



# **QuADRANT, Clinical Audit and Radiation Protection Setting the Scene**

**Georgi Simeonov**  
**DG Energy (ENER)**  
**Radiation Protection and  
Nuclear Safety Unit (D3)**

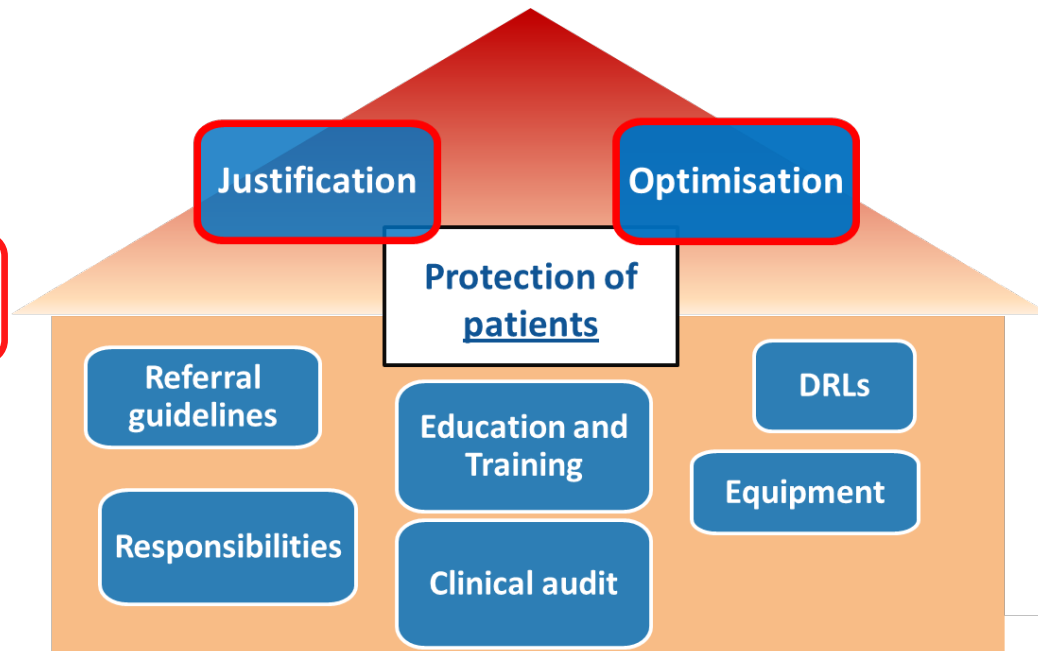


## Euratom Treaty (1957): Chapter III Health and Safety

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

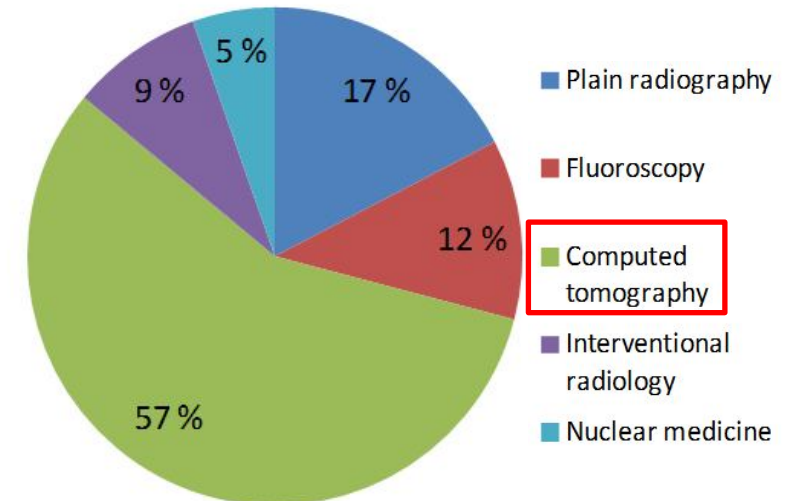
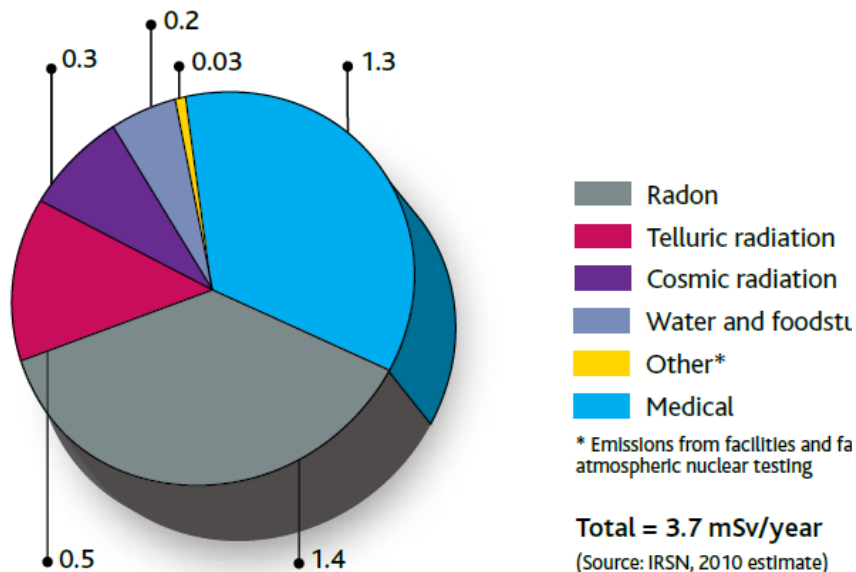
### ☞ Basic Safety Standards Directive (BSS, 2013)

