

**L.N. 472 of 2004**

**THE PUBLIC HEALTH ACT, 2003  
(ACT NO. XIII OF 2003)**

**Ionising Radiation Medical Exposure Regulations, 2004**

IN exercise of the powers conferred by article 26 (m) of the Public Health Act, 2003, the Minister of Health, the Elderly and Community Care has made the following regulations:-

**1.** (1) The title of these regulations is Ionising Radiation Medical Exposure Regulations, 2004. Title and scope.

(2) The scope of these regulations is to transpose Directive 97/43/Euratom.

**2.** The Superintendent of Public Health shall have the power to enforce these regulations. Enforcement.

**3.** In these regulations, unless the context otherwise requires: Interpretation.

“adequate training” means training which satisfies requirements for theoretical knowledge and practical experience as determined by the Board. Such training shall be commensurate with the functions and the specific area of practice of practitioners or operators, as appropriate;

“the Board” means the Radiation Protection Board as constituted by article 3 of the Nuclear Safety and Radiation Protection Regulations, 2003;

“child” means a person who has not yet attained the age of 18 years;

“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 the responsibility regarding individual medical exposures attributed to a practitioner, notably: justification, optimization, clinical evaluation of the outcome, cooperation with other specialists and 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;

“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 standardised 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;

“employer” shall have the same meaning as assigned to radiation employer in the Nuclear Safety and Radiation Protection Regulations, 2003;

“equipment” means equipment which delivers ionizing radiation to a person undergoing a medical exposure and equipment which directly controls or influences the extent of such exposure;

“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;

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

“inspection” means an investigation by the Board or any authorised person or persons or any body corporate established by

or under any law, on behalf of the Board to verify compliance with these regulations;

“medical physics expert” means an expert in radiation physics or radiation technology applied to exposure, within the scope of these regulations, who holds a science degree or equivalent and who is experienced in the application of physics to the diagnostic and therapeutic uses of ionising radiation and whose training and competence to act in a specific area of practice is recognised by the Board; 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 within the scope of these regulations;

“medical radiological procedure” means any procedure concerning medical exposure;

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

“occupational health surveillance” means the medical surveillance for workers as specified by Occupational Health and Safety Authority by virtue of the General Provisions for Health and safety at Work Places Regulations, 2003;

“operator” means any person who is entitled, to carry out practical aspects;

“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;

“practical aspects” means the physical conduct of any of the exposure referred to in regulation 5 (1) 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;

“practitioner” means a medical doctor, dentist or other health professional, who takes clinical responsibility for an individual

medical exposure and whose training and competence to act in a specific area of practice is recognised by the Board;

“referrer” means a medical doctor, dentist or other health professional recognised by the Board, who is entitled, in accordance with the employer’s procedures, to refer individuals for medical exposure to a practitioner;

“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;

“quality control” is a part of quality assurance and means the set of operations (programming, co-ordinating, 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;

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

“radiological installation” means a facility containing radiological equipment;

“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.

Application.

**5. (1)** 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 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 helping, other than as part of their occupation, in the support and comfort of individuals undergoing medical exposure.

**6.** (1) All medical exposures shall be effected under the clinical responsibility of a practitioner. Justification.

(2) No new type of practice involving medical exposure shall be adopted unless authorised by the Board.

(3) Existing types of practices involving medical exposure shall be reviewed by the Board whenever new evidence about their efficacy or consequences is acquired.

**7.** (1) No practitioner may authorise a medical exposure unless he has given due consideration to: Conditions justifying medical exposures.

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

(b) the target volumes intended for a radiotherapeutic purpose which volumes are individually planned taking into account that doses of non-target volumes and tissues shall be as low as practicable and consistent with the intended radiotherapeutic purpose of the exposure;

(c) the total potential diagnostic benefits or the total therapeutic benefits it produces;

(d) the direct health benefits to the individual and the benefits to society;

(e) the individual detriment that the exposure might cause;

(f) the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.

(2) Any medical exposure in terms of regulation 5(1)(d) requires the prior approval of the Board acting on the advice of an ethics committee.

Duties of  
employer.

**8.** (1) The employer shall ensure that written procedures for medical exposures are in place and 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 the individual is or may be pregnant or 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;

(h) procedures for medical and biomedical research programmes as referred to in regulation 5(1)(d), including the use of dose constraints;

(i) procedures for the giving of information and written instructions as referred to in regulation 11(1);

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

(k) procedures to ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced so far as reasonably practicable.

(l) procedures for the carrying out of clinical audit as appropriate.

(2) The employer shall take steps to ensure that the written procedures are complied with by the practitioner and the operator.

