Guidance Document

FOR

MEDICAL EXPOSURE (THE IONISING RADIATION) REGULATIONS, 2012

LN 353/ 2012

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Preface

The Legal Notice

The scope of the Medical Exposure (Ionising Radiation) Regulations 2012 (LN ***/2012) is to provide the legal framework for medical exposures to ionising radiation. In view that the regulation falls under the Public Health Act (Act 13 of 2003) responsibility for the regulation is
with the Superintendent of Public Health. The legal notice made provisions for guidelines to be issued.

**The Guidelines**

Pursuant to regulation 42 of the regulations the Superintendent has consulted with the Radiation Protection Board (Board) to create these guidelines.

The titles and numbering in these guidelines refer to the title and regulation numbers of the legal notice.

**Enforcement of the Legal notice**

From the Public Health Act the Superintendent shall act through the Radiation Protection Board to enforce these regulations.

The Board inspectors whose duties include securing compliance with these (and other regulations), will refer to both the LN 353/2012 as well as to these guidelines.

**Application**

4(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.**”

Individuals directly or indirectly exposed to a medical exposure, are also covered in these regulations.

The Nuclear Safety and Radiation Protection Regulations, 2003 (LN44/2003) defines these individuals as comforters and carers as “individuals (other than as part of their occupation), who, helping knowingly or willingly, incur an exposure to ionising radiation in the support and comfort of patient who is undergoing medical exposure for his medical diagnosis or treatment”.

“They may include members of the public who, for example:

(a) visit patients in hospital after those patients have been administered with radiopharmaceuticals (most notably for therapeutic purposes) or have undergone brachytherapy;

(b) offer support for those patients at home after they have been discharged from hospital; or
(c) (in some cases) offer support to a young child or disabled person while that child or person receives a diagnostic X-ray examination;

and are likely to receive 1 millisievert or more in a year resulting from direct radiation or contamination during the comfort and support they offer.

Radiation employers will need to make suitable arrangements to satisfy themselves that these individuals are aware of the risks involved in supporting and comforting a patient and are willing to incur the exposures they will receive. These arrangements may involve effective communication with the patient or directly with the comforter and carer.

The exposure of comforters and carers should normally be controlled, as far as reasonably achievable, by using time, distance and shielding, taking into account the wishes of the individual to offer comfort and support to the patient. As comforters and carers are not subject to dose limits, the dose constraint is important as a means of helping to plan general arrangements for restricting any unnecessary exposure of such people.

In most cases, comforters and carers would normally be expected to keep to these general arrangements. However, they may choose to depart from them, for example by spending more time with a seriously ill patient than is recommended, thereby incurring a dose greater than the numerical value of the dose constraint. That is perfectly reasonable provided that they do so willingly and are aware that they may incur a small additional risk from this increased exposure.

The Board recommends that in this context, medical exposures incurred by individuals, other than as part of their own medical diagnosis or treatment, should not in general exceed 5 millisieverts from their involvement in one series or course of treatment. Normally it should be possible to design procedures that will keep doses received by comforters and carers below this level while they offer comfort and support to patients. Radiation employers in the health-care sector considering arrangements to protect comforters and carers may wish to take account of this recommended value (together with advice from professional bodies) in selecting appropriate dose constraints.

Health-care employers would normally take account of any dose constraints in devising standard procedures for restricting the exposure of comforters and carers visiting patients administered with radiopharmaceuticals and for deciding when such patients ought to be discharged. In practice, these arrangements will often reflect general good practice for restricting the exposure of people who act as comforters and carers.¹

### Justification

#### 5(1)

“All medical exposures shall be effected under the clinical responsibility of a practitioner.”

The practitioner is clinically responsible, as defined in the definitions, for each individual exposure. It is of fundamental importance that clear systems of justification are in place in order to ensure each exposure is justified by a practitioner.

**Conditions justifying medical exposures**

All medical exposures shall be referred by a prescriber. The prescriber has to ensure that he provides sufficient clinical information whenever requesting a medical exposure. All hospitals or clinics shall adopt a referral system.

The practitioner is responsible for the justification of each individual medical exposure that has been referred by a prescriber.

The practitioner must satisfy himself that there will be sufficient net health benefit to the patient, the benefit to comforters and carers against the detriment that the exposure might cause.

