TEMPLATE FOR DEVELOPING A

Patient Radiation Protection Manual

For facilities using medical ionising radiation

(FIRST EDITION August 2013)

Medical Exposure Radiation Unit
## Document Control

### Revision History

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I List of stakeholders consulted with on the Patient Radiation Protection Manual and members of the Medical Exposure Radiation Unit
II Glossary of definitions as defined in SI 478 (2002) and SI 303 (2007)
Purpose, Background and Scope of Radiation Protection Manual

Purpose of Radiation Protection Manual Template

The purpose of this Manual template is to support the practical application of the safe and optimal use of medical ionising radiation for patients.

The manual is designed to be a working document which locations will add to and adapt to their own needs.

By adapting this manual, the service provider has an assurance that they have arrangements in place to inform the continuous improvement of the safety of the service.

The benefit of the manual is:

- To keep locations informed of their responsibilities under the relevant regulatory requirements to protect patients and the roles and responsibilities of all personnel involved in delivering ionising radiation to patients.
- To support locations in protecting patients by providing guidance and sample templates on specific topics and areas of responsibility that contribute to patient safety.
- To provide a central repository for all material and information relevant to patient radiation that national and local updates can be added to.
- To provide evidence that the location is complying with regulatory requirements, with national healthcare standards, accreditation and quality systems and future licensing requirements.
- To aid training and education of personnel involved in the use of ionising radiation

Background

The National Radiation Safety Committee (NRSC) is tasked with providing expert advice to the CEO, HSE on the medical use of ionising radiation. The NRSC recommended in 2010 that all Holders keep a Radiation Protection Manual on site.

The manual was developed using an evidence-based approach where possible and was produced by the Medical Exposure Radiation Unit (MERU). The manual has been piloted in a number of locations and broad consultation has taken place. 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.
Scope of 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 in keeping with the scope of their practice.

How to Adapt this Manual at Location

The manual is designed to be a working document which locations will add to and personalise to their own needs.

The Practitioner in Charge is responsible for ensuring that 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 that this person is a member of the Radiation Safety Committee.

The person assigned should ensure that the manual is personalised and adapted to suit local practices and protocols. In looking for documentation to complete the manual it is likely that some gaps will be identified and some work required to complete a local policy or protocol. A quality improvement plan which identifies gaps, what actions will be taken and by who and when should be completed as part of the process. Where possible, the Medical Exposure Radiation Unit has included national guidance and some templates to assist in this process. As additional guidelines are developed, these will be issued to locations.

The location manual and the Quality Improvement Plan (QIP) should then be approved and adopted by the Practitioner in Charge and the Radiation Safety Committee. Progress reports from the QIP should be given at each meeting and the manual reviewed annually.

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 under each section of this manual of all documents relating to Radiation Protection. This list should be made available with consideration given to online access for relevant personnel.

National Standards for Safer Better Healthcare

The manual is designed to incorporate the objectives of the National Standards for Safer Better Healthcare (HIQA 2012). Completing and maintaining this manual can be used as examples of good practice to meet a number of national standards.
Key Performance Indicators (KPIs)

Key Performance Indicators are listed within every section of this manual. Performance indicators are measurable indicators that demonstrate progress towards a specific target. They enable decision makers to assess progress towards the achievement of an outcome, objective or goal within an agreed timeframe.

The KPIs are listed as a support to locations to enable them to show progress in improving patient radiation protection. They may be used as a basis for inspection, audit or hospital licensing in the future. The MERU has established the initial KPIs listed throughout this document. These will be reviewed on a regular basis and improved over time. Locations are also invited to include their own KPIs.

Feedback

The development of this manual is an iterative process and will be constantly reviewed and improved based on the experience of its application at locations. All feedback is welcome and should be directed to rachel.brennan1@hse.ie.

Disclaimer

This document is intended to act as a guideline to the legislation and national standards. It should be read in conjunction with the regulations referred to throughout the document and other regulations and documents outlining responsibilities associated with the use of 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.

Every effort has been made to ensure the accuracy of web addresses; however, web addresses may change over time.
Legislative Framework for Radiation Protection

- **International Commission for Radiological Protection (ICRP)**
- **European Atomic Energy Community Treaty (EURATOM)**
- **Workers and General Public**
- **Patients**
- **Medical Exposure Directive 97/43/EURATOM**
- **Basic Safety Standard**
  - BSS 96/26/EURATOM
- **Transposed into Irish Legislation**
  - **Dept of Health / HSE**
  - **Radiological Protection Institute of Ireland (RPII)**
    - SI 125 (2000)
    - SI 875 (2005) (HASS)
  - **Protection of Workers and the Public**
  - **Protection of the Patient**
  - **Patient Radiation Protection Manual**

Radiation Protection Legislation Structure
Introduction

Legislation for the Protection of Individuals Receiving Medical Exposures (Patients) in Ireland

The system of Radiation Protection used throughout Ireland and the European Union is based on the recommendations of the International Commission for Radiological Protection (ICRP)\(^2\). This system is embodied in various European directives most notably the Basic Safety Standards (BSS)\(^3\), 96/29/EURATOM and the Medical Exposure Directive (MED), 97/43/EURATOM\(^4\). The BSS was transposed into Irish legislation by Statutory Instrument (SI) 125 (2000)\(^5\) (workers and the public). The Medical Exposures Directive 97/43 EURATOM (MED) was transposed into Irish law by Statutory Instruments 478 (2002)\(^6\), 303 (2007)\(^7\) and 459 (2010)\(^8\).

