STATUTORY RULES OF NORTHERN IRELAND

2000 No. 194

HEALTH AND SAFETY

The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000

Made - - - - 24th May 2000

Coming into operation in accordance with regulation 1

The Department of Health, Social Services and Public Safety(**1**) being a designated Department(**2**) for the purposes of section 2(2) of the European Communities Act 1972(**3**) in relation to the making of safety measures in regard to radioactive substances and the emission of ionising radiation, in exercise of the powers conferred by that section, hereby makes the following Regulations:—

Citation and commencement

1. These Regulations may be cited as the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000 and shall come into operation—

(a) except for regulation 4(1) and 4(2), on 27th June 2000;

(b) as regards regulation 4(1) and 4(2), on 1st January 2001.

Interpretation

2.—(1) In these Regulations—

"adequate training" means training which satisfies the requirements of Schedule 2;

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

"child" means a person under the age of 18;

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

"Department" means the Department of Health, Social Services and Public Safety—

(**1**) *See* S.I.1999/283
(**2**) S.I. 1977/1718
(**3**) 1972 c. 68

"diagnostic reference levels" means dose levels in medical radiodiagnostic practices or, in the case of radioactive medicinal products, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment;

"dose constraint" means a restriction on the prospective doses to individuals which may result from a defined source;

"the Directive" means Council Directive 97/43/Euratom(**4**) laying down measures on health protection of individuals against the dangers of ionising radiation in relation to medical exposure;

"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 or practical aspects, at a given radiological installation;

"employer's procedures" means the procedures established by an employer pursuant to regulation 4(1);

"equipment" means equipment which delivers ionising radiation to a person undergoing a medical exposure and equipment 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, a medical exposure;

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

"individual detriment" means clinically observable deleterious effects that are expressed in individuals or their descendants the appearance of which is either immediate or delayed and, in the latter case, implies a probability rather than a certainty of appearance;

"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;

"medical exposure" means any exposure to which regulation 3 applies and which involves an individual being exposed to ionising radiation;

"medical physics expert" means a person who holds a science degree, or its equivalent, who is experienced in the application of physics to the diagnostic and therapeutic uses of ionising radiation;

"medico-legal procedure" means a procedure performed for insurance or legal purposes without a medical indication;

"occupational health surveillance" means medical surveillance for workers;

"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 pursuant to regulation 5(3), medical physics experts as referred to in regulation 9 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 as referred to in regulation 11(3);

"patient dose" means the dose, concerning patients or other individuals undergoing medical exposure;

"practical aspect" means the physical conduct of any of the exposures referred to in regulation 3 and any supporting aspects including handling and use of radiological equipment, and the assessment of technical and physical parameters including radiation doses, calibration and

(**4**) O.J. No. L180, 9.7.97, p. 22

maintenance of equipment, preparation and administration of radioactive medicinal products and the development of films;

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

"quality assurance" means any planned and systematic action necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily and safely complying with agreed standards and includes quality control;

"quality control" means the set of operations (programming, co-ordinating, implementing) intended to maintain or to improve quality and includes monitoring, evaluation and maintenance at required levels of performance;

"radiodiagnostic" means pertaining to *in vivo* diagnostic nuclear medicine, medical diagnostic radiology and dental radiology;

"radioactive medicinal product" has the meaning given in the Medicines (Administration of Radioactive Substances) Regulations 1978(**5**);

"radiological" means pertaining to radiodiagnostic and radiotherapeutic procedures and interventional radiology or other planning and guiding radiology;

"radiological installation" means a facility containing equipment;

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

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

"registered dental practitioner" means a person registered in the dentists register under the Dentists Act 1984;

"registered medical practitioner" means a registered person within the meaning of the Medical Act 1983.

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

Application

3. These Regulations shall apply to the following medical exposures—

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

(b) the exposure of individuals as part of occupational health surveillance;

(c) the exposure of individuals as part of health screening programmes;

(d) the exposure of patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes;

(e) the exposure of individuals as part of medico-legal procedures.

Duties of Employer

4.—(1) The employer shall ensure that written procedures for medical exposures including the procedures set out in Schedule 1 are in place and—

(**5**) S.I. 1978/1006
(**6**) 1954 c. 33 (N.I.)

(a) shall take steps to ensure that they are complied with by the practitioner and operator; or

(b) where the employer is conncurrently practitioner or operator, he shall comply with these procedures himself.

(2) The employer shall ensure that written protocols are in place for every type of standard radiological practice for each equipment.

