

Radiation and Nuclear Safety Authority Regulation on Radiation Practices Subject to a Safety Licence

Adopted in Helsinki on 2 July 2019

In accordance with a decision of the Radiation and Nuclear Safety Authority, the following provisions are issued by virtue of the Radiation Act (859/2018):

Chapter 1

General regulations

Section 1

Scope of application

This regulation applies to radiation practices subject to a safety licence.

This regulation is not applicable to the use of nuclear energy as referred to in the Nuclear Energy Act (990/1987).

Chapter 2

Experts, radiation safety officer and the induction of workers

Section 2

Information on experts and the radiation safety officer

The management system for a radiation practice must include the information referred to in section 29, subsection 2, paragraph 2 of the Radiation Act, concerning the radiation safety expert, medical physics expert, and radiation safety officer as well as the obligations and duties referred to in sections 112–115 if the practice results in medical exposure.

The management system must include information on the deputizing arrangements of the radiation safety officer.

Section 3

Deputizing arrangements of a radiation safety officer

A radiation safety officer must be appointed a deputy meeting the requirements specified in section 41 of the Radiation Act when the category of radiation exposure is 1.

Section 4

Induction of workers

The undertaking must ensure that the workers referred to in section 33, subsection 1 are informed of the following in connection to the induction:

- 1) the health effects of the radiation exposure related to the work;
- 2) the radiation protection procedures and precautions generally applied in the practice in question and particularly in the task and workstation assigned to them;
- 3) the procedures to be followed during radiation safety deviations;
- 4) the importance of complying with the requirements concerning radiation safety;
- 5) the notification concerning pregnancy or breastfeeding referred to in section 100 of the Radiation Act.

Employers must ensure that external workers are provided with the information referred to in subsection 1.

Section 5

Additional induction requirements in the use of high-activity sealed sources

An undertaking using a high-activity sealed source must, in addition to the induction of workers provided in section 9:

- 1) address the safe management of high-activity sealed sources and the specific requirements of their control;
- 2) provide information on the consequences of the loss of adequate control of high-activity sealed sources;
- 3) ensure that workers are adequately prepared for radiation safety deviations.

Employers must ensure that outside workers are provided with the information referred to in subsection 1.

Chapter 3

Dose constraints for occupational and public exposure and constraints for potential exposure

Section 6

Quantities of dose constraints and potential exposure

Dose constraints are provided for as an effective dose per year and the constraints for potential exposure as effective dose resulting from a one-off incident.

The realization of an incident leading to potential exposure is reviewed as the expected number of incidents per person-year in terms of occupational exposure and per year in terms of public exposure. Person-year means the product of the number of potentially exposed workers and working years.

Section 7

Dose constraints for occupational exposure

The dose constraint for occupational exposure in radiation practices is 0.3 mSv, if the category of occupational exposure in the practice is 3. However, the dose constraint may be greater than this if it is shown to be justified in the safety assessments.

The dose constraint for occupational exposure for aviation is 6 mSv. However, the dose constraint may be greater than this in some restricted special circumstances in which the exposure cannot be limited to 6 mSv through reasonable means.

Section 8

Dose constraints for public exposure

The dose constraint for public exposure is 0.1 mSv. However, the dose constraint may be greater than this if it is shown to be justified in the safety assessments, excluding the situations referred to in section 9.

Section 9

Dose constraints for public exposure resulting from discharges and waste

The dose constraint for public exposure resulting from discharges and waste in radiation practices may not be greater than 0.1 mSv:

- 1) in discharges of radioactive substances to the sewerage system, waterways or the air;
- 2) in the reuse, recycling, utilization, or disposal of waste containing radioactive substances.

Section 10

Dose constraints concerning the design and construction of facilities where radiation sources are used and stored

The dose constraint concerning the design and construction of facilities where radiation sources are used and stored may not be greater than:

- 1) 6 mSv for a radiation worker in a supervised area;
- 2) 0.3 mSv for occupational exposure in an area other than a controlled or supervised area;
- 3) the dose constraint for public exposure referred to in section 8.

