STATUTORY INSTRUMENTS.

S.I. No. 256 of 2018

EUROPEAN UNION (BASIC SAFETY STANDARDS FOR PROTECTION AGAINST DANGERS ARISING FROM MEDICAL EXPOSURE TO IONISING RADIATION) REGULATIONS 2018

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I, SIMON HARRIS, Minister for Health, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving effect to Council Directive 2013/59/EURATOM of 5 December 2013[1], as affected by Corrigendum to Council Directive 2013/59/EURATOM[2], insofar as it relates to medical exposures, hereby make the following regulations:

PART 1

PRELIMINARY

Citation

1. These Regulations may be cited as the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018.

Interpretation

2. (1) In these Regulations—

"Authority" means the Health Information and Quality Authority;

"clinical responsibility" means responsibility of a practitioner for individual medical exposures, in particular, justification; optimisation; clinical evaluation of the outcome; cooperation with other specialists and staff, as appropriate, regarding practical aspects of medical radiological procedures; obtaining information, if appropriate, on previous examinations; providing existing medical radiological information or records to other practitioners or the referrer, as required; and giving information on the risk of ionising radiation to patients and other individuals involved, as appropriate;

"compliance notice" means a notice served pursuant to Regulation 26;

"Directive" means Council Directive 2013/59/EURATOM of 5 December 2013[1] as affected by Corrigendum to Council Directive 2013/59/EURATOM[2];

"ethics committee" means an ethics committee established or recognised under the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (S.I. No. 190 of 2004) for the purposes of Regulation 8(2);

[1]OJ No. L 13, 17.1.2014, p. 1.
[2]OJ No. L 72, 17.3.2016, p. 69.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 15*th January*, 2019.

"medical exposure" means exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health, as well as exposure incurred by carers and comforters and by volunteers in medical or biomedical research;

"medical physics expert" means an individual having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure, whose competence in this respect is recognised by the Minister pursuant to Regulation 19(2);

"Minister" means the Minister for Health;

"new type of practice" means a practice of a class or type which was not carried out in the State before the coming into operation of these Regulations;

"practical aspects of medical radiological procedures" 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, and image processing;

"practitioner" means a person, being a member of one of the classes of persons referred to in Regulation 5, who has clinical responsibility for an individual medical exposure;

"prohibition order" means an order served pursuant to Regulation 27;

"radiation protection adviser" means an individual or a body, having the knowledge, training and experience needed to give radiation protection advice in order to ensure the effective protection of individuals, which meets such criteria of competence as may from time to time be specified in writing by the Environmental Protection Agency;

"Register of Medical Physics Experts" means the register established and maintained by the Minister pursuant to Regulation 19(1)(*b*);

"referrer" means a person, being a member of one of the classes of persons referred to in Regulation 4(1), who is entitled to refer an individual for medical radiological procedures to a practitioner;

"undertaking" means a person or body who, in the course of a trade, business or other undertaking (other than as an employee), carries out, or engages others to carry out, a medical radiological procedure or the practical aspects of a medical radiological procedure.

(2) A word or expression which is used in these Regulations and which is also used in the Directive has, unless the context otherwise requires, the same meaning in these Regulations as it has in the Directive.

Responsibility for functions under Directive

3. (1) The Authority is designated as the competent authority in the State for the purposes of Articles 55, 60, 63, 76, 77, 96, 104 and 105 of the Directive, insofar as those Articles relate to medical exposures.

(2) The Minister is designated as the competent authority in the State for the purpose of recognition of competence of medical physics experts under Article 79(1)(*d*) of the Directive.

(3) In exercising their powers and carrying out their functions under these Regulations and the Directive, the Authority and the Minister—

(*a*) shall comply with the transparency requirements of Article 77 of the Directive, and

(*b*) may obtain advice from appropriate third parties and may pay such parties for such advice.

(4) The Authority shall co-operate with the Environmental Protection Agency in the carrying out of the Agency's functions under the Directive, in particular in relation to the withdrawal of authorisation, registration or licences as appropriate, and may share data with the Agency for that purpose.

PART 2

REQUIREMENTS IN RELATION TO MEDICAL EXPOSURES

Referrers

4. (1) A person shall not refer an individual for medical radiological procedures to a practitioner unless the person referring ("the referrer") is—

(*a*) a registered nurse or registered midwife within the meaning of the Nurses and Midwives Act 2011 (No. 41 of 2011) who meets the standards and requirements set down from time to time by the Nursing and Midwifery Board of Ireland in relation to the prescribing of medical ionising radiation by nurses or midwives,

(*b*) a registered dentist within the meaning of the Dentists Act 1985 (No. 9 of 1985),

(*c*) a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007),

(*d*) a person whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005 (No. 27 of 2005), or

(*e*) a health care professional registered with the General Medical Council of the United Kingdom, and practising medicine in Northern Ireland,

who is entitled in accordance with his or her employer's procedures to refer individuals for exposure to a practitioner.

(2) A person shall not carry out a medical radiological procedure on the basis of a referral from a person other than a referrer.

Practitioners

5. A person shall not take clinical responsibility for an individual medical exposure unless the person taking such responsibility ("the practitioner") is—

(*a*) a registered dentist within the meaning of the Dentists Act 1985 (No. 9 of 1985),

(*b*) a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007), or

(*c*) a person whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005 (No. 27 of 2005).

Undertaking

6. (1) Subject to paragraph (2), an undertaking shall notify the Authority, no later than one month before commencing practices, of the proposed commencement, in such form and manner as may be prescribed by the Authority from time to time.

(2) An undertaking which, on the commencement of these Regulations, is carrying out practices shall notify the Authority, no later than 3 months after the commencement of these Regulations, of such activity, in such form and manner as may be prescribed by the Authority, and may continue such activity pending said notification.

(3) An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.

(4) An undertaking is responsible for the failure of any person employed or engaged by it to comply with a requirement of these Regulations.

Justification of practices

7. (1) The Authority shall justify new types of practices involving medical exposure in advance before being generally adopted.

(2) A person shall not carry out a new type of practice involving medical exposure unless such new type of practice has been justified in advance by the Authority pursuant to paragraph (1).

(3) The Authority shall consider a review of any existing class or type of practice if one of the conditions set out in paragraph (4) is satisfied and make a new justification decision in respect of that class or type of practice.

(4) The conditions referred to in paragraph (3) are that—

(*a*) new and important evidence about the efficacy or potential consequences of the class or type of practice is acquired, or

(*b*) new and important information about other techniques and technologies is acquired.

(5) A person shall not carry out a class or type of practice which has been reviewed by the Authority under paragraph (3) and found not to be justified.

(6) Justification under this Regulation shall take into account medical and, where relevant, associated occupational and public exposures.

Justification of medical exposures

8. (1) A person shall not carry out a medical exposure unless it—

(*a*) shows a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct benefits to health of an individual and the benefits to society, against the individual detriment that the exposure might cause, and

(*b*) takes into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.

(2) An undertaking shall ensure that each medical or biomedical research project involving medical exposure for which it is responsible has been examined and approved by an ethics committee prior to the commencement of such project.

