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

involvement in a medical exposure, shall ensure that doses arising from the exposure are kept as low as reasonably practicable consistent with the intended purpose.

(2) In relation to all medical exposures for radiotherapeutic purposes the practitioner shall ensure that exposures of target volumes are individually planned, taking into account that doses of non-target volumes and tissues shall 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 shall select equipment and methods to ensure that for each medical 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 shall pay special attention to—

(a) quality assurance;

(b) assessment of patient dose or administered activity; and

(c) adherence to diagnostic reference levels for radiodiagnostic examinations falling within regulation 3(*a*), (*b*), (*c*) and (*e*)

as set out in the employer's procedures.

(4) For each medical or biomedical research programme falling within regulation 3(*d*), the employer's procedurers shall 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 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 patients undergoing treatment or diagnosis with radioactive medicinal products, the employer's procedures shall provide that, where appropriate, written instructions and information are provided to—

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

(b) where the patient is a child who lacks capacity so to consent, the person with parental responsibility for the child; or

(c) where the patient is an adult who lacks capacity so to consent, the person who appears to the practitioner to be the most appropriate person.

(6) The instructions and information referred to in paragraph (5) shall—

(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 on paragraph (5) as appropriate prior to the patient leaving the hospital or other place where the medical exposure was carried out.

(7) In complying with the obligations under this regulation, the practitioner and the operator shall pay special attention to—

(a) the need to keep doses arising from medico-legal exposures as low as reasonably practicable;

(b) medical exposures of children;

(c) medical exposures as part of a health screening programme;

(d) medical exposures involving high doses to the patient;

(e) where appropriate, females 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 expectant mother and the unborn child; and

(f) where appropriate, females who are breastfeeding and who are undergoing exposures in nuclear medicine, taking into account the exposure of both the female and the child.

(8) The employer shall take steps to ensure that a clinical evaluation of the outcome of each medical exposure is recorded in accordance with the employer's procedures or, where the employer is concurrently practitioner or operator, shall so record a clinical evaluation, including where appropriate, factors relevant to patient dose.

(9) In the case of fluoroscopy—

(a) the operator shall ensure that examinations without devices to control the dose rate are limited to justified circumstances; and

(b) no person shall carry out an examination without an image intensification or equivalent technique.

Clinical audit

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

Expert advice

9.—(1) The employer shall ensure that a medical physics expert shall be involved in every medical exposure to which these Regulations apply in accordance with paragraph (2).

(2) A medical physics expert shall be—

(a) closely involved in every radiotherapeutic practice other than standardised therapeutic nuclear medicine practices;

(b) available in standardised therapeutic nuclear medicine practices and in diagnostic nuclear medicine practices;

(c) involved as appropriate for consultation on optimisation, including patient dosimetry and quality assurance, and to give advice on matters relating to radiation protection concerning medical exposure, as required, in all other radiological practices.

Equipment

10.—(1) The employer shall draw up, keep up-to-date and preserve at each radiological installation an inventory of equipment at that installation and, when so requested, shall furnish it to the Department.

(2) The inventory referred to in paragraph (1) shall contain the following information—

(a) name of manufacturer;

(b) model number;

(c) serial number or other unique identifier;

(d) year of manufacture, and

(e) year of installation.

(3) The employer shall ensure that equipment at each radiological installation is limited to the amount necessary for the proper carrying out of medical exposures at that installation.

Training

11.—(1) Subject to the following provisions of this regulation, no practitioner or operator shall carry out a medical exposure or any practical aspect without having been adequately trained.

(2) A certificate issued by an institute or person competent to award degrees or diplomas or to provide other evidence of training shall, if such certificate so attests, be sufficient proof that the person to whom it has been issued has been adequately trained.

(3) Nothing in paragraph (1) above shall prevent a person from participating in practical aspects of the procedure as part of practical training if this is done under the supervision of a person who himself is adequately trained.

(4) Every employer shall keep and have available for inspection by the Department an up-to-date record of all practitioners and operators engaged by him to carry out medical exposures or any practical aspect of such exposures showing the date or dates on which training qualifying as adequate training was completed by such practitioner or operator and the nature of the training.

(5) Where the employer enters a contract with another to engage a practitioner or operator otherwise employed by that other, the latter shall be responsible for keeping the records required by paragraph (4) and shall supply such records to the employer forthwith upon request.

Enforcement

12.—(1) The provisions of these Regulations shall be enforced as if they were health and safety regulations made under Article 17 of the Health and Safety at Work (Northern Ireland) Order 1978(**7**) and, except as provided in paragraph (2), the provisions of that Order, as regards enforcement and offences, shall apply for the purposes of these Regulations.

(2) The enforcing authority for the purposes of these Regulations shall be the Department.

