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

CHAPTER VII U.K.

MEDICAL EXPOSURES

Article 55 *U.K.*

Justification

1 Medical exposure shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct benefits to health of an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.

2 Member States shall ensure that the principle defined in paragraph 1 is applied and in particular that:

a new types of practices involving medical exposure are justified in advance before being generally adopted;

b all individual medical exposures are justified in advance taking into account the specific objectives of the exposure and the characteristics of the individual involved.

c if a type of practice involving medical exposure is not justified in general, a specific individual exposure of this type can be justified, where appropriate, in special circumstances, to be evaluated on a case-by-case basis and documented.

d the referrer and the practitioner, as specified by Member States, seek, where practicable, to obtain previous diagnostic information or medical records relevant to the planned exposure and consider these data to avoid unnecessary exposure.

e medical exposure for medical or biomedical research are examined by an ethics committee, set up in accordance with national procedures and/or by the competent authority;

f specific justification for medical radiological procedures to be performed as part of a health screening programme are carried out by the competent authority in conjunction with appropriate medical scientific societies or relevant bodies.

g the exposure of carers and comforters show a sufficient net benefit, taking into account the direct health benefits to a patient, the possible benefits to the carer / comforter and the detriment that the exposure might cause.

h any medical radiological procedure on an asymptomatic individual, to be performed for the early detection of disease, is part of a health screening programme, or requires specific documented justification for that individual by the practitioner, in consultation with the referrer, following guidelines from relevant medical scientific societies and the competent authority. Special attention shall be given to the provision of information to the individual subject to medical exposure, as required by point (d) of Article 57(1).

Article 56 U.K.

Optimisation

1 Member States shall ensure that all doses due to medical exposure for radiodiagnostic, interventional radiology, planning, guiding and verification purposes are kept as low as reasonably achievable consistent with obtaining the required medical information, taking into account economic and societal factors.

For all medical exposure of patients for radiotherapeutic purposes, exposures of target volumes shall be individually planned and their delivery appropriately verified taking into account that doses to non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.

2 Member States shall ensure the establishment, regular review and use of diagnostic reference levels for radiodiagnostic examinations, having regard to the recommended European diagnostic reference levels where available, and where appropriate, for interventional radiology procedures, and the availability of guidance for this purpose.

3 Member States shall ensure that for each medical or biomedical research project involving medical exposure:

a the individuals concerned participate voluntarily;

b these individuals are informed about the risks of exposure;

c a dose constraint is established for individuals for whom no direct medical benefit is expected from exposure;

d in the case of patients who voluntarily accept to undergo an experimental medical practice and who are expected to receive a diagnostic or therapeutic benefit from this practice, the dose levels concerned shall be considered on an individual basis by the practitioner and/or referrer prior to the exposure taking place.

4 Member States shall ensure that the optimisation includes the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical radiological procedures, quality assurance, and the assessment and evaluation of patient doses or the verification of administered activities, taking into account economic and societal factors.

5 Member States shall ensure that:

a dose constraints are established for the exposure of carers and comforters, where appropriate;

b appropriate guidance is established for the exposure of carers and comforters.

6 Member States shall ensure that in the case of a patient undergoing treatment or diagnosis with radionuclides, the practitioner or the undertaking, as specified by Member States, provides the patient or their representative with information on the risks of ionising radiation and appropriate instructions with a view to restricting doses to persons in contact with the patient as far as reasonably achievable. For therapeutic procedures these shall be written instructions.

These instructions shall be handed out before leaving the hospital or clinic or a similar institution.

Article 57 U.K.

Responsibilities

1 Member States shall ensure that:

a any medical exposure takes place under the clinical responsibility of a practitioner;

b the practitioner, the medical physics expert and those entitled to carry out practical aspects of medical radiological procedures are involved, as specified by Member States, in the optimisation process;

c the referrer and the practitioner are involved, as specified by Member States, in the justification process of individual medical exposures;

d wherever practicable and prior to the exposure taking place, the practitioner or the referrer, as specified by Member States, ensures that the patient or their representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure. Similar information as well as relevant guidance shall be given to carers and comforters, in accordance with point (b) of Article 56(5).

2 Practical aspects of medical radiological procedures may be delegated by the undertaking or the practitioner, as appropriate, to one or more individuals entitled to act in this respect in a recognised field of specialisation.

Article 58 U.K.

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;

(b) information relating to patient exposure forms part of the report of the medical radiological procedure;

(c) referral guidelines for medical imaging, taking into account the radiation doses, are available to the referrers;

(d) in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice. In particular:

(i) in radiotherapeutic practices other than standardised therapeutic nuclear medicine practices, a medical physics expert shall be closely involved;

(ii) in standardised therapeutical nuclear medicine practices as well as in radiodiagnostic and interventional radiology practices, involving high doses as referred to in point (c) of Article 61(1), a medical physics expert shall be involved;

(iii) **[**[X1]for other medical radiological practices not covered by points (i) and (ii), a medical physics expert shall be involved, as appropriate, for consultation and advice on matters relating to radiation protection concerning medical exposure.**]**

(e) clinical audits are carried out in accordance with national procedures;

(f) appropriate local reviews are undertaken whenever diagnostic reference levels are consistently exceeded and that appropriate corrective action is taken without undue delay.

