MEDICAL IONISING RADIATION COMMITTEE

STATUTORY INSTRUMENTS
S.I. No. 478 of 2002

European Communities (Medical Ionising Radiation Protection) Regulations 2002

EEC Directive 97/43/EURATOM

Health Protection of Individuals against the danger of Ionising Radiation in relation to Medical Exposures, May 2000.

Stationery Office, Dublin Ireland

S.I. No. 478 of 2002

European Communities (Medical Ionising Radiation) Regulations 2002

The Minister for Health and Children, in exercise of the powers conferred on him by Section 3 of the European Communities Act, 1972, hereby makes the following Regulations for the purpose of giving effect to Council Directive 97/43/ EURATOM on health protection of individuals against the dangers of ionising radiation in relation to medical exposures.

Citation
1. These regulations may be cited as the European Communities (Medical Ionising Radiation Protection) Regulations, 2002.

Definitions2. For the purpose of these Regulations, the following terms have the meaning hereby assigned them:

"Medical Council" means the Council established by the Medical Practitioners Act, 1978.

"Dental Council" means the Council established by the Dentists Act, 1985.

"Radiological Protection Institute of Ireland" means the Institute established by the Radiological Protection Act, 1991.

"The Minister" means the Minister for Health and Children

"Chief executive officer" means the chief executive officer of a health board established under the Health Act, 1970, the thief executive officer of the Eastern Regional Health Authority and the chief executive officer of an area health board within the meaning of the Health (Eastern Regional Health Authority) Act, 1999.

"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, with modification of practices where indicated and the application of new standards if necessary.

"Clinical responsibility" means responsibility regarding individual medical exposures attributed to a practitioner, notably: justification; optimisation; clinical evaluation of the outcome; co-operation with other specialists and the staff, as appropriate, regarding practical aspects; obtaining information, if appropriate, of previous examinations; providing existing radiological information and/or records to other practitioners and/or prescribers, as required; giving information on the risk of ionising radiation to patients and other individuals involved, as appropriate.

"Diagnostic reference levels" means dose levels in medical radio diagnostic 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. These levels are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied.

"Dose Constraint" means a restriction on the prospective doses to individuals Which may result from a defined source, for use at the planning stage in radiation protection whenever optimisation is involved.

"Exposure" means the process of being exposed to ionizing radiation.

"Health screening" means a procedure using radiological installations for early diagnosis in population groups at risk.

"Holder" means any natural or legal person who has the legal responsibility under national law for a radiological installation.

"Medical exposure" means exposure of an individual to ionizing radiation for any of the purposes specified in regulation 4.

"Medical physicist" means an expert in radiation physics or radiation technology applied to exposure, whose training and competence to act is recognised by the competent authority, and who, as appropriate, acts or gives advice on patient dosimetry, on the development and use of complex techniques and equipment, on optimisation, on quality assurance, including quality control, and on other matters relating to radiation protection, concerning exposure.

"Medical radiological procedure" means any radio diagnostic or radio therapeutic procedure involving the use of ionising radiation on an individual for medical purposes.

"Medico-legal procedures" mean procedures performed for insurance or legal purposes without a medical indication.

"Occupational health surveillance" means the medical surveillance of workers.

"Patient dosimetry" means the dosimetry concerning patients
or other individuals undergoing medical exposure.

"Practical Aspects" means the physical conduct of a medical exposure and any supporting aspects including 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-phamaceuticals and the development of films.

"Practitioner" means:

(a) a person whose name is entered on the register established under Section 26 of the Medical Practitioners Act, 1978 and who meets such other requirements as may be specified by the Medical Council from time to time to allow them to take responsibility for an individual medical exposure; or

(b) a person whose name is entered on the register established under Section 26 of the Dentists Act, 1985 and who meets such other requirements as may be specified by the Dental Council from time to 'time to allow
them to take responsibility for an individual medical exposure; or

(c) a person whose name is entered on such other register or registers as the Minister may, from time to time, establish in relation to persons who are entitled to take clinical responsibility for an individual medical exposure and who meets such other requirements as the Minister may' prescribe.

