

# FACTSHEET

## What is the 2013/59/EURATOM directive? What does it mean to RT professionals?

The EU council directive 2013/59/EURATOM lays down basic safety standards for protection against the dangers arising from exposure to ionizing radiation. The directive must be transposed into national law within a five-year time span.

### Article 58

#### Procedures

Member States shall ensure that:

- (a) written protocols for every type of standard medical radiological procedure are established for each equipment for relevant categories of patients



*work instructions for all procedures*

### Article 63

#### Accidental and unintended exposures

Member States shall ensure that:

- (a) all reasonable measures are taken to minimize the probability and magnitude of accidental or unintended exposures of individuals subject to medical exposure;
- (b) for radiotherapeutic practices the quality assurance program includes a study of the risk of accidental or unintended exposures;



*proactive risk analysis*

- (c) for all medical exposures the undertaking implements an appropriate system for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice;
- (e) (i) the undertaking declares as soon as possible to the competent authority the occurrence of significant events as defined by the competent authority;
- (ii) the results of the investigation and the corrective measures to avoid such events are reported to the competent authority within the time period specified by the Member State;



*reactive risk analysis & incident reporting*

### Article 105

#### Enforcement

Member States shall ensure that the competent authority has the power to require any individual or legal person to take action to remedy deficiencies and prevent their recurrence or to withdraw, where appropriate, authorization when the results of a regulatory inspection or another regulatory assessment indicate that the exposure situation is not in compliance with the provisions adopted pursuant to this Directive.



*prevent recurrence or to withdraw authorization*

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## Council Directive 2013/59/EURATOM transposed into German law Strahlenschutzgesetz (StrlSchG) & Strahlenschutzverordnung (StrlSchV)

The EU council directive 2013/59/EURATOM was transposed into German law (StrlSchG) and ordinance (StrlSchV) in 2018

### §121 StrlSchV (Article 58 EURATOM)

#### Measures in the application

The radiation protection officer must ensure that written work instructions are drawn up for examinations and treatments involving ionizing radiation. These are to be made available to the persons working in these applications for inspection at any time.



*work instructions for all procedures*

### §126 StrlSchV (Article 63)

#### Risk analysis prior radiation treatments

The radiation protection officer has to ensure that an analysis to identify and assess the risk of accidental exposure of the treated person is carried out prior to first use or a significant change in a method of treatment of radioactive material or ionizing radiation.



*proactive risk analysis*

### §105 StrlSchV (Article 63 c-f EURATOM)

#### Avoidance, detection and mitigation of the effects of an incident

The radiation protection officer shall ensure that appropriate measures are taken in a systematic manner in the application of radioactive substances or ionizing radiation to humans in order to:

1. to avoid an incident
2. to recognize an incident and
3. in the event of an incident, minimize the adverse effects.



*reactive risk analysis & incident reporting*

### §14 StrlSchG

#### Specific requirements for activities related to the use in humans

(1) The permission for an activity ... in connection with the application of ionizing radiation ... in humans is granted only if, the quality required for the application ... is achieved during treatments.

Risk analysis is therefore initialized only by § 126 StrlSchV to otherwise permit as presupposing measure of the quality management system.



*risk analysis required for operating license*