

2018 No.

HEALTH AND SAFETY

The Ionising Radiation (Medical Exposure) Regulations 2018

Made - - - - ***

Laid before Parliament ***

Coming into force - - 6th February 2018

The Secretary of State, being the Minister designated for the purposes of section 2(2) of the European Communities Act 1972(a) 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 and by section 56 of the Finance Act 1973(b), makes the following Regulations.

Citation and commencement

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

Interpretation

2.—(1) In these Regulations—

“accidental exposure” means an exposure of individuals, other than emergency workers, as a result of an accident;

“adequate training” means training which satisfies the requirements of Schedule 4, and the expression “adequately trained” is to be similarly construed;

“assessment” means prior determination of amount, parameter or method;

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

“child” means a person under the age of eighteen in England and Wales or a person under the age of sixteen in Scotland;

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

“diagnostic reference levels” means dose levels in medical radiodiagnostic or interventional radiology practices, or, in the case of radio-pharmaceuticals, levels of activity, for typical

(a) 1972 c. 68; section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c. 51), and by Part 1 of the Schedule to the European Union (Amendment) Act 2008 (c. 7).

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

examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment;

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

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

“employer’s procedures” means the procedures established by an employer pursuant to regulation 6(1);

“equipment” means equipment which—

- (a) delivers ionising radiation to a person undergoing exposure; and
- (b) which directly controls or influences the extent of such exposure;

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

“health screening” means a procedure using medical radiological installations for early diagnosis in population groups at risk;

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

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

“Licensing Authority”—

- (a) for the purpose of licensing any practitioner in respect of the administration of radioactive substances means the Secretary of State;
- (b) for the purpose of licensing any employer in respect of the administration of radioactive substances means—
 - (i) in England, the Secretary of State;
 - (ii) in Scotland, the Scottish Ministers; and
 - (iii) in Wales, the Welsh Ministers;

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

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

“medical radiological installation” means a facility where medical radiological procedures are performed;

“medical radiological procedure” means any procedure giving rise to medical exposure;

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

“operator” means any person who is entitled, in accordance with the employer’s procedures, to carry out practical aspects including those to whom practical aspects have been allocated, medical physics experts and, except where they do so under the direct supervision of a person

who is adequately trained, persons participating in practical aspects as part of practical training;

“patient dose” means the dose concerning patients or other individuals undergoing medical exposure;

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

“practitioner” means a registered health care professional, within the meaning of section 25(3) of the National Health Service Reform and Health Care Professions Act 2002^(a), who is entitled in accordance with the employer’s procedures to take responsibility for an individual exposure;

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

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

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

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

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

“referrer” means a registered health care professional, within the meaning of section 25(3) of the National Health Service Reform and Health Care Professions Act 2002, who is entitled in accordance with the employer’s procedures to refer individuals for exposure to a practitioner;

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

“relevant enforcing authority” means—

- (a) in England, the Secretary of State;
- (b) in Scotland, the Scottish Ministers; and
- (c) in Wales, the Welsh Ministers;

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

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

- (a) is an employer;
- (b) is a referrer;
- (c) is an operator; or
- (d) is a practitioner,

(a) 2002 c. 17.

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

Application

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

- (a) to patients as part of their own medical diagnosis or treatment;
- (b) to individuals as part of health screening programmes;
- (c) to patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes;
- (d) to carers and comforters;
- (e) to asymptomatic individuals;
- (f) involving non-medical imaging using medical radiological equipment.

The Licensing Authority

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

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

- (a) issued for such period as the Licensing Authority may consider appropriate;
- (b) subject to any conditions which the Licensing Authority may consider to be appropriate; and
- (c) varied or revoked at any time.

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

Requirement to hold a licence

5.—A person is required by these Regulations to hold a valid licence issued by the Licensing Authority if that person—

- (a) is an employer, in which case that person must hold a licence in respect of each medical radiological installation at which radioactive substances are to be administered for such purposes as may be specified in that licence; or
- (b) is a practitioner, in which case that person must hold a licence in order to justify, within the meaning of regulation 11 (justification of individual exposures) an exposure involving the administration of radioactive substances for such purposes as may be specified in that licence.

