



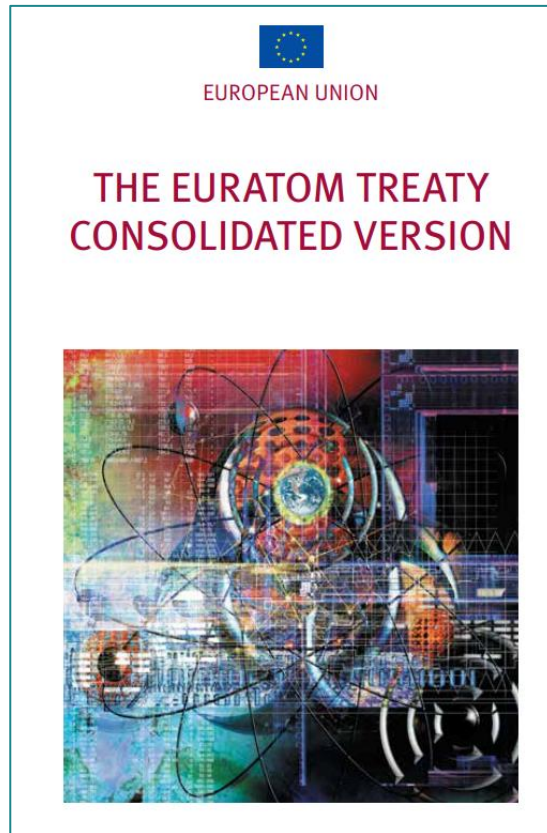
EU JUST CT 

Scene setter and Policy background

Michael Hübel

Head of Unit, Radiation Protection and Nuclear Safety
Directorate General for Energy (DG ENER)

