VERŻJONI ELETTRONIKA

L.N. 353 of 2012

PUBLIC HEALTH ACT
(CAP. 465)

Medical Exposure (Ionising Radiation) Regulations, 2012

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

Citation and scope.

1. (1) The title of these regulations is the Medical Exposure (Ionising Radiation) Regulations, 2012.

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

Enforcement.

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

Interpretation.

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

"adequate training" is the term used to ensure that both practitioners and persons performing the practical aspects, have the necessary requirements to carry out their duties. These requirements include the need for:

Cap. 464.

(a) the registration with the relevant Health Care Professions Regulatory Council in terms of Health Care Professions Act as applicable;

(b) initial training with any qualification; and

(c) proven experience and ongoing training;

"approval" means the process whereby the employer entitles different persons to act in the different aspects of medical exposures;

S.L. 365.15

"the Board" means the Radiation Protection Board as constituted by regulation 9 of the Nuclear Safety and Radiation Protection Regulations;

"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; optimisation; 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 prescribers, 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 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;

"employer" means any natural or legal person who has the legal responsibility under Maltese law for a given radiological installation;

"experience" means the activity accomplished in specific areas under the direct supervision of an approved individual in that specific area and includes the performance of work in that specific area, but does not include time spent during organised training;

"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;

"medical physics expert" means an expert in radiation physics or radiation technology applied to exposure, within the scope of these

regulations, whose training and competence to act in a specific area of practice is recognised by Superintendent of Public Health, 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 required by law in force at the time;

"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 4(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 health care professional registered with a regulatory body as defined by the Health Care Professions Act, who is authorised by the employer to take clinical responsibility for an individual medical exposure;

Cap. 464.

"prescriber" means a medical doctor, dentist or other registered healthcare professional who is authorised, in accordance with the employer's procedures, to refer individuals for medical exposure to a practitioner;

"qualification" means the written testimony of the education and, or training carried out;

"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;

VERŻJONI ELETTRONIKA

"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;

"radiographer" shall have the meaning as ascribed by the Health Care Professions Act; Cap. 464.

"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.

4. (1) These regulations shall apply to the following medical exposures: Application.

(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.

5. All medical exposures shall be effected under the clinical responsibility of a practitioner. Justification.

Conditions justifying medical exposures.

6. (1) Practitioners are to justify medical exposures in advance and may only authorise a medical exposure if due consideration is given to:

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

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

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

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

(e) 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 4(1)(d) requires the prior approval of the Board acting on the advice of an ethics committee.

(3) 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.

(4) An exposure that cannot be justified shall be prohibited.

Duties of the employer.

7. (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 prescribers and, or practitioners, and persons performing the practical aspects;

(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 4(1)(d), including the use of dose constraints;

(i) procedures for the giving of information and written instructions as referred to in regulation 20;

(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 as far as reasonably achievable;

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

(2) The employer shall take steps to ensure that the written procedures referred to in sub-regulation (1) are complied with.

(3) In the case where the employer is also the practitioner, 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 and shall make available to prescribers the relevant radiation doses for each type of medical exposure;

(b) quality assurance programmes for standard operating procedures;

(c) diagnostic reference levels for radiodiagnostic examinations falling within regulation 4(1)(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 4(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 4(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.

(8) The employer shall ensure persons performing the practical aspects as detailed in regulation 19 and practitioners have the appropriate qualification and experience.

(9) The employer shall facilitate the continuing education and training of employees.

(10) The employer shall have readily available updated documentation on the qualification and appropriate level of training requirements needed by the persons who carry out the practical aspects of each specific procedure.

(11) When the employer acts as either the practitioner or the person performing the practical aspects or concurrently, he is responsible accordingly.

Employer's approval required.

8. The employer shall approve individuals to act in different aspects of certain types of medical exposures.

VERŻJONI ELETTRONIKA

Employer to establish procedure.

9. (1) The employer shall establish a procedure as required by regulation 7(1)(b) to identify the appropriately qualified persons entitled to act in their different capacities.

