Guidance for developing a

PATIENT RADIATION PROTECTION MANUAL

For locations using ionising radiation

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

(FIRST EDITION)
Medical Exposure Radiation Unit
# Document Control

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INTRODUCTION

National Arrangements for Radiation Protection Regulation

The HSE regulates to ensure patients are protected from the unnecessary harmful effects of exposure to ionising radiation. The HSE is advised on regulation by the National Radiation Safety Committee whose remit includes both public and private facilities and consequently, this manual is applicable to both.

The Radiological Protection Institute of Ireland (RPII) regulates to protect workers and members of the public from the harmful effects of exposure to all ionising radiation. There are a number of areas where regulations overlap as many safety measures taken to protect patients are also of benefit to workers and public, and vice versa.

Purpose of Guidance Manual

To ensure best practice in patient radiation protection, the National Radiation Safety Committee recommended in 2010 that all holders keep a “Radiation Protection File” on site. This guidance manual was developed to assist locations to produce the Patient Radiation Protection Manual for their location and it has been re-named as the “Patient Radiation Protection Manual”.

The purpose of the manual is to assist locations to comply with national legislation and to apply best practice guidelines in patient radiation protection.

• The manual provides locations with the opportunity to review the availability of specific local protocols, policies, etc., to include them in the manual and to identify those that need to be developed or updated.
• The manual is a useful central reference file for all patient radiation protection documentation with easy access for those involved in delivering ionising radiation to patients e.g. radiologists, radiation oncologists, radiographers, radiation therapists, radiation safety officers, referrers, etc.
• The manual may be used as a teaching tool for students during training e.g. trainee radiologists/radiation oncologists, student radiographers/radiation therapists, radiation safety officers, etc.
• The manual can also be used as guidance to review and monitor patient radiation protection practices and prepare for clinical audit in radiology.
• The manual aims to provide standardised, accountable records of local practice and should be available to view by the Medical Exposure Radiation Unit if requested.

Scope of Guidance Manual

The manual applies to all facilities that use medical ionising radiation, in public and private facilities in Ireland. Depending on the size and scope of the practice, some parts of the manual may need to be expanded or may not be relevant. Dentists and Chiropractors have agreed a separate manual format with the NRSC which is keeping with the scope of their practice.
Development of Guidance Manual

The guidance manual was developed using an evidence based approach where possible and was produced by the project team of the Medical Exposure Radiation Unit. The manual has been piloted in a number of locations and a broad consultation with stakeholders took place from January to June 2012 (appendix XI). The project team collected and collated the relevant legislation, literature and guidelines that contribute to the optimal use of ionising radiation. Different approaches have been adopted for different sections of this manual as the level of evidence can vary from the availability of a national guideline or regulation to an example of good local practice. Accordingly, there is variation in how each section is presented and they are not uniform.

Contents of Guidance Manual

The manual is divided into sections for each topic relevant to patient radiation protection. In each section there is an introduction to the topic with reference to the relevant legislation, guidance notes, international, national and local protocols. All sections should be reviewed for local adaption and some sections will need completion by the location, particularly where local hospital protocols can be included in the file. Locations should set a regular review date to ensure the continued relevance and accuracy of the contents.

- How to use this guidance manual

The Practitioner in Charge has responsibility to ensure a Patient Radiation Protection Manual is developed and maintained for their location. The Practitioner in Charge may assign responsibility to a designated person. In some locations, this is the Radiation Safety Officer although locations may delegate this responsibility to another person. It is recommended this person is a member of the Radiation Safety Committee.

The responsible person should review this guidance manual and adapt it to suit local practices and protocols. Some practices and protocols have nationally agreed standards but in many cases, practices and protocols are developed locally which adhere to legislative requirements and evidence based best practice.

The location manual should then be approved and adopted by the Practitioner in Charge and the Radiation Safety Committee and a review date and procedure set to ensure its ongoing relevance and accuracy.

All existing staff using ionising radiation and new staff at induction should be made aware of the contents of the manual and it should be accessible to all staff. In addition, each department should provide a list in this manual of all documents relating to Radiation Protection (sample template below). This list should be made available with consideration given to online access for relevant personnel.

- Disclaimer

This document is intended to act as a guideline to the regulations. It must be read in conjunction with the regulations referred to throughout the document and other regulations and documents outlining responsibilities attaching to medical ionising radiation which are relevant to service users or supersede the publication of this document.
It does not purport to be comprehensive or to be a legal interpretation or to constitute legal or professional advice. Further guidance documents and changes in the regulations can be expected in the future, that will necessitate the updating of the guidance in the manual. The advice given is wide-ranging and does not replace an employer’s legal responsibilities for implementing compliant local procedures. It is the responsibility of service users to identify the best available information relevant to their practice. Every effort has been made to ensure accuracy of web addresses however, the web addresses may change over time.

- **Sample template to record all relevant Radiation Protection documentation**

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Signed: ________________________  Chair, Radiation Safety Committee
Signed: ________________________  Practitioner in Charge
Date: ________________________  Revision Due Date: ________________________
Introduction

Radiation Protection Legislation

International Commission for Radiological Protection (ICRP)

European Atomic Energy Community Treaty (EURATOM)

Workers and General Public

Basic Safety Standard

BSS 96/26/EURATOM

Medical Exposure Directive 97/43/EURATOM

Patients

Transposed into Irish Legislation

Radiological Protection Institute of Ireland (RPII)
SI 125 (2000)
SI 875 (2005) (HASS)

Protection of Workers and the Public


Dept of Health / HSE

Protection of the Patient

Patient Radiation Protection Manual
LEGISLATION

Radiation Protection Legislation

The system of Radiation Protection used throughout Ireland and the rest of Europe is based on the recommendations of the International Commission for Radiological Protection (ICRP)\(^1\). This system is embodied in various European directives most notably the Basic Safety Standards (BSS), 96/29/EURATOM and the Medical Exposure Directive (MED), 97/43/EURATOM.

This BSS was transposed into Irish legislation by, Statutory Instrument 125/2000 (workers and the public), the Medical Exposures Directive was transposed into Irish law by Statutory Instrument 478/2002/303/2007 and 459/2010 (patients).

Following the publication of ICRP 103(2007), the European Commission has decided to consolidate the Basic Safety Standards and the Medical Exposure Directive (97/43/Euratom). The final version will take some years to be transposed in to Irish legislation.

Protection of Individuals Receiving Medical Exposures (Patients) in Ireland

The Medical Exposure Directive 97/43 Euratom(MED) deals with the protection of individuals (patients) against the dangers of ionising radiation in relation to medical exposure. This Directive is the main legal instrument dealing with the protection of patients undergoing diagnostic and therapeutic procedures using radiation. One of the aims of MED is to eliminate unnecessary medical exposures and to this end the principles of Justification and Optimisation in a context where dose limits are not applied to medical procedures are central.


National Arrangements for Patients’ Regulation

SI 478 (2002) allows for the CEO of the HSE to introduce additional regulations with respect to radiation protection of the patients as he/she sees fit. The role of the Medical Exposure Radiation Unit, HSE is to regulate patient radiation protection practices in radiological facilities, both private and public, and receives advice from the National Radiation Safety Committee. The Medical Exposure Radiation Unit is also the executive, administrative and advisory unit for the National Radiation Safety Committee.

Regulatory Role of the Medical Exposure Radiation Unit:

- Conduct/oversee clinical audit in facilities using medical ionising radiation.
- Manage the statutory incident reporting system.
- Develop and provide guidance and direction to holders, practitioners, other staff and statutory bodies on relevant matters as guided by the National Radiation Safety Committee.
• Ensure quality assurance programmes are in place.
• Maintain a register of installations.
• Support and manage the work of the National Radiation Safety Committee and the subcommittees.

Advisory Role of the National Radiation Safety Committee:

• Provide advice to the CEO, HSE and the Minister of Health and Department of Health on measures that are necessary to protect patients in both public and private facilities from the unnecessary harmful effects of ionising radiation.
• Produce an annual report which includes a report on Population Dose from medical exposures to ionising radiation.
• Receive reports of clinical audits, incidents and inspections.
• Gather lifetime data on equipment and an assurance that each piece of equipment is recorded as being maintained.
• Monitor Radiation Diagnostic Reference Levels as established by the Medical and Dental Councils.
• Advise on guidance and direction to Holders, practitioners, other staff and statutory bodies on relevant matters.

Protection of Workers and General Public in Ireland

The BSS lays down the requirements for protection of workers and the general public against the dangers of ionising radiation. It encapsulates the principles of Justification, Optimisation and Dose Limitation articulated by the ICRP and develops them into a regulatory system that can control the practices involving ionising radiation that impact on public and workers’ safety.


National Arrangements for Workers and the General Public Regulation

The RPII is the competent authority to ensure that Irish people and the environment are adequately protected from the harmful effects of ionising radiation. It fulfils this statutory responsibility through a system of regulatory control and inspections, by providing advice to the public and the Government, by monitoring people’s exposure to radiation, by providing technical support to Ireland’s plan to deal with radiation emergencies and by cooperating with similar bodies internationally.

S.I. 125 requires all practices which use radioactive sources and/or irradiating apparatus (such as an X-ray unit) to hold a valid licence from the RPII, unless they have been exempted. Licensees must also adhere to the conditions the RPII attaches to each licence. Inspections undertaken by the RPII are designed to assess compliance with both the legislative requirements as set out in S.I. No. 125 of 2000, S.I. No. 875 of 2005 (for HASS sources) and the licence conditions. Inspectors also assess the level of radiation protection in place at each licensed facility and encourage licensees to strive to attain best practice in relation to radiation protection.
## List of National Legislation and Regulations

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<td>2012</td>
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Irish Framework for Complying with Radiation Protection

The Requirements of the National Radiation Safety Committee (HSE):

Guidance to Holders (2010)
Guidance from the National Radiation Safety Committee to Holders of Medical/Dental Ionising Radiation Equipment addresses some of the key responsibilities to assist holders to comply with the regulations (see section 1.0).

Radiation Protection Guidance Manual (Patient)
While the Radiation Safety Procedures satisfy the requirements of the RPII licence, some issues regarding patient safety are not addressed. This was recognised by the NRSC, following an audit of compliance with Patient radiation protection practices in 2008. The NRSC subsequently recommended that all holders should hold a Radiation Protection Guidance Manual at their location and outlined suggestions for a Dental and Chiropractic Radiation Protection file (see sections 1.1.4, 1.7 and 1.8).

In 2012, the NRSC recommended that all holders keep and maintain a Radiation Protection Manual at their location. The manual incorporates the additional requirements placed on Holders with regard to patient radiation protection. The manual is intended to complement the Radiation Safety Procedures or local rules, it does not duplicate or replace them. However, there should be a clear reference to the existence of and access to the contents of the Radiation Safety Procedures or local rules. (See section 2.0 where each location inserts a list of their relevant documentation and where they are kept.)

Occupationally exposed employees and members of the public

Licence
All users of sources of ionising radiation are required to hold a valid licence, issued by the RPII. The licensee has responsibility for ensuring that a good radiation protection philosophy exists in regard to the licensed practices, and that all licence requirements are met. Appendix VII outlines the obligations of RPII’s licensees. In the context of hospitals which fall under the medical band of licensees, licences are issued for five categories of hospitals namely levels 1 to 5. (see appendix X) A copy of the RPII licence is required to be on display in a prominent public location on each of the premises listed on the licence where licensed items are held. A copy of the licence conditions is required to be maintained by the licensee. Chiropractor and dental level 1-3 licensees also fall under the medical band of licensees and the requirements outlined above also apply to these categories of licensees. Check section 2.0 to see where the licence conditions document for your location is kept.
**Radiation Safety Committees**

Licensees falling into categories Hospital Levels 2 - 5 and Dental Level 3 are required to have a Radiation Safety Committee in place to ensure compliance with the licence conditions. In 2010, the National Radiation Safety Committee issued guidance to all Holders of ionising radiation equipment to extend the remit of Radiation Safety Committees (see section 1.1.2). It recommended that smaller practices join a Radiation Safety Committee, where possible. Most hospitals and public sector dental practices have, or are party to, a Radiation Safety Committee.

The Radiation Safety Committee advises the hospital / practice of their obligations with regard to Radiation Safety issues. The scope of the Radiation Safety Committee includes all of the relevant regulated activities that occur in the hospital / practice.

