

EURATOM BASIC SAFETY STANDARDS

Council Directive 2013/59/Euratom

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This presentation is without prejudice to the interpretation given to the Directive by the services of the European Commission and to the legal obligation of Member States to transpose the exact requirements of the Directive; in this presentation quotes are not always exact for reasons of simplicity and visibility,

Role of the European Union

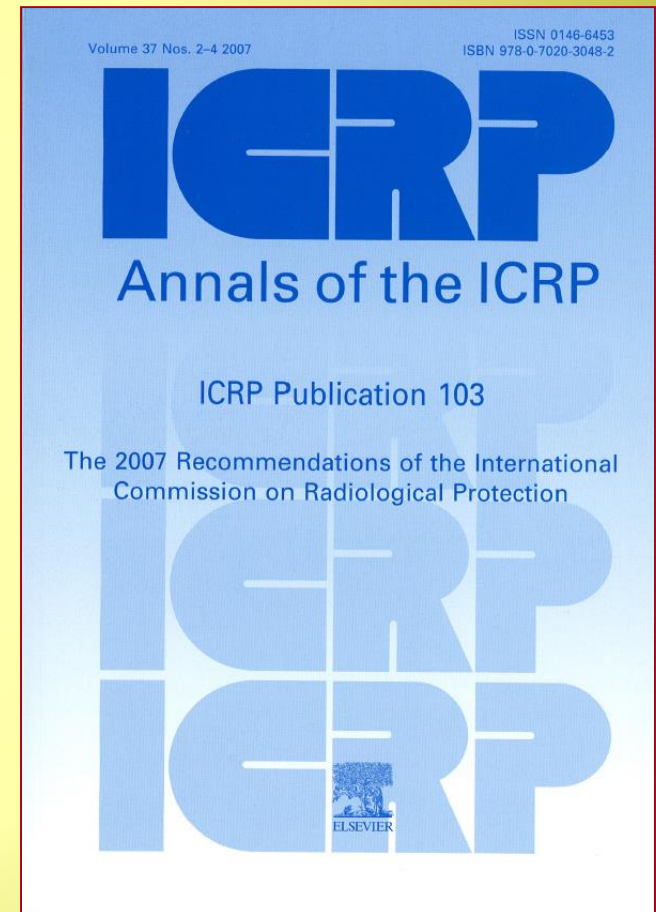
- *Euratom Treaty (1957)*
 - **allow the development of nuclear energy while**
 - **establishing uniform Basic Safety Standards**
- *Article 2:*

In order to perform its task, the Community shall, as provided in this treaty:

 - a)
 - b) *establish uniform safety standards to protect the **health of workers and of the general public** and ensure that they are applied;*
- *Chapter III "Health and Safety"*
 - **Article 30: The expression "basic standards" means:**
 - a) ...
 - b) maximum permitted levels of exposure and contamination
 - c) ...
 - **Article 31: Euratom procedure and group of Experts**
 - **Article 33: Harmonisation, draft legislation**
 - **Articles 35-38**
ensuring the protection of the "environment"

Revision of EU-BSS

- *Allow for international BSS (IAEA and co-sponsors)*
- *Allow for ICRP*
 - ✓ **Exposure situations**
 - rather than processes: practices/interventions
 - ✓ **Incorporate natural radiation sources**
 - Strengthen the requirements
- *Review of regulatory control system*
 - ✓ **Graded approach to regulatory control**
- *Consolidation of 5 current Directives*
 - ✓ **All categories of exposure**



Consolidation of European Radiation Protection Legislation

- *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*
- *Radon, Commission Recommendation 90/143/Euratom*

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 ...