(2) The employer shall maintain lists of individuals that he has approved as prescriber, practitioners and persons performing the practical aspects. The lists shall clearly specify any limitations of his approvals for individuals.

Employer to verify adequacy of employees.

10. (1) Employers shall ensure that individuals considered for approval under these regulations shall have the sufficient education and adequate training. Documentation of prior approval may be used by an employer as evidence for approval for comparable functions of approval.

(2) Documented evidence of qualification and experience and continuous education shall be kept by employer and shown to the Board on request.

(3) To be considered for approval, the individual shall satisfy the employer's minimum criteria for the applicable approval being sought.

Employer to adopt proper vetting.

11. (1) The employer is responsible to ensure that any individual whose work relates to medical exposure is approved by ensuring that the necessary requirements for that individual have been met.

(2) Each employer shall maintain on record all personnel qualifications and shall include:

(a) name of the individual;

(b) approval area, namely: practitioner, person performing the practical aspects of medical equipment for medical purposes; person performing the practical aspects for other purposes;

(c) qualification certificates to demonstrate training (both academic and practical);

(d) examination results if applicable (including vision examinations pursuant to regulation 10 of the Minimun Health and Safety Requirements for Work with Display Screen Equipment Regulations) and their expiry; S.L. 424.14

(e) documentation of any continuing professional development;

(f) contract or signed statement of employment of the individual to act in the approved capacity.

(3) A new employer may approve an individual to work in the same capacity provided that:

(a) the individual has proof of prior approval, and

(b) the individual was working in the same capacity in the last six months.

(4) Individuals not meeting the requirements referred to in sub-regulation (3) are to receive the appropriate training including examination if applicable.

Revocation of approval.

12. The employer's approval shall be deemed revoked when:

(a) employment is terminated, or

(b) preliminary investigations for accidents indicate gross individual negligence, or

(c) approved work has not been carried out for six consecutive months.

Complying with employer's instruction.

13. The persons performing the practical aspects, practitioner and the prescriber shall comply with the employer's procedures.

Duties and requirements of prescribers.

14. Prescribers shall:

(a) ensure and document that the medical exposure of the patient is warranted based on the medical indications;

(b) make reference to referral criteria;

(c) refer the patient to a practitioner, providing adequate clinical details;

(d) state on each individual referral the clinical question to be answered;

(e) where practical, seek to obtain previous diagnostic information or medical records relevant to the planned exposure and consider this data to avoid unnecessary exposure;

(f) seek the outcome of the exposure and act on the result;

(g) comply with the employer's procedures.

15. Prescribers shall have the following qualifications and experience: Prescribers' qualifications and experience.

Qualification	Registered medical doctors, or dentists, or Practitioners when additional exposures are clinically indicated
Experience	No initial experience needed.

16. (1) Without prejudice to regulation 21(4)(e), the 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 achievable and consistent with the intended diagnostic or therapeutic purpose, and in doing so shall pay special attention to: Duties and requirements of practitioners.

(a) quality assurance, and

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

(c) adherence to diagnostic reference levels for radiodiagnostic examinations falling within regulation 4(1)(a), (b), (c) and (e) as set out in the employer's procedures.

(2) The practitioner shall sanction medical exposures.

(3) The practitioner shall take clinical responsibility for medical exposure.

(4) The practitioner shall make arrangements to satisfy himself that the individual medical exposure as prescribed is justified, by ensuring that there is sufficient net benefit by this exposure for the patient, the benefit to comforters and carers against the detriment that the exposure might cause. This should be based on his knowledge of the hazard associated with the exposure and the clinical information supplied by the prescriber.

(5) The practitioner, where practical, shall seek to obtain previous diagnostic information or medical records relevant to the planned exposure and consider this data to avoid unnecessary exposure.

(6) The practitioner shall comply with the employer's procedures.