**Radiation Safety Procedures (also referred to as “Local Rules”)**

The conditions attached to licences issued by the RPII in respect of any activity involving ionising radiation require the licensee to draft, approve and maintain Radiation Safety Procedures. In the medical setting, these procedures are often referred to as ‘local rules’.

The procedures should be approved by the licensee’s CEO, General Manager (or equivalent). Appendix VIII outlines a typical layout and content of the Radiation Safety Procedures.

The Radiation Safety Procedures are prepared by the Radiation Safety Committee on behalf of the licensee. It is the duty of the Radiation Protection Adviser to prepare and submit to the Radiation Safety Committee the Radiation Safety Procedures required.

**Radiation Safety Manual**

The Radiological Protection Institute of Ireland (RPII) suggest that, where a large number of “Radiation Safety Procedures” are in use these may usefully be compiled to create a “Radiation Safety Manual”. Appendix VIII reproduces the RPII guidance where this approach is advocated.
Section 1

Guidelines on Holders’ Responsibilities for Patient Radiation Protection.
Section 1 Guidelines on Holders’ Responsibilities for Patient Radiation Protection

Guidance from the National Radiation Safety Committee to Holders of Medical/Dental Ionising Radiation Equipment addresses some of the key responsibilities to assist holders to comply with the regulations. The NRSC document is intended to act as a guideline to the regulations. The regulation concerns important issues of quality and patient safety.

http://www.hse.ie/eng/about/Who/qualityandpatientsafety/medexpradiatonunit/Legislation.html - legislation and responsibilities/Guidance on Responsibilities

**Holdes’ Responsibilities Guidelines**

Significant responsibility for the protection of patients from the harmful effects of ionising radiation rests with the Holder who must ensure that appropriate provisions are put in place to meet the requirements of the regulations. The Holder means “any natural or legal person who has the legal responsibility under national law for a radiological installation”. In almost all cases the Holder will also be the Undertaking [licensee with the Radiological Protection Institute of Ireland] as defined under SI 125 (2000) and will have additional responsibilities set out in that statutory instrument. Practitioners in Charge, Practitioners, Radiographers, Medical Physics Experts and Referrers and each person involved in the use of ionising radiation for the purpose of medical exposures also have the duty to comply with the provisions of the regulations.

1.1 Governance and Structures

The regulations state that a Holder may establish a local radiation safety committee in respect of a particular installation and that committee shall have regard to the advice of the National Radiation Safety Committee. A number of other responsibilities are required of Holders. The National Radiation Safety Committee has reviewed these and recommended the following to assist Holders in fulfilling their legal requirements.

**1.1.1. National Radiation Safety Committee Recommendation**

The National Radiation Safety Committee has made the following recommendations to assist Holders in fulfilling their legal requirements and has provided advice on a local governance framework.

**1.1.2 Radiation Safety Committees.**

Radiation Safety Committees are recommended to be in place in organisations that have a large volume of procedures and/or higher risk practices. This does not generally apply to smaller practices with one simple x-ray unit such as a dental practice DXA scanning practice or chiropractor practice.

Many Holders have established Radiation Safety Committees to meet the licence requirements of the Radiological Protection Institute of Ireland, under SI 125 (2000). Where these committees exist, it is recommended that their terms of reference are expanded to additionally advise the Holder on the following:
Radiation Safety committee will:

- Ensure and monitor compliance with SI 478/303/459
- Monitor risks and incidents
- Monitor quality assurance programmes
- Review and prioritise clinical audit
- Monitor equipment, maintenance and replacement criteria
- Monitor staff education and training
- Monitor patient dose levels
- Establish local Diagnostic Reference Levels
- Other responsibilities as may be delegated by the National Radiation Safety Committee or the Competent Authority

**Note**
*Arrangements similar or additional to above, such as risk or clinical audit committees, particularly in radiotherapy, that achieve the same aims within the quality, safety and risk framework of the facility may also be considered to be appropriate. These would need to demonstrate good governance and have an integrated approach to ensure the above agenda is delivered on.*

It is recommended that Radiation Safety Committees meet at minimum twice per year (4 times per year in radiotherapy) and be integrated in to the governance, risk and safety framework of the organisation.

It is recommended that membership of Radiation Safety Committee includes, at a minimum:

- The CEO/Manager (*see below*), or their representative, should ideally chair the Committee
- Risk Manager
- Practitioner in Charge at a minimum and the possibility for an additional Consultant Radiologist and/or Consultant Radiation Oncologist as appropriate
- Radiography Services Manager and/or Radiation Therapy Services Manager as appropriate
- Radiation Protection Adviser (**see note below**) / Medical Physics Expert
- A representative from each department using ionising radiation for patients
- Nurse, where nurses are referrers/operators
- Representation from satellite hospitals/clinics, as appropriate
- Occupational Health Physician, Specialist in Public Health Medicine or other medical practitioner may be co-opted on to the committee where any persons require ongoing medical surveillance as a result of radiation exposure (including classified Category A workers as specified in article 25 of SI 125 (2000)).
- Other Medical or Dental practitioners may be co-opted on to the Radiation Safety Committee where relevant.

**Note**
*The CEO/hospital manager has the corporate responsibility and should ideally chair the committee but may nominate a suitable person to chair.*

**(**) The responsibilities of the Radiation Protection Adviser are set out in SI 125 (2000) and in the conditions that the Radiological Protection Institute of Ireland attaches to its licences.

**Note:**
The membership requirement for Radiation Safety Committees as outlined in DOH circular B423/1 of 1983 has been updated by these guidelines
1.1.3 Dental Radiation Safety Committees
Where these exist, it is recommended that their terms of reference are similarly extended. Their membership will differ to the above but should be reviewed and modified, where appropriate.

There may be some cases where the National Radiation Safety Committee will advise a Holder to establish a Radiation Safety Committee and the National Radiation Safety Committee will make contact directly with that Holder.

1.1.4 Patient Radiation Protection Manual (Patient)
It is recommended that all Holders keep a Radiation Protection Manual on site. An example of the suggested contents of this Manual, particularly for dentistry, is listed in section 1.7. A further example, relating to Chiropractors, is listed in section 1.8. The Medical Exposure Radiation Unit will distribute guidelines on the contents and upkeep of this file to all Holders in 2012. This file will be expected to be made available, if requested, to the Medical Exposure Radiation Unit, HSE which has a responsibility to audit clinical practice.

1.2 Personnel involved in the use of ionising radiation.

1.2.1 Engagement and training of persons involved in the use of ionising radiation.
It is recommended that the Holder ensures that all persons involved in the use of ionising radiation have the appropriate qualifications, authorisation, registration and training required to carry out their functions in compliance with the regulations and are aware of their responsibilities. It is recommended that the holder ensures that appropriate ongoing induction and training is provided, particularly when new or updated practices are introduced and when there is a change of personnel.

The Holder is required to:
- Designate one individual as Practitioner in Charge (a Practitioner has a specific definition in SI 478(2002)) who will recommend referral criteria for use of the facility.
- Designate a named Medical Physics Expert for the facility.

1.3 Equipment

1.3.1 Equipment Suitability
In addition to the requirements placed on the Holder by the Radiological Protection Institute of Ireland, SI 478 (2002) requires that the Holder has and maintains a written inventory of all radiological equipment and the National Radiation Safety Committee recommends that it is available if requested.

The Holder must ensure that their equipment complies with criteria of acceptability and take appropriate action if it fails to meet the criteria, based on the advice or action of the Medical Physics Expert.
National Radiation Safety Committee Recommendation
The National Radiation Safety Committee is awaiting the publication of the European Commission Radiation Criteria for Acceptability of Radiological, Nuclear Medicine and Radiotherapy Installations. A draft version is available to download at http://ec.europa.eu/energy. The recommendation of the National Radiation Safety Committee will be notified to Holders in a separate guidance document. The regulations currently require that the National Radiation Safety Committee authorises the extended use of all equipment beyond its anticipated lifetime. The decision on the continued use of equipment beyond its anticipated lifetime is most appropriately made at individual location. The National Radiation Safety Committee will issue guidance to Holders on the decision making process and how to inform the committee on the extended use of equipment.

1.4 Systems

1.4.1 Adverse Incident Reporting
It is recommended that Holders ensure they have systems in place to prevent and report adverse incidents. Notwithstanding the incident reporting requirements of the Radiological Protection Institute of Ireland, the National Radiation Safety Committee has issued recommendations and guidance to all Holders in 2010 on an external reporting mechanism for the reporting of adverse incidents (http://www.hse.ie/eng/about/Who/radiation%20patient%20safety%20incident%20notification.pdf).

1.4.2 Clinical audit
The Holder should ensure that the clinical practice is externally audited in accordance with the criteria adopted by the Irish Medical / Dental Councils at least once every five years.

The National Radiation Safety Committee in partnership with the Faculty of Radiologists and the HSE has issued guidance on external and internal clinical audit in agreement with the Irish Medical / Dental Councils (http://www.hse.ie/eng/about/Who/qualityandpatientsafety/medexpradiationunit/ClinicalAuditJointDocument.pdf). The guidance was developed within the context of national developments resulting from the Report of the Commission on Patient Safety and Quality Assurance, 2008 and the Adverse Event, Clinical Audit and Patient Safety Protocols being developed.

1.4.3 Quality Assurance
Quality Assurance means “all those planned and systematic actions necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily and comply with agreed standards.” Holders must ensure that appropriate quality assurance programmes are implemented.
1.5 Protocols and Standards

1.5. Referral criteria
The Holder must ensure that referral criteria are advised to referrers, based on the recommendation of the Practitioner in Charge.

1.5.2 Diagnostic Reference Levels
Diagnostic Reference Levels means “dose levels in medical radio diagnostic practices or, in the case of radio-pharmaceuticals, levels of activity for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment. These levels are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied.” Those that have been established nationally are available at [http://www.hse.ie/eng/about/Who/qualityandpatientsafety/medexpradiationunit/Publications_and_Annual_Report.html](http://www.hse.ie/eng/about/Who/qualityandpatientsafety/medexpradiationunit/Publications_and_Annual_Report.html)

1.6 Other Responsibilities

In addition to Holders’ responsibilities, personnel involved in the use of ionising radiation for medical exposures have been assigned particular responsibilities in SI 478/303. The following is a summary and must be read in conjunction with the regulations and other laws, regulations or other responsibilities attaching to these roles.

1.6.1 Responsibility of the Practitioner in Charge (in addition to responsibilities of the Practitioner).
- Recommend referral criteria. It is expected that most departments already have criteria in place for many procedures. The Faculty of Radiologists has recommended the use of the RCR (UK) referral criteria recommendations (iREFER) for diagnostic practice and these would be an acceptable foundation on which to base local criteria.
- Approve adjustments to be made to the equipment that are considered necessary by the Medical Physics Expert.

1.6.2 Responsibility of the Practitioner.
- Clinically responsible (along with his/her colleagues) for all ionising radiation exposures performed in their institution. “Clinical responsibility” means responsibility regarding individual medical exposures attributed to a Practitioner, notably: justification; optimisation; clinical evaluation of the outcome; co-operation with other specialists and the staff, as appropriate, regarding practical aspects; obtaining information, if appropriate, of previous examinations; providing existing radiological information and/or records to other Practitioners and/or referrers, as required; giving information on the risk of ionising radiation to patients and other individuals involved, as appropriate.
- Authorise radiological procedures subject to the conditions in the regulations.
- May not authorise the use of a practice which has been considered by the Medical and Dental Councils and which has not been approved by them.
- Make arrangements to satisfy himself / herself that the procedure prescribed is justified.
• Consult with the Medical Physics Expert assigned to the installation on optimisation, including the consistent production of adequate diagnostic information or therapeutic outcome, patient dosimetry, and quality assurance, including quality control and the assessment and evaluation of patient doses or administered activities, and on matters relating to radiation protection concerning medical exposures.

1.6.3 Responsibility of the Referrer

• Shall state in writing/electronically the reason for requesting the particular procedure.
• Shall enquire as to and provide the Practitioner with the pregnancy status of relevant females for all ionising radiation exposures.
• With the Practitioner, shall seek, where practicable, to obtain previous diagnostic information or medical records relevant to the planned exposure and consider these data to avoid unnecessary exposure.