The process of justification has to take into account the factors mentioned in regulation 6(1) and in doing so pay special attention to

- a) exposures in medico-legal ground,
- b) exposures that have no direct health benefit for the individual undergoing exposure and
- c) the urgency of the exposure, where appropriate, in cases involving:
  - (i) breastfeeding females in nuclear medicine
  - (ii) comforters and carers and females where pregnancy cannot be ignored.

This should be based on his knowledge of the hazard associated with the exposure and the clinical information supplied by the prescriber. In order to be able to demonstrate that justification has taken place a formal system of authorisation is required. The method of authorisation may depend on local circumstances and must include a signature of the practitioner. It is recommended that the employer specify a method of authorisation to be used locally to ensure a consistent approach.\(^2\)

The referral and authorisation shall be kept on record for each individual exposure.

“In cases where the prescriber is the same person as the practitioner and/or the person carrying out the practical aspects (e.g. some dental practitioners), justification and authorisation still must be carried out, but this may be done by the same person.”\(^3\)

The criteria referred to in regulation 6(1)(e) highlight the need, where practicable, to choose techniques involving the minimum necessary amount of exposure to ionising radiation. These

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\(^3\) Ibid., p. 8., 8.3.2.
are to be preferred where they have the same objective. In practice, use of such techniques will be influenced by availability. The implications of delaying diagnosis or treatment in order to provide the preferred method should be weighed against the potential detriment associated with an increased radiation dose of other techniques. If the most appropriate technique is not available, consideration should be given having the medical exposure performed at a different facility.  

If the practitioner feels that the exposure is not justified he must not perform the exposure and must inform the prescriber accordingly.

**Duties of Employer**

**General Guidance on regulation 7(1)**

This regulation requires the employer to establish written standard operating procedures.

The following is specific guidance under regulation 7, this does not preclude the employer from producing any other procedures deemed necessary.

The employer shall at all times be responsible to ensure that written procedures are available for all activities and verify compliance thereto. Procedures have to be regularly reviewed and updated.

7(1a) “Procedures to correctly identify the individual to be exposed to ionising radiation”

This procedure should specify how such identification is carried out and who is responsible for the identification of patients.

7(1b) “Procedures to identify individuals entitled to act as prescribers and/or practitioners and persons performing the practical aspects.”

The employer shall keep a list of personnel entitled to act as prescribers, practitioners and persons performing the practical aspects within his facility. The employer shall have documented policy describing the qualification and appropriate level of training requirements needed by practitioners and persons performing the practical aspects of each specific procedure. The employer must follow the minimum requirements stated in regulations 15, 17 and 19.

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4 *Ibid.*, p. 8., 8.5.2
7(1c) “Procedures to be observed in the case of medico-legal exposures”.

It should be noted that unless there is a net benefit out of these exposures, than these should not be performed.

7(1d) “Procedures for making enquiries of females of child-bearing age to establish whether the individual is or may be pregnant or breast feeding.”

It is recommended that such procedures include the age range of individuals who should be asked about pregnancy or breast feeding. The minimum age range should include individuals between the ages of 10 and 55.

The Board will exclude dental practices from the requirement to have these procedures.

7(1e) “Procedures to ensure that quality assurance programmes are followed.”

All employers shall establish a quality assurance programme. It should be pointed out that such a programme does not only include the quality control of equipment (e.g. acceptance and constancy tests), but also other areas such as staff qualification, record keeping etc. All the procedures produced by the employer for the various aspects of these and other radiation safety regulations (such as LN44/2003), should form part of the quality assurance programme.

7(1f) “Procedures for the assessment of patient dose and administered activity.”

It is a requirement to ensure that all patient doses are assessed and recorded. This information shall be made available to the Board in order for dose estimates from medical exposure for the population and for relevant groups of the population to be determined.

7(1g) “Procedures for the use of diagnostic reference levels.”

The employer shall establish procedures for the use of Diagnostic Reference Levels. Reference should be made to the European Reference Levels (RADIATION PROTECTION 109. Guidance on diagnostic reference levels (DRLs) for medical exposures (http://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/109_en.pdf)
7(1h) “Procedures for medical and biomedical research programmes as referred, including the use of dose constraints.”

This regulation requires the employer’s procedures to provide safeguards for medical and biomedical research programmes and to specify how and by whom these shall be effected. The research co-coordinator may be the person best placed to carry out some of these tasks and, where he does so, he will be the person performing the practical aspects.5

The employer shall have procedures in place for providing information to these individuals about the risks of these exposures.

