



# BASIC SAFETY STANDARDS – Council Directive 2013/59/Euratom

Most relevant changes for medical imaging

# CONTEXT

- **EURATOM Treaty** signed in March 1957
  - Article 2: "... the Community shall ... establish uniform standards to protect the health of workers and of the general public"
- First **Basic Safety Standards Directive** adopted in 1959 → updated in 1962, 1966, 1976, 1980, 1984 and 1996 to consider advances in scientific knowledge on the effects of ionising radiation in line with the recommendations of ICRP and on the basis of operational experiences
- Medical exposures have been included in specific legislation since 1984
- Binding law in all EU Member States
- Laying down basic safety standards against the dangers arising from exposure to ionising radiation





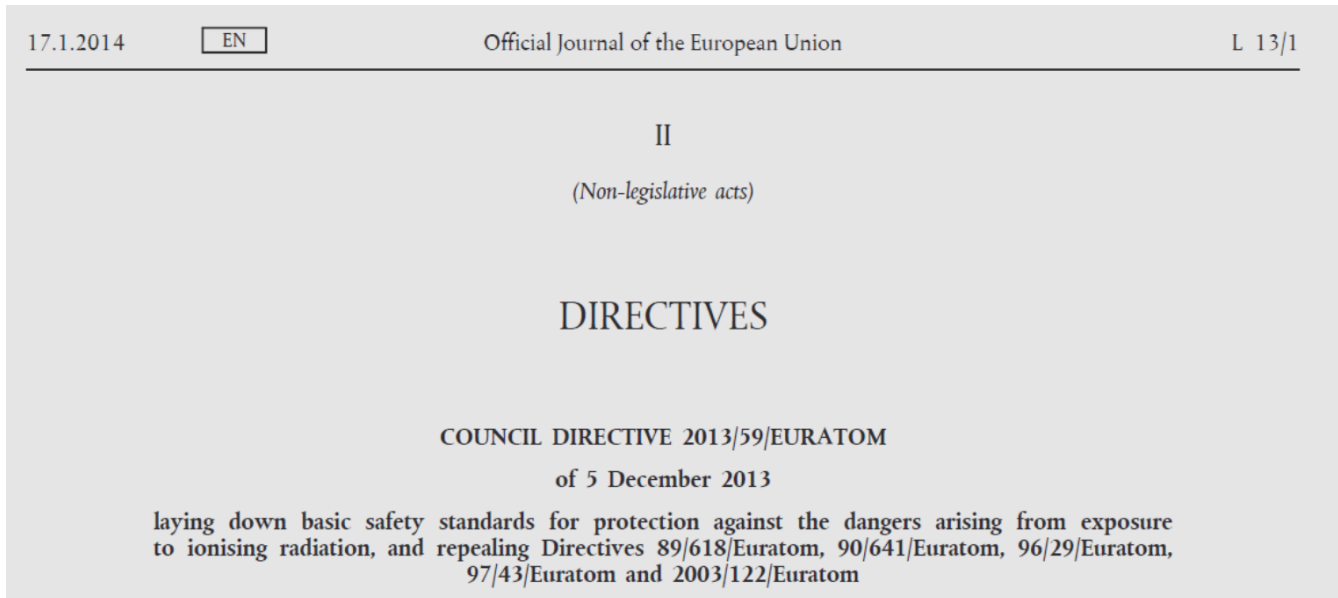
# COUNCIL DIRECTIVE 2013/59/Euratom

- **2013/59/Euratom** passed on 5 December 2013 → EU Member States must transpose the BSS Directive into national laws, regulations and administrative provisions **by 6 February 2018**
  - Member States shall communicate to the EC... draft provisions
  - Any recommendations the EC may wish to issue with regard to such draft provisions shall be made within three months
- **Chapter VII: Medical Exposure**
  - Protection of patients and other individuals submitted to medical exposure



# COUNCIL DIRECTIVE 2013/59/Euratom

- **Consolidating** different European radiation protection laws into a single piece of legislation – *Directive 89/618/Euratom* (Public Information), *Directive 90/641/Euratom* (Outside Workers), *Directive 96/29/Euratom* (Basic Safety Standards), *Directive 97/43/Euratom* (Medical Exposures) and *Directive 2003/122/Euratom* (High Activity Sources)





# Most relevant changes for medical imaging

1. Definitions
2. Justification
3. Optimisation
4. Responsibilities
5. Procedures
6. Training
7. Equipment
8. Accidental and unintended exposures
9. New dose limit for the lens of the eyes
10. Population dose estimates
11. Non-medical human imaging

# Most relevant changes for medical imaging

## 1. Definitions

- Medical and Non-Medical Imaging Exposures
- Referrer instead of prescriber
- Radiation Protection Expert/Radiation Protection Officer/Medical Physics Expert

## 2. Justification (Art. 19 & 55)

- Information about new techniques & technologies can trigger justification review for existing class / type of practice
- Associated occupational & public exposures to be taken into account in justification
- Health screening: justification by authority and scientific bodies
- Asymptomatic individuals: guidelines, documenting, info to the 'client'



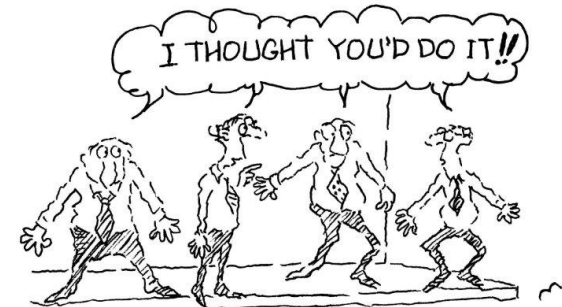
# Most relevant changes for medical imaging