1.6.4 Responsibility of the Medical Physics Expert

Medical Physics Expert conducts the following activities or gives advice on the following:
• Patient dosimetry.
• The development and use of complex techniques and equipment.
• Optimisation, particularly in therapeutic and high dose procedures, paediatric, pregnancy and breast feeding.
• Quality assurance, including quality control.
• Periodic examinations of equipment and records, agree such adjustments to be made to the equipment subject to the approval of the Radiologist in Charge, maintain a record of each examination and adjustment of equipment.
• Acceptance testing of new equipment and checking of equipment after major maintenance.
• The Medical Physics Expert must express their views on continued suitability of use of equipment beyond its anticipated lifetime, based on equipment criteria.
• Other matters relating to radiation protection.

1.6.5 Responsibility of the Radiographer

• Ensure adherence to justification procedures.
• Advise on dose optimisation.
• A Radiographer appointed as Radiation Safety Officer in designated locations records and maintains records of regular Quality Control tests.
• The Radiation Safety Officer, records and audits patient dose information for compliance with DRLs.
• In Clinical Audit, the Radiographic Services Manager ensures that agreed standards and protocols are in place and adhered to.
• In Adverse Incident reporting relating to ionising radiation for medical exposures, the Radiographic Services Manager ensures incidents are recorded and managed according to agreed protocols.
1.7 Radiation Protection in Dental Practices

Dental radiography differs from medical radiography in that, in the majority of cases, the dentist acting in a single handed capacity is defacto the referrer, the radiographer and the radiologist when a radiographic examination is required.

The dentist may also, by way of being a single handed practitioner, automatically becomes the “Practitioner in Charge” for the purposes of the legislation.

Outside of large organisations such as the HSE dental and orthodontic services and the Dental Schools, the majority of dental practitioners operate in a general dental practice setting with some practitioners in specialist / limited practice.

As private dental practices will often be staffed by the dental practitioner, occasionally an associate and his / her support staff, it would be impractical to have a Radiation Safety Committee. Instead, dentists who are RPII x-ray licence holders are required to hold a file of compliance on site.

The practice Dental Radiation or “Compliance File” should contain the following:

- A copy of the current x-ray licence including schedules 1, 2 and 3
- Personnel Dosimetry reports to be held for 7 years
- Commissioning reports - to be held for the life time of the equipment
- Annual service reports – to be held for the life time of the machine
- Maintenance reports – to be held for the life time of the machine
- Reports from the Radiation Protection Advisor
- Reports from the Medical Physics Expert, including a record of the annual number of exposure per machine type, where possible
- Copy of the safety operating procedures (local rules)
- Clinical Audit reports and associated data
- Details of radiation incidents and reports
- Quality assurance programme data to be held for the lifetime of the machine and a record of the replacement review date for each machine
- Staff training and induction reports
- Evidence of safe disposal of developer chemistry and lead foil
- Any correspondence relating to the radiographic practice at that location
- Written protocols for all imaging procedures
- Pregnancy protocols
- DRLs where available

Note: this is not an exhaustive list and additional documents may be considered necessary for inclusion.
1.8 Radiation Protection in Chiropractor Practices (sample only)

As chiropractor practices will often be staffed by the Chiropractor, occasionally an associate and his / her support staff, it would be impractical to have a Radiation Safety Committee. Instead, Chiropractors who are RPII x-ray licence holders are required to hold a file of radiation protection compliance on site.

The practice Patient Radiation Protection or “Compliance” File should contain the following:

- A copy of the current x-ray licence including schedules 1, 2 and 3
- Personnel Dosimetry reports to be held for 7 years
- Commissioning reports - to be held for the life time of the equipment
- Annual service reports – to be held for the life time of the equipment
- Maintenance reports – to be held for the life time of the machine
- Reports from the Radiation Protection Advisor
- Reports from the Medical Physics Expert, including a record of the annual number of exposure per machine type, where possible
- Copy of the safety operating procedures (local rules)
- Clinical Audit reports and associated data
- Details of radiation incidents and reports
- Quality assurance programme data to be held for the lifetime of the machine and a record of the replacement review date for each machine
- Staff training and induction reports
- Evidence of safe disposal of developer chemistry and lead foil
- Any correspondence relating to the radiographic practice at that location
- Written protocols for all imaging procedures
- Pregnancy protocols
- DRLs
Section 2

Local Radiation Protection Procedures & Documentation
Section 2 Local Radiation Protection Documentation

2.1 Local Documentation

2.1.1 Radiation Safety Procedures / Local Rules (General Public and Staff (see introduction, page 8 and appendices VII and X) (RPIL Requirement)

The conditions attached to licences issued by the RPII in respect of any activity involving ionising radiation require the licensee to draft, approve and maintain a Radiation Safety Procedures. In the medical setting, extracts from these procedures are often referred to as ‘local rules’.

The procedures should be approved by the licensee’s CEO, General Manager (or equivalent). Appendix VIII outlines a typical layout and content of the Radiation Safety Procedures.

The local rules / radiation safety procedures are prepared by the Radiation Safety Committee on behalf of the licensee. It is the duty of the Radiation Protection Adviser to prepare and submit to the Radiation Safety Committee the Radiation Safety Procedures required.

2.1.2 Radiation Protection Manual (Patient)
(National Radiation Safety Committee requirement)

The Radiation Protection Manual should be reviewed, updated and signed off by the Radiation Safety Committee annually and Practitioner in Charge.

The following pages of this Patient Radiation Protection Manual provide useful guidance and templates to assist in the development and maintenance of these records.

Each unit using Ionising Radiation must have a copy of the Radiation Safety Procedures/Local Rules and Radiation Protection Manual (Patient) relevant for its practice to ensure that the appropriate requirements are met.

All workers involved with Ionising Radiation should read both documents and sign a statement that they have read and understood them.
Section 3

Personnel involved with Ionising Radiation
Section 3 Personnel involved with Ionising Radiation

All staff involved in delivering ionising radiation to patients shall have adequate theoretical and practical training for the purpose of radiological practices, as well as relevant competence in radiation protection.

Each location should assign responsibility to an individual to maintain the Radiation Protection training records of all relevant staff at the facility. The Radiation Safety Officer should be considered as the assigned individual, where relevant. Competence in this area and the requirement for refresher training should be reviewed at regular intervals. The Radiation Safety Committee is responsible to monitor education and training of staff in Radiation Protection.

Insert here “The training record of all staff at location involved in the use of Ionising Radiation”

3.1 Template to record induction and training of staff in Radiation Protection.
Include all practitioners, referrers, radiographers, nurses, operators, physicists and all other relevant staff.

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3.2 Records of Radiation Protection Training
Records of Radiation Protection training of staff will be available, and updated regularly.
Section 4

Radiology Equipment and Reports
Section 4 Radiology Equipment, Licence and Reports

An inventory of equipment and a copy of the RPII licence should be kept at individual location and a note made on the template (2.2) of where to access this information.

4.1 Copy of Licence Schedule

A copy of the current RPII licence should be displayed in the facility.

4.2 Inventory of Radiation Equipment

An inventory of all ionising radiation equipment is required and demonstrates that relevant equipment used to provide diagnostic imaging services to patients is registered on the RPII licence and its nominal replacement date has been set and reviewed.

4.2.1 Make of Equipment
4.2.2 Model Serial Number of X-ray tube
4.2.3 Installation Data/Acceptance/Testing date and reports.
4.2.4 Nominal Replacement date and decision on the continued use of equipment beyond its anticipated lifetime

Each piece of radiation equipment is required to have a replacement due date set for it and a decision made as to its appropriate use thereafter. Equipment should be certified for use, limited use or discontinuation by the Practitioner in Charge, the MPE, the RSM/RTSM/Clinical Services Manager as appropriate and the Engineer. The holder then records his / her decision for the continued use of each piece of equipment.

The regulations currently require that the National Radiation Safety Committee authorises the extended use of all equipment beyond its anticipated lifetime. The decision on the continued use of equipment beyond its anticipated lifetime is most appropriately made at location.

• The National Radiation Safety Committee will issue guidance to Holders on the decision making process of how to inform the committee on the extended use of equipment, including
  o assurance from the Holder that a process is in place to review all equipment and is up to date and
  o a process to notify the NRSC of exceptions and decision taken by holder on the restricted use or removal of the equipment.

4.3 Service Records

Services records are required to be kept and maintained for all ionising radiation equipment to include;
QA Reports
Routine Radiographer QA Reports
Physics Annual QA Reports
Service Reports
Confirmation Action Taken
Section 5

Incident Reporting
Section 5 Incident Reporting

All Radiation Incidents are recorded locally. There are requirements to report patient radiation incidents to the Medical Exposure Radiation Unit as outlined below. In addition, the Radiological Protection Institute of Ireland requires incidents to staff and members of the public to be reported to them (ref 5.9 below). In some cases, incidents are required to be reported to both MERU and RPII.

5.1 Medical Exposure Radiation Unit Guidelines

The role of an incident reporting system is to enhance patient safety by learning from failures in the healthcare system.

The National Radiation Safety Committee has issued guidelines on a national reporting mechanism for the reporting of incidents to patients.

Guidance on the types of incidents that are notifiable to the Medical Exposure Radiation Unit and also guidance on how non-notifiable incidents are defined.

5.2 Guide to Defining and Managing all Patient Radiation Incidents

5.2.1 Recording of incidents

All incidents should be managed through the normal risk management route within the organisation and tabled on the Radiation Safety Committee agenda. All incidents should be recorded, reported, reviewed and investigated, where considered appropriate, locally. A sample form to record patient radiotherapy incidents at the location is currently being developed.

5.3 Definition of Patient Radiation Incident

Examples of Radiology, Nuclear Medicine and Radiotherapy (Diagnostic Imaging, CT, PET-CT, Nuclear Medicine, Cardiology and Interventional Radiology studies) Patient Safety Incidents

- **Exposure Greater than intended, for example;**
  - A diagnostic exposure “greater than intended” (see table 2 page ).(D006)
  - Incorrect Radiopharmaceutical.(D010)
  - Therapeutic nuclear medicine – administered activity differing by a factor of 1.1.(D013)

- **Exposure where none intended, for example;**
  - Incorrect Patient. (up to 1mSv) (D001)
  - Incorrect Procedure.(D002)
  - Incorrect Anatomy.(D003)
  - Equipment failure, accident, error or mishap causing patient exposure.(D005)
• **Radiotherapy dose variations, for example;**
  - Radiotherapy Dose variation from prescribed total dose from 5% up to 10%. (D018)
  - Radiotherapy Dose variation from a fractional dose from 10% up to 20%. (D017)
  - Deterministic effects. (D004)
  - Any other relevant radiation incident considered to have patient safety implications. (D023)
    - A near miss under any of the above headings.

### 5.4 Definition of noifiable Patient Radiation Incident

**Examples of Radiology, Nuclear Medicine and Radiotherapy** (Diagnostic Imaging, CT, PET-CT, Nuclear Medicine, Cardiology and Interventional Radiology studies) **Notifiable Patient Safety Incidents**

**Exposure much greater than intended, for example;**
- Diagnostic overexposure of adult as a result of more than twice the exposure intended that leads to an overexposure of > 10mSv or 20 times the dose intended, regardless of the dose level.
- Diagnostic overexposure of a child as a result of more than twice the exposure intended that leads to an overexposure of > 3mSv or 15 times the dose intended, regardless of the dose level.
- Inadvertent deterministic effects produced as a result of interventional radiology.
- Therapeutic nuclear medicine - administered activity differing by a factor of 1.2.
- Therapeutic dose given instead of diagnostic dose e.g. radiiodine.
- Dose given to carers without consent that is greater than medical council guidelines of 3 mSv, and 15mSv for adults 60 years or over.

**Exposure where none intended, for example;**
- Inadvertent dose to the breastfed child over 1 mSv.
- Inadvertent Dose to foetus over 1 mGy.
- Incorrect patient (radiology or radiotherapy) exposed to over 1mSv.

**Radiotherapy dose significant variation, for example;**
- Radiotherapy Dose variation from prescribed total dose of greater than 10%.
- Radiotherapy Dose variation from a fractional dose of greater than 20%.
- Radiotherapy – completely incorrect volume.
- Radiotherapy – inadvertent setup variation that will/could impact on normal tissues/organs at risk (e.g., heart, lung, eyes, kidney, etc.).