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

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

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

- (a) those matters described in Schedule 2; and
- (b) any other matter in relation to which these Regulations mandate the establishment of procedures.

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

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

- (a) complies with the provisions of regulation 17(1); and
- (b) undertakes continuing education and training after qualification including, in the case of clinical use of new techniques, training related to these techniques and the relevant radiation protection requirements; or
- (c) where the employer is concurrently practitioner or operator, it is the employer's duty to ensure such continuing education and training as may be appropriate is undertaken.

(4) The employer must ensure that written protocols are in place for every type of standard radiological practice for all medical radiological equipment for relevant categories of patients.

(5) The employer must—

- (a) establish recommendations concerning referral criteria for medical exposures, including radiation doses, and ensure that these are available to the referrer;
- (b) establish quality assurance programmes for standard operating procedures;
- (c) regularly review and make available to an operator, diagnostic reference levels for radiodiagnostic examinations falling within regulation 3(a), (b), (e) and (f) having regard to European and national diagnostic reference levels where available;
- (d) establish dose constraints—
 - (i) for biomedical and medical research programmes falling within regulation 3(c) where no direct medical benefit for the individual is expected from the exposure; and
 - (ii) with regard to the protection of carers and comforters within regulation 3(d).

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

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

Employer's duties: clinical audit

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

Employer's duties: accidental or unintended exposure

8.—(1) The employer's procedures must provide that the referrer, the practitioner, and the patient or their representative are informed of the occurrence of any relevant clinically significant unintended or accidental exposure and of the outcome of the analysis of this exposure.

(2) The employer's quality assurance programme must, in respect of radiotherapeutic practices, include a study of the risk of accidental or unintended exposures.

(3) The employer must establish a system for recording analyses of events involving or potentially involving accidental or unintended exposures proportionate to the radiological risk posed by the practice.

(4) Where the employer knows or has reason to believe that an accident or unintended exposure has or may have occurred in which a person, while undergoing an exposure was or could have been exposed to ionising radiation defined as significant, the employer must—

- (a) make an immediate preliminary investigation of the incident;
- (b) unless that investigation shows beyond a reasonable doubt that no such exposure has occurred immediately notify the relevant enforcing authority;
- (c) conduct or arrange for a detailed investigation of the circumstances of the exposure and an assessment of the dose received; and

- (d) notify the relevant enforcing authority of the outcome of the investigation and any corrective measures adopted, within the time period specified by the relevant enforcing authority.

Relevant enforcing authority's duties: accidental or unintended exposure

9. The relevant enforcing authority must put in place mechanisms enabling the timely dissemination of information, relevant to radiation protection in respect of medical exposures, regarding lessons learned from significant events.

Duties of the practitioner, operator and referrer

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

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

(3) Practical aspects of an exposure or part of it may be allocated 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 is responsible for each and every practical aspect which the operator carries out as well as for any authorisation given pursuant to regulation 11(5).

(5) The referrer must supply the practitioner with sufficient medical data (such as previous diagnostic information or medical records) relevant to the exposure requested by the referrer to enable the practitioner to decide whether there is a sufficient net benefit as required by regulation 11(1)(b).

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

Justification of individual exposures

11.—(1) A person must not carry out an exposure unless—

- (a) in the case of the administration of radioactive substances, the practitioner and employer are licensed to undertake the intended exposure;
- (b) 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
- (c) it has been authorised by the practitioner or, where paragraph (5) applies, the operator;
- (d) in the case of an exposure as referred to in regulation 3(c), it has been approved by an ethics committee and in the case of the administration of radioactive substances, approved by an expert committee who can advise on the administration of radioactive substances to humans;
- (e) in the case of an exposure falling within regulation 3(f), it complies with the employer's procedures for such exposures; and
- (f) in the case of an individual of childbearing age, the person has enquired whether that individual is pregnant or breastfeeding.

