

Consultation on the transposition of European Council Directive 2013/59/Euratom (Medical Exposures) in Northern Ireland

Proposed Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018

CONSULTATION DOCUMENT

October 2017

Contents

1. Introduction	3
2. Background	4
3. Legislative context	5
Current legislative provisions for medical exposure in Northern Ireland	5
Need for new Regulations	5
4. Key features of IR(ME)R (NI) 2018	6
Definition of “referrer”	6
Medical physics experts	6
Carers and comforters	7
Equipment	7
Exposure to ionising radiation for non-medical imaging purposes	7
Licensing	8
5. Assessment of regulatory, equality and other impacts	8
Regulatory Impact Assessment	9
Equality Impact Assessment and Human Rights Implications	9
Rural proofing	9
6. How to respond to this consultation	10
Annex I	11
Draft regulations	11
Annex II	27
Regulatory Impact Assessment Screening	27
Annex III	29
Consultation response questionnaire	29
Annex IV	33
Freedom of Information Act 2000 – confidentiality of consultations	33

Acknowledgement

This consultation document is based on the: *Consultation on the transposition of European Council Directive 2013/59/Euratom (Medical Exposures) - Laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation*¹ issued by the Department of Health in England, whose assistance is gratefully acknowledged.

¹ <https://www.gov.uk/government/consultations/regulations-on-medical-exposure-to-ionising-radiation>

1. Introduction

This consultation relates to transposition and implementation, in Northern Ireland, of 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. In order to transpose the requirements of the directive which relate to medical exposure, the Department of Health (the Department) is proposing to revoke and replace:

- The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000
- The Ionising Radiation (Medical Exposure) (Amendment) Regulations (Northern Ireland) 2010.

A similar process is being undertaken in England, Scotland and Wales, led by the Department of Health in England (DH), in conjunction with the Health Departments of the Devolved Administrations in Wales and Scotland. This process will also cover repeal and replacement of the following, UK-wide legislation:

- The Medicines (Administration of Radioactive Substances) Regulations 1978
- The Medicines (Administration of Radioactive Substances) Order 1978
- The Medicines (Administration of Radioactive Substances) Amendment Regulations 1995
- The Medicines (Administration of Radioactive Substances) Amendment Regulations 2006

Other aspects of the Directive, not relating to medical exposure, are the responsibility of other Government Departments and Agencies and separate consultation processes are being conducted. The Department is working with these other bodies and other UK administrations to ensure comprehensive transposition and implementation of the Directive. In particular, the Health and Safety Executive for Northern Ireland (HSENI) has recently consulted² on proposals for the Ionising Radiation Regulations (Northern Ireland) 2017 (to be made by the Department for the Economy) which will transpose requirements of the directive related to occupational health and safety

The purpose of this consultation is to seek views from the public and interested parties on the proposed regulations: **The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018**. The consultation will run from 24 October to 19 December 2017. All responses must be received into the Department by 5pm on the closing date. The Department invites your comments on the specific questions identified in Annex III. Information on how to respond is set out on page 28.

² <https://www.hseni.gov.uk/sites/hseni.gov.uk/files/consultations/%5Bcurrent-domain%3Amachine-name%5D/Ionising%20Radiations%20consultation%20document.pdf>

2. Background

EC Directive 2013/59/Euratom³ (generally known as the Basic Safety Standards Directive (BSSD)) was developed in response to the recommendations of the International Commission on Radiological Protection, published in 2007. It includes basic measures for the health protection of individuals against the dangers of ionising radiation in relation to medical exposure.

The aim of the Directive is to update and consolidate five existing directives and one Commission recommendation relating to radiation protection into one Directive. These are:

- Basic Safety Standards Directive 96/29/Euratom
- Medical Exposure Directive 97/43/Euratom
- Outside Workers Directive 90/641/Euratom
- Control of High Activity Sealed Radioactive Sources and Orphan Sources Directive 2003/122/Euratom
- Public Information Directive 89/618/Euratom
- Indoor Exposure to Radon Recommendation 90/143/Euratom

The BSSD as a whole was negotiated by a range of Government Departments and Agencies reflecting the UK Government leads for occupational, public and medical exposures. Development of approaches to transposition of the BSSD has followed a similar approach, with DH, in conjunction with Health Departments of the Devolved Administrations, leading for medical exposures. Co-ordination and overall responsibility for transposition of the BSSD lies with the Department for Business, Energy and Industrial Strategy (BEIS). The BSSD has a transposition date of 6 February 2018 and as a full member of the European Union, the UK is bound to comply with this requirement. This requirement is not affected by the decision that the UK will leave the European Union, following the referendum of 23 June 2016.

