
**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

ARRANGEMENT OF REGULATIONS

Regulation

PART I - PRELIMINARY

1. Title.
2. Interpretation.

**PART II - ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS**

3. Control of administration of radioactive medicinal products.
4. Grant of certificates.
5. Duration and renewal of certificates.
6. Suspension, revocation and variation of certificates.
7. Hearings and written representations.

PART III - MEDICAL EXPOSURES

8. Application of this Part.
9. Duties of employer.
- 9A. Employer's duties re accidental or unintended exposure.
- 9B. Competent authority's duties re accidental and unintended exposure.
10. General responsibilities and duties of referrer, practitioner and operator.
11. Justification of individual medical exposures.
12. Optimisation.
13. Clinical audit.
14. Expert advice.
15. Radiological equipment.
- 15A. Equipment installed on or after 6 February 2018.
16. Training.

**PART IV - ENFORCEMENT AND SUPPLEMENTARY
PROVISIONS**

17. Appointment and powers of inspectors.
18. Improvement notices.
19. Prohibition notices.
20. Provisions supplementary to regulations 18 and 19.
21. Appeal against improvement notice or prohibition notice.
22. Power to deal with cause of imminent danger.
23. Offences and penalties.

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

**Subsidiary
2002/054**

24. Defence of due diligence.
25. Onus of proving limits of what is practicable etc.
26. Evidence.
27. Civil liability.
28. Application to the Crown.
29. Transitional provision.
30. Revocation.

SCHEDULES

- Schedule 1. Employer's Procedures.
- Schedule 2. Adequate Training.
- Schedule 3. Medical Physics Expert.

1995-09

Health Protection (Ionising Radiation)

**Subsidiary
2002/054**

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

In exercise of the powers conferred upon it by section 2 of the Health Protection (Ionising Radiation) Act 1995, and section 23 of the Interpretation and General Clauses Act and of all other enabling powers, and for the purpose of implementing in the law of Gibraltar, in part, Council Directive 97/43/Euratom, the Government has made the following regulations—

PART I

PRELIMINARY

Title.

1. These regulations may be cited as the Ionising Radiation (Administration of Medicinal Products and Medical Exposures) Regulations 2002.

Interpretation.

2.(1) In these Regulations, unless the context otherwise requires—

“the 2004 Regulations” means the Ionising Radiation Regulations 2004;

“absorbed dose” has the same meaning as in the 2004 Regulations;

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

“activity” has the same meaning as in the 2004 Regulations;

“adequate training” means training which satisfies the requirements of Schedule 2; and the expression “adequately trained” shall be similarly construed;

“administer” has the meaning assigned to that word by section 41(1) of the Medical and Health Act except that—

- (a) the reference to an animal shall be disregarded; and
- (b) an Order which includes any additional substance or article within the meaning of the expression “medicinal product” may vary the meaning of “administer” in relation to such additional substance or article;

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

**Subsidiary
2002/054**

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

“child” means a person under the age of eighteen;

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

“comforter and carer” means an individual who, other than as part of his occupation, knowingly and willingly incurs an exposure to ionising radiation resulting from the support and comfort of another person who is undergoing or who has undergone any medical exposure;

“competent authority” means the person or body for the time being appointed in writing by the Minister, for the purposes of these Regulations;

“diagnostic reference levels” means dose levels in medical radiodiagnostic practices or, in the case of radioactive medicinal products, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment;

“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 patients or standard phantoms for broadly defined types of equipment;

“directions” means directions in writing;

“dose constraint” means a constraint set as a prospective upper bound of individual doses, used to define the range of options considered in the process of optimisation for a given radiation source in a planned exposure situation;

“the Directive” means 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, and

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

repealing Directives 89/618/Euratom, 90/641/Euratom,
96/29/Euratom, 97/43/Euratom and 2003/122/Euratom;

“effective dose” has the same meaning as in the 2004 Regulations;

“employer” means any natural or legal person who, in the course of a trade, business or other undertaking, carries out (other than as an employee), or engages others to carry out, those exposures described in regulation 8 or practical aspects, at a given radiological installation;

“employer’s procedures” means the procedures established by an employer pursuant to regulation 9(1);

“equipment” means equipment which-

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

“equivalent dose” has the same meaning as in the 2004 Regulations;

“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);

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

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

“individual detriment” means clinically observable deleterious effects that are expressed 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;

“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 (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

**Subsidiary
2002/054**

“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;

“medical exposure” means any exposure under paragraphs (a) to (e) of regulation 8;

“medicinal product” has the meaning assigned to that expression by section 41(1) of the Medical and Health Act except that—

- (a) the reference to animals in paragraph (a) of the definition of the expression shall be disregarded;
- (b) it includes substances used in dental surgery for filling dental cavities;
- (c) it also includes substances and articles of such other descriptions or classes as may be specified by an order for the purposes of these Regulations;

“medical physics expert” means a person who holds a science degree or its equivalent and who is experienced to act or give advice in the application of physics to the diagnostic and therapeutic uses of ionising radiation;

“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 medical exposure;

“the Minister” means the Minister with responsibility for Health;

“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;

“occupational health surveillance” means a health professional or body competent to perform medical surveillance of exposed workers and

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

whose capacity to act in that respect is recognised by the competent authority;

“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 pursuant to regulation 10(3), medical physics experts as referred to in regulation 14 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 as referred to in regulation 16(3);

“patient” means a person undergoing medical examination or treatment;

“patient dose” means the dose concerning patients or other individuals undergoing medical exposures to which these Regulations apply;

