

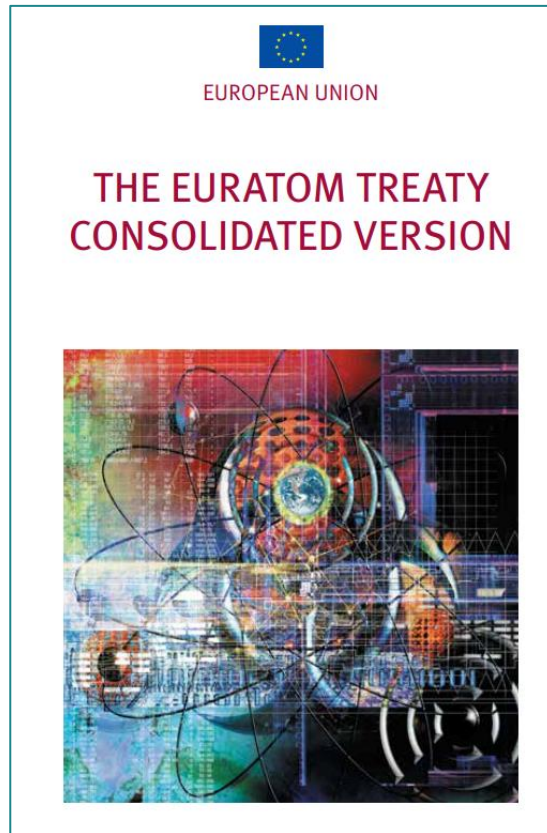


# Therapeutic Nuclear Medicine in the Basic Safety Standards Directive 2013/59/Euratom

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# 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**

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- ☞ Council Directive 2013/59/Euratom  
Basic Safety Standards (BSSD)
- ☞ 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**



# BSSD requirements for therapeutic nuclear medicine

## 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**



# BSSD requirements for therapeutic nuclear medicine

## 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



# BSSD requirements for therapeutic nuclear medicine

## 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**



# BSSD requirements for therapeutic nuclear medicine

## 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**



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#EUCancerPlan

For further information



Medical uses of radiation  
(europa.eu)



SAMIRA Action Plan  
(europa.eu)