The BSSD includes ten Chapters and nineteen Annexes. The majority of the requirements relating to medical exposures are included within Chapter VII although other chapters address related and relevant requirements for medical exposures such as definitions, training, licensing, non-medical imaging and requirements relating to the Medical Physics Expert. These are all addressed within this consultation document.

Other chapters of the BSSD directly address occupational and public exposure. These are not considered as part of this consultation process because they are outside the scope of the Department's responsibility.

³ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013L0059>

3. Legislative context

Current legislative provisions for medical exposure in Northern Ireland

The current Northern Ireland (NI) regulations relating to medical exposures involving ionising radiation are listed in Section 1 and were based on previous European Council Directives made under the Euratom Treaty⁴, which was established in 1957. The Medical Exposure Directive provides the basis for The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000⁵ – known as IR(ME)R (NI) 2000. A number of Basic Safety Standards Directives have been adopted since 1959 and provide the basis for the UK-wide The Medicines (Administration of Radioactive Substances) Regulations 1978⁶ – known as MARS 1978.

IR(ME)R (NI) 2000 includes regulations on justification and optimisation, which are the two fundamental radiation protection principles that apply to medical exposures. The Regulations also provide a framework for radiation protection by identifying and placing responsibilities on duty holders – the employer, the practitioner, the operator and the referrer. In addition, the Regulations address clinical audit, expert advice, equipment and training. IR(ME)R (NI) 2000 are made under the section 2(2) of the European Communities Act 1972 and the provisions of the regulations are enforced as if they were health and safety regulations made under Article 17 of the Health and Safety at Work (Northern Ireland) Order 1978, with the Department as the enforcing authority.

MARS 1978 provides a system of certification for doctors and dentists who wish to administer radioactive substances to humans for the purpose of diagnosis, treatment or research. This is in response to an original requirement for a system of prior authorisation required under a Basic Safety Standards Directive from 1976, since repeated in subsequent Directives up to 1996. MARS 1978 are made under section 60 of the Medicines Act 1968 and enforced under the same Act.

Need for new Regulations

The BSSD introduces new requirements relating to medical exposure. BSSD implementation also offers an opportunity to update the existing regulations and make new ones which also include requirements that may have been addressed previously through administrative means. This is in line with the European Commission preference and the UK Government's approach to transposition.

A similar process taking place in England, Scotland and Wales will update the existing GB Regulations and the UK-wide MARS 1978 and consolidate them into a single set of Regulations – The Ionising Radiation (Medical Exposure) Regulations 2018 (IR(ME)R 2018).

IR(ME)R (NI) 2018 are intended to add clarity but do not seek to go further than the BSSD requires. This should minimise costs to stakeholders while still providing enhanced protection against radiation to people who are subject to medical exposure.

⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A12012A%2FTXT>

⁵ <http://www.legislation.gov.uk/nisr/2000/194/contents/made>

⁶ <http://www.legislation.gov.uk/uksi/1978/1006/contents/made>

4. Key features of IR(ME)R (NI) 2018

The draft IR(ME)R (NI) 2018 are attached to this consultation at Annex 1.

The major additions within Chapter VII of the BSSD include new requirements for accidental and unintended exposures (Article 63) and additional requirements relating to equipment (Article 60). These are addressed in IR(ME)R (NI) 2018 by Regulations 8-9 and 15-17 respectively. Other Articles have been enhanced and the Department proposes that specific requirements of IR(ME)R (NI) 2018 are revised from the previous regulations to reflect this. The intention is to consolidate into IR(ME)R (NI) 2018 all requirements of the BSSD that are intended to provide protection for those undergoing medical exposures. In particular, the following key issues will be addressed:

Definition of “referrer”

The definition of “referrer” in IR(ME)R (NI) 2018 (Regulation 2) relates to health care professionals which the Department would consider are entitled to refer patients and individuals for procedures involving exposure to ionising radiation. In Northern Ireland there are a number of situations where health care facilities have agreements to accept referrals from health care professionals in the Republic of Ireland (ROI) and vice versa. The definition for “referrer” in IR(ME)R (NI) 2000, as amended by The Ionising Radiation (Medical Exposure) (Amendment) Regulations (Northern Ireland) 2010, only referred to UK professional bodies, which has led to some issues in cases of cross border referrals.

Republic of Ireland (ROI) legislation on protection from medical ionising radiation is also currently being reviewed to take account of BSSD. The Department is in discussion with the ROI Department of Health, Health and Social Care Trusts and health care profession representatives in Northern Ireland and the Departmental Solicitor’s Office to agree a final provision in the regulations to address this problem. The definition in the attached draft regulations is, therefore, likely to be refined before the regulations are made.