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Uitgave
in de Nederlandse taal

Wetgeving

57e jaargang
17 januari 2014

Inhoud

II Niet-wetgevingshandelingen

RICHTLIJNEN

- ★ Richtlijn 2013/59/Euratom van de Raad van 5 december 2013 tot vaststelling van de basisnormen voor de bescherming tegen de gevaren verbonden aan de blootstelling aan ioniserende straling, en houdende intrekking van de Richtlijnen 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom en 2003/122/Euratom 1

Chapters

- I Subject matter and scope*
- II Definitions*
- III System of radiation protection*
- IV Requirements for radiation protection education, training and information*
- V Justification and regulatory control of practices*
- VI Occupational exposures*
- VII Medical exposures*
- VIII Public exposures*
- IX General responsibilities of member states and competent authorities and other requirements for regulatory control*
 - Institutional infrastructure
 - Control of radioactive sources
 - Orphan sources
 - Significant events
 - Emergency exposure situations
- X Final provisions*

New BSS: main novelties

- *Scope:*
 - ✓ **Protection of the environment**
 - ✓ **Radon in dwellings, workplaces**
 - ✓ **Building materials**
- *Graded approach to regulatory control*
 - ✓ **Registration and licencing**
 - ✓ Licencing requirements
 - ✓ **Exemption/clearance criteria**
 - ✓ **NORM industries managed as practices**
- *Justification*
 - Justification and type approval of consumer goods,
 - Justification and regulatory control of non-medical imaging exposures
- *Protection of Workers*

New BSS: main novelties

- *Experts and services, Training*
 - ✓ **RPE/RPO**
 - ✓ **MPE**
- *Medical exposures*
 - ✓ **Integration in overall protection system**
 - ✓ Justification
 - ✓ **Roles and responsibilities**
 - ✓ Accidental or unintended exposures
- *Protection of members of the public*
 - ✓ **Discharge authorisations**
 - ✓ **Protection of the environment**
- *Emergency preparedness*
 - ✓ **International coordination**
 - ✓ **Emergency workers**

Implications for the future of Radiation Protection

- *New philosophy based on ICRP*
 - ✓ **(planned) exposure situations defined differently**
 - ✓ **Broad coherence with international BSS**
- *Comprehensive integrated body of legislation*
- *Enhanced role of the regulatory authority*
 - ✓ **Graded approach,**
 - ✓ **Judgment,**
 - ✓ **Transparency.**
- *Larger scope:*
 - ✓ **Protection of the environment,**
 - ✓ **NORM,**
 - ✓ **building materials,**
 - ✓ **Radon in workplaces,**
 - ✓ **Non-medical imaging exposures.**

Graded approach to regulatory control

- *Proportionality and*
- *Effectiveness of regulatory control*

Member States shall require any notified practice to be subject to regulatory control commensurate with the magnitude and likelihood of exposures resulting from the practice,

and commensurate with the impact that regulatory control may have on reducing such exposures or improving radiological safety

Graded approach to regulatory control

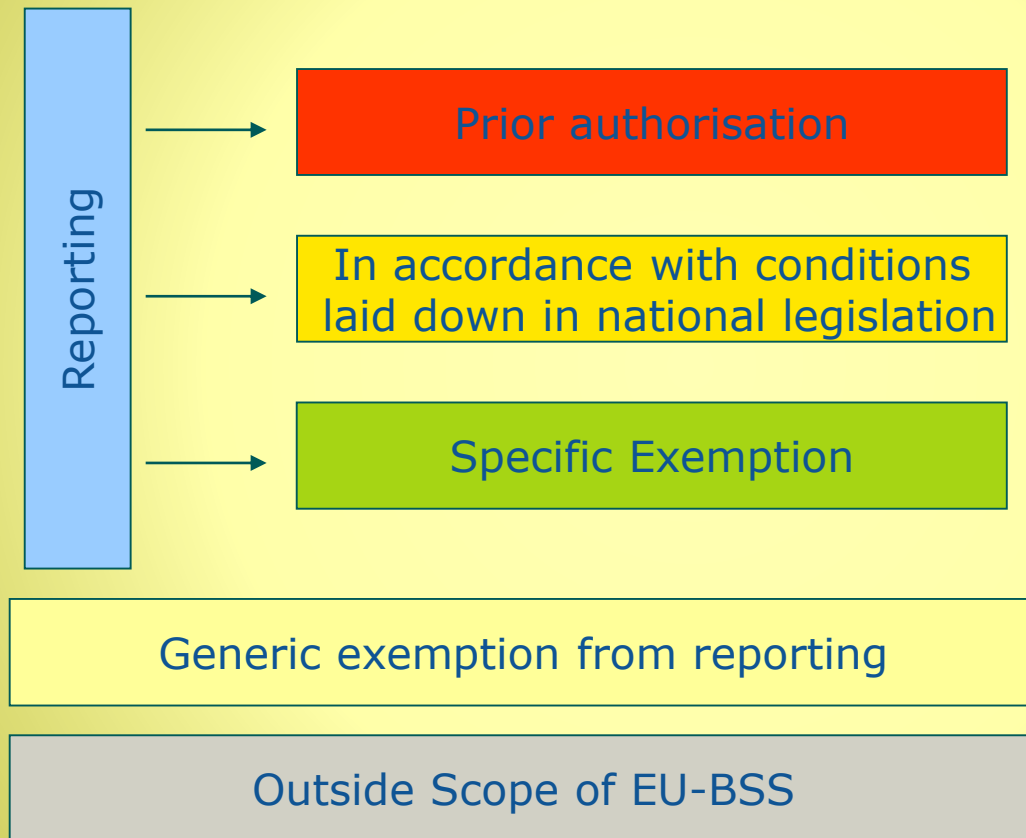
- *3-tier system*
 - **Notification, registration, licencing**
- *Notification (cf. reporting)*
- *Registration*
 - ✓ **Cf. current « authorisation in cases of a limited risk, in accordance with conditions laid down in legislation »**
 - ✓ **No need for individual examination**
 - ✓ **Subject to inspection**
- *Licensing*
 - ✓ **Cf. “prior authorisation”**