## 3. Optimisation (Art. 56)

- Doses for verification purposes to be kept ALARA
- Diagnostic Reference Levels (DRLs) are mandatory: establishment, regular review and use
- DRLs to cover interventional radiology where appropriate
- Written instructions required for nuclear medicine therapy patients leaving the hospital

## 4. Responsibilities (Art. 57)

- Any medical exposure takes place under the clinical responsibility of the practitioner
- Optimisation process involvement: practitioner, Medical Physics Expert (MPE), radiographer
- Justification process involvement: referrer, practitioner
- Information to patients on benefits & risks prior to exposure
- Tasks of Radiation Protection Expert/Radiation Protection Officer/Medical Physics Expert



# Most relevant changes for medical imaging

## 5. Procedures (Art. 58)

- Written protocols for every type of standard medical radiological procedure, for each piece of equipment, and for “relevant categories of patients” (children)
- Patient exposure information as part of examination report
- Stronger Medical Physics Expert involvement in interventional radiology, CT, paediatric, screening, etc.
- Appropriate corrective action without undue delay when DRLs are consistently exceeded

## 6. Training (various Articles)

- Member States shall establish adequate legislative and administrative framework for education & training in radiation protection
- Medical Physics Experts (MPE) are allowed to be “a group of individuals”, Continuing Professional Development requirements were extended to MPE, MPE recognition arrangements needed



# Most relevant changes for medical imaging

## 7. Equipment (Art. 60 & 78)

- Use of fluoroscopy equipment without a device to automatically control dose rate, or without an image intensifier or equivalent device, is prohibited
- New interventional radiology and CT equipment need to have a device or feature informing of relevant parameters for assessing the patient dose
- Existing CT and interventional radiology equipment
  - Provide patient dose information, post procedure
  - Capacity to transfer to examination record (prior 2017 may be exempted)



# Most relevant changes for medical imaging

## 8. Accidental and unintended exposures (Art. 63)

- Internal system to record and analyse incidents and accidents
- National system for reporting significant events to the competent authority
- Information to referrer, practitioner and patient about clinically significant unintended or accidental exposures and the results of the analysis
- Mechanisms for the timely dissemination of information on lessons learned from significant events

## 9. New dose limit for the lens of the eyes (Art. 9)

- Effective dose: 20 mSv in any single year (50 mSv may be authorised)
- Lens of the eye: 20 mSv in a single year or 100 mSv in any five consecutive years subject to a maximum dose of 50 mSv in a single year
- Apprentices and students have more restrictive dose limits



# Most relevant changes for medical imaging

## 10. Population dose estimates (Art. 64)

- Take into account age and gender of the exposed populations

## 11. Non-medical human imaging (Art. 22)

- Non-medical imaging exposure (NMIE): deliberate exposure of humans for imaging purposes where the primary intention of the exposure is not to bring a health benefit to the individual being exposed
  - E.g. for employment, immigration and insurance purposes
- Justification at three levels: 1) types of practices, 2) each particular application of a generally accepted type, and 3) individual NMIE using medical equipment
- NMIE using medical equipment may be exempt from dose constraints and dose limits
- Where practicable, specific protocols and DRLs are put in place

# EUROPEAN SOCIETY OF RADIOLOGY – Activities



- **EuroSafe Imaging:**

- <http://www.eurosafeimaging.org/>
- Is the European Society of Radiology's flagship initiative to promote quality and safety in medical imaging.
- The **mission** of EuroSafe Imaging is to support and strengthen medical radiation protection across Europe following a holistic, inclusive approach.
- **Objectives:**
  - Promoting appropriateness in medical imaging
  - Maintaining doses within diagnostic reference levels (DRLs)
  - Using the as-low-as-reasonably-achievable (ALARA) principle and up to date equipment
  - Empowering patients with better information and communication
  - Joining forces with other stakeholders

# EUROPEAN SOCIETY OF RADIOLOGY – Activities

- **Clinical Audit:**

- Required under the BSS Directive and therefore mandatory
- The [ESR Audit Tool](#), prepared by the ESR Audit and Standards Subcommittee aids departments in carrying out audit, thereby complying with the directive, and assuring the protection of their patients
- ESR Audit Tool provides clear guidance on how to perform effective audit against 17 Patient Safety Standards that the ESR considers essential



- **Clinical Decision Support:**

- [ESR iGuide](#) is a Clinical Decision Support system for European imaging referral guidelines developed by ESR and National Decision Support Company (NDSC), based on ACR Select system & content
- Designed to be a user-friendly system available to referring physicians at the point of care
- Prototype introduced during ECR 2015, pilot tests started in 2016

# MAIN MESSAGES

- New European BSS impacts radiology departments and requires Member States, the radiology community (incl. medical physics experts) and the industry to adapt their regulations, procedures and equipment to the new high standards of radiation safety
- Changes in justification, patient information, responsibilities and dose reporting are most significant
- DRLs and the role of medical physics experts are clarified
- Dose limits of the eye lens are lower than in the previous directive
- Responsibilities in radiation safety have been clarified

# REFERENCES

- Council Directive [2013/59/Euratom](#) of 5 December 2013 laying down basic safety standards for 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 (2014). OJ of the EU. L13, 1–73.
- European Society of Radiology (ESR) Insights Imaging (2015) 6: 411. doi:10.1007/s13244-015-0410-4. <https://link.springer.com/article/10.1007/s13244-015-0410-4>
- European Commission presentation “European Basic Safety Standards Directive 2013/59/Euratom and Activities in Radiation Protection in Medicine”, Mr. Simeonov (2016).