(3) The Authority shall, after consultation with the relevant professional body or bodies, carry out specific justification for medical radiological procedures to be performed as part of a health screening programme prior to the commencement of such programme.

(4) An undertaking shall ensure that medical radiological procedures to be performed as part of a health screening programme are not carried out unless the specific justification under paragraph (3) has been issued by the Authority for the particular medical radiological procedure.

(5) An undertaking shall ensure that, in the case of a medical radiological procedure on an asymptomatic individual, performed for the early detection of disease—

(*a*) the procedure is part of a health screening programme, or requires specific documented justification for that individual by the practitioner, in consultation with the referrer, following guidelines published by the Authority in accordance with paragraph (6), and

(*b*) special attention is given to the provision of information to the individual, as required by paragraph (13).

(6) The Authority shall, after consultation with the relevant professional body or bodies, publish guidelines on the specific justification of medical radiological procedure on an asymptomatic individual, performed for the early detection of disease but not as part of a health screening programme.

(7) The relevant professional body or bodies to be consulted, under paragraphs (3) and (6) shall be determined by the Authority.

(8) An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved.

(9) Where a type of practice involving medical exposure is not justified in general, an undertaking shall ensure that a specific individual exposure of this type is justified, where appropriate, in special circumstances, to be evaluated by the practitioner on a case-by-case basis and documented.

(10) A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral—

(*a*) is in writing,

(*b*) states the reason for requesting the particular procedure, and

(*c*) is accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment in accordance with paragraph (1).

(11) A practitioner carrying out a medical radiological procedure on foot of a referral shall, having taken into account any medical data provided by the referrer under paragraph (10)(*c*), satisfy himself or herself that the procedure as prescribed in the referral is justified.

(12) The referrer and the practitioner shall seek, where practicable, to obtain previous diagnostic information or medical records relevant to a planned exposure and consider these data to avoid unnecessary exposure.

(13) Wherever practicable and prior to a medical exposure taking place, the referrer or the practitioner shall ensure that—

(*a*) the patient or his or her representative,

(*b*) in the case of a patient who is under sixteen years of age, a parent or legal guardian of the patient, or

(*c*) in the case of a patient who lacks, or may lack, capacity under the Assisted Decision-Making (Capacity) Act 2015 (No. 64 of 2015), the intervener in respect of the patient,

is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure.

(14) An undertaking shall ensure that, in circumstances where there is to be an exposure to a carer or comforter, such exposure shows a sufficient net benefit taking into account—

(*a*) the direct health benefits to the patient,

(*b*) the possible benefits to the carer or comforter, and

(*c*) the detriment that the exposure might cause.

(15) An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical exposure, and shall provide such records to the Authority on request.

Optimisation

9. (1) An undertaking shall ensure that all doses due to medical exposure for radiodiagnostic, interventional radiology, planning, guiding and verification purposes are kept as low as reasonably achievable consistent with obtaining the required medical information, taking into account economic and societal factors.

(2) For all medical exposure of patients for radiotherapeutic purposes, an undertaking shall ensure that the exposures of target volumes are individually planned, their delivery appropriately verified taking into account that doses to non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.

(3) An undertaking shall ensure that for each medical or biomedical research project involving medical exposure—

(*a*) the individuals concerned participate voluntarily in the research project and are informed in advance about the risks of exposure, and

(*b*) in the case of patients who voluntarily accept to undergo an experimental medical practice and who are expected to receive a diagnostic or therapeutic benefit from this practice, individual dose levels are considered by the practitioner or the referrer, or both, prior to the exposure taking place.

(4) An undertaking shall ensure that optimisation under this Regulation includes the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical radiological procedures, quality assurance, and the assessment and evaluation of patient doses or the verification of administered activities taking into account economic and societal factors.

(5) An undertaking shall establish appropriate guidance for the exposure of carers and comforters.

(6) An undertaking shall ensure that, wherever practicable and prior to the exposure taking place, the practitioner or the referrer provides the carers and comforters with—

(*a*) adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure, and

(*b*) the guidance established under paragraph (5).

(7) In the case of a patient undergoing treatment or diagnosis with radionuclides, the practitioner or the undertaking shall provide—

(*a*) the patient or his or her representative,

(*b*) in the case of a patient who is under sixteen years of age, a parent or legal guardian of the patient, or

(*c*) in the case of a patient who lacks, or may lack, capacity under the Assisted Decision-Making (Capacity) Act 2015 (No. 64 of 2015), the intervener in respect of the patient,

with the information referred to in paragraph (8), before he or she leaves the hospital or other place where the exposure was carried out.

(8) The information to be provided under paragraph (7) is the following:

(*a*) information on the risks of ionising radiation; and

(*b*) appropriate written instructions with a view to restricting doses to persons in contact with the patient as far as reasonably achievable.

Responsibilities

10. (1) An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.

(2) An undertaking shall ensure that the optimisation process for all medical exposures involves—

(*a*) the practitioner,

(*b*) the medical physics expert, and

(*c*) those entitled to carry out practical aspects of medical radiological procedures as specified by the undertaking or practitioner under paragraph (4).

(3) An undertaking shall ensure that the justification process of individual medical exposures involves—

(*a*) the practitioner, and

(*b*) the referrer.

(4) Practical aspects of a medical radiological procedure may be delegated by—

(*a*) the undertaking, or

(*b*) the practitioner,

as appropriate, to one or more individuals, who are registered or recognised by—

(i) the Dental Council,

(ii) the Minister,

(iii) the Nursing and Midwifery Board of Ireland,

(iv) the Radiographers Registration Board, or

(v) the Medical Council,

as appropriate, and have completed a course in radiation safety as prescribed pursuant to Regulation 22(3) by the appropriate body.

(5) An undertaking shall retain a record of each delegation pursuant to paragraph (4) for a period of five years from the date of the delegation, and shall provide such records to the Authority on request.

(6) An undertaking or practitioner shall not delegate practical aspects of a medical radiological procedure to a person other than an individual referred to in paragraph (4).

(7) A person shall not carry out practical aspects of a medical radiological procedure unless he or she is a practitioner or a person delegated pursuant to paragraph (4).

Diagnostic reference levels

11. (1) The Authority shall, after consultation with the relevant professional body or bodies, establish national diagnostic reference levels for radiodiagnostic examinations, having regard to the recommended European diagnostic reference levels where available, and where appropriate for interventional radiology procedures.

(2) The Authority shall regularly review the national diagnostic reference levels established under paragraph (1), in consultation with the relevant professional body or bodies.

(3) The Authority shall publish—

(*a*) the national diagnostic reference levels established under paragraph (1),

(*b*) the details of the reviews of such levels under paragraph (2), and

(*c*) guidance in relation to the establishment, review and use of diagnostic reference levels,

on its website.

(4) The relevant professional body or bodies to be consulted under paragraphs (1) and (2) shall be determined by the Authority.

(5) An undertaking shall ensure that diagnostic reference levels for radiodiagnostic examinations, and where appropriate for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels established under paragraph (1) where available.