**Inadvertent deterministic effects from radiotherapy.**

**Any other relevant radiation incident considered to have serious patient safety implications.**

**A near miss under any of the above headings.**
5.5 Reporting a notifiable incident to the Medical Exposure Radiation Unit

All notifiable incidents should be reported upon discovery to the Medical Exposure Radiation Unit. In case of doubt, the incident may be reported verbally to the Unit which will, following consideration of the circumstance, advise whether formal reporting is required.

Contact Details:  
Ciara Norton,  
Medical Exposure Radiation Unit,  
Health Service Executive,  
Mill Lane,  
Palmerstown,  
Dublin 20.  
01-6201807  
ciara.norton@hse.ie.

Incidents requiring immediate urgent attention should be managed through an organisation’s local risk management structures. In the unlikely event of a radiation emergency, holders may also be required to follow the procedures established by the Radiological Protection Institute of Ireland.

5.6 Investigation of notifiable incidents

There are five main objectives in investigating incidents;

1. Ascertain events leading to the incident.
2. Establish cause of incident.
3. Implement immediate action to prevent further harm or recurrence.
4. Estimate dose received by patient.
5. Record exposure factors and other relevant technical details.

It is important to identify from the outset, or as early as possible, the persons who will be involved in the investigation, including those conducting the investigation and those whose evidence is to be considered.

People involved should include;

- Person in charge of the facility.
- Risk Manager/Advisor.
- Staff where incident took place/referrers/practitioners.
- Patient/Accompanied Persons who was exposed to medical ionising radiation.
- Person responsible for carrying out exposure.
- Radiation Protection Advisor/Medical Physics Expert.
- Radiation Safety Officer, where applicable.

The above list should not be considered to be exhaustive and other persons may be involved in the investigation depending on the circumstances.

There should be a documented protocol in place on the communication of incidents to patients.
5.7 Investigation Report for Patient Radiation Incidents

The findings of the investigation must be documented in an investigation report. The Medical Exposure Radiation Unit has developed a sample template report for notifiable incidents, appendix I. It is recommended that this is used as the investigation report or as a reference document for locations when completing their investigation report. This is to ensure that all relevant areas are addressed in the report submitted, including:

- All relevant facts concerning the incident.
- Consequences for exposed patient.
- Calculations and measurement of all exposures and other technical factors.
- Details of discussion with patient and carers.
- Recommendations to avoid recurrence.
- Details of follow up actions with staff involved.
- Details of follow up actions with patient.

A root cause/systems analysis of the incident should be conducted, for example using the fishbone diagram to aid analysis (appendix III). The report should be signed and dated by the person who prepared it and the practitioner. The reports should be signed by the CEO/Hospital Manager and discussed at the Radiation Safety Committee meetings and audit committees and forwarded to the Medical Exposure Radiation Unit.

5.8 Other Reporting requirements to the Medical Exposure Radiation Unit

The Medical Exposure Radiation Unit will request each location to submit the total number of incidents that have been recorded in addition to the notifiable incidents. This will be requested annually from the locations. Please refer to Appendix III for Recording Template.

<table>
<thead>
<tr>
<th>Diagnostic Procedures</th>
<th>Dose multiples greater than intended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limbs and Joints (except hip); chest (single PA film); skull; dental; DXA</td>
<td>5</td>
</tr>
<tr>
<td>Thoracic spine; lumbar spine; hip; pelvis; abdomen; dental CT; Brain CT</td>
<td>3</td>
</tr>
<tr>
<td>IVU; barium swallow; barium meal; barium follow through; barium enema; CT chest; diagnostic nuclear medicine</td>
<td>3</td>
</tr>
<tr>
<td>CT abdomen or pelvis, PET-CT; cardiology; interventional radiology</td>
<td>2</td>
</tr>
</tbody>
</table>

Table 2
Guide to “Greater than Intended”

Guidelines for Reporting Patient Safety Incidents from Medical Ionising Radiation
Http://www.hse.ie/eng/about/Who/Incident%20reporting.html12
5.9 Radiological Protection Institute of Ireland Incident Reporting Requirements

Incidents involving workers, members of the public or the environment may give rise to public concern should always be reported to the RPII regardless of their radiological significance. The incident may be reported verbally to the RPII which will advise whether formal reporting is required.

Web Address: www.rpii.ie
Guidelines for reporting Radiological Incidents to the Radiological Protection Institute of Ireland. March 2009

Section 6

Patient Pregnancy Protocols
Section 6 Patient Pregnancy Protocols

6.1 Patients

Locations should have pregnancy protocols in place. Pregnancy protocols should be developed locally which incorporate both the legislative requirements of SI 478 and the RPII guidelines on the protection of the unborn child during diagnostic medical exposures.

A recent national audit on pregnancy protocols was issued in 2012. The MERU will issue national recommendations on pregnancy protocols based on the outcome of the audit.

SI 478

Article 20 - Special Protection during Pregnancy and Breastfeeding.

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

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

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

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

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

In addition, Art. 10.3 (Medical Exposures Directive) states:

10.3 Without prejudice to Article 10 (1) and (2), any measure contributing to increasing the awareness of women subject to this Article, such as public notices in appropriate places, could be helpful.

6.2 Protection of the unborn child during diagnostic medical exposures

The RPII have produced guidelines on the protection of the unborn child during diagnostic medical exposures, May 2010 (appendix IV). The aim of these guidelines is to provide a concise summary of the actions to be taken when dealing with women of childbearing age.

Section 7

Patient Protocols
Section 7 Protocols and Standards

7.1 Referral Criteria

SI 478:

14.2. The Practitioner in charge of an installation shall recommend, having regard to these regulations and subject to the approval of the Holder, the referral criteria for referrers when referring patients for a radiological procedure.

14.3. The Holder shall ensure that the criteria referred to in paragraph 14.2 are advised to referrers. e.g. Clinicians, GPs etc

Locations in Ireland have adopted referral criteria for use by their referrers. There are a number of criteria available, including

- The Royal College of Radiologists (UK)\textsuperscript{15} produced referral criteria guidelines in 1996 and most recently they were updated in 2012 and available on-line in 2012. (www.irefer.org.uk - Making the best use of Clinical Radiology).

- Australian "Diagnostic Imaging Pathways" (http://www.imagingpathways.health.wa.gov.au/includes/index.html),\textsuperscript{16}

- ACR Appropriateness criteria (www.acr.org/Quality-Safety/Appropriateness-Criteria)\textsuperscript{17}

7.2 Patient Identification check

Each department should have a protocol in place to correctly identify patients who are undergoing a medical ionising procedure. An exposure must not be undertaken if the patient identification cannot be verified.

Responsibility

The referrer is responsible for ensuring that sufficient details are included on the request form to enable the patient to be unambiguously identified.

The Radiographer/Operator initiating the exposure is responsible for making the final check on identifying the patient.

Practice

Identifying the patient is an active rather than passive procedure. A 3 point ID check: the patient should be asked to give their full name, date of birth and address and these details should be checked against the request card, wrist band for in patients or other available documentation. Correctly matching patients with their intended diagnostic imaging or radiotherapy treatment and the anatomical site and side (if applicable) of the diagnostic imaging / radiotherapy procedure is also a requirement. In radiotherapy photo ID may also be used to identify patients.
If the patient is unable to respond to the above questions because of illness, language or learning difficulties etc, a relative, nurse etc, must be able to verify the patient’s identity, the method by which the patient is identified should be noted on the request form. Children under 16 years: the responsible parent or guardian should verify their identity if appropriate.

For patients with communication problems, the ID check can be carried out with the accompanying person or by an appropriate communication method with the patient, for example the interpreter.

Particular care needs to be taken in correctly identifying patients with the same or similar names and the referrer must ensure that sufficient details are included on the request form to enable the patient to be unambiguously identified by the practitioner, operator and any other relevant staff members.

7.3 Correct Patient Identification and Procedure Matching

When any high dose radiological interventional procedure /radiotherapy treatment is being performed, correct patient identification and procedure matching should be performed to ensure the correct patient receives the correct procedure. Each department should have a protocol in place where this applies. The “WHO Surgical Safety Checklist for Radiological Interventions ONLY” should be considered for relevant procedures, available at http://www.nrls.npsa.nhs.uk/resources/?EntryId45=73612

The Medical Exposure Radiation Unit has conducted a national audit on patient identification and plans to issue guidance on patient identification to radiology departments in 2012.

7.4 Patient Consent

Patient consent is required for radiology procedures and all radiotherapy treatments. Each department should have a protocol in place for patient consent.

The Medical Exposure Radiation Unit has conducted a national audit on patient consent and plans to issue guidance on patient consent to radiology departments in 2012.

7.5 Justification

SI 478 (2002)

7.1 “Medical exposure referred to in regulation 4.1 shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefit it produces, including the direct health benefits to an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving less exposure to ionising radiation”.

Written protocols should be in place and take in to account prioritisation criteria for patients. Previous diagnostic information and medical records should be sought, relevant to the planned procedure to avoid unnecessary additional exposure.
7.6 Optimisation

**SI 478 (2002):**

7.7.1. 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, taking into account economic and social factors.

7.7.2 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.

All locations must have protocols in place for the optimisation of procedures; ensuring doses due to medical exposure are kept as low as reasonably achievable.

7.7 Imaging Protocols

Imaging protocols must be in place for each radiological procedure and kept in an easily accessible location. They are agreed locally for each piece of equipment and should include details of;

- Number of radiographic views for each procedure
- Radiographic technique appropriate for each procedure
- Exposure factors, positioning technique, etc.

Separate technique charts should be available for each piece of equipment, as appropriate.

A technique chart should be on display, with all relevant information in close proximity to each piece of x-ray equipment for quick reference.

7.8 Bio-medical and medical research projects

Where a facility conducts bio-medical and medical research projects, they must adhere to the following;

**SI 478 states:**

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

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

---

36
Article 10.3. “In the case of patients who voluntarily accept to undergo an experimental diagnostic or therapeutic practice and who are expected to receive a diagnostic or therapeutical benefit from this practice, the target levels of doses shall be planned on an individual basis by the practitioner”.

The use of ionising radiation in any research project will ALWAYS require medical ethical approval.

When it is clear that there is a direct medical benefit to a patient from a procedure involving irradiation, the regulations in the relevant sections of the Local Rules and accompanying Operating Procedures are applicable.

Medical research projects involving irradiations which are not of direct benefit to individual patients or which involve the irradiation of volunteers must be referred to the Hospital Ethics Committee and to the Radiation Safety Committee.

These Committees must be satisfied that:-

a. The results required from the research can be acquired only by the use of radiation.
b. The research is being conducted by properly trained and qualified staff who are also authorised users of radioactive materials/irradiating equipment.
c. There is a clear objective for the research and that procedures are carefully planned to keep all doses as low as possible.
d. A reasonable estimate of doses to the volunteers is supplied and is acceptable.
e. The number of subjects to be studied and the type of volunteer to be used is clearly stated (e.g. 20 male subjects between the ages of 50 and 70 years).
f. The usual ethical requirements with respect to volunteers will be strictly observed.
g. The research conforms to criteria as set out by the Medical and Dental Councils.

7.9 Health Screening

SI 459 (2010) outlines procedures to be followed when providing a health screening programme.
Section 8

Clinical Audit
Section 8 Clinical Audit

8.1 Guidance on Clinical Audit

E.U. Member States are required to implement Clinical Audit in Radiology (EC Directive 97/43 Euratom (MED) SI 478 15.1 – 15.5 is the translation of article 6.4 of the Medical Exposure Directive, Clinical Audit must be carried out in accordance with national procedures.

The CEO of the HSE, in Statutory Instrument 478 (2002) is required to appoint an auditor (Article 15.2). In addition to the ongoing programme for clinical audit, the CEO/Hospital Manager is required, to ensure that the clinical practice is audited by the HSE at least once every five years in accordance with the Clinical Audit Criteria published by the Medical and Dental Councils.

The report of the Commission (2008) on Patient Safety and Quality Assurance “Building a Culture of Patient Safety”19 recognised the importance of Clinical Audit. “Clinical Audit arguably constitutes the single most important method which any healthcare organisation can use to understand and ensure the quality of the service it provides.