It is also required that individual target levels of doses for patients who voluntarily undergo experimental diagnostic or therapeutic practices in cases where some benefit to the patient is expected are planned. The practitioner is identified as the person who is most able to set these target levels, due to his knowledge of ionising radiation and its potential risks. The practitioner may seek advice from others to clarify the doses involved. It is recognised that where there is potential benefit for patients from exposures as part of research, setting a constraint is inappropriate.6

7(1k) “Procedures to ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced so far as reasonably achievable.”

The main emphasis in accident prevention should be on equipment and procedures in radiotherapy, but due attention must also be paid to accidents in nuclear medicine and diagnostic equipment.7

7(3) “In the case where the employer is also the practitioner, he shall comply with these procedures himself”

These procedures still have to be produced and complied with, even when the employer is concurrently practitioner or person performing the practical aspects.

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5 Ibid., p. 9., 9.4.1
6 Ibid., p. 9., 9.6.1
7 European Council Directive 97/43/Euratom, Art. 11
7(4) “The employer shall ensure that written protocols are in place for every type of standard radiological practice for each equipment”

The written protocols required under this regulation should not be confused with employer’s procedures required by regulation 7(1). Protocols cannot be absolute or totally comprehensive as it is not possible to produce detailed and rigid protocols for every examination. However, they should be specific to each type of examination and machine as appropriate, e.g. in diagnostic practice, for a particular x-ray room, x-ray exposure factors for a specific examination (PA chest: 120kV 2mAs). They must be written down and their status clear. Protocols should allow latitude for professional judgment. Where, on commissioning, exposure values are programmed via the console into the x-ray generator, it is recommended that a record of the values be kept in the department together with any changes to these values, whether for individual patients, or as a result of agreed protocol changes.8

In radiotherapy, the protocols might refer to standard dose regimes, energies and beam projections and may be specific to each consultant if necessary. Such protocols would not negate the need for individual planning to produce the intended therapeutic effect.9

Written protocols must always refer to the manufacturer’s instructions for use.

7(5a) “referral criteria for medical exposures and shall make available to prescribers the relevant radiation doses for each type of medical exposure”

The employer has to establish referral criteria. These have to be made available to all prescribers to that employer’s site. It is mandatory that such criteria be produced whatever the size of the hospital/clinic. Reference should be made to the Radiation Protection 118, European Referral Guidelines for imaging10 https://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/118_en.pdf

7(5b) “quality assurance procedures for standard operating procedures”

These quality assurance procedures should include all the procedures mentioned in this guidance including a provision for periodic review of these procedures, procedures for record keeping and also procedures for periodic and incidental maintenance of equipment including quality control checks.

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8 UK Department of Health, *op.cit*. p. 4-5., 6.2.1
9 *Ibid* p. 5., 6.2.2
10 *Ibid* p. 5., 6.3.2
7(5c)  “diagnostic reference levels…”

This regulation requires the employer to establish his own diagnostic reference levels for standard radiodiagnostic examinations. It is required that they are in line with European levels, where available (Radiation Protection 109, Guidance on diagnostic reference levels (DRLs) for medical exposures).


These levels shall be made available to the RPB on request. The RPB will compare them to the European levels.

7(5d)  “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”

This regulation requires dose constraints to be applied where no direct medical benefit for the individual is expected from the exposure. The constraint must be set by the employer in his procedures and must not be exceeded. The constraint should be set at a level to facilitate the research, and be deemed appropriate by the practitioner.\(^1\) The dose constraints to be established by the employer under this regulation should be applied to research protocols involving standard radiodiagnostic procedures. Such research should be subject to a dose constraint based on the total dose from all radiodiagnostic procedures included in the protocol.\(^2\)

This section does not preclude the need to comply with other regulatory requirements for medical research programmes. The relevant Competent Authorities are to be consulted in case of research studies.

7(5e)  “appropriate guidance and dose constraints for exposure of individuals referred to in regulation 4(2)”

 Guidance on dose constraints is to be established by the employer for the exposure of comforters and carers, bearing in mind that these persons have no direct medical benefit from the exposure.

7(6)  Review of diagnostic reference levels

This regulation requires the employer to carry out the review of patient doses. This review should provide insights into why diagnostic reference levels are being exceeding and therefore corrective action can be taken.