(6) An undertaking shall ensure that appropriate reviews are carried out to determine whether the optimisation of protection and safety for patients is adequate, where for a given examination or procedure typical doses or activities consistently exceed the relevant diagnostic reference level, and shall ensure that appropriate corrective action is taken without undue delay.

(7) An undertaking shall retain a record of reviews and corrective actions carried out under paragraph (6) for a period of five years from the date of the review, and shall provide such records to the Authority on request.

(8) An undertaking shall make available to the persons listed in Regulation 10(2) the guidance published by the Authority pursuant to paragraph (3)(*c*).

Dose constraints for medical exposures

12. (1) The Authority shall, where appropriate and after consultation with the relevant professional body or bodies, establish dose constraints for medical exposure of—

(*a*) carers and comforters, and

(*b*) individuals participating in medical or biomedical research involving medical exposure, where no direct medical benefit is expected from exposure,

for the purpose of prospective optimisation of protection, and shall publish same on its website.

(2) The relevant professional body or bodies to be consulted under paragraph (1) shall be determined by the Authority.

(3) Dose constraints shall be established under paragraph (1) in terms of individual effective or equivalent doses over a defined appropriate time period.

(4) An undertaking shall ensure that relevant dose constraints established under paragraph (1) are used in the optimisation of protection and safety in any radiological procedure in which an individual acts as a carer or comforter.

(5) An undertaking shall ensure that relevant dose constraints established under paragraph (1), as specified or approved by an ethics committee on a case by case basis as part of a proposal for medical or biomedical research, are used in the optimisation of protection and safety for persons subject to medical exposure as part of medical or biomedical research.

Procedures

13. (1) An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.

(2) An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.

(3) An undertaking shall ensure that referral guidelines for medical imaging, taking into account the radiation doses, are available to referrers.

(4) An undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Minister.

Equipment

14. (1) An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.

(2) An undertaking shall implement and maintain—

(*a*) appropriate quality assurance programmes, and

(*b*) appropriate programmes of assessment of dose or verification of administered activity.

(3) An undertaking shall carry out the following testing on its medical radiological equipment:

(*a*) acceptance testing before the first use of the equipment for clinical purposes; and

(*b*) performance testing on a regular basis and after any maintenance procedure liable to affect the equipment's performance.

(4) A person shall not use medical radiological equipment for clinical purposes unless testing in accordance with paragraph (3)(*a*) has been carried out.

(5) The Authority shall—

(*a*) take steps to ensure that the necessary measures are taken by an undertaking to improve inadequate or defective performance of medical radiological equipment in use, and

(*b*) adopt specific criteria for the acceptability of equipment in order to indicate when appropriate corrective action is necessary, including taking the equipment out of service.

(6) An undertaking shall—

(*a*) take any measures directed by the Authority under paragraph (5)(*a*), and

(*b*) comply with any criteria adopted by the Authority under paragraph (5)(*b*).

(7) A person shall not use fluoroscopy equipment without a device to automatically control the dose rate, or without an image intensifier or equivalent device.

(8) Subject to paragraph (9), an undertaking shall ensure that—

(*a*) equipment used for external beam radiotherapy with a nominal beam energy exceeding 1 MeV has a device to verify key treatment parameters,

(*b*) any equipment used for interventional radiology has a device or a feature informing the practitioner, and those carrying out practical aspects of the medical procedures, of quantity of radiation produced by the equipment during the procedure,

(*c*) any equipment used for interventional radiology and computed tomography has a device or a feature informing the practitioner, at the end of the procedure, of relevant parameters for assessing the patient dose,

(*d*) any equipment used for planning, guiding and verification purposes has a device or a feature informing the practitioner, at the end of the procedure, of relevant parameters for assessing the patient dose,

(*e*) equipment used for interventional radiology and computed tomography has the capacity to transfer the information required under subparagraph (*c*) to the record of the examination, and

(*f*) without prejudice to subparagraphs (*b*) to (*e*), medical radiodiagnostic equipment producing ionising radiation has a device, or an equivalent means, informing the practitioner of relevant parameters for assessing the patient dose and, where appropriate, the capacity to transfer this information to the record of the examination.

(9) Paragraph (8)(*a*), (*b*), (*d*), (*e*) and (*f*) shall not apply in the case of equipment installed prior to 6 February 2018.

(10) An undertaking shall provide to the Authority, on request, an up-to-date inventory of medical radiological equipment for each radiological installation,

in such form and manner as may be prescribed by the Authority from time to time.

(11) An undertaking shall retain records in relation to equipment, including records evidencing compliance with this Regulation, for a period of five years from their creation, and shall provide such records to the Authority on request.

Special practices

15. An undertaking shall ensure that in the case of medical exposure—

(*a*) of children,

(*b*) as part of a health screening programme, or

(*c*) involving high doses to the patient, which may be the case in interventional radiology, nuclear medicine, computed tomography or radiotherapy,

appropriate medical radiological equipment, practical techniques and ancillary equipment are used, and special attention is given to quality assurance programmes and the assessment of dose or verification of administered activity for these practices.

Special protection during pregnancy and breastfeeding

16. (1) An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall—

(*a*) inquire as to whether an individual subject to the medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned, and

(*b*) record the answer to any inquiry under subparagraph (*a*) in writing, retain such record for a period of five years and provide such records to the Authority on request.

(2) If pregnancy cannot be ruled out for an individual subject to medical exposure, and depending on the medical radiological procedure involved, in particular if abdominal and pelvic regions are involved, special attention shall be given to the justification, particularly the urgency, and to the optimisation, taking into account both the expectant individual and the unborn child.

(3) In the case of a breastfeeding individual, in nuclear medicine, depending on the medical radiological procedure, special attention shall be given to the justification, particularly the urgency, and to the optimisation, taking into account both the individual and the child.

(4) Without prejudice to paragraphs (1), (2) and (3), an undertaking shall take measures to increase the awareness of individuals to whom this Regulation applies, through measures such as public notices in appropriate places.

Accidental and unintended exposures and significant events

17. (1) An undertaking shall ensure that—

(*a*) all reasonable measures are taken to minimise the probability and magnitude of accidental or unintended exposures of individuals subject to medical exposure,

(*b*) for radiotherapeutic practices, the quality assurance programme includes a study of the risk of accidental or unintended exposures,

(*c*) for all medical exposures, an appropriate system is implemented for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice,

(*d*) arrangements are made to inform the referrer and the practitioner, and the patient, or their representative, about clinically significant unintended or accidental exposures and the results of the analysis,

(*e*) the Authority is notified, promptly and as soon as possible, of the occurrence of any significant event, as defined by the Authority in guidelines issued for that purpose, and

(*f*) the results of the investigation into any significant event notified under subparagraph (*e*) and the corrective measures to avoid such events, are reported to the Authority within the time period specified for such events by the Authority in guidelines issued by it for that purpose.

(2) The Authority shall ensure that mechanisms are in place for the timely dissemination of information, relevant to radiation protection in medical exposure, regarding lessons learned from significant events.