Medical physics experts

While IR(ME)R (NI) 2000 included a specific Regulation (Regulation 9) on the need for expert advice and the involvement and availability of a Medical Physics Expert (MPE), it did not address criteria for or methods of recognition of MPEs. The BSSD describes in greater detail the role of the MPE, and IR(ME)R (NI) 2018 addresses this, the need for national recognition and the role of the MPE in providing the employer with advice on compliance with the Regulations. These points are included in an expanded Regulation 14 and a new Schedule (3) to the Regulations.

In order to address the requirement in the BSSD (and, therefore, in regulations) for MPEs to be recognised by the competent authority, DH has established a UK-wide

medical physics recognition scheme. Existing MPEs in Northern Ireland, who are entitled to act in that capacity by an employer under IRMER (NI) (2000), will need to apply to join a list of already authorised MPEs before 31 December 2017. All persons wishing to be recognised as MPEs for the first time after 31 December 2017 will be required to apply for recognition through an Assessing Body. Further details on the recognition scheme are available at:

www.gov.uk/government/publications/medical-physics-experts-recognition-scheme

The Department will be contacting employers and professional bodies in autumn 2016 to make them aware of these requirements. The recognition arrangements detailed above will result in the formation of a list for existing MPEs and a register for new MPEs following assessment. Details of how MPEs will transition from the list to the register will be released in due course by DH.

Carers and comforters

Exposure of carers and comforters is included within the BSSD definition of medical exposure. Although carers and comforters were previously addressed by the Department of Enterprise, Trade and Investment (DETI) in the health and safety legislation, the Ionising Radiations Regulations (Northern Ireland) 2000⁷, it is proposed that BSSD requirements for carers and comforters, including a new requirement for justification of individual exposures of carers and comforters, are included within IR(ME)R (NI) 2018 (Regulation 11).

Equipment

Although the BSSD includes some new requirements for equipment, those relating to quality assurance programmes and performance testing for medical equipment are largely unchanged. It is proposed that these requirements of Article 60, along with new requirements, are included within IR(ME)R (NI) 2018, rather than as previously within the DETI's Ionising Radiations Regulations (Northern Ireland) 2000.

Exposure to ionising radiation for non-medical imaging purposes

Outside of Chapter VII, Article 22 addresses practices involving the deliberate exposure of humans for non-medical imaging purposes. Further detail is provided at Annex V of the BSSD. The BSSD differentiates between those procedures that use medical radiological equipment and others that do not. It is proposed that the former are included within IR(ME)R (NI) 2018 to ensure the same regulatory framework and level of protection are provided to those subject to such exposures. Some of these exposures were previously dealt with by IR(ME)R (NI) 2000 as medico-legal exposures.

⁷ <http://www.legislation.gov.uk/nisr/2000/375/contents/made>

Licensing

Article 28(a) of the BSSD introduces requirements for licensing of the deliberate administration of radioactive substances to persons for diagnosis, treatment or research. This, along with Annex IX of the Directive, provides detailed requirements for licensing as compared to prior-authorisation in previous Basic Safety Standards Directives. To implement this, it is proposed that IR(ME)R (NI) 2018 include a requirement for licensing of practitioners and employers who wish to administer radioactive substances for these purposes. This will enable MARS 1978 to be revoked entirely, and responsibilities relating to such administrations to be consistent with those of other medical exposures.

Employers who provide services involving the administration of radioactive substances would need to hold an appropriate licence at each site, with each licence being granted either indefinitely or for a fixed term.

Individuals who act as IR(ME)R (NI) 2018 practitioners for the administration of radioactive substances would also need to hold an appropriate practitioner's licence. Each practitioner will only require one licence, regardless of the number of sites where they work and each licence would be granted for a fixed term.

Applications for employer and practitioner licences in Northern Ireland will continue to be managed by Public Health England (PHE) on behalf of the Department and assessed by the Administration of Radioactive Substances Advisory Committee (ARSAC).

PHE will develop a new IT system to allow applicants to submit their applications online. PHE proposes to charge fees for some types of applications to cost recover for the design, operation and maintenance of this system. The total cost of the new IT system has not been finalised and therefore the fees included within IR(ME)R (NI) 2018 are subject to final confirmation.

Further information on application processes will be provided in guidance which will be available later this year.

5. Assessment of regulatory, equality and other impacts

The requirements within the BSSD for medical exposure (largely Chapter VII of the BSSD) are similar in structure and content to those included in the previous Medical Exposure Directive, with articles addressing justification, optimisation, responsibilities, procedures, training (and recognition), equipment, special practices, pregnancy and breastfeeding and estimates of population doses. These articles are enhanced, but many of these changes are already addressed within existing NI, or UK-wide legislation, administrative processes and good practice within healthcare. The impact of the BSSD and IR(ME)R (NI) 2018 on stakeholders is likely to be low, as described below.

