410/2012 Coll.

DECREE

of the Ministry of Health and the State Office for Nuclear Safety

of 21 November 2012

laying down rules and procedures for medical exposure

The Ministry of Health, in agreement with the State Office for Nuclear Safety, sets out, pursuant to Section 95(4) of Act No. 373/2011 Coll., on Specific Health Services, (hereinafter referred to as the "Act"), to implement Section 72(3) of the Act:

Section 1

This Decree incorporates the relevant European Union legislation 1) and regulates

a) rules for health protection of individuals against the dangers arising from ionising radiation in relation to medical exposure,

b) rules and procedures for radiation protection of individuals in medical exposure not regulated by national radiological standards.

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1) Council Directive 97/43/EURATOM of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/EURATOM.

Section 2

Scope and method for the optimisation of radiation protection in medical exposure

In addition to the procedures stipulated by legislation governing the peaceful utilisation of nuclear energy and ionising radiation 2), the following procedures shall be defined as part of the optimisation of radiation protection in medical exposure:

a) in examination in the field of radiodiagnostics, including interventional radiology and cardiology, the imaging method shall be used to ensure that the doses absorbed in tissues are as low as reasonably achievable without limiting the obtaining of the required radiodiagnostic information,

b) in examination in the field of nuclear medicine, only the necessary amount of radionuclide with the required purity and activity shall be applied to ensure sufficient diagnostic information with the minimum radiation dose to the patient,

c) in performance in the field of radiotherapy, the medical exposure shall be directed to a target volume of tissues on which the radiation therapy is focused; the target volume of tissues shall be exposed only to the extent necessary to achieve the required medical effect and exposures of other tissues shall be as low as reasonably achievable without reducing the medical benefit.

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2) Act No. 18/1997 Coll., on Peaceful Utilisation of Nuclear Energy and Ionising Radiation (the Atomic Act) and on Amendments and Additions to Related Acts, as amended.

Section 3

Scope of activities of prescriber and practitioner who are involved in medical exposure

(1) As part of medical exposure justification process, the prescriber and the practitioner shall

a) always take into account the efficacy, benefits and risks of available techniques having the same objective but involving no or less exposure to ionising radiation,

b) consult the patient before every use of the ionising radiation source for the purposes of medical exposure with regard to the previous applications of radionuclides and ionising radiation of possible relevance to the considered examination or treatment; for woman of childbearing age, consult the woman with regard to the pregnancy or breastfeeding; enter the identified data of possible relevance to the considered examination or treatment in the patient's medical records.

(2) Furthermore, the prescriber

a) if he/she recommends medical exposure, in the application for medical exposure in addition to the requirements set out in legislation governing the content and elements of medical records 3) shall further state
   1. clinical diagnosis and numerical diagnosis according to the International Statistical Classification of Diseases and Related Health Problems,
   2. information about the facts relevant to the patient’s medical exposure,
   3. objective, expected benefit and justification of request for medical exposure,
   4. information about previous applications of radionuclides and ionising radiation of possible relevance to the considered examination or treatment,

b) shall prepare special written justification, concerning verification of non-introduced method with medical exposure for which no binding opinion is issued by the State Office for Nuclear Safety pursuant to Section 36 of the Act.

(3) The practitioner shall further consider the objective and expected benefit of the requested medical exposure and shall

a) approve the conduct of exposure; in such case, the practitioner shall, in compliance with the local radiological standards, specify the workplace, specific source of ionising radiation, date and time of medical exposure, or

b) reject the conduct of exposure; in such case, the practitioner shall state this fact in information relating to examination or treatment, and

add his/her name and, if applicable, names, and surname, date and signature; attach his/her recognised electronic signature to electronic information relating to examination or treatment.

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3) Act No. 372/2011 Coll., on Health Services and Conditions for their Provision (Act on Health Services), as amended.
Decree No. 98/2012 Coll., on Medical Records.

Section 4

Rules and procedures for radiation protection of individuals exposed for medico-legal procedures without a medical indication

The recognised medical procedures shall apply to exposure of an individual as part of medico-legal procedures without a medical indication. When determining whether or not the exposure is justified as part of medico-legal procedures, the special nature of the purpose of this exposure, which is not the diagnostic or medical benefit including direct health benefit to an individual undergoing exposure, shall be taken into account. The dose or exposure parameters making it possible to estimate the dose or the activity determined and applied as part of medical exposure shall be entered in medical records kept for an individual mentioned in the first sentence.

Section 5

Rules and procedures for radiation protection in medical exposure as part of occupational medical services and preventive health care

(1) The recognised medical procedures shall apply to medical exposure of an individual as part of occupational medical services and preventive health care including health screening. When determining whether or not the exposure is justified, the special nature of the purpose of this exposure, which is the identification of a disease, shall be taken into account. The dose or exposure parameters making it possible to estimate the dose or the activity determined and applied as part of medical exposure shall be entered in medical records kept for a patient.

(2) Medical exposure as part of preventive care, including newly introduced health screenings, may be carried out only if the optimisation study demonstrates that the society-wide benefit arising from preventive care will be higher than the possible detriment caused by ionising radiation.

