UNOFFIAL ENGLISH TRANSLATION

The Protection from Ionising Radiation (Medical Exposure) Regulations of 2002 which have been made by the Council of Ministers exercising the power conferred to it by Section 40 of the Protection from Ionising Radiation Law of 2002, having been presented to, and approved by, the House of Representatives, are published in the Official Journal of the Republic according to paragraph (3) of Section 3 of the Deposition of Regulations Published made under a Law, Law (N.99 of 1989 as amended by N.227 of 1990).

THE PROTECTION FROM IONISING RADIATION LAW OF 2002

Regulations made under Section 40

The Protection from Ionising Radiation
(Medical Exposure) Regulations of 2002

Arrangement of Regulations

The Protection from Ionising Radiation Law of 2002

Regulations made under Section 40

For the purpose of harmonisation with the European Community Act with title- "COUNCIL DIRECTIVE 97/43/EURATOM of the 30th of June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom EEL 180, 9.7.1997, p.22"

The Council of Ministers, in exercising the powers Conferred on it by Section 40 of the Protection from Ionising Radiation Law of 2002 after proposal by the Minister, hereby makes the following Regulations.

Short title

1.- These Regulations shall be cited as the Protection from Ionising Radiation (Medical Exposure) Regulations of 2002.

Interpretation

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

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

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

"Radiological" means pertaining to radiodiagnostic and radiotherapeutic procedures and interventional radiology or other planning and guiding radiology.

"Radiological installation" means a facility containing radiological equipment.

"Competent Authority" means the Minister of Labour and Social Insurance.

"Diagnostic Reference Levels" means dose levels in medical radiodiagnostic 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.

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

“Patient dose” means the dose, concerning patients or other individuals undergoing medical exposure.

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

“Pregnant” or **“breastfeeding”** has the meaning assigned to these terms in the Health and Safety at Work Laws of 1996 to 2002 or any regulations issued through these laws.

“Inspection” means an investigation by the Competent Authority to verify compliance with the provisions on radiological protection for medical radiological procedures, equipment in use or radiological installations.

“Practitioner” means a Radiologist, Radiation Oncologist, Nuclear Medicine doctor, dentist or other doctor or health professional, who is entitled to take clinical responsibility for an individual medical exposure in accordance with the requirements of the Legislation.

“Medical Radiological Procedure” any procedure concerning medical exposure.

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

“Medico-legal procedures” means procedures performed for insurance or legal purposes without a medical indication.

“Medical Physics Expert” means an expert in radiation physics or radiation technology applied to exposure, within the scope of this Directive, whose training and competence to act is recognized by the competent authorities; and who, as appropriate, acts or gives advice on patient dosimetry, on the development and use of complex techniques and equipment, on optimization, on quality assurance, including quality control, and on other matters relating to radiation protection, concerning exposure within the scope of this Directive.

“Suitable qualifications or training” means the qualifications or training which satisfy the requirements of the Schedule two.

“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; optimization; clinical evaluation of the outcome; cooperation 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 referrers, as required; giving information on the risk of ionizing radiation to patients and other individuals involved, as appropriate.

"Law" means the Law for the Protection from Ionising Radiation of 2002

"Referrer" means a medical doctor, dentist or other health professional, who is entitled to refer individuals for medical exposure to a practitioner, in accordance with the requirements of the Legislation.

"Quality control" which is part of quality assurance, 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.

"Practical Aspects" means the physical conduct of any of the exposure referred to in paragraph 1 of Regulation 4 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-pharmaceuticals and the development of films.

"Operator" means any person who, according to written instructions of the Employer or the Licensee is authorised to perform practical tasks in accordance with paragraph 3 of Regulation 6, Medical Physics Experts mentioned in Regulation 11 and persons performing such tasks as part of their training, except when performing these tasks under the supervision of a suitably qualified person.

(2) Not withstanding paragraph (1) of this regulation, all terms referred in these Regulations, unless a different meaning is given in the text, have the meaning given to them by the Law or any Regulations made under it.

Scope of the Regulations

3. These Regulations prescribe the general principles for the radiation protection of individuals in relation to medical exposure to ionising radiation as referred to in Regulation 4.

Application

4.- (1) These Regulations apply to the following medical exposure situations:

(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.