Regulatory Impact Assessment

Regulatory impact assessments (RIAs) are carried out for purposes of determining whether policy proposals are likely to have any direct or indirect impact on businesses or on the voluntary/community sector. An RIA screening has been carried out on these proposals and is provided at Annex II. Most of the additional costs to stakeholders relate to recognition of Medical Physics Experts and licensing requirements for employers and practitioners for the administration of radioactive substances to humans for the purposes of diagnosis, treatment and research. The screening concludes that the new legislation will have negligible cost impact on businesses, charities, social economy enterprises or the voluntary sector in Northern Ireland and will not otherwise adversely affect these groups. The Department considers that a full RIA is not required for IR(ME)R (NI) 2018.

Equality Impact Assessment and Human Rights Implications

Section 75 of the Northern Ireland Act 1998 requires public authorities, in carrying out their functions relating to Northern Ireland, to have due regard to the need to promote equality of opportunity between:

- persons of different religious belief, political opinion, racial group, age, marital status or sexual orientation;
- men and women generally;
- persons with a disability and persons without; and
- persons with dependants and persons without.

In addition, and without prejudice to the above obligations, public authorities should also, in carrying out their functions relating to Northern Ireland, have regard to the desirability of promoting good relations between persons of different religious belief, political opinion or racial group.

In accordance with guidance produced by the Equality Commission for Northern Ireland and in keeping with Regulation 75 of the Northern Ireland Act 1998, the proposals for the IR(ME)R (NI) 2018 have been screened for equality impact and a preliminary decision has been taken that a full Equality Impact Assessment is not required. In addition, it is considered that the provisions of the Regulations are compatible with the European Convention on Human Rights and the European Convention on the Rights of the Child.

Rural proofing

Rural proofing is the process by which policies, strategies and plans are assessed to determine whether they have a differential impact on rural areas and, where appropriate, adjustments are made to take account of particular rural circumstances, ensuring the fair and equitable treatment of rural communities. A rural proofing screening has been carried out as part of in the development of these legislation proposals and the Department concludes that they will not impact differentially on the rural needs of the people in Northern Ireland.

6. How to respond to this consultation

- If you wish to respond to this consultation, please do so by completing and returning the response questionnaire at **Annex III**. The questionnaire may also be downloaded from the e-consultation section of the Department's website: (<https://www.health-ni.gov.uk/consultations>).
- Additional copies of the consultation document can be obtained by contacting the Department's Secondary Care Directorate (contact details below).
- If you require any of these documents in another format or language, please contact the Department's Secondary Care Directorate.
- The closing date for responses is **19 December 2017**. Responses received after this date will only be considered in exceptional circumstances and with prior agreement from the Department.
- The completed response questionnaire can be returned via email or post and all queries you may have regarding this consultation should be addressed to the Department's Secondary Care Directorate.

Phone: 02890 378650

By email: IRMER2018Consultation@health-ni.gov.uk

By post: IR(ME)R (NI) 2018 Consultation
Secondary Care Directorate
Department of Health
Room 1
Annex 1
Castle Buildings
Stormont Estate
Belfast, BT4 3SQ

- Please ensure that the completed response questionnaire includes: your name, organisation (if relevant), address, telephone number and email (if applicable), and whether your comments represent your own view or the corporate view of your organisation.

2018 No. 0000

HEALTH AND SAFETY**The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland)
2018**

Made - - - - - *XXX 2018*

Coming into operation - *XXX 2018*

The Department of Health⁽⁸⁾, being a designated Department⁽⁹⁾ for the purposes of section 2(2) of the European Communities Act 1972⁽¹⁰⁾, 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⁽¹¹⁾; and with the consent of the Department of Finance in respect of the powers conferred by that section 56, makes the following Regulations:

Citation and commencement

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

Interpretation

2.—(1) In these Regulations—

“accidental exposure” means an exposure to ionising radiation of individuals as a result of an accident;

“adequate training” means training which satisfies the requirements of Schedule 4;

“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;

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

⁽⁸⁾ Formerly the Department of Health, Social Services and Public Safety; see 2016 c.5 (N.I.), s. 1(5)

⁽⁹⁾ S.I. 1977/1718

⁽¹⁰⁾ 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)

⁽¹¹⁾ 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

“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, medical exposures described in regulation 3 or practical aspects, at a given 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;

“exposure” means the act of exposing or condition of being exposed to ionising radiation emitted outside the body (external exposure) or within the body (internal exposure);

“health screening” means a procedure 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” means the Department;

“medical exposure” means an exposure coming within any of paragraphs (a), (b) or (c) of regulation 3;

“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 Department;

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

“medical radiological procedure” means any procedure giving rise to a 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 exposures to which these Regulations apply;

“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⁽¹²⁾, who is entitled in accordance with the employers 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 generally acceptable 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;

(12) 2002 c.17

“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;

“radiological installation” means a facility where exposures to which these Regulations apply are performed;

“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, or a health care professional who is a registered member of a profession regulated by a regulatory body of any EEA State, considered by the Department as equivalent to those listed in section 25(3) of that act, 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 the Department;

“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,

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 describes that individual.

