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REGULATION OF THE MINISTER FOR HEALTH[1]

of 13 December 2022

on the categories and eligibility criteria for unintended and accidental exposures, actions to be taken at the health care unit after their occurrence, and the scope of information covered by the Central Database of Unintended and Accidental Exposures[2].

Pursuant to Article 33m(12) of the Act of 29 November 2000 on the Atomic Law (Dz. U. of 2021, item 1941, and of 2022, item 974), it is ordered as follows:

§ 1. This Regulation establishes:

1) the categories of unintended and accidental exposures, and the criteria for qualifying these exposures into the respective categories,

2) actions to be taken at the health care unit after the occurrence of unintended or accidental exposures, appropriate to the category into which the exposure have been classified, including measures to reduce the adverse health effects on the patients to whom the unintended or accidental exposure occurred,

3) the scope of information covered by the register referred to in Article 33m(11) of the Act of 29 November 2000 on the Atomic Law, hereinafter referred to as the "Act".

§ 2. Unintended and accidental exposures, hereinafter referred to as the "events", are divided into Category I, II and III.

§ 3. 1. In X-ray diagnostics and fluoroscopy:

1) Category I events include:

   a) repetition of a procedure that is not due to clinical indications and leads to a total dose exceeding the indicators specified in point 2,

   b) performance of a procedure resulting in an unexpected deterministic effect,

   c) performance of a procedure to an erroneously identified person,

   d) performance of a procedure in the wrong anatomical area;

2) Category II events include:

[1] The Minister of Health heads the department of government administration - health, pursuant to § 1(2) of the Regulation of the Prime Minister of 27 August 2020 on the detailed scope of activities of the Minister of Health (Dz. U. of 2021, item 932).

[2] This Regulation implements within its scope the Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ EU L 13, 17.1.2014, p. 1, OJ EU L 72, 17.3.2016, p. 69, OJ EU L 152, 11.6.2019, p. 128 and OJ EU L 324, 13.12.2019, p. 80).

a) four times exceeding the value of the diagnostic reference level,

b) in the case of head CT scans, exceeding the value of 120 mGy of the Weighted Computed Tomography Dose Index (CTDIw),

c) for tomographic examinations other than head examinations - exceeding the value of 200 mGy of the Weighted Computed Tomography Dose Index (CTDIw),

d) for fluoroscopy - exceeding 200 Gy·cm^2 of the total dose-area product (DAP).

2. The provisions of paragraph (1)(1)(c) and (d) shall not apply in exposure activities involving only the taking of intraoral dental radiographs with X-ray machines used exclusively for this purpose, or in exposure activities involving only the taking of bone densitometry with X-ray machines used exclusively for this purpose.

3. Exceedances of the diagnostic reference level referred to in paragraph (1)(2)(a) or exceedances of the values referred to in paragraph (1)(2)(b), (c) or (d) shall not be counted as Category II events, if such excess is clinically justified.

§ 4. 1. In interventional radiology:

1) Category I events include:

a) repetition of a procedure leading to a total dose exceeding the indicators specified in point 2,

b) performance of a procedure resulting in an unexpected deterministic effect,

c) performance of a procedure to an erroneously identified person,

d) performance of a procedure in the wrong anatomical area;

2) Category II events include:

a) four times exceeding the value of the diagnostic reference level,

b) in the case of procedures carried out for diagnostic purposes - exceeding 2.5 Gy of the total amount of air kerma at the reference point or 250 Gy·cm^2 of the total amount of the dose-area product (DAP),

c) the occurrence within 21 days after the procedure of the effect of radiation damage to the skin of at least the second degree, if during the implementation of the procedure there was an excess of 5 Gy of the total amount of air kerma at the reference point or 500 Gy·cm^2 of the total amount of the dose-area product (DAP).

2. Repetition of the procedure referred to in paragraph (1)(1)(a) shall not be counted as Category I event, if this repetition is clinically justified.

3. Exceeding the value of the diagnostic reference level or the values referred to in paragraph (1)(2)(a) and (b), respectively, shall not be counted as the Category II event, if this exceeding or this value is clinically justified.

