

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

**Subsidiary
2002/054**

This version is out of date

Regulations made under section 2 of the Health Protection (Ionising Radiation) Act 1995, and section 23 of the Interpretation and General Clauses Act

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(LN. 2002/054)

1.8.2002

Implementing:
Directive 97/43/EURATOM

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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—

“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;

“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

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agreed standards for good medical radiological procedures, intended to lead to modification of practices where indicated and the application of new standards if necessary;

"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;

"directions" means directions in writing;

"dose constraint" means a restriction on the prospective doses to individuals which may result from a defined source;

"the Directive" means Council Directive 97/43/Euratom laying down measures on health protection of individuals against the dangers of ionising radiation in relation to medical exposure;

"employer" means any natural or legal person who, in the course of a trade, business or other undertaking, carries out (other than as an employee), or engages others to carry out, medical exposures 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 delivers ionising radiation to a person undergoing a medical exposure and equipment which directly controls or influences the extent of such exposure;

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

"health screening" means a procedure using ionising radiation for early diagnosis in population groups at risk;

"individual detriment" means clinically observable deleterious effects that are expressed in individuals or their descendants, the

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appearance of which is either immediate or delayed and, in the latter case, implies a probability rather than a certainty of appearance;

“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 to which regulation 8 applies and which involves an individual being exposed to ionising radiation;

“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 in the application of physics to the diagnostic and therapeutic uses of ionising radiation;

“medico-legal procedure” means a procedure performed for insurance or legal purposes without a medical indication;

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

“notice” means notice in writing;

“occupational health surveillance” means medical surveillance for workers;

“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

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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 exposure;

“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 radioactive medicinal products and the development of films;

“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;

“purpose” in relation to the administration of a radioactive medicinal product, means the purpose of diagnosis, treatment or research;

“quality assurance” means any planned and systematic action necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily and safely, complying with agreed standards and includes 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;

“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;

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“radioactive substance” means any substance that contains one or more radionuclides of which the activity or the concentration cannot be disregarded as far as radiation protection is concerned;

“radiodiagnostic” means pertaining to in vivo diagnostic nuclear medicine, medical diagnostic radiology 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 containing equipment;

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

“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.

(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.

(3) In these Regulations—

- (a) any reference to a numbered regulation or Schedule is a reference to the regulation or Schedule so numbered in these Regulations;
- (b) any reference to a numbered sub-regulation is a reference to the sub-regulation so numbered in the regulation in which that reference appears;

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- (c) any reference to a numbered paragraph is a reference to the paragraph so numbered in the sub-regulation or Schedule in which that reference appears.

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 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—

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- (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—
 - (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;

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- (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,
 - (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—

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- (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,
 - (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;

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- (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 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.

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(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 occupational health surveillance;
 - (c) the exposure of individuals as part of health screening programmes;
 - (d) the exposure of patients or other individuals voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes;
 - (e) the exposure of individuals as part of medico-legal procedures.

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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.

(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) diagnostic reference levels for radiodiagnostic examinations falling within regulation 8(a), (b), (c) and (e), having regard to European diagnostic reference levels, where available;
- (d) dose constraints for biomedical and medical research programmes falling within regulation 8(d), where no direct health benefit is expected for the individual receiving the exposure.

(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

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(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.

(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.

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

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- (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).

(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(e), it complies with the employer's procedures for such exposures; and

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- (e) in the case of a female of childbearing age, he has enquired whether she is pregnant or breastfeeding, if relevant.
- (2) A medical exposure may be justified when it shows a sufficient net benefit–
- (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) The practitioner shall pay special attention to the justification–
- (a) of those medical exposures where there is no direct health benefit for the individual receiving it and especially where such exposures are on medico-legal grounds;
 - (b) (depending on the type of medical exposure, in particular if abdominal and pelvic regions are involved) of those medical exposures involving females where pregnancy cannot be excluded, taking into account the exposure of both the expectant mother and the unborn child and, in particular, the urgency of the exposure; and
 - (c) (depending on the type of medical examination or treatment) of nuclear medicine exposures involving females who are breastfeeding, taking into account the exposure of both the female and the child and, in particular, the urgency of the exposure.

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(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, 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 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), (c) and (e),

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;

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- (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.

(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
- (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) the need to keep doses arising from medico-legal exposures as low as reasonably practicable;

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- (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) 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) nuclear medicine exposures of females who are breastfeeding, taking into account the exposure of the female 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, 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.

(9) In the case of fluoroscopy—

- (a) the operator shall ensure that examinations without devices to control the dose rate are limited to justified circumstances; and
- (b) no person shall carry out an examination without an image intensification or equivalent technique.

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;
- (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.

Radiological equipment.

15.(1) The employer shall–

- (a) draw up, keep up-to-date and preserve, an inventory of the radiological equipment kept at each radiological installation; and
- (b) when so requested, furnish such inventory to the competent authority.