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 guidelines with respect to radiation protection of patients as appropriate. The role of the Medical Exposure Radiation Unit, HSE is to regulate patient radiation protection practices in radiological facilities, both private and public, and receive 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 (MERU):

The MERU is tasked with;

- Conducting/overseeing clinical audit in facilities using medical ionising radiation.
- Managing the mandatory incident reporting system.
- Developing and providing guidance and direction to Holders, Practitioners, other staff and statutory bodies on relevant matters as guided by the National Radiation Safety Committee.
- Ensuring quality assurance programmes are in place.
- Maintaining a register of installations.
- Supporting and managing the work of the National Radiation Safety Committee and its subcommittees.
Statutory Role of the National Radiation Safety Committee:

The role of the Statutory National Radiation Safety Committee is to

- Provide advice to the CEO of the HSE and the Minister for 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.
- Advise on guidance and direction to Holders, Practitioners, other staff and Statutory Bodies on relevant matters.

Legislation Relating to Radiation Protection

Legislation:

1. 1991 Radiological Protection Act (1991)\(^9\).
5. 2002 Radiological Protection (Amendment) Act, (No. 3 of 2002)\(^11\).
Publications Relating to Patient Radiation Protection

A number of key documents and reports have been published to assist with the interpretation and implementation of the requirements of the legislation. Some of these documents are listed below. This is not an exhaustive list and other documents related to radiation protection may be referenced in other parts of the manual.

HSE:

1. 2010 Guidance on Responsibilities in European Communities (Medical Ionising Radiation Protection) Regulations (Statutory Instrument (SI) 478 of 2002), as amended by the European Communities (Medical Ionising Radiation Protection) (Amendment) Regulations (SI 303 of 2007). (Section 1 of this manual)\(^{14}\).
3. 2008 Formal Baseline Clinical Audit of Current Practice in Medical Ionising Radiation Protection, Reports 1 – Diagnostic Radiology and Nuclear Medicine and 2 – Radiotherapy\(^ {15}\).
4. 2010 Guidelines for reporting patient safety incidents from medical ionising radiation\(^ {16}\) (Section 3 of this manual).
5. 2011 Population Dose from CT Scanning\(^ {17}\).
6. 2012 Population Dose from Dental Radiography\(^ {18}\).
7. 2013 Population Dose from General X-ray and Nuclear Medicine\(^ {19}\).
8. 2011 Requirements for Clinical Audit in Medical Radiological Practices (Diagnostic Radiology, Radiotherapy and Nuclear Medicine), (Section 6 of this manual)\(^ {20}\).
9. 2011 The Use of Lead Aprons in Dental Radiology - Joint position statement by the RPII and HSE\(^ {21}\).

Others

1. 2010 Guidelines on the protection of the unborn child during diagnostic medical exposures (RPII) (section 5)\(^ {22}\).
2. 2012 iRefer guidelines – making the best use of radiology (RCR UK) (Section 6)\(^ {23}\).
3. 2013 Dose Data Med II\(^ {24}\).
4. 2008 Radiation Doses Received by the Irish Population (RPII)\(^ {25}\).
5. 2009 Code of Practice on the Design of Diagnostic Medical Facilities where Ionising Radiation is used (RPII)\(^ {26}\).
6. 2009 Guidelines for reporting incidents to the RPII\(^ {27}\).
7. 2008 Requirements and Standards for Nurse education programmes with authority to prescribe ionising radiation (x-ray), An Bord Altranais\(^ {28}\).
8. 2009 A Guiding Framework for the implementation of nurse prescribing of medical ionising radiation (x-ray) in Ireland\(^ {29}\).
Legislation for the 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 those practices involving ionising radiation that impact on public and workers’ safety.


National Arrangements for Workers and the General Public Regulation

The Radiological Protection Institute of Ireland (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.

Irish Framework for Complying with Regulations - Local Procedures and Documentation Required

Licence

All users of sources of ionising radiation are required to hold a valid licence, issued by the RPII. The licensee is responsible for ensuring that a good radiation protection philosophy exists in regard to the licensed practices, and that all licence requirements are met. The section on licensing in this chapter 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 list at end of this chapter. 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.
Radiation Safety Procedures (also referred to as “Local Rules”) / Radiation Safety Manual

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. Guidance notes produced by the RPII (below) outline 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.