\(^{1}\) Ibid p. 9., 9.5.1
\(^{2}\) Ibid p. 5., 6.6.1
7(7) Exposure to ionising radiation to an extent much greater than intended

If such an incident has or believed to have occurred, the employer has to carry out a preliminary investigation. Unless this investigation establishes that no such incident occurred, the RPB has to be immediately notified and a detailed investigation has to be carried out. The notification is required to be made directly to the Board.

During the preliminary and, if applicable, during the detailed investigation, any process in connection with the incident, (from the receipt of the patient to the final reporting) shall be stopped from use until the investigation is carried out and any corrective actions taken. For example, these processes may include all the steps from patient receipt to the final reporting.

The table below shows the interpretation of the term “much greater than intended”

<table>
<thead>
<tr>
<th>Diagnostic medical exposures</th>
<th>Guideline multiplying factor applied to intended dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interventional radiology, radiographic and fluoroscopic procedures involving contrast agents, nuclear medicine with intended dose &gt;5mSv and computed tomography examinations</td>
<td>1.5</td>
</tr>
<tr>
<td>Mammography, nuclear medicine with intended E ( \leq 5 \text{mSv but} &gt;0.5\text{mSv}, ) all other radiographic examinations not referred to elsewhere in this table.</td>
<td>10</td>
</tr>
<tr>
<td>Radiography of extremities, skull, dentition, shoulder, chest, elbow, knee and nuclear medicine with intended E ( \leq 0.5\text{mSv} )</td>
<td>20</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Guideline multiplying factor applied to intended dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beam therapy, brachytherapy (1.1 \text{ (whole course) or} 1.2 \text{ (any fraction)})</td>
</tr>
<tr>
<td>Unsealed radionuclide therapy (1.2 \text{ (any administration)})</td>
</tr>
</tbody>
</table>

### Procedural failures

<table>
<thead>
<tr>
<th>Incident</th>
<th>Employer’s Duty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect diagnostic procedure</td>
<td>Preliminary investigation and inform the Board</td>
</tr>
<tr>
<td>Wrong patient exposed to a dose of radiation</td>
<td>Preliminary investigation and inform the Board</td>
</tr>
<tr>
<td>Reject exposures due to other parameters resulting in inadequate diagnostic information</td>
<td>Perform Reject Analyses and take corrective action. The reports, analyses and corrective actions to be documented and made available to the Board</td>
</tr>
</tbody>
</table>

Any preliminary investigation reports shall be kept by the employer for a period of at least 2 years from the date it was made. If a detailed investigation is made, the report shall be kept for a period of at least 30 years from the date it was made.

### 8 Approval for functions

Approval is the process whereby the employer entitles different persons to act in different aspects of certain types of medical exposures. Individuals can only perform duties in those areas for which they are approved.

### 9 Identifying Individuals to perform aspects of medical exposures

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. This procedure should describe the responsibilities of prescribers, practitioners and persons performing the practical aspects for different types of medical exposures. This procedure shall be kept on record.

Employers 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.

These legal instruments also require that other functions, such as quality control, darkroom operations, maintenance..., form part of the practical aspects and as such form an integral part of medical exposures.
10 Education, Training and Experience required for approval

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.

It is important to note that documented evidence of qualification and experience shall be kept and supplied to the Board on request.

One important aspect for practitioners and persons performing the practical aspects is the need of in-house induction training, the duration of which will depend on the complexity and size of hospital/clinic. This induction training is to be kept on record for each individual.

To be considered for approval, the individual shall satisfy the minimum criteria for the applicable approval being sought given in regulations 15, 17 and 19.

Duties and requirements for Prescribers

14 Prescribers shall

In complying with recommendation 14(2) reference can be made to RP118 and Royal College of Radiologist document as an example of referral criteria. Radiological facilities may however develop their own referral criteria based on their available resources (HR and medical equipment).

15. Prescribers shall have the following qualification and experience

Although experience is not essential for prescribers, prescribers are strongly encouraged to make themselves familiar with medical exposure to ionising radiation

Complying with employer’s instruction

The prescriber, practitioner and the person performing the practical aspects must comply with the employer’s procedures and where these include detailed standard operating procedures, they must be followed explicitly e.g. patient identification and checking procedures. All those matters, required by the Regulations to be in employers’ procedures (Regulation 7), are binding.14

The employer needs to keep records that his employees have seen his instructions.