(2) The matters referred to in paragraph (1)(b) 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 in accordance with paragraph (1)(b) must have regard, in particular to—

- (a) recommendations from appropriate medical scientific societies or relevant bodies where a procedure is to be performed as part of any health screening programme;
- (b) whether in circumstances where there is to be an exposure to a comforter or carer such an exposure would show a sufficient net benefit taking into account—
 - (i) the likely direct health benefits to a patient;
 - (ii) the possible benefits to the carer or comforter; and
 - (iii) the detriment that the exposure might cause;
- (c) in the case of asymptomatic individuals on whom any medical radiological procedure—
 - (i) is to be performed for the early detection of disease;
 - (ii) is to be performed as part of a health screening programme;
 - (iii) requires specific documented justification for that individual by the practitioner, in consultation with the referrer,
any guidelines issued by appropriate medical scientific societies, relevant bodies or published by the Secretary of State;
- (d) the urgency of the exposure, where appropriate, in cases involving—
 - (i) an individual where pregnancy cannot be excluded, in particular if abdominal and pelvic regions are involved, taking into account the exposure of both the person concerned and any unborn child; and
 - (ii) an individual who is breastfeeding and who undergoes an exposure involving the administration of radioactive substances, taking into account the exposure of both the individual and the child.

(4) In deciding whether to justify an exposure under paragraph (1)(b) the practitioner must take account of any data supplied by the referrer pursuant to regulation 10(5) and must 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 must do so in accordance with guidelines issued by the practitioner.

(6) In this regulation—

“ethics committee” means—

- (a) an ethics committee established or recognised in accordance with Part 2 of the Medicines for Human Use (Clinical Trials) Regulations 2004(a);
- (b) the Ethics Committee constituted by regulations made by the Scottish Ministers under section 51(6) of the Adults with Incapacity (Scotland) Act 2000(b); or
- (c) any other committee established to advise on the ethics of research investigations in human beings, and recognised for that purpose by or on behalf of the Secretary of State, the Scottish Ministers or the Welsh Ministers; and

“individual detriment” means clinically observable deleterious effects 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.

Optimisation

12.—(1) In relation to all exposures to which these Regulations apply except those occurring further to radiotherapeutic procedures, the practitioner and the operator, to the extent of their

(a) S.I. 2004/1031.

(b) 2000 asp 4.

respective involvement in an exposure, must ensure that doses arising from the exposure are kept as low as reasonably practicable consistent with the intended purpose.

(2) In relation to all exposures for radiotherapeutic purposes the practitioner must ensure that exposures of target volumes are individually planned, their delivery appropriately verified taking into account that doses to non-target volumes and tissues must 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 must select equipment and methods to ensure that for each 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 must 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), (e) and (f),

as set out in the employer's procedures.

(4) For each medical or biomedical research programme falling within regulation 3(c), the employer's procedures must 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 regulation 3(d), the employer's procedures must provide that appropriate guidance is established for the exposure of carers and comforters.

(6) In the case of patients undergoing treatment or diagnosis with radioactive substances, the employer's procedures must provide that, where appropriate, written instructions and information are provided to—

- (a) the patient, where the patient has capacity to consent to the treatment or diagnostic procedure; or
- (b) where the patient is a child who lacks capacity (within the meaning of the Mental Capacity Act 2005^(a) in the case of a child aged sixteen or seventeen) so to consent, a person with parental responsibility (within the meaning of the Children Act 1989^(b)) for the child; or
- (c) where the patient is an adult who lacks capacity (within the meaning of the Mental Capacity Act 2005) so to consent, the person who appears to the practitioner to be the most appropriate person.

(7) The instructions and information referred to in paragraph (6) must—

- (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 in paragraph (6) as appropriate prior to the patient leaving the hospital or other place where the exposure was carried out.

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

(a) 2005 c. 9.
(b) 1989 c. 41.