(3) The optimisation study is a procedure that ensures exposure justification and optimisation in medical exposure, which is a part of preventive care, including health screenings, and is conducted before incorporating the medical exposure into procedures as part of the provision of preventive care. During the development of the optimisation study, the expected number of individuals to undergo medical exposure, the expected success in identifying the screened disease and its treatment, and the expected number of individuals who could be injured on the basis of the probability of the stochastic effects of ionising radiation shall be mainly compared with each other. At the same time, it is assessed whether or not the same purpose could be achieved by using the method without ionising radiation.

(4) The optimisation study shall be repeated if a significant deviation from indicators used as a basis for the study occurs during the provision of preventive health care.

Section 6

Rules and procedures for radiation protection of healthy individuals or patients voluntarily participating in medical verification of non-introduced method related to medical exposure

(1) Medical exposure of healthy individuals or patients (hereinafter referred to as “medical exposure of an individual”) voluntarily participating in medical verification of non-introduced method related to medical exposure may be carried out if

a) such individuals are notified in writing of exposure risk and the provision of information was entered in medical records kept for such individuals,
b) such individuals participate on a voluntary basis and their consent to exposure is given in writing.

The dose or exposure parameters making it possible to estimate the dose or the activity applied as part of medical exposure shall be entered in medical records.

(2) Medical exposure of individuals participating in verification of non-introduced method with medical exposure for which no binding opinion is issued by the State Office for Nuclear Safety pursuant to Section 36 of the Act, may be carried out provided that the rules and procedures referred to in paragraph 1 are observed, as well as

a) the following dose constraints are fulfilled:
    1. diagnostic reference levels 4), or
    2. effective dose per individual 1 mSv for the calendar year, however maximum 10 mSv for the period of 10 consecutive calendar years,

b) it was assessed and justified in writing in medical records whether any other method not involving ionising radiation could be used, and
c) special written justification as set out in Section 3(2) point b) was developed.

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4) Section 2 point hh) of Act No. 18/1997 Coll.
Decree No. 307/2002 Coll., on Radiation Protection, as amended.

Section 7

Rules and procedures for radiation protection of patients exposed during pregnancy and breastfeeding

Medical exposure of patients during pregnancy and breastfeeding is possible only in urgent cases or on the ground of indication for the needs of the child's birth; this always requires careful consideration of the necessity to obtain the required diagnostic information or medical benefit to be achieved when using ionising radiation sources. At the same time, ionising radiation source and procedures should be selected to provide maximum protection to an embryo or fetus. For breastfeeding women undergoing examination as part of nuclear medicine, similar attention shall be given to the justification of medical exposure and to the assessment of its urgency.

Section 8

Rules and procedures for radiation protection of minor as part of his/her medical examination or treatment

When examining a minor, medical exposure may be applied only with the use of appropriate medical devices and procedures intended for this group of patients. Special attention shall be given to assessment of exposure during medical exposure of a minor.

Section 9

Rules and procedures for the assessment of local radiological standards and their compliance with national radiological standards

(1) Local radiological standards and their compliance with national radiological standards are reviewed by conducting an external clinical audit. A legal person authorised by the Ministry of Health to conduct an external clinical audit under Section 75 of the Act (hereinafter referred to as the "authorised person") shall verify and assess whether local radiological standards
a) are developed in the radiological workplace for each ionising radiation source and for all standard performance in connection with medical exposure carried out in that workplace,
b) are based on national radiological standards, specific conditions in the workplace in the health facility and the scope of the health services provided,
c) contain the correct method of determination and assessment of patient doses or administered activities,
d) contain indication criteria for the justification of medical exposure,
e) determine local diagnostic reference levels and define the method of assessment and recording of their observance in the radiological workplace,

f) contain requirements for recording and evaluation of repeated medical exposures of patients and their causes,
g) contain requirements for registration, recording and archiving of all data needed for the determination of dose or activity applied to a patient, in particular
1. exposure parameters of medical exposure or activity applied to a patient,
2. identification of ionising radiation source,
3. reports of status tests and constancy tests of ionising radiation source, and
h) are regularly updated and revised.

(2) In addition, the authorised person shall verify whether the person responsible for local radiological standards is appointed.

(3) In order to obtain the necessary information, the authorised person shall use
a) interviews with workers in the workplace undergoing a clinical audit,
b) inspection in the workplace undergoing a clinical audit,
c) information provided in the questionnaire,
d) documentary check,
e) monitoring of the implementation of working procedures in practice,
f) control measurements.

Section 10

Minimum requirements for the staff required to conduct external clinical audit

An external clinical audit for each individual evaluated radiological workplace undergoing a clinical audit shall be conducted by
a) physician with specialised qualification in the field of
1. radiology and imaging method for workplaces with diagnostic X-ray apparatuses,
2. nuclear medicine for nuclear medicine workplaces, or
3. radiation oncology for radiotherapeutic workplaces,
b) clinical radiological physicist with special professional qualification for the field of radiodiagnostics, radiotherapy or nuclear medicine,
c) radiology assistant with specialised qualification for the relevant evaluated activity, and
d) physician or health professional with specialised qualification in the relevant field by type of the evaluated workplace, if appropriate.

Section 11

Entry into force

This Decree shall enter into force on 1 December 2012.

Minister:
doc. MUDr. Heger, CSc., m. p.