



Medical exposure in the European Commission's proposal for revised Euratom radiation protection Directive

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Euratom Treaty, 1957

- **Article 2:** ... the Community shall ... establish **uniform standards** to protect the health of workers and of the general public and ensure that they are applied;
- **Article 30:** Basic standards shall be laid down within the Community for the **protection of the health of workers and the general public against dangers arising from ionising radiations** ...
- **Article 31:** The basic standards shall be worked out by the **Commission** after it has obtained the opinion of a **group of persons** appointed by the Scientific and Technical Committee from among scientific experts, and in particular **public health experts**, in the Member States ...



Euratom Basic Safety Standards

- First Directive established in 1959
 - » Amended in 1962, 1966, 1976, 1980, 1984, and 1996
- Current “Basic Safety Standards”
 - » Council Directive 96/29/Euratom laying down basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation
- Medical Exposure
 - » Council Directive 97/43/Euratom on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive

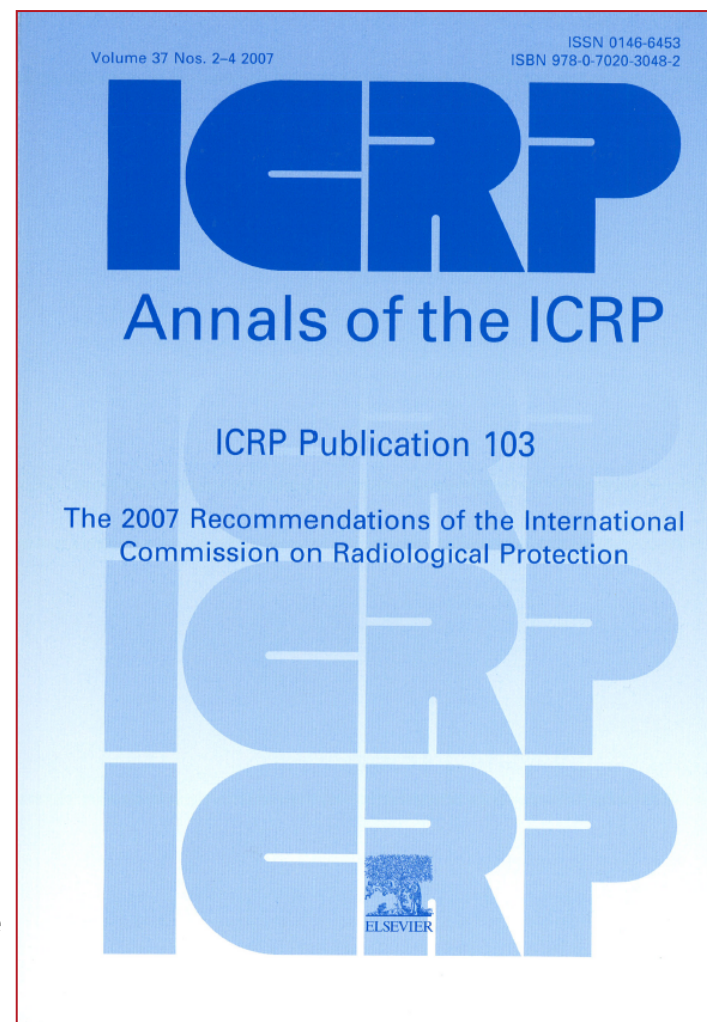
Revision of Euratom BSS

Two objectives

- Revision of the requirements in the Euratom Basic Safety Standards Directive 96/29/Euratom
- Consolidation of existing 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](#)

Motivation of the Revision

- New scientific findings and recommendations:
 - » ICRP Publication 103, 2007
 - » New scientific data; e.g. on radiation induced cataract, epidemiological findings on radon in dwellings
 - » Cover natural radiation sources
 - » Additional ICRP guidance to come
- Regulatory experience since 1996:
 - » Clarify and strengthen requirements
- Harmonisation with the Revision of the **International Basic Safety Standards**