"Practitioner in charge" means a practitioner who has been appointed by the holder to be the person in charge of an installation.

"Prescriber" means:

(a) a person whose name is entered on the register established under Section 26 of the Medical Practitioners Act, 1978; or
(b) a person whose name is entered on the register established under Section 26 of the Dentists Act, 1985; or
(c) a person whose name is entered on such other register or registers as the Minister may, from time to time, establish in relation to persons who are entitled to refer individuals for medical exposure to a practitioner and who meets such other requirements as the Minister may prescribe from time to time.

"Quality Assurance" means all those planned and systematic actions necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily and comply with agreed standards.

"Quality control" means the set of operations (programming, coordinating, implementing) intended to maintain or to improve quality. It covers monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled.

"Radiation Safety Committee" means a committee established in accordance with regulation 22.

"Radiographer" means a person who has successfully completed an approved course of training for that category of persons and who is qualified to be employed as a radiographer by a health board.

"Radiological" means pertaining to radio diagnostic and radio therapeutic procedures, and intervention radiology or other planning and guiding radiology.

"Radiological installation" means a premises where patients are examined or treated and which contains radiological equipment.

"Radio diagnostic" means pertaining to in vivo diagnostic nuclear medicine, medical diagnostic radiology, and dental radiology.

"Radio therapeutic" means pertaining to radiotherapy including nuclear medicine for therapeutic purposes.

References

3. In these regulations words or phrases shall have the meaning assigned to them under regulation 2 and references to regulations or paragraphs, except where otherwise indicated, shall be construed as a reference to an article or a paragraph in these regulations.

4.1. These regulations shall apply to the following medical exposure:

(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 healthy individuals or patients voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes;
(e)the exposure of individuals as part of medico-legal procedures.

4.2.These regulations shall also apply to exposure of individuals knowingly and willingly helping (other than as part of their occupation) in the support and comfort of individuals undergoing medical exposure.

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5. The provisions of these regulations shall be without prejudice to the rights and responsibilities of the Radiological Protection Institute of Ireland in relation to the custody, transportation, handling, holding, storage, use, manufacture, production, processing, importation, distribution, exportation or other disposal of radioactive devices, nuclear devices or irradiating apparatus.

Schedules of Criteria for Installations

6. Radiological and nuclear medicine equipment, apparatus and installations being used for diagnostic or therapeutic purposes, including general radiography, fluoroscopy, computer tomography, mammography, radiography, nuclear medicine and radiotherapy shall comply with the criteria as may be specified by the competent authority from time to time.

7.1 Medical exposure referred to in regulation 4.1 shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefit it produces, including the direct health benefits to an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionizing radiation.

7.2. Medical radiological procedures may only be authorised by, and be performed under the clinical responsibility of, a practitioner.

7.3. Medical radiological procedures which, in the opinion of the Medical or Dental Councils, involve exposing the patient to unusually high doses of radiation or where there is an unusually high risk associated with the procedure, may only be authorised by, and be performed under the clinical responsibility of, a practitioner or a person referred to in regulation 13 who has completed such additional training as the Medical or Dental Councils may from time to time prescribe.

7.4 A practitioner, a radiographer or a person referred to' in regulation 13 may perform a medical radiological procedure subject to the conditions specified in paragraphs 7.2 and 7.3.

7.5 (a). All doses due to medical exposure for radiological purposes except radiotherapeutic procedures referred to in regulation 4.1 shall be kept as low as reasonably achievable consistent with obtaining the required diagnostic information, taking into account economic and social factors.

7.5 (b) For all medical exposure of individuals for radiotherapeutic purposes, as mentioned in regulation 4.1 (a), exposures of target volumes shall he individually planned, taking into account that doses of non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.

