STATUTORY RULES OF NORTHERN IRELAND

2018 No. 17

HEALTH AND SAFETY

The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018

Made - - - -	*1st February 2018*
Coming into operation	*6th February 2018*

The Department of Health(**1**), being a designated Department(**2**) for the purposes of section 2(2) of the European Communities Act 1972(**3**) 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(**4**); and with the consent of the Department of Finance in respect of the powers conferred by section 56, makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 and shall come into operation on 6th February 2018.

Interpretation

2.—(1) In these Regulations—

"accidental exposure" means an exposure to ionising radiation of individuals as a result of an accident;

"adequate training" means training which satisfies the requirements of Schedule 3;

"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;

"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,

(**1**) Formerly the Department of Health, Social Services and Public Safety; see 2016 c.5 (N.I.), s. 1(5)
(**2**) S.I. 1977/1718
(**3**) 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)
(**4**) 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

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;

"Department" means the Department of Health;

"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 constraint 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, medical 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;

"exposure" means the act of exposing or condition of being exposed to ionising radiation emitted outside the body (external exposure) or within the body (internal 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" means the Department;

"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 Department;

"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 employers 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 acceptable 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, or a medical practitioner registered with the Medical Council of Ireland, 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(**5**);

"relevant enforcing authority" means the Department;

"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 who 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.

(**5**) 2002 c. 17

(3) The Interpretation Act (Northern Ireland) 1954(**6**) shall apply to these Regulations as it applies to an Act of the Northern Ireland Assembly.

Application

3. These Regulations apply to the exposure of ionising radiation in Northern Ireland—

(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 may consider appropriate;

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

(c) varied or revoked at any time.

(3) Schedule 1 makes further provision relating to matters concerning 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.

(**6**) 1954 c. 33

(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 of such exposures—

(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 these 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 reference 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) (non-medical imaging) 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.

Employer's duties: clinical audit

7. The employer's procedures must include provision for the carrying out of clinical audit as appropriate.

Employer's duties: accidental or unintended exposure

8.—(1) The employer's procedures must provide that the referrer, the practitioner, and the individual exposed or their representative (if there is one) are informed of the occurrence of a clinically significant unintended or accidental exposure and of the outcome of the analysis of this exposure.