§ 5. In diagnostics related to the administration of radiopharmaceutical products to patients:

1) Category I events include:

a) repetition of a procedure that is not due to clinical indications, leading to a total dose exceeding the indicators referred to in point 2,

b) performance of a procedure resulting in an unexpected deterministic effect,

c) performance of a procedure to an erroneously identified person,

d) performance of a procedure using a radiopharmaceutical product with therapeutic activity instead of diagnostic activity,

e) performance of a procedure using the wrong radiopharmaceutical product;

Category II events include exceeding the scheduled effective dose value by more than 20 mSv or the equivalent dose value by more than 100 mSv, per examination.

§ 6. In treatment related to the administration of radiopharmaceutical products to patients:

1) Category I events include:

a) performance of a procedure to an erroneously identified person,

b) performance of a procedure using the wrong radiopharmaceutical product,

c) performance of a procedure that results in an unexpected deterministic effect;

2) Category II events include:

a) performance of a procedure in which the deviation of the value of the activity administered to the patient from the planned value exceeds 10%,

b) performance of a procedure in which extravasation occurred after administration of a radiopharmaceutical product, if more than 15% of the activity was administered incorrectly,

c) accidental contamination of a patient with a radioactive substance during the performance of a procedure if, as a result of the contamination, the value of the effective dose exceeded 20 mSv or the value of the equivalent dose exceeded 100 mSv.

§ 7. In radiotherapy (radiation therapy):

1) Category I events include:

a) performance of radiotherapy in the wrong anatomical area also in the case of a single fraction,

b) performance of radiotherapy to an erroneously identified person,

c) use of the wrong treatment plan,

d) performance of radiotherapy in which the deviation of time between fractions exceeds 7 days, unless the deviation was caused by the person undergoing radiotherapy,

c) performance of radiotherapy that results in an unexpected deterministic effect;

2) Category II events include:

a) performance of radiotherapy, in which the deviation of the value of the total dose in the target volume or critical organs from the planned values exceeds 10%,

b) performance of radiotherapy in which the fractional dose value is greater than 120% of the planned dose value.

§ 8. 1. Category III events include:

1) performance of a diagnostic examination or procedure in the abdominal area, or

2) administration of a radiopharmaceutical product for diagnostic or therapeutic purposes, or

3) performance of radiation therapy

- on a pregnant woman, if the pregnancy status has been established already after the procedure and the dose value to the embryo or fetus exceeds 20 mSv.

2. Where the performance of a diagnostic examination or procedure was directly related to saving the life of a pregnant woman, undergoing this diagnostic examination or procedure, the provision of paragraph (1)(1) shall not apply.

§ 9. 1. In the case of unintended or accidental exposure occurring in a health care unit, the head of the health care unit shall review the quality assurance programme referred to in Article 7(2) of the Act, and, if necessary, make appropriate changes to the programme to minimize the likelihood of such an event occurring in the future.

2. In the case of radiation therapy, in addition to the activities referred to in paragraph (1), the head of the health care unit shall update the risk assessment of unintended or accidental exposures referred to in Article 7(2b)(2) of the Act.

3. The head of the health care unit shall provide information on unintended or accidental exposure and the results of the analysis of this exposure, as referred to in Article 7(2b)(4) of the Act, to the referrer, the practitioner, as well as

the patient or the patient's representative. In the case of Category III events, the results of the analysis shall include data on the exposure of the embryo or fetus.

4. A person with a high risk of deterministic effect as a result of unintended or accidental exposure shall undergo follow-up examinations performed at least once a week for a period of 21 days after the exposure or, if necessary, specialized treatment.

§ 10. 1. In the case of the occurrence of a category I event in a health care unit, an event report shall be prepared, including:

1) the date of occurrence of the event,

2) the name of the specific procedure, during the performance of which the event occurred, and a description of this procedure,

3) the number of persons who underwent medical exposure during the period in which the error leading to the event was likely to occur,

4) parameters allowing calculation of the value of doses received by the persons referred to in point 3,

5) a description of the event, including information that allows verification of the correct classification of the event into the appropriate category.