17. Practitioners shall have the following qualification and Practitioners' qualifications and experience.

experience::

Qualification	Medical doctors who are on the Specialist Registers held by the: Medical Council for Radiology; Radiotherapy; Nuclear Medicine, or Medical doctors who are on the Specialist Register held by the Medical Council for Cardiology, Gastrenterology, Respiratory Medicine, Rheumatology Orthopaedic Surgery and Surgery while carrying out interventions, or Dental surgeons, or Registered Radiographers
Experience	At least one month on the job experience under the supervision of an approved practitioner, excluding dental surgeons. No initial experience for dental work performed by dental surgeons.

Delegation of practitioner functions.

18. The physical conduct of any of the exposures referred to in regulation 4(1) and the administration of radio-pharmaceuticals may be delegated by the employer or the practitioner, as appropriate, to one or more individuals authorized by the Superintendent of Public Health to act in this respect.

Qualification and experience for persons performing the practical aspects.

19. (1) As the practical aspects of different procedures for medical exposures carry different levels of risk, both to the person performing the practical aspects and to the patient, the Board has categorised medical exposures as shown in the below table. This categorisation is being done in relation to persons performing the practical aspects only:

Risk Level	Type of medical exposure
High	Radiotherapy Brachytherapy Nuclear Medicine (diagnostic and therapeutic) Interventional Radiology Fluoroscopic Techniques CT Mammography
Medium	General Diagnostic Radiography Dental Radiography
Low	Low output Diagnostic Radiography (e.g. bone density)

(2) Persons performing the practical aspects shall have the following qualification and experience as detailed below:

(a) Persons performing the practical aspects of radiation producing medical equipment for medical purposes:

High Risk Procedures	Qualification	Practitioners, or Surgeons during surgery provided a registered radiographer is in attendance during the procedure.
	Experience	First time registered radiographers shall have at least three months on the job training under the supervision of a registered radiographer approved to work in the specific area.
Medium Risk Procedures	Qualification	Practitioners, or Dentists for dental medical exposures
	Experience	First time registered radiographers, Practitioners, excluding dentists, shall have at least one month on the job training under the supervision of an approved individual in the specific area. No initial experience for dental work performed by dental surgeons' specific area.
Low Risk Procedures	Qualification	Practitioners, or Other persons approved under regulation 18
	Experience	No initial experience for practitioners. Persons approved by the Superintendent of Public Health shall have two months on the job training under the supervision of a Practitioner.

(b) Persons performing the practical aspects administering sealed or unsealed radioactive sources for medical exposure purposes:

Brachytherapy	Qualification	Radiotherapist/oncologist on specialist register or Radiographer (Therapy) as per code of practice issued by Council for the Professions Complementary to Medicine
	Experience	One month or several procedures of on the job training under the supervision of an approved individual in the specific area.
Therapeutic Nuclear Medicine	Qualification	Nuclear Medicine Physician on specialist register, or registered Medical Doctor directed by the Nuclear Medicine Physician on specialist register.
	Experience	One month or several procedures on the job training under the supervision of an approved individual in the specific area.
Diagnostic Nuclear Medicine	Qualification	Nuclear medicine physician on specialist register, radiographer or other individuals as approved under regulation 18 directed by the nuclear medicine physician on the specialist register
	Experience	One month on the job training under the supervision of an approved individual in the specific area.

(c) Persons performing the practical aspects of other aspects of medical exposures:

Gamma Camera	Qualification	Nuclear medicine physician on specialist register, or registered radiographer or other suitably qualified individuals under the direct supervision of the nuclear medicine physician on specialist register or radiographer
	Experience	Three months on the job experience under the supervision of Nuclear medicine physician on specialist register, or registered radiographer.

Image Processing	Qualification	Basic academic and, or technical qualification to the satisfaction of the practitioner supervising the activity.
	Experience	Supervision by practitioner.