General purpose of Clinical Audit.

➢ Improve the quality of patients’ care
➢ Improve effective use of resources
➢ Enhance the provision and organisation of clinical services
➢ Further professional education and training

What can be audited in Radiology Departments.

All parts of the patients’ pathway from referral to final patient outcome can be audited.

Structure Audit

➢ Facilities
➢ Staff

Process Audit – Patient Pathway

➢ Waiting times for procedures
➢ Justification process
➢ Radiation doses delivered
➢ Reporting process

Outcome Audit

➢ Patient Complaints
➢ Patient satisfaction ratings
➢ Peer Review of reported images etc
8.2 Guidance Documents

The EU has issued guidelines to assist countries in meeting their clinical audit requirements -
The European Commission Guidelines on Clinical Audit for Medical Radiological Practices, 2009

International Atomic Energy Agency
In addition, the International Atomic Energy Agency, of which Ireland is a member, has issued a
toolkit for clinical audit in diagnostic radiology; Comprehensive Clinical Audits of Diagnostic

A toolkit was also produced for Radiotherapy; Comprehensive Audits of Radiotherapy Practices:


Medical Council
Medical Council has issued criteria for clinical audit as required in the Irish legislation, these
guidelines are available from:
http://www.hse.ie/eng/about/Who/Criteria_for_Clinical_Audit.pdf

Faculty of Radiologists
Guidelines for the implementation of a National Quality Assurance Programme in Radiology -
version 1

Sample Audits
The Royal College of Radiologists, UK has produced “Clinical Audit in Radiology – 100+
Recipes” 1995. Godwin R., de Lacey, G. And Manhire A.

8.3 Roles and Responsibilities for Clinical Audit

An effective programme for clinical audit at a location requires a supporting governance structure
with clear accountabilities assigned to individuals to facilitate and mandate the practice of clinical
audit. For example, locations should have a multidisciplinary hospital/organisation Committee,
such as a Patient Safety Committee, Risk Management Committee, Clinical Audit Committee,
chaired by the CEO or Hospital Manager, that has the authority to make decisions and implement
changes based on clinical audits that have taken place. A sample local governance structure is
portrayed in table 8.7.3.

The CEO/Hospital Manager has responsibility in all facilities (and through the Clinical Director in
HSE locations) to ensure structures and effective processes are in place for radiological clinical
audit and integrated in to existing and planned clinical governance and clinical audit
arrangements for the location.
The Radiologist/Radiation Oncologist appointed as the Practitioner in Charge has the lead responsibility for clinical audit activity in the facility, monitoring and ensuring that changes are implemented as a result.

The Practitioner in Charge will ensure audit plans are delivered on and that the audit results are reported to the hospital CEO and Board (where applicable) on an annual basis, or appoint another Radiologist/Radiation Oncologist with this responsibility. The role of the Radiographic Services Manager in clinical audit is to ensure that agreed standards and protocols are in place and adhered to. The Radiation Safety Officer may be assigned specific responsibility to monitor and ensure clinical audit takes place.

Although audit is mainly a multidisciplinary activity, clinical audit carried out by individual clinicians can be a valuable foundation on which departments can build audit plans, particularly annual plans. All individuals, both professionals and administrators, also have a responsibility for regularly auditing their own activity.

The National Radiation Safety Committee recommends the following to assist in delivering on audit responsibilities:

It is recommended that the Radiation Safety Committee should oversee the hospital’s responsibility and extend its terms of reference to include clinical audit, as follows:

- The annual clinical audit plan of the Radiological Clinical Audit Working Group should be presented to the Radiation Safety Committee who recommends it to the CEO/Hospital Manager / Hospital Board through local structures, such as a Hospital Clinical Audit Committee.
- Approve the annual progress report of the Radiological Clinical Audit Working Group and present it to the CEO/Hospital Manager / Hospital Board through local structures.
- Review the work of the Radiological Clinical Audit Working Group at each meeting and provide advice on priorities and risks.
- The membership of the Radiation Safety Committee should include the chair of the Radiological Clinical Audit Working Group and the Radiation Safety Officer.
- Have formal links to the clinical governance committee and other related hospital committees and be integrated within the hospital, safety, risk and clinical governance frameworks.

### 8.4 Radiological Clinical Audit Working Group

A working group, chaired by the Radiologist/Radiation Oncologist with lead responsibility for Clinical Audit, should be established and meet frequently, at minimum four times per year.
8.5 **Recommended Terms of Reference for Radiological Clinical Audit Working Group.**

- Produce an annual clinical audit plan, based on a risk assessment to identify high dose, high risk or high volume procedures, to be recommended to the Radiation Safety Committee.

- The agreed plan for audit should include consideration of relevant hospital priorities and of guidance which may be issued by the NRSC, Faculty of Radiologists or HSE from time to time.

- Conduct audits as agreed in work plan and ensure work programme is assigned as appropriate.

- Monitor the audit process to ensure that it is effective and provides a clear record of adherence to the audit cycle ([table 8.7.1](#)) and that recommendations are implemented.

- Monitor and deliver staff education and training in audit as required.

- Produce an annual progress report for approval by the Radiation Safety Committee. This report will detail types of audit, numbers of audits completed, recommended actions, changes implemented and review dates set.

8.6 **Recommended membership of Radiological Clinical Audit Working Group**

As recommended in “Criteria for Clinical Audit” (Medical Council);

‘An Audit Committee within the Radiological installation is essential. This must be sponsored by the holder and should be led by a senior clinical radiologist, nuclear medicine physician or radiation oncologist, and should be broadly based with participation by all sectors of the departmental staff, management representatives and representatives of the department’s “customers” i.e. referring physicians and patients.’

It is recommended that the following members are included on the working group:

- Radiologist/Radiation Oncologist with lead responsibility for Clinical Audit, chair.

- Radiographer with lead responsibility for Clinical Audit / Radiation Safety Officer.

- Clinical Audit Facilitator, where applicable or representative of the Clinical Director (HSE locations), or equivalent.

- Radiation Protection Adviser / Medical Physics Expert.

Additional members can be added when additional expertise is required for specific audits, for example, dental or nurse prescribing audits.
8.7 List of Audits Completed and Audit related reports, and changes implemented

Please insert here a list of Audits Completed and Audit related reports, and changes implemented for your location, or insert the list of audits completed and a reference to where they are stored.

Also include local clinical audit protocols, guidance, annual reports, etc. and a reference to where they are stored.

**SAMPLE TABLE TO RECORD AUDIT ACTIVITY:**

<table>
<thead>
<tr>
<th>Audit Topic</th>
<th>N/A</th>
<th>Written policy and procedure available</th>
<th>Audited and audit report available</th>
<th>Changes have been implemented based on report recommendations</th>
<th>Recorded Evidence of improvement?</th>
<th>Re-audit report available or planned</th>
</tr>
</thead>
<tbody>
<tr>
<td>Justification/referral criteria</td>
<td>Insert date</td>
<td>Insert date</td>
<td>Insert date</td>
<td>Insert date</td>
<td>Insert date</td>
<td>Insert date</td>
</tr>
<tr>
<td>Reject Analysis</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Dose / Diagnostic Reference Levels</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Image Quality and Optimisation</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Patient Identification</td>
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<tr>
<td>Pregnancy Status Questioning</td>
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<tr>
<td>Patient Consent</td>
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<tr>
<td>Patient Communication</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Incident management</td>
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<td></td>
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<tr>
<td>Risk management</td>
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<td></td>
<td></td>
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<tr>
<td>Treatment preparation/verification</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Treatment prescription</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Planning procedures</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment delivery</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>In vivo Dosimetry</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Record and Verify</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Imaging for treatment verification (image guided RT)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 8.7.1

Clinical Audit Cycle

1. Select topic
2. Agree standards of best practice
3. Define methodology
4. Pilot and data collection
5. Analysis and Reporting
6. Make Recommendations
7. Implement change
8. Re-audit
### Table 8.7.2

**Clinical Audit in Radiology: 100+ Recipes.** London: Royal College of Radiologists, which is acknowledged as being an invaluable resource on the concept of undertaking audit in a systematic and logical way, repeating the cycle and choosing audits which are relevant.

The Royal College of Radiologists  
38 Portland Place  
London  
W1B 1JQ  
Telephone: +44 (0) 20 7636 4432  
Fax: +44 (0) 20 7323 3100  
http://www.rcr.ac.uk/27

### Clinical Audit Spiral

This diagram is from Godwin, R. et al, referenced above.

![Clinical Audit Spiral Diagram](image_url)

The Audit Spiral Diagram emphasises the improvement and/or reassurance aspects of audit, rather than audit for audit’s sake.
Table 8.7.3

Sample Clinical Audit Structures and Responsibilities

The arrangements set out below are an example to indicate the accountability and governance arrangements for Radiological Clinical Audit. These will vary depending on location and committees and roles may vary in name. However, all Responsibilities should be imbedded in the hospital structure with accountability up to and including the CEO.

<table>
<thead>
<tr>
<th>Individual Responsibility</th>
<th>Committee Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEO / Hospital Manager</td>
<td>Hospital Board / Regional Director</td>
</tr>
<tr>
<td>Clinical Director</td>
<td>Clinical Governance Committee and/or Hospital Clinical Audit / Risk / Patient Safety Committee</td>
</tr>
<tr>
<td>Practitioner in Charge</td>
<td>Radiation Safety Committee</td>
</tr>
<tr>
<td>Clinical Lead for Radiology Audit</td>
<td>Radiology Clinical Audit Working Group</td>
</tr>
<tr>
<td>Radiation Safety Officer</td>
<td>Individual Clinician /staff member</td>
</tr>
</tbody>
</table>
Section 9

Diagnostic Reference Levels (DRLs)
Section 9 Diagnostic Reference Levels (DRLs)

9.1 Definition of DRL

“Diagnostic reference levels” means dose levels in medical radio-diagnostic practices or in the case of radio-pharmaceuticals, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment. These levels are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied.

Diagnostic Reference Levels should be reviewed regularly for each location, compared with national or referenced averages and a note made of any significant variances and the justification for it.

National DRLs were published by the Medical Council and are available on their website, www.medicalcouncil.ie/About-Us/Legislation/Medical-Ionising-Radiation/. 28

A sample template to record and review CT DRLs for locations is attached in Appendix VIII this template can be used when setting DRLs for locations for all diagnostic procedures.

9.2 Nuclear Medicine

Guidance on diagnostic reference levels in Nuclear Medicine is available from ARSAC.

Administration of Radioactive Substances Advisory Committee (ARSAC); www.arsac.org.uk/29

9.3 Irish Paediatric diagnostic reference levels in nuclear medicine imaging.

Paediatric Reference Levels in Nuclear Medicine30 (Appendix V)
9.4 Irish CT Reference Levels\textsuperscript{31} (Appendix IX)

<table>
<thead>
<tr>
<th>Adult proposed DRLS from 2009 Irish CT Survey (MERU).</th>
<th>75th Percentile DLP from the survey (mGy.cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain</td>
<td>950</td>
</tr>
<tr>
<td>Cervical Spine</td>
<td>470</td>
</tr>
<tr>
<td>High Resolution Thorax</td>
<td>890</td>
</tr>
<tr>
<td>Thorax</td>
<td>460</td>
</tr>
<tr>
<td>Abdomen/Pelvis</td>
<td>640</td>
</tr>
<tr>
<td>Thorax/Abdomen/Pelvis</td>
<td>850</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Paediatric proposed DRLS from 2009 Irish CT Survey (MERU)</th>
<th>75th Percentile DLP from the survey (mGy.cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain Newborn</td>
<td>340</td>
</tr>
<tr>
<td>1-4 years</td>
<td>470</td>
</tr>
<tr>
<td>5-9 years</td>
<td>620</td>
</tr>
<tr>
<td>10-15 years</td>
<td>850</td>
</tr>
<tr>
<td>Adult</td>
<td>950</td>
</tr>
<tr>
<td>Abdomen/Pelvis Newborn</td>
<td>130</td>
</tr>
<tr>
<td>1-4 years</td>
<td>160</td>
</tr>
<tr>
<td>5-9 years</td>
<td>230</td>
</tr>
<tr>
<td>10-15 years</td>
<td>400</td>
</tr>
<tr>
<td>Adult</td>
<td>640</td>
</tr>
</tbody>
</table>

9.5 General X-Ray DRLs

UK DRLs and effective dose levels are available on the Health Protection Agency Website. Appendix V.\textsuperscript{32}

\url{http://www.hpa.org.uk/Topics/Radiation/UnderstandingRadiation/UnderstandingRadiationTopics/MedicalRadiation/DiagnosticRadiology/}

Band Classification of the typical doses of ionising radiation from common imaging procedures (refer). Appendix VI\textsuperscript{33}

Some published articles outlining typical patient doses in Ireland from common imaging procedures. Appendix VI(a)\textsuperscript{34}
References
The accuracy, quality and relevance of these works is not guaranteed or uniform and more recent information may have superseded these works. This list is not exhaustive. It does not include all the resources that may be relevant to service users. It is the responsibility of service users to identify the best available evidence relevant to their practice.