“practical aspect” means the physical conduct of any of the exposures referred to in regulation 8 and any supporting aspects including the handling and use of radiological equipment, and the assessment of technical and physical parameters including radiation doses, calibration and maintenance of equipment, preparation and administration of radio-pharmaceuticals and image processing;

“practitioner” means a registered medical practitioner, dental practitioner or other health professional who is entitled, in accordance with the employer’s procedures, to take responsibility for an individual medical exposure;

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

“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;

“radiation source” means an entity that may cause exposure, such as by emitting ionising radiation or by releasing radioactive material;

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

**Subsidiary
2002/054**

“radioactive medicinal product” means a medicinal product which is, which contains or which generates a radioactive substance and which is, contains or generates that substance in order, when administered, to utilise the radiation emitted therefrom;

“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” means pertaining to radiodiagnostic and radiotherapeutic procedures and interventional radiology or other planning and guiding 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;

“reference level” means in an emergency exposure situation or in an existing exposure situation, the level of effective dose or equivalent dose or activity concentration above which it is judged inappropriate to allow exposures to occur as a result of that exposure situation, even though it is a limit that may be exceeded;

“referrer” means a registered medical practitioner, dental practitioner or other health professional who is entitled, in accordance with the employer’s procedures, to refer individuals for medical exposure to a practitioner.

“Sievert” or “Sv” means the special name of the unit of equivalent or effective dose, and one sievert is equivalent to one joule per kilogram;

“storage” means the holding of radioactive material, including spent fuel, a radioactive source or radioactive waste, in a facility with the intention of retrieval;

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

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

(2) For the purposes of Part III of these Regulations—

- (a) any reference to an employer includes a reference to a self-employed person and any duty imposed by that Part on an employer in respect of his employee shall extend to a self-employed person in respect of himself;
- (b) where a person acts as employer, referrer, practitioner and operator concurrently (or in any combination of these roles) he shall comply with all the duties placed on employers, referrers, practitioners and operators (or on whichever combination of roles is played by him) under these Regulations accordingly.

PART II

**ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS**

Control of administration of radioactive medicinal products.

3.(1) No person shall administer to a human being (otherwise than to himself) any radioactive medicinal product unless he is—

- (a) a doctor or a dentist holding a certificate issued by the competent authority for the purposes of this regulation in respect of radioactive medicinal products (hereinafter referred to as a “certificate”); or
- (b) a person acting in accordance with the directions of such a doctor or dentist.

(2) Neither the doctor or dentist holding the certificate nor any person acting in accordance with the directions of a doctor or dentist shall administer any radioactive medicinal product under a certificate issued to that doctor or dentist unless that product is of a description or falls within a class specified in the certificate.

(3) Where the purpose for which the administration of a radioactive medicinal product of a description or falling within a class specified in the certificate is also specified, neither the doctor nor the dentist holding the

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

**Subsidiary
2002/054**

certificate nor any person acting in accordance with the directions of that doctor or dentist shall administer the said radioactive medicinal product under that certificate unless it is for the purpose specified therein.

(4) Where the persons to whom any radioactive medicinal product which is of a description or falls within a class of radioactive medicinal product specified in the certificate may be administered is also specified, neither the doctor nor the dentist holding the certificate nor any person acting in accordance with the directions of that doctor or dentist shall administer any such radioactive medicinal product under that certificate except for the purpose of diagnosis or treatment of a person specified therein.

Grant of certificates.

4.(1) A certificate may specify—

- (a) particular descriptions or classes of radioactive medicinal products; and
- (b) in relation to particular descriptions or classes of radioactive medicinal products—
 - (i) the purpose for which they may be administered; and
 - (ii) where it is proposed to administer any such products for the purpose of diagnosis or treatment, particulars relating to the person to whom they may be administered.

(2) The competent authority may grant to any doctor or dentist a certificate if—

- (a) an application for the grant of a certificate has been—
 - (i) made in writing,
 - (ii) signed by the doctor or dentist, as the case may be (“the applicant”),
 - (iii) submitted in such form (if any) as may have been approved by the competent authority; and
 - (iv) accompanied by the prescribed fee;
- (b) the application contains the following particulars—

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

- (i) the name, address, qualifications and relevant experience of the applicant and the post or position which the applicant holds or is to hold and in which he proposes to administer or to have administered radioactive medicinal products;
 - (ii) the particular descriptions or classes of radioactive medicinal products the applicant proposes to administer or to have administered and the purpose for which they are to be administered;
 - (iii) details of the equipment, facilities and staff available to the applicant for the proposed administration of radioactive medicinal products;
 - (iv) where the application relates to a proposal to administer radioactive medicinal products to particular persons, information sufficient to enable those persons to be identified; and
 - (v) such other information as the competent authority may reasonably require, which may include such evidence or report on the applicant, in relation to the activity or activities falling within these Regulations (in the form, if any, specified by the competent authority), prepared by a person recognised by the authority as qualified to provide that evidence or report; and
- (c) the competent authority is reasonably satisfied—
- (i) that the applicant is fitted, by reason of his knowledge, experience, competence and skill, to hold a certificate and to administer radioactive medicinal products of a description or falling within a class specified in the application;
 - (ii) as to the radiation hazards associated with the use of products—
 - (aa) of a description or falling within a class of radioactive medicinal products,

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

**Subsidiary
2002/054**

(bb) for the purpose for which they are to be administered,

specified in the application; and

(iii) that the applicant has available to him suitable equipment and facilities and the services of suitably qualified staff to enable radioactive medicinal products of the description or falling within the class specified in the application to be administered safely.

