

Radiation Protection in Medicine in the Revised Euratom BSS

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The Euratom Treaty

- Rome, 25 March **1957**
- Article 2: "... the Community shall ... establish **uniform standards** to protect the health of workers and of the general public"
- **Article 31**: "The basic standards shall be worked out by the Commission after it has obtained the opinion of a **group of ... scientific experts**
 - 'Art.31 GoE', **WP on Medical Exposure**



Euratom Radiation Protection Law

- Euratom "**Basic Safety Standards**" (BSS) Directives
 - » **Binding Law** for all EU Member States
 - » First adopted in **1959**, covers workers and public
 - » Regular revision, current **Directive 96/29/Euratom**
- Supplementing legislation in **other areas**
 - » **Medical**, Directives 84/466/Euratom and **97/43/Euratom**
 - » Outside workers, Directive 90/641/Euratom
 - » Foodstuff contamination
 - » Etc.

Patient Protection in Euratom Law

- 97/43/Euratom, MED – **Medical Exposure Directive**
 - » lays down general principles of **radiation protection**
 - » in relation to the **exposure of:**
 - **patients** as part of their own medical diagnosis or treatment
 - individuals as part of **occupational health surveillance**
 - individuals as part of **health screening** programmes
 - volunteers in **(bio)medical research** programmes
 - individuals as part of **medico-legal** procedures
 - individuals knowingly and willingly helping (other than as part of their occupation) in the support and comfort of individuals undergoing medical exposure – "**carers and comforters**"

Revision of Euratom RP Law

- European Commission **proposal, May 2012**
http://ec.europa.eu/energy/nuclear/radiation_protection/doc/2012_com_242.pdf
- "Revised Euratom (EU) BSS"
- Grouping **five current Directives**
 - » Euratom BSS, 96/29/Euratom
 - » MED, 97/43/Euratom
 - » Etc.
- Some changes, including in **'Medical' Chapter VII**
- Ongoing discussion in the Council of the EU, **adoption 2013 (?)**

Patient Protection in the Revised BSS

● Justification

- » Main elements of MED 97/43/Euratom kept
 - weighing benefit vs. risk, taking into account alternative techniques
 - 2-level justification – type of practice / individual patient
 - involvement of the referrer and the practitioner
- » **New**: early detection of disease in **asymptomatic individuals**
 - health **screening programme** – justification **by competent authority** in conjunction with appropriate medical scientific societies or professional bodies, **OR**
 - specific **documented justification** for that individual by the practitioner, in consultation with the referrer, **following guidelines** from relevant medical scientific societies and competent authorities
 - *Special attention to **provision of information***

Patient Protection in the Revised BSS

● Optimization

- » Main elements of MED 97/43/Euratom kept
 - ALARA commensurate with the intended outcome
 - Multi-stage implementation: selection of equipment, QA, evaluation of patient doses, etc.
 - Diagnostic reference levels (DRLs)
- » **New**: stronger requirement on DRLs
 - MS shall **ensure** (not just "promote") the establishment, **regular review** and use of DRLs
- » **New**: emphasis on **interventional radiology**
 - **DRLs** ... when appropriate, for interventional radiology
 - Number of other mentions in existing requirements

Patient Protection in the Revised BSS

● Responsibilities

- » Main elements of MED 97/43/Euratom kept
 - clinical responsibility of the practitioner
 - practical aspects: delegation to individuals entitled to act in recognized field of specialization
- » **New**: provision of **information to patients**
 - Wherever practicable and prior to the exposure taking place, the **practitioner or the referrer**, as specified by Member States, **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.

Patient Protection in the Revised BSS

● Procedures

- » Main elements of MED 97/43/Euratom kept
 - written protocols for standard medical radiological procedures
 - referral guidelines for medical imaging
 - need to involve medical physics expert (MPE)
 - Clinical audit
- » **New:** protocols for **relevant categories of patients**
- » **New:** stronger involvement of **MPE in DR and NM**
 - New **definition** and detailed description of **MPE's tasks** included in other parts of the Directive