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

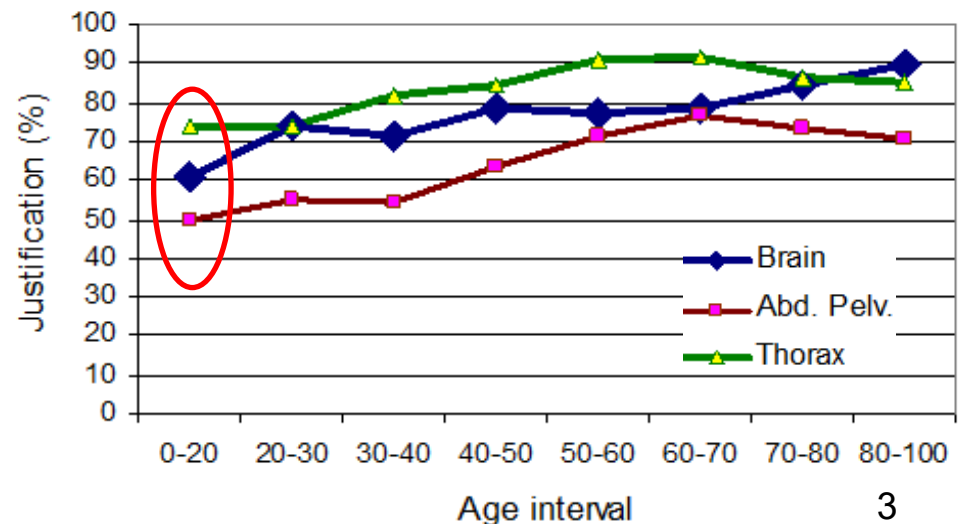


## Developments: Medical imaging

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

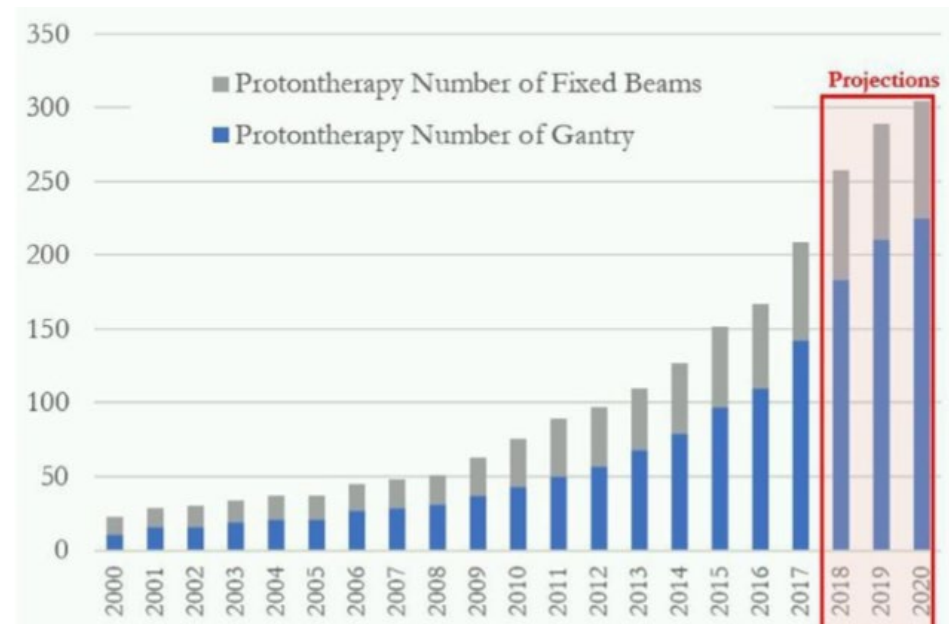
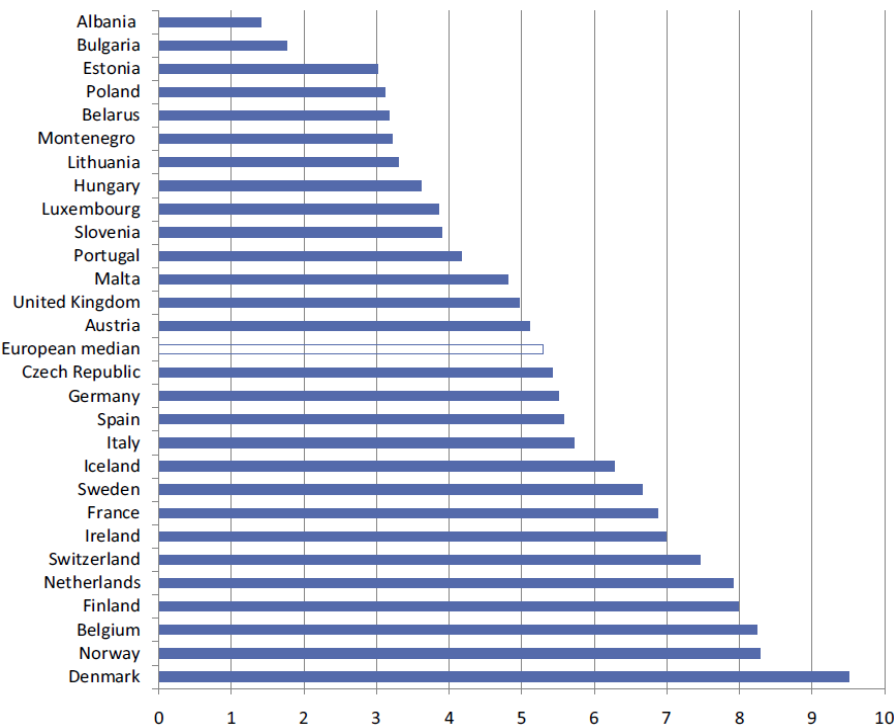