(3) Where the competent authority is considering an application which—

(a) is made by a doctor or dentist who already holds a certificate which specifies descriptions or classes of radioactive medicinal products other than those specified in the application; and

(b) in accordance with a requirement under subregulation (2)(b)(iv) contains information which identifies the particular persons to whom it is proposed to administer radioactive medicinal products for the purpose of diagnosis or treatment,

nothing in subregulation (2)(c) shall require the competent authority to reconsider (for the purposes of granting a certificate which specifies one or more of those persons as persons to whom radioactive medicinal products, of a description or falling within class of radioactive medicinal products specified in the application, may be administered) a matter previously considered by it in connection with the grant of the certificate already held by the applicant.

Duration and renewal of certificates.

5.(1) Subject to subregulation (3), a certificate shall remain in force for—

(a) a period not exceeding 5 years; or

(b) such shorter period as may be specified in the certificate.

(2) The competent authority may renew a certificate if—

(a) an application for its renewal has been—

(i) made in writing,

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

- (ii) signed by the applicant; and
- (iii) accompanied by the prescribed fee;
- (b) the application contains the following particulars—
 - (i) either confirmation that the details contained in the application for the grant of the certificate in respect of which the application for a renewal is made remain complete and correct or details of any changes in the matters stated in the application for the grant of the said certificate; and
 - (ii) such other information as the competent authority may reasonably require, which may include such evidence or report on the applicant, in relation to the activity or activities falling within these Regulations (in the form, if any, specified by the competent authority), prepared by a person recognised by the authority as qualified to provide that evidence or report; and
- (c) the competent authority remains satisfied as to the matters specified in regulation 4(2)(c).

(3) Where an application for the renewal of a certificate has been duly made whilst that certificate remains in force, then, notwithstanding subregulation (1), that certificate shall continue to remain in force until such time as the competent authority has determined the application.

Suspension, revocation and variation of certificates.

6.(1) The competent authority may suspend (for such period as it may determine) or revoke a certificate on one or more of the following grounds—

- (a) a material change has occurred in relation to any of the matters stated in the application;
- (b) the competent authority is no longer satisfied that the holder of the certificate has available to him either or both of the following—
 - (i) suitable equipment or facilities,
 - (ii) the services of suitably qualified staff.

(2) The competent authority may vary a certificate—

- (a) by adding thereto particular descriptions or classes of radioactive medicinal products and the purpose for which they may be administered or, in relation to descriptions and classes of radioactive medicinal products already specified in the certificate, an additional purpose for which they may be administered;
- (b) by deleting therefrom particular descriptions or classes of radioactive medicinal products or any purpose for which such radioactive medicinal products may be administered, in both cases, if the competent authority is no longer satisfied as to the radiation hazards associated with their use and where only one description or one class of radioactive medicinal product is specified in the certificate, the competent authority may revoke it.

(3) Without prejudice to any requirement of regulation 7 relating to the service of any notice referred to therein, where in the exercise of any power conferred by this regulation the competent authority suspends, revokes, or varies a certificate, it shall serve notice on the holder of the certificate giving particulars of the suspension, revocation or variation, as the case may be, and of the reasons for its decision to suspend, revoke or vary the certificate.

Hearings and written representations.

7.(1) Subject to subregulation (6) below, if the competent authority proposes—

- (a) to refuse to grant or renew a certificate; or
- (b) to suspend, revoke or vary a certificate,

it shall serve notice on the applicant or holder, as the case may be—

- (i) stating what it proposes to do;
- (ii) giving its reasons; and
- (iii) specifying the time allowed for the applicant or holder to notify the competent authority of his desire either to be

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

heard or to make representations in writing, in relation thereto.

(2) Where the applicant or holder fails to notify the competent authority of his desire to be heard or make representations in writing within the time allowed, the competent authority may proceed to refuse to grant or renew a certificate or suspend, revoke or vary the certificate, in accordance with its proposal.

(3) Where the applicant or holder duly notifies the competent authority of his desire to be heard or make representations in writing, the competent authority shall afford him the opportunity of appearing before, and being heard by, a person appointed for the purpose by the competent authority or of making representations in writing to the competent authority before making its decision.

(4) Any decision to refuse to grant or renew a certificate or suspend, revoke or vary a certificate shall be notified in writing to the applicant or holder and shall be accompanied by a notice stating the reasons for the decision.

(5) In this regulation “the time allowed” means the period of twenty-eight days after the service of a notice under subregulation (1) or such extended period as the competent authority may allow, in any particular case.

(6) This regulation shall not apply to a proposal to vary a certificate so as to include any additional description or class of radioactive medicinal product which was specified in, or which falls within a class which was specified in, the application for that certificate.

PART III

MEDICAL EXPOSURES

Application of Part III.

8. These Regulations shall apply to the following medical exposures—
- (a) the exposure of patients as part of their own medical diagnosis or treatment;
 - (b) the exposure of individuals as part of health screening programmes;

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

**Subsidiary
2002/054**

- (c) the exposure of comforters and carers;
- (d) the exposure of patients or other individuals voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes;
- (e) the exposure of asymptomatic individuals;
- (f) the exposure of individuals undergoing non-medical imaging using medical radiological equipment.

Duties of Employer.

9.(1) The employer shall ensure that written procedures for medical exposures, including the procedures set out in Schedule 1, are in place; and

- (a) shall take steps to ensure that they are complied with by the practitioner and operator; or
- (b) where the employer is concurrently practitioner or operator, comply with these procedures himself.

(2) The employer shall ensure that written protocols are in place for every type of standard radiological practice for each piece of equipment, including practices involving non-medical imaging.

