Protection of Patients in the Revised Euratom Basic Safety Standards Directive

Georgi Simeonov
Directorate-General for Energy (DG ENER)
Unit D3 Radiation Protection
Luxembourg

Proteção Radiológica na Saúde
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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**"
Patient protection in the revised BSSD

- 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**

Patient protection in the revised BSS Directive

- **Chapter VII Medical Exposures**
- **Chapter II Definitions**
- **Chapter IV Education, Training and Information**
- **Chapter V Justification and Regulatory Control**
- **Chapter IX General Responsibilities of MS and Other Requirements for Regulatory Control**
REVISED EURATOM BSS - CHANGES WITH REGARD TO PROTECTION OF PATIENTS
● **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*
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

» **New**, introduced by *WPAQ*: exposures of target volumes in RT – delivery shall be *appropriately verified*
Responsibilities

» Main elements of MED 97/43/Euratom kept
  • involvement of practitioner and referrer in justification
  • 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.

» New, introduced by WPAQ: involvement in optimization – practitioner, MPE, persons involved in 'practical aspects'
• **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**: information relating to patient exposure shall be part of the report of the procedure

» **New**: stronger involvement of MPE in radiodiagnostic and IR practices "involving high doses" (as in Article 60.1.c)

  • New definition and detailed description of MPE's tasks included in other parts of the Directive (see text of 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 (not in Medical Chapter)
  - Member States shall establish an adequate legislative and administrative framework for education and training
  - Stronger requirements for recognition of MPE (together with RPE, dosimetry and occupational health services)

- Rejected by WPAQ: Member States shall (ensure) encourage the introduction of a course on radiation protection in the basic curriculum of medical and dental schools.
**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**, as agreed by WPAQ:
  • **RT equipment** with beam energy > 1 MeV
    - device to **verify key treatment parameters. New equipment** (installed prior to transposition deadline, i.e. 4 years after BSSD publication in OJ) **may be exempted** from this requirement
Equipment (continued)

» **New**, as agreed by WPAQ:

- **IR equipment**
  - device or feature informing ... of quantity of radiation produced by the equipment during the procedure *

- **IR, CT and new equipment used for planning, guiding and verification purposes**
  - device or feature informing the practitioner, at the end of the procedure, of relevant parameters for assessing the patient dose

- **IR and CT equipment**
  - the capacity to transfer the information required under 3(d) to the record of the examination *

- **New radiodiagnostic equipment**
  - device or equivalent means informing the practitioner of relevant parameters for assessing the patient dose. Where appropriate, the capacity to transfer this information to the record of the examination

* New equipment may be exempted
- **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 **largely unchanged** (editorial changes including for gender neutrality)
    - 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**
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 for record keeping and analysis of events, commensurate with the radiological risk posed by the practice
  - Reporting to the authorities of significant events and associated corrective actions
  - Information to referrer, practitioner and patient (or legal guardian) about clinically significant exposures
  - Dissemination of information on lessons learnt
Estimates of population doses

» MED 97/43/Euratom
  • Member States shall ensure that the distribution of individual dose estimates from medical exposure referred to in Article 1 (2) is determined for the population and for relevant reference groups of the population as may be deemed necessary by the Member State.

» Changes, as agreed by WPAQ
  • Member States shall ensure that the distribution of individual dose estimates from medical exposure for radiodiagnostic and interventional radiology purposes is determined, taking into consideration, where appropriate, the distribution by age and gender of the exposed population
EURATOM PUBLICATIONS IN SUPPORT OF THE (REVISED) BSS DIRECTIVE
Since 1976 the European Commission has published publications covering a wide range of issues relating to ionizing radiation and radiation protection (Radiation Protection series). The following Radiation Protection publications dealing with medical exposures have been issued in the past decade or so and are expected to still have relevance today:

• **RP 172. Cone beam CT** for dental and maxillofacial radiology. Evidence based guidelines
  ➢ resulting from FP7 SEDENTEXCT, [http://www.sedentexct.eu/](http://www.sedentexct.eu/)

• **RP 162. Criteria for Acceptability** of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy

• ...
Medical Physics Expert Guidelines
- Qualification framework, curricula, staffing
- Publication – end 2013

MEDRAPET
- Publication – end 2013

Risk analysis of accidental and unintended exposures in radiotherapy
- Review of the available general risk assessment methods
- Guidelines on event reporting and learning systems for RT
- Publication – mid 2014
Future Euratom RP guidance

» Diagnostic Reference Levels for **Paediatric Imaging**
  • European **Guidelines** on Paediatric DRLs
  • European **Paediatric DRLs**
  • European workshop, **fall 2015**
  • Publication, **mid 2016**

» **ACCIRAD II**
  • Reference methodology for external beam radiotherapy-dedicated **proactive risk assessment**
  • Guidelines for **reporting of adverse events** and near misses in external beam RT including event **classification scales**
  • Reference methodology for external beam RT-dedicated **reactive analysis of adverse events** and near misses
  • European workshops, **fall 2015 and fall 2016**
  • Publication, **mid 2017**
TAKE HOME POINTS
Comprehensive **legal system** for radiation protection of patients has been functioning in the EU for **more than 10 years**.

The **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.

- Adequate radiation protection in clinical environment can only be achieved if good day-to-day cooperation and dialogue is in place between medical practitioners, medical physicists and radiographers.

- The EC will continue providing support to Member States (guidelines, meetings) to facilitate the implementation in practice of the new requirements.
Thank you for your attention!