Euratom legal framework for radiation protection in medicine

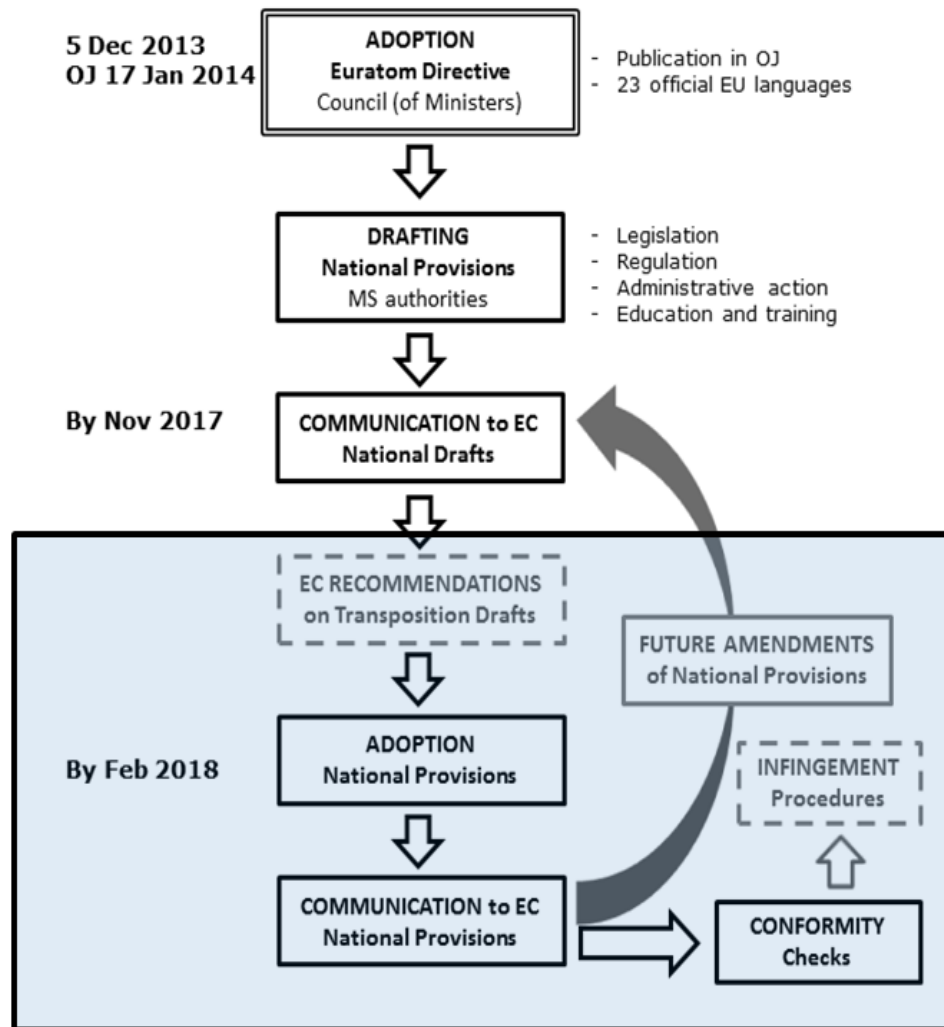


Chapter III Health and Safety

- ➔ **Basic safety standards** for the protection of the health of workers and the general public against dangers arising from ionising radiations
- ➔ Article 31 **Group of Experts**, standing Working Party on Medical Exposure (**WP MED**)

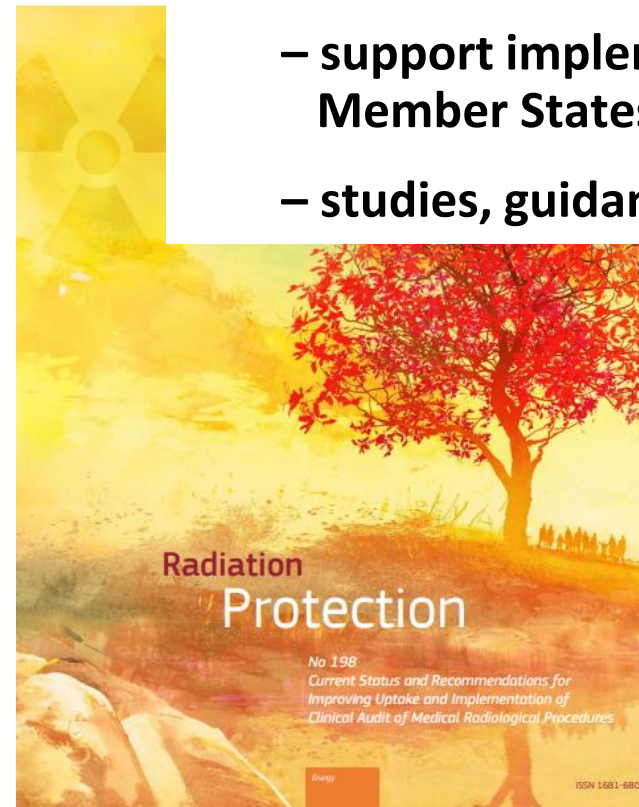
- ➔ **Council Directive 2013/59/Euratom**, Basic Safety Standards (BSSD)
- ➔ **Chapter VII, Medical Exposure**

Implementation of Euratom law in Member States



EU Radiation Protection series

- support implementation in Member States
- studies, guidance, etc.