Patient Protection in the Revised BSS

● Training

- » Main elements of MED 97/43/Euratom kept
 - theoretical and practical training, competence in RP
 - continuing education and training after qualification
 - specific training for new techniques
- » **New** in the revised BSS Directive
 - Member States **shall establish** an adequate **legislative and administrative framework** for education and training
 - Member States **shall ensure** the introduction of a **course on radiation protection** in the basic curriculum of **medical and dental schools**
 - Stronger requirements for **recognition of MPE** (together with RPE, dosimetry and occupational health services)

Patient Protection in the Revised BSS

● Equipment

- » Main elements of MED 97/43/Euratom kept
 - strict surveillance, up-to-date inventory for competent authority
 - QA, acceptance and performance testing, acceptability criteria
 - fluoroscopy without image intensifier prohibited
- » **New**: fluoroscopy without AEC **prohibited**
- » **New**: **device or feature** for providing **information** on relevant parameters **for assessing patient dose**
 - all **CT** and **IR** equipment **in use**
 - all **other new radiodiagnostic** equipment
- » **New**: Capacity to transfer the patient dose information to the **report of the examination**

Patient Protection in the Revised BSS

● Special practices

- » Requirements of MED 97/43/Euratom unchanged
 - exposure of children, screening and high-dose procedures
 - appropriate equipment and practical techniques
 - special attention to QA and dose assessment
 - appropriate training in these medical radiological practices

● Protection during pregnancy and breastfeeding

- » Requirements of MED 97/43/Euratom kept unchanged
 - referrer / practitioner shall inquire, as specified by MS
 - special attention to justification, in particular urgency
 - special attention to optimization, taking into account both (expectant) mother and (unborn) child
- » **New:** Measures to **increase awareness - mandatory**

Patient Protection in the Revised BSS

● Accidental and unintended exposures

- » MED 97/43/Euratom quite brief and general
 - all reasonable steps to minimise probability and magnitude, taking into account economic and social factors
 - main emphasis on radiotherapy, "some attention" to diagnostic
- » **New**: considerably **expanded and strengthened**
 - Radiotherapy: prior **risk study**, as part of QA
 - Internal **system to record and analyse** (all) events
 - Reporting of **significant events to authorities**
 - **Dissemination** of information on **lessons learnt**
 - **Information** to referrer, practitioner and patient

Patient Protection in the Revised BSS

● Protection of medical staff

- » Staff doses shall be taken into account in **justification of new types of ME practice**
- » Assessment of staff doses – part of **optimization in ME**
- » Changes in occupational **dose limit**
 - uniform definition of the annual occupational dose limit - **no averaging** over 5years
 - the limit on the equivalent dose for the **lens of the eye** shall be **20 mSv in a year** or, where applicable, the same value as specified for the limit on effective dose year

Take Home Points

- Comprehensive **legal system** for radiation protection of patients has been functioning in the EU for **more than 10 years**.
- Ongoing **revision of Euratom BSS** offers unique opportunity for **integrated system** for protection of the public, staff and patients.
- The **revised BSS** maintains the existing patient protection framework adding several **important updates and advances**.
- **Uptake** by national **regulators** and **health professionals** is needed to fully benefit from the advances in EU regulation.
- The EC will provide **support to Member States** (guidelines, meetings) to facilitate the **implementation in practice** of the new requirements.

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Medical Applications

Ionizing radiation has been used in medicine for more than a century and has proven to be an essential component of modern medical diagnosis and treatment. The technology has made much progress in the past decades, in X-ray imaging through the development of digital and computerized technology, in nuclear medicine through the introduction of mobile radioisotopes and teletherapy, and in the protection of the so-called computer-aided treatment planning and novel techniques for the precise delivery of the radiation to the tumour.

At the same time, ionizing radiation is a cause of concern because the exposure of the human body may cause health detriment. At present, no major public health problem is due to medical procedures, hugely exceeds any other man-made exposure. The potential for the patients and other individuals exposed in medical practice, is therefore one of a main priority task for the European Commission under the Health and Safety Chapter of the Euratom Treaty.

News

- 28/09 - [EC breakout session at the Bonn Conference was announced](#) 
- 29/06 - [The European Observatory on the supply of medical radioisotopes was set-up](#)
- 18/04 - [Radiation Protection No. 172 "Cone Beam CT for Dental and Maxillofacial Radiology" has been published](#) 

Forthcoming events

Thank you for your attention!

http://ec.europa.eu/energy/nuclear/radiation_protection/medical/applications_en.htm