(3) The Interpretation Act (Northern Ireland) 1954⁽¹³⁾ shall apply to these Regulations as it applies to an Act of the Northern Ireland Assembly.

Application

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

- (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) to individuals undergoing 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).

⁽¹³⁾ 1954 c. 33

Requirement to hold a licence

5.—(1) 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 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.

(4) The employer must ensure, where appropriate, that, written protocols are in place for every type of standard radiological practice coming within these Regulations.

(5) The employer must—

- (a) establish recommendations concerning referral guidelines for medical exposures, including radiation doses, and ensure that these are available to the referrer;
- (b) establish quality assurance programmes for written procedures and written protocols;
- (c) regularly review and make available to an operator, diagnostic reference levels in respect of an exposure 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 individual exposed or their representative are informed of the occurrence of a 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 exposure.

(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 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 in respect of justification and optimisation

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 he 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 on 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);
 - (c) it has been authorised by the practitioner or, where paragraph (5) applies, the operator;
 - (d) in the case of an exposure taking place in the course of a research programme under regulation 3(c), that programme 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 potential, the person has enquired whether that individual is pregnant or breastfeeding, if relevant.
- (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 carer or comforter 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 Department;
- (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)(c), the operator must do so in accordance with guidelines issued by the practitioner.

(6) In this regulation—

“appropriate medical scientific societies” means tbc;

“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⁽¹⁴⁾;
- (b) 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 Department;

“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;

“relevant bodies” means tbc.

Optimisation

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

⁽¹⁴⁾ S.I. 2004/1031

(2) In relation to all radiotherapeutic exposures 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 have regard, in particular 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 he 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 (Northern Ireland) 2016⁽¹⁵⁾) in the case of a child aged sixteen or seventeen) so to consent, a person with parental responsibility (within the meaning of Article 6 of the Children (Northern Ireland) Order 1995⁽¹⁶⁾) for the child; or
- (c) where the patient is an adult who lacks capacity (within the meaning of the Mental Capacity Act (Northern Ireland) 2016) 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 radiological installation where the exposure was carried out.

(8) In complying with the obligations under this regulation, the practitioner and the operator must have regard, in particular to—

- (a) medical exposures of children;
- (b) medical exposures as part of a health screening programme;
- (c) medical exposures involving high doses to the individual being exposed;
- (d) where appropriate, individuals in relation to 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

⁽¹⁵⁾ 2016 c.18

⁽¹⁶⁾ S.R. 1995 No. 755 (N.I. 2)

- (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 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 the distribution by age and gender of the exposed population and, when so requested, shall provide it to the Department.

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 Department;
- (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, in all other radiological practices;
- (e) give advice on—
 - (i) dosimetry and quality assurance matters relating to radiation protection concerning exposures;
 - (ii) physical measurements for the evaluation of the dose delivered;
 - (iii) medical radiological equipment; and
- (f) contribute in particular 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 that a person may be exposed to from an exposure described in regulation 3, by way of the ordinary operation of that equipment; and
 - (ii) the administered activity to be verified;
- (b) 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)(b) 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 acceptable performance criteria for equipment; 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 1MeV 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 relevant training undertaken by all practitioners and operators engaged by the employer to carry out any exposures or any practical aspect of such exposures 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.

Raising of awareness

18. Any person who has control over a radiological installation must take measures to raise awareness of the effects of ionising radiation amongst individuals capable of childbearing or breastfeeding.

Enforcement

19.—(1) These Regulations are to be enforced as if they were health and safety regulations made under Article 17 of the Health and Safety at Work (Northern Ireland) Order 1978⁽¹⁷⁾ and, except as provided in paragraph (2) and regulation 21, the provisions of that Order, as regards enforcement and offences, are to apply for the purposes of these Regulations.

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

Defence of due diligence

20. 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

21.—(1) The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000⁽¹⁸⁾ are revoked.

(2) The Medicines (Administration of Radioactive Substances) Regulations 1978⁽¹⁹⁾ and the Medicines (Radioactive Substances) Order 1978⁽²⁰⁾ are revoked to the extent that they apply to Northern Ireland.