(3) The employer shall establish—

- (a) recommendations concerning referral criteria for medical exposures, including radiation doses, and shall ensure that these are made available to the referrer;
- (b) quality assurance programmes for standard operating procedures;
- (c) regularly review and make available to an operator, diagnostic reference levels in respect of an exposure falling within—
 - (i) regulation 8(a)—
 - (aa) establish recommendations concerning referral guidelines for medical exposures, including radiation doses, and ensure that these are available to the referrer,

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

- (bb) where the exposure does not involve interventional radiology procedures, in which cases regard shall be had to European and national diagnostic reference levels where available,
- (ii) regulation 8(b), or (e) in which cases regard shall be had to European and national diagnostic reference levels where available,
- (iii) regulation 8(f) (non-medical imaging) where practicable;
- (d) dose constraints-
 - (i) for biomedical and medical research programmes falling within regulation 8(d) where no direct health benefit is expected for the individual receiving the exposure, and
 - (ii) with regard to the protection of comforters and carers within regulation 8(c).

(3A) A dose constraint shall be established in terms of individual effective or equivalent doses over a defined appropriate time period.

(4) The employer shall—

- (a) take steps to ensure that every practitioner or operator engaged by him to carry out medical exposures or any practical aspect of any such exposures—
 - (i) has been adequately trained for the purpose, such that he does not contravene regulation 16(1); and
 - (ii) undertakes continuing education and training after qualification including, in the case of clinical use of new techniques, training related to these techniques and the relevant radiation protection requirements; or
- (b) ensure that he personally undertakes such continuing education and training as may be appropriate where the employer himself is concurrently practitioner or operator or both.

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

**Subsidiary
2002/054**

(5) Where the employer knows or has reason to believe that an incident has or may have occurred in which a person, while receiving a medical exposure was exposed (otherwise than as a result of a malfunction or defect in equipment) to ionising radiation to an extent much greater than intended, he shall make an immediate preliminary investigation of the incident.

(6) Unless the preliminary investigation made pursuant to subregulation (5) shows beyond reasonable doubt that no such overexposure has occurred, the employer shall—

- (a) notify the Minister forthwith; and
- (b) make or arrange for a detailed investigation of the circumstances of the exposure and an assessment of the dose received.

(7) Whenever diagnostic reference levels are consistently exceeded, the employer shall undertake appropriate reviews and ensure that corrective action is taken, where appropriate.

(8) The employer shall take measures to raise awareness of the effects of ionising radiation amongst individuals capable of childbearing or breastfeeding.

Employer's duties re accidental or unintended exposure.

9A.(1) The employer's procedures shall 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 shall, in respect of radiotherapeutic practices, include a study of the risk of accidental or unintended exposures.

(3) The employer shall 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 shall—

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

- (a) make an immediate preliminary investigation of the incident;
- (b) unless that investigation shows beyond a reasonable doubt that no such exposure has occurred, immediately notify the Minister;
- (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 Minister of the outcome of the investigation and any corrective measures adopted, within the time period specified by the Minister.

Competent authority's duties re accidental and unintended exposure.

9B. The competent authority shall 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.

General responsibilities and duties of Referrer, Practitioner and Operator.

10.(1) The referrer shall supply the practitioner with sufficient medical data relevant to the medical exposure requested by the referrer (such as previous diagnostic information or medical records) to enable the practitioner to decide whether such an exposure may be justified in accordance with regulation 11(2).

- (2) The practitioner shall be responsible for–
 - (a) justifying medical exposures;
 - (b) authorising medical exposures; and
 - (c) carrying out medical exposures, except to the extent that the practical aspects of any such exposure are carried out by another, pursuant to subregulation (4).
- (3) The practitioner and the operator shall comply with the written procedures for medical exposures put in place by the employer pursuant to regulation 9(1).

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

**Subsidiary
2002/054**

(4) The employer or, where appropriate, the practitioner may assign, in accordance with the employer's procedures, the practical aspects of a medical exposure, or part of it, to one or more individuals entitled to act in this respect in a recognised field of specialisation.

(5) The practitioner and the operator shall cooperate with such other specialists and staff as are involved in a medical exposure, as appropriate, regarding its practical aspects.

(6) The operator shall be responsible for—

- (a) authorising medical exposures when it is not practicable for the practitioner to do so; and
- (b) each and every practical aspect which he carries out.

Justification of Individual Medical Exposures.

11.(1) No person shall carry out a medical exposure unless—

- (a) it has been justified by the practitioner, in accordance with subregulation (2); and
- (b) subject to subregulation (4), it has been authorised by the practitioner; and
- (c) in the case of a medical or biomedical exposure falling within regulation 8(d), it has been approved by the Gibraltar Health Authority; and
- (d) in the case of an exposure falling within regulation 8(f), it complies with the employer's procedures for such exposures; and
- (e) in the case of a female of childbearing age, he has enquired whether she is pregnant or breastfeeding, if relevant; and
- (f) in the case of the administration of radioactive substances, the practitioner and employer are authorised to undertake the intended exposure.

(2) A medical exposure may be justified when it shows a sufficient net benefit—

IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002

- (a) weighing the total potential diagnostic or therapeutic benefits it produces (including any direct health benefit to the individual receiving it and the benefits to society) against the individual detriment that the exposure might cause; and
- (b) taking into account—
 - (i) the specific objectives of the exposure and the characteristics of the individual involved;
 - (ii) the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation; and
 - (iii) any data supplied by the referrer pursuant to regulation 10(1),

with a view to avoiding any unnecessary exposure.

