Unofficial translation from Finnish.
Legally binding only in Finnish and Swedish.

REGULATION STUK S/2/2018

Radiation and Nuclear Safety Authority Regulation on a Plan for Radiation Safety Deviations and Actions During and After Radiation Safety Deviations

Adopted in Helsinki on 14 December 2018

In accordance with a decision of the Radiation and Nuclear Safety Authority, the following provisions are issued by virtue of sections 129, subsection 2, 130, subsection 6 and 131, subsection 5 of the Radiation Act (859/2018):

Section 1

Limitation of scope of application

This regulation shall not apply to the use of nuclear energy as referred to in the Nuclear Energy Act (990/1987) and to the use of laser equipment.

Section 2

Plan for radiation safety deviations

The plans for radiation safety deviations shall include separate operating instructions for each place of use in the event of a radiation safety deviation.

The plan shall include training and exercises on the immediate actions to be taken to limit radiation exposure.

Additionally, the plan shall specify measures for determining the causes of a radiation safety deviation and for learning from it.

Section 3

Operating instructions for each place of use

In a practice of category 1 radiation exposure, each place of use shall have written operating instructions in place that are available to the workers. The operating instructions shall at least specify:

1) the immediate measures to be taken to limit radiation exposure, including:
   a) identifying and limiting the radiation hazard area;
   b) preventing outsiders from accessing the radiation hazard area;
   c) the use of respirators if it is suspected that radioactive substances have entered into the breathing air;
   d) prevention of the dispersion of contamination;
   e) notifying the radiation safety officer of the radiation safety deviation;
   f) prevention of the accumulation of radioactive iodine into the thyroid gland;
   g) accelerating the decorporation of radionuclides;
   h) removal of sealed source radiotherapy appliance from the patient;
   i) removal of the patient from the radiation beam;

Council Directive 2013/59/Euratom (32013L0059); OJEU L 13, 17.01.2014, p. 1
Reported to the Commission in accordance with Article 33 of the Treaty establishing the European Atomic Energy Community.

STUK
SÄTEILYTURVAKESKUS
STRÅLSÄKERHETSCENTRALEN
RADIATION AND NUCLEAR SAFETY AUTHORITY

Osoite / Address | Laippatie 4, 00880 Helsinki
Postiosoite / Postal address | PL / P.O. Box 14, FI-00811 Helsinki, FINLAND
Puh. / Tel. (09) 759 881, +358 9 759 881 | Fax (09) 759 88 500, +358 9 759 88 500 | www.stuk.fi

2) the procedure for recording the course of events, including:
   a) the measures carried out and the times thereof;
   b) the names and contact information of the individuals who were exposed or otherwise involved in the radiation safety deviation and, concerning workers, the information referred to in section 42 of the Government Decree;
   c) detailed information concerning the exposure;
3) the procedure for reporting a radiation safety deviation:
   a) to competent authorities;
   b) to those involved in the radiation safety deviation;
4) the actions for determining the magnitude of the radiation exposure;
5) the urgent actions for assessing the state of health of those who were exposed;
6) instructions for informing the patient and his or her attending physician;
7) the procedure for obtaining advice from a radiation safety expert and medical physics expert.

In a practice of radiation exposure categories 2 or 3, each place of use shall have written operating instructions in place that are available to the workers, and at least the information referred to in paragraphs 1, 2, 3, 4 and 7 of subsection 1 shall be included in the operating instructions.

Section 4

Significant unintended medical exposure

The unintended medical exposure is significant if:

1) the dose caused to the patient by electron or photon radiation generated with radiotherapy appliance deviates or could have deviated from the planned total dose by at least 25%;
2) the dose caused to two or more successive patients by electron or photon radiation generated with radiotherapy appliance deviates or could have deviated from the planned total dose by 5–25%;
3) the activity received by the patient in radionuclide therapy deviates or could have deviated from the planned activity by at least 25%;
4) the activity received by two or more successive patients in radionuclide therapy deviates or could have deviated from the planned activity by 10–25%;
5) a wrong patient is exposed when the medical exposure is of category 1;
6) the additional effective dose caused to the patient or to a wrong patient by the examination or procedure is at least 10 mSv;
7) the examination, procedure or treatment causes deterministic detriment to the patient as a result of additional radiation exposure;
8) the absorbed dose caused to the foetus as a result of additional exposure is at least 10 mGy;
9) systematic additional exposure is caused to at least 10 patients and the exposure of a single patient is at least 50% higher than in a planned exposure in a practice of 1 or 2 medical exposure;
10) at issue of other medical exposure of which it is important to inform other operators to avoid the occurrence of a similar radiation safety deviation.