The 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”. The RPII guidance indicates where this approach is advocated.

Radiation Safety Committee

Local Radiation Safety Committees are required to be in place in most locations. 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.

The remit of the Local Radiation Safety Committee covers both RPII requirements and Patient Radiation protection requirements.
Licensing – what you need to know


Every business or organisation which is involved – or may become involved - in storing, using, transporting, or disposing of radioactive materials, irradiation apparatus or other sources of ionising radiation, must apply to the RPII for a licence.

- Types of licence
- New applicants
- Obligations of licensees
- Renewing your licence
- Inspections
- Enforcement
- Approved Dosimetry Services

Types of licence

There are various categories of licence including

- Industrial Radiography
- Industrial Users
- Hospitals/Medical
- Government Departments & State Agencies
- Distributors
- Third Level Colleges
- Veterinary Surgeons
- Dental Surgeons.

The duration of these licences varies depending on the licensed activities.

New applicants

- Before you acquire radioactive materials or irradiating apparatus, you need a licence from the RPII
- A licence is a legal requirement under Statutory Instrument 125 (2000)
- If you acquire a source of ionising radiation without a licence you could be prosecuted
- As a licensee you must appoint an approved Radiation Protection Adviser (RPA) to advise your practice on all aspects of radiation protection.

Obligations of licensees

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
• 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
• 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 Service.

Renewing your licence
• You must apply to renew your licence at least 30 days before its expiry date
• When renewing your licence, you must ensure that all details are correct.

Inspections
The RPII routinely carries out inspections to ensure that licensees are in compliance with safety procedures and licensing conditions. Its inspection activities are accredited by the Irish National Accreditation Board to ISO 17020.
Inspections are divided into two parts
1. Administrative details – this will include a review of all documentation relating to the licence, personal dosimetry, disposals, acquisitions, quality assurance testing, training, servicing etc.
2. Audit of Equipment/Facilities – this will include a visual examination of the licensed items and protective equipment; and an assessment of the radiation protection shielding, storage arrangements etc. The inspector may also make measurements as appropriate.

In addition to routine inspections, the RPII may carry out inspections where:
• A complaint has been made against a licensee
• A radiation incident has been reported
• There is reasonable suspicion that a source of ionising radiation is being held or used without a licence
• There are concerns over documentation submitted to support a licensing application or amendment.
Enforcement
The RPII has a number of options for dealing with failure to comply with the regulations and licensing conditions. They include:

- **Direction**: ordering persons to vacate buildings, premises and land and to refrain from performing any acts which could escalate the danger
- **Licence suspension or withdrawal**
- **Prosecution**.

The chosen option decided upon will depend upon the seriousness of the breach of the regulations or licensing conditions.

Approved Dosimetry Services
From 2013 dosimetry services operating in Ireland must be approved by the RPII in accordance with S.I. 125 of 2000 as amended by S.I. 152 of 2012. The new approval mechanism is intended to provide confidence that dosimetry services operating in Ireland are technically competent and provide an appropriate service.

Details on the dosimetry services that have been approved by the RPII to operate in Ireland are given in:

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.
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.
## CRITERIA TO BE USED TO ASSIGN LICENCE CATEGORIES, RPII
### BAND - Medical

<table>
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<th>Category</th>
<th>Description</th>
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<tr>
<td>Hospital Level 1 (HL1)</td>
<td>Licensee with only <strong>one</strong> 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>Licensee who uses DXA units only</td>
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<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>
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<tr>
<td>Hospital Level 2 – Mobile Lithotripsy/Cardiac Catheterisation</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>
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<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>
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<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>
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<td>Hospital Level 4 Transportation</td>
<td>A HL4 hospital who is additionally licensed for the transport of radioactive sources</td>
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<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>
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<td>Hospital Level 5 – Transportation</td>
<td>A HL5 hospital who is licensed for the transport of radioactive sources</td>
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<td>Chiropractor</td>
<td>Licensee uses one or more X-ray units for diagnostic procedures</td>
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<tr>
<td>Cyclotron Radiopharmaceutical Production</td>
<td>Licensee uses a cyclotron for the manufacture of radiopharmaceuticals.</td>
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<tr>
<td>Irradiating Blood Products</td>
<td>Licensee uses one or more sealed sources for the irradiation of blood products</td>
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## BAND - Dental

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<tr>
<th>Category</th>
<th>Description</th>
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<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>
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<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>
Section 1
Governance and Workforce

Contents
Governance - Guidelines on Holders’ Responsibility for Patient Radiation Protection
Workforce - Responsibilities

Local documentation to be added to this section:
Membership and Terms of Reference of Radiation Safety Committee (RSC)
Minutes and actions from RSC Meetings.
Induction and training of Staff in Radiation Protection (sample template enclosed)

Key Performance Indicators for this section;
Membership and Terms of Reference of RSC meets NRSC guidelines.
Minutes and record of attendance of RSC meeting held in the last 12 months are available.
A record of actions taken following recommendations of the RSC is available.
Induction and training dates for all staff working with ionising radiation protection is recorded.
The training record is reviewed annually by the RSC.