7.6. Health screening programmes shall be undertaken only with the prior consent of the Minister, which he may refuse to give, and in accordance with such criteria as he, or such persons as he might nominate, may specify.

7.7 (a) All practices involving medical exposure which, in the opinion of the Medical or Dental Councils, are new, shall be subject to the approval of the Medical or Dental Councils and shall be conducted in accordance with such guidelines as they may direct.
7.7 (b) All existing types of practices involving medical exposure may be reviewed whenever new important evidence about their efficacy or consequences is acquired.

7.8. If a new type of practice involving an exposure is not yet approved in accordance with sub paragraph 7.7 (a), a specific individual exposure of this type may be authorised by a practitioner where he or she is of the opinion that such a procedure is warranted.

7.9. A practitioner may not authorise the use of a practice which has been considered by the Medical or Dental Councils and which has not been approved by them.

7.10. A prescriber may prescribe a medical radiological procedure in respect of an individual and that prescription shall be in writing.

7.11. A prescriber shall state in writing on each individual prescription his or her reason for requesting the particular procedure and the practitioner shall make arrangements to satisfy him- or herself that the procedure as prescribed is justified.

7.12. The prescriber and the practitioner shall seek, where practicable, to obtain previous diagnostic information or medical records relevant to the planned exposure and consider these data to avoid unnecessary exposure.

8. Exposures on medico-legal grounds, where there is no direct health benefit for the person undergoing the exposure, shall be performed only on foot of a specific written direction from the courts and providing the procedure required does not, in the opinion of the practitioner, pose a threat to the patient's health and the dose is kept as low as reasonably achievable.

Exposures for occupational Health Surveillance

9. Medical exposures for occupational health surveillance shall not be permitted, save where, in the opinion of the Medical or Dental Councils and in consultation with a medical officer of the Health and Safety Authority, there are special circumstances pertaining to a particular employment or category of employment which warrant such exposures, exposures may be undertaken in accordance with such standards as shall be directed by the Medical or Dental Councils.

10.1. Medical exposure for biomedical and medical research shall not be permitted save in accordance with such criteria as may be directed by the Medical or Dental Councils and approved by the local medical ethics committee.

10.2. Without prejudice to the generality of paragraph 10.1, the practitioner shall ensure that for each biomedical and medical research project each participating individual shall participate voluntarily, the practitioner shall seek where practicable to obtain previous diagnostic information or medical records relevant to the individual, that the individual is informed about the risks of this exposure and that he or she gives his or her informed consent in writing and that a dose constraint is established for that individual.

10.3. In the case of patients who voluntarily accept to undergo an experimental diagnostic or therapeutic practice and who are expected to receive a diagnostic or therapeutic benefit from this practice, the target levels of doses shall be planned on an individual basis by the practitioner.

Diagnostic ReferenceLevels

11. 1. The Medical and Dental Councils shall promote the establishment and the use of standard diagnostic reference levels for radio diagnostic examinations as referred to in sub paras. 4.1(a), (b), (c) and (e).

Written Protocols

11.2. Written protocols for every type of standard radiological practice shall be established by the Medical or Dental Councils in respect of each type of equipment.

Protection of Helpers

12.1(a) The Medical and Dental Councils shall establish the dose constraint for exposure of those individuals knowingly and willingly helping (other than as part of their occupation) in the support and comfort of patients undergoing medical diagnosis or treatment where appropriate.

12.1(b) The Medical and Dental Councils shall establish guidelines in respect of medical exposure of individuals covered under regulation 4.2.

12.1(c) Exposure referred to in regulation 4.2 shall show a sufficient net benefit, taking into account also the direct health benefits to a patient, the benefits to individuals referred to in regulation 4.2 and the detriment that the exposure might cause.

