Radiation Protection of Medical Staff in the Revised EURATOM BSS 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**

- **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 Exposures**: 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 workplaces, 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
  - In particular between Member States
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**
Protection of workers in current BSS

- Provisions in Directive 96/29/Euratom provide already a very high level of protection for workers through
  - Measures for the restriction of exposure
    - Classification and delineation of areas
    - Classification of exposed workers
    - Assessment of the implementation of arrangements for the radiological protection of exposed workers
  - Assessment of exposure
    - Monitoring of the workplace
    - Individual monitoring
    - Monitoring in case of accidental or emergency exposure
    - Recording and reporting of results
  - Medical surveillance of exposed workers
Issues in occupational exposure

- Optimization of protection
  - dose constraints as optimization tool, including for organ doses
- Implementation of dose limit for occupational exposure
  - varies over Europe - 20 mSv/year or 100 mSv in 5 consecutive years with a maximum of 50 mSv/year
- Not all workers in environments with an enhanced level of natural radiation are covered
  - Council Directive 96/29/Euratom only addresses air crew exposure
- Outside Workers Directive needs coherent integration
  - Definitions, responsibilities of the undertaking, the employer and the outside worker
- Follow-up of dose records of cross-border outside workers
  - Radiation passbook and national dose registries
Protection of workers in revised BSS

- Occupational dose limit now 20 mSv in any single year
  - only in special circumstances specified in national legislation 50 mSv/year (with an average of 100 mSv in five consecutive years)
- Dose limits for the lens of the eye – expected to be lowered, awaiting guidance from ICRP
- Dose constraints also apply to organ/tissue doses
- Protection of workers covers now also
  - Exposure from practices involving NORM, radon in workplaces
  - Emergency workers
- Contents of the Outside Workers Directive fully integrated
- Very few changes specific to medical staff
Specific for medical staff

- Justification of procedures
  » In the justification of medical radiological procedures account shall (also) be taken of the radiation detriment from the exposure of the medical radiological staff and of other (than the patient) individuals

- Optimization of protection in medical procedures
  » The optimization process shall include … the assessment and evaluation of patient and staff doses
Integration of the Outside Workers Directive

- **Outside worker**: any exposed worker of category A, who is not employed by the undertaking responsible for the supervised and controlled area, but performs activities in these areas, including trainees, apprentices and students.

- **Undertaking**: legally responsible for a given radiation source (licensee or registrant)

- **Employer of outside workers**: not defined but used in the common sense
Protection of OW - responsibilities

**Undertaking**: Operational aspects of RP at its premises
- Check that worker has passed as medically fit
- Ensure specific training
- Issue necessary personal protective equipment
- Provide individual exposure monitoring and operational dosimetric monitoring
- Ensure compliance with the system of protection
- Ensure recording of radiological data after activity

**Employer**: ensure that RP of OW complies with legislation
- Ensure compliance with the system of protection
- Provide general radiation protection information and training
- Ensure assessment of exposure and medical surveillance
- Ensure reporting and registration of radiological data of individual monitoring (radiation passport, national dose registry)
Individual and workplace monitoring

New challenges:

» Naturally occurring radionuclides, e.g. radon exposure at workplaces

» Organ doses, e.g. exposure of the lens of the eye or extremities
  • Significant occupational exposures to specific organs occur in rapidly developing medical
techniques such as interventional cardiology

» Updated Technical Recommendations for Monitoring Individuals Occupationally Exposed to External Radiation - RP 160
Recording and reporting of monitoring results

- Results of individual monitoring need to be
  - Noted in an individual radiological monitoring document for outside workers - dose passport
    - For the content of such a passport see work of the HERCA WG on Outside workers & dose passport
  - Submitted to a centralised national network - national dose registry
**BSS Directive adoption procedure**

- Internal Commission procedures – during 2010/ beginning 2011
  - Impact assessment
  - Inter-service consultations
- Adoption of proposal by the Commission – March 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)
Protection of staff in COM(2010)423

- **Communication** from the Commission to the Council and the European Parliament on medical applications of ionizing radiation and security of supply of radioisotopes for nuclear medicine, 8 August 2010

- **Staff-related issues:**
  - Wide variations in the practice and in the corresponding radiation doses among different medical establishments
    - In some cases medical staff receiving doses around or even above the established dose limits
  - Problems with the effective monitoring of the medical staff doses
    - Partly relating to the attitude and the radiation safety culture of the staff
  - Protection of the lens of the eye
    - Member States may consider reviewing the arrangements for radiation protection, dosimetry and medical surveillance of staff exposed to high eye doses
THANK YOU FOR YOUR ATTENTION