Medical radiation exposure in the European Union

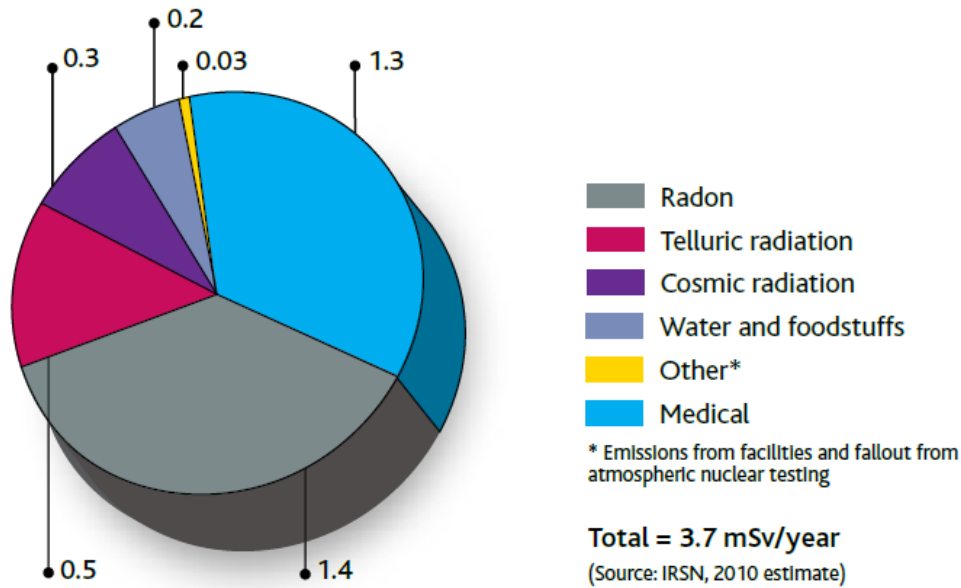
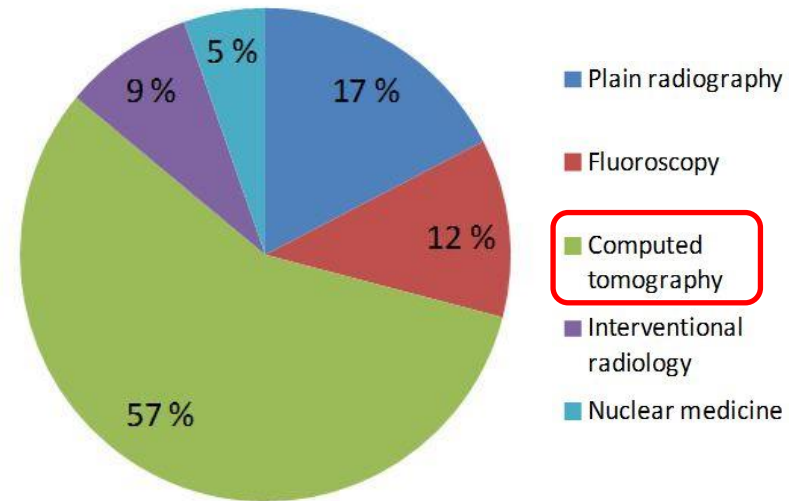
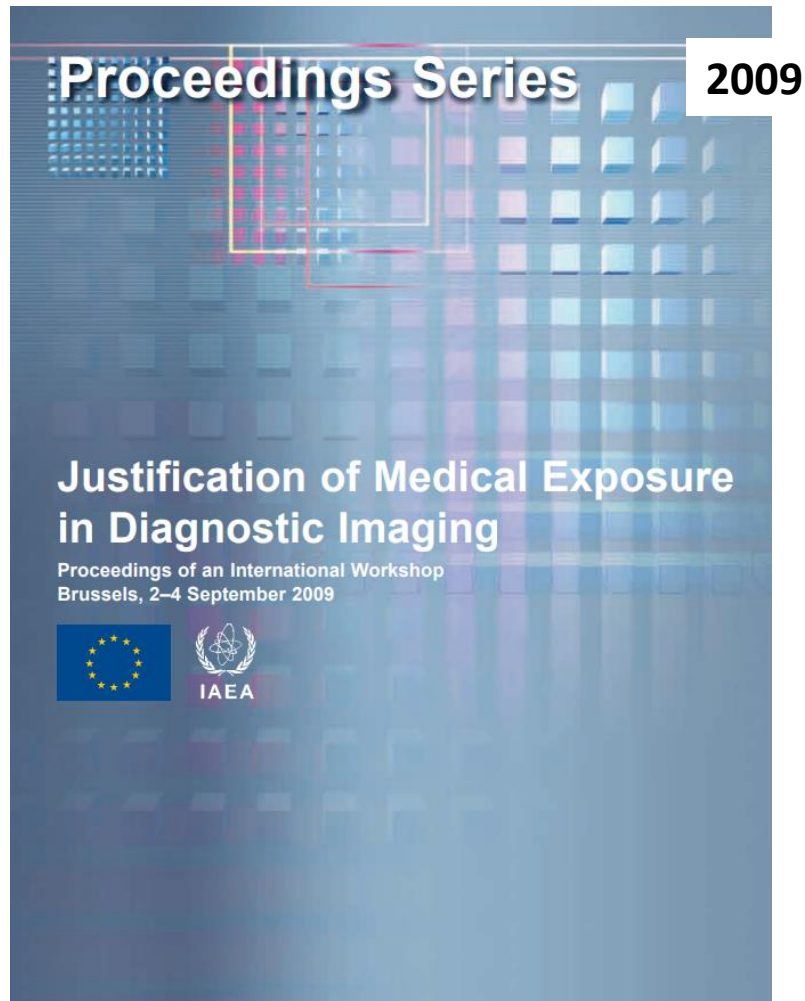


