



# IONISING RADIATION (MEDICAL EXPOSURE) REGULATIONS 2019

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Statutory Document No. 2019/0282

*Health and Safety at Work Etc. Act 1974*

## IONISING RADIATION (MEDICAL EXPOSURE) REGULATIONS 2019<sup>1</sup>

*Approved by Tynwald:* 17 July 2019  
*Coming into Operation:* 1st August 2019

The Department of Environment, Food and Agriculture makes the following Regulations, after consulting such organisations as it considers represent the interests affected by the regulations<sup>1</sup>, under sections 15(1), (2), (3)(c), (4)(a), (5)(a), (6)(b), (8) and (10) and 82(3)(a) of, and paragraphs 1(1)(a), 2, 4 to 9, 11, 13, 14, 16, 20, 21 and 23 of Schedule 3 to, the Health and Safety at Work Etc. Act 1974<sup>2</sup> (an Act of Parliament), as it has effect in the Island<sup>3</sup>.

### 1 Title

These Regulations are the Ionising Radiation (Medical Exposure) Regulations 2019.

### 2 Commencement

If approved by Tynwald, these Regulations come into operation on 1 August 2019<sup>4</sup>.

### 3 Interpretation

(1) In these Regulations —

“**the 1974 Act**” means the Health and Safety at Work etc. Act 1974 as it applies in the Island;

“**accidental exposure**” means an exposure of an individual as a result of an accident;

<sup>1</sup> As required by section 82(4) of the Health and Safety at Work Etc. Act 1974 as it applies to the Island

<sup>2</sup> 1974 c.37

<sup>3</sup> SD 155/98 as amended by SD 984/07

<sup>4</sup> Tynwald approval is required under section 82(5) of the Health and Safety at Work Etc. Act 1974 as it applies in the Island.

“**adequate training**” means training which satisfies the requirements of Schedule 3 and the expression “**adequately trained**” is to be construed accordingly;

“**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 an 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;

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

“**employer**” means any person who, in the course of a trade, business or other undertaking, carries out (other than as an employee), or engages others to carry out, those exposures described in regulation 4 or practical aspects, at a given radiological installation;

“**employer’s procedures**” means the procedures established by an employer pursuant to regulation 7(1);

“**equipment**” means equipment which –

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

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

“**health care professional**” has the same meaning as that prescribed in section 3 of the Health Care Professionals Act 2014<sup>5</sup>;

“**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;

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<sup>5</sup> AT 9 of 2014

- “**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  $3 \times 10^{15}$  hertz or more capable of producing ions directly or indirectly;
- “**Licensing Authority**” for the purpose of licensing any practitioner or employer in respect of the administration of radioactive substances, for the purpose of these Regulations, means the Department or the United Kingdom Licensing Authority as defined in the Ionising Radiation (Medical Exposure) Regulations 2017<sup>6</sup> (as in operation from time to time);
- “**medical exposure**” means an exposure coming within any of paragraphs (a) to (e) of regulation 4;
- “**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 Licensing Authority;
- “**medical radiological**” means pertaining to radiodiagnostic and radiotherapeutic procedures, and interventional radiology or other medical uses of ionising radiation for planning, guiding and verification purposes;
- “**medical radiological 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;

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<sup>6</sup> SI 2017 No. 1322

“**practitioner**” means a health care professional who is entitled in accordance with the employer’s procedures to take responsibility for an individual exposure;

“**quality assurance**” means all those planned and systematic actions necessary to provide adequate assurance that a structure, system, component or procedure will perform satisfactorily in compliance with generally applicable standards and 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 and includes monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled;

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

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

“**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 health care professional who is entitled in accordance with the employer’s procedures to refer individuals for exposure to a practitioner; and

“**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 is —

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

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

## 4 Application

These Regulations apply to the exposure of ionising radiation in the Island —

- (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; and
- (f) to individuals undergoing non-medical imaging using medical radiological equipment.

## **5 The Licensing Authority**

- (1) The Licensing Authority may 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 considers appropriate;
  - (b) subject to such conditions as the Licensing Authority may consider appropriate; and
  - (c) varied or revoked at any time.
- (3) Schedule 1 makes further provision relating to the application for, and the issue of, a licence described in paragraph (1).

## **6 Requirement to hold a licence**

- (1) A person must 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 12 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.