Estimates of population doses

18. (1) The Authority shall ensure that the distribution of individual dose estimates from medical exposure for radiodiagnostic and interventional radiology purposes is determined, taking into consideration where appropriate the distribution by age and gender of the exposed.

(2) An undertaking shall provide information, records and data on medical exposures, as specified by the Authority and at its request, to facilitate the estimation of population doses under paragraph (1).

PART 3

MEDICAL PHYSICS EXPERTS

Recognition of medical physics experts

19. (1) The Minister shall—

(*a*) establish requirements for the recognition of medical physics experts, and

(*b*) establish and maintain a register, to be known as the Register of Medical Physics Experts, which shall contain details of persons having the competencies, measured in terms of knowledge, training and expertise, to be recognised as medical physics experts in the State, for a specified period as may be determined by the Minister.

(2) The Minister may recognise a person as a medical physics expert to act or give advice on matters relating to radiation physics applied to medical exposure, whether in relation to practices generally or a particular type of practice, and the register referred to in paragraph (1)(*b*) shall be divided into parts corresponding to those types of practice and the name of each person recognised under paragraph (1)(*b*) shall be entered in the appropriate part of that register accordingly.

(3) The Minister may amend the particulars relating to the types of practice in respect of which a person is recognised under paragraph (2).

(4) For the purposes of paragraph (1)(*a*), the Minister may, after consultation with the Irish College of Physicists in Medicine and such other professional bodies as he or she considers appropriate, determine and publish educational, training, retraining or other requirements (whether relating to qualifications, types of practice, work activities or otherwise) to be met before he or she recognises a person under paragraph (2).

(5) Persons whose names are entered on the voluntary register of medical physics experts maintained by the Irish College of Physicists in Medicine, in the categories of diagnostic radiology and imaging physics and therapeutic applications of ionising radiation, shall be automatically registered in the Register of Medical Physics Experts on the establishment of such register under paragraph (1) and such temporary registration shall lapse on the earlier of—

(*a*) the expiration of the period of registration on such voluntary register, or

(*b*) the date when the person's name is entered on the register following a successful application for registration to the Minister pursuant to the requirements published under paragraph (1)(*a*).

(6) The Minister may remove the name of a person from the Register of Medical Physics Experts where he or she is of the view that such person no longer meets the requirements established under paragraph (1)(*a*).

(7) The Minister may attach conditions to the entry of the name of a person in the Register of Medical Physics Experts, as he or she considers appropriate.

(8) The Minister may charge fees in relation to the performance of his or her functions under this Regulation.

(9) An undertaking shall put in place the necessary arrangements to ensure the continuity of expertise of persons for whom it is responsible who have been recognised as a medical physics expert under this Regulation.

(10) The Minister and the Irish College of Physicists in Medicine may share data, including personal data, for the purposes of this Regulation.

(11) A person whose name the Minister—

(*a*) refuses to enter in,

(*b*) removes from, or

(*c*) attaches conditions to entry in

the Register of Medical Physics Experts may appeal the decision of the Minister to so refuse, remove or attach, to the High Court within 21 days of the making of the said decision of the Minister.

(12) On considering an appeal under paragraph (11), the High Court shall—

(*a*) confirm the decision of the Minister, or

(*b*) quash the decision of the Minister and substitute such other decision as it considers appropriate, which may be a decision—

(i) to enter or restore the name of the appellant in the Register of Medical Physics Experts with no conditions attached to such entry or restoration, or

(ii) to enter or restore the name of the appellant in the Register of Medical Physics Experts with such conditions attached to such entry or restoration as it considers appropriate.

Responsibilities of medical physics experts

20. (1) An undertaking shall ensure that a medical physics expert, registered in the Register of Medical Physics Experts, acts or gives specialist advice, as appropriate, on matters relating to radiation physics for implementing the requirements of Part 2, Part 4, Regulation 21 and point (*c*) of Article 22(4) of the Directive.

(2) An undertaking shall ensure that, depending on the medical radiological practice, the medical physics expert referred to in paragraph (1)—

(*a*) takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure,

(*b*) gives advice on medical radiological equipment, and

(*c*) contributes, in particular, to the following:

(i) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels;

(ii) the definition and performance of quality assurance of the medical radiological equipment;

(iii) acceptance testing of medical radiological equipment;

(iv) the preparation of technical specifications for medical radiological equipment and installation design;

(v) the surveillance of the medical radiological installations;

(vi) the analysis of events involving, or potentially involving, accidental or unintended medical exposures;

(vii) the selection of equipment required to perform radiation protection measurements; and

(viii) the training of practitioners and other staff in relevant aspects of radiation protection.

(3) The medical physics expert referred to in paragraph (1) shall, where appropriate, liaise with the radiation protection adviser.

Involvement of medical physics experts in medical radiological practices

21. (1) An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice.

(2) In carrying out its obligation under paragraph (1), an undertaking shall, in particular, ensure that—

(*a*) in radiotherapeutic practices other than standardised therapeutic nuclear medicine practices, a medical physics expert shall be closely involved,

(*b*) in standardised therapeutical nuclear medicine practices as well as in radiodiagnostic and interventional radiology practices, involving high doses as referred to in Regulation 15(*c*), a medical physics expert shall be involved, and

(*c*) for other medical radiological practices not covered by subparagraphs (*a*) and (*b*), a medical physics expert shall be involved, as appropriate, for consultation and advice on matters relating to radiation protection concerning medical exposure.

PART 4

EDUCATION, INFORMATION AND TRAINING

Education, information and training in field of medical exposure

22. (1) Subject to paragraph (2), an undertaking shall ensure that—

(*a*) practitioners, and

(*b*) individuals to whom the practical aspects of medical radiological procedures are delegated pursuant to Regulation 10(4)

have adequate education, information and theoretical and practical training for that purpose, as well as relevant competence in radiation protection, in accordance with the provisions of this Regulation.

(2) Nothing in paragraph (1) prevents a person from participating in practical aspects of a medical radiological procedure as part of a relevant training programme if such participation is supervised by a person who is adequately trained.

(3) The persons referred to in paragraph (1) must have successfully completed training, including theoretical knowledge and practical experience, in medical radiological practices and radiation protection, as prescribed by—

(*a*) the Dental Council,

(*b*) the Irish College of Physicists in Medicine,

(*c*) the Nursing and Midwifery Board of Ireland,

(*d*) the Radiographers Registration Board, or

(*e*) a training body approved by the Medical Council having the relevant expertise in medical ionising radiation to provide such course,

as appropriate, having regard to the European Commission's Guidelines on Radiation Protection Education and Training of Medical Professionals in the European Union (Radiation Protection No. 175).

(4) An undertaking shall ensure that the persons referred to in paragraph (1) undertake 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.

(5) An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the exposure, and shall provide such records to the Authority on request.

(6) Where an undertaking enters into a contract with another party to engage a practitioner or an individual referred to in paragraph (1)(*b*) employed by that other party, such other party is responsible for keeping the records required by paragraph (5) and must supply such records to the undertaking forthwith upon request.