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14 UK Department of Health, op.cit. p. 7 (7.2.1).
Written instructions and information

The employer shall have a procedure for giving verbal and written information to patients or persons responsible for the patient. This procedure shall state when this information is to be given and to whom. It shall also state who is responsible for giving this information. This information shall be given before the patient leaves the hospital/clinic.

Optimisation

For all medical exposure of individuals for radiotherapeutic purposes, as mentioned in Regulation 4 (1) (a), exposures of target volumes shall be 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.

Regulation 21(1) requires special attention to certain factors in the optimisation process. One such factor is high doses to the patient. This will be relevant to procedures, such as interventional radiology, radiotherapy and some CT scanning, which deliver an increased radiation dose compared to most routine diagnostic examinations.\(^\text{15}\)

It shall be ensured that appropriate radiological equipment, practical techniques and ancillary equipment are used for the medical exposure
- of children,
- as part of a health screening programme,
- involving high doses to the patient, such as interventional radiology, computed tomography or radiotherapy.

Another factor is potential pregnancy in particular if abdominal and pelvic regions are involved. Special attention shall be given to the justification, particularly the urgency, and to the optimization of the medical exposure taking into account the exposure both of the expectant mother and the unborn child. Where practicable, the scheduling of the exposure should be influenced by the date of the last menstrual period.

In practice, the dose to the uterus, and, where pregnancy is confirmed, to the unborn child, is likely to vary with the anatomical site and magnitude of the exposure in radiology and with the administered activity and radiopharmaceutical in nuclear medicine.\(^\text{16}\)

In the case of breastfeeding females, in nuclear medicine depending on the type of medical examination or treatment, special attention shall be given to the justification, particularly the


urgency, and to the optimization of the medical exposure, taking into account the exposure both for the mother and the child.

In practice, depending on the administered activity and radiopharmaceutical used, it may be necessary to advise the patient temporarily to cease breast feeding.\textsuperscript{17}

Without prejudice to the above, any measure contributing to increasing the awareness of women subject to pregnancy and breastfeeding, such as public notices in appropriate places, could be helpful.\textsuperscript{18}

Persons performing the practical aspects to ensure that, in fluoroscopy, examinations without devices to control the dose rate are limited to justified circumstances. An example of when such justification may exist is in paediatric radiology where devices designed to control the dose rate can result in doses greater than necessary\textsuperscript{19}

\textbf{Medical Physics Experts}

\textit{25 Continued Professional Development for medical physics experts}

Continued professional development will be required in such areas as:

\begin{itemize}
  \item Attending and/or contributing to training courses, seminars, workshops etc. as well as scientific meetings such as conferences, professional sessions etc.
  \item Self-study, research and publication (e.g. regular reading of journals/ text books/ standards literature /legislation etc., & contributing to such literature).
  \item Service innovation (adapting/creating protocols, introduction of new services etc)
  \item Education and training of medical physicists and related professions
\end{itemize}

\textbf{Training}

\textit{26 Training}

Individuals being considered by the employer for approval should have completed sufficient organised training to become thoroughly familiar with the specific work for which they are being considered.

\textsuperscript{17} Ibid., p. 11, 9.9.3.
\textsuperscript{19} UK Department of Health, \textit{op.cit}. p. 11 (9.11.1).
Individuals who have not undergone any radiation safety training must have radiation safety training. The recommended course structures for radiation safety training is given below.

Training may also be required on the use of specific equipment for which an individual is seeking approval.

If additional training is required the training programmes must include sufficient formal assessments at the end of the training to ensure that the necessary information has been comprehended.

All assessments must be documented

**Recommended Training for Persons performing the practical aspects**

“...Persons performing the practical aspects shall have successfully completed training, including theoretical knowledge and practical experience, in -

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

(ii) such of the subjects detailed in section B as are relevant to their specific area of practice.