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

- (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 –
  - (a) complies with the provisions of regulation 18(1); and
  - (b) undertakes continuing education and training after qualification including, in the case of clinical use of new techniques, training related to those 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, including practices involving non-medical imaging.
- (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 –
    - (i) regulation 4(a) –
      - (A) where the exposure involves interventional radiology procedures, in which case, diagnostic reference levels are to be provided where appropriate; and
      - (B) where the exposure does not involve interventional radiology procedures, in which cases regard must be had to European and national diagnostic reference levels where available;
    - (ii) regulation 4(b) or (e) in which cases regard must be had to European and national diagnostic reference levels where available;
    - (iii) regulation 4(f) where practicable;
  - (d) establish dose constraints –
    - (i) for biomedical and medical research programmes falling within regulation 4(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 falling within regulation 4(d).
- (6) A dose constraint must be established by the employer 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.
- (8) The employer must take measures to raise awareness of the effects of ionising radiation amongst individuals capable of childbearing or breastfeeding.

## **8 Employer's duties: clinical audit**

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

## **9 Employer's duties: accidental or unintended exposure**

- (1) The employer's procedures must provide that the referrer, the practitioner, and the individual exposed or their representative (if there is one) 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 exposures.
- (3) The employer must establish a system for recording analyses of events involving or potentially involving accidental or unintended exposures proportionate to the radiological risk posed by the practice.
- (4) Where the employer knows or has reason to believe that an accidental or unintended exposure has or may have occurred in which a person, while undergoing –
  - (a) any exposure, was or could have been exposed to levels of ionising radiation significantly greater than those generally considered to be proportionate in the circumstances;
  - (b) a radiotherapeutic exposure was or could have been exposed to levels of ionising radiation significantly lower than those generally considered to be proportionate in the circumstances,the employer must –
  - (i) undertake an immediate preliminary investigation of the incident;

- (ii) unless that investigation shows beyond a reasonable doubt that no such exposure has occurred, immediately notify the Department;
- (iii) conduct or arrange for a detailed investigation of the circumstances of the exposure and an assessment of the dose received; and
- (iv) notify the Department, within the time period specified by the Department, of the outcome of the investigation and any corrective measures adopted.

## **10 Duties of the Department: accidental or unintended exposure**

The Department 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.

## **11 Duties of the practitioner, operator and referrer**

- (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 practical aspect which the operator carries out as well as for any authorisation given pursuant to regulation 12(5).
- (5) The referrer must supply the practitioner with sufficient medical data (such as previous diagnostic information or medical records) relevant to the exposure requested by the referrer to enable the practitioner to decide whether there is a sufficient net benefit as required by regulation 12(1)(b).
- (6) The practitioner and the operator must co-operate, regarding practical aspects, with other specialists and staff involved in an exposure, as appropriate.

## **12 Justification of individual exposures**

- (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 4(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 4(f) (non-medical imaging), 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 where a 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; or
  - (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 persons or 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 11(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 –
- “ethics committee”** means –
- (a) the Isle of Man Research Ethics Committee (IOMREC); or
  - (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 of Health and Social Care; and

**“individual detriment”** means clinically observable deleterious effects in individuals or their descendants, the appearance of which is either immediate or delayed and, in the latter case, implies a probability rather than a certainty of appearance.

### 13 Optimisation

- (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.

- (2) In relation to all radiotherapeutic exposures the practitioner must ensure that exposures of target volumes are individually planned and 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 and evaluation of patient dose or administered activity; and
  - (c) adherence to such diagnostic reference levels for radiodiagnostic examinations falling within regulation 4(a), (b), (e) and (f) as the employer may have established, as set out in the employer's procedures.
- (4) For each medical or biomedical research programme falling within regulation 4(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, either alone or with the input of the referrer, 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 4(d), the employer's procedures must provide that appropriate guidance is established for the exposure of carers and comforters.
- (6) In the case of patients undergoing treatment or diagnosis with radioactive substances, the employer's procedures must provide that, where appropriate, written instructions and information are provided to —
  - (a) the patient, where the patient has capacity to consent to the treatment or diagnostic procedure;