(d) Persons performing the practical aspects of radiation producing medical equipment for non medical purposes:

Quality Control Procedures	Qualification	Medical physics experts, or radiographers, engineers, or persons specifically trained to carry out the quality control of the relevant equipment.
	Experience	At least nine months on the job experience under the supervision of an approved QC individual or 300 hours of continuous training in quality control.
Installation and Maintenance	Qualification	Engineers or technicians specifically trained by the manufacturer in the areas that are needed to carry out their duty or trained by other engineers/ technicians certified competent by the manufacturer
	Experience	One month experience under the supervision of an experienced installer.

Written instructions and information.

20. (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.

21. (1) 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.

(2) The optimisation process shall include the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcome as well as the practical aspects, quality assurance including quality control and the assessment and evaluation of patient doses or administered activities.

(3) Practitioners and persons performing the practical aspects shall be personally and professionally responsible for their respective aspects of optimisation as defined in these regulations.

(4) In complying with the obligations under these regulations, the practitioner 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 reasonably achievable;

(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) 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 achievable and consistent with the intended radiotherapeutic purpose of the exposure;

(f) where appropriate, females 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

(g) 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.

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

VERŻJONI ELETTRONIKA

(6) Fluoroscopic examinations without devices to control the dose rate shall be limited to justified circumstances.

(7) Individuals who participate in biomedical and medical research projects referred to in regulation 4(1)(d) shall participate voluntarily and shall be informed about the risks of such exposure.

22. The employer shall ensure that a medical physics expert is: Medical physics experts.

(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.

23. The role of the medical physics expert shall be to give advice on or perform the following: Medical physics experts' role.

(a) Dosimetry, including:

- advising employer on radiation doses delivered to patients and diagnostic reference levels, and

- establishing adequate protocols to ensure accurate patient dosimetry, and

- confirmation that the prescribed dose is the dose delivered, and

- methods to optimise patient dose (the medical physics expert should consider and review all aspects leading to a medical exposure to aim to reduce unnecessary patient doses), and

- surveys of radiation equipment and the environment.

(b) Quality assurance, including:

- acceptance testing, and

- constancy testing, and

- advising on when equipment should be taken out of clinical use or returned back into clinical use.

(c) Advise the employer on the purchase of new equipment and its installation requirements.

(d) The development and use of equipment.

(e) Other matters relating to radiation protection concerning the medical exposures not limited to patient exposure and may include radiation protection of staff, public and the environment.

(f) Advise the employer on training needs for all categories of staff involved in the Medical exposure process.

Criteria to be met by medical physics experts.

24. Medical physics experts shall meet the following criteria:

(a) training as recommended by The European Federation of Organisations for Medical Physics at the level of M.Sc.; and

(b) two years full time work experience supervised by a person who meets the requirements of paragraph (a) and who has at least two years experience within that sub-speciality (radiotherapy, nuclear medicine, radiology); and

(c) from three years after the publication of these regulations, a minimum further two years work in sub-speciality (radiotherapy, nuclear medicine, radiology) with continued professional development.

Medical physics experts' requirements for continued development.

25. Requirements for continued professional development for medical physics experts shall meet the continued professional development requirements stipulated by Superintendent of Public Health.

Training.

26. (1) The employer shall ensure:

(a) that practitioners, those individuals mentioned in regulations 18 and 22 have adequate theoretical and practical training for the purpose of radiological practices, as well as relevant competence in radiation protection;

(b) the organization of training related to these techniques and the relevant radiation protection requirements.

(2) Individuals undergoing relevant training programmes may participate in practical aspects for the procedures mentioned in

VERŻJONI ELETTRONIKA

regulation 18 provided that they are constantly under direct supervision.

Equipment.

27. The Superintendent of Public Health shall take all those steps he may consider necessary to avoid the unnecessary proliferation of radiological equipment.

Employer's responsibility for equipment.

28. (1) The employer shall ensure that:

(a) all radiological equipment in use is kept under strict surveillance regarding radiation protection;

(b) an up-to-date inventory of radiological equipment for each radiological installation is available;

(c) appropriate quality assurance programmes including quality control measures and patient dose or administered activity assessments are implemented by the holder of the radiological installation; and

(d) necessary measures are taken to improve inadequate or defective features of the equipment.