(3) The transitional provisions in paragraph (4) applies in respect of the revocations in paragraph (2).

(4) 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.

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

Sealed with the Official Seal of the Department of Health on 16th January 2018



Name
A senior officer of the
Department

SCHEDULE 1 Licensing

Regulation 4

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.

⁽¹⁷⁾ S.I. 1978/1039 (N.I. 9) as amended by S.I. 1998/2795 (N.I. 18)

⁽¹⁸⁾ S.R. 2000 No. 194

⁽¹⁹⁾ S.I. 1978/1006

⁽²⁰⁾ S.I. 1978/1004

- (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

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 subparagraph (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 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 diagnostic reference levels established by the employer 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 exposures 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 14

Medical Physics Experts

8. 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

9. 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

<i>Management and Radiation Protection of the individual being exposed</i>	
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
<i>Statutory Requirements and Non-Statutory Regulations</i>	
	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

<i>All Modalities</i>	
General	Fundamentals of radiological anatomy Factors affecting radiation dose Dosimetry Fundamentals of clinical evaluation Identification of the individual being exposed
<i>Diagnostic radiology</i>	
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

	<p>Contra-indications</p> <p>Use of contrast injection systems</p>
<hr/>	
<i>Radiotherapy</i>	
<hr/>	
General	<p>Production of ionising radiation</p> <p>Treatment of malignant disease</p> <p>Treatment of benign disease</p> <p>Principles of external beam radiotherapy</p> <p>Principles of brachytherapy</p>
Specialised Techniques	<p>Intra-operative radiotherapy</p> <p>Stereotactic radiotherapy and radiosurgery</p> <p>Stereotactic ablative radiotherapy</p> <p>Proton therapy</p> <p>MR Linac therapy</p>
Radiobiological Aspects for Radiotherapy	<p>Fractionation</p> <p>Dose rate</p> <p>Radiosensitisation</p> <p>Target volumes</p>
Practical Aspects for Radiotherapy	<p>Localisation equipment selection</p> <p>Therapy equipment selection</p> <p>Verification techniques including on-treatment imaging</p> <p>Treatment planning systems</p>
Radiation Protection Specific to Radiotherapy	<p>Side effects – early and late</p> <p>Toxicity</p> <p>Assessment of efficacy</p>
<hr/>	
<i>Nuclear Medicine</i>	
<hr/>	
General	<p>Atomic structure and radioactivity</p> <p>Radioactive decay</p> <p>Principles of molecular imaging and non-imaging exposures</p> <p>Principles of molecular radiotherapy</p>
Molecular Radiotherapy	<p>Dose rate</p> <p>Fractionation</p> <p>Radiobiology aspects</p> <p>Radiosensitisation</p>
Specialised Techniques	<p>Quantitative imaging – advanced applications</p> <p>Hybrid imaging – advanced applications</p> <p>Selective Internal Radiation Therapy</p>
Principles of Radiation Detection, Instrumentation and Equipment	<p>Types of detection systems</p> <p>Optimisation of image quality and radiation dose</p> <p>Image acquisition, artefacts, processing, display and storage</p>
Radiopharmaceuticals	<p>Calibration</p> <p>Working practices in the radiopharmacy</p> <p>Preparation of individual doses</p>
Radiation Protection Specific to Nuclear Medicine	<p>Conception, pregnancy and breastfeeding</p> <p>Arrangements for radioactive individuals</p>
<hr/>	

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

Regulatory Impact Assessment Screening

Proposed Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 and underpinning policy

Introduction

This regulatory impact assessment screening has been undertaken for the purposes of determining whether the proposed Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 (IR(ME)R (NI) 2018) and underpinning policy are likely to have a direct or indirect impact on businesses or on the community and voluntary sector in terms of imposing costs or savings on these organisations. 'Business' does not include public bodies such as Health and Social Care (HSC) Trusts.

Background

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 is generally known as the Basic Safety Standards Directive (BSSD). In order to transpose the requirements relating to medical exposure of the Directive into legislation in Northern Ireland, the Department of Health (the Department) is proposing to make *The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018*. The proposed new regulations will be similar to the existing *Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000* (which will then be revoked) but will incorporate enhanced measures to cover new requirements of BSSD, including:

- Addressing accidental and unintended exposures;
- Additional requirements relating to equipment;
- Recognition of Medical Physics Experts (MPEs) by the competent authority;
- New licensing arrangements for employers and practitioners for the administration of radioactive substances;

Further details on the proposals for IR(ME)R (NI) 2018 can be found in the main body of this consultation document.