- (b) where the patient is a child who lacks capacity (within the meaning of Chapter 15 of the Code of Practice 2011 issued under section 116 of the Mental Health Act 1998<sup>7</sup> in the case of a child aged sixteen or seventeen) so to consent, a person with parental responsibility (within the meaning of the Children and Young Persons Act 2001<sup>8</sup>) for the child; or
  - (c) where the patient is an adult who lacks capacity (within the meaning of Chapter 15 of the Code of Practice 2011 issued under the Mental Health Act 1998) 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 pay particular attention in relation 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 whom pregnancy cannot be excluded and who are undergoing a medical exposure, in particular if abdominal and pelvic regions are involved, taking into account the exposure of both the individual and any unborn child; and
  - (e) where appropriate, individuals who are breastfeeding and who are undergoing a medical exposure involving the administration of radioactive substances, taking into account the exposure of both the individual and the child.
- (9) The employer must take steps to ensure that a clinical evaluation of the outcome of each exposure, other than where the person subject to the exposure is a carer or a comforter, is recorded in accordance with the employer’s procedures including, where appropriate, factors relevant to patient dose.

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<sup>7</sup> AT 8 of 1998.

<sup>8</sup> AT 20 of 2001.

## 14 Estimates of population doses

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, must provide the dose estimates to the Department.

## 15 Expert advice

- (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) be closely involved in every radiotherapeutic practice other than standardised therapeutic nuclear medicine practices;
  - (b) be involved in practices including standardised therapeutic nuclear medicine practices, diagnostic nuclear medicine practices and high dose interventional radiology and high dose computed tomography;
  - (c) be involved as appropriate for consultation on optimisation, in all other radiological practices not mentioned in sub-paragraphs (a) and (b); and
  - (d) give advice on –
    - (i) dosimetry and quality assurance matters relating to radiation protection concerning exposures;
    - (ii) physical measurements for the evaluation of dose delivered; and
    - (iii) medical radiological equipment.
- (3) A medical physics expert must also contribute to the following matters –
  - (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; and
  - (i) the provision of advice to an employer relating to compliance with these Regulations.
- (4) The medical physics expert must, where appropriate, liaise with a radiation protection adviser and a radioactive waste adviser.
- (5) In this regulation –
- (a) “radiation protection adviser” means an individual who, or a body which, is competent to advise on radiation protection in relation to occupational and public exposures; and
  - (b) “radioactive waste adviser” means an individual who, or a body which is competent to provide expert advice on radioactive waste management and environmental radiation protection.

## **16 Equipment: general duties of the employer**

- (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 to which these Regulations apply, by way of the ordinary operation of that equipment; and
    - (ii) the administered activity to be verified; and
  - (b) draw up, keep up-to-date and preserve at each radiological installation an inventory of equipment at that installation and, when so requested, must provide it to the Department.
- (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; and
  - (c) performance testing following a maintenance procedure which is capable of affecting the equipment’s performance.



- (4) A person must not 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) 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, following the application of any criteria specified under sub-paragraph (b), equipment is ascertained to be defective; such corrective action may include taking the equipment out of service.

## **17 Equipment installed on or after the date these regulations come into operation**

- (1) This regulation only applies in respect of –
  - (a) equipment installed on or after the date these regulations come into operation; and
  - (b) an employer who has control of any such equipment.
- (2) Equipment used for external beam radiotherapy with a nominal beam energy 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 exposure, 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 exposure.

## **18 Training**

- (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 adequate 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 Department 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 ("employer A") enters into a contract with another employer ("employer B") to engage a practitioner or operator otherwise employed by that employer B, employer B is responsible for keeping the records required by paragraph (4) and must supply such records to employer A immediately upon request.
- (6) Schedule 3 makes further provision about the training of practitioners and operators.

## **19 Defence of due diligence**

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 the person took all reasonable steps and exercised all due diligence to avoid committing the offence.

## **20 Transitional provisions**

- (1) This regulation applies to any employer or practitioner required to hold a licence under regulation 6 who is –
  - (a) operating an the installation (in the case of an employer); or
  - (b) practising (in the case of a practitioner),immediately before the date these Regulation come into force and where such operation or practice continues after that date.

