

EURATOM BASIC SAFETY STANDARDS STANDARDS **Council Directive 2013/59/Euratom**

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BVS-ABR December 2014

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,

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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"

Consolidation of European Radiation Protection Legislation

- *Basic Safety Standards, Directive 96/29/Euratom*
- *Control of high-activity sealed radioactive sources and orphan sources, Directive 2003/122/Euratom*
- *Medical Exposures, Directive 97/43/Euratom*
- *Outside Workers, Directive 90/641/Euratom*
- *Public Information, Directive 89/618/Euratom*
- *Radon, Commission Recommendation 90/143/Euratom*

New BSS: main novelties

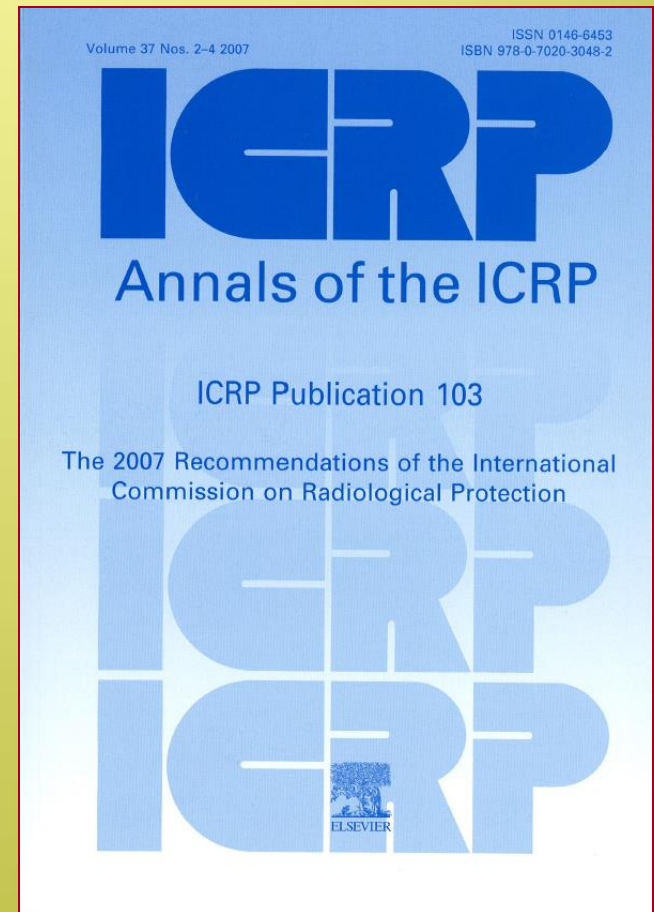
- *Scope:*
 - ✓ **Protection of the environment**
 - ✓ **Radon in dwellings, workplaces**
 - ✓ **Building materials**
- *Graded approach to regulatory control*
 - ✓ **Registration and licencing**
 - ✓ Licencing requirements
 - ✓ **Exemption/clearance criteria**
 - ✓ **NORM industries managed as practices**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

New BSS: main novelties

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

Revision of EU-BSS

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



Exposure situations: Euratom approach

- *Planned: new source or new pathway of exposure resulting from the human activity*
 - industries processing naturally occurring radioactive materials (NORM)
 - operation of aircraft and spacecraft (specially authorised)
- *Existing: resulting from features of the location (not the type of human activity)*
 - indoor Radon (ingress from soil)
 - commodities managed together with the exposure situation:
 - building materials (gamma exposure, radon exhalation)
 - foodstuffs (post-accidental situation)
- *Responsibility of the employer for exposure to radon at work managed in the same way as for a planned exposure situation*

Indoor Radon

Radon Action Plan (Art. 103)

National surveys

“Radon prone areas”

Long term objectives in terms of lung cancer prevention, allow for smoking

Radon in dwellings

Establishment of a national reference level $\leq 300 \text{ Bq/m}^3$

No more distinction between new/old buildings, buildings with public access

Identification of existing dwellings exceeding the reference level

→ *encourage radon-reducing measures*

Information on indoor radon exposure, importance of measurements, technical means for radon reduction

Radon in workplaces

National reference level $\leq 300 \text{ Bq/m}^3$

Managed as occupational exposure above 6 mSv/y (or equivalent time-integrated exposure)