References

1. Recommendations of International Commission for Radiological Protections (ICRP)
7. www.hse.ie (guidance Documents)
   http://www.hse.ie/eng/about/Who/qualityandpatientsafety/medexp_radiatonunit/Legislation.html
9. HSE Holders guidance documents
10. HSE guidance documents on external and internal Clinical Audit
    (http://www.hse.ie/eng/about/Who/qualityandpatientsafety/medexp_radiatonunit/Clinical
    Audit Joint Document.pdf)
11. National diagnostic reference levels
    http://www.hse.ie/eng/about/Who/qualityandpatientsafety/medexp_radiatonunit/Publications_and_Annual_Report.html
15. www.ireferr.org.uk (referral criteria).
17. www.acr.org/Quality-Safety/Appropriateness-Criteria
    Culture of Patient Safety”
20. The European Commission Guidelines on Clinical Audit for Medical Radiological
    Practices, 2003 (RP159)
    Improvement, 2010 (IAEA).
    Improvement, 2007 (IAEA)
23. Quality Management Audits in Nuclear Medicine Practices, 2008 (IAEA)
25. Guidelines for the implementation of a National Quality Assurance Programme in
    Radiology- version 2

References
References

29. Administration of Radioactive Substances Advisory Committee (ARSAC) www.arsac.org.uk
30. Paediatric Diagnostic Reference Levels for commonly performed diagnostic procedures, British Journal Review – http://bjr.bjrjournals.org/cgi/reprint/81/971/918
31. Proposed CT Reference Levels from CT Survey 2012 (MERU) Irish CT survey.
33. Band classification of typical doses of ionising radiation from common imaging procedures (irefer) see Appendix VI
34. Some published articles outlining typical patient doses in Ireland from common imaging procedures Appendix VI(a)
35. Appendix I - Sample Template Report form of investigation and findings of patient radiation incident (MERU).
37. Appendix III – Template for recording patient radiation incidents annually.
38. Appendix IV- Pregnancy guidelines for staff
41. Appendix VI(A) List of published articles outlining typical patient doses in Ireland from common imaging procedures
42. Appendix VII – Obligations of RPII’s licences
44. Appendix IX- Local Diagnostic Reference Levels DRL’s – CT Exams
45. Appendix X-Criteria to be used to assign licence categories, RPII
46. Appendix XI –List of stakeholders consulted with on the Patient Radiation Protection Manual and members of the Medical Exposure Radiation Unit
47. Appendix XII- Glossary of definitions as defined in SI 478 (2002) and S1 303 (2007)

The Medical Council have adopted the following Policies and Documents;

- Fluoroscopic Devices - 03/09/2004.pdf
- Diagnostic Reference Levels - 03/12/2004.pdf
- Radiation Protection 99 - Guidance on medical exposures in medical and biomedical research.pdf
- Radiation Protection 100 - Guidance for protection of unborn children and infants irradiated due to parental medical exposures.pdf
Appendices
## Appendix I

### SAMPLE TEMPLATE FOR REPORT OF INVESTIGATION AND FINDINGS OF PATIENT RADIATION INCIDENT.

The use of this template is optional and it can be used as a reference guide for prompt questions or to modify local templates as required.

### Hospital: __________________ Reference: ________ MERU reference: ________

### 1. Incident

<table>
<thead>
<tr>
<th>Date of Incident:</th>
<th>Time of Incident:</th>
<th>Location of incident:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient age:</td>
<td>Patient sex:</td>
<td>M ☐ F ☐ Incident definition (see MERU guidance):</td>
</tr>
</tbody>
</table>

Incident description: (Accurately describe, in chronological order, the relevant details of what happened immediately before, during and after the incident and others involved):

How was the incident discovered, and by who?

### 2. Investigation

<table>
<thead>
<tr>
<th>Who led the investigation?</th>
<th>Who was on investigation team?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Was risk management involved in the investigation? ☐ Y ☐ N ☐
Was a formal system /root cause analysis conducted? ☐ Y ☐ N ☐

Briefly outline the methodology used by the investigation team:

Is there a written protocol on communication with the patient or open disclosure? ☐ Y ☐ N ☐
Was it decided to communicate with patient and/or carers? ☐ Y ☐ N ☐
If yes, what was the communication with the patient, including discussions and plans?

Was the communication with the patient consistent with the written protocol? ☐ Y ☐ N ☐
Who else was consulted and informed during investigation (including referrer and Radiologist in Charge, other relevant staff)?

Was incident reported to regulatory bodies and Insurers (e.g., RPII, HSA, IMB, CIS, Serious Incident Management Team for HSE), please state which:

Is the investigation complete? ☐ Y ☐ N ☐
If no, date for completion:

---

Appendices
### 3. Cause of Incident

From the findings of the investigation, what were the direct, indirect and root causes of the incident? (refer to system analysis techniques for cause descriptions)

Which was identified as the main cause?

### 4. Patient Radiation Dose

What was the Dose to the Patient in relation to that prescribed/not prescribed: (as a total figure (mSv/mGy) and as a percentage greater than intended):

What are the consequences/clinical impact to the patient as a result of the incident?

If ongoing medical surveillance for the patient is required, has a plan been implemented? [Y] [N] [N/A]

### 5. Recommendations and Actions

List any immediate action that was taken to minimise harm to patient or recurrence for others:

What are the findings of the report and recommendations to prevent a similar incident occurring in future, including follow up actions with patients, staff and others?

List actions already taken (including the date):

List additional actions that must be taken and the timeframe for completion.

Was this investigation discussed at the Radiation Safety Committee or tabled for next meeting? [Y] [N]

What date is set for review of actions?

Any other information relevant to this report, e.g., is there learning for other locations?

<table>
<thead>
<tr>
<th>Person responsible for implementation of actions:</th>
<th>Signed: Practitioner:</th>
<th>Relevant</th>
<th>Signed:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chair, Radiation Safety Committee:</td>
<td>Signed:</td>
<td>CEO/Hospital Manager:</td>
<td>Signed:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reported completed by:</th>
<th>Role:</th>
<th>Email:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signed:</td>
<td>Date:</td>
<td>Tel:</td>
</tr>
</tbody>
</table>

Please return signed copy to: Private and Confidential, Medical Exposure Radiation Unit, HSE, Mill Lane, Palmerstown, Dublin 2
Appendix II36

Root Cause Analysis Investigation. Fishbone Diagram – tool

Guide to system analysis can be found on the HSE website.

This diagram is copy right of the NHS
**Appendix III**

**Annual Template to record Patient Radiation Incidents**

Please provide total number of incidents/near misses (which includes incidents already reported to the Medical Exposure Radiation Unit) for the period ____________ (annually).

Hospital Name: _______________________________________
Reference Number: ________

<table>
<thead>
<tr>
<th>Sub Speciality(STARSweb code in brackets)*</th>
<th>Total Number of Patient Radiation Incidents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiology – General (9100)</td>
<td></td>
</tr>
<tr>
<td>CT(9300)</td>
<td></td>
</tr>
<tr>
<td>Nuclear Medicine/PET CT (9400)</td>
<td></td>
</tr>
<tr>
<td>Interventional Radiology/Fluoroscopy (9500)</td>
<td></td>
</tr>
<tr>
<td>External Beam (9200)</td>
<td></td>
</tr>
<tr>
<td>Brachytherapy (G100)</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
</tr>
</tbody>
</table>

How many of the total were near misses? [ ]

*Stars web code in brackets is relevant only to HSE public hospitals.

<table>
<thead>
<tr>
<th>Incident Type</th>
<th>Number of Patient Radiation Incidents per type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect patient (D001)</td>
<td></td>
</tr>
<tr>
<td>Incorrect procedure (D002)</td>
<td></td>
</tr>
<tr>
<td>Incorrect anatomy (D003)</td>
<td></td>
</tr>
<tr>
<td>Deterministic effects from interventional radiology (D004)</td>
<td></td>
</tr>
<tr>
<td>Equipment failure, accident, error or mishap causing patient exposure (D005)</td>
<td></td>
</tr>
<tr>
<td><strong>Multiple exposures greater than intended</strong> D006</td>
<td></td>
</tr>
<tr>
<td>Adult: &gt; twice Diagnostic overexposure &gt;10mSv or 20 times dose intended (D007)</td>
<td></td>
</tr>
<tr>
<td>Child: &gt; twice Diagnostic overexposure &gt; 3mSv or 15 times dose intended (D008)</td>
<td></td>
</tr>
<tr>
<td>Inadvertent dose to foetus &gt; 1mGy (D009)</td>
<td></td>
</tr>
<tr>
<td>Inadvertent radiopharmaceutical (D010)</td>
<td></td>
</tr>
<tr>
<td>Inadvertent dose to the breastfed child over 1mSv (D011)</td>
<td></td>
</tr>
<tr>
<td>Therapeutic N Med - Administered activity different by 20% of intended (D012)</td>
<td></td>
</tr>
<tr>
<td>Therapeutic N Med - Administered activity different by 10% to 20% of intended (D013)</td>
<td></td>
</tr>
<tr>
<td>Therapeutic dose given instead of diagnostic dose e.g. radiiodine (D014)</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy Dose variation from prescribed total dose of greater than 10% (D015)</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy Dose variation from prescribed dose of greater than 20% (D016)</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy – Variation in fractional dose from 10% up to 20% (D017)</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy – Variation in or prescribed dose from 5% up to 10% D018</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy - completely incorrect volume. (D019)</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy - setup variation that will/could impact on organs at risk (D020)</td>
<td></td>
</tr>
<tr>
<td>Inadvertent deterministic effects (D021)</td>
<td></td>
</tr>
<tr>
<td>Dose given to carers without consent greater than medical council guidelines (D022)</td>
<td></td>
</tr>
<tr>
<td>Any other radiation exposure incident to patient (D023)</td>
<td></td>
</tr>
</tbody>
</table>

Signed: ______________________, Chair, Radiation Safety Committee

Signed: ______________________, Risk Manager

Signed: ______________________, CEO/Hospital Manager
Appendix IV

INTRODUCTION

Under S.I. No. 478 (2002) medical exposures to be carried out on pregnant females shall be done in accordance with procedures approved by the Medical and Dental Councils. The Medical Council has approved the use of a minimally modified version of EC Radiation Protection 1002 as a guidance document when dealing with pregnant/possibly pregnant patients.

The aim of these Guidelines is to provide a concise summary of the actions to be taken when dealing with women of childbearing age in a format that is easily accessible to professionals working in the area. The guidelines are written in accordance with current legislation1,3 and RP100 as approved by the Medical Council. This requires that, for relevant examinations, the pregnancy status of female patients be established and certain processes followed thereafter.

Prepared in collaboration with:

- Medical Council of Ireland
- Faculty of Radiology, Royal College of Surgeons in Ireland
- Irish Institute of Radiography and Radiation Therapy
- Irish Nuclear Medicine Association
- Association of Physical Scientists in Medicine
SPECIFIC GUIDELINES

- These guidelines apply to women of childbearing age. An age range of 12 to 55 years is a useful practical guide but should be used with caution.

- The guidelines are recommended for any radiography, fluoroscopy or computed tomography examination involving irradiation between the diaphragm and symphysis pubis and for any radionuclide imaging examination.

- For those examinations listed above, the referring clinician must enquire about the pregnancy status of the patient.