- (a) medical exposures of children;
- (b) medical exposures as part of a health screening programme;
- (c) medical exposures involving high doses to the patient;
- (d) where appropriate, individuals 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 individual and any unborn child; and
- (e) where appropriate, individuals who are breastfeeding and who are undergoing a medical exposure involving the administration of radioactive substances, taking into account the exposure of both the individual and the child.

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

Estimates of population doses

13. The employer must collect dose estimates from medical exposures for radiodiagnostic and interventional procedures, taking into consideration, where appropriate, the distribution by age and gender of the exposed population and, when so requested, must provide it to the Secretary of State

Expert advice

14.—(1) The employer must ensure that a suitable medical physics expert is appointed and involved, in accordance with paragraph (2), in relation to every type of exposure to which these Regulations apply.

(2) A medical physics expert must—

- (a) meet such criteria of competence as may from time to time be specified in guidance issued by the Secretary of State;
- (b) be closely involved in every radiotherapeutic practice other than standardised therapeutic nuclear medicine practices;
- (c) be involved in practices including standardised therapeutic nuclear medicine practices, diagnostic nuclear medicine practices and high dose interventional radiology and high dose computed tomography;
- (d) be involved as appropriate for consultation on optimisation, including patient dosimetry and quality assurance, and to give advice on matters relating to radiation protection concerning exposures, as required, in all other radiological practices; and
- (e) contribute to the matters specified in Schedule 3.

Equipment: general duties of the employer

15.—(1) An employer who has control over any equipment must—

- (a) implement and maintain a quality assurance programme in respect of that equipment which must as a minimum permit—
 - (i) the assessment of the dose of ionising radiation to a person from an exposure described in regulation 3 may be exposed by way of the ordinary operation of that equipment; and
 - (ii) the administered activity to be verified;
- (b) ensure that any feature of that equipment designed to protect a person from an exposure described in regulation 3 is fully operative;

- (c) draw up, keep up-to-date and preserve at each medical radiological installation an inventory of equipment at that installation and, when so requested, must provide it to the relevant enforcing authority.
- (2) The inventory referred to in paragraph (1)(c) must 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) An employer must undertake adequate—
- (a) testing of any equipment before it is first used for a medical radiological purpose;
 - (b) performance testing at regular intervals;
 - (c) performance testing following a maintenance procedure which is capable of affecting the equipment's performance.
- (4) No person is permitted to use fluoroscopy equipment unless that equipment features—
- (a) a device to control automatically the dose rate; or
 - (b) an image intensifier or equivalent device.
- (5) Equipment used for interventional radiology and computed tomography must have a device or other feature capable of informing the practitioner, at the end of an exposure, of relevant parameters for assessing the patient dose.
- (6) An employer must—
- (a) take steps to put in place any measures necessary to improve inadequate or defective performance of equipment;
 - (b) specify criteria by which the degree of a piece of equipment's effectiveness is capable of being ascertained; and
 - (c) specify what corrective action is necessary when, further to the application of any criteria specified under paragraph (b), equipment is ascertained to be defective; such corrective action may include taking the equipment out of service.

Equipment installed on or after 6th February 2018

- 16.**—(1) This regulation only applies in respect of—
- (a) equipment installed on or after 6th February 2018; and
 - (b) an employer who has control of any such equipment.
- (2) Equipment used for external beam radiotherapy with a nominal beam exceeding 1 MeV must have a device, or other feature, the purpose of which is, to verify key treatment parameters.
- (3) Equipment used for interventional radiology must have a device or other feature capable of informing any person involved in the conduct of an exposure of the amount of radiation produced by the equipment during such an exposure.
- (4) Equipment used for planning, guiding and verification purposes, must have a device or other feature capable of informing the practitioner, at the end of an exposure, of relevant parameters for assessing the dose.
- (5) Equipment used for interventional radiology and computed tomography must have the capacity to transfer, to the record of a person's examination, information relating to relevant parameters for assessing the dose.
- (6) Insofar as not already provided in this regulation, any equipment producing ionising radiation must—
- (a) have a device, or other feature, capable of informing the practitioner of relevant parameters for assessing the patient dose; and

- (b) where appropriate, have the capacity to transfer this information to the record of a person's examination.