(3) In considering the weight to be given to the matters referred to in subregulation (2), the practitioner justifying an exposure in accordance with subregulation (1)(b) shall have regard, in particular to-

- (a) recommendations from appropriate medical scientific societies or relevant bodies where a procedure is to be performed as part of any health screening programme;
- (b) whether in circumstances where there is to be an exposure to a comforter or carer such an exposure would show a sufficient net benefit taking into account—
 - (i) the likely direct health benefits to a patient,
 - (ii) the possible benefits to the comforter or carer, 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,

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

**Subsidiary
2002/054**

- (iii) requires specific documented justification for that individual by the practitioner, in consultation with the referrer,

any guidelines issued by appropriate medical scientific societies, or relevant bodies;

- (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) Where it is not practicable for the practitioner to authorise an exposure as required by subregulation (1)(b), the operator may do so in accordance with guidelines issued by the practitioner.

Optimisation.

12.(1) In relation to all medical exposures to which these Regulations apply except radiotherapeutic procedures, the practitioner and the operator, to the extent of their respective involvement in a medical exposure, shall ensure that doses arising from the exposure are kept as low as reasonably practicable, consistent with the intended purpose of the exposure.

(2) In relation to all medical exposures for radiotherapeutic purposes under regulation 8(a), the practitioner shall ensure that exposures of target volumes are individually planned, their delivery appropriately verified, taking into account that doses of non-target volumes and tissues shall be as low as reasonably practicable and consistent with the intended radiotherapeutic purpose of the exposure.

(3) Without prejudice to subregulations (1) and (2), the operator shall select equipment and methods to ensure that for each medical exposure the dose of ionising radiation to the individual receiving the exposure is as low as reasonably practicable and consistent with the intended diagnostic or

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

therapeutic purpose of the exposure and in doing so shall pay special attention to—

- (a) quality assurance;
- (b) assessment of patient dose or administered activity; and
- (c) adherence to diagnostic reference levels for radiodiagnostic examinations falling within regulation 8(a), (b), (e) and (f),

as set out in the employer's procedures.

(4) For each medical or biomedical research programme falling within regulation 8(d), the employer's procedures shall 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 exposure from which the patients are expected to receive a diagnostic or therapeutic benefit.

(4A) In the case of regulation 8(c), the employer's procedures shall provide that appropriate guidance is established for the exposure of comforters and carers.

(5) In the case of patients receiving treatment or diagnosis with radioactive medicinal products, the employer's procedures shall 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;
- (b) where the patient is a child who lacks capacity so to consent, the person with parental responsibility for the child; or

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

**Subsidiary
2002/054**

- (c) where the patient is an adult who lacks capacity so to consent, the person who appears to the practitioner to be the most appropriate person.
- (6) The instructions and information referred to in subregulation (5) shall—
- (a) specify how doses to persons in contact with the patient may be restricted so far as reasonably practicable so as to protect those persons;
 - (b) set out the risks associated with ionising radiation; and
 - (c) be provided to the patient or other person specified in subregulation (5) as appropriate, prior to the patient leaving the hospital or other place where the treatment or diagnosis was carried out.
- (7) In complying with the obligations under this regulation, the practitioner and the operator shall pay special attention to—
- (a) *Deleted.*
 - (b) medical exposures of children;
 - (c) medical exposures as part of a health screening programme;
 - (d) medical exposures involving high doses to the patient;
 - (e) where appropriate, medical exposures of females in whom pregnancy cannot be excluded, in particular if abdominal and pelvic regions are involved, taking into account the exposure of the expectant mother and the unborn child;
 - (f) where appropriate, medical exposures involving the administration of radioactive substances to individuals who are breastfeeding, taking into account the exposure of both the individual and the child.
- (8) The employer shall take the appropriate steps to ensure that a clinical evaluation of the outcome of each medical exposure is recorded, other than where the person subject to the exposure is a comforter or carer, in accordance with the employer's procedures or, where the employer is concurrently practitioner or operator, shall so record a clinical evaluation, including, where appropriate, factors relevant to patient dose.

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

(9) The employer shall collect dose estimates from medical exposures for radiodiagnostic and interventional radiology purposes, taking into consideration, where appropriate, the distribution by age and gender of the exposed population and, when so requested, shall provide it to the Minister.

Clinical Audit.

13. The employer's procedures shall include provision for the carrying out of clinical audit in accordance with procedures laid down by the Minister.

Expert advice.

14.(1) The employer shall ensure that a medical physics expert shall be involved in every medical exposure to which these Regulations apply, in accordance with subregulation (2).

(2) A medical physics expert shall be—

- (a) closely involved in every radiotherapeutic practice other than standardised therapeutic nuclear medicine practices;
- (b) available in standardised therapeutic nuclear medicine practices and in diagnostic nuclear medicine practices, high dose interventional radiology and high dose computed tomography;
- (c) involved, as appropriate, in all other radiological practices—
 - (i) for consultation on optimisation, including patient dosimetry and quality assurance; and
 - (ii) to give advice as required on matters relating to radiation protection concerning medical exposure, and
- (d) contribute in particular to matters specified in Schedule 3.

Radiological equipment.

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

- (a) implement and maintain a quality assurance programme in respect of that equipment which shall as a minimum permit—

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

**Subsidiary
2002/054**

- (i) the assessment of the dose of ionising radiation that a person may be exposed to from an exposure described in regulation 8, 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, an inventory of the radiological equipment kept at each radiological installation, and when so requested, furnish such inventory to the Minister;
 - (c) ensure that all medical radiological equipment in use is kept under strict surveillance regarding radiation protection.
- (2) The inventory referred to in subregulation (1) shall 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 shall 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.

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

(5) Equipment used for interventional radiology and computed tomography shall 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 shall-

- (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, and such corrective action may include taking the equipment out of service.

Equipment installed on or after 6 February 2018.