Council Directive 96/29/Euratom

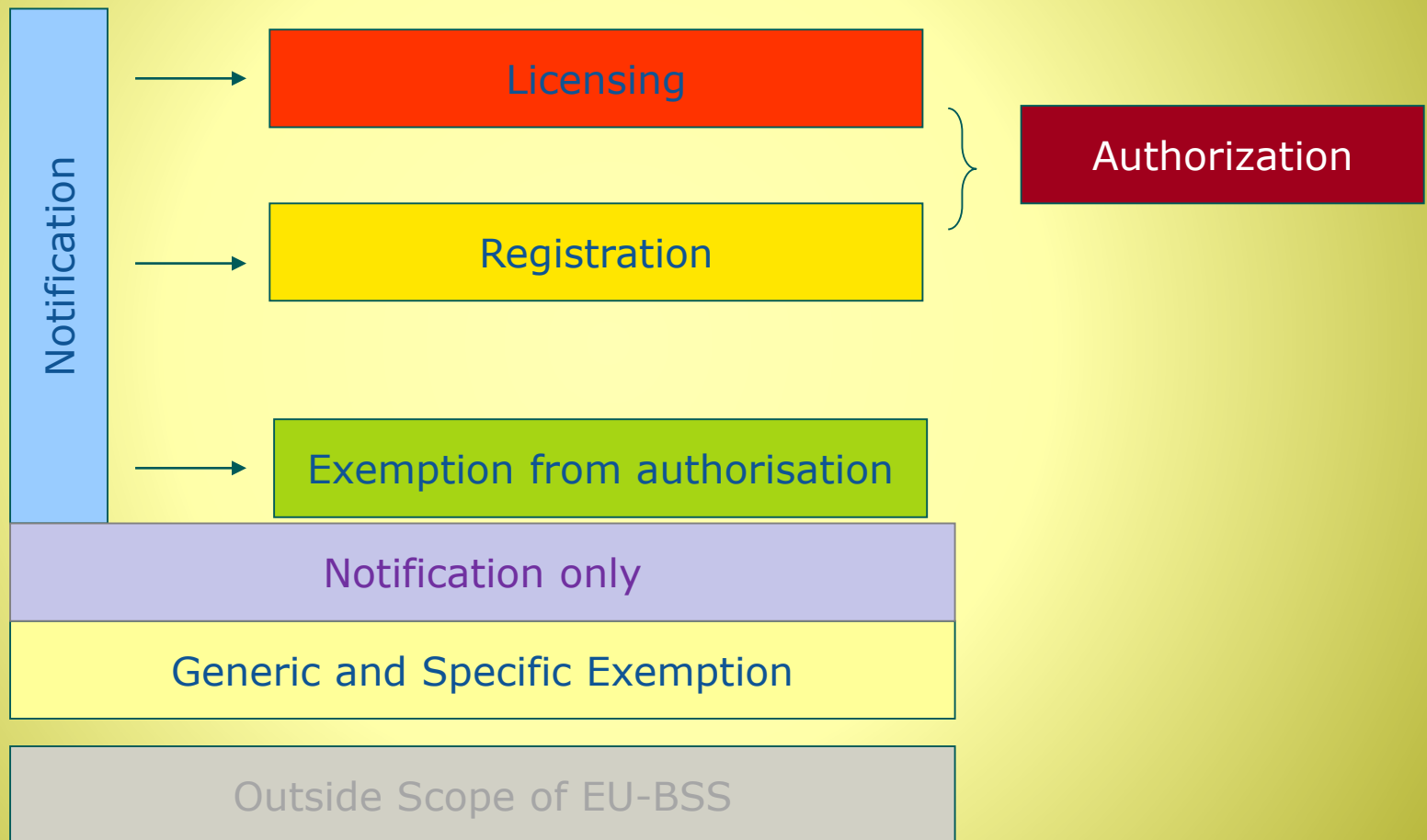
Exemption and clearance

- *Article 3 allows exemption from reporting*
 - **Annex 1 contains exemption values**
 - **activity concentration and total activity**
- *Article 5 requires national competent authorities to set clearance levels*
 - **following the criteria in Annex 1 (10 μ Sv) and**
 - **taking into account guidance by EU**

Graded Approach 1996



Graded Approach 2013



Practices subject to authorisation

- *Practices subject to registration (or licencing):*
 - ✓ **the operation of radiation generators or accelerators or radioactive sources;**
 - Except electron microscopes
- *Practices subject to licencing:*
 - ✓ **The deliberate administration of radioactive substances to persons (and animals) ... for the purpose of medical ... diagnosis, treatment or research;**
 - ✓ **The operation of any nuclear (fuel cycle) facility**
 - ✓ **The addition of radioactive substances to consumer goods**
 - ✓ **High activity sealed sources**
 - ✓ **Facilities for managing radioactive waste**
 - ✓ **practices discharging significant amounts of radioactive material with airborne or liquid effluent into the environment.**

General exemption and clearance criteria

The general criteria for the exemption of practices from notification or authorisation or for the clearance of materials from authorised practices are as follows:

- (a) the radiological risks to individuals caused by the practice are sufficiently low, as to be of no regulatory concern; and*
- (b) the type of practice has been determined to be justified; and*
- (c) the practice is inherently safe.*

General exemption and clearance criteria

For the purpose of exemption from notification or for the purpose of clearance, ... an assessment shall be made in the light of the general criteria ... above. For compliance with the general criterion, it shall be demonstrated that workers should not be classified as exposed workers, and the following criteria for the exposure of members of the public are met in all feasible circumstances:

For artificial radionuclides:

The effective dose expected to be incurred by a member of the public due to the exempted practice is of the order of 10 μ Sv or less in a year.

For naturally-occurring radionuclides:

The dose increment, allowing for the prevailing background radiation from natural radiation sources, liable to be incurred by an individual due to the exempted practice is of the order of 1 mSv or less in a year. The assessment of doses to members of the public shall take into account not only pathways of exposure through airborne or liquid effluent, but also pathways resulting from the disposal or recycling of solid residues. Member States may specify dose criteria lower than 1 mSv per year for specific types of practices or specific pathways of exposure.