(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.

Duties of the employer or licensee, Schedule one

5.-(1) Each employer or licensee shall ensure that there are written procedures concerning each type of medical exposure, including the instructions listed in the Schedule one, and

(a) Shall take all necessary actions so as to ensure that these instructions are adhered to by the referrers or the operators or

(b) when the employer or licensee is also a referrer or operator he shall follow these procedures himself.

(2) Every employer or licensee shall ensure that written protocols for each practice involving a Medical Exposure and for each piece of radiological equipment are available and are being used.

(3) Every employer or licensee shall ensure that-

(a) referral criteria are set and used with respect to medical exposures, including exposures to ionising Radiation, and that these criteria are available to referrers;

(b) quality assurance programs are in action for all standard procedures;

(c) diagnostic reference levels are set and used for Radiodiagnostic examinations which involve cases mentioned in sub-paragraphs (a), (b), (c) and (e) of paragraph (1) of Regulation 4, taking into account the diagnostic reference levels which are published by the Minister, through a Notification in the Official Journal of the Republic;

(d) dose constraints are set and used for medical and biomedical research on the basis of sub-paragraph (d) of paragraph (1) of Regulation 4, in cases when no health gain is expected for the exposed person.

(4) Every employer or licensee shall adopt all necessary measures so as to make sure that every practitioner or operator which they employ or cooperate with and who performs medical exposures or practical parts of such exposures-

(a) complies with Regulation 13; and

(b) is continuously trained, after he qualifies, including, in cases where new techniques are being used, training in these techniques and in the relevant radiation protection requirements; or

(c) whenever the employer or licensee is also a referrer or operator he shall ensure that he undertakes continuous and satisfactory training.

(5) Whenever the employer or licensee is informed of, or has reasons to believe that, there has been or may have been, an incident that was not caused by a malfunction or fault of the equipment, that resulted in a person, during a medical exposure, being exposed to radiation doses higher than the ones initially intended he shall proceed to an immediate preliminary investigation of the incident and, unless the investigation proves beyond any reasonable doubt that no overexposure took place, shall immediately notify the Radiation Inspection and Control Service about the incident and proceed with, or arrange for, a detailed investigation of the incident and an assessment of the dose received by the person during that medical exposure.

(6) Whenever the diagnostic reference levels, set according to paragraph (3) of Regulation 5 are systematically exceeded, the employer or licensee shall proceed with an investigation of the matter and make sure that all necessary rectifying measures are taken.

Duties of the practitioner, operator and referrer

6.-(1) Every practitioner or operator shall follow the procedures set by the employer or licensee who employs him or cooperates with him, for each medical exposure.

(2) The practitioner is responsible and bears the responsibility for the justification of each medical exposure, as well as for anything else stated in these Regulations.

(3) The practical aspects of a procedure or part of it may be delegated, according to instructions given by the employer or licensee or the practitioner, as appropriate, to one or more individuals entitled to act in this respect as a result of their specialization or qualifications.

(4) The operator is responsible and bears the responsibility for each practical aspect of a procedure he performs as well as for each authorisation he gives pursuant to paragraph (6) of Regulation 7, provided that that authorisation is not accompanied by instructions from the Practitioner.

(5) The referrer shall provide the practitioner with sufficient medical information, including past diagnostic information or medical examinations relevant to the medical exposure requested so as to help the Practitioner with his decision with respect to whether there is sufficient benefit to the patient, as required by sub-paragraph (a) of paragraph (1) of Regulation 7.

(6) The practitioner and the referrer shall cooperate, regarding practical aspects, with other specialists and persons involved in the medical exposure, when necessitated by the nature of the procedure.

(7) Whenever a person is concurrently acting as, or in any combination of the roles of, employer, licensee, practitioner, referrer and operator he shall comply with all requirements placed on employers, licensees, practitioners, referrers and operators by these Regulations, depending on the situation.