Similar legislation is being introduced concurrently by the Department of Health in England (DH), for England Scotland and Wales. As part of this process DH has carried out a Regulatory Triage Assessment²¹. This has identified that the main impacts on businesses will be in costs for the new licensing arrangements and the recognition scheme for MPEs. The new licensing arrangements will mean the introduction of licences for both employers and practitioners and a fixed fee. However, most applicants will be from the HSC. In order to establish a recognition scheme for MPEs, DH, as the UK Competent Authority has asked a not-for-profit company known as RPA2000 to undertake the recognition of new

²¹ www.gov.uk/government/uploads/system/uploads/attachment_data/file/627849/Annex_II_Regulatory_Triage_Assessment.pdf

MPEs from February 2018. Applicants will have to pay a fee to RPA2000 in order to undergo the recognition process. Existing MPEs will pay an annual maintenance fee to stay on the register. Again, most applicants will be from the HSC.

Screening Questions	Response to Screening Questions	Full Appraisal Required	Justification/Key Issues and Groups to Focus On
Is the policy or amendment to the policy likely to have a direct or indirect impact on businesses	Yes – but considered negligible	No	<p>Currently there is one private (non-HSC) facility in Northern Ireland which would require licencing of employers or practitioners for the purposes of the proposed regulations. The Department estimates the maximum licencing cost for this facility to be £700 per annum*, which it considers negligible compared to other running costs.</p> <p>The Department estimates there are currently approximately five MPEs working in Northern Ireland who are not employed by HSC. The estimated maximum cost to business of annual MPE maintenance fees is £150*. Application for a new MPE would be a one-off cost of £300* and, outside of HSC bodies, would only occur infrequently. The Department considers these costs negligible compared to other running costs.</p>
Is the policy or amendment to the policy likely to have a direct or indirect impact on community and voluntary sector	No	No	<p>Currently there are no voluntary or community facilities in Northern Ireland which would require licencing of employers or practitioners for the purposes of the proposed regulations.</p> <p>The Department is not aware of any exclusively non-HSC MPEs working in Northern Ireland for voluntary or community facilities.</p>
Conclusion		No	A full Regulatory Impact Assessment is not required.

* This cost estimate is based on calculations carried out by DH part of a regulatory triage assessment. Full details of calculations and assumptions are available at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/627849/Annex_II_Regulatory_Triage_Assessment.pdf

Consultation response questionnaire

You can respond to the consultation document by email or post.

Before you submit your response, please read **Annex IV** at the end of this questionnaire, regarding the Freedom of Information Act 2000 and the confidentiality of responses to public consultation exercises.

Responses should be sent to:

By email: IRMER2018Consultation@health-ni.gov.uk

By post: IR(ME)R (NI) 2018 Consultation
Secondary Care Directorate
Department of Health
Room 1
Annex 1
Castle Buildings
Stormont Estate
Belfast, BT4 3SQ

RESPONSES CANNOT BE CONSIDERED AFTER 5pm 19 December 2017

I am responding: as an individual on behalf of an organisation

(please tick a box)

Name:

Job Title:

Organisation:

Address:

Tel:

email:

We are seeking your views and comments on a number of provisions which we intend to include in the new Regulations to reflect the new requirements introduced by the BSSD. The areas of interest are:

1. Definition of referrer

The Department is in discussion with the Republic of Ireland's Department of Health, Health and Social Care Trusts and health care profession representatives in Northern Ireland and the Departmental Solicitor's Office to agree a definition of referrer that will facilitate cross-border referrals from health care professionals for procedures involving exposure to ionising radiation.

- Do you support the expansion of the definition of "referrer" in IR(ME)R (NI) 2018 to facilitate cross-border referrals?
- Do you envisage any other cross-border issues pertaining to IR(ME)R (NI) 2018? If so, please give details.

2. Duties of the employer with regard to accidental and unintended exposures

IR(ME)R (NI) 2018 will expand requirements for reporting of incidents. This will require the Competent Authority to define significant events (in effect as now) but does not require it to define clinically significant accidental or unintended exposures.

- Do you support reporting of significant events under IR(ME)R (NI) 2018, regardless of whether these result from equipment or procedural failure?
- Do you agree that the definition of clinically significant exposures should be the responsibility of professional scientific and medical societies rather than the Competent Authority?
- Do you support the view that any such exposure should however be considered as a significant event and reported to the Competent Authority?
- Do you support the reporting of significant events in radiotherapy where doses are less than intended?

3. Duties of the employer with regard to quality assurance programmes for equipment when used in medical exposures

IR(ME)R (NI) 2018 offers an opportunity to include in one set of Regulations requirements relating to medical exposure (rather than occupational or public exposure) associated with medical radiological equipment, including inventories, surveillance and quality assurance programmes.

- Do you support inclusion of these requirements within IR(ME)R (NI) 2018?

4. Medical physics experts

The BSSD is more prescriptive about the role of the medical physics expert.