Figure VIII.1 - Average exposure to ionizing radiation of the population in France



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

Previous Commission support for justification of medical exposures



Council Conclusions on justification of medical exposures



Brussels, 3 December 2015
(OR. en)

14617/15

Council conclusions on Justification of medical imaging [...]

URGES / INVITES Member States to:

- [...]
- define the **roles and responsibilities** of all health care professionals involved in justification process
- raise **awareness** among health care professionals and patients
- ensure proper **implementation of referral guidelines** for imaging
- strengthen the **application of clinical audit** in relation to justification
- establish initial and continuous **training of health care professionals**

SAMIRA: Strategic Agenda for Medical Ionising Radiation Applications



➤ **Security of supply of medical radioisotopes**



➤ **Quality and safety of medical applications**



➤ **Innovation and technological development**

Steering Group on Quality and Safety (SGQS) of medical applications

Member State and Norway **Health** and **Radiation Protection** authorities

- Data collection
- Guidance and evidence
- Regulatory co-ordination
- Workforce availability, E&T
- Access to equipment and procedures



Guidance and recommendations

Sharing of good practices

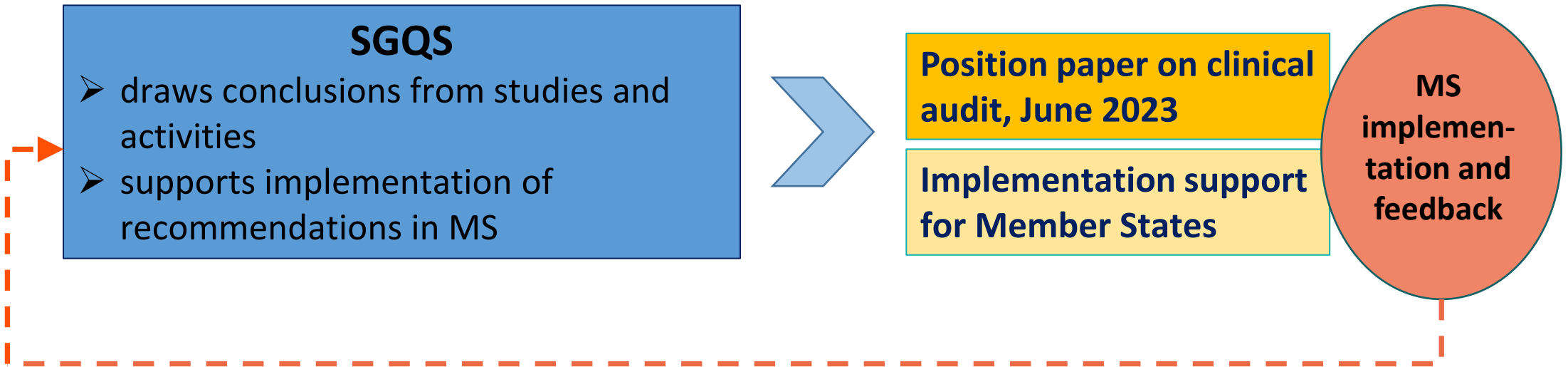
MS implementation and feedback

EU general budget

EU4Health programme

Euratom R&T programme

SAMIRA action on clinical audit



Clinical audit position paper

- Based on QuADRANT study and subsequent RP 198, HERCA work:
 - National framework and infrastructure for clinical audit (resources, bodies, standards!)