Defence of due diligence

13. In any proceedings against any person for an offence consisting of the contravention of these Regulations it shall be a defence for that person to show that he took all reasonable steps and exercised all due diligence to avoid committing the offence.

Revocation

14. The Ionising Radiation (Protection of Patients) Regulations (Northern Ireland) 1988(**8**) are hereby revoked.

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 24th May 2000.

L.S.

Paul Simpson
Senior Officer of the
Department of Health, Social Services and
Public Safety

(**7**) S.I. 1978/1039 (N.I. 9) as amended by S.I. 1998/2795 (N.I. 18)
(**8**) S.R. 1988 No. 263

SCHEDULE 1 Regulation 4(1)

Employer's Procedures

The written procedures for medical exposures shall include:—

(a) procedures to identify correctly individuals to be exposed to ionising radiation;

(b) procedures to identify individuals entitled to act as referrer or practitioner or operator;

(c) procedures to be observed in the case of medico-legal exposures;

(d) procedures for making enquiries of females of childbearing age to establish whether the individual is or may be pregnant or breastfeeding;

(e) procedures to ensure that quality assurance programmes are followed;

(f) procedures for the assessment of patient dose and administered activity;

(g) procedures for the use of diagnostic reference levels established by the employer for radiodiagnostic examinations falling within regulation 3(*a*),(*b*),(*c*) and (*e*), specifying that these are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied;

(h) procedures for determining whether the practitioner or operator is required to effect one or more of the matters set out in regulation 7(4) including criteria on how to effect those matters and in particular procedures for the use of dose constraints established by the employer for biomedical and medical research programmes falling within regulation 3(d) where no direct medical benefit for the individual is expected from the exposure;

(i) procedures for the giving of information and written instructions as referred to in regulation 7(5);

(j) procedures for the carrying out and recording of an evaluation for each medical exposure including, where appropriate, factors relevant to patient dose;

(k) procedures to ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced so far as reasonably practicable.

SCHEDULE 2 Regulation 2(1)

Adequate training

Practitioners and operators shall have successfully completed training, including theoretical knowledge and practical experience, in

(1) such of the subjects detailed in section A as are relevant to their functions as practitioner or operator; and

(2) such of the subjects detailed in section B as are relevant to their specific area of practice.

A. **Radiation production, radiation protection and statutory obligations relating to ionising radiations**

1. **Fundamental Physics of Radiation**

1.1 **Properties of radiation**

Attenuation of ionising radiation

Scattering and absorption

1.2 **Radiation hazards and dosimetry**

Biological effects of radiation

Risks/benefits of radiation

Dose optimisation

Absorbed dose, dose equivalent, effective dose and their units

1.3 **Special attention areas**

Pregnancy and potential pregnancy

Infants and children

Medical and biomedical research

Health screening

High dose techniques

2. **Management and Radiation Protection of the Patient**

2.1 **Patient selection**

Justification of the individual exposure

Patient identification and consent

Use of existing appropriate radiological information

Alternative techniques

Clinical evaluation of outcome

Medico-legal issues

2.2 **Radiation protection**

General radiation protection

Use of radiation protection devices

— patient

— personal

Procedures for untoward incidents involving overexposure to ionising radiation

3. **Statutory Requirements and Advisory Aspects**

3.1 **Statutory requirements and non-statutory recommendations**

Regulations

Local rules and procedures

Individual responsibilities relating to medical exposures

Responsibility for radiation safety

Routine inspection and testing of equipment

Notification of faults and DH hazard warnings

Clinical Audit

B. **Diagnostic Radiology, Radiotherapy and Nuclear Medicine**

4. **Diagnostic Radiology**

4.1. **General**

Fundamentals of radiological anatomy

Fundamentals of radiological techniques

Production of X-rays

Equipment selection and use

Factors affecting radiation dose
Dosimetry
Quality assurance and quality control

4.2. **Specialised techniques**
Image intensification/fluoroscopy
Digital fluoroscopy
Computerised Tomography scanning
Interventional procedures
Vascular imaging

4.3. **Fundamentals of Image Acquisition etc**
Image quality v. radiation dose
Conventional film processing
Additional image formats, acquisition, storage and display

4.4. **Contrast Media**
Non-ionic and ionic
Use and preparation
Contra-indications to the use of contrast media
Use of automatic injection devices

5. **Radiotherapy**

5.1. **General**
Production of ionising radiation
Use of radiotherapy —
benign disease
malignant disease
external beam
brachytherapy

5.2. **Radiobiological Aspects for Radiotherapy**
Fractionation
Dose rate
Radiosensitisation
Target volumes

5.3. **Practical aspects for radiotherapy**
Equipment
Treatment planning

5.4. **Radiation Protection Specific to Radiotherapy**
Side effects — early and late
Toxicity
Assessment of efficacy