(3) In the case where the employer is concurrently practitioner or operator, he shall comply with these procedures himself.

(4) The employer shall ensure that written protocols are in place for every type of standard radiological practice for each equipment.

(5) The employer shall establish:

(a) referral criteria for medical exposures, including radiation doses, and shall ensure that these are available to the referrer;

(b) quality assurance programmes for standard operating procedures;

(c) diagnostic reference levels for radiodiagnostic examinations falling within regulations 5(1)(a), 5(1)(b), 5(1)(c) and 5(1)(e) having regard to European diagnostic reference levels where available, which levels must be approved by the Board.

(d) dose constraints for biomedical and medical research programmes falling within regulation 5(1)(d) where no direct medical benefit for the individual is expected from the exposure;

(e) appropriate guidance and dose constraints for exposure of individuals referred to in regulation 5(2).

(6) The employer shall review diagnostic reference levels and shall ensure corrective actions are taken when such levels are consistently exceeded:

Provided that the employer keeps a record of these levels, which record is also submitted to the Board.

(7) Where the employer knows or has reason to believe that an incident has or may have occurred in which a person, while undergoing a medical exposure was exposed to ionising radiation to an extent much greater than intended, the employer shall make an immediate preliminary investigation of the incident and, unless that investigation shows beyond a reasonable doubt that no such overexposure has occurred, the employer shall forthwith notify the Board and make or arrange for a detailed investigation of the circumstances of the exposure and an assessment of the dose received.

Complying with employer's instructions.

**9.** The practitioner and the operator shall comply with the employer's procedures.

Duties of practitioner, referrer and operator.

**10.** Without prejudice to regulation 7(1)(b), the operator and practitioner shall select equipment and methods to ensure that for each medical exposure the dose of ionising radiation to the individual undergoing the exposure is as low as reasonably practicable and consistent with the intended diagnostic or therapeutic purpose and in doing so shall pay special attention to:

- (a) quality assurance; and
- (b) assessment of patient dose or administered activity; and
- (c) adherence to diagnostic reference levels for radiodiagnostic examinations falling within regulations 5(1)(a), 5(1)(b), 5(1)(c) and 5(1)(e) as set out in the employer's procedures.

Written instructions and information.

**11.** (1) In the case of patients undergoing 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 a treatment or diagnostic procedure; or
- (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 to consent, the practitioner shall decide in the best interest of the patient.

(2) The patient shall be informed how the doses can be restricted as far as reasonably possible in order to protect persons in contact with him.

Optimisation.

**12.** (1) In complying with the obligations under these regulations, the practitioner and the operator shall ensure optimisation of the medical exposure and shall pay special attention to:

- (a) the need to keep doses arising from medico-legal exposures as low as practicable;
- (b) medical exposures of children;

(c) medical exposure as part of a health screening programme;

(d) medical exposures involving high doses to the patient;

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

(f) where appropriate, females who are breastfeeding and who are undergoing exposures in nuclear medicine, taking into account the exposure of both the female and the child.

(2) No person shall, in the case of fluoroscopy, carry out an examination without an image intensification or equivalent technique:

Provided that examinations without devices to control the dose rate shall be limited to justified circumstances.

**13.** The employer shall ensure that a medical physics expert is: Expert advice.

(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 for consultation on optimisation, including patient dosimetry and quality assurance, calibration of equipment, and to give advice on matters relating to radiation protection concerning medical exposure, as required, in all other radiological practices.

**14.** It shall be the duty of all persons to comply with any requirement or duty prescribed on them by these regulations and to render all assistance to and co-operate fully, by all possible means, with the Board or its duly authorised officers. General duty.

**15.** (1) Any breach of any provisions of these regulations shall be deemed an offence. Enforcement.

(2) Any action taken by the Board with respect to these regulations shall be deemed to have been taken on behalf of the Superintendent of Public Health.

(3) In any proceedings for an offence under these regulations consisting of a failure to comply with a duty or requirement, it shall be for the accused to prove that it was not practicable to do more than was in fact done to satisfy any of the requirements under these regulations.

Board to prescribe rules.

**16.** It shall be the duty of the Board to prescribe rules in consultation with the Superintendant of Public Health on any matter regarding:

- (a) radiological equipment;
- (b) training of employers, practitioners, referrers and operators;
- (c) duties of employers, practitioners, referrers and operators;
- (d) qualifications of, practitioners, referrers, and any other experts ; and
- (e) on any other matter concerning these regulations or as prescribed by the European Community.

Repeal L.N. 408 of 2003.

**17.** The Ionising Radiation Medical Exposure Regulations, 2003 are hereby repealed.