Building materials

- Exposure to external radiation from building materials is an existing exposure situation
- Specific requirements laid down in Article 75

➤ Annexes:

XIII: types of building materials deemed to be of concern

VIII: activity concentration index and its application:

$$I = C_{Ra226}/300 \text{ Bq/kg} + C_{Th232}/200 \text{ Bq/kg} + C_{K40}/3000 \text{ Bq/kg}$$

- ✓ *Requires uniform reference level for indoor external exposure to gamma rays of 1 mSv per year*
- ✓ *If > 1 mSv/y: Competent authority to decide on appropriate measures/restrictions (e.g. specific requirements in relevant building codes)*

Building materials and NORM residues

- *Regulation (EU) No. 305/2011 lays down harmonised conditions for the marketing of construction products*
 - ✓ **Need for development of CEN codes**
 - ✓ **Need for national building codes**
- *NORM industries managed as a planned exposure situation, but graded approach to regulatory control*
 - **Application of the concept of clearance**
- *Novel approach for mixing/dilution*
 - ✓ **The recycling of secondary NORM materials in building materials may be judged to be justified and be authorised**

Building materials (Annex XIII)

- *Natural materials*
 - **Alum-shale**
 - **of igneous origin (granitoides etc)**
- *Materials incorporating residues from NORM industries*
 - **Fly ash**
 - **Phosphogypsum**
 - **Phosphorus slag**
 - **Tin slag**
 - **Copper slag**
 - **Red mud (Aluminium production)**
 - **Residues from steel production**

Industrial NORM practices (Annex VI)

*Extraction of rare earths
Production of thorium
compounds
Niobium/tantalum ore
Oil and gas
Geothermal energy
TiO₂ pigment production
Zircon and zirconium industry
Thermal phosphorous production
Production of phosphate
fertilizers
Cement production
Maintenance of boilers of coal-
fired power plants
Phosphoric acid production
Tin/lead/copper smelting
Ground water filtration
Mining*