Relevant National Healthcare Standards;
Standard 5 (Leadership and Governance)
Standard 6 (Workforce)
Section 1 Governance and Workforce

Governance
Guidance from the National Radiation Safety Committee to Holders of Medical/Dental Ionising Radiation Equipment addresses some of the key responsibilities in assisting 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.

These regulations are intended to protect the patient from harmful effects of exposure to ionising medical/dental radiation.

The National Baseline Audits conducted in 2008 in Radiology, Nuclear Medicine, Dentistry and Radiotherapy in 2008 recommended that “The HSE and the National Radiation Safety Committee should clarify and promote the requirements of SI 478 and ensure that all Holders of ionising radiation equipment are aware of these”.

This document is an initial guidance from the National Radiation Safety Committee to Holders of Medical/Dental Ionising Radiation Equipment in Ireland. It addresses some of the key responsibilities of Holders to assist them in complying with the relative provisions of the regulations. It also provides some advice on implementation issues, such as governance structures.

Disclaimer
This document is intended to act as a guideline to the regulations. It must be read in conjunction with the regulations referred to above and other laws, regulations or other responsibilities attaching to these roles. 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 this guidance in due course. The advice given is wide-ranging and does not undermine an employer’s legal responsibilities for implementing compliant local procedures.

This regulation concerns important issues of quality and patient safety. Currently, a national review is being undertaken to implement the recommendations from the Report of the Commission on Patient Safety and Quality Assurance, 200831. This, and other national developments will have consequences for the implementation of SI 478 (2002) in the future. The National Radiation Safety Committee may issue further guidance in this regard.
Holders’ 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 Prescribers and each person involved in the use of ionising radiation for the purpose of medical/dental exposures to patients 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 nominee from senior management
- 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 Safety Officer
- Radiation Protection Adviser (**see note below) / Medical Physics Expert
- A representative from each department outside of Radiology using ionising radiation for patients, particularly where higher doses are involved (e.g., cardiology)
- Nurse Referrer
- Clinician Referrer that places high demand on radiology
- Representation from satellite hospitals/clinics, as appropriate
- Occupational Health Physician, Specialist in Public Health Medicine or other medical practitioner will be required to 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, e.g., Practitioner in Charge.
(**) 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 in which 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 an updated Radiation Protection Manual on site. An example of the suggested contents of this Manual, particularly for dentistry, is given in Section 1.7. A further example, relating to Chiropractors, is listed in Section 1.8. 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 be made available if requested.

The Holder must ensure that their equipment complies with the Criteria for Acceptability of Radiological Equipment (RP 162) and take appropriate action if it fails to meet the criteria, based on the advice and action of the Medical Physics Expert.

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 NRSC has developed criteria to devolve the decision to the appropriate level. This criteria for continued use of radiological equipment adopted by the NRSC is outlined in section 2 of the Radiation Protection Manual.
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, in 2010 the National Radiation Safety Committee has issued recommendations and guidance to all Holders on an external reporting and learning mechanism for the reporting of adverse incidents to patients.

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


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

1.5.1 Referral Criteria
The Holder must ensure that Referrers are advised of referral criteria, based on the recommendation of the Practitioner in Charge. The NRSC and the Faculty of Radiologists have endorsed the use of the RCR (UK) Referral Criteria “Making the best use of clinical radiology”. The HSE has purchased on-line access (iRefer) for all facilities and staff involved in prescribing and using ionising radiation.

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/medexp Radiat onunit/Publications_and_A nnual_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 associated with these roles.

1.6.1 Responsibility of the Practitioner in Charge (in addition to responsibilities of the Practitioner)

- Recommend referral criteria. The NRSC and the Faculty of Radiologists have recommended the use of the Referral Criteria “Making the best use of clinical radiology”. (iRefer) and these are 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 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 him / 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.

February 2010
National Radiation Safety Committee

Version 2, Updated August 2013
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 de facto 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 become 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 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
Workforce

Service Providers plan, organise and manage their workforce to achieve the service objectives for high quality, safe and reliable healthcare.

All staff involved in delivering ionising radiation to patients shall have adequate theoretical and practical training in radiological practices, as well as relevant competence in radiation protection. This also extends to any personnel engaged to provide a service for patients.

Responsibilities

The Holder has overall responsibility for education and training. In practical terms this should be delegated to and is most appropriately the responsibility of the Practitioner in Charge of the facility. The Practitioner in Charge is responsible for ensuring that all persons involved in the use of ionising radiation have the appropriate qualifications, competency, authorisation, registration and training required to carry out their functions in compliance with the regulations and are aware of their responsibilities. An Bord Altranais has published “Requirements and Standards for Nurse Education Programmes for Authority to Prescribe Ionising Radiation (Xray)”. The HSE subsequently published “A Guiding Framework for the Implementation of Medical Ionising Radiation (X-ray) in Ireland” which requires a Local Implementation Group to be in place at locations where nurses prescribe ionising radiation procedures.