If there are several facilities in which radiation sources are used and stored, the space-specific dose constraints must be set in such a way that their maximum sum is equal to what is specified in subsection 1.

Section 11

Constraints for potential occupational exposure

The potential occupational exposure from a one-off incident may not be greater than 100 mSv, excluding a highly unlikely incident or sequence of incidents with a realization probability that cannot be reduced through practical measures.

If the potential occupational exposure resulting from a one-off incident is greater than 6 mSv, the expected number of the incidents may not be greater than one in ten person-years.

Section 12

Constraints for potential public exposure

The potential public exposure from a one-off incident may not be greater than 10 mSv, excluding a highly unlikely incident or sequence of incidents with a realization probability that cannot be reduced through practical measures.

The potential public exposure from a one-off incident may not be greater than 1 mSv if there can be more than 100 exposed persons, excluding a highly unlikely incident or sequence of incidents with a realization probability that cannot be reduced through practical measures.

If the potential public exposure resulting from a one-off incident is greater than 0.3 mSv, the expected number of the incidents may not be greater than one in ten years.

Chapter 4

Safety assessment concerning radiation practices

Section 13

Coverage of safety assessment

The safety assessment concerning radiation practices must be carried out as a review specific to a practice and place of use. The assessment may nevertheless be carried out as an appliance-based review applicable to the type of practice in question, provided that only radiation appliances whose radiation safety in use is based primarily on the appliance's structural properties are used in the practice.

However, the safety assessment must be carried out as a review specific to the practice and place of use if the appliance-based review indicates that the category of occupational or public exposure is 1 or 2.

Section 14

Conducting and reviewing a safety assessment

The safety assessment concerning a radiation practice must be carried out prior to the commencement of the practice and it must be reviewed in terms of occupational, public, and medical exposure:

- 1) every two years, if the category of radiation exposure is 1;
- 2) every three years, if the category of radiation exposure is 2;
- 3) every five years, if the category of radiation exposure is 3.

The safety assessment must also be reviewed, if this is not clearly unnecessary in terms of radiation safety, in connection to a change of the practice, after a radiation safety deviation, and to account for experiences gained from other comparable practices, the results of a safety research, and the development of technology.

Section 15

Assessing radiation exposure

The safety assessment concerning a radiation practice must present the following per worker and population group:

- 1) radionuclides, radiation types, radiation energies, and exposure pathways;
- 2) the key structural solutions and operational arrangements by which radiation exposure is limited; furthermore, in terms of these solutions and arrangements:
 - a) the estimated radiation dose and its key assessment criteria;
 - b) the number of persons exposed;
 - c) the applicable dose constraint and its selection criteria.

Public exposure must be assessed in terms of a representative person as referred to in the Radiation and Nuclear Safety Authority Regulation on Radioactive Waste and Discharges of Radioactive Substances in the Use of Unsealed Sources (STUK S/2/2019).

Section 16

Identifying radiation safety deviations

The identification of radiation safety deviations must account for events internal and external of the practice with an impact on radiation safety as well as the impact of human errors on the occurrence of the event.

Section 17

Assessing potential exposure

The safety assessment concerning a radiation practice must present the following of the most significant identified radiation safety deviations per groups of workers, members of the public and patients:

- 1) a description of the deviation;
- 2) the key structural solutions and operational arrangements by which:
 - a) the probability of the deviation's realization is reduced;
 - b) the deviation's consequences are mitigated;
 - c) the practice is returned to a safe status.
- 3) taking into account the solutions and arrangements referred to in paragraph 2:
 - a) the number of potentially exposed persons;
 - b) the magnitude of the potential exposure;
 - c) the probability of potential exposure;
 - d) the applicable constraint for potential exposure.

Section 18

Entry into force

This regulation enters into force on 3 July 2019 and is valid until further notice.
This regulation applies to any matters pending on the date of its entry into force.

In Helsinki on 2 July 2019

Director General

Petteri Tiippana

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Availability of the regulation, guidance and advice

This regulation has been published as part of the regulations issued by the Radiation and Nuclear Safety Authority (STUK) and it is available from the Radiation and Nuclear Safety Authority.

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