**A) Radiation production, radiation protection and statutory obligations relating to ionising radiations**

1. **Fundamental Physics of Radiation**
   1.1 Properties of Radiation
   Attenuation of ionising radiation
   Scattering and absorption

1.2 Radiation Hazards and Dosimetry
   Biological effects of radiation
   Risks/benefits of radiation
   Dose optimisation
   Absorbed dose, dose equivalent, effective dose and their units

1.3 Special Attention Areas
   Pregnancy and potential pregnancy
   Infants and children
   Medical and biomedical research
   Health screening
   High dose techniques

2 **Management and Radiation Protection of the Patient**

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

2.2 Radiation Protection
   General radiation protection
Use of radiation protection devices
  patient
  personal
Procedures for untoward incidents involving overexposure to ionising radiation

3. Statutory Requirements and Advisory Aspects
   3.1 Statutory Requirements and Non-Statutory Recommendations
      Regulations
      Local rules and procedures
      Individual responsibilities relating to medical exposures
      Responsibility for radiation safety
      Routine inspection and testing of equipment
      Notification of faults and Health Department hazard warnings
      Clinical audit

B) Diagnostic radiology, radiotherapy and nuclear medicine

4. Diagnostic Radiology
   4.1 General
      Fundamentals of radiological anatomy
      Fundamentals of radiological techniques
      Production of X-rays
      Equipment selection and use
      Factors affecting radiation dose
      Dosimetry
      Quality assurance and quality control
   4.2 Specialised Techniques
      Image intensification/fluoroscopy
      Digital Fluoroscopy
      Computed Tomography Scanning
      Interventional procedures
      Vascular imaging
   4.3 Fundamentals of Image Acquisition etc.
      Image quality v. radiation dose
      Conventional film processing
      Additional image formats, acquisition, storage and display
   4.4 Contrast Media
      Non-ionic and ionic
      Use and preparation
      Contra-indications to the use of contrast media
      Use of automatic injection devices

5. Radiotherapy
   5.1 General
      Production of ionising radiations
      Use of radiotherapy
      benign disease
      malignant disease
      external beam
      brachytherapy
   5.2 Radiobiological Aspects for Radiotherapy
      Fractionation
      Dose rate
      Radiosensitisation
      Target volumes
   5.3 Practical Aspects for Radiotherapy
      Equipment
Equipment

General Guidance on equipment

Reference must also be made during installation and maintenance to the manufacturer’s instructions for use.

Equipment used in connection with medical exposure includes all equipment whose design, construction, installation, maintenance and any fault that might develop in it, can affect the magnitude or distribution of the absorbed dose received by the patient. It includes equipment intended to be used in connection with diagnostic or therapeutic procedures using ionising radiation and interventional radiology. It covers both radiation equipment and ancillary equipment such as image intensifiers, intensifying screens, film cassettes, digital fluorography

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systems, couches, anti-scatter grids, beam modifiers (e.g. filters and wedges), dose calibrators and film processing units.\textsuperscript{21}

Employers shall ensure that any equipment installed post the publication of legal notice ***/20** Rules meets the requirements of this regulation.

In the case of equipment in use before the date of legal notice ***/20** was issued, employers will have 6 months from the publication of this regulation to ensure the requirements are met. (This will include a test equivalent to the Acceptance Test and other aspects relating to quality assurance and maintenance.)

Employers should be aware that technology evolves and equipment design and specification may change significantly. Procedures and associated programmes should therefore be reviewed regularly to ensure they remain relevant to any new equipment and in compliance with the relevant regulations.\textsuperscript{22}

\textbf{General Duties of the employer under other Maltese Regulations}

The employer’s responsibilities do not fall solely under LN ***/2012 but also under LN 44/2003, LN 210/2008 and LN 13/2006 as outlined below.

\textbf{LN 44/2003 Nuclear Safety and Radiation Protection Regulations}

Employers referred to in this document are defined as radiation employers in LN44/2003. For simplicity, these are referred to as employers throughout the rest of this document. Employers must comply with aspects of LN44/2003 which apply to the exposure to ionising radiation of employees and other persons (other than those undergoing medical exposure) arising out of work involving medical exposures.

Employers should also be aware that when new, modified or second hand equipment is put into service, the employees are made aware of such equipment and any necessary training or instruction given to them. (Changes referred to in this paragraph have to be notified to the Board)

\textbf{LN 210/2008 Medical Devices Regulations}

Any new equipment that is placed on the market and put into service, which originates from inside or outside the European Union (EU), needs to meet the requirements of LN210/2008. Any previously owned equipment brought into the EU for the first time also needs to meet the requirements of LN210/2008. The

\textsuperscript{21} UK Health & Safety Executive \textit{Guidance Note PM77(Third edition) Equipment used in connection with medical exposure}, 2006. p. 2., 6

\textsuperscript{22} Ibid p.2., 8
regulations also apply to “fully refurbished” medical devices. Full refurbishment occurs when a device is completely rebuilt or made as new from used devices and is assigned a new useful life.