(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) The employer shall ensure that the radiological equipment at each radiological installation–

- (a) has passed appropriate performance and safety tests (“acceptance testing”) before it is first used for clinical purposes;

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- (b) is subject to performance testing on a regular basis thereafter;
- (c) is limited to that which is necessary for the proper carrying out of medical exposures at that installation; and
- (d) is kept under strict surveillance, regarding radiation protection.

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.

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;

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- (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.

(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–

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

(2) A person on whom a notice is served may appeal, within 21 days from the date of its service, to the Industrial 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.

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(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—

- (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 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.

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(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).

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;
- (c) procedures to be observed in the case of medico-legal exposures;
- (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 are followed;
- (f) procedures for the assessment of patient dose and administered activity;
- (g) procedures for the use of diagnostic reference levels established by the employer for radiodiagnostic examinations falling within regulation 8(a), (b), (c) and (e), specifying that these are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied;
- (h) procedures for determining whether the practitioner or operator is required to effect one or 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);

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- (j) procedures for the carrying out and recording of an evaluation for each medical exposure including, where appropriate, factors relevant to patient dose; and
- (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.

SCHEDULE 2

Regulation 2(1)

ADEQUATE TRAINING

Practitioners and operators shall have successfully completed training, including theoretical knowledge and practical experience in–

- (i) such of the subjects detailed in section A as are relevant to their functions as practitioner or operator; and
- (ii) such of the subjects detailed in section B as are relevant to their specific area of practice.

Section A

Radiation production, radiation protection and statutory obligations relating to ionising radiations.

1. Fundamental Physics of Radiation.

1.1 Properties of Radiation.

Attenuation of ionising radiation.
Scattering and absorption.

1.2 Radiation Hazards and Dosimetry.

Biological effects of radiation.
Risks/benefits of radiation.
Dose optimisation.
Absorbed dose, dose equivalent, effective dose and their units.

1.3 Special Attention Areas.

Pregnancy and potential pregnancy.
Infants and children.
Medical and biomedical research.
Health screening.
High dose techniques.

2. Management and Radiation Protection of the Patient.

2.1 Patient Selection.

Justification of the individual exposure.
Patient identification and consent.
Use of existing appropriate radiological information.
Alternative techniques.
Clinical evaluation of outcome.
Medico-legal issues.

2.2 Radiation Protection.

General radiation protection.
Use of radiation protection devices—
- patient,
- personal.
Procedures for untoward incidents involving overexposure to
ionising radiation.

3. Statutory Requirements and Advisory Aspects.

**3.1 Statutory Requirements and Non-Statutory
Recommendations.**

Regulations.
Local rules and procedures.
Individual responsibilities relating to medical exposures.
Routine inspection and testing of equipment.
Notification of faults and Health Department Health
Warnings of health hazards.
Clinical audit.

**Section B.
Diagnostic radiology, radiotherapy
and nuclear medicine**

4. Diagnostic Radiology.

4.1 General.

Fundamentals of radiological anatomy.
Fundamentals of radiological techniques.
Production of X-rays.
Equipment selection and use.

Factors affecting radiation dose.
Dosimetry.
Quality assurance and quality control.

4.2 Specialised Techniques.

Image intensification/fluoroscopy.
Digital Fluoroscopy.
Computed Tomography Scanning.
Interventional procedures.
Vascular imaging.

4.3 Fundamentals of Image Acquisition etc.

Image quality v. radiation dose.
Conventional film processing.
Additional image formats, acquisition, storage and display.

4.4 Contrast Media.

Non-ionic and ionic.
Use and preparation.
Contra-indications to the use of contrast media.
Use of automatic injection devices.

5. Radiotherapy

5.1 General

Production of ionising radiations.
Use of radiotherapy—
- benign disease,
- malignant disease,
- external beam,
- brachytherapy.

5.2 Radiobiological Aspects for Radiotherapy.

Fractionation.
Dose rate.
Radiosensitisation.
Target volumes.

5.3 Practical Aspects for Radiotherapy.

Equipment.
Treatment planning.

5.4 Radiation Protection Specific to Radiotherapy.

Side effects—
- early,
- late.
Toxicity.
Assessment of efficacy.

6. Nuclear Medicine.

6.1 General

Atomic structure and radioactivity.
Radioactive decay.
The tracer principle.
Fundamentals of diagnostic use.
Fundamentals of therapeutic use—
- dose rate,
- fractionation,
- radiobiology aspects.

6.2 Principles of Radiation Detection, Instrumentation and Equipment.

Types of systems.
Image acquisition, storage and display.
Quality assurance and quality control.

6.3 Radiopharmaceuticals.

Calibration.
Working practices in the radiopharmacy.
Preparation of individual doses.
Documentation.

6.4 Radiation Protection Specific to Nuclear Medicine.

Conception, pregnancy and breastfeeding.

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Arrangements for radioactive patients.
Disposal procedures for radioactive waste.