The Practitioner in Charge should ensure that appropriate induction and ongoing training is provided, particularly when new or updated practices are introduced and when there is a change of personnel.

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 for this task, where relevant. Personnel records should be maintained to ensure staff have the required knowledge, competence and skill mix to adequately meet departmental needs. These records should be reviewed at regular intervals for anticipated changes in service delivery and to address the need for ongoing training and education in radiation protection. The Radiation Safety Committee is responsible for monitoring the education and training of staff in Radiation Protection.
### Local documentation for Section 1 Governance and Workforce

**NOTE:**
If the local documentation is not held in this file please indicate where it is held and ensure that it can be easily accessed upon request and readily available to the relevant personnel.

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<tr>
<th>Document Title</th>
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Sample Template to record induction and training of staff in Radiation Protection

Include all Practitioners, Referrers, Radiographers, Independent Nurse Referrers, Operators, Physicists and all other relevant staff.

<table>
<thead>
<tr>
<th>Name</th>
<th>Profession</th>
<th>Qualification</th>
<th>Title</th>
<th>Radiation Protection Training date</th>
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Person assigned responsibility to maintain training and education records (print Name):

_________________________________________

Date training records last reviewed by Radiation Safety Committee: ________________________

A copy of the radiation protection certificate of attendance is held on the individual’s personnel file in HR.
Section 2
Radiology Equipment and Reports

Contents
Risk Assessment
RPII Licence of Equipment
Inventory of Radiation Equipment
Criteria of Acceptability
Setting and Reviewing Nominal Replacement Dates
National Inventory of Equipment, MERU
Service Records

Local documentation to be added to this section:
Records of equipment risk assessments
Copy of RPII Licence
Inventory of Equipment and Replacement due dates
QA Reports
Routine Radiographer QA Reports
Physics Annual QA Reports
Service Reports
Confirmation Action Taken
Details of Service Level Agreement, where applicable

Key Performance Indicators for this section;
Copy of RPII licence on display.
All service records up to date.
All Quality Assurance records up to date.
Replacement due dates are set for all ionising radiation equipment and are up to date.

Relevant National Healthcare Standards;
Standard 3.1.4, 3.1.6, (Safe Care and Support)
Section 2 Radiology Equipment, Licence and Reports

Risk Assessment
Service providers should have processes in place to identify and manage risks associated with radiological equipment to minimise the risk of harm to patients.

RPII Licence of Equipment
A copy of the RPII licence should be kept on display at each facility.

Inventory of Radiation Equipment
A local inventory of all ionising radiation equipment is required to be held at all facilities. This should demonstrate that relevant diagnostic imaging equipment is registered on the RPII licence and its nominal replacement date has been set and reviewed. A template inventory is included under local documentation.

Criteria of Acceptability
The holder must ensure that equipment complies with the Radiation Protection Advisors (RPA's) approved QA program, within which the criteria of acceptability will be recommended. Guidance documents such as “Criteria for Acceptability of Radiological Equipment (RP-162)\(^3\) may be useful to the Radiation Protection Advisor and Medical Physics Expert (MPE) in setting criteria.

Setting and Reviewing Nominal Replacement Dates
The Holder in an individual institution has a central role in the decision to continue use of equipment after the due date for replacement. The Holder should be advised of this matter by the assigned Medical Physics Expert (MPE).

Legislation requires the NRSC to decide on continued use of equipment. However, the involvement of the NRSC in day-to-day decisions about the continued use of equipment could be problematic as the frequency of NRSC meetings is not sufficient to meet clinical need and the NRSC is too far removed from service provision.

To address this problem the NRSC has adopted the following criteria for continued use of radiological equipment:

1. The MPE should certify to the Practitioner in Charge, in writing, that the equipment meets the criteria of acceptability for radiological equipment.
2. The Radiography Services Manager / Clinical Specialist Radiographer should certify in writing that the equipment is suitable for use.
3. The engineer or agency contracted to service the equipment should certify in writing that the equipment is operating within specification and provide a statement regarding the continued availability of replacement parts.
4. The Practitioner in Charge should certify in writing that, having consulted with the MPE, the patient dose levels arising from the use of the equipment, and image quality where appropriate, are within acceptable limits for clinical diagnosis.

5. Upon completion of these steps, the Practitioner in Charge recommends the certification to the RSC and the RSC advises their recommendation to the holder.

It is suggested that all Cardiac Angiography, Computed Tomography (CT), Mammography and Fluoroscopy equipment over eight years old is reviewed and a new replacement date given. All other ionising radiation equipment over 12 years old should be reviewed. All new equipment should have an initial replacement due date set (not longer than the above dates) as advised by the MPE to the Practitioner in Charge and noted by the RSC.