PART 5

COMPLIANCE AND ENFORCEMENT

Interpretation of Part 5

23. In this Part—

"authorised person" means a person appointed under Regulation 24;

"dwelling" means a premises occupied by a person as his or her place of private residence (whether or not as his or her principal private residence);

"inspect" includes search;

"record" includes, in addition to a record in writing—

(*a*) a disc, tape, sound-track or other device in which information, sounds or signals are embodied so as to be capable, with or without the aid or some other instrument, of being reproduced in legible or audible form,

(*b*) a film, tape or other device in which visual images are embodied so as to be capable, with or without the aid or some other instrument, of being reproduced in visual form, and

(*c*) a photograph,

and any reference to a copy of a record includes—

(i) in the case of a record to which paragraph (*a*) of this definition applies, a transcript of the sounds or signals embodied therein,

(ii) in the case of a record to which paragraph (*b*) of this definition applies, a still reproduction of the images embodied therein, and

(iii) in the case of a record to which paragraphs (*a*) and (*b*) of this definition apply, such a transcript together with such a still reproduction;

"relevant thing" means any article, substance, equipment, device or object used in relation to medical exposures.

Authorised persons

24. (1) For the purposes of ensuring compliance with these Regulations, the Authority—

(*a*) may appoint such and so many persons as it thinks fit to be authorised persons for the purposes of these Regulations, and

(*b*) shall furnish each authorised person appointed by it with a certificate of appointment.

(2) An authorised person shall, when performing a function imposed under these Regulations on an authorised person, produce his or her certificate of appointment for inspection if requested to do so by a person affected by the performance of that function.

(3) For the purposes of ensuring compliance with these Regulations, an authorised person may—

(*a*) subject to paragraph (6), enter (if necessary by the use of reasonable force), at all reasonable times, any premises at which he or she has reasonable grounds for believing that—

(i) any trade, business or activity connected with a medical radiological procedure is or has been carried on, or

(ii) a relevant thing or any books, records or other documents (including documents stored in non-legible form) relating to such trade, business or activity are kept,

(*b*) at such premises inspect and take copies of any books, records, other documents (including documents stored in non-legible form), or extracts therefrom, which he or she finds in the course of his or her inspection,

(*c*) remove any such books, records or other documents from such premises and detain them for such period as he or she reasonably considers to be necessary for the purposes of his or her functions under these Regulations,

(*d*) carry out, or have carried out, such tests, examinations, analyses, inspections and checks of—

(i) the premises,

(ii) any relevant thing at the premises, or

(iii) any machinery or plant at the premises,

as he or she reasonably considers to be necessary for the purposes of his or her functions under these Regulations,

(*e*) require any person at the premises or the owner or person in charge of the premises and any person employed there to give to him or her such assistance and information and to produce to him or her such books, records or other documents (and in the case of documents or records stored in non-legible form, produce to him or her a legible reproduction thereof) that are in that person's power or procurement, as he or she may reasonably require for the purposes of his or her functions under these Regulations,

(*f*) direct that a relevant thing found at the premises that he or she, upon reasonable grounds, believes contravenes a provision of these Regulations not be used or distributed or moved from the premises without the consent of the authorised person,

(*g*) secure for later inspection any premises or part of any premises in which a relevant thing is found or ordinarily kept, or books, records or other documents are found or ordinarily kept, for such period as may reasonably be necessary for the purposes of his or her functions under these Regulations,

(*h*) without payment, take possession of and remove from the premises for any test, examination or analysis any relevant thing found there, and detain it for such period as he or she considers reasonably necessary for the purposes of his or her functions under these Regulations,

(*i*) without payment, take samples of any relevant thing, detained pursuant to subparagraph (*h*), for the purposes of any test, examination, or analysis,

(*j*) where the taking of samples of any relevant thing pursuant to subparagraph (i) is, for whatever reason, not practicable, purchase or take without payment the relevant thing concerned for the purposes of any test, examination or analysis,

(*k*) stop any person, vehicle, vessel or container at the premises,

(*l*) board and search any such vehicle, vessel or container,

(*m*) require the name and address of any person at the premises, including the person to whom a relevant thing is being delivered or who is causing it to be delivered,

(*n*) make a record whether in writing, by photography or otherwise,

(*o*) inspect and copy or extract information from any data within the meaning of the Data Protection Acts 1988 and 2003,

(*p*) require a person, having authority to do so, to break open any container, receptacle or package, or to permit him or her to do so, as he or she may reasonably require for the purposes of his or her functions under these Regulations,

(*q*) require a person, who makes available facilities such as post office boxes, telecommunications or electronic mail addresses or other like facilities, to give him or her such assistance and information as he or she may reasonably require for the purposes of his or her functions under these Regulations in any case where the authorised person has reasonable grounds for believing that any relevant thing is being supplied by mail,

(*r*) interview in private any person—

(i) working at premises referred to in subparagraph (*a*), or

(ii) who at any time was or is in receipt of a service at such premises and who consents to be interviewed, or

(*s*) if the authorised person, in respect of premises referred to in subparagraph (*a*), considers an explanation necessary and expedient for the purposes of monitoring compliance with these Regulations, require a person who is in charge of the premises or possesses or is in charge of any relevant documents or records to provide an explanation of any—

(i) document, record or relevant thing inspected, copied or provided in accordance with this Regulation,

(ii) other information provided to the authorised person in the course of the carrying out of his or her duties, or

(iii) other matters which are the subject of the functions being exercised by the authorised person under this Regulation.

(4) An authorised person may, for the purpose of obtaining any information which may be required in relation to a matter under investigation under these Regulations, at all reasonable times enter any premises, at which there are reasonable grounds to believe that any trade or business or any activity connected with a medical radiological procedure is, or has been, carried on, and may pay or make tender of payment, for any such procedure.

(5) When performing a function under these Regulations, an authorised person may, subject to any warrant under paragraph (7), be accompanied by such number of—

(*a*) other authorised persons,

(*b*) members of An Garda Síochána, or

(*c*) persons with expertise as he or she considers appropriate in the circumstances of the case.

(6) An authorised person shall not enter a dwelling, other than—

(*a*) with the consent of the occupier, or

(*b*) in accordance with a warrant issued under paragraph (7).

(7) Upon the application of an authorised person, a judge of the District Court, if satisfied that there are reasonable grounds for believing that—

(*a*) a relevant thing is to be found in any dwelling, or is being or has been subjected to any process or stored in any dwelling,

(*b*) a dwelling is occupied in whole or in part by an undertaking engaged in any trade, business or activity referred to in paragraph (3)(*a*)(i), or

(*c*) relevant things, books, records or other documents (including documents stored in non-legible form) referred to in paragraph (3)(*a*)(ii) are being stored or kept in any dwelling, any location, physical or virtual, connected to the dwelling or to persons occupying, associated with or using the dwelling,

may issue a warrant authorising a named authorised person accompanied by such other authorised persons, members of An Garda Síochána, or persons with expertise, as may be necessary, at any time or times, within one month of the date of issue of the warrant, to enter the dwelling and perform any of the functions of an authorised person under paragraph (3)(*b*) to (*s*).