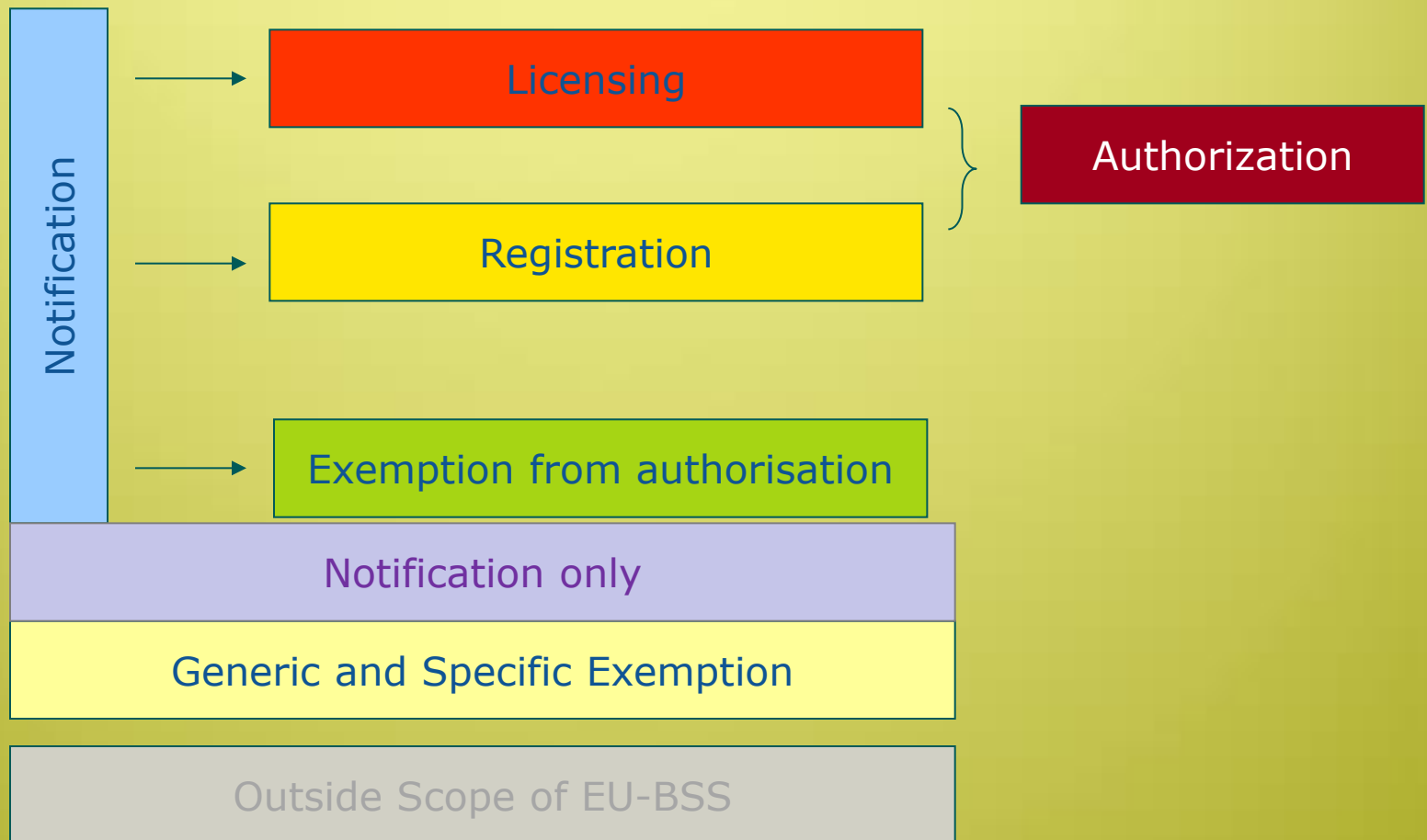
Graded approach to regulatory control

- *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



Notification and exemption

- *All practices shall be notified, except those involving materials containing*
 - **Quantities of radioactivity (Bq) or**
 - **Substances with concentrations of activity (kBq/kg) below exemption values**
- *Total activity: current exempt quantities (Bq) (Table B)*
- *Concentrations: Artificial radionuclides (Table A part 1):*
 - **General exemption values based on RS-G-1.7**
- *Higher values (MS's, not harmonised) for:*
 - ✓ **Moderate amounts (Table B: 1996 values)**
 - ✓ **Specific applications**
- *MS's may exempt further types of practices, subject to:*
 - ✓ **Compliance with general exemption criteria**
 - ✓ **10 μ Sv/y (artificial) to 1 mSv/y (NORM)**
- *Application of the concept of clearance*

Justification of products and practices

- General requirement on transparency (Article 77)
 - ✓ In relation to justification of types or classes of practices
- Information to undertaking on any equipment (Article 78)
 - ✓ Demonstration that design is optimal
 - ✓ For medical equipment: risk assessment and clinical evaluation
- Practices involving consumer products (Article 20)
 - ✓ Requirement on information on consumer products for which the intended use is likely to be a new class of practice
 - relevant information as listed in Annex IV
 - ✓ Allow placing on the market of a consumer product only if its intended use is justified and if it fulfils the exemption criteria
 - ✓ Information to points of contact in other MS's

Categories of exposure

- *Occupational exposure*
means exposure of workers, apprentices and students, incurred in the course of their work;
- *Medical exposure*
means exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health, as well as exposure incurred by carers and comforters and by volunteers in medical or biomedical research;
- *Non-medical imaging exposure*
means any deliberate exposure of humans for imaging purposes where the primary intention of the exposure is not to bring a health benefit to the individual being exposed;
- *Public exposure*
means exposure of individuals, excluding any occupational or medical exposure;

Occupational exposures

- Protection of workers covers now also
 - ✓ Practices involving naturally occurring radioactive materials (NORM)
 - ✓ Radon in workplaces
 - ✓ Aircraft crew and spacecraft crew (specially authorised exposure)
 - ✓ Emergency workers
- Contents of the Outside Workers Directive fully integrated
 - ✓ Clear definitions and clear assignment of responsibilities for the undertaking, the employer and the outside worker
 - ✓ Including category B workers
- Data system on occupational exposures
- Dose limit for occupational exposure
 - ✓ Now 20 mSv in any single year
 - ✓ Except in authorised special circumstances (100 mSv in 5 y)
 - ✓ Dose limit for the lens of the eye lowered to 20 mSv per year