Based on the advice of the above personnel the Holder may decide to limit or suspend use of the equipment. The decision to permit limited use of the equipment should be based on a risk assessment (approved by the RSC) for such use, and shall be in writing.

This process of validating the continuing use of radiological equipment should be repeated at regular intervals – annually or more frequently if there is evidence that the equipment performance has deteriorated significantly since the last assessment.

The documentation supporting the decision of the Holder must be retained on file to be available for inspection during the statutory external clinical audits. If the auditors have concerns about any issues arising from an inspection of these documents they shall report their findings to the CEO of the HSE and to the NRSC.

**National Inventory of Equipment, MERU**

The MERU holds an inventory of equipment which is updated on an annual basis. The inventory of replacement dates is not kept up to date on an annual basis by the MERU and Holders are expected to include and update this information in their inventory. The MERU may request replacement dates information from Holders once the above process has been established and implemented at locations. Alternatively this information may be requested as part of an audit or inspection by regulators.

In the future the equipment inventory held by the MERU may be updated by the holder to denote any limitation or suspension of use. The MERU may update the NRSC on the levels of equipment continued in use past the nominal replacement date, and under limited or suspended use.

**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
- Details of Service Level Agreement, where applicable
Local Documentation for Section 2 Radiology Equipment, Licence and Reports

**Insert:**
Records of equipment risk assessments  
Copy of RPII Licence  
Inventory of Equipment and Replacement due dates  
QA Reports  
Routine Radiographer QA Reports  
Physics Annual QA Reports  
Service Reports  
Confirmation Action Taken  
Details of Service Level Agreement, where applicable

**NOTE:**
If the local documentation is not held in this file please indicate where it is held and ensure that it can be easily accessed upon request and readily available to the relevant personnel.

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Location Held</th>
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<tbody>
<tr>
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</tbody>
</table>
# Sample Template Inventory of Ionising Radiation Equipment

<table>
<thead>
<tr>
<th>Location</th>
<th>Maker</th>
<th>Unit</th>
<th>Category</th>
<th>Serial no X-Ray tube</th>
<th>Installation date</th>
<th>Nominal Replacement Date</th>
<th>Decision on continued use</th>
<th>Date for review of decision</th>
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</tbody>
</table>

Reviewed annually by the RSC

RPII licence up to date: _____________________

Review date: _____________________________

Signed (Chair of RSC): _____________________
Section 3
Incident Reporting and Learning

Contents
Guidelines to defining and managing all radiation incidents
Definition of a Patient Radiation Incident
Definition of a Near Miss Patient Radiation Incident
Definition of Non-Notifiable Incidents
Definition of Patient Radiation Incidents Notifiable To MERU
Report a Notifiable Incident to Medical Exposure Radiation Unit
Investigation Procedure for Notifiable Incidents
Contents of Investigation Report
Other Reporting Requirements to Medical Exposure Radiation Unit
STARSweb Pick List Coding Of Incidents
Template for investigation of an incident
Template for recording Radiotherapy incidents
Template for recording Diagnostic incidents
Fishbone Diagram
Annual template to record incident numbers

Local documentation to be added to this section:
Local incident protocols and templates
Annual record of Incident numbers
Incident reports and investigation reports
Documentation of improvements made resulting from incident investigation or incident review
Record of staff briefings and communications on incidents

Key Performance Indicators for this section;
Annual record kept of patient radiation incidents reported
All notifiable incidents are appropriately investigated and acted upon.
Evidence of improvements made resulting from incident investigations
Evidence of staff awareness of incident procedures

Relevant National Healthcare Standards;
Standards 3.3, 3.5 (Safe Care and Support)
Guidelines for reporting and learning from patient safety incidents from medical ionising radiation

1.0 BACKGROUND:
The National Radiation Safety Committee has issued these guidelines on a national reporting mechanism for the reporting of and learning from incidents to patients.

The National Baseline Audit on the Implementation of Statutory Instrument (SI) 478 (2002) conducted in 2008 recommended the establishment of a notification system for incidents to patients to be managed by the Medical Exposure Radiation Unit, HSE. The National Radiation Safety Committee is an expert advisory committee established under SI 478 to advise the CEO, HSE on Radiation Safety Issues for Patients. The National Radiation Safety Committee has produced these guidelines as an aid to classifying radiation incidents to patients. In addition, Holders shall ensure that they have systems in place to prevent and manage incidents and an escalation process as appropriate.

The fundamental role of an incident reporting system is to enhance patient safety by learning from failures in the health care system. It provides useful data from which locations can compare local practices with national averages and improve practices based on implementing actions to prevent occurrence of similar incidents.

This document provides guidance on the types of incidents that are notifiable to Medical Exposure Radiation Unit and gives a guide to how non-notifiable incidents are defined. It should be noted that not every incident or scenario can be included in this documentation and the list is not exhaustive.

All incidents should initially be reported, reviewed, and where necessary, further investigated by an organisation’s local risk management structures. The notifiable incidents and near-misses, as set out in section 3.0, must also be reported to the Medical Exposure Radiation Unit.