12.2. In the case of a patient undergoing a treatment or diagnosis with radio nuclides, the practitioner shall provide the patient or legal guardian with written instructions, with a view to the restriction of doses to persons in contact with the patient as far as reasonably achievable and shall provide information on the risks of ionising radiation

Specialists
13.1. The practical aspects for any medical radiological procedure or part thereof may be delegated by the practitioner to one or more individuals entitled to act in this respect in a recognised field of medical specialisation provided that individual has successfully completed such a course or courses in radiation safety as the Medical or Dental Councils may specify.

13.2.An individual performing a medical radiological procedure in accordance with para.13.1 shall ensure that a radiographer is in attendance at all times during the procedure.

13.3.Where, in the case of an emergency, it is not possible for a radiographer to be present the specialist may proceed without the radiographer being present but shall do so in accordance with such requirements as may be specified by the Radiation Safety Committee.

14.1. Each holder shall appoint a practitioner to act as the practitioner in charge in respect of each installation.

Referral Procedures
4.2 . The practitioner in charge of an installation shall recommend, having regard to these regulations and subject to the approval of the holder, the referral criteria for prescribers when referring patients for a radiological procedure.

14.3. The holder shall ensure that the criteria referred to in paragraph 14.2 are advised to prescribers.

14.4. Where a practitioner accepts a referral from a person who is not a prescriber the practitioner is deemed to be the prescriber and shall comply with the duties of a prescriber.

15.1. The Medical and Dental Councils shall, within two years of the making of these regulations and in consultation with the Faculty of Radiologists of the Royal College of Surgeons of Ireland (RCSI), adopt criteria for c.

15.2. The chief executive officer shall maintain a register of all installations in his or her functional area and he or she shall appoint a person who is for the time being a member of the Faculty of Radiologists, RCSI or other comparable faculty or body, to conduct clinical audits in accordance with the criteria established under paragraph 15.1 of these regulations, and the costs associated with that audit shall be borne by the holder.

15.3. Each holder shall ensure that the clinical practice conducted in his or her installation or installations, is audited in accordance with the criteria adopted under paragraph 15.1 at least once every five years and the first audit under these regulations shall be undertaken not later than three years from the date of adoption of the criteria for clinical audit specified in paragraph 15.1.

15.4.Notwithstanding the provisions of paragraphs 15.3 a person appointed under para.15.2 may, with the approval of the chief executive officer, and without notice, attend at any installation for the purposes of conducting a clinical audit and the holder and practitioner shall co-operate with that clinical audit.

15.5.A copy of the auditor's report shall be sent to the holder, to the practitioner in charge and to the chief executive officer who appointed him / her.

Undergoing Training
16. Individuals undergoing relevant training programmes may participate in practical aspects of radiological procedures under the direction of a practitioner.

17. The holder shall ensure that appropriate quality assurance programmes, including quality control measures and patient dose or administered activity assessment, are implemented for the installation.

Monitoring and Surveillance of Equipment

17.1. A named medical physicist shall be assigned, whole time or part time, to each installation by the holder and that medical physicist shall be given all reasonable access to the equipment and associated records and shall conduct periodic examinations of the equipment and records and shall agree such adjustments to be made to the equipment subject to the approval of the practitioner in charge, as he or she considers necessary, and he or she shall maintain a record of each examination and adjustment.

17.2 (a) The practitioner shall consult with the medical physicist assigned to the installation on optimisation, including the consistent production of adequate diagnostic information or therapeutic outcome, patient dosimetry, and quality assurance, including quality control and the assessment and evaluation of patient doses or administered activities, and on matters relating to radiation protection concerning medical exposures.

17.2(b) In radiotherapeutic practices, a medical physics expert shall be closely involved. In standardised therapeutical nuclear medicine practices and in diagnostic nuclear medicine practices, a medical physics expert shall be available.