(8) Where an authorised person, upon reasonable grounds, believes that a person has committed an offence under these Regulations, he or she may require that person to provide him or her with his or her name, date of birth, and the address at which he or she ordinarily resides, and to produce corroborative evidence of same.

(9) Where an authorised person has reasonable cause to suspect that—

(*a*) an offence is being or has been committed under these Regulations, or

(*b*) evidence of an offence or contravention may be, is or has been on or in any premises,

the authorised person may, in addition to the powers exercisable by him or her under paragraph (3)—

(i) search a person, where the authorised person considers it necessary,

(ii) seize and detain a vessel, vehicle, container, machinery or relevant thing, or

(iii) dispose of a relevant thing, or require the owner or person in charge of or in possession of a relevant thing to deal with or dispose of it (or any other thing used in connection with, or that may have been in contact with, the relevant thing) in a manner that the authorised person thinks fit.

(10) An authorised person may dispose of, or cause to be disposed, a relevant thing, or a sample of a relevant thing, taken under this Regulation, in such manner and at such place as the authorised person considers appropriate in the circumstances of the case.

(11) The costs (including ancillary costs) of any seizure, detention or disposal carried out by the Authority under paragraph (9) or (10) shall be recoverable

as a simple contract debt in any court of competent jurisdiction from the undertaking.

(12) Nothing in this Regulation shall be taken to compel the production by any person of a document which he or she would be exempt from producing in proceedings in a court on the ground of legal professional privilege.

(13) Where the Authority is satisfied that an authorised person has discharged his or her duties in relation to the enforcement of the provisions of these Regulations in a bona fide manner, the Authority shall indemnify the authorised person against all actions or claims howsoever arising in respect of the discharge by him or her of his or her duties.

(14) An authorised person shall be paid, out of moneys at the disposal of the Authority, such remuneration (if any) and such allowances for expenses as the Authority, with the consent of the Minister and the Minister for Public Expenditure and Reform, may from time to time determine.

Inspections

25. (1) The Authority shall establish—

(*a*) a system or systems of inspection to enforce the provisions of these Regulations and to initiate surveillance and corrective action where necessary, and

(*b*) an inspection programme taking into account the potential magnitude and nature of the hazard associated with practices, a general assessment of radiation protection issues in the practices, and the state of compliance with these Regulations.

(2) The Authority shall ensure that the findings from each inspection are recorded and communicated to the undertaking concerned.

(3) The Authority shall ensure that outlines of the inspection programmes and the main findings from their implementation are available to the public on its website.

(4) The Authority shall ensure that mechanisms are in place for the timely dissemination to relevant parties and, where appropriate, international organisations, of protection and safety information concerning significant lessons learned from inspections and from reported incidents and accidents and related findings.

Compliance notice

26. (1) Where an authorised person is of the opinion that there is non-compliance with a requirement of these Regulations, the authorised person may, following consultation with the Chief Executive Officer of the Authority or another officer of the Authority designated for that purpose, serve, or arrange to have served, on the undertaking or other person concerned a notice ("compliance notice") in accordance with paragraph (2).

(2) A compliance notice shall—

(*a*) be signed by the authorised person issuing it, or the officer consulted in accordance with paragraph (1),

(*b*) identify the requirement(*s*) of these Regulations with which there has not been compliance,

(*c*) for the purpose of ensuring compliance by the person concerned, require the person to do or refrain from doing such act or acts as is or are specified in the notice by such date as is so specified, and

(*d*) contain information regarding the bringing of an appeal under paragraph (5) against the notice, including the manner in which an appeal shall be brought.

(3) A compliance notice shall not specify a date in accordance with paragraph (2)(*c*) that falls on or before the date by which an appeal under paragraph (5) shall be brought.

(4) An authorised person may, following consultation with the Chief Executive Officer of the Authority or another officer of the Authority designated for that purpose—

(*a*) withdraw a compliance notice at any time, as he or she considers appropriate, or

(*b*) where no appeal is brought under this Regulation, specify a date extending the period specified in the notice for the purposes of paragraph (2)(*c*), and notify the person in writing accordingly.

(5) A person may appeal a compliance notice served on the person to the District Court not later than 14 days after the service of the compliance notice concerned.

(6) A person who appeals against a compliance notice shall at the same time notify the Authority of the appeal and the grounds for the appeal and the Authority shall be entitled to appear, be heard and adduce evidence at the hearing of the appeal.

(7) The District Court shall, upon an appeal under this Regulation, do one of the following:

(*a*) affirm the compliance notice concerned; or

(*b*) direct the authorised person to withdraw the compliance notice concerned.

(8) An authorised person shall comply with a direction under paragraph (7).

(9) A person who fails to comply with a compliance notice by the specified date is guilty of an offence.

(10) This Regulation shall not operate to prevent or restrict—

(*a*) the entitlement of any person to bring proceedings for the purpose of securing compliance with these Regulations by a person, or

(*b*) the bringing or prosecuting of any proceedings for an offence under these Regulations.

(11) In this Regulation "specified date" means, in relation to a compliance notice—

(*a*) the date specified in the notice in accordance with paragraph (2)(*c*), where no appeal against the notice is brought under this Regulation, or

(*b*) the day falling immediately after the expiration of the period of seven days from the date on which the District Court so affirms the notice, where an appeal against the notice is brought under paragraph (5) and the District Court affirms the notice in accordance with paragraph (7)(*a*).

Prohibition Order

27. (1) Where an authorised person is of the opinion that—

(*a*) there is non-compliance with a requirement of these Regulations,

(*b*) there is a serious risk to patients, carers, comforters or volunteers in medical or biomedical research, or

(*c*) there is a failure to comply with a compliance notice,

the authorised person may, with the approval of the Chief Executive Officer of the Authority, or another officer of the Authority designated for that purpose, serve, or arrange to have served, on the undertaking or other person concerned an order ("prohibition order") in accordance with paragraph (2).

(2) A prohibition order shall—

(*a*) be signed by the authorised person issuing it, or the Chief Executive Officer or other officer approving it, in accordance with paragraph (1),

(*b*) state that the authorised person is of the opinion that one or more of the grounds listed in paragraph (1) for the serving of a prohibition order exists,

(*c*) specify the particular non-compliance or serious risk at issue,

(*d*) where relevant identify the part or parts of the compliance notice with which there has not been compliance, and

(*e*) as appropriate, direct the undertaking or person served with the order to cease, or arrange for the cessation of—

(i) the carrying on of a particular medical radiological procedure or practice,

(ii) the referring of individuals for medical radiological procedures,

(iii) the acceptance of referrals from a particular person,

(iv) the taking of clinical responsibility for medical radiological procedures or practices,

(v) the use of particular medical radiological equipment,

(vi) a particular health screening programme, or

(vii) a particular research project.

(3) The approval referred to in paragraph (1) may be given orally or in writing and if given orally shall be recorded in writing as soon as practicable.