15A.(1) This regulation only applies in respect of-

- (a) equipment installed on or after 6 February 2018; and
- (b) an employer who has control of any such equipment.

(2) Equipment used for external beam radiotherapy with a nominal beam exceeding 1 MeV shall have a device, or other feature, the purpose of which is, to verify key treatment parameters.

(3) Equipment used for interventional radiology shall 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, shall 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 shall 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 shall-

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

**Subsidiary
2002/054**

- (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.

16.(1) Subject to the following provisions of this regulation, no practitioner or operator shall carry out a medical 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, if such certificate so attests, shall be sufficient proof that the person to whom it has been issued has been adequately trained.

(3) Nothing in subregulation (1) shall prevent 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 himself is adequately trained.

(4) The employer shall keep and have available for inspection by the competent authority an up-to-date record of-

- (a) the training received by all practitioners and operators engaged by him to carry out medical exposures or any practical aspect of such exposures; or
- (b) his own training, where the employer is concurrently practitioner or operator or both,

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 shall be responsible for-

- (a) keeping the records required by subregulation (4)(a); and
- (b) supplying such records to the employer forthwith, upon request.

IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002

PART IV

ENFORCEMENT AND SUPPLEMENTARY PROVISIONS

Appointment and powers of inspectors.

17.(1) The competent authority may appoint as inspectors (under whatever title it may from time to time determine) such persons having suitable qualifications as it thinks necessary for the purpose of enforcing these Regulations.

(2) Every appointment of a person as an inspector under this regulation shall be made by an instrument in writing, specifying which of the powers conferred on inspectors by these Regulations are to be exercisable by that person, which powers may be varied at any time by the competent authority by a further instrument in writing and an inspector shall be entitled to exercise only those powers which are so specified.

(3) When exercising or seeking to exercise any of the powers specified in his instrument of appointment, an inspector shall produce such instrument or a duly authenticated copy thereof, if so required.

(4) An inspector may—

- (a) at any reasonable time (or, in a situation which in his opinion is or may be dangerous, at any time) enter any premises in which any person is carrying on or proposes to carry on, any activity falling within these Regulations, for the purpose of ascertaining whether any such person, premises and equipment on such premises complies with these Regulations;
- (b) make such examination and investigation as may be necessary for the purpose mentioned in paragraph (a);
- (c) require any person whom he has reasonable cause to believe to be able to give any information relevant to any examination or investigation carried out under paragraph (b) to answer (in the absence of persons other than a person nominated by him to be present and any person whom the inspector may allow to be present) such questions as the inspector thinks fit to ask and to sign a declaration of the truth of his answers;

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

**Subsidiary
2002/054**

- (d) require the production of, inspect and take copies of or of any entry in—
 - (i) any books or documents which by virtue of any of these Regulations are required to be kept; and
 - (ii) any other books or documents which it is necessary for him to see for the purposes of any examination or investigation under paragraph (b);
- (e) require any person to afford him such facilities and assistance with respect to any matter or things within that person's control or in relation to which that person has responsibilities as are necessary to enable the inspector to exercise any of the powers conferred on him by this regulation;
- (f) exercise any other power which is necessary for the purpose mentioned in paragraph (a).

(5) Any information obtained by an inspector in exercise of his powers under these Regulations shall—

- (a) except as is necessary for the purpose of a disclosure to which paragraph (b)(iii) applies, have erased from it the name of any person who has received treatment, together with any details which might enable any such person to be identified;
- (b) be used only for the purpose of giving effect to the obligations of the competent authority under these Regulations and shall not be disclosed to any other person except—
 - (i) in the prosecution of an offence under regulation 23;
 - (ii) to an expert or adviser engaged by the competent authority to provide to the authority information, analysis or advice for the purpose of enabling the authority to enforce these Regulations, and such person shall be subject to the like obligation of confidentiality as by this regulation is imposed on the authority;
 - (iii) to any person who by reason of having received treatment, in the opinion of the authority, should be so informed.

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

(6) For the purpose of this regulation, “received treatment” means having been—

- (a) the subject of the administration of a radioactive medicinal product; or
- (b) subject to a medical exposure,

to which these Regulations apply.

Improvement notices.

18. If an inspector is of the opinion that a person—

- (a) is contravening one or more of these Regulations; or
- (b) has contravened one or more of those provisions in circumstances that make it likely that the contravention will continue to be repeated,

he may serve on him a notice (“an improvement notice”) stating that he is of that opinion, specifying the provision or provisions as to which he is of that opinion, giving particulars of the reasons why he is of that opinion, and requiring that person to remedy the contravention or, as the case may be, the matters occasioning it within such period (ending not earlier than the period within which an appeal against the notice can be brought under regulation 21) as may be specified in the notice.

Prohibition notices.

19.(1) This regulation applies to any activities which are being or are likely to be carried on by or under the control of any person, being activities to or in relation to which any of these Regulations apply or will, if the activities are so carried on, apply.

(2) If as regards any activities to which this regulation applies an inspector is of the opinion that, as carried on or likely to be carried on by or under the control of the person in question, the activities involve or, as the case may be, will involve a risk of serious personal injury, the inspector may serve on that person a notice (“a prohibition notice”).

(3) A prohibition notice shall—

- (a) state that the inspector is of that opinion;

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

**Subsidiary
2002/054**

- (b) specify the matters which in his opinion give or, as the case may be, will give rise to that risk;
- (c) where in his opinion any of those matters involves or, as the case may be, will involve a contravention of any of these Regulations, state that he is of that opinion, specify the provision or provisions as to which he is of that opinion, and give particulars of the reasons why he is of that opinion; and
- (d) direct that the activities to which the notice relates shall not be carried on by or under the control of the person on whom the notice is served unless the matters specified in the notice in pursuance of paragraph (b) and any associated contraventions of provisions so specified in pursuance of paragraph (c) have been remedied.

