## STATUTORY INSTRUMENTS

# 2017 No. 1322

## The Ionising Radiation (Medical Exposure) Regulations 2017

#### Optimisation

**12.**—(1) In relation to all exposures to which these Regulations apply except radiotherapeutic exposures, the practitioner and the operator, to the extent of their respective involvement in an exposure, must ensure that doses arising from the exposure are kept as low as reasonably practicable consistent with the intended purpose.

(2) In relation to all radiotherapeutic exposures the practitioner must ensure that exposures of target volumes are individually planned and their delivery appropriately verified taking into account that doses to non-target volumes and tissues must be as low as reasonably practicable and consistent with the intended radiotherapeutic purpose of the exposure.

(3) Without prejudice to paragraphs (1) and (2), the operator must select equipment and methods to ensure that for each exposure the dose of ionising radiation to the individual undergoing the exposure is as low as reasonably practicable and consistent with the intended diagnostic or therapeutic purpose and in doing so must have regard, in particular to—

- (a) quality assurance;
- (b) assessment and evaluation of patient dose or administered activity; and
- (c) adherence to such diagnostic reference levels for radiodiagnostic examinations falling within regulation 3(a), (b), (e) and (f) as the employer may have established,

as set out in the employer's procedures.

(4) For each medical or biomedical research programme falling within regulation 3(c), the employer's procedures must provide that—

- (a) the individuals concerned participate voluntarily in the research programme;
- (b) the individuals concerned are informed in advance about the risks of the exposure;
- (c) the dose constraint set down in the employer's procedures for individuals for whom no direct medical benefit is expected from the exposure is adhered to; and
- (d) individual target levels of doses are planned by the practitioner, either alone or with the input of the referrer, for patients who voluntarily undergo an experimental diagnostic or therapeutic practice from which the patients are expected to receive a diagnostic or therapeutic benefit.

(5) In the case of regulation 3(d), the employer's procedures must provide that appropriate guidance is established for the exposure of carers and comforters.

(6) In the case of patients undergoing treatment or diagnosis with radioactive substances, the employer's procedures must provide that, where appropriate, written instructions and information are provided to—

(a) the patient, where the patient has capacity to consent to the treatment or diagnostic procedure;

- (b) where the patient is a child who lacks capacity (within the meaning of the Mental Capacity Act 2005(1) in the case of a child aged sixteen or seventeen) so to consent, a person with parental responsibility (within the meaning of the Children Act 1989(2)) for the child; or
- (c) where the patient is an adult who lacks capacity (within the meaning of the Mental Capacity Act 2005) so to consent, the person who appears to the practitioner to be the most appropriate person.
- (7) The instructions and information referred to in paragraph (6) must—
  - (a) specify how doses resulting from the patient's exposure can be restricted as far as reasonably possible so as to protect persons in contact with the patient;
  - (b) set out the risks associated with ionising radiation; and
  - (c) be provided to the patient or other person specified in paragraph (6) as appropriate prior to the patient leaving the radiological installation where the exposure was carried out.

(8) In complying with the obligations under this regulation, the practitioner and the operator must pay particular attention in relation to—

- (a) medical exposures of children;
- (b) medical exposures as part of a health screening programme;
- (c) medical exposures involving high doses to the individual being exposed;
- (d) where appropriate, individuals in whom pregnancy cannot be excluded and who are undergoing a medical exposure, in particular if abdominal and pelvic regions are involved, taking into account the exposure of both the individual and any unborn child; and
- (e) where appropriate, individuals who are breastfeeding and who are undergoing a medical exposure involving the administration of radioactive substances, taking into account the exposure of both the individual and the child.

(9) The employer must take steps to ensure that a clinical evaluation of the outcome of each exposure, other than where the person subject to the exposure is a carer or a comforter, is recorded in accordance with the employer's procedures including, where appropriate, factors relevant to patient dose.

### **Commencement Information**

I1 Reg. 12 in force at 6.2.2018, see reg. 1

<sup>(1) 2005</sup> c. 9; see section 2 as to the meaning of "capacity".

<sup>(2) 1989</sup> c. 41; see section 3 as to the meaning of "parental responsibility".

**Changes to legislation:** There are currently no known outstanding effects for the The Ionising Radiation (Medical Exposure) Regulations 2017, Section 12.