(4) A prohibition order shall take effect—

(*a*) where the prohibition order so declares, immediately the order is received by the person on whom it is served, or

(*b*) in any other case—

(i) where no appeal is taken against the prohibition order, on the expiration of the period during which such an appeal may be taken or the day specified in the prohibition order as the day on which it is to come into effect, whichever is the later, or

(ii) where an appeal is taken, on the day next following the day on which the prohibition order is confirmed on appeal or the appeal is withdrawn or the day specified in the prohibition order as the day on which it is to come into effect, whichever is the later.

(5) The bringing of an appeal against a prohibition order which is to take effect in accordance with paragraph (4)(*a*) shall not have the effect of suspending the operation of the prohibition order, but the appellant may apply to the District Court to have the operation of the prohibition order suspended until the appeal is disposed of and, on such application, the District Court may, if it thinks it proper to do so, direct that the operation of the prohibition order be suspended until the appeal is disposed of.

(6) In the event of non-compliance or delay by the undertaking or person on whom the prohibition order has been served, an authorised person shall, with the approval of the Chief Executive Officer or another officer designated for that purpose by the Authority, take whatever steps are considered necessary to ensure compliance with the direction given under this Regulation and this may

include the taking out of service, seizure and destruction of medical radiological equipment or the making of any arrangements for such taking out of service, seizure or destruction.

(7) (*a*) A person who is aggrieved by a prohibition order may, within the period of seven days beginning on the day on which the prohibition order is served on him or her, appeal against the order to a judge of the District Court in the District Court district in which the prohibition order was served in the prescribed manner and in determining the appeal the judge may—

(i) if he or she is satisfied that in the circumstances of the case it is reasonable to do so, confirm the prohibition order, with or without modification, or

(ii) cancel the prohibition order.

(*b*) Where on the hearing of an appeal under this paragraph a prohibition order is confirmed, notwithstanding paragraph (5), the judge of the District Court by whom the appeal is heard may, on the application of the appellant, suspend the operation of the prohibition order for such period as in the circumstances of the case the judge considers appropriate.

(8) A person who appeals against a prohibition order or who applies for a direction suspending the application of the prohibition order under paragraph (5) shall at the same time notify the Authority of the appeal or the application and the grounds for the appeal or the application and the Authority shall be entitled to appear, be heard and adduce evidence on the hearing of the appeal or the application.

(9) The Chief Executive Officer of the Authority may, for stated reasons, revoke or vary a prohibition order made in accordance with this Regulation and the Board shall be notified at the next available meeting of the Board of any such revocation or variation and the reasons therefore.

(10) The Board of the Authority shall be notified at the next available meeting of the Board of the service of a prohibition order.

(11) The Chief Executive Officer of the Authority shall, in the interest of patient safety, make such arrangements as he or she considers necessary or appropriate to bring the matter giving rise to a prohibition order to the attention of the public.

(12) (*a*) Where a prohibition order has been served and activities are carried on in contravention of the prohibition order, the High Court may, on the application of the Authority, by order prohibit the continuance of the activities.

(*b*) An application to the High Court for an order under this paragraph shall be by motion and the Court, when considering the matter, may

make such interim or interlocutory order (if any) as it considers appropriate and the order by which an application under this paragraph is determined may contain such terms and conditions (if any) as to the payment of costs as the Court considers appropriate.

Provision of information to the Authority

28. (1) The Authority may require an undertaking to provide it with any information or statistics the Authority needs in order to determine the level of compliance by the undertaking with these Regulations.

(2) Where required by the Authority under paragraph (1), the undertaking shall provide information or statistics within such reasonable period of time set out in the request from the Authority.

PART 6

OFFENCES AND PENALTIES

Offences

29. (1) A person who contravenes—

(*a*) Regulation 4(1) or (2),

(*b*) Regulation 5,

(*c*) Regulation 6(1), (2) or (3),

(*d*) Regulation 7(2) or (5),

(*e*) Regulation 8(1), (2), (4), (5), (8), (9), (10), (11), (12), (13), (14) or (15),

(*f*) Regulation 9(1), (2), (3), (4), (5), (6) or (7),

(*g*) Regulation 10(1), (2), (3), (5), (6) or (7),

(*h*) Regulation 11(5), (6), (7) or (8),

(*i*) Regulation 12(4) or (5),

(*j*) Regulation 13(1), (2), (3) or (4),

(*k*) Regulation 14(1), (2), (3), (4), (6), (7), (8), (10) or (11),

(*l*) Regulation 15,

(*m*) Regulation 16(1) or (4),

(*n*) Regulation 17(1),

(*o*) Regulation 18(2),

(*p*) Regulation 19(9),

(*q*) Regulation 20(1), (2) or (3),

(*r*) Regulation 21(1),

(*s*) Regulation 22(1), (3), (4), (5) or (6),

(*t*) Regulation 26(9), or

(*u*) Regulation 28(2)

is guilty of an offence.

(2) A person who—

(*a*) in purported compliance with a request or requirement under these Regulations gives information to the Authority that he or she knows to be false or misleading in any material respect,

(*b*) fails to comply with a notice or order under these Regulations, except where the operation of that notice or order has been suspended or has been withdrawn or revoked by the Authority,

(*c*) discloses any confidential information to which he or she has access by virtue of these Regulations, otherwise than in accordance with these Regulations,

(*d*) obstructs or interferes with the Authority, an authorised person, a member of An Garda Síochána or person with expertise, in the course of performing a function conferred on him or her by these Regulations or a warrant under Regulation 24(7),

(*e*) impedes the performance by the authorised person, member of An Garda Síochána, or person with expertise, as the case may be, referred to in subparagraph (*d*), of such function or fails or refuses to comply with a request or requirement of, or to answer a question asked by, the authorised person, member, or person with expertise, as the case may be,

(*f*) in purported compliance with a request or requirement referred to in subparagraph (*e*), or in answer to a question referred to in subparagraph (*e*), gives information to the authorised person, member of An Garda Síochána, or person with expertise, as the case may be, that he or she knows to be false or misleading in any material respect,

(*g*) falsely represents himself or herself to be an authorised person, or

(*h*) with the intent to defraud or deceive, tampers or interferes with any sample taken under these Regulations,

is guilty of an offence.

(3) For the purposes of these Regulations, every contravention of a provision of these Regulations shall be deemed a separate contravention and every contravention of a paragraph or a subparagraph of such provision shall also be deemed to be a separate contravention and shall carry the same penalty as for a single contravention of any such provision.

(4) Where a body corporate, or a person acting on behalf of a body corporate, commits an offence under these Regulations and the offence is committed with the consent, connivance or approval of, or is attributable to any neglect or default on the part of, any director, manager, secretary or any other officer of such body, or a person purporting to act in any such capacity, such person is also guilty of an offence and is liable to be proceeded against and punished as if he or she were guilty of the first-mentioned offence.

(5) Where the affairs of a body corporate are managed by its members, paragraph (4) applies as if the reference to a director in that subsection were a reference to a member of the body corporate.

(6) In proceedings for an offence under these Regulations, it is a defence for a person charged with the offence to prove both of the following—

(*a*) commission of the offence was due to a reasonable mistake or the reliance on information supplied to him or her, or to the act or default of another person, an accident or some other cause beyond his or her control, and

(*b*) he or she exercised due diligence and took all reasonable precautions to avoid commission of the offence.