Editorial Information

X1 Substituted by Corrigendum to 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 (Official Journal of the European Union L 13 of 17 January 2014).

Article 59 U.K.

Training and recognition

Member States shall ensure that training and recognition requirements, as laid down in Articles 79, 14 and 18, are met for the practitioner, the medical physics expert and the individuals referred to in Article 57(2).

Article 60 U.K.

Equipment

1 Member States shall ensure that:

a all medical radiological equipment in use is kept under strict surveillance regarding radiation protection;

b an up-to-date inventory of medical radiological equipment for each medical radiological installation is available to the competent authority;

c appropriate quality assurance programmes and assessment of dose or verification of administered activity are implemented by the undertaking; and

d acceptance testing is carried out before the first use of the equipment for clinical purposes, and performance testing is carried out thereafter on a regular basis, and after any maintenance procedure liable to affect the performance.

2 Member States shall ensure that the competent authority takes steps to ensure that the necessary measures are taken by the undertaking to improve inadequate or defective performance of medical radiological equipment in use. They shall also adopt specific criteria for the acceptability of equipment in order to indicate when appropriate corrective action is necessary, including taking the equipment out of service.

3 Member States shall ensure that:

a the use of fluoroscopy equipment without a device to automatically control the dose rate, or without an image intensifier or equivalent device, is prohibited.

b equipment used for external beam radiotherapy with a nominal beam energy exceeding 1 MeV has a device to verify key treatment parameters. Equipment installed prior to 6 February 2018 may be exempted from this requirement.

c any equipment used for interventional radiology has a device or a feature informing the practitioner and those carrying out practical aspects of the medical procedures

of quantity of radiation produced by the equipment during the procedure. Equipment installed prior to 6 February 2018 may be exempted from this requirement.

d any equipment used for interventional radiology and computed tomography and any new equipment used for planning, guiding and verification purposes has a device or a feature informing the practitioner, at the end of the procedure, of relevant parameters for assessing the patient dose.

e equipment used for interventional radiology and computed tomography has the capacity to transfer the information required under 3(d) to the record of the examination. Equipment installed prior to 6 February 2018 may be exempted from this requirement.

f without prejudice to points (c), (d) and (e) of paragraph 3, new medical radiodiagnostic equipment producing ionising radiation has a device, or an equivalent means, informing the practitioner of relevant parameters for assessing the patient dose. Where appropriate, the equipment shall have the capacity to transfer this information to the record of the examination.

Article 61 U.K.

Special practices

1 Member States shall ensure that appropriate medical radiological equipment, practical techniques and ancillary equipment is used in medical exposure:

a of children;

b as part of a health screening programme;

c involving high doses to the patient, which may be the case in interventional radiology, nuclear medicine, computed tomography or radiotherapy.

Special attention shall be given to quality assurance programmes and the assessment of dose or verification of administered activity for these practices.

2 Member States shall ensure that practitioners and those individuals referred to in Article 57(2) who perform the exposures referred to in paragraph 1 obtain appropriate training on these medical radiological practices as required by Article 18.

Article 62 U.K.

Special protection during pregnancy and breastfeeding

1 Member States shall ensure that the referrer or the practitioner, as appropriate, inquire, as specified by Member States, whether the individual subject to medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure.

2 If pregnancy cannot be ruled out and depending on the medical radiological procedure, in particular if abdominal and pelvic regions are involved, special attention shall be given to the justification, particularly the urgency, and to the optimisation, taking into account both the expectant individual and the unborn child.

3 In the case of a breastfeeding individual, in nuclear medicine, depending on the medical radiological procedure, special attention shall be given to the justification, particularly the urgency, and to the optimisation, taking into account both the individual and the child.

4 Without prejudice to paragraphs 1, 2 and 3, Member States shall take measures to increase the awareness of individuals to whom this Article applies, through measures such as public notices in appropriate places.

Article 63 U.K.

Accidental and unintended exposures

Member States shall ensure that:

(a) all reasonable measures are taken to minimise the probability and magnitude of accidental or unintended exposures of individuals subject to medical exposure;

(b) for radiotherapeutic practices the quality assurance programme includes a study of the risk of accidental or unintended exposures;

(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;

(d) arrangements are made to inform the referrer and the practitioner, and the patient, or their representative, about clinically significant unintended or accidental exposures and the results of the analysis;

(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;

(f) mechanisms are in place for the timely dissemination of information, relevant to radiation protection in medical exposure, regarding lessons learned from significant events.

Article 64 U.K.

Estimates of population doses

Member States shall ensure that the distribution of individual dose estimates from medical exposure for radiodiagnostic and interventional radiology purposes is determined, taking into consideration where appropriate the distribution by age and gender of the exposed.