STATUTORY INSTRUMENTS

2017 No. 1322

HEALTH AND SAFETY

The Ionising Radiation (Medical Exposure) Regulations 2017

Made - - - -	*20th December 2017*
Laid before Parliament	*22nd December 2017*
Coming into force - -	*6th February 2018*

The Secretary of State, being the Minister designated(**1**) for the purposes of section 2(2) of the European Communities Act 1972(**2**) in relation to safety measures in regard to radioactive substances and the emission of ionising radiation, in exercise of the powers conferred by that section and by section 56 of the Finance Act 1973(**3**), makes the following Regulations. Regulation 4 and Schedule 1 (the Licensing Authority) are made with the consent of the Treasury.

Citation and commencement

1. These Regulations may be cited as the Ionising Radiation (Medical Exposure) Regulations 2017 and come into force on 6th February 2018.

Interpretation

2.—(1) In these Regulations—

"accidental exposure" means an exposure of an individual as a result of an accident;

"adequate training" means training which satisfies the requirements of Schedule 3 and the expression "adequately trained" is to be construed accordingly;

"assessment" means prior determination of amount, parameter or method;

"carers and comforters" means individuals knowingly and willingly incurring an exposure to ionising radiation by helping, other than as part of their occupation, in the support and comfort of individuals undergoing or having undergone an exposure;

(**1**) S.I. 1977/1718; there are no relevant amendments.

(**2**) 1972 c. 68; section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c. 51), and by Part 1 of the Schedule to the European Union (Amendment) Act 2008 (c. 7). In so far as these Regulations deal with matters that are within the devolved competence of Scottish Ministers, the power of the Secretary of State to make regulations in relation to those matters in or as regards Scotland is preserved by section 57(1) of the Scotland Act 1998 (c. 46).

(**3**) 1973 c. 51; amendments have been made to section 56 by S.I. 2011/1043; there are other amendments to that section which are not relevant for the purposes of these Regulations.

"clinical audit" means a systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where indicated, and the application of new standards if necessary;

"diagnostic reference levels" means dose levels in medical radiodiagnostic or interventional radiology practices, or, in the case of radio-pharmaceuticals, levels of activity, for typical examinations for groups of standard-sized individuals or standard phantoms for broadly defined types of equipment;

"dose constraint" means a restriction set on the prospective doses of individuals which may result from a given radiation source;

"employer" means any person who, in the course of a trade, business or other undertaking, carries out (other than as an employee), or engages others to carry out, those exposures described in regulation 3 or practical aspects, at a given radiological installation;

"employer's procedures" means the procedures established by an employer pursuant to regulation 6(1);

"equipment" means equipment which—

(a) delivers ionising radiation to a person undergoing exposure; or

(b) which directly controls or influences the extent of such exposure;

"evaluation" means interpretation of the outcome and implications of, and of the information resulting from, an exposure;

"health screening" means a procedure for early diagnosis in population groups at risk;

"interventional radiology" means the use of X-ray imaging techniques to facilitate the introduction and guidance of devices in the body for diagnostic or treatment purposes;

"ionising radiation" means the transfer of energy in the form of particles or electromagnetic waves of a wavelength of 100 nanometres or less or a frequency of 3×10^{15} hertz or more capable of producing ions directly or indirectly;

"Licensing Authority"—

(a) for the purpose of licensing any practitioner in respect of the administration of radioactive substances means the Secretary of State;

(b) for the purpose of licensing any employer in respect of the administration of radioactive substances means—

  (i) in England, the Secretary of State;

  (ii) in Scotland, the Scottish Ministers; and

  (iii) in Wales, the Welsh Ministers;

"medical exposure" means an exposure coming within any of paragraphs (a) to (e) of regulation 3;

"medical physics expert" means an individual or a group of individuals, having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to exposure, whose competence in this respect is recognised by the Secretary of State;

"medical radiological" means pertaining to radiodiagnostic and radiotherapeutic procedures, and interventional radiology or other medical uses of ionising radiation for planning, guiding and verification purposes;

"medical radiological procedure" means any procedure giving rise to a medical exposure;

"non-medical imaging exposure" means any deliberate exposure of humans for imaging purposes where the primary intention of the exposure is not to bring a health benefit to the individual being exposed;

"operator" means any person who is entitled, in accordance with the employer's procedures, to carry out practical aspects including those to whom practical aspects have been allocated, medical physics experts and, except where they do so under the direct supervision of a person who is adequately trained, persons participating in practical aspects as part of practical training;

"patient dose" means the dose concerning patients or other individuals undergoing exposures to which these Regulations apply;

"practical aspect" means the physical conduct of a medical exposure and any supporting aspects, including handling and use of medical radiological equipment, the assessment of technical and physical parameters (including radiation doses), calibration and maintenance of equipment, preparation and administration of radio-pharmaceuticals, clinical evaluation and image processing;

"practitioner" means a registered health care professional who is entitled in accordance with the employer's procedures to take responsibility for an individual exposure;

"quality assurance" means all those planned and systematic actions necessary to provide adequate assurance that a structure, system, component or procedure will perform satisfactorily in compliance with generally applicable standards and quality control is a part of quality assurance;

"quality control" means the set of operations (programming, coordinating, implementing) intended to maintain or to improve quality and includes monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled;