(2) The employer shall also adopt specific criteria of acceptability for equipment in order to indicate when appropriate remedial action is necessary, including, if appropriate, taking the equipment out of service.

EC Declaration of Conformity requirement.

29. The Board shall require the employer to provide a copy of the EC Declaration of Conformity, issued by the manufacturer.

New equipment.

30. A device showing the quantity of the radiation produced by the equipment shall be required for new equipment, where practicable.

Installation tests.

31. Upon installation of the equipment the supplier/installer shall perform installation tests (also often referred to as critical tests) to ensure that all the safety features and warning devices of the equipment are functioning. During installation, the manufacturer's instructions for use must be followed. These tests shall be performed whenever new, second hand, refurbished and relocated equipment has been installed, as well as after major maintenance has been performed. Installation test results shall be kept by the employer and made available to the Board whenever so required.

Quality control systems.

32. (1) Within their quality assurance programme, employers shall also have quality control systems for radiological equipment and its ancillary equipment that they are responsible for.

(2) Quality control systems shall include the following tests:

(a) acceptance tests;

(b) constancy tests.

Acceptance tests.

33. (1) Acceptance tests need to be carried out:

(a) on installation of equipment;

(b) within six months of the publication of these regulations for all other existing equipment not covered by the above;

(c) after relocation or major modifications have been made to existing equipment;

(d) after major adjustments of functional parameters, repairs or maintenance have been performed;

(e) components or sub-assemblies have been added, modified, replaced or removed.

(2) Acceptance testing must be carried out in accordance with international standards.

(3) Test results shall be compared to and meet the specified tolerances. In the absence of such, as in the case of aged equipment, then European Union Criteria for acceptability may be used.

(4) The records for such testing shall be kept for the lifetime of the equipment and made available to the Board whenever these are requested.

(5) After the installation and acceptance testing are carried out, the test reports and any other relevant documentation has to be passed on the Board. The Board will then review the test results and any other information that is deemed necessary.

(6) The information to be supplied to the Board with regard to acceptance tests that have been performed is as follows:

(a) full equipment details including:

- type of equipment
- manufacturer
- model

- serial numbers
- year of manufacture
- year of Installation
- for x-ray equipment: Max KV. Max mA
- location of equipment;

(b) particulars of the test:

- reason for performing test
- person or persons performing test
- date of test
- name of standard followed
- specified tolerances, manufacturers' specification and other reference documents if appropriate
- details of test equipment used, including calibration dates;

(c) previous tests:

- details of any on-site/factory tests performed by manufacturer and results of such tests;

(d) for each of the required parameters tested the report shall include:

- test procedure followed
- measured values
- manufacturers' specification for that parameter
- if no manufacturers' specification available, the reason why and which value the measured value was compared to
- statement if the equipment passes that parameter.

Responsibility for fitness of equipment.

34. (1) The responsibility to ensure that the equipment is fit for clinical use resides with the employer.

(2) The clinical use of equipment prior to clearance from the Board is prohibited.

Constancy test.

35. (1) Immediately after an acceptance test has indicated that the functional performance of the equipment is satisfactory, an initial constancy test, or a series of initial constancy tests, shall be carried out to establish the baseline values (values obtained to be used as reference for future tests).

(2) Constancy testing shall be carried out in accordance with international standards.

(3) A constancy test is to be carried out at regular intervals, the frequency of which will be in accordance to the relevant international standard, and immediately after preventive and corrective maintenance. A constancy test shall also be carried out when malfunction of equipment is suspected.

(4) These results shall be kept at the practice and made available to the Board whenever so requested.

(5) The records for such testing shall be kept for three years from the last date of entry and made available to the Board whenever these are requested.

(6) These tests are to be performed as often as the standard stipulates and shall not exceed two years.

Redundant equipment.