Training

17.—(1) Subject to the following provisions of this regulation a practitioner or operator must not carry out any 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 is, if such certificate so attests, sufficient proof that the person to whom it has been issued has been adequately trained.

(3) Nothing in paragraph (1) above prevents 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 is adequately trained.

(4) The employer must keep and have available for inspection by the relevant enforcing authority an up-to-date record of all training undertaken by all practitioners and operators engaged by him to carry out any exposures or any practical aspect of such exposures or, where the employer is concurrently practitioner or operator, of the employer's own training, showing the date or dates on which training qualifying as adequate training was completed and the nature of the training.

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

(6) Schedule 4 makes further provision about the training of practitioners and operators.

Enforcement

18. These Regulations are to be enforced as if they were health and safety regulations made under section 15 of the Health and Safety at Work etc. Act 1974(a) and, except as provided in regulation 20, the provisions of that Act, as regards enforcement and offences, are to apply for the purposes of these Regulations.

Defence of due diligence

19. In any proceedings against any person for an offence consisting of the contravention of these Regulations it is a defence for that person to show that all reasonable steps were taken and all due diligence was exercised to avoid committing the offence.

Revocation and transitional provision

20.—(1) Ionising Radiation (Medical Exposure) Regulations 2000 are revoked.

(2) The Medicines (Administration of Radioactive Substances) Regulations 1978(b) and the Medicines (Radioactive Substances) Order 1978(c) are also revoked, subject to the transitional provision in paragraph (3).

(3) Any certificate issued to a person under the Medicines (Administration of Radioactive Substances) Regulations 1978 which is valid on 6th February 2018 is deemed—

- (a) to be a licence issued under these Regulations for as long as that certificate remains valid; and
- (b) to license the employer responsible for the medical radiological installation for the matters specified in that certificate.

(a) 1974 c. 37; section 15(1) was substituted by paragraph 6 of Schedule 15 to the Employment Protection Act 1975 (c. 71) and amended by S.I. 2002/794.

(b) S.I. 1978/1006, amended by S.I. 1995/2147, 2005/2754 and 2006/2407.

(c) S.I. 1978/1004.

(4) Nothing in paragraph (3) prevents a person from applying for a licence under these Regulations on or after the date that they come into force.

Date _____
Parliamentary Under Secretary of State
Department of Health
Name

SCHEDULE 1

Regulation 4

Licensing

Licence applications: general

1.—(1) A person required by these Regulations to hold a licence must make an application to the Licensing Authority in the form specified from time to time by the Licensing Authority.

(2) A person applying for a licence under sub-paragraph (1) must provide to the Licensing Authority—

- (a) such of the information described in paragraph 2 as the Licensing Authority may from time to time specify necessary to determine the licence application;
- (b) upon request in writing, any other information which the Licensing authority requires for the purpose of considering the licence application;
- (c) the fee specified in paragraph 4.

(3) A person issued a licence described in sub-paragraph (1) (“the licensee”) must apply to the Licensing Authority if the licensee seeks a material change to any matter dealt with by that licence.

Licence applications: indicative list of information

2. The information referred to in paragraph 1(2) is information relating to—

- (a) responsibilities and organisational arrangements for protection and safety;
- (b) staff competences, including information and training;
- (c) design features of the facility and of radiation sources;
- (d) anticipated occupational and public exposures in normal operation;
- (e) safety assessment of the activities and the facility in order to—
 - (i) identify ways in which potential exposures or accidental and unintended medical exposures could occur;
 - (ii) estimate, to the extent practicable, the probabilities and magnitude of potential exposures;
 - (iii) assess the quality and extent of protection and safety provisions, including engineering features, as well as administrative procedures;
 - (iv) define the operational limits and conditions of operation;
- (f) emergency procedures;
- (g) maintenance, testing, inspection and servicing so as to ensure that the radiation source and the facility continue to meet the design requirements, operational limits and conditions of operation throughout their lifetime;
- (h) management of radioactive waste and arrangements for the disposal of such waste, in accordance with applicable regulatory requirements;
- (i) management of disused sources;
- (j) quality assurance.