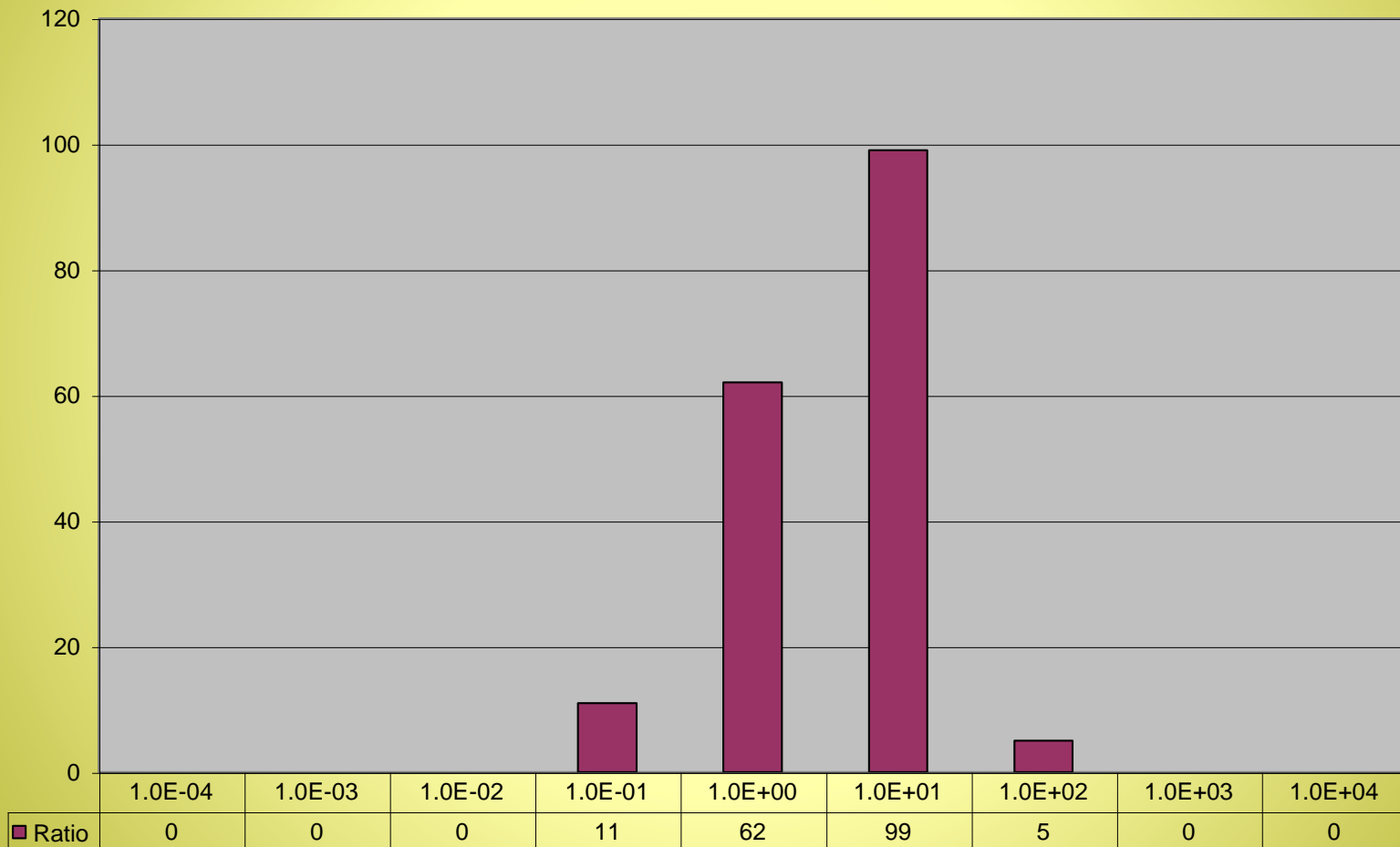
Exemption values and Clearance levels

- *Total activity: current exempt quantities (Bq) (Table B)*
- *Concentrations (kBq/kg): same levels for both concepts*
- *Harmonisation with International BSS*
 - ✓ **Exemption values**
 - ✓ **General clearance levels**
- *Artificial radionuclides (Table A part 1):*
 - ✓ **General exemption or clearance: based on RS-G-1.7**
- *Application to NORM industries*
- *Naturally occurring radionuclides (Table A part 2):*
 - ✓ **RS-G-1.7 exemption value 1 kBq/kg (10 kBq/kg for K-40)**
 - ✓ **Exemption criterion 1 mSv per y**

BSS Recital

There is benefit in having the same activity concentration values both for the exemption of practices from regulatory control and for the clearance of materials from authorised practices. After a comprehensive review, it has been concluded that the values recommended in IAEA document RS-G-1.7 can be used both as default exemption values, replacing the activity concentration values laid down in Annex I to Directive 96/29/Euratom, and as general clearance levels, replacing the values recommended by the Commission in Radiation Protection No 122 .

ratio of values in RS-G-1.7 to RP 122 Part I



Exemption and Clearance

- *Same general (exemption and clearance) criteria and default general clearance levels set equal to exemption values*
- *Clarification of the concepts of exemption and clearance*