2. In the case of radiotherapy and treatment using radiopharmaceutical products, employees who may have contributed to the occurrence of the event, until the causes and circumstances of the event will be determined in accordance with the procedure set forth in Article 33m(8) of the Act, may participate in the implementation of medical radiological procedures, upon written approval by the head of the health care unit.

§ 11. 1. In case of occurrence of a Category II event at the health care unit:

1) if the cause of the occurrence of the event was the failure of radiological or auxiliary equipment - the person authorized to operate this device shall:

   a) shut down the equipment,

   b) if the failure of the equipment was found during the exposure - stop the exposure, unless there is no doubt that the continuation of the exposure is associated with a lower risk of harm to the health of the patient,

   c) in the case of a malfunction of the equipment during the administration of radiopharmaceutical products to the patient - perform actions to reduce the effects of the administration of radiopharmaceutical products, unless there is no doubt that the performance of these actions will increase the risk of harm to the patient's health,

   d) report the occurrence of an equipment malfunction to the person responsible at the health care unit for the technical condition of radiological equipment and auxiliary equipment;

2) an incident report shall be prepared containing:

   a) the date of occurrence of the event,

   b) the name of the specific procedure, during the performance of which the event occurred, and a description of this procedure, as well as the identifier of the device on which the procedure was performed,

   c) the number of patients on whom medical radiological procedures were performed during the period in which the event occurred or may have occurred,

   d) parameters allowing calculation of the value of doses received by patients referred to in letter c,

   e) a copy of the results of operational tests, when the event was related to the failure of radiological or auxiliary equipment,

   f) a description of the event, including information that allows verification of the correct classification of the event into the appropriate category.

2. Radiological or auxiliary equipment, the failure of which was the cause of the incident, may be used again in a health care unit after written approval from the head of the health care unit.

3. In the case of failure of a therapeutic device used in radiotherapy or treatment by radiopharmaceutical products, the provision of paragraph (2) shall apply, unless the consultant referred to in Article 33m(2) of the Act will notify the head of the health care unit in writing of his/her negative opinion as to the possibility of returning the therapeutic device to use, prior to the completion of the verification referred to in Article 33m(8) of the Act.

§ 12. In the case of the occurrence of a category III event in a health care unit, an event report shall be prepared, including:

1) the date of occurrence of the event,

2) the name of the specific procedure, during the performance of which the event occurred, and a description of this procedure, as well as the identifier of the device on which the procedure was performed,

3) the week of the patient's pregnancy at the time of the event,

4) parameters allowing calculation of the value of doses received by the patient and by the embryo or fetus,

5) a description of the event, including information that allows verification of the correct classification of the event into the appropriate category.

§ 13. The protocol referred to in § 10 (1), § 11 (1) (2), and § 12 shall be submitted by the head of the health care unit immediately, no later than within 7 days from the date of the occurrence of the event, to the consultant referred to in Article 33m (2) of the Act, for the purposes of the verification carried out by him/her and the verification carried out pursuant to Article 33m (8) of the Act.

§ 14. The Central Register of Unintended and Accidental Exposures, referred to in Article 33m(11) of the Act, shall contain:

1) category of unintended or accidental exposure;

2) identification of the scopes of activities of the health care units with the performance of which unintended and accidental exposures, reported under Article 33m(1) of the Law, are associated:

   a) X-ray diagnostics and fluoroscopy,

   b) interventional radiology,

   c) nuclear medicine - diagnostics,

   d) nuclear medicine - therapy,

   e) radiotherapy;

3) the date of occurrence of the event;

4) name of the health care unit where the event occurred.

§ 15. In cases of accidents related to the use of ionizing radiation in radiotherapy and treatment using radiopharmaceutical products, initiated and not concluded before the date of entry into force of this Regulation, the current provisions shall apply.

§ 16. This Regulation shall enter into force 14 days following its promulgation.[3]

Minister of Health: A. Niedzielski

[3] This regulation was preceded by the Regulation of the Minister of Health of 18 February 2011 on the conditions for the safe use of ionizing radiation for all types of medical exposure (Dz. U. of 2017, item 884), which expired on 24 September 2022 in accordance with Article 37(2)(2) of the Act of 13 June 2019 amending the Atomic Law and the Fire Protection Act (Dz. U., item 1593, and of 2020, item 284).