(4) A direction given in pursuance of subregulation (3)(d) shall take effect—

- (a) at the end of the period specified in the notice; or
- (b) immediately, if the notice so declares.

Provisions supplementary to regulations 18 and 19.

20.(1) In this regulation “a notice” means an improvement notice or a prohibition notice.

(2) Where a notice which is not to take immediate effect has been served—

- (a) the notice may be withdrawn by an inspector at any time before the end of the period specified therein in pursuance of regulation 18 or regulation 19(4), as the case may be; and
- (b) the period so specified may be extended or further extended by an inspector at any time when an appeal against the notice is not pending.

Appeal against improvement or prohibition notice.

21.(1) In this regulation “a notice” means an improvement notice or a prohibition notice.

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

(2) A person on whom a notice is served may appeal, within 21 days from the date of its service, to the Employment Tribunal and on such an appeal the Tribunal may either cancel or affirm the notice and, if it affirms it, may do so either in its original form or with such modifications as the Tribunal may in the circumstances think fit.

(3) Where an appeal under this regulation is brought against a notice within the period allowed under subregulation (2) then—

- (a) in the case of an improvement notice, the bringing of the appeal shall have the effect of suspending the operation of the notice until the appeal is finally disposed of or, if the appeal is withdrawn, until the withdrawal of the appeal;
- (b) in the case of a prohibition notice, the bringing of the appeal shall have the like effect if, on the application of the appellant, the Tribunal so directs (and then only from the giving of the direction).

Power to deal with cause of imminent danger.

22.(1) Where, in the case of any article or substance found by him in any premises which he has power to enter, an inspector has reasonable cause to believe that, in the circumstances in which he finds it, the article or substance is a cause of imminent danger of serious personal injury, he may seize it and cause it to be rendered harmless (whether by destruction or otherwise).

(2) Before there is rendered harmless under this regulation—

- (a) any article that forms part of a batch of similar articles; or
- (b) any substance,

the inspector shall, if it is practicable for him to do so, take a sample thereof and give to a responsible person at the premises where the article or substance was found by him a portion of the sample marked in a manner sufficient to identify it.

(3) As soon as may be after any article or substance has been seized and rendered harmless under this regulation, the inspector shall prepare and sign a written report giving particulars of the circumstances in which the article or substance was seized and so dealt with by him, and shall—

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

**Subsidiary
2002/054**

- (a) give a signed copy of the report to a responsible person at the premises where the article or substance was found by him; and
- (b) unless that person is the owner of the article or substance, serve a signed copy of the report on the owner;

and if, where paragraph (b) applies, the inspector cannot after reasonable enquiry ascertain the name or address of the owner, the copy may be served on him by giving it to the person to whom a copy was given under paragraph (a).

Offences and penalties.

23.(1) It is an offence for a person—

- (a) to fail to discharge a duty to which he is subject by virtue of any of these Regulations;
- (b) to contravene any requirement or prohibition imposed by any of these Regulations.

(2) A person guilty of an offence under subregulation (1) is liable on summary conviction to a fine of four times the amount at level 5 on the standard scale.

(3) Where an offence under these Regulations committed by a body corporate is proved to have been committed with the consent or connivance of, or to have been attributable to any neglect on the part of, any director, manager, secretary or other similar officer of the body corporate or a person who was purporting to act in any such capacity he, as well as the body corporate, is guilty of that offence and is liable to be proceeded against and punished accordingly.

(4) Where the commission by any person of an offence under these Regulations is due to the act or default of some other person, that person is guilty of the offence, and a person may be charged with and convicted of the offence by virtue of this subregulation whether or not proceedings are taken against the first mentioned person.

(5) Where there would be or would have been the commission of an offence under this regulation by the Crown but for the circumstance that, by virtue of regulation 28(1), this regulation does not bind the Crown, and that fact is due to the act or default of a person other than the Crown, that person is guilty of an offence which, but for that circumstance, the Crown would be

IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002

committing or would have committed, and may be charged with and convicted of that offence accordingly.

Defence of due diligence.

24. In any proceedings against any person for an offence consisting of the contravention of these Regulations it shall be a defence for that person to show that he took all reasonable steps and exercised all due diligence to avoid committing the offence.

Onus of proving limits of what is practicable etc.

25. In any proceedings for an offence in contravention of these Regulations consisting of a failure to comply with a duty or requirement to do something so far as is practicable or so far as is reasonably practicable, it shall be for the accused to prove (as the case may be) that it was not practicable or not reasonably practicable to do more than was in fact done to satisfy the duty or requirement.

Evidence.

26.(1) Where an entry is required by any of these Regulations to be made in any register or other record, the entry, if made, shall, as against the person by or on whose behalf it was made, be admissible as evidence of the facts stated therein.

(2) Where an entry which is required to be made in any register or other record with respect to the observance of any of these Regulations has not been made, that fact shall be admissible as evidence that that regulation has not been observed.

Civil liability.

27.(1) Breach of any duty or prohibition imposed by these Regulations, in so far as it causes damage, shall be actionable in civil proceedings.

(2) Any term of an agreement which purports to exclude or restrict the operation of subregulation (1), or any liability arising by virtue of that subregulation, shall be void.

(3) In this regulation “damage” includes the death of, or injury to, any person (including any disease and any impairment of a person’s physical or mental condition).

IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002

Subsidiary
2002/054

Application to the Crown.

28.(1) The provisions of these Regulations, except regulations 18 to 26, shall bind the Crown.

