVS - Netherlands)

Presentations

- Exemption and Clearance applied to the Regulation of NORM across HERCA countries – Marta García-Talavera (CSN – Spain)
- Accumulation of nuclides like 137Cs from fallout – Antti Kallio (STUK – Finland)
- Consumer products or commodities containing natural occurring radionuclides (NORM) - Peter Görts (ANVS – Netherlands)

Main insights, remarks

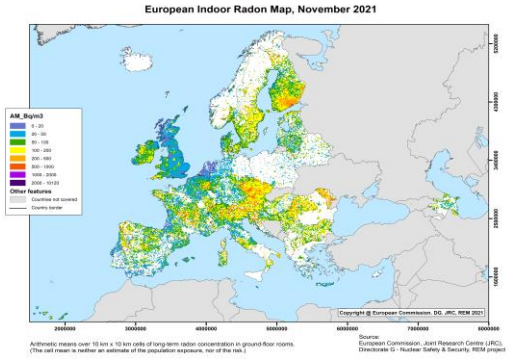
✓ The HERCA guidance document "Application of the concepts of exemption and clearance to the regulation of NORM across HERCA countries" is very useful because illustrates how exemption and clearance are implemented in the member countries and Clearance for liquid NORM remains a challenge

✓ "Commodity" not defined in EU BSS and it is needed sharing of information to get a common understanding

✓ Exposure to Cs-137 from fallout in biomass combustion ash is very similar to NORM exposure and there are opinions as to whether it should be considered an existing or planned exposure situation

✓ Work on an information exchange system and common approach on products/trade that contain NORM, such as bracelets

5. Summary of sessions



S7 Radon

Session leader *Heloisa Fonseca (APA - Portugal)*

Presentations

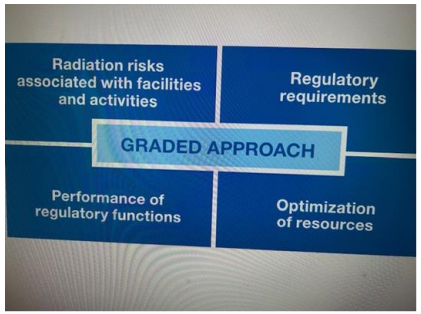
- Discussions on the Article 103.3 EU BSS – Francesco Bochicchio – (ISS – Italy)
- Radiation protection measures at workplaces with Rn levels above the RL– Marta García-Talavera (CSN - Spain)

Main insights, remarks

✓ Along with European Commission publication Radiation Protection No. 193: Radon in Workplaces, there is consensus that a) exposure assessment should be performed by a recognized dosimetry service or a recognized radiation protection expert competent in radon exposure assessment, and b) if exposure of workers may exceed an effective dose of 6 mSv per year, the exposure of workers needs to be assessed individually.

✓ The practical application of ICRP 137 dose coefficient factors (DCF) and doses from previous DCF remains a topic of mutual interest and will be further explored at a workshop to be organized by the German Ministry for Climate Action. “Fit for purpose: A German contribution to the new ICRP recommendations“ (6-8 November 2024)”

5. Summary of sessions



S8 Graded Approach

Session leader *Mika Markkanen (STUK - Finland)*

Presentations

- Some Finnish experiences in implementing the graded approach - Mika Markkanen (STUK, Finland)
- Selected issues related to graded approach in regulatory practice in the Czech Republic – Jana Povolná (SUJB - Czech Republic)
- Portuguese experiences in implementing the graded approach - Pedro Rosario (APA – Portugal)

Main insights, remarks

✓ Graded approach should be implemented through 1) grading regulatory processes and 2) grading regulatory requirements for practices. Mature regulators focus on performance as much as compliance

✓ The graded approach requires that all parties involved share a common understanding and knowledge of the risks involved in the practice

✓ Exemption and clearance were considered very important tools for implementing the graded approach.