17.3. The holder shall ensure that a written inventory of all radiological equipment in use in his or her radiological installation is maintained and that the form of that inventory complies with such form or forms as may be specified by the Radiological Protection Institute of Ireland.
17.4. Notwithstanding the requirements referred to in para.17.3, the inventory of equipment shall specify the dates of instal1ation of the equipment and new components of that equipment, the dates on which it was inspected by any duly authorized person, and the projected date of replacement of the equipment or components of that equipment.

17.5 The written inventory referred to in paragraphs 17.3 and 17.4 shall be furnished to the competent authority on request.

17.6 (a) Equipment, or components of equipment, which are continued in use after the due date of replacement shall require a specific decision to so continue their use by the holder and that decision shall be in writing.

17.6 (b) The medical physicist shall submit his views to the holder and to the Radiation Safety Committee.

17.6 (c) The Radiation Safety Committee and decide on the continued use and inform the holder.

17.7. The equipment in an installation and the inventory of equipment shall, without prejudice to the generality of the rights of the Radiological Protection Institute of Ireland, be subject to inspection by inspectors appointed by the Radiological Protection Institute of Ireland.

17.8. Acceptance testing of each item of equipment shall be carried out by the medical physicist assigned to the installation before the first use of the equipment for medical exposures and the equipment may not be used for medical exposures without the tests satisfying the criteria of acceptability and the outcomes of these tests shall be recorded in writing by the physicist.

17.9. The medical physicist assigned to the installation shall conduct performance tests after any major maintenance procedure and on a regular basis and shall record the results of such tests.

17.10. The holder shall ensure that the equipment shall comply with the criteria of acceptability and shall take appropriate remedial action including taking the equipment out of service if it fails to meet the criteria.

Certain types of Equipment

18.1.The conduct of fluoroscopy examinations without an image intensification or equivalent techniques are prohibited.

18.2.The use of fluoroscopic devices which do not have a device to control the dose rate shall be limited to circumstances as the Medical or Dental Councils may determine.

18.3. Radio diagnostic equipment brought into use after the enactment of these Regulations shall have a device informing the practitioner of the quantity of radiation produced by the equipment during the radiological procedure.

Appropriate Equipment

19. The holder shall ensure that appropriate radiological equipment, practical techniques and ancillary equipment shall
be used for the medical exposure of children, as part of a health screening programme, or for radiological procedures involving high doses to the patient, such as interventional radiology, computed tomography or radio therapy. Special attention shall be given to the quality assurance programmes, including quality control measures and patient dose or administered activity assessment, for these practices.

Special Protection during Pregnancy and Breast Feeding

20.1. In the case of a female of childbearing age, the prescriber, the practitioner, the radiographer, and persons referred to in Regulations 13 and 16 shall inquire whether she is pregnant, or breast feeding if relevant, and shall record her answers in writing.

20.2(a) In the case of a female of childbearing age if pregnancy cannot be excluded or where the records fall to indicate whether the patient is pregnant or not, the prescriber, the practitioner, the radiographer and persons referred to in Regulations 13 and 16 shall treat the patient as if she were pregnant.

20.2 (b) If pregnancy cannot be excluded, depending on the type of medical exposure, in particular if abdominal and pelvic regions are involved, special attention shall be given to the justification, particularly the urgency, and to the optimisation of the medical exposure taking into account the exposure both of the expectant mother and the unborn child.

20.3. In the case of a female who is breast feeding, in nuclear medicine, the prescriber, the practitioner, the radiographer and persons referred to in regulations 13 and 16 shall in recording their justification for continuing with a procedure have specific regard and make written reference to that fact. Special attention shall be given to the justification, particularly the urgency, and to the optimisation of the medical exposure, taking into account the exposure for both the mother and for the child.

20.4. Procedures to be conducted on pregnant or breast feeding females shall be done in accordance with procedures approved by the Medical and Dental Councils.

Instructions and Protocols

21. Working instructions and written protocols and quality assurance programmes to prevent accidental exposure shall be established and implemented by the practitioner in respect of each installation.