**Contribution to medical exposure in the EU**  
(RP 180, EC 2015)



# Developments: Radiotherapy

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

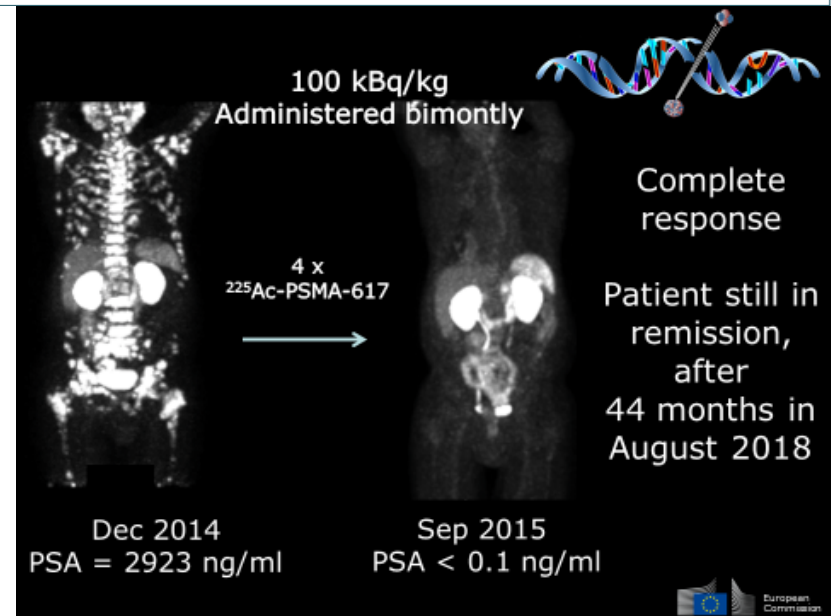
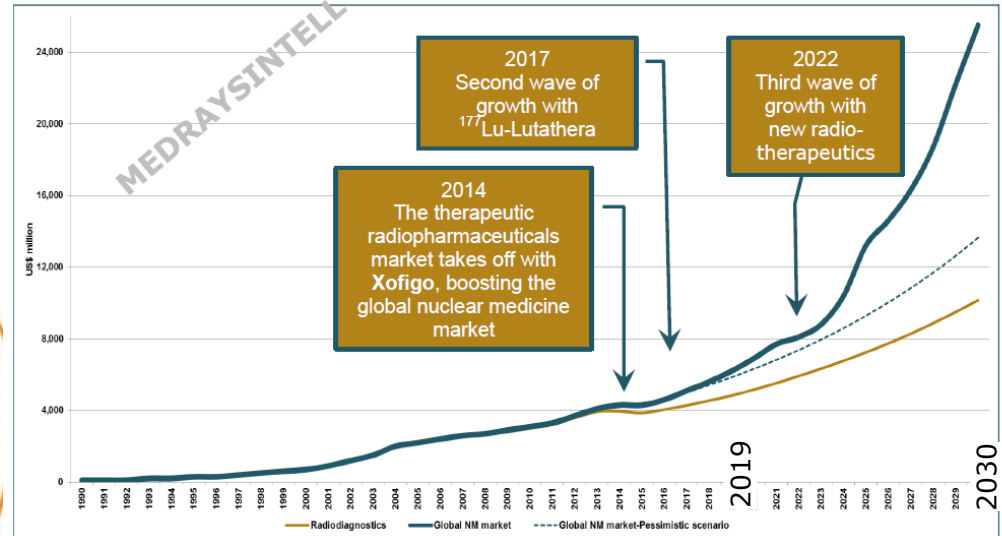
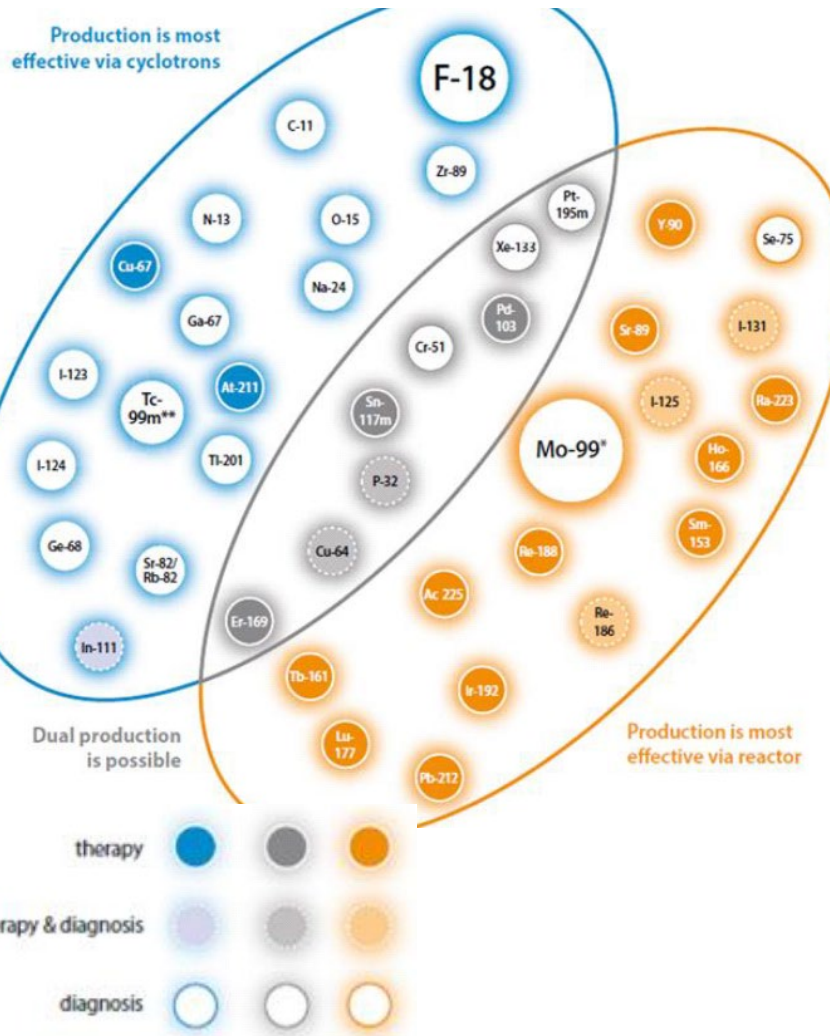


Average number of radiotherapy treatment machines (MV units) per million inhabitants in 28 European countries (ESTRO Survey)

Protontherapy, number of beams and gantries in the world (SAMIRA study, 2019)



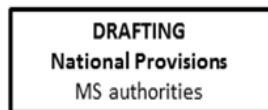
## Developments: Nuclear medicine



5 Dec 2013  
OJ 17 Jan 2014



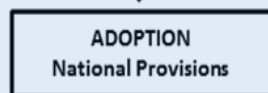
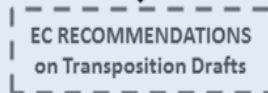
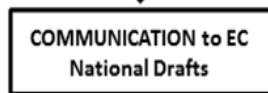
- Publication in OJ
- 23 official EU language