Licence applications: urgent cases

3. The licensing authority may, on a case by case basis, relax any of the requirements relating to the making of an application for a licence in respect of a proposed urgent medical radiological exposure.

Licence applications: employer and practitioner fees

4. The fee payable by a person described in column 1 of Table 1 in respect of an application type specified in column 2 of that table is the corresponding amount in column 3.

Table 1

<i>Licence type (1)</i>	<i>Application type (2)</i>	<i>Fee (£) (3)</i>
Employer	New	329
	Amendment of an existing licence	235
	Renewal of an existing licence	141
	Notification	0
Practitioner	New	0
	Amendment of an existing licence	0
	Renewal of an existing licence	0
	Particular patient request	0

Fees in respect of a research approval

5. The fee payable by a person seeking research approval from an expert committee as described in regulation 11(1)(d) for the purpose of exposures coming within regulation 3(c) is specified in the entry in column 2 of Table 2 which corresponds with the nature of the application described in column 1.

Table 2

<i>Application type (1)</i>	<i>Fee (£) (2)</i>
New (multicentre)	517
New (single centre)	423
New (low dose <1mSv)	235
Amendment	329
Notification	0

Review

6.—(1) A person who is aggrieved (“an aggrieved person”) by—

- (a) a decision of the Licensing Authority—
 - (i) refusing to issue a licence or research approval;
 - (ii) imposing a limit of time upon a licence or research approval; or
 - (iii) revoking a licence or research approval; or
- (b) the terms of any conditions attached to a licence or to a research approval by the Licensing Authority,

may ask the Licensing Authority for a review.

(2) Any aggrieved person must request the Licensing Authority to undertake a review described in paragraph (1)—

- (a) within 28 days of the date that the person was notified of the decision, or the terms, which caused them to become an aggrieved person; and

(b) must particularise in writing the reasons for seeking the review.

(3) The Licensing Authority must undertake a review, and provide the results of that review in writing to the aggrieved person.

SCHEDULE 2

Regulation 6

Employer's Procedures

7. The employer's written procedures for exposures must include procedures—
- (a) to identify correctly the individual to be exposed to ionising radiation;
 - (b) to identify individuals entitled to act as referrer or practitioner or operator;
 - (c) for making enquiries of individuals of childbearing age to establish whether the individual is or may be pregnant or breastfeeding;
 - (d) to ensure that quality assurance programmes are followed;
 - (e) for the assessment of patient dose and administered activity;
 - (f) for the use of diagnostic reference levels established by the employer for radiodiagnostic examinations falling within regulation 3(a), (b), (e) and (f), specifying that these are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied;
 - (g) for determining whether the practitioner or operator is required to effect one or more of the matters set out in regulation 12(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(c) where no direct medical benefit for the individual is expected from the exposure;
 - (h) for the giving of information and written instructions as referred to in regulation 12(6);
 - (i) providing that wherever practicable, and prior to an exposure taking place, the patient or their representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the exposure;
 - (j) for the carrying out and recording of an evaluation for each exposure including, where appropriate, factors relevant to patient dose;
 - (k) to ensure that the probability and magnitude of accidental or unintended exposures to patients from radiological practices are reduced so far as reasonably practicable;
 - (l) to ensure that the referrer, the practitioner, and the patient or their representative are informed of the occurrence of any relevant clinically significant unintended or accidental exposure, and of the outcome of the analysis of this exposure.
 - (m) to be observed in the case of non-medical imaging exposures.
 - (n) to establish appropriate dose constraints and guidance for the exposure of carers and comforters.