Experts and Services

- **RPExpert:** gives competent advice to the undertaking in specified areas of expertise
- **RPOfficer:** is technically competent in radiation protection matters to supervise or implement the arrangements.
- Member States shall ensure that arrangements are in place for the recognition of:
 - a) occupational health services;
 - b) dosimetry services;
 - c) radiation protection experts;
 - d) medical physics experts.
- Member States shall ensure the continuity of expertise of these experts and services and specify the recognition requirements.
- The Commission shall transmit this information to other MS's

Medical Physics Expert; Medical Education & Training

- *Member States shall require the **MPE** to act or give specialist advice, ... , on matters relating to radiation physics for implementing the requirements set out in Chapter VII ... of this Directive.*
- *Member States shall ensure that training and recognition requirements, ... are met for the practitioner, the medical physics expert and the "individuals involved in practical aspects".*
- **Education, information and training in the field of medical exposure**
 - **Member States shall encourage the introduction of a course on radiation protection in the basic curriculum of medical and dental schools.**

Medical exposures

- *“Medical exposure” means exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health ...*
- *Recitals:*
 - In the medical area, important technological and scientific developments have led to a notable increase in the exposure of patients.
 - In this respect, the Directive should emphasise the need for justification of medical exposure, including the exposure of asymptomatic individuals and should strengthen the requirements concerning information to be provided to patients, the recording and reporting of doses from medical procedures, the use of diagnostic reference levels and the availability of dose-indicating devices.
 - **It should be noted that according to the World Health Organisation the concept of health is understood to cover the physical, mental and social well-being of an individual and not merely the absence of disease or infirmity.**

Justification and non-medical imaging

- Broad understanding of Health
- Special attention to justification of non-medical imaging:
 - ✓ General type of practice and each particular application
 - ✓ Individually (specific objectives, individual)
 - ✓ Regular review of (routine) screening without individual justification
- Public exposure (dose limits and constraints)
 - ✓ Except NMIE practices using medical radiological equipment
- Practices using medical radiological equipment:
 - ✓ Same requirements as for medical exposures apply
 - ✓ Specific protocols, consistent with the objective of the exposure and required image quality
 - ✓ Specific diagnostic reference levels

Unintended exposures

- **Unintended exposure** means medical exposure that is significantly different from the medical exposure intended for a given purpose.
- **Recital:** Accidental and unintended medical exposures are a source of continuing concern. Whereas for medical devices post-market surveillance is required under Directive 93/42/EEC of 14 June 1993 concerning medical devices, it is the role of the competent authority in radiation protection to address their prevention and the follow-up in case of their occurrence. In this respect, the role of quality assurance programmes, including a study of risks in radiotherapy, to avoid such incidents should be emphasised, and recording, reporting, analysis and corrective action should be required in such cases.
- **For all medical exposures the undertaking implements an appropriate system for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice;**
- **Significant events:**
 - arrangements are made to inform the referrer and the practitioner, and the patient, or their representative, about clinically significant unintended or accidental exposures and the results of the analysis;
 - the undertaking declares as soon as possible to the competent authority the occurrence of significant events as defined by the competent authority;
 - the results of the investigation and the corrective measures to avoid such events are reported to the competent authority within the time period specified by the Member State.

Medical exposures

The incorporation of the Medical Directive in the consolidated Basic Safety Standards Directive yields a benefit for:

- **Integration of the principles of Justification and Optimisation**
- **The protection of medical staff**
Especially in interventional radiology
- **Follow-up of accidental and unintended exposures**
- **Clear and more prominent role of the Regulatory Authority**
Registration, licencing, inspection
- **A clear regime for non-medical imaging**
As opposed to "medico-legal exposures"
- **Defined role of MPE and E & T for the medical profession**

Implications for the future of Radiation Protection

- *Comprehensive integrated body of legislation*
- *Larger scope:*
 - ✓ **Protection of the environment,**
 - ✓ **NORM,**
 - ✓ **Building materials,**
 - ✓ **Radon in workplaces,**
 - ✓ **Non-medical imaging exposures.**
- *Enhanced role of the regulatory authority*
 - ✓ **Graded approach,**
 - ✓ **Judgment,**
 - ✓ **Transparency.**
- *Integration of radiation protection and other (TFEU) legislation*