6. **Nuclear Medicine**

6.1. **General**

Atomic structure and radioactivity

Radioactive decay

The tracer principle

Fundamentals of diagnostic use

Fundamentals of therapeutic use

dose rate

fractionation

radiobiology aspects

6.2. **Principles of Radiation Detection, Instrumentation and Equipment**

Types of systems

Image acquisition, storage and display

Quality assurance and quality control

6.3. **Radiopharmaceuticals**

Calibration

Working practices in the radiopharmacy

Preparation of individual doses

Documentation

6.4. **Radiation Protection Specific to Nuclear Medicine**

Conception, pregnancy and breastfeeding

Arrangements for radioactive patients

Disposal procedures for radioactive waste

EXPLANATORY NOTE

(This note is not part of the Regulations.)

These Regulations partially implement, as respects Northern Ireland, Council Directive 97/43/ Euratom (O.J. No. L180. 9.797. p. 22) laying down basic measures for the health protection of individuals against dangers of ionising radiation in relation to medical exposure. The Regulations impose duties on those responsible for administering ionising radiation to protect persons undergoing medical exposure whether as part of their own medical diagnosis or treatment or as part of occupational health surveillance, health screening, voluntary participation in research or medico-legal procedures.

Regulation 2 is an interpretation provision. Amongst other definitions, there is a definition of adequate training, a concept which is defined with reference to the matters set out in Schedule 2 to the Regulations, and a definition of employer which goes beyond the term as conventionally understood and includes the self-employed, partners in a partnership and contractual relationships.

Regulation 3 sets out the medical exposures to which the Regulations apply.

Regulation 4 requires the employer to provide a framework of procedures for medical exposures. A sole practitioner is required to establish and follow his own procedures. The employer's procedures must cover the matters set out in Schedule 1 as a minimum. Regulation 4 also requires the employer to establish written protocols for standard radiological practices, recommendations concerning referral criteria, quality assurance programmes for standard operating procedures, diagnostic reference levels, and dose constraints and to carry out investigations of incidents and appropriate reviews. Other regulations require the employer to take steps to ensure that a clinical evaluation is recorded of each medical exposure (regulation 7); to ensure that clinical audit is carried out (regulation 8) and that a medical physics expert is involved in every medical exposure as appropriate (regulation 9); to keep an inventory of equipment and to ensure that equipment is limited to a necessary amount (regulation 10).

Regulation 5 sets out the respective responsibilities of practitioners, operators and referrers and makes clear that where the employer also acts in one or more of these roles concurrently he is responsible accordingly. Practitioners and operators are required to follow the framework of procedures provided by the employer and be adequately trained. The practitioner is responsible for the justification of a medical exposure and for authorisation save where this is carried out by the operator. The operator is responsible for each practical aspect he carries out as well as any authorisation given by him. The referrer must provide medical data as required by the practitioner.

Regulation 6 prohibits any medical exposure from being carried out which has not been justified and authorised and sets out matters to be taken into account for justification.

Regulation 7 provides for the optimisation process, which involves ensuring that doses arising from exposures are kept as low as reasonably practicable. The practitioner and the operator are responsible for elements of the optimisation of medical exposures as specified in regulation 7. Regulations 6 and 7 provide that special attention be given to exposures in medico-legal procedures, health screening or voluntary participation in research, where no direct medical benefit is expected from the exposure or where the exposure involves high doses, pregnant or potentially pregnant or breastfeeding females and children. Regulation 7 also provides that certain information and instructions be given where radioactive medicinal products are administered.

Regulation 8 provides for clinical audit to be carried out and regulation 9 for medical physics experts to be consulted where appropriate. Regulation 10 requires the employer to maintain an inventory of equipment and to ensure that the amount of equipment is limited to what is necessary.

Regulation 11 prohibits a practitioner or operator from carrying out a medical exposure without having been adequately trained and requires the employer to keep a record of training qualifications of all practitioners and operators engaged by him. In addition, the employer is under an obligation to take steps to ensure compliance with the training requirements including continuing education after qualification (regulation 4). Again, sole practitioners and partners must keep records about their own training and comply with the requirements themselves. Proof of adequate training is provided by way of a certificate or other evidence attesting to a person's training.

Regulation 12 provides that the regulations are made enforceable as health and safety regulations under the Health and Safety at Work etc. Act 1974, except that the enforcing authority is the Department.

Regulation 13 provides that it is a defence to proceedings for an offence under the regulations that all reasonable steps were taken and due diligence exercised.

Regulation 14 revokes the Ionising Radiation (Protection of Patients) Regulations (Northern Ireland) 1988 (S.R. 1988 No. 263).