- Legislation
- Regulation
- Administrative action
- Education and training



By Nov 2017



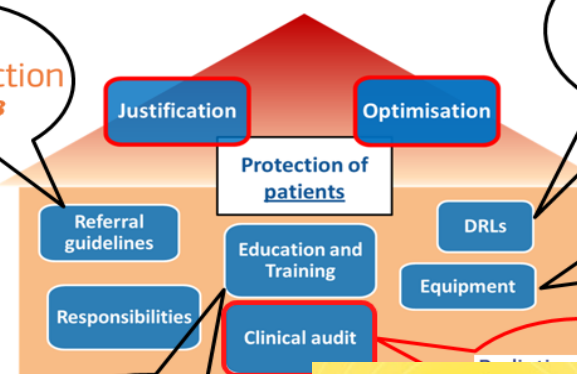
FUTURE AMENDMENTS  
of National Provisions

INFINGEMENT  
Procedures

CONFORMITY  
Checks

By Feb 2018

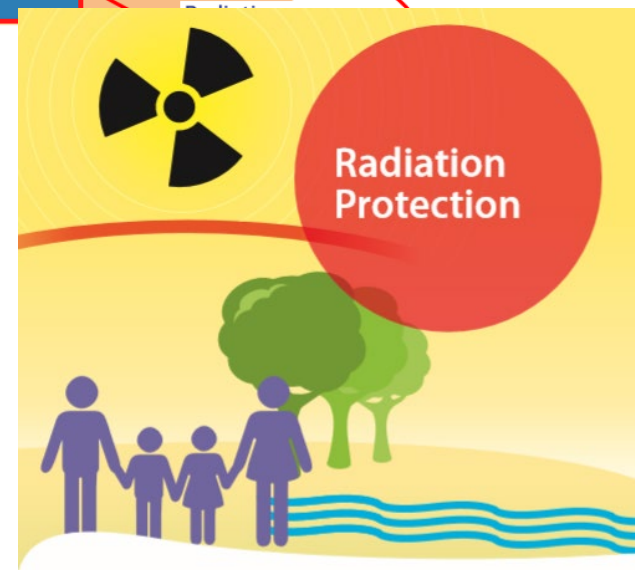
Radiation  
Protection  
No 178



Radiation  
Protection  
No 185  
EUCLID

Radiation  
Protection  
No 162

Radiation  
Protection  
No 174, 175



# Official Journal of the European Union

★ Council Directive 2013/59/Euratom of 5 December 2013 **basic safety standards** protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom .....

(12) "clinical audit" means a systematic examination or review of medical radiological procedures which seeks to improve **quality and outcome of patient care** structured 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;

# Official Journal of the European Union

★ **Council Directive 2013/59/Euratom**

## *Article 57*

### **Responsibilities**

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

## *Article 59*

### **Training and recognition**

## *Article 58*

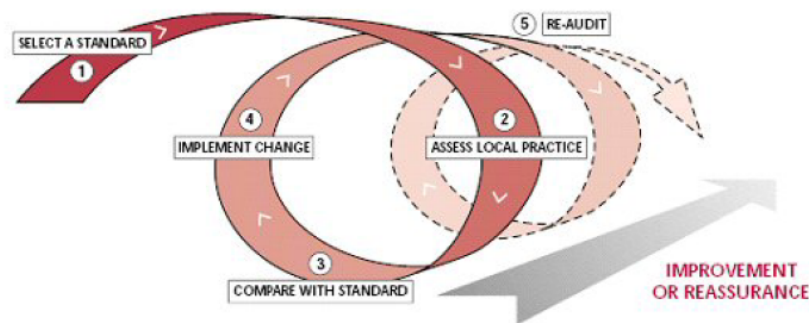
### **Procedures**

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

## *Article 60*

### **Equipment**





The audit cycle. Reprinted from Goodwin R, de Lacey G, Manhire A (eds). *Clinical Audit in Radiology: 100+ Recipes*, 1996 by permission of The Royal College of Radiologists.

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.

**EUROPE'S BEATING  
CANCER PLAN**  
LET'S STRIVE FOR MORE

#EUCancerPlan

## 👉 **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



QuADRANT

### ❖ Workforce availability, education and training

### ❖ Equal access to modern technology and interventions

# **Thank you for your attention!**

**<https://ec.europa.eu/energy/en/topics/nuclear-energy/radiation-protection/radiation-medical-use>**