SCHEDULE 3

Regulation 14

Medical Physics Experts

1. The matters specified in this Schedule are—
- (a) optimisation of the radiation protection of patients and other individuals subject to exposures, including the application and use of diagnostic reference levels;
 - (b) the definition and performance of quality assurance of the equipment;
 - (c) acceptance testing of equipment;

- (d) the preparation of technical specifications for equipment and installation design;
- (e) the surveillance of the medical radiological installations;
- (f) the analysis of events involving, or potentially involving, accidental or unintended exposures;
- (g) the selection of equipment required to perform radiation protection measurements;
- (h) the training of practitioners and other staff in relevant aspects of radiation protection;
- (i) the provision of advice to an employer relating to compliance with these Regulations;
- (j) the medical physics expert is, where appropriate, to liaise with the radiation protection expert.

SCHEDULE 4

Regulation 17

Adequate Training

1. Practitioners and operators must have successfully completed training, including theoretical knowledge and practical experience, in—

- (a) such of the subjects detailed in Table 1 as are relevant to their functions as practitioner or operator; and
- (b) such of the subjects detailed in Table 2 as are relevant to their specific area of practice.

Table 1 - Radiation production, radiation protection and statutory obligations relating to ionising radiations

Fundamental Physics of Radiation

Properties of Radiation	Attenuation of ionising radiation Scattering and absorption
Radiation Hazards and Dosimetry	Biological effects of radiation Risks/benefits of radiation Dose optimisation Absorbed dose, equivalent dose, effective dose and their units
Special Attention Areas	Pregnancy and potential pregnancy Infants and children Medical and biomedical research Health screening High dose techniques
Management and Radiation Protection of the Patient	
Patient Selection	Justification of the individual exposure Patient identification and consent Use of existing appropriate radiological information Alternative techniques Clinical evaluation of outcome
Radiation Protection	General radiation protection Use of radiation protection devices: patient Use of radiation protection devices: personal Procedures for untoward incidents involving overexposure to ionising radiation

Statutory Requirements and Advisory Aspects

Statutory Requirements and Non-Statutory Recommendations	Regulations
	Local rules and procedures
	Individual responsibilities relating to exposures
	Responsibility for radiation safety
	Routine inspection and testing of equipment
	Clinical audit

Table 2 - Diagnostic radiology, radiotherapy and nuclear medicine

<i>Diagnostic radiology</i>	
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
Specialised Techniques	Image intensification/fluoroscopy Digital Fluoroscopy Computed Tomography Scanning Interventional procedures Vascular imaging
Fundamentals of Image Acquisition etc.	Image quality v radiation dose
Contrast Media	image formats, acquisition, storage and display Non-ionic and ionic Use and preparation Contra-indications to the use of contrast media Use of automatic injection devices
Radiotherapy General	Production of ionising radiations Use of radiotherapy: benign disease Use of radiotherapy: malignant disease Use of radiotherapy: external beam Use of radiotherapy: brachytherapy
Radiobiological Aspects for Radiotherapy	Fractionation Dose rate Radiosensitisation Target volumes
Practical Aspects for Radiotherapy	Equipment
Radiation Protection Specific to Radiotherapy	Treatment planning Side effects—early and late Toxicity Assessment of efficacy
Nuclear Medicine General	Atomic structure and radioactivity Radioactive decay The tracer principle Fundamentals of diagnostic use

	Fundamentals of therapeutic use: dose rate Fundamentals of therapeutic use: fractionation Fundamentals of therapeutic use: radiobiology aspects Types of systems
Principles of Radiation Detection, Instrumentation and Equipment	
	Image acquisition, storage and display Quality assurance and quality control Calibration Working practices in the radiopharmacy Preparation of individual doses Documentation
Radiopharmaceuticals	
	Conception, pregnancy and breastfeeding
Radiation Protection Specific to Nuclear Medicine	
	Arrangements for radioactive patients Disposal procedures for radioactive waste

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are part of a package of regulations which transpose European Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation with respect to medical exposures. They repeal and consolidate a number of domestic pieces of legislation relating to the medical exposure of ionising radiation, and implement a number of new requirements introduced by European Council Directive 2013/59/Euratom.