QuADRANT, Clinical Audit and Radiation Protection

Setting the Scene

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Euratom Treaty (1957): Chapter III Health and Safety

- **Basic safety standards** for the protection of the health of workers and the general public against dangers arising from ionising radiations

**Basic Safety Standards Directive (BSS, 2013)**

- 96/29/Euratom, BSS
- 97/43/Euratom, Medical Exposure
- 89/618/Euratom
- 90/641/Euratom
- 2003/122/Euratom
- 90/143/Euratom, Radon Recommendation
Developments: Medical imaging

- > 500 million exams in EU annually
- Remarkable rise of computed tomography
- Hybrid modalities and other novelties
- Justification and optimisation issues

Figure VIII.1 - Average exposure to ionizing radiation of the population in France

Contribution to medical exposure in the EU (RP 180, EC 2015)
Developments: Radiotherapy

- Constant progress and increased complexity
- Imaging & therapy integration, precision increases
- Several legal regimes apply (TFEU, Euratom)

Average number of radiotherapy treatment machines (MV units) per million inhabitants in 28 European countries (ESTRO Survey)

Protontherapy, number of beams and gantries in the world (SAMIRA study, 2019)
Developments: Nuclear medicine

- **2017**: Second wave of growth with $^{177}$Lu-Lutathera
- **2022**: Third wave of growth with new radiotherapeutics

**2014**: The therapeutic radiopharmaceuticals market takes off with Xofigo, boosting the global nuclear medicine market.

**100 kBq/kg Administered Bi monthly**

- Complete response: Patient still in remission, after 44 months in August 2018.
- Dec 2014
  - PSA = 2923 ng/ml
- Sep 2015
  - PSA < 0.1 ng/ml

(12) "clinical audit" means a systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care by structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where appropriate, and the application of new standards if necessary.

Article 57
Responsibilities

- Clinical responsibility
- Optimisation process
- Justification process
- Information to patients

Article 58
Procedures

- Written protocols
- Referral guidelines
- Diagnostic reference levels
- MPE involvement – graded approach
- Practical aspects
- Clinical audit

Article 59
Training and recognition

Article 60
Equipment
The purpose of a multidisciplinary clinical audit can be generally summarized as:

- To improve the **quality of patient care**
- To promote the **effective use of resources**
- To enhance the provision and **organization of clinical services**
- To further **professional education and training** in a healthcare team environment.

SAMIRA: Strategic Agenda for Medical Ionising Radiation Applications

- **SAMIRA Action Plan**
  - **General Objective:** ensure that EU citizens have access to high quality radiological and nuclear technologies in medicine, at the highest safety standards

- **Three main action areas**
  - supply of medical radioisotopes,
  - quality and safety of medical applications,
  - innovation and technological development of medical ionising radiation applications
SAMIRA Action Plan
Quality and Safety

❖ **European Initiative on Quality and Safety (EIQS)**

- Build EU governance
- Coordinate legal implementation
- EU support action
- Share good practice

❖ Workforce availability, education and training

❖ Equal access to modern technology and interventions
Thank you for your attention!