- The referring clinician has a responsibility to ensure that the examination is justified and shall provide the practitioner with all relevant information as part of the examination request.

- For high dose examinations, involving greater than 10 mGy to the fetus, the 10 day rule should be applied. In practice this means that abdominal or pelvic CT and some barium studies should be scheduled in the first 10 days of their menstrual cycle. This timing refers to patients with a regular 28 day cycle and should be scaled according to cycle length. For further information on fetal doses, see Table 1.

- For urgent examinations that are justified irrespective of pregnancy status, a clinical waiver section within the request, should be completed by the referring clinician.

- When a female patient of reproductive capacity presents for any of the relevant examinations above, the following process should be applied:
  - The patient should be explicitly asked by the radiologist, the radiographer or the medical specialist (if relevant), whether she is or might be pregnant and her answer should be recorded in writing. The record should be kept according to local protocol. The date of the first day of the last menstrual period (LMP) of the patient should be recorded. This can be useful when retrospective analysis of uterine exposure is required.

  A brief but simple explanation should follow, such as: "I have to ask because radiation in pregnancy may increase the risk of childhood cancer above the natural baseline level" (see Table 1 for the risk levels or refer patient to physicist if patient requires more information).

  - The examination may proceed if the patient states that she is not pregnant.

  - When a patient answers that she:
    - is pregnant, or
    - might be pregnant or
    - cannot exclude the possibility of pregnancy and the menstrual period is overdue
    the referring clinician should be asked to review the justification for the examination, bearing in mind the possible presence of a fetus.
When there is definite pregnancy, or potential for an unknown pregnancy, the review of justification should consider the following:

- Is there a suitable alternate approach to imaging using non-ionising radiation, e.g. ultrasound or magnetic resonance?

- Is the examination critical to immediate and essential patient management, or could management proceed if the examination is deferred until pregnancy can be completed or definitely excluded?

- Is the likely foetal radiation dose and risk of the examination greater than the benefit of the examination and/or greater than the risk incurred by not doing the examination? Examples of doses accrued from specific examinations are given in Table 1.

- The use of contraception does not rule out pregnancy. Whilst contraceptive use mitigates against the likelihood of pregnancy, the efficacy of the method used is a matter for professional judgment and where there is doubt, these guidelines should be followed.

- Pregnancy tests should not replace proper inquiry. Whilst positive pregnancy tests are useful in directing further justification, negative pregnancy tests undertaken before the period is due should be treated with caution. In particular, a negative urinary pregnancy test, taken at the point of care, should be confirmed with a more sensitive laboratory based test with the required sensitivity in those women where the possibility of pregnancy cannot be ruled out.

- When an examination is justified during pregnancy or when pregnancy cannot be ruled out, all accepted methods of optimising the examination and reducing the dose delivered should be applied.

**ADDITIONAL GUIDANCE**

- Where there is uncertainty about the dose delivered to the uterus as a result of local procedures, equipment or techniques, the advice of the Radiation Protection Adviser (RPA) should be sought.

- A clearly displayed multi-lingual notice briefly explaining the importance of declaring a pregnancy before an X-ray examination is recommended.

- The difficulties associated with requests to X-ray anaesthetised patients should be addressed by a local policy where pregnancy status is established prior to anaesthesia.

- For non-English speaking patients, the hospital interpretation services should be used.

- The difficulties associated with questioning minors about their pregnancy status should be addressed by a local protocol that takes account of associated legal issues.

- Additional information on risk estimates can be found in reference 4.
REFERENCES


2. European Commission, Radiation Protection 100, Guidance for unborn children and infants irradiated due to parental medical exposures 1998, as amended under licence by the Medical Council.


4. Health Protection Agency, Protection of Pregnant Patients during Diagnostic Medical Exposures to Ionising Radiation, Advice from the Health Protection Agency, the Royal College of Radiologists and the College of Radiographers, Documents of the Health Protection Agency, RCE-9, March 2009.


11. Contact Us

Radiological Protection Institute of Ireland
2 Clonskeagh Square
3 Dublin 14 Ireland
Tel: 01 2697766
Fax: 01 2697437
Website: www.rpii.ie

Radiological Protection Institute of Ireland
An Instituted Eireannach urn Chosaint Raideolafoch
**Appendix V**

**Patient Dose Information**

Typical effective doses, equivalent periods of natural background radiation and lifetime fatal cancer risks from diagnostic medical exposures

<table>
<thead>
<tr>
<th>Diagnostic procedure</th>
<th>Typical effective doses (mSv)</th>
<th>Equivalent period of natural background radiation</th>
<th>Lifetime additional risk of fatal cancer per examination</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>X-ray examinations:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Limbs and joints (except hip)</td>
<td>&lt; 0.01</td>
<td>&lt; 1.5 days</td>
<td>1 in a few million</td>
</tr>
<tr>
<td>Teeth (single bitewing)</td>
<td>&lt; 0.01</td>
<td>&lt; 1.5 days</td>
<td>1 in a few million</td>
</tr>
<tr>
<td>Teeth (panoramic)</td>
<td>0.01</td>
<td>1.5 days</td>
<td>1 in 2 million</td>
</tr>
<tr>
<td>Chest (single PA film)</td>
<td>0.02</td>
<td>3 days</td>
<td>1 in a million</td>
</tr>
<tr>
<td>Skull</td>
<td>0.07</td>
<td>11 days</td>
<td>1 in 300,000</td>
</tr>
<tr>
<td>Cervical spine (neck)</td>
<td>0.08</td>
<td>2 weeks</td>
<td>1 in 200,000</td>
</tr>
<tr>
<td>Hip</td>
<td>0.3</td>
<td>7 weeks</td>
<td>1 in 67,000</td>
</tr>
<tr>
<td>Thoracic spine</td>
<td>0.7</td>
<td>4 months</td>
<td>1 in 30,000</td>
</tr>
<tr>
<td>Pelvis</td>
<td>0.7</td>
<td>4 months</td>
<td>1 in 30,000</td>
</tr>
<tr>
<td>Abdomen</td>
<td>0.7</td>
<td>4 months</td>
<td>1 in 30,000</td>
</tr>
<tr>
<td>Lumbar spine</td>
<td>1.3</td>
<td>7 months</td>
<td>1 in 15,000</td>
</tr>
<tr>
<td>Barium swallow</td>
<td>1.5</td>
<td>8 months</td>
<td>1 in 13,000</td>
</tr>
<tr>
<td>IVU (kidneys and bladder)</td>
<td>2.5</td>
<td>14 months</td>
<td>1 in 8000</td>
</tr>
<tr>
<td>Barium meal</td>
<td>3</td>
<td>16 months</td>
<td>1 in 6700</td>
</tr>
<tr>
<td>Barium follow</td>
<td>3</td>
<td>16 months</td>
<td>1 in 6700</td>
</tr>
<tr>
<td>Barium enema</td>
<td>7</td>
<td>3.2 years</td>
<td>1 in 3000</td>
</tr>
<tr>
<td>CT head</td>
<td>2</td>
<td>1 year</td>
<td>1 in 10,000</td>
</tr>
<tr>
<td>CT chest</td>
<td>8</td>
<td>3.6 years</td>
<td>1 in 2500</td>
</tr>
<tr>
<td>CT abdomen/pelvis</td>
<td>10</td>
<td>4.5 years</td>
<td>1 in 2000</td>
</tr>
<tr>
<td><strong>Nuclear medicine studies:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lung ventilation (Kr-81m)</td>
<td>0.1</td>
<td>2.4 weeks</td>
<td>1 in 200,000</td>
</tr>
<tr>
<td>Lung perfusion (Tc-99m)</td>
<td>1</td>
<td>6 months</td>
<td>1 in 20,000</td>
</tr>
<tr>
<td>Kidney scan (Tc-99m)</td>
<td>1</td>
<td>6 months</td>
<td>1 in 20,000</td>
</tr>
<tr>
<td>Thyroid scan (Tc-99m)</td>
<td>1</td>
<td>6 months</td>
<td>1 in 20,000</td>
</tr>
<tr>
<td>Bone scan (Tc-99m)</td>
<td>4</td>
<td>2 years</td>
<td>1 in 5000</td>
</tr>
<tr>
<td>Dynamic cardiac (Tc-99m)</td>
<td>6</td>
<td>2.7 years</td>
<td>1 in 3300</td>
</tr>
<tr>
<td>Myocardial perfusion (Tl-201)</td>
<td>18</td>
<td>8 years</td>
<td>1 in 1100</td>
</tr>
</tbody>
</table>

1. UK average = 2.2mSv per year; regional averages range from 1.5 - 7.5 mSv per year

2. Approximate lifetime risk for patients 16 - 69 years old: for paediatric patients multiply risks by about 2 for geriatric patients divide risks by about 5

Last reviewed: 4 September 2008

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Table 3. Band classification of the typical doses of ionising radiation from common imaging procedures

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Typical effective dose (mSv)</th>
<th>Examples</th>
<th>Lifetime additional risk of fatal cancer/exam</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>0</td>
<td>US: MRI</td>
<td>0</td>
</tr>
<tr>
<td>☢️</td>
<td>&lt;1</td>
<td>CXR; XR limb, pelvis, lumbar spine; mammography</td>
<td>&lt;1:20,000</td>
</tr>
<tr>
<td>☢️☢️</td>
<td>1-5</td>
<td>IVU; NM (eg, bone); CT head and neck</td>
<td>1:20,000 – 1:4,000</td>
</tr>
<tr>
<td>☢️☢️☢️</td>
<td>5.1-10</td>
<td>CT chest or abdomen; NM (eg, cardiac)</td>
<td>1:4,000 – 1:2,000</td>
</tr>
<tr>
<td>☢️☢️☢️☢️</td>
<td>&gt;10</td>
<td>Extensive CT studies, some NM studies (eg, some PET-CT)</td>
<td>&gt;1:2,000</td>
</tr>
</tbody>
</table>

The average annual background dose in most parts of Europe falls within the 1-5mSv range (☢️). Cancer risks from radiation vary considerable with age and sex, with higher risks from radiation vary considerably with age and sex, with higher risks in infants and females. Cancer risk indicated in this table is averaged for adults. This should be taken in the context of the considerably higher 1 in 3 average lifetime risk for cancer and must be balanced against the benefit of the investigation.

[Key: US=ultrasound; MRI=magnetic resonance imaging; CXR=chest X-ray; XR=X-ray; IVU=intravenous urography; NM=nuclear medicine; CT=computed tomography; PET-CT=positron emission tomography co-registered with CT.]

Typical effective doses from radiological examinations and associated risks are based on data supplied by Steve Ebdon-Jackson, Head, Medical Exposure Department, Health Protection Agency.
Appendix VI(a)

Some published articles outlining typical patient doses in Ireland from common imaging procedures


Appendix VII

Obligations of RPII’s Licensees.

Accessed 19 January 2012,
http://www.rpii.ie/Licensing/Licensing-%E2%80%93-what-you-need-to-know.aspx

It is a condition of licensing that you

- Keep records of all radioactive materials and irradiating apparatus
- Inform the RPII of any change in the inventory of licensed items
- Keep records of dose monitoring, disposals, incidents, faults, and other relevant information involving the licensed items
- Ensure that any proposed changes to licensed facilities (e.g. new X-ray equipment, relocation of materials or equipment) are approved by the Radiation Protection Adviser (RPA) or Radiation Protection Officer (RPO)
- Develop and maintain a Radiation Safety Manual/Radiation Safety Procedures. The document shall be updated at least once during the licence period. For more information on drafting these documents see Guide for the Compilation of a Radiation Safety Manual
- Notify the local Fire Officer of the location and nature of all radioactive materials
- Inform the RPII of the loss or theft of any licensed items, or of any incident or accident involving a licensed item
- Carry out an assessment of the potential radiation hazards prior to acquiring a licensable item
- Display a copy of the licence in a public place
- Ensure proper labelling of all radioactive materials and irradiating apparatus
- Make sure that all licensed items are subject to routine maintenance in accordance with the manufacturers’ instructions, and undergoes appropriate quality assurance testing, as recommended by the RPA/RPO
- Display a sign warning female patients to declare their known or suspected pregnancy (in the case of medical and dental practitioners)
- Obtain authorisation from the RPII prior to the disposal of any licensed item
- Ensure that, when licensed equipment or material is sold, the purchaser is aware of their obligation to acquire a licence from the RPII
- Ensure that, when X-ray equipment is disposed of, it is rendered incapable of producing ionising radiation
- Have an agreement in place with the supplier of any sealed radioactive sources to take back the source when no longer of use.
- This list is not exhaustive. Specific categories of licences are governed by additional legal obligations. Further information can be obtained by contacting the RPII’s Regulatory Services Division.
Appendix VIII

Guidance Notes For the compilation of radiation safety procedures/local rules
Radiological Protection Institute of Ireland July 2007

Introduction
The conditions attached to licenses issued by the RPII in respect of any activity involving ionising radiation require the licensee to draft, approve and maintain a Radiation Safety Manual (in those cases where only small sources of radiation are involved the manual is more often referred to as ‘Radiation Safety Procedures’ since the content can be contained in a few pages only). The Manual/Procedures should be approved by the licensee's Managing Director (or equivalent) usually after receiving ‘no objections’ from the Regulatory Service of the Radiological Protection Institute of Ireland. A typical layout and content of the Manual is given below.

