Therapeutic Nuclear Medicine in the Basic Safety Standards Directive 2013/59/Euratom

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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)


- **Chapter VII, Medical Exposure**
Article 2: Scope

This Directive applies in particular to:

(a) the manufacture, production, processing, handling, disposal, use, storage, holding, transport, import to, and export from the Community of radioactive material
Article 4: Definitions

(48) **Medical exposure** means exposure incurred by patients ... carers and comforters and volunteers in medical or biomedical research

(50) **Medical radiological** means pertaining to radiodiagnostic and radiotherapeutic procedures, and interventional radiology ...

(81) **Radiotherapeutic** means pertaining to radiotherapy, **including nuclear medicine for therapeutic purposes**
Article 56: Optimisation

1. For all medical exposure of patients for radiotherapeutic purposes
   - exposures of target volumes shall be individually planned and their delivery appropriately verified
   - doses to non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure
Article 56: Optimisation

5. Member States shall ensure that:

(a) dose constraints are established for the exposure of carers and comforters, where appropriate

(b) appropriate guidance is established for the exposure of carers and comforters
BSSD requirements for therapeutic nuclear medicine

Article 83. Medical Physics Expert (MPE)

2. ... **MPE takes responsibility for dosimetry** ... and contribute in particular to the following:
   (a) **optimisation** of the radiation protection ...

Article 58. Procedures

(d) MPE is appropriately involved, ... in particular:
   (i) in radiotherapeutic practices **other than standardised therapeutic nuclear medicine** practices, MPE **shall be closely involved**
   (ii) in **standardised therapeutical nuclear medicine** practices MPE **shall be involved**
Article 65: Operational protection of members of the public

1. Member States shall ensure that the operational protection of members of the public ... include ... the following:

(c) examination and approval of plans for the discharge of radioactive effluents

2. The competent authority shall, where appropriate, establish authorised limits as part of the discharge authorisation and conditions for discharging radioactive effluents
For further information

Medical uses of radiation (europa.eu)

SAMIRA Action Plan (europa.eu)

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