Under the terms of the Clinical Indemnity Scheme, all hospitals and healthcare facilities within the Public Health Sector in Ireland have an obligation to report to the State Claims Agency all clinical incidents. This includes those related to the use of Medical Ionising Radiation in diagnosis and treatment. Therefore these public hospitals and healthcare facilities are to continue reporting incidents through their local reporting structures to enable the incidents to be logged onto the STARSWeb Incident Reporting System. The State Claims Agency have adopted the list of specialities, sub specialties and incident types, (see appendix 1) in order to ensure consistency of the types of incidents that are reported in relation to the use of Medical Ionising Radiation in diagnosis and treatment.

Practices that fall outside of these definitions can be assessed for quality and appropriateness by other mechanisms, such as regular monitoring and checking systems through good local governance and risk management. Clinical audit, Quality Assurance Programmes, ongoing training and education of staff and reviewing and updating of procedures in line with good practice are some organisational methods that can be applied.

More information on incident reporting is available on the webpage:
http://www.hse.ie/eng/about/Who/qualityandpatientsafety/safepatientcare/medexpadiationunit/meru.html

National Radiation Safety Committee
2.0 GUIDE TO DEFINING AND MANAGING ALL RADIATION INCIDENTS

2.1 Recording of incidents
All patient radiation 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 and reviewed and investigated where considered appropriate.

DEFINITION OF A PATIENT RADIATION INCIDENT

A patient radiation incident occurs where the delivery of radiation during an imaging procedure or treatment is different to that intended or where there is none intended for the patient, resulting in unnecessary variation in exposure, unless due to patient factors.

Dose variation due to the patient or the patient condition is not defined as a radiation incident. However, such an event will require appropriate recognition and review within the location’s risk management framework to ensure any patient safety issues are addressed promptly. A location may decide to report this to the MERU if it considers there is a patient safety implication.

DEFINITION OF A NEAR MISS PATIENT RADIATION INCIDENT

A near miss is a potential patient radiation incident that is detected before an imaging procedure or treatment (radiology/radiotherapy/nuclear medicine) takes place. There is no adverse outcome; the potential risk was identified and prevented.

A near miss is normally an error that was identified outside of the routine checking/process that is in place. Where an error is discovered as part of the normal checking process, this is unlikely to be a near miss as the checking process is designed to discover these errors. However, such events will require appropriate recognition and review within the location’s risk management framework to ensure any patient safety issues are addressed promptly. The same reporting and notification criteria apply to near miss and patient radiation incidents.

DEFINITION OF NON-NOTIFIABLE INCIDENTS (no report required for MERU) but documented at location.

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

5.2.1 Exposure Greater than intended up to notifiable levels, for example;
- A diagnostic exposure “greater than intended” (see appendix 2).
- Incorrect procedure / incorrect anatomy
- Therapeutic nuclear medicine – administered activity differing by a factor of 1.1.

5.2.2 Exposure where none intended, for example;
- Incorrect Patient exposed to less than 1 milliSievert.
- Inadvertent dose to foetus less than 1 milliSievert
5.2.3 Radiotherapy dose variations, for example;

- Radiotherapy Dose variation from prescribed total dose from 5% up to 10%, including partial incorrect volume.
- Radiotherapy Dose variation from a fractional dose from 10% up to 20%, including partial incorrect volume.

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

5.2.5 A near miss under any of the above headings.

3.0 DEFINITION OF PATIENT RADIATION INCIDENTS NOTIFIABLE TO MERU

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

3.1.1 Exposure much greater than intended, for example;

- Diagnostic overexposure (including nuclear medicine) of an adult as a result of more than twice the exposure intended (*see example below) that leads to an overexposure of > 10mSv or 20 times the dose intended, regardless of the dose level.
- Diagnostic overexposure (including nuclear medicine) 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.
- 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.

3.1.2 Exposure where none intended, for example;

- Dose to the breastfed child over 1 mSv.
- Inadvertent dose to foetus over 1 milliSievert.
- Incorrect patient (radiology, nuclear medicine or radiotherapy) exposed to over 1 milliSievert.

3.1.3 Radiotherapy dose significant variation, for example;

- Radiotherapy Dose variation from prescribed total dose of greater than 10%, including partial incorrect volume.
- Radiotherapy Dose variation from a fractional dose of greater than 20%, including partial incorrect volume.
- Radiotherapy - completely incorrect volume.
- Deterministic effects from radiotherapy

3.1.4 Any other relevant radiation incident considered to have serious patient safety implications.
3.1.5 A near miss under any of the above headings.

* Greater than twice intended:

**Example 1:** Patient required a CT brain (2mSv) and received a CT abdomen pelvis in error (14mSv). Patient then receives the correct CT brain procedure. Intended dose is 2mSv; patient got 16mSv, which is greater than twice that intended and greater than 10mSv more than intended. Therefore this incident is notifiable.