(7) If reliance on the defence provided by paragraph (6) involves the allegation that the commission of the offence was due to reliance on information supplied by another person or to the act or default of another person, the person charged with the offence shall not, without leave of the court, be entitled to rely on that defence unless, not less than seven working days before the hearing, he or she has served on the prosecutor written notice providing information identifying, or assisting in the identification of, that other person.

Penalties

30. (1) A person guilty of an offence under these Regulations is liable—

(*a*) on summary conviction to a fine not exceeding class A or to imprisonment for a term not exceeding one year or both, or

(*b*) on conviction on indictment to a fine not exceeding €225,000 or imprisonment for a term not exceeding 3 years or both.

(2) Where a person is convicted of an offence under these Regulations, the court shall, unless it is satisfied that there are special and substantial reasons for not so doing, order the person to pay to the Authority, as the case may be, the costs and expenses, measured by the court, incurred by the Authority in relation to the investigation, detection and prosecution of the offence, including costs

and expenses incurred in the taking of samples, the carrying out of tests, examinations and analyses and in respect of the remuneration and other expenses of employees, consultants and advisors engaged by the Authority.

(3) An order for costs and expenses under paragraph (2) is in addition to, and not instead of, any fine or penalty the court may impose under paragraph (1).

Summary proceedings may be brought by Authority

31. Summary proceedings for an offence under these Regulations may be brought and prosecuted by the Authority.

PART 7

AMENDMENT, REVOCATIONS AND TRANSITIONAL PROVISIONS

Amendment of Health Act 2007

32. Section 8(1) (as amended by section 97 of the Child and Family Agency Act 2013 (No. 40 of 2013)) of the Health Act 2007 (No. 23 of 2007) is amended—

(*a*) in paragraph (*m*)(ii), by substituting "Disability Act 2005;" for "Disability Act 2005.", and

(*b*) by inserting the following paragraph after paragraph (*m*):

"(*n*) to exercise such powers and perform such functions of the State and the competent authority under Council Directive 2013/59/Euratom of 5 December 2013 as are conferred on the Authority by the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 (S.I. No. 256 of 2018).".

Amendment of European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004

33. The European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (S.I. No. 190 of 2004) are amended—

(*a*) in Regulation 3—

(i) in paragraph (1), by inserting "and to the conducting of medical and biomedical research under Regulation 8(2) of the Ionising Radiation Regulations" after "of these regulations", and

(ii) in paragraph (3), by inserting ", except in the case of trials carried out for the purposes of the Ionising Radiation Regulations" after "non-interventional trials",

(*b*) in Regulation 4(1), by inserting the following definition:

"'Ionising Radiation Regulations' means the European Union (Basic Safety Standards for Protection Against Dangers Arising

from Medical Exposure to Ionising Radiation) Regulations 2018 (S.I. No. 256 of 2018);",

(*c*) in Regulation 6—

(i) by inserting after paragraph (3) the following paragraph:

"(3A) Ethics committees may be established pursuant to paragraph (2) or (3) for the purposes of Regulation 8(2) of the Ionising Radiation Regulations, either solely for that purpose or in addition to their function in relation to clinical trials.", and

(ii) in paragraph (5), by inserting "or Regulation 8(2) of the Ionising Radiation Regulations" after "under these Regulations",

(*d*) in Regulation 7—

(i) in paragraph (3)(*b*), by inserting ", or that the committee may act as an ethics committee for the purposes of Regulation 8(2) of the Ionising Radiation Regulations" after "may act as an ethics committee",

(ii) by inserting after paragraph (3) the following:

"(3A) In granting recognition to an ethics committee for the purposes of Regulation 8(2) of the Ionising Radiation Regulations, where the committee does not propose to consider clinical trial research, the Supervisory Authority shall specify any other conditions or limitations that apply to that committee.",

(iii) in paragraph (4)(*b*), by inserting ", or direct that the committee may, instead or in addition, act as an ethics committee for the purposes of Regulation 8(2) of the Ionising Radiation Regulations" after "may act as an ethics committee",

(iv) in paragraph (4)(*c*), by inserting "or (3A)" after "paragraph (3)",

(v) in paragraph (5), by inserting ", where applicable, or that the committee may act as an ethics committee for the purposes of Regulation 8(2) of the Ionising Radiation Regulations" after "may act as an ethics committee", and

(vi) by inserting after paragraph (5) the following paragraph:

"(6) An ethics committee to which recognition has been granted under this Regulation on the commencement of the Ionising Radiation Regulations shall be deemed to have also been recognised for the purpose of those Regulations.",

(*e*) in Regulation 8(*b*), by inserting "or Regulation 8(2) of the Ionising Radiation Regulations" after "under these Regulations", and

(*f*) in paragraph 1(1) of Schedule 2—

(i) by substituting for the definition of "expert member" the following:

"'expert member' means a member of an ethics committee who is a health care professional or who has professional qualifications or experience relating to—

(*a*) the conduct of, or use of statistics in, clinical research, unless the said qualifications or experience relate only to the ethics of clinical research or medical treatment, or

(*b*) in the case of a committee acting as an ethics committee for the purposes of Regulation 8(2) of the Ionising Radiation Regulations, medical exposure to ionising radiation for medical or biomedical research;", and

(ii) in the definition of "lay member", by inserting ", or advise on medical exposure to ionising radiation" after "or conduct of clinical research".

Revocations

34. (1) The following are revoked:

(*a*) the European Communities (Medical Ionising Radiation Protection) Regulations 2002 (S.I. No. 478 of 2002);

(*b*) the European Communities (Medical Ionising Radiation Protection) (Amendment) Regulations 2007 (S.I. No. 303 of 2007); and

(*c*) the European Communities (Medical Ionising Radiation Protection) (Amendment) Regulations 2010 (S.I. No. 459 of 2010).

(2) References in other enactments to Regulations revoked under paragraph (1) shall, where the context so admits, be construed as references to these Regulations.

Transitional provisions

35. (1) Notwithstanding Regulation 8(2), prior examination and approval by an ethics committee is not required in the case of a medical or biomedical research project involving medical exposure which has received ethical approval or begun prior to the commencement of these Regulations.

(2) Notwithstanding Regulation 8(3) and (4), specific justification is not required in the case of medical radiological procedures to be performed as part of a health screening programme which has begun prior to the commencement of these Regulations.

L.S.

GIVEN under my Official Seal,
8 January 2019.

SIMON HARRIS,
Minister for Health.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations give effect to Council Directive 2013/59/EURATOM of 5 December 2013 which lays down basic safety standards for protection against the dangers arising from exposure to ionising radiation. In particular, these Regulations provide for requirements in relation to medical exposures and enforcement of such requirements.

These Regulations revoke the European Communities (Medical Ionising Radiation Protection) Regulations 2002, and the amendments thereto.

These Regulations amend the Health Act 2007 and the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004.

These Regulations may be cited as the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018.

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