STATUTORY INSTRUMENTS

2017 No. 1075

The Ionising Radiations Regulations 2017

PART 6

ARRANGEMENTS FOR THE CONTROL OF RADIOACTIVE SUBSTANCES, ARTICLES AND EQUIPMENT

Equipment used for medical exposure

33.—(1) Every employer who has to any extent control of any equipment or apparatus which is used in connection with a medical exposure must, having regard to the extent of its control over the equipment, ensure that such equipment is of such design or construction and is so installed and maintained as to be capable of restricting so far as is reasonably practicable the exposure to ionising radiation of any person who is undergoing a medical exposure to the extent that this is compatible with the intended clinical purpose or research objective.

(2) An employer who has to any extent control of any radiation equipment which is used for the purpose of diagnosis and which is installed on or after the date of the coming into force of these Regulations must, having regard to the extent of the employer's control over the equipment, ensure that such equipment is provided, where practicable, with suitable means for informing the user of that equipment of the quantity of radiation produced by that equipment during a radiological procedure.

(3) Every employer in respect of whom a duty is imposed by paragraph (1) must, to the extent that it is reasonable for the employer to do so having regard to the extent of the employer's control over the equipment, make arrangements for a suitable quality assurance programme to be provided in respect of the equipment or apparatus for the purpose of ensuring that it remains capable of restricting so far as is reasonably practicable exposure to the extent that this is compatible with the intended clinical purpose or research objective.

(4) Without prejudice to the generality of paragraph (3), the quality assurance programme required by that paragraph must require the carrying out of—

(a) in respect of equipment or apparatus first used on or after the date of the coming into force of this regulation, adequate testing of that equipment or apparatus before it is first used for clinical purposes;

(b) adequate testing of the performance of the equipment or apparatus at appropriate intervals and after any major maintenance procedure to that equipment or apparatus;

(c) where appropriate, such measurements at suitable intervals as are necessary to enable the assessment of representative doses from any radiation equipment to persons undergoing medical exposures.

(5) Every employer who has to any extent control of any radiation equipment must take all such steps as are reasonably practicable to prevent the failure of any such equipment where such failure could result in an exposure to ionising radiation greater than that intended and to limit the consequences of any such failure.

(6) Where an employer suspects or has been informed that an incident may have occurred in which a person while undergoing a medical exposure was, as the result of a malfunction of, or

defect in, radiation equipment under the control of that employer, exposed to ionising radiation to an extent much greater than that intended, the employer must make an immediate investigation of the suspected incident.

(7) Unless the immediate investigation referred to in paragraph (6) shows beyond reasonable doubt that no such incident has occurred, the employer must immediately notify the appropriate authority of the incident and make or arrange for a detailed investigation of the circumstances of the exposure and an assessment of the dose received.

(8) An employer who makes an investigation in accordance with paragraph (6) or (7) must make a report of that investigation and must—

(a) in relation to an investigation made under paragraph (6), keep the report or a copy of the report for a period of at least 2 years from the date on which it was made; and

(b) in relation to an investigation made under paragraph (7), keep the report or a copy of the report for a period of at least 30 years from the date on which it was made.

(9) In this regulation—

"appropriate authority" means—

(a) in connection with the application of this regulation in relation to, or in relation to any activity carried out on, any nuclear premises, the ONR;

(b) otherwise, the Executive;

"radiation equipment" means equipment which delivers ionising radiation to the person undergoing a medical exposure and equipment which directly controls the extent of the exposure.