"radioactive substance" means any substance that contains one or more radionuclides the activity or activity concentration of which cannot be disregarded from a radiation protection point of view;

"radiodiagnostic" means pertaining to in-vivo diagnostic nuclear medicine, medical diagnostic radiology using ionising radiation, and dental radiology;

"radiological installation" means a facility where exposures to which these Regulations apply are performed;

"radiotherapeutic" means pertaining to radiotherapy, including nuclear medicine for therapeutic purposes;

"referrer" means a registered health care professional who is entitled in accordance with the employer's procedures to refer individuals for exposure to a practitioner;

"registered health care professional" means a person who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002(**4**);

"relevant enforcing authority" means—

(a) in England, the Care Quality Commission(**5**);

(b) in Scotland, the Scottish Ministers; and

(c) in Wales, the Welsh Ministers;

(**4**) 2002 c. 17. Section 25 has been amended by paragraph 17 of Schedule 10 and Part 2 of Schedule 15 the Health and Social Care Act 2008 (c. 14), sections 220, 222 and 224 of and paragraphs 56 and 62 of Schedule 15 to the Health and Social Care act 2012 (c. 7), section 5(1) of the Health and Social Care (Safety and Quality) Act 2015 (c. 28), paragraph 1 and 2 of Schedule 4 to the Children and Social Work Act 2017 (c. 16).

(**5**) Established by section 1 of the Health and Social Care Act 2008 (c. 14).

"unintended exposure" means any exposure to ionising radiation which is significantly different from the exposure intended for a given purpose.

(2) In these Regulations, where an individual is—

(a) an employer;

(b) a referrer;

(c) an operator; or

(d) a practitioner,

and is also an individual coming within at least one other of sub-paragraphs (a) to (d), that individual is subject to each of the duties applying to every person described in a sub-paragraph which also describes that individual.

Application

3. These Regulations apply to the exposure of ionising radiation in England and Wales and Scotland—

(a) to patients as part of their own medical diagnosis or treatment;

(b) to individuals as part of health screening programmes;

(c) to patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes;

(d) to carers and comforters;

(e) to asymptomatic individuals;

(f) to individuals undergoing non-medical imaging using medical radiological equipment.

The Licensing Authority

4.—(1) The Licensing Authority may upon payment of a fee (where required) issue a licence to a person required by these Regulations to hold a licence.

(2) A licence described in paragraph (1) may be—

(a) issued for such period as the Licensing Authority considers appropriate;

(b) subject to such conditions as the Licensing Authority may consider appropriate; and

(c) varied or revoked at any time.

(3) Schedule 1 makes further provision relating to the application for, and the issue of, a licence described in paragraph (1).

Requirement to hold a licence

5.—(1) A person must hold a valid licence issued by the Licensing Authority if that person—

(a) is an employer, in which case that person must hold a licence in respect of each radiological installation at which radioactive substances are to be administered for such purposes as may be specified in that licence; or

(b) is a practitioner, in which case that person must hold a licence in order to justify, within the meaning of regulation 11 an exposure involving the administration of radioactive substances for such purposes as may be specified in that licence.

(2) In this regulation, "purpose" when describing the purpose for which a licence is issued, means diagnosis, treatment or research.

Employer's duties: establishment of general procedures, protocols and quality assurance programmes

6.—(1) The employer must ensure that written procedures are in place in respect of—

(a) those matters described in Schedule 2; and

(b) any other matter in relation to which these Regulations mandate the establishment of procedures.

(2) The employer must take steps to ensure that any written procedures are complied with by the referrer, practitioner and operator.

(3) The employer must take steps to ensure that every practitioner or operator engaged by the employer to carry out exposures or any practical aspect—

(a) complies with the provisions of regulation 17(1); and

(b) undertakes continuing education and training after qualification including, in the case of clinical use of new techniques, training related to those techniques and the relevant radiation protection requirements.

(4) The employer must ensure, where appropriate, that written protocols are in place for every type of standard radiological practice coming within these Regulations, including practices involving non-medical imaging.

(5) The employer must—

(a) establish recommendations concerning referral guidelines for medical exposures, including radiation doses, and ensure that these are available to the referrer;

(b) establish quality assurance programmes for written procedures and written protocols;

(c) regularly review and make available to an operator, diagnostic reference levels in respect of an exposure falling within—

(i) regulation 3(a)—

(aa) where the exposure involves interventional radiology procedures, in which case, diagnostic references levels are to be provided where appropriate; and

(bb) where the exposure does not involve interventional radiology procedures, in which cases regard must be had to European and national diagnostic reference levels where available;

(ii) regulation 3(b) or (e) in which cases regard must be had to European and national diagnostic reference levels where available;

(iii) regulation 3(f) where practicable;

(d) establish dose constraints—

(i) for biomedical and medical research programmes falling within regulation 3(c) where no direct medical benefit for the individual is expected from the exposure; and

(ii) with regard to the protection of carers and comforters falling within regulation 3(d).

(6) A dose constraint must be established by the employer in terms of individual effective or equivalent doses over a defined appropriate time period.

(7) The employer must ensure appropriate reviews are undertaken whenever diagnostic reference levels are consistently exceeded and ensure that corrective action is taken where appropriate.

(8) The employer must take measures to raise awareness of the effects of ionising radiation amongst individuals capable of childbearing or breastfeeding.