Topical issues for BSS revision

- Review of the **regulatory control system**
 - » Graded approach to regulatory control
 - » Harmonisation of exemption and clearance
- Introduce more binding requirements on **natural radiation sources**
 - » NORM industries, building material, radon in dwellings and work places, cosmic radiation (exposure to air crew and space crew)
- Highlight the importance of **education, training and information**
- Strengthen cooperation in **emergency preparedness, planning and response**

Structure of revised BSS

- **Preamble**
- **Title I:** Subject matter and Scope
- **Title II:** Definitions
- **Title III:** System of Protection
- **Title IV:** Responsibilities for Regulatory Control
- **Title V:** Requirements for Radiation Protection Education, Training and Information
- **Title VI:** Justification and Regulatory Control of Planned Exposure Situations
- **Title VII:** Protection of Workers, Apprentices and Students
- **Title VIII: Protection of patients and other individuals submitted to medical exposure**
- **Title IX:** Protection of Members of the Public
- **Title X:** Protection of the Environment
- **Title XI:** Final provisions
- 17 **Annexes**

Proposed changes on medical exposure

- Definition of medical exposure
 - » exposure incurred by:
 - patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment,
 - research volunteers,
 - carers and comforters
 - » intended to benefit the health or the wellbeing of the exposed individual

Proposed changes on medical exposure

● Justification

- » accounting for the **staff exposure**, Art. 80.1
- » justification of **health screening by health authority** and appropriate professional bodies, Art. 80.1(d)
- » **asymptomatic individuals**, Art. 80.3
 - part of an approved health screening programme, or
 - **specific documented justification** for that individual by the practitioner, in consultation with the referrer, if appropriate, following guidelines from relevant professional bodies or competent authorities
 - special attention to **provision of information**

Proposed changes on medical exposure

- Optimization

- » diagnostic reference levels (**DRL**), when appropriate, **for interventional radiology procedures**, Art. 81.2(a)

- Information

- » The practitioner shall ensure that the patient or legal guardian is provided with **adequate information** relating to the benefits and risks associated with the radiation dose from the medical exposure to enable informed consent, Art. 82.3

Proposed changes on medical exposure

- The Medical Physics Expert
 - » **New definition** and responsibilities, Art. 20
 - » **Level of involvement**, commensurate with the radiological risk, Art. 83.3
 - radiotherapy – closely involved
 - NM, radiodiagnostic and interventional radiology procedures – involved
 - simple radiodiagnostic procedures - involved, as appropriate, for consultation and advice

Proposed changes on medical exposure

- Equipment, Art. 85
 - » **Interventional** radiology and **CT** systems – **device** (or feature) informing the practitioner of the quantity of radiation produced during the procedure
 - » Any **other** (new) medical radiodiagnostic equipment - a device (or feature) **or equivalent tool**
 - » Radiation **dose shall form part of the report** on the examination

Proposed changes on medical exposure

- Education, information and training, Art. 45
 - » Member States **shall** ensure the introduction of a course on radiation protection in the basic curriculum of medical and dental schools.
 - » Member States shall ensure that mechanisms are in place for the **timely dissemination** of appropriate information relevant to radiation protection in medical exposure on **lessons learned from significant events**

Proposed changes on medical exposure

- Accidental and unintended exposures, Art. 88
 - » QAP for RT includes a **study of risk** of accidental or unintended exposures
 - » **registration and analysis system** of events
 - » **reporting** to the competent authorities **of significant events**, including the results of the investigation and the corrective measures
 - » **inform** the referrer, the practitioner and the patient

BSS adoption procedure

- Opinion of the Group of Experts referred to in Article 31 of the Euratom Treaty – 24 February 2010
- Internal Commission procedures – during 2010 and 1st half 2011
 - » Impact assessment
 - » Inter-service consultations
- Adoption of proposal by the Commission – mid 2011
- Opinion of Economic and Social Committee
- Proposal to Council and European Parliament
- Discussion/amendment in Atomic Questions Group of Council
- Adoption by Council
- Transposition into national legislation
 - » Recommendations on drafts submitted by Member States (Article 33 Euratom)

**THANK YOU
FOR
YOUR ATTENTION**