36. (1) If any of the tests show that the equipment has or is producing doses higher than acceptable levels for medical exposures, or a malfunction has occurred that could effect patient dose, it shall be removed from clinical use and shall be reported to the Board.

(2) Acceptable levels are deemed the tolerances specified in the manufacturers' specifications or the current European Union criteria whichever is the most stringent.

(3) If the equipment is deemed to be redundant, with no intention of scrapping, then the employer shall remain responsible for accounting for that equipment and if the equipment is sold, leased or given to another approved employer, the Board shall be notified prior to this happening.

Reverting equipment to clinical use.

37. (1) The employer shall have procedures for bringing the equipment back into clinical use following any event referred to in

VERŻJONI ELETTRONIKA

regulation 36(1).

(2) Once the employer is satisfied that the equipment is fit to be put back into clinical use (after ensuring that tests were performed to ensure this), he is then bound to inform the Board.

(3) Clearance shall only be issued after the Board reviews all documentation pertaining to the tests mentioned above.

(4) All equipment used for testing shall be routinely re-calibrated according to its instructions for use; in the absence of any specified re-calibration period, the equipment calibration period shall not exceed a period of two years.

Quality records.

38. (1) Any records generated through the quality assurance or quality control systems that provide documentary evidence of the operational performance of the equipment are to be kept by the employer and shall be made available to the Board whenever these are requested. These records shall be kept on site and maintained in accordance with the provisions of this regulation.

(2) Acceptance test records and baseline value records shall be kept for the lifetime of the equipment.

(3) Other test records shall be kept for a minimum of three years from last date of entry.

Prevention of equipment failure.

39. (1) The employer shall take all reasonably practicable steps to prevent failure of radiation equipment where such failure could result in exposure of patients to ionising radiation greater than intended.

(2) If the employer becomes aware of potential defects in equipment during use, he will need to assess, in consultation with the supplier (or, where relevant, the service agent or original manufacturer) and the medical physics experts and the qualified expert, in terms of the Nuclear Safety and Radiation Protection Regulations, if appropriate, whether any further action is necessary.

S.L. 365.15

(3) The employer shall have a contingency plan for responding to equipment failures or malfunction. Following equipment failure and subsequent repair, the employer shall consider the likelihood and consequences of recurrence before returning the equipment to clinical use.

Special practices.

40. (1) Employers shall ensure that appropriate radiological equipment, practical techniques and ancillary equipment are used for the medical exposure:

VERŻJONI ELETTRONIKA

(a) of children,

(b) as part of a health screening programme,

(c) involving high doses to the patient, such as interventional radiology, computed tomography or radiotherapy.

(2) In the case of the medical exposures referred to in sub-regulation (1), special attention shall be given to the quality assurance programmes, including quality control measures and patient dose or administered activity assessment.

Offences.

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

(2) 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.

Guidance documents.

42. The Superintendent of Public Health, in consultation with the Board, may issue guidance documents on any matter regarding:

(a) equipment used in connection with medical exposures;

(b) training of practitioners, prescribers and persons performing the practical aspects;

(c) duties of employers, practitioners, prescribers and persons performing the practical aspects;

(d) qualifications of practitioners, prescribers and any other expert; and

(e) on any other matter concerning these regulations.

Notification.

S.L. 419.06

43. These regulations have been notified in terms of Directive 98/34/EC, as amended by Directive 98/48/EC, as transposed by the Notification Procedure Regulations.

Revokes the Ionising Radiation Medical Exposure Regulations, 2004. L.N. 472 of 2004.

44. The Ionising Radiation Medical Exposure Regulations, 2004 are hereby revoked.

Ippubblikat mid-Dipartiment tal-Informazzjoni (doi.gov.mt) — Valletta — *Published by the Department of Information (doi.gov.mt) — Valletta*
Mitbugħ fl-Istamperija tal-Gvern fuq karta riċiklata — *Printed at the Government Printing Press on recycled paper*

Prezz/*Price*
€2.16