(2) Although they do not bind the Crown, regulations 23 to 26 shall apply to persons in the public service of the Crown, as they apply to other persons.

(3) For the purposes of these Regulations, persons in the service of the Crown shall be treated as employees of the Crown, whether or not they would be so treated apart from this subregulation.

Transitional provision.

29. Where, on the coming into effect of these Regulations, a person is carrying on an activity to which these Regulations apply, it shall be sufficient compliance with these Regulations if that person complies with the applicable requirement or requirements of these Regulations within three months of the coming into effect of these Regulations.

Revocation.

30. The Ionising Radiation (Administration of Medicinal Products and Medical Exposures) Regulations 1995 are revoked.

SCHEDULE 1

Regulation 9(1)

EMPLOYER'S PROCEDURES

The written procedures for medical exposures shall include—

- (a) procedures to identify correctly the individual to be exposed to ionising radiation;
- (b) procedures to identify individuals entitled to act as referrer or practitioner or operator within a specified scope of practice;
- (c) *Deleted.*
- (d) procedures for making enquiries of females of childbearing age to establish whether she may be pregnant or is breastfeeding;
- (e) procedures to ensure that quality assurance programmes in respect of written procedures, written protocols, and equipment are followed;
- (f) procedures for the assessment of patient dose and administered activity;
- (g) procedures for the use and review of diagnostic reference levels established by the employer for radiodiagnostic examinations falling within regulation 8(a), (b), (e) and (f);
- (h) procedures 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 8(d) where no direct medical benefit for the individual is expected from the exposure;
- (i) procedures for the giving of information and written instructions, as referred to in regulation 12(5);

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

**Subsidiary
2002/054**

- (j) procedures for the carrying out and recording of an evaluation for each medical exposure including, where appropriate, factors relevant to patient dose;
- (k) procedures to ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced so far as reasonably practicable;
- (l) procedures 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;
- (m) procedures 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;
- (n) procedures to be observed in the case of non-medical imaging exposures; and
- (o) procedures to establish appropriate dose constraints and guidance for the exposure of comforters and carers.

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

SCHEDULE 2**Adequate training**

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

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

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

Fundamental Physics of Radiation

Properties of Radiation	Excitation and ionisation Attenuation of ionising radiation Scattering and absorption
Radiation Hazards and dosimetry	Biological effects of radiation - stochastic and deterministic Risks and benefits of radiation Absorbed dose, equivalent dose, effective dose, other dose indicators and their units

Management and Radiation Protection of the individual being exposed

Special Attention Areas	Pregnancy and potential pregnancy Asymptomatic individuals Breastfeeding Infants and children Medical and biomedical research Health screening Non-medical imaging Carers and comforters High dose techniques
Justification	Justification of the individual exposure Use of existing appropriate radiological information Alternative techniques

IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE MEDICINAL PRODUCTS AND MEDICAL EXPOSURES) REGULATIONS 2002

Subsidiary
2002/054

Radiation Protection	<ul style="list-style-type: none"> 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
-----------------------------	--

Statutory Requirements and Non-Statutory Regulations

<ul style="list-style-type: none"> Regulations Non-statutory guidance Local procedures and protocols Individual responsibilities relating to exposures Responsibility for radiation safety Clinical audit

Table 2 - Diagnostic radiology, radiotherapy and nuclear medicine

All Modalities

General	<ul style="list-style-type: none"> Fundamentals of radiological anatomy Factors affecting radiation dose Dosimetry Fundamentals of clinical evaluation Identification of the individual being exposed
Diagnostic radiology	
General	<ul style="list-style-type: none"> Principles of radiological techniques Production of X-rays Equipment selection and use
Specialised Techniques	<ul style="list-style-type: none"> Computed Tomography – advanced applications Interventional procedures Cone Beam Computed Tomography Hybrid imaging
Fundamentals of Image Acquisition etc.	<ul style="list-style-type: none"> Optimisation of image quality and radiation dose Image formats, acquisition, processing, display and storage
Contrast Media	<ul style="list-style-type: none"> Use and preparation Contra-indications Use of contrast injection systems
Radiotherapy	
General	<ul style="list-style-type: none"> Production of ionising radiation

**IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE
MEDICINAL PRODUCTS AND MEDICAL EXPOSURES)
REGULATIONS 2002**

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

Health Protection (Ionising Radiation)

1995-09

IONISING RADIATION (ADMINISTRATION OF RADIOACTIVE MEDICINAL PRODUCTS AND MEDICAL EXPOSURES) REGULATIONS 2002

**Subsidiary
2002/054**

Radiation Protection Specific to Nuclear Medicine

Working practices in the radiopharmacy
Preparation of individual doses
Conception, pregnancy and breastfeeding
Arrangements for radioactive individuals

SCHEDULE 3

Medical Physics Expert

1. The matters specified in this Schedule are-
 - (a) optimisation of the radiation protection of patients and other individuals subject to exposures, including the application and use of diagnostic reference levels;
 - (b) the definition and performance of quality assurance of the equipment;
 - (c) acceptance testing of equipment;
 - (d) the preparation of technical specifications for equipment and installation design;
 - (e) the surveillance of the medical radiological installations;
 - (f) the analysis of events involving, or potentially involving, accidental or unintended exposures;
 - (g) the selection of equipment required to perform radiation protection measurements;
 - (h) the training of practitioners and other staff in relevant aspects of radiation protection;
 - (i) the provision of advice to an employer relating to compliance with these Regulations;
 - (j) the medical physics expert is, where appropriate, to liaise with and radiation protection supervisor under the 2004 Regulations.”.