Justification of individual medical exposures

7.-(1) No person shall carry out a medical exposure on any person, in the cases stated in paragraph (1) of Regulation 4 unless-

(a) it has been justified by the practitioner who has concluded that it will show a sufficient net benefit, taking into special consideration the matters set out in paragraph (3); and

(b) it has been authorised by the practitioner or, where paragraph (6) applies, the operator; and

(c) in the case of a medical exposure as referred to in sub-paragraph (d) of paragraph (1) of Regulation 4 he has a special license from the Minister, following a suggestion from the Technical Licensing Committee, who, in this respect, examines matters of deontology and ethics;

(d) in the case of a medical exposure falling within sub-paragraph (e) of paragraph (1) of Regulation 4 it complies fully with the employer's or licensee procedures for such exposures; and

(e) in the case of a female of childbearing age, he has enquired whether she is pregnant or breastfeeding.

(2)(a) All new practices involving medical exposure shall be justified in advance before being generally adopted; and

(b) all existing types of practices involving medical exposure must be reviewed whenever new and important evidence about their efficacy or consequences is acquired.

(3) The facts that must be considered by the practitioner during the justification process, for the medical exposure include-

(a) the specific objectives of the exposure and the characteristics of the individual involved;

(b) the total potential diagnostic or therapeutic benefits, taking into consideration the direct health benefits to the individual and the total benefits to society from the exposure;

(c) the health detriment that the exposure may cause; and

(d) the effectiveness, benefits and risk of other available alternative techniques having the same objective but involving no or less exposure to ionising radiation.

(4) In considering the weight to be given to the matters referred to in paragraph (2), the practitioner during the justification process of an exposure shall pay special attention to—

(a) exposures for medico-legal processes;

(b) exposures that have no direct health benefit for the health of the individual undergoing the exposure; and

(c) the urgency of the exposure, where appropriate, in cases involving—

(i) a female where pregnancy cannot be excluded, in particular if abdominal and pelvic regions are involved, taking into account the exposure of both the expectant mother and the unborn child; and

(ii) breastfeeding women who undergo nuclear medicine procedures, taking into account the exposure of both the expectant mother and the unborn child

(5) During the justification of an exposure under sub-paragraph (a), paragraph (1) the practitioner shall take into account all data supplied by the referrer pursuant to paragraph (5), Regulation 6 in order to avoid unnecessary exposures.

(6) Where it is not practicable for the practitioner to authorise an exposure as required by sub-paragraph (b), paragraph (1), the operator shall authorise such an exposure in accordance with guidelines issued by the practitioner.

(7) No person shall be exposed according to paragraph (2) of Regulation 4 unless this exposure is justified and enough benefit will be resulted, taking into account the immediate health benefit for the patient, the benefit for the person mentioned in paragraph (2) of Regulation 4 and the detriment that could be produced by the exposure.

Optimisation

8.-(1) Excluding radiotherapeutic procedures mentioned in paragraph (1) Regulation 4, in all medical exposure situations the practitioner and the operator, to the extent of their respective involvement in a medical exposure, shall ensure that doses to exposed persons are kept as low as reasonably practicable consistent with the collection of the necessary diagnostic data and taking into account economic and social factors.

(2) In all medical exposures for radiotherapeutic purposes 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 paragraphs (1) and (2), the operator shall select suitable equipment and methods so as to ensure that for each medical exposure the dose of ionising radiation to the patient is as low as reasonably practicable and consistent with the intended diagnostic or therapeutic purpose and in doing so shall pay special attention to—

(a) quality assurance and quality control;

(b) assessment of patient dose or administered activity; and

(c) strict adherence to diagnostic reference levels set by the employer or the Licensee, falling within sub-paragraph (c) of paragraph (3) of Regulation 5, and

(d) economic and social factors.

(4) For each medical or biomedical research programme falling within sub-paragraph (d), paragraph (1) of Regulation 4, 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 constraints set down in the procedures for individuals for whom no direct medical benefit is expected from the exposure are strictly adhered to; and

(d) for patients who voluntarily undergo an experimental diagnostic or therapeutic practice and for whom a diagnostic or therapeutic benefit from this practice is expected, individual target levels of doses shall be planned by the practitioner.

(5) In the case of patients undergoing treatment or diagnosis with radionuclides, 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; or

(b) where the patient is a child who lacks capacity so as to consent, the person with parental responsibility for the child; or

(c) where the patient is an elder who lacks capacity so as to consent to the treatment, the person who appears to the practitioner to be the most appropriate person.