- (2) An application for a licence must be made to the Licensing Authority within four months of the date these Regulations come into operation.
- (3) Subject to compliance with these Regulations and paragraph (2) such operation or practice may continue unless the Licensing Authority provides notice that the employer or the practitioner must cease to do so.
- (4) Where an application is made under paragraph (2) to the Department —
  - (a) the Department must provide a receipt to the applicant within 5 working days of receiving the application;
  - (b) the application is deemed to have been received when it has been received by the Department;
  - (c) after consideration of the application the Department must provide to the applicant —
    - (i) a notice confirming that the licence has been granted, including any conditions or time limits to which the licence is subject;
    - (ii) a notice confirming the Department's refusal to grant a licence and the reasons for such refusal; or
    - (iii) a request for any further information required by the Department to consider the application.
- (5) A notice under paragraph (3)(c)(i) or (ii) may include —
  - (a) directions to the employer including (but not limited to) the cessation of the operation of the installation;
  - (b) directions to the practitioner including (but not limited to) that the practitioner must cease practising; and
  - (c) conditions on the employer or practitioner (which may include a limit of time).
- (6) The provisions in Schedule 1 apply to applications made under this regulation.
- (7) In this regulation “applicant” means a person making an application for a licence under this regulation.
- (8) This regulation is without prejudice to any power of the Department under the 1974 Act.

**MADE 19 JUNE 2019**



**SCHEDULE 1**

[Regulations 5 and 20]

**LICENSING****1 Licence applications: general**

- (1) A person required by regulation 6 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; and
  - (b) upon request in writing, any other information which the Licensing Authority requires for the purpose of considering the licence application.
- (3) Where the Licensing Authority is not the Department a person applying for a licence under sub-paragraph (1) must provide a copy of —
  - (a) the licence application; and
  - (b) the outcome of the application,to the Department within 10 working days of the application being made or the outcome being received (as applicable).
- (4) 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.

**2 Licence applications: indicative list of information**

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; and
- (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; and
- (j) quality assurance.

### **3 Licence applications: urgent cases**

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.

### **4 Licence applications to the Department: audits and inspections**

- (1) If an application is made for a licence to the Department may require that —
  - (a) an audit or inspection be undertaken by a relevant external organisation or specialist; and
  - (b) a copy of the resulting report be provided to the Department.
- (2) All costs associated with the undertaking of any such audit or inspection and the provision of the resulting report are payable by the applicant directly to the relevant external organisation or specialist.

### **5 Review**

- (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 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 sub-paragraph (1); and
  - (b) must particularise in writing the reasons for seeking the review.

## **6 Licence applications: appeals after review by the Department**

- (1) A person who is aggrieved by, —
  - (a) a decision of the Department —
    - (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 Department,

after the decision or terms (as applicable) have been reviewed by the Department pursuant to paragraph 5, may appeal to the Health and Safety Tribunal.
- (2) Section 44 of the 1974 Act applies for the purposes of paragraph 5(1) as it applies to an appeal under section 44(1) of the 1974 Act.
- (3) The Health and Safety (Improvement and Prohibition Notices and Licences Appeals to Industrial Tribunal) Rules 1981 apply to an appeal under paragraph 6(1) as they apply to an appeal under section 44(1) of the 1974 Act.

**SCHEDULE 2**

[Regulation 7]

**EMPLOYER'S PROCEDURES**

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 4(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 13(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 4(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 13(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; and



- (n) to establish appropriate dose constraints and guidance for the exposure of carers and comforters.

## SCHEDULE 3

[Regulation 18]

## ADEQUATE TRAINING

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**

<i>Fundamental Physics of Radiation</i>	
<b>Properties of radiation</b>	Excitation and ionisation Attenuation of ionising radiation Scattering and absorption
<b>Radiation hazards and dosimetry</b>	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>	
<b>Special attention areas</b>	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
<b>Justification</b>	Justification of the individual exposure Use of existing appropriate radiological information Alternative techniques
<b>Radiation protection</b>	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

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*Statutory Requirements and Non-Statutory Guidance*

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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**

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*All Modalities*

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

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<b>General</b>	Principles of radiological techniques Production of X-rays Equipment selection and use
<b>Specialised techniques</b>	Computed Tomography: advanced applications Interventional procedures Cone Beam Computed Tomography Hybrid imaging
<b>Fundamentals of image acquisition etc.</b>	Optimisation of image quality and radiation dose Image formats, acquisition, processing, display and storage
<b>Contrast media</b>	Use and preparation Contraindications Use of contrast injection systems

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*Radiotherapy*

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

## ENDNOTES

### Table of Endnote References

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<sup>1</sup> The format of this legislation has been changed as provided for under section 75 of, and paragraph 2 of Schedule 1 to, the Legislation Act 2015. The changes have been approved by the Attorney General after consultation with the Clerk of Tynwald as required by section 76 of the Legislation Act 2015.