 - Regulatory control of clinical audit (implementation, risk-based grading, regulatory control!)
 - Clinical audit inclusion in accreditation and certification schemes
 - Support for successful implementation (education, integration into departments, sharing of information)
 - Involvement of patient representatives and use of anonymised patient data



Ongoing EU activities on Quality and Safety of medical applications

DG ENER budget

- EU-JUST-CT – **justification** of computed tomography
- SIMPLERAD – coordination of legal bases for **radiopharmaceuticals**
- **Monitoring** and control of **patients radiation exposure** study
- MARLIN – learning from **patients-related incidents**

EU JUST CT 

 Simplerad

Ongoing EU activities on Quality and Safety of medical applications

EU4Health WP

- **i-Violin** – **optimisation tools** in cancer computed tomography imaging
- **EU-REST** – **workforce** availability, education and training
- **INTERACT** – Inter-specialty cancer **training programme**



Ongoing EU activities on Quality and Safety of medical applications

Euratom Research and Training programme

- **PIANOFORTE** - **Partnership** for research in radiation protection
- **SECURE** - dosimetry aspects in **new radionuclide therapies**
- Etc.



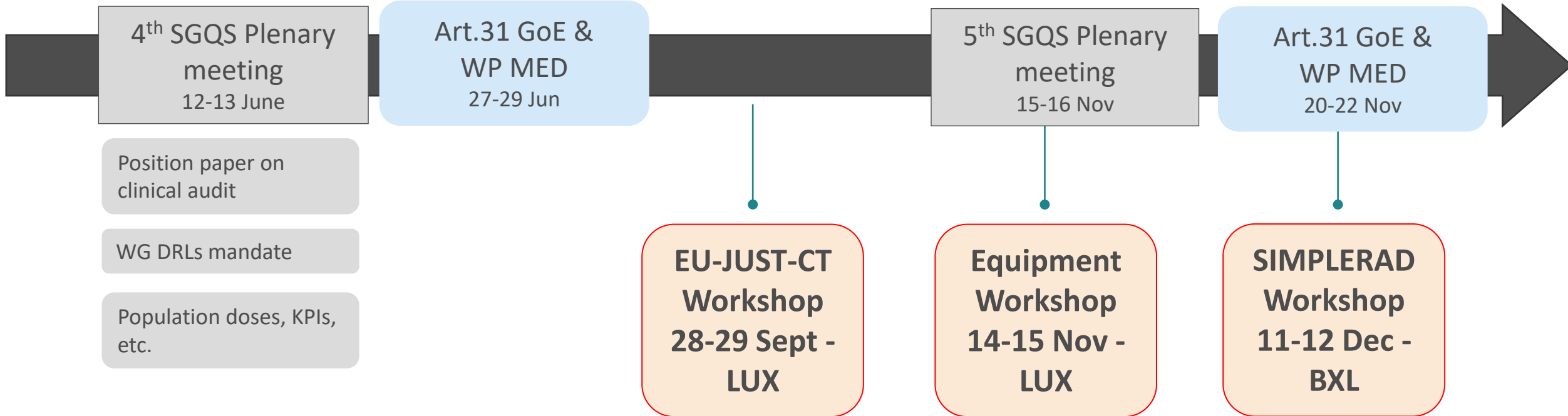
SAMIRA activities on innovation and technological development



- **Strategic Research Agenda and Roadmap** for medical application of ionising radiation
- Develop **Synergies** between **Radiation Protection, Health and Digitisation**



EC meetings on radiation protection in medicine



#EUSamira
#EUCancerPlan

For further information



Medical uses of radiation
(europa.eu)



SAMIRA Action Plan
(europa.eu)