Clearance levels means values established by the competent authority or in national legislation, and expressed in terms of activity concentrations, at or below which materials arising from any practice subject to notification or authorisation may be released from the requirements of this Directive;

Release from regulatory control (Art. 30)

1. *Member States shall ensure that the disposal, recycling or reuse of radioactive materials arising from any authorised practice is subject to authorisation.*
2. *Materials for disposal, recycling or reuse may be released from regulatory control provided that the activity concentrations:*
 - (a) for solid material do not exceed the clearance levels set out in Table A of Annex VI; or**
 - (b) comply with specific clearance levels and associated requirements for specific materials or for materials originating from specific types of practices; these specific clearance levels shall be established in national legislation or by the national competent authority, following the general exemption and clearance criteria set out in Annex VI, and taking into account technical guidance provided by the Community.**

Specific clearance levels (Recital)

Specific clearance levels, as well as corresponding Community guidance, remain important tools for the management of large volumes of materials arising from the dismantling of authorised facilities.

Radiation Protection 89: Recommended radiological protection criteria for the recycling of metals from dismantling of nuclear installations,

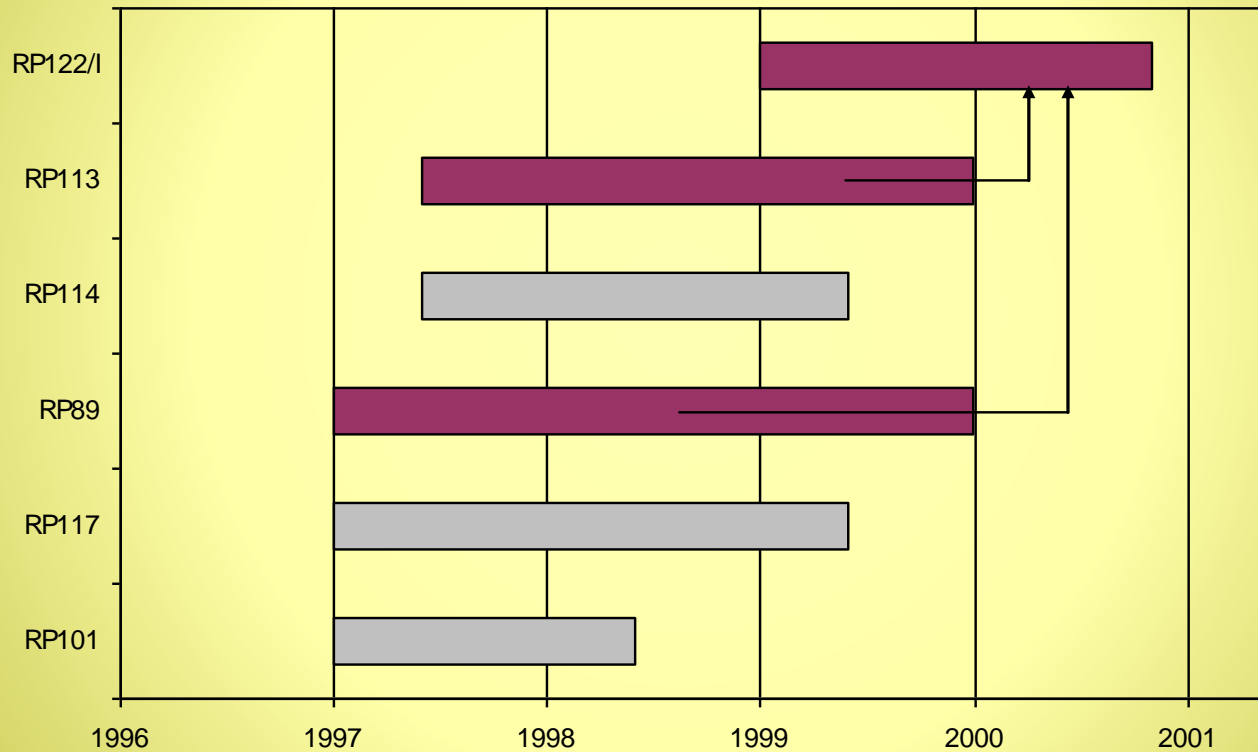
Radiation Protection 113: Recommended Radiological Protection Criteria for the Clearance of Buildings and Building Rubble from the Dismantling of Nuclear Installations,

Radiation Protection 122: Practical Use of the Concepts of the Clearance and Exemption.