(3) The employer shall establish—

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

(b) quality assurance programmes for standard operating procedures;

(c) diagnostic reference levels for radiodiagnostic examinations falling within regulation 3(*a*), (*b*), (*c*) and (*e*) having regard to European diagnostic reference levels where available;

(d) dose constraints for biomedical and medical research programmes falling within regulation 3(*d*) where no direct medical benefit for the individual is expected from the exposure.

(4) The employer shall take steps to ensure that every practitioner or operator engaged by the employer to carry out medical exposures or any practical aspect of such exposures—

(a) complies with the provisions of regulation 11(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; or

(c) where the employer is concurrently practitioner or operator, he shall himself ensure that he undertakes such continuing education and training as may be appropriate.

(5) Where the employer knows or has reason to believe that an incident has or may have occurred in which a person, while undergoing a medical exposure was, otherwise than as a result of a malfunction or defect in equipment, exposed to ionising radiation to an extent much greater than intended, he shall make an immediate preliminary investigation of the incident and, unless that investigation shows beyond a reasonable doubt that no such overexposure has occurred, he shall forthwith notify the appropriate authority and make or arrange for a detailed investigation of the circumstances of the exposure and an assessment of the dose received.

(6) The employer shall undertake appropriate reviews whenever diagnostic reference levels are consistently exceeded and ensure that corrective action is taken where appropriate.

Duties of the Practitioner, Operator and Referrer

5.—(1) The practitioner and the operator shall comply with the employer's procedures.

(2) The practitioner shall be responsible for the justification of a medical exposure and such other aspects of a medical exposure as is provided for in these Regulations.

(3) Practical aspects of a medical exposure or part of it may be delegated in accordance with the employer's procedures by the employer or the practitioner, as appropriate, to one or more individuals entitled to act in this respect in a recognised field of specialisation.

(4) The operator shall be responsible for each and every practical aspect which he carries out as well as for any authorisation given pursuant to regulation 6(5) where such authorisation is not made in accordance with the guidelines referred to in regulation 6(5).

(5) The referrer shall supply the practitioner with sufficient medical data (such as previous diagnostic information or medical records) relevant to the medical exposure requested by the referrer to enable the practitioner to decide on whether there is a sufficient net benefit as required by regulation 6(1)(*a*).

(6) The practitioner and the operator shall cooperate, regarding practical aspects, with other specialists and staff involved in a medical exposure, as appropriate.

(7) For the avoidance of doubt, where a person acts as employer, referrer, practitioner and operator concurrently (or in any combination of these roles) he shall comply with all the duties placed on employers, referrers, practitioners or operators under these Regulations accordingly.

Justification of Individual Medical Exposures

6.—(1) No person shall carry out a medical exposure unless—

(a) it has been justified by the practitioner as showing a sufficient net benefit giving appropriate weight to the matters set out in paragraph (2); and

(b) it has been authorised by the practitioner or, where paragraph (5) applies, the operator; and

(c) in the case of a medical or biomedical exposure as referred to in regulation 3(*d*), it has been approved by a Local Research Ethics Committee; and

(d) in the case of an exposure falling within regulation 3(*e*), it complies with the employer's procedures for such exposures; and

(e) in the case of a female of childbearing age, he has enquired whether she is pregnant or breastfeeding, if relevant.

(2) The matters referred to in paragraph (1)(*a*) are—

(a) the specific objectives of the exposure and the characteristics of the individual involved;

(b) the total potential diagnostic or therapeutic benefits, including the direct health benefits to the individual and the benefits to society, of the exposure;

(c) the individual detriment that the exposure may cause; and

(d) the efficacy, benefits and risk of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.

(3) In considering the weight to be given to the matters referred to in paragraph (2), the practitioner justifying an exposure pursuant to paragraph (1)(*a*) shall pay special attention to—

(a) exposures on medico-legal grounds;

(b) exposures that have no direct health benefit for the individuals undergoing the exposure; and

(c) the urgency of the exposure, where appropriate, in cases involving—

(i) a female where pregnancy cannot be excluded, in particular if abdominal and pelvic regions are involved, taking into account the exposure of both the expectant mother and the unborn child; and

(ii) a female who is breastfeeding and who undergoes a nuclear medicine exposure, taking into account the exposure of both the female and the child.

(4) In deciding whether to justify an exposure under paragraph (1)(*a*) the practitioner shall take account of any data supplied by the referrer pursuant to regulation 5(5) and shall consider such data in order to avoid unnecessary exposure.

(5) Where it is not practicable for the practitioner to authorise an exposure as required by paragraph (1)(*b*), the operator shall do so in accordance with guidelines issued by the practitioner.

Optimisation

7.—(1) In relation to all medical exposures to which these Regulations apply except radiotherapeutic procedures the practitioner and the operator, to the extent of their respective