Section 5

Reporting a radiation safety deviation

The notification referred to section 130, subsection 2 of the Radiation Act shall be made by telephone or using other such means of communication with which the notifying party can ensure that the message has been duly received.

Outside of regular office hours, the Radiation and Nuclear Safety Authority shall be contacted by calling the emergency response centre.

The notification shall include:

1) the name of the undertaking and the number of the safety licence;
2) the name of the radiation safety officer;
3) the name and contact details of the individual who submits the notification;
4) the time and place of the event;
5) the radiation source;
6) description of the radiation safety deviation;
7) information about those who may have been exposed and their exposure to radiation; if no radiation dose measurement results are available, the dose shall be estimated based on the available exposure data;
8) an assessment of radioactive substances which may have been released to the environment;
9) the immediate measures taken;
10) initial assessments of the cause of the radiation safety deviation.

A notification made orally shall be confirmed in writing without delay.

Section 6

Radiation safety deviations subject to notification of summarized information

The summarized information referred to in section 131(4) of the Radiation Act shall be notified to the Radiation and Nuclear Safety Authority in aggregate form on an annual basis.

The radiation safety deviations concerning the previous calendar year shall be notified to the Radiation and Nuclear Safety Authority by 1 February.

The notification of summarized information in aggregate form on radiation safety deviations concerning unintended medical exposure shall include at least the information specified in Table 1 of Annex 1.

Section 7

Report on a radiation safety deviation

A written report shall be prepared on the radiation safety deviation that includes the information referred to in section 5, subsection 3 above completed with the details of the event or observation and more detailed information on the causes leading to the radiation safety deviation and the resulting effects. Additionally, the report shall specify measures for preventing the occurrence of similar radiation safety deviations.

The undertaking shall submit the report referred to in subsection 1 above to the Radiation and Nuclear Safety Authority without delay.

Section 8

Entry into force

This regulation enters into force on 15 December 2018 and is valid until further notice. This regulation applies to any matters pending on the date of its entry into force.

In Helsinki on 14 December 2018

Director General Petteri Tiippana

Director Tommi Toivonen

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.

Visiting address: Laippatie 4, FI-00880 Helsinki
Mailing address: P.O. Box 14, FI-00811 Helsinki
Telephone: +358 9 759 881
Collection of regulations: http://www.finlex.fi/en/viranomaiset/normi/555001/

ANNEX 1

Table 1. Radiation safety deviations concerning an unintended medical exposure to be notified in aggregate form.

Type of radiation safety deviation	**Cause and factor contributing to the occurrence of a radiation safety deviation**	**Number of radiation safety deviations per year**
Referral made for a wrong person, as a result of which a wrong person was exposed to radiation	Human error	
	Other cause	
Wrong examination, procedure or anatomical object in the referral, which resulted in incorrect examination or procedure	Human error	
	Other cause	
Examination or procedure carried out on a wrong person	The patient's identity was not verified by reliable means prior to the examination or procedure	
	Other cause	
A wrong examination or procedure was carried out or a wrong anatomical object was scanned	Human error	
	Other cause	
Failed examination or procedure (other than injection of a radiopharmaceutical or contrast medium) or additional exposure related to them	Incorrect or deficient operating instructions	
	Human error	
	Isolated appliance or system failure	
	Systematic appliance or system failure	
	Other cause	
Failed injection of radiopharmaceutical or contrast medium	Human error	
	Technical fault in equipment or device	
	Other cause	
Unnecessarily repeated examination	No information about the similar examination previously carried out or the results of the previous examination unavailable	
	Other cause	
Inadvertent exposure of foetus	Pregnancy in such an early stage that it could not be verified	
	Possibility of pregnancy not verified in a reliable manner prior to the examination or procedure	
	Other cause	
Additional exposure of carers and comforters	Human error	
	Incorrect or deficient operating instructions or failure to observe the instructions	
	Other cause	
A near-miss incident resulting from the same cause more than once	Error in conduct of operations	
	Error in system or appliance	
	Other cause	
Other radiation safety deviation related to medical exposure	Other cause	