• Section 1
  Technical description of licensed items covering particulars, as appropriate, such as x-ray machine/isotope type; half life; radiation source holder type; serial number; activity; makers name; ISO 2919 classification.

• Section 2
  Normal Operating Procedures

• Section 3
  Emergency Operating Procedures (Contingency Plans) such as in case of fire, explosion, spill or loss; (including methods of contacting responsible personnel outside working hours)

• Section 4
  Details of planned maintenance such as routine radiation surveys; wipe testing; performance testing; routine surveillance when equipment is not in use.

• Section 5
  Radiological safety procedure such as dosimetry; designation of controlled and supervised areas; radiation labels and notices; testing and calibration of monitoring equipment.

• Section 6
  Administration, such as name of Radiological Protection Officer and Deputy; terms of reference; reporting lines and working relations with other members of staff and management; list of qualified operators; list of Category A and B workers.

• Section 7
  Records. Description of method keeping records which are required by licence or Radiation Safety Manual.

• Section 8
  Transport. How to package and transport the licensed items in order to comply with condition of licence.
Appendix IX

Local Diagnostic Reference Levels (DRLs), CT exams

Location: ______________________________________

Location Diagnostic Reference Levels have been reviewed and compared to reference standards. I recommend their adoption for this location for the year ____.

<table>
<thead>
<tr>
<th>All CT Procedures</th>
<th>75th Percentile DLP from Irish CT Dose Survey (2010)(mGy.cm)/Medical Council DRL */International studies DRL</th>
<th>Location DRL DLP (mGy.cm)</th>
<th>Where local DRL is higher than national or reference DRL, give justification:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain</td>
<td>950</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cervical Spine</td>
<td>470</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hi Res Thorax</td>
<td>890</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thorax</td>
<td>460</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdomen/ Pelvis</td>
<td>640</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thorax/Abdomen/ Pelvis</td>
<td>850</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Notes for completion:

* The Medical Exposure Radiation Unit recommends the use of Irish CT Dose Survey DRLs where available and Medical Council DRLs for other studies where available. International studies can be referenced for the remainder of exams. State origin of international DRL.
• Complete this table and list all CT procedures conducted at location.
• Justify all variances to the reference DRL, in particular where local DRLs are higher.

Recommended by: (print name), ________________________ Practitioner in Charge

Signed: _____________________________

Approved by: (print name), ________________________ Chief Executive Officer

Signed: _____________________________

Date: _____________________________

Notify: Radiation Safety Committee, all relevant staff

File: Local Rules / Radiation Protection File

Review: Annually or when there is a significant change to protocol
## APPENDIX X^45

**CRITERIA TO BE USED TO ASSIGN LICENCE CATEGORIES, RPII**

### BAND - Medical

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Level 1 (HL1)</td>
<td>Licensee with only one simple (general, mobile, chest, mammography etc) X-ray unit. Non-simple X-ray units would include CT, interventional, fluoroscopy etc – these would be covered in HL2.</td>
</tr>
<tr>
<td>Hospital Level 1 – Bone Densitometer</td>
<td>Licences who use DXA units only</td>
</tr>
<tr>
<td>Hospital Level 2 (HL2)</td>
<td>Licensee with either one non simple X-ray units (CT, fluoroscopy) or multiple X-ray units (e.g. multi room hospital, clinic etc).</td>
</tr>
<tr>
<td>Hospital Level 2 – Mobile Lithotripsy/Cardiac Cathorisation</td>
<td>Licensees who use fluoroscopic X-ray units (i.e. not an X-ray unit that would qualify as a HL1) in different hospitals for the purpose of lithotripsy or cardiac catheterisation e.g. Focus Medical, Cardinal Healthcare</td>
</tr>
<tr>
<td>Hospital Level 3 (HL3)</td>
<td>Licensee who uses unsealed radioactive sources for in-vitro application only. These licensees may also have diagnostic X-ray units</td>
</tr>
<tr>
<td>Hospital Level 3 – Transportation</td>
<td>A HL3 hospital who is additionally licensed for the transport of radioactive sources</td>
</tr>
<tr>
<td>Hospital Level 4 (HL4)</td>
<td>Licensee who uses unsealed radioactive sources for in-vivo applications i.e. the hospital has a nuclear medicine department. These licensees will generally also have diagnostic X-ray units.</td>
</tr>
<tr>
<td>Hospital Level 4 Transportation</td>
<td>A HL4 hospital who is additionally licensed for the transport of radioactive sources</td>
</tr>
<tr>
<td>Hospital Level 5 (HL5)</td>
<td>Licensee who uses radiotherapy equipment e.g. linear accelerator, Co-60, brachytherapy etc. These licensees may also have diagnostic and nuclear medicine facilities.</td>
</tr>
<tr>
<td>Hospital Level 5 – Transportation</td>
<td>A HL5 hospital who is licensed for the transport of radioactive sources</td>
</tr>
<tr>
<td>Chiropractor</td>
<td>Licensee uses one or more X-ray units for diagnostic procedures</td>
</tr>
<tr>
<td>Cyclotron Radiopharmaceutical Production</td>
<td>Licensee uses a cyclotron for the manufacture of radiopharmaceuticals.</td>
</tr>
<tr>
<td>Irradiating Blood Products</td>
<td>Licensee uses one or more sealed sources for the irradiation of blood products</td>
</tr>
</tbody>
</table>
### BAND - Dental

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental Level 1</td>
<td>Dentists in private practice (no limit on number of X-ray units)</td>
</tr>
<tr>
<td>Dental Level 2</td>
<td>Government Departments (Defence and Justice)</td>
</tr>
<tr>
<td>Dental Level 2– Dublin Dental Hospital</td>
<td>Third level teaching hospital</td>
</tr>
<tr>
<td>Dental Level 3</td>
<td>HSE Dental Clinics.</td>
</tr>
</tbody>
</table>
List of stakeholders consulted with on the Patient Radiation Protection Manual and members of the Medical Exposure Radiation Unit

Stakeholders:

<table>
<thead>
<tr>
<th>Name</th>
<th>Position/Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Adrian Brady</td>
<td>Dean, Faculty of Radiologists/Prof of Radiology NUI Galway, Member of NACMET and NIMIS.</td>
</tr>
<tr>
<td>Mr Shane Foley</td>
<td>President, Irish Institute of Radiography and Radiation Therapy</td>
</tr>
<tr>
<td>Mr Fintan Bradley</td>
<td>Irish Association of Physicists in Medicine Limited (IAPM)</td>
</tr>
<tr>
<td>Dr Tracey Cooper</td>
<td>Health Information Quality Authority (HIQA)</td>
</tr>
<tr>
<td>Mr Derek Greene</td>
<td>Radiation Safety Advisory Group, Voluntary Hospitals Risk Management Forum</td>
</tr>
<tr>
<td>Dr. Tom Ryan</td>
<td>Regulatory Director, Radiological Protection Institute of Ireland (RPII)</td>
</tr>
<tr>
<td>Ms Caroline Spillane</td>
<td>CEO, Medical Council</td>
</tr>
<tr>
<td>Mr David O’Flynn</td>
<td>Chief Officer and Registrar, Dental Council</td>
</tr>
<tr>
<td>Mr Fintan Hourihan</td>
<td>CEO, Irish Dental Association</td>
</tr>
<tr>
<td>Ms Edwina Dunne</td>
<td>Head of Health Care Audit, Quality Safety and Risk, HSE</td>
</tr>
<tr>
<td>Mr Michael Shannon</td>
<td>Area Director, Dublin Mid-Leinster, Nursing and Midwifery Planning and Development, HSE</td>
</tr>
<tr>
<td>Dr. Niall Sheehy</td>
<td>Clinical Lead, National Radiology Programme, HSE</td>
</tr>
<tr>
<td>Dr. Patricia Cunningham</td>
<td>Chair, Radiation Protection Committee, Faculty of Radiologists</td>
</tr>
<tr>
<td>Mr John Keegan</td>
<td>Department of Health</td>
</tr>
<tr>
<td>Ms Juliet Kelly</td>
<td>Network Lead Radiation Therapy, National Cancer Control Programme, HSE</td>
</tr>
<tr>
<td>Dr Ronan McDermott</td>
<td>Chairman, Irish Nuclear Medicine Association</td>
</tr>
<tr>
<td>Ms Ann Dolan</td>
<td>Radiography Services Managers Group</td>
</tr>
<tr>
<td>Ms Ciara Norton</td>
<td>Manager</td>
</tr>
<tr>
<td>Ms Rachel Brennan</td>
<td>Administrator</td>
</tr>
<tr>
<td>Ms Bernadette Moran</td>
<td>Radiographic Advisor</td>
</tr>
<tr>
<td>Ms Mandy Lewis</td>
<td>Medical Physics Advisor</td>
</tr>
<tr>
<td>Dr Andrew Bolas</td>
<td>Dental Advisor</td>
</tr>
<tr>
<td>Dr Neil O’Donovan</td>
<td>Radiologist Advisor</td>
</tr>
</tbody>
</table>
APPENDIX XII

Glossary of definitions as defined in SI 478 (2002) and S1 303 (2007)

- "Clinical audit" means a systematic examination or review of medical radiological procedures which seeks to improve the quality and the outcome of patient care through structured review whereby radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices where indicated and the application of new standards if necessary.

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

- "Competent authority" means the Minister for Health and Children.

- "Diagnostic reference levels" means dose levels in medical radio diagnostic practices or, in the case of radio-pharmaceuticals, levels of administered activity for typical examination for groups of standard-sized patients or standard phantoms for broadly defined types of equipment. These levels are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied."

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

- "Exposure" means the process of being exposed to ionising radiation.

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

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

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

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

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

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

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

"Practical Aspects" means the physical conduct of a medical exposure and any supporting aspects including handling and use of radiological equipment, and the assessment of technical and physical parameters including radiation doses, calibration and maintenance of equipment, preparation and administration of radio-pharmaceuticals and the development of films.

"Practitioner" means:

➢ a person whose name is entered on the register established under Section 26 of the Medical Practitioners Act, 1978 and who meets such other requirements as may be specified by the Medical Council from time to time to allow them to take responsibility for an individual medical exposure; or
➢ a person whose name is entered on the register established under Section 26 of the Dentists Act, 1985 and who meets such other requirements as may be specified by the Dental Council from time to time to allow them to take responsibility for an individual medical exposure; or
➢ a person whose name is entered on such other register or registers as the Minister may, from time to time, establish in relation to persons who are entitled to take clinical responsibility for an individual medical exposure and who meets such other requirements as the Minister may prescribe.

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

"Prescriber/referrer" means a person whose name is entered on the register established under Section 26 of the Medical Practitioners Act, 1978; or (b) a person whose name is entered on the register established under Section 26 of the Dentists Act, 1985; or (c) a person whose name is entered on such other register or registers as the Minister may, from time to time, establish in relation to persons who are entitled to refer individuals for medical exposure to a practitioner and who meets such other requirements as the Minister may prescribe from time to time; or
a person whose name is entered on the register of nurses as maintained by An Bord Altranais established by the Nurses Act 1985 and who meets the standards and requirements set down by An Bord Altranais from time to time to allow them to refer individuals for medical exposures 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 and comply with agreed standards.

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

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

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

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

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