✓ The graded approach is widely used especially for planning inspections and related activities

5. Summary of sessions

S9 Recognition of RPE-RPO-MPE

Session leader *Sotiris Economides (EEAE- Greece)*

Presentations

- RPE-RPO recognition requirements in Europe – Sotiris Economides (EEAE- Greece)
- Experience of the implementation of RP Expert (RPE)– RP Officer (RPO) concepts in Europe – Barbara Godthelp (ANVS - Netherlands)
- EFOMP: E&T requirements/ Implementation of MPE– Paddy Gilligan (EFOMP)

Main insights, remarks

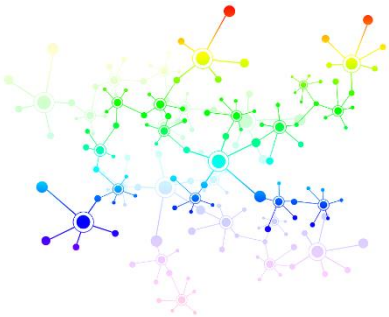
✓ There are many similarities in the implementation of RPE and RPO concepts among MS, but different approaches in requirements concerning qualifications, training, experience…

✓ The cross-border recognition of RPEs based on the Directive 2005/36/EC (on the recognition of professional qualifications) is very complex for different regulations among MS

✓ There are on going efforts to harmonize standards and strive towards mutual recognition of MPEs among MS

✓ The combined role of MPE/RPE in medical facilities is an widely accepted policy

5. Summary of sessions



S10 Interface with other EU Directives

Session leader *Carol Rousse (chaired by Jean-Luc Lachaume)* (ASN - France)

Presentations

- Design of Devices Emitting Ionising Radiations (excluding medical devices) A Need for an Enhanced European Framework? Benoit de Carme Carnavelet (ASN – France)
- Interactions with other regulations – HERCA's view -Barbara Godthelp (ANVS – Netherlands)

Main insights, remarks

✓ Requirements for medical devices, nuclear medicine, are rather common across Europe
✓ In medical applications the main issue is to ensure that different European directives, regulation under development don't contradict regulations with overlaps
✓ For research and industrial applications, both for devices and operation, the main issue is to harmonize requirements, to advance in mutual recognition of standards

5. Summary of sessions

European Commission

Presentation

- *Basic Safety Standards Directive Transposition and Implementation an overview* - Stefan Mundigl (EC))

Main insights, remarks

✓ The Directive is already implemented in regulations of all countries in virtually every aspect. Some specific issues pending are foreseen to be finished by the end of 2024

✓ Next step: EC is going to monitor the effective implementation of the Directive 2013/59

✓ EC has the duty to respond in case of complains from European citizens for lack of implementation

✓ EC has the will to interact more intensively with ICRP in the process of preparing future ICRP general recommendations because Europe is the geographical area that more closely follows ICRP recommendations

6. Workshop closure

Pilar Lucio – HERCA Vice Chair

Javier Zarzuela – Workshop Chair

7. Overall assessment of the workshop

The Task Group considers the workshop very successful and an appreciated event because:

- ✓ The number of attendees was the highest in a HERCA initiative ever
- ✓ All sessions were interactive with many questions and prompted lively debates that demonstrated the audience's interest
- ✓ All sessions draw conclusions that provide valuable input to discussions on the future radiation protection system and EU legislation and international standards implementing it

However, some attendees claimed that the number of presentations and time devoted to some sessions was not enough

8. Measures after the Workshop

The Task Group (TG) proposed to the BoH (December 2024):

- ✓ To continue the analysis of the Euratom BSS in line with the HERCA strategy approved in 2021;
- ✓ In addition to identifying gaps, ambiguities, and difficulties in their implementation, the analysis could discuss what should change in the future;
- ✓ To arrange further workshop(s) on the need basis (in 2026/2027 for example).

The HERCA BoH decided:

- ✓ To approve the Workshop report and to distribute it to the European Commission and the ICRP
- ✓ That the HERCA working groups could focus more on the gaps they identify in the topics they work on
- ✓ The results of the workshop will be presented in international fora, examples:
  - ✓ Meeting of the Euratom Article 31 GoE
  - ✓ IAEA GC