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 under these Regulations ("the licensee") must apply to the Licensing Authority if the licensee seeks a material change to the licence in respect of 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 radiological installation 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 fees

4.—(1) 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.

(2) No fee is payable where the amount specified in column 3 is "0".

Table 1

Licence type (1)	*Application type (2)*	*Fee (£) (3)*
Employer	New	250
	Amendment of an existing licence	200
	Renewal of an existing licence	200
	Notification	0
Practitioner	New	0
	Amendment of an existing licence	0
	Renewal of an existing licence	0
	Particular patient request	0

Review

5.—(1) A person who is aggrieved ("an aggrieved person") by—

(a) a decision of the Licensing Authority—

(i) refusing to issue a licence;

(ii) imposing a limit of time upon a licence; or

(iii) revoking a licence; or

(b) the terms of any conditions attached to a licence by the Licensing Authority,

may ask the Licensing Authority for a review.

(2) Any aggrieved person seeking a review must—

(a) within 28 days of and including the date that the person was notified of the decision, or the terms, which caused them to become an aggrieved person request the Licensing Authority to undertake a review described in paragraph (1); 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.

Destination of fees

6. A fee payable under these Regulations is payable to the Secretary of State for Health.

SCHEDULE 2

Regulation 6

Employer's Procedures

1. 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 within a specified scope of practice;

(c) for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breastfeeding;

(d) to ensure that quality assurance programmes in respect of written procedures, written protocols, and equipment are followed;

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

(f) for the use and review of such diagnostic reference levels as the employer may have established for radiodiagnostic examinations falling within regulation 3(a), (b), (e) and (f);

(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 individual to be exposed 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 exposure to individuals from radiological practices are reduced so far as reasonably practicable;

(l) to ensure that the referrer, the practitioner, and the individual exposed 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 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	Excitation and ionisation
	Attenuation of ionising radiation
	Scattering and absorption
Radiation Hazards and Dosimetry	Biological effects of radiation – stochastic and deterministic
	Risks and benefits of radiation
	Absorbed dose, equivalent dose, effective dose, other dose indicators and their units
Management and Radiation Protection of the individual being exposed	
Special Attention Areas	Pregnancy and potential pregnancy
	Asymptomatic individuals
	Breastfeeding
	Infants and children
	Medical and biomedical research
	Health screening
	Non-medical imaging
	Carers and comforters
	High dose techniques
Justification	Justification of the individual exposure
	Use of existing appropriate radiological information
	Alternative techniques
Radiation Protection	Diagnostic reference levels
	Dose constraints
	Dose optimisation
	Dose reduction devices and techniques
	Dose recording and dose audit
	General radiation protection
	Quality assurance and quality control including routine inspection and testing of equipment
	Risk communication
	Use of radiation protection devices

Fundamental Physics of Radiation	
Statutory Requirements and Non-Statutory Regulations	
	Regulations
	Non-statutory guidance
	Local procedures and protocols
	Individual responsibilities relating to exposures
	Responsibility for radiation safety
	Clinical audit

Table 2

Diagnostic radiology, radiotherapy and nuclear medicine

All Modalities	
General	Fundamentals of radiological anatomy
	Factors affecting radiation dose
	Dosimetry
	Fundamentals of clinical evaluation
	Identification of the individual being exposed
Diagnostic radiology	
General	Principles of radiological techniques
	Production of X-rays
	Equipment selection and use
Specialised Techniques	Computed Tomography: advanced applications
	Interventional procedures
	Cone Beam Computed Tomography
	Hybrid imaging
Fundamentals of Image Acquisition etc.	Optimisation of image quality and radiation dose
	Image formats, acquisition, processing, display and storage
Contrast Media	Use and preparation
	Contraindications
	Use of contrast injection systems
Radiotherapy	
General	Production of ionising radiation
	Treatment of malignant disease
	Treatment of benign disease

All Modalities	
Specialised Techniques	Principles of external beam radiotherapy
	Principles of brachytherapy
	Intra-operative radiotherapy
	Stereotactic radiotherapy and radiosurgery
	Stereotactic ablative radiotherapy
	Proton therapy
	MR Linac therapy
Radiobiological Aspects for Radiotherapy	Fractionation
	Dose rate
	Radiosensitisation
	Target volumes
Practical Aspects for Radiotherapy	Localisation equipment selection
	Therapy equipment selection
	Verification techniques including on-treatment imaging
	Treatment planning systems
Radiation Protection Specific to Radiotherapy	Side effects – early and late
	Toxicity
	Assessment of efficacy
Nuclear Medicine	
General	Atomic structure and radioactivity
	Radioactive decay
	Principles of molecular imaging and non-imaging exposures
	Principles of molecular radiotherapy
Molecular Radiotherapy	Dose rate
	Fractionation
	Radiobiology aspects
	Radiosensitisation
Specialised Techniques	Quantative imaging – advanced applications
	Hybrid imaging – advanced applications
	Selective Internal Radiation Therapy
Principles of Radiation Detection, Instrumentation and Equipment	Types of detection systems

All Modalities	
	Optimisation of image quality and radiation dose
	Image acquisition, artefacts, processing, display and storage
Radiopharmaceuticals	Calibration
	Working practices in the radiopharmacy
	Preparation of individual doses
Radiation Protection Specific to Nuclear Medicine	Conception, pregnancy and breastfeeding
	Arrangements for radioactive individuals

SCHEDULE 4 Regulation 21

Consequential amendments

Amendment of the Ionising Radiations Regulations (Northern Ireland) 2017

1.—(1) The Ionising Radiations Regulations (Northern Ireland) 2017(**1**) are amended as follows.

(2) In regulation 2(1) (interpretation)—

(a) for the definition of "carers and comforters" substitute—

> ""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 a medical exposure (other than as a carer and comforter);";

(b) in the definition of "medical exposure", after paragraph (d), insert—

> "(e) carers and comforters;".

(3) In regulation 3 (application)—

(a) in paragraph (2), omit "33";

(b) omit paragraph (4).

(4) Regulation 33 (equipment used for medical exposure) is revoked.

(5) In regulation 35(6) (duties of employees)—

(a) in sub-paragraph (a), after "overexposure;" insert "or";

(b) in sub-paragraph (b), omit "or" the second time it appears;

(c) omit sub-paragraph (c).

(6) In regulation 38(2)(d) (exemption certificates)—

(a) before "25(2)" insert "and";

(b) omit "and 33(1)".

(**1**) S.R. 2017 No. 229