- Do you object to medical physics experts advising employers on compliance?
- Do you think the Regulations should require employers to appoint MPEs?

5. Carers and comforters

The BSSD defines medical exposure as including exposures made to carers and comforters and requires that such exposures are justified individually and subject to dose constraints.

- Do you support the inclusion of requirements for carers and comforters within IR(ME)R (NI) 2018?

6. Non-medical imaging

The BSSD has introduced non-medical imaging as a new type of exposure and categorises these exposures as those resulting from the use of medical radiological equipment and those that do not.

- Do you support the inclusion of non-medical imaging using medical radiological equipment within IR(ME)R (NI) 2018?
- Do you think dose constraints or dose limits should be applied to such exposures?

7. Licensing for the administration of radioactive substances

IR(ME)R (NI) 2000 and MARS 1978 (and associated amending regulations) will be replaced by IR(ME)R (NI) 2018 and similar regulations in England, Scotland and Wales. A dual licensing system will be introduced to satisfy more stringent requirements of the BSSD and charges for licences will need to be made on a cost recovery basis.

- Do you agree that charges should not be levied on practitioners who wish to hold a licence?
- Do you think licences for employers should be for a fixed period or reviewed only when amendments are sought?
- Do you support a single licence for practitioners?

8. Diagnostic reference levels (DRLs)

The BSSD extends requirements for DRLs but retains the requirement that DRLs should have regard to European DRLs where available

- Do you support extending requirements in IR(ME)R (NI) 2018 to having regard to National DRLs as well as European values?

9. Adequate training

Training requirements for practitioners and operators are listed in Schedule 4 of the draft Regulations.

- Please provide comments on Schedule 4 – amendments and deletions - noting that the intention of the Schedule is not to replace or replicate the detail of established training programmes.

Equality Implications

Section 75 of the Northern Ireland Act 1998 requires the Department to have due regard to the need to promote equality of opportunity between persons of different religious belief, political opinion, racial group, age, marital status or sexual orientation; between men and women generally; between persons with a disability and persons without; and between persons with dependants and persons without. The Department is also required to have regard to the desirability of promoting good relations between persons of a different religious belief, political opinion or racial group.

The Department has therefore screened the policy implications of the draft Regulations for equality impact and a preliminary decision has been taken that a full Equality Impact Assessment is not required. If you disagree with this decision, we invite you to consider the recommendations from a Section 75 perspective by considering and answering the questions below. Answering these questions will contribute to the completion and outcome of the Department's screening exercise.

E1. Are the actions/proposals set out in this consultation document likely to have an adverse impact on any of the nine equality groups identified under Section 75 of the Northern Ireland Act 1998? If yes, please state which group or groups and provide comment on how these adverse impacts could be reduced or alleviated in the proposals.

E2. Are you aware of any indication or evidence – qualitative or quantitative – that the actions/proposals set out in this consultation document may have an adverse impact on equality of opportunity or on good relations? If yes, please give details and comment on what you think should be added or removed to alleviate the adverse impact.

E3. Is there an opportunity to better promote equality of opportunity or good relations? If yes, please give details as to how.

E4. Are there any aspects of these recommendations where potential human rights violations may occur?

Thank you for your comments.

Please return your response questionnaire.

Responses must be received no later than 5pm 19 December 2017

Freedom of Information Act 2000 – confidentiality of consultations

The Department will publish a summary of responses following completion of the consultation process. Your response, and all other responses to the consultation, may be disclosed on request. The Department can only refuse to disclose information in exceptional circumstances. **Before** you submit your response, please read the paragraphs below on the confidentiality of consultations and they will give you guidance on the legal position about any information given by you in response to this consultation.

The Freedom of Information Act gives the public a right of access to any information held by a public authority, namely, the Department in this case. This right of access to information includes information provided in response to a consultation. The Department cannot automatically consider as confidential information supplied to it in response to a consultation. However, it does have the responsibility to decide whether any information provided by you in response to this consultation, including information about your identity should be made public or be treated as confidential.

This means that information provided by you in response to the consultation is unlikely to be treated as confidential, except in very particular circumstances. The Lord Chancellor's Code of Practice on the Freedom of Information Act provides that:

- the Department should only accept information from third parties in confidence if it is necessary to obtain that information in connection with the exercise of any of the Department's functions and it would not otherwise be provided;
- the Department should not agree to hold information received from third parties "in confidence" which is not confidential in nature; and
- acceptance by the Department of confidentiality provisions must be for good reasons, capable of being justified to the Information Commissioner.

For further information about confidentiality of responses please contact the Information Commissioner's Office (or see website at: <http://www.informationcommissioner.gov.uk/>).