(d) persons who, according to paragraph (2) of Regulation 4, willingly and knowingly help, outside the framework of their profession, with the support and relief of patients undergoing medical exposures.

(6) The instructions and information referred to in paragraph (5) shall include—

(a) ways in which the doses resulting from the patient's exposure can be restricted as far as reasonably possible so as to protect persons in contact with the patient;

(b) set out the risks associated with ionising radiation; and

shall be provided to the patient or other person specified in paragraph (5) as appropriate prior to the patient leaving the hospital or other place where the medical exposure was carried out.

(7) For the purpose of complying with 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;

(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 to persons that result in very large doses to these persons like interventional radiology, computed tomography or radiotherapy;

(f) medical exposures of females who could potentially be pregnant,

in particular if the abdominal and pelvic regions are involved, taking into account the exposure of both the expectant mother and the unborn child; and

(g) medical exposures of females who are breastfeeding and who are undergoing exposures in diagnostic or therapeutic nuclear medicine, taking into account the exposure of both the female and the child.

(8) Each employer or licensee shall take all suitable steps to ensure that a clinical evaluation of the outcome of each medical exposure, is recorded in accordance with the employer's or licensee set procedures or, where the employer is concurrently practitioner or operator, shall so record a clinical evaluation, including the patient´s 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 a fluoroscopic examination without an image intensification or other equivalent technique.

Dose limits for persons helping voluntarily

9.-(1) No person exposed to ionising radiation, as referred to in paragraph (2) of Regulation 4, shall receive doses exceeding 5mSv during the time it takes for the performance of the radiological procedure.

(2) Each employer or licensee shall ensure that the doses received by the persons referred to in paragraph (1) of this Regulation are recorded in a suitable register and that this dose information is presented or sent from the employer or the licensee to the competent authority, when asked.

Clinical Audit

10. The employer's or licensee procedures, as referred to in paragraph (1) of Regulation 5 shall include provision for the carrying out of clinical audit.

Medical Physics Expert

11.-(1) The employer shall ensure that a medical physics expert shall be involved in every medical exposure in accordance with paragraph (2).

(2) A medical physics expert shall —

(a) be closely involved in every radiotherapeutic practice;

(b) be available in standardised therapeutic nuclear medicine practices and in diagnostic nuclear medicine practices;

(c) be involved, as appropriate, for consultation on optimisation, including patient dosimetry and quality assurance and quality control, and to give advice on matters relating to radiation protection concerning medical exposure, as required, in all other

radiological practices.

Equipment-Equipment inventory

12.-(1) Every employer or licensee shall draw up, and preserve, at each radiological installation an inventory of equipment which shall be kept up-to-date, and when so requested, shall furnish it to the competent authority.

(2) The inventory referred to in paragraph (1) shall, at the least, contain the following information—

(a) name and address of manufacturer,
(b) model number,
(c) serial number,
(d) year of manufacture,
(e) year of installation.

(3) Every employer or licensee shall ensure that the operational equipment at each radiological installation under his control is limited to the amount necessary for the proper carrying out of medical exposures at that installation.

(4) No person is allowed to put into use new radiological equipment for medical exposures unless an acceptance testing is carried out and thereafter such testing shall be performed on a regular basis, and after any major maintenance procedure.

(5) No person is allowed to put into use new radiodiagnostic equipment unless it has, where practicable, a device informing the practitioner of the quantity of radiation produced by the equipment during the radiological procedure.

(6) Each person using radiological equipment shall inform immediately the employer or licensee responsible for this equipment as soon as he notices or finds out that the equipment functions are insufficient or faulty.

(7) Each employer or licensee who notices or finds out that the equipment used in his radiological centre is insufficient or its functions are faulty shall immediately take action for its repair or replacement.

(8) It is forbidden to use radiological equipment for medical exposures if it is not built to standard acceptable to the competent authority or if during its operation it creates a health risk that contravenes these Regulations.

Education and Training

13.-(1) Subject to the provisions of the following paragraphs of this regulation no practitioner or operator shall carry out a medical exposure or any practical aspect without having suitable theoretical and practical training in the radiological techniques, as well as suitable professional qualifications in the field of radiation protection.