Part I: Guidance on general clearance levels for practices

Part II: Application of the concepts of exemption and clearance to Natural Radiation Sources

EC guidance on Clearance



Release from regulatory control (Art. 30)

3. *Member States shall ensure that for the clearance of materials containing naturally-occurring radionuclides, where these result from authorised practices in which natural radionuclides are processed for their radioactive, fissile or fertile properties, the clearance levels comply with the dose criteria for clearance of materials containing artificial radionuclides.*
4. **Member States shall not permit the deliberate dilution of radioactive materials for the purpose of them being released from regulatory control. The mixing of materials that takes place in normal operations where radioactivity is not a consideration is not subject to this prohibition. The Competent Authority may authorise, in specific circumstances, the mixing of radioactive and non-radioactive materials for the purposes of re-use or recycling.**

Scrap metal (BSS Recital)

Council Regulation (EU) No. 333/2011 of 31 March 2011 establishes criteria determining when certain types of scrap metal cease to be waste under Directive 2008/98/EC of the European Parliament and of the Council; measures need to be taken to prevent the accidental melting of orphan sources as well as to ensure compliance of metals released from nuclear installations, for instance during their dismantling, with clearance criteria.

Code of Conduct

CODE OF CONDUCT ON THE TRANSBOUNDARY MOVEMENT OF RADIOACTIVE MATERIAL INADVERTENTLY INCORPORATED INTO SCRAP METAL AND SEMI-FINISHED PRODUCTS OF THE METAL RECYCLING INDUSTRIES

- *Follow-up to:*
 - Accidental melting of a Cs-137 source in Algeciras
 - IAEA Conference in Tarragona (2009)
- Implementing Council Regulation (EU) 333/2011 establishing criteria determining when certain types of scrap metal cease to be waste under Directive 2008/98/EC of EP and Council

Article 106 Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by **6 February 2018**.

2. When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

- Recital (53) In accordance with the Joint Political declaration of Member States and the Commission on explanatory documents of 28 September 2011, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the **relationship between** the components of a **directive** and the **corresponding parts of national transposition instruments**. With regard to this Directive, the transmission of such documents is justified.
- Article 33 Euratom: draft legislation **at least 3 months before**

Minimum requirements

- *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.*

Article 77: Transparency

*Member States shall ensure that **information in relation to the justification** of classes or types **of practices, the regulation** of radiation sources and **of radiation protection** is made available to undertakings, workers, members of the public, as well as patients and other individuals subject to medical exposure. This obligation includes ensuring that the competent authority provides information within its fields of competence.*

Information shall be made available in accordance with national legislation and international obligations, provided that this does not jeopardise other interests such as, inter alia, security, recognised in national legislation or international obligations.

Conclusions

- *Graded approach to regulatory control*
 - **More flexibility**
 - **More judgement by the regulatory authority**
- *Coherent approach artificial/natural radiation*
 - **Exemption/clearance criteria 10 μ Sv respectively 1 mSv/y**
- *Clear formulation of concept of clearance*
- *Approach for mixing/dilution*
- *Harmonisation?*
 - **International harmonisation of the exemption-clearance levels**
 - **Clearance policy still optional**
 - **Need for traceability (especially for metals)**
 - **Overall requirement for transparency of regulatory decisions**



Annales de l'Association belge de Radioprotection
Annalen van de Belgische Vereniging voor Stralingsbescherming

The history of exemption of practices from regulatory control and of clearance of materials containing radioactive substances, pp.1-31

[Vol.40, n°1, 2015](#)

<http://www.bvsabr.be/js/tinyMCE/plugins/moxiemanager/data/files/annals/Ann-40-1.pdf>



25 JAHRE REGELUNGEN ZUR FREIGABE VON MATERIALIEN IM STRAHLENSCHUTZ

Travemünde 14. – 16. September 2015: 9. Freigabesymposium: Entlassung von radioaktiven Stoffen aus dem Geltungsbereich des Atomgesetzes

International Conference about Release of Materials from Regulatory Control, **6-9 November 2017 in Berlin.**

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