Radiation Safety Committee

22.1. Each health board shall establish a committee to be known as the Radiation Safety Committee and that committee shall be comprised of not more than ten members and shall advise the chief executive officer on any matter pertaining to the safety of radiological installations in the functional area of the health board and general operational practices in such installations and may issue guidance notes to holders, practitioners, practitioners in charge and prescribers to assist them to comply with the relevant provisions of these regulations.

22.2.Notwithstanding the generality of paragraph 22.1, a holder may establish a local radiation safety committee in respect of a particular installation and that committee shall have regard to the advice of the committee referred to in paragraph 22.1 and the members of the local committee shall be comprised of such persons as the holder may consider appropriate.

22.3. The members of the Radiation Safety Committee shall be appointed by the chief executive officer for a period of not more than five consecutive years and should a vacancy arise the chief executive officer will appoint a replacement.

22.3.Practitioners, prescribers, radiographers, medical physicists assigned to installations, or persons referred to in regulations 13 and 16, shall provide the Radiation Safety Committee with such assistance and information as the committee may from time to time reasonably require.

22.5 The Radiation Safety Committee shall meet at least twice each year and shall review the reports of inspectors of the competent authority and such other material as it is required to by the chief executive officer.

22.6. The Radiation Safety Committee shall monitor the population dosage for the health board functional area and will include their findings in an annual report.

22.7.The chief executive officer will provide the Radiation Safety Committee with such resources as he or she considers necessary to perform its functions.

22.8. The Radiation Safety Committee shall furnish the chief executive officer with an annual report and such other reports as the chief executive officer may require.

23.1. A person who contravenes these regulations shall be guilty of an offence and shall be liable to a fine not exceeding €3,000.

23.2.Summary proceedings in relation to an offence under these regulations may be brought and prosecuted by the chief executive officer or by the Minister or a person or officer nominated by the Minister for that purpose.

23.3.Where an offence under these regulations is committed by a body corporate, or by a person purporting to act on behalf of a body corporate or unincorporated body or persons, and is proved to have been committed with the consent or approval of, or to have been facilitated by, any neglect on the part of any person who, when the offence is committed, is a director, member of a committee of management or other controlling authority of the body concerned, or a manager, secretary or other officer of the body, that person shall also be deemed to have committed the offence and may be proceeded against and punished accordingly.

Expenses

24. The expenses incurred by the Minister in the administration of these regulations shall, to such extent as may be sanctioned by the Minister for Finance, and unless otherwise provided for in these regulations, be paid
out of moneys provided by the Oireachtas.

General Safety Arrangements

25. Nothing in these regulations shall prevent a chief executive officer, acting on the advice of the Radiation Safety Committee, from, introducing measures or arrangements pertaining to any installation in the board's functional area which, in his or her opinion, are necessary to protect the health and safety of patients, the general public or persons employed in the installation and holders shall comply with such measures or arrangements.

26. The following regulations are hereby revoked

- European Communities (Medical Ionising Radiation), Regulations, 1988. (S.I. No 189 of 1988).
- European Community (Radiological and Nuclear Medicine Installations), Regulations, 1998 (S.I. No 250 of 1998.)

Given under the Official Seal of the Minister for Health and Children, this 15th day of October, 2002.

L.S.
Micheál Martin
Minister for Health and Children

Explanatory Memorandum

(This note is not part of the regulations and does not purport to be a legal interpretation)

These regulations lay down measures for the radiation protection of individuals in relation to medical exposure of patients as part of their own medical diagnosis or treatment; the exposure of individuals as part of occupational health surveillance; the exposure of individuals as part of health screening programmes; the exposure of healthy individuals or patients voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes; the exposure of individuals as part of medical legal procedures; the exposure of individuals knowingly or willingly helping (other than as part of their occupation) in the support and comfort of individuals undergoing medical exposure. These regulations revoke EC Directive 84/466 EURATOM.