(2) Any trainee or student can perform practical tasks, which form part of his regular training, subject to the condition that this is done under the supervision of a person suitably and sufficiently qualified, according to these Regulations.

(3) Every employer or licensee shall prepare and maintain at each radiological installation a suitable register with information about all practitioners, operators, medical physics experts which he employs or cooperates with, and in the case where he is at the same time a practitioner and an operator, information concerning his personal training in which the time periods when the abovementioned persons received training and the nature of that training is shown.

(4) The register mentioned in paragraph (3) shall be kept up to date and shall be presented or sent to the competent authority by the employer or licensee, when requested.

SCHEDULE ONE

(Regulation 5)

Written procedures that shall be prepared by every employer or licensee with respect to medical exposures

1. Procedures to identify correctly the individual to be exposed to ionising radiation.

2. Procedures to identify individuals entitled to act as referrer or practitioner or operator.

3. Procedures to be observed in the case of medico-legal exposures.

4. Procedures for making enquiries of females of childbearing age so as to establish whether they may be pregnant or breastfeeding

5. Procedures to ensure that quality assurance programmes are followed.

6. Procedures for the assessment of patient dose and administered activity.

7. Procedures for the use of diagnostic reference levels which are expected not to be exceeded for standard procedures when good practice regarding diagnostic and technical performance is applied.

8. Procedures for determining whether the practitioner or operator is required to take any action set out in paragraph (4) of Regulation 8, including procedures for the use of dose constraints for biomedical or medical research programmes, where no direct medical benefit for the individual is expected from the exposure.

9. Procedures for the giving of written instructions and information as referred to in paragraph (5) of Regulation 8.

10. Procedures for the carrying out of clinical audit.

11. 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 TWO

(Regulation 2)

Minimum education and training requirements on radiation protection for practitioners and operators

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

(a) such of the subjects detailed in Part A as are relevant to their functions as practitioner or operator; and

(b) such of the subjects detailed in Part B as are relevant to their specific area of radiological practice.

PART A

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 Topics

- Pregnancy and radiation
- Children and radiation
- Medical and biomedical research
- Health screening
- High dose techniques

2. Management and Radiation Protection of the Patient

2.1 Patient Selection

- Justification of the exposure
- Patient identification and consent
- Use of existing appropriate radiological information for the patient
- Alternative techniques
- Clinical evaluation of the exposure outcome

- Medico-legal issues

2.2 Radiation Protection

- General radiation protection
- Use of radiation protection equipment

  - Patient
  - personnel

- Procedures for unpleasant 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 at every radiological installation
- Responsibilities relating to medical exposures
- Responsibility for radiation protection
- Daily inspection and testing of equipment
- Notification of faults
- Clinical audit

PART B

4. Diagnostic Radiology

4.1 General

- Fundamentals of radiology - anatomy
- Fundamentals 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 intensifier/fluoroscopy
- Digital Fluoroscopy
- Computed Tomography
- Interventional procedures
- Angiography

4.3 Fundamentals of Image Acquisition etc.

- Image quality versus radiation dose
- Conventional film processing
- New methods for development, printing, storage and display

4.4 Image contrast control methods

- 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
    - radiobiology
    - sealed sources

5.2 Radiological Aspects of Radiotherapy

- Fractionation
- Dose rate
- Radio sensitisation
- Tumour data - Target

5.3 Practical Aspects for Radiotherapy

- Equipment
- Treatment planning

5.4 Radiation Protection Specific to Radiotherapy

- Side effects (immediate and long term)
- Toxicity
- Assessment of efficacy

6. Nuclear Medicine

6.1 General

- Atomic structure and radioactivity

- Nuclear reactions
- Tracers
- Use of radioisotopes for diagnosis
- Use of radioisotopes for therapy

    - dose rate
    - fractionation
    - aspects of radiobiology

6.2 Radiation Detection, Instrumentation and Equipment

- Types of detection systems
- Image printing storage and display
- Quality assurance and quality control

6.3 Products

- Calibration
- Working practices in the use of radiopharmaceutical products
- Preparation of individual doses
- Documentation

6.4 Radiation Protection Specific to Nuclear Medicine

- Conception, pregnancy and breastfeeding
- Arrangements for radioactive patients
- Disposal procedures for radioactive waste