Any equipment which does not meet the requirements of LN210/2008 will not be given approval to be put into clinical use by the Board.


Employers have certain obligations with respect to the safety and security of high activity sources, such sources may be used in certain types of medical exposures.

**Procedure for putting equipment into clinical use**

The employer has a duty under Regulation 17 of LN44/2003 to notify the Board 30 days prior to starting a new practice or making a material change to a practice.

It is advisable that prior to procuring new equipment, the employer carries out this notification in order to ensure that the employer has prior approval for this equipment/practice.

The employer’s QA programme shall include the methodology for performing the above tests.

**29 Requirements for placing equipment on the Maltese Market**

All devices that are placed on the Maltese market or put into service in Malta must meet the requirements of the Medical Devices Regulations, 2008 (LN 210/2008) and as such must be CE-marked. This applies to both new and imported second-hand devices. The CE-mark is the only mark that demonstrates compliance with the essential safety requirements relating to the protection of the health and safety of patients and users. It does not necessarily mean that the device is set to its optimized level.

It is advisable to make arrangements to ensure that when procuring equipment that it can be installed, accepted and regularly maintained in line with the requirements of these regulations.

**30 Requirements for new equipment**

Examples of these devices are dose area product (DAP) meters, mAs indicators. These devices may not be practicable for certain types of equipment, such as dental, mammographic, CT and bone densitometry equipment. Examples include devices to display the following parameters.
• exposure time on fixed kV/mA dental X-ray units;
• kV, mAs, target and filter (also compressed breast thickness where available) on mammographic units;
• CTDIvol and DLP on CT scanners; and
• scan time on bone densitometry units.

31 Installation Test
The Installation Test only ensures that safety features and warning devices operate correctly and that radiation protection features are adequate.\textsuperscript{24}

The Installation Test should include tests on:
• Functioning of warning devices;
• Interlocks and cut off switch controls;
• Automatic Exposure Controls;
• Timers;
• Light and X-Ray beam alignment;
• Adequacy of shielding through radiation dose survey;……

It is advisable that the employer’s Medical Physics Expert (MPE) and Qualified Expert (as defined by LN 44/2003) are present during this installation test so that any report issued by the installer could be verified and endorsed.

33 Acceptance test
The purpose of an Acceptance Test is to check the compliance of the equipment with specified tolerances

During an Acceptance Test, it will usually be essential for the Employer or his representative to work in close cooperation with the manufacturer's service personnel or personnel authorized by the manufacturer.

35 Constancy test
A constancy test is intended to monitor the constancy of the functional performance of the equipment by means of a test method that is simple, quick and easy to carry out, usually involving measurements of relative values.

36 Removal of Equipment from clinical use
If the employer decides to scrap the equipment, then the employer should seek the services of an engineer or technician who shall disable the equipment in order to render it un-usable. The

\textsuperscript{23} [Ibid., p. 4., 24]
\textsuperscript{24} [Ibid., p.4., 25]
engineer or technician shall make a written statement to this regard to the employer, who in turn will copy the Board with this written statement. If the equipment includes a radioactive source, then the Board shall be informed immediately prior to removing the source. The source shall be stored at the employer’s practice until a proper disposal route is arranged.

39 Steps to prevent failure of radiation equipment

If the failure of a single component can give rise to an unintended exposure of the patient, the employer may need to have additional controls in place. Suitable controls include ensuring that the exposure is automatically terminated within an appropriate preset time, tube current-time product, or dose, to protect the patient. Where this is not reasonably practicable, the employer may need to ensure that failure of equipment to terminate an exposure correctly is immediately detectable so that action can be taken by the person performing the practical aspects.  

The employer should have in place appropriate mechanisms to quickly detect malfunctions and/or defects in radiation equipment. Special care should be taken in cases where detection of exposures greater than intended is not straightforward; for example in the case of some modern imaging technology (such as computed or direct digital radiography), during radiotherapy, or the use of radionuclide calibrators for diagnostic nuclear medicine. Poor image quality cannot be relied upon to identify malfunctions in diagnostic X-ray or radionuclide imaging equipment. The employer should ensure that appropriate checks are made after each exposure or prior to each administration of radioactive material, so that exposures greater than intended are prevented or quickly detected.

25 Ibid p.7., 42
26 Ibid p.7., 43