**Example 2:** Patient got a second CT chest, abdomen and pelvis unnecessarily (13mSv). Although they got a dose greater than 10mSv more than intended, they did not get more than twice the dose intended and this is not notifiable but should be recorded locally.

**Example 3:** Patient required a chest x-ray (0.02mSv) and received a CT Brain (2mSv) in error. Patient received more than 20 times the dose intended and therefore this is a notifiable incident.

Inadvertent – unintentional or unexpected

**When to notify MERU of Incorrect patient incident**

Where a patient receives a radiological exam in error where "no dose is intended", i.e., they should not have received any ionising radiation, this is classified in the guidelines as "incorrect patient". These are notifiable to the MERU if in excess of 1 mSv. All incorrect patient incidents should be recorded locally and audited regularly.

**When to notify MERU of Incorrect procedure**

Where the patient had been due a radiological procedure but got/potentially got a different procedure, this is classified as incorrect procedure. All incorrect procedures should be monitored and recorded as an incident according to appendix 2 and a regular audit of unnecessary procedures should take place.

Incorrect procedures are notified to MERU when there is a diagnostic overexposure of an 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.
4.0 REPORT A NOTIFIABLE INCIDENT TO 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:
Rachel Brennan,
Medical Exposure Radiation Unit,
Health Service Executive,
rachel.brennan1@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.

5.0 INVESTIGATION PROCEDURE FOR 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. Address cause of incident to improve patient safety and minimise recurrence.
6. Learning from incident is supported and disseminated locally throughout the organisation and through regional clinical governance structures.

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.

6.0 CONTENTS OF INVESTIGATION REPORT

The findings of the investigation must be documented in an investigation report. The MERU has produced a template which locations should use to complete report or incorporate the questions in to their investigation report (appendix 3). It is recommended that the report should include at least the following information:

- All relevant facts concerning the incident.
- Root cause/systems analysis to identify cause/s of 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.
- Details of dissemination of learning, both internally and externally.

The report should be signed and dated by the person who prepared it, the relevant referring clinician and the practitioner. The reports should be signed by the CEO/Hospital Manager and discussed at the Radiation Safety Committee meetings, clinical governance committees and audit committees and forwarded to the Medical Exposure Radiation Unit.

5.0 OTHER REPORTING REQUIREMENTS TO 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 every calendar year. Locations are encouraged to ensure that they have an effective mechanism that identifies and facilitates recording of patient radiation incidents, which may require updating risk management protocols and incident recording forms. A national patient radiation incident recording form has been adopted for radiotherapy centres (2013) which will provide consistency in incident recording (appendix 4).
Appendix 1

Radiation pick lists available on STARSWeb Incident Reporting System (To be updated)

<table>
<thead>
<tr>
<th>Name</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Speciality</strong></td>
<td></td>
</tr>
<tr>
<td>Radiology</td>
<td>9000</td>
</tr>
<tr>
<td><strong>Sub-specialities</strong></td>
<td></td>
</tr>
<tr>
<td>Radiology – General (including mammography)</td>
<td>9100</td>
</tr>
<tr>
<td>CT</td>
<td>9300</td>
</tr>
<tr>
<td>Nuclear Medicine/PET CT/PET MR</td>
<td>9400</td>
</tr>
<tr>
<td>Interventional Radiology/Fluoroscopy</td>
<td>9500</td>
</tr>
<tr>
<td>Cardiac Cath Lab</td>
<td></td>
</tr>
<tr>
<td>Other (refer to StarsWeb codes)</td>
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</tr>
<tr>
<td><strong>Speciality</strong></td>
<td></td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>G000</td>
</tr>
<tr>
<td><strong>Sub-specialities</strong></td>
<td></td>
</tr>
<tr>
<td>External Beam</td>
<td>9200</td>
</tr>
<tr>
<td>Brachytherapy</td>
<td>G100</td>
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**Incident Type General**

<table>
<thead>
<tr>
<th>Incident Type Specific</th>
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</thead>
<tbody>
<tr>
<td>Incorrect patient &lt; 1milliSievert</td>
<td>tba</td>
</tr>
<tr>
<td>Incorrect patient &gt; 1 milliSievert</td>
<td>D001</td>
</tr>
<tr>
<td>Incorrect procedure</td>
<td>D002</td>
</tr>
<tr>
<td>Incorrect anatomy</td>
<td>D003</td>
</tr>
<tr>
<td><strong>Multiple exposures greater than intended</strong></td>
<td>D006</td>
</tr>
<tr>
<td>Adult: &gt; twice Diagnostic overexposure &gt;10mSv or 20 times dose intended</td>
<td>D007</td>
</tr>
<tr>
<td>Child: &gt; twice Diagnostic overexposure &gt;3mSv or 15 times dose intended</td>
<td>D008</td>
</tr>
<tr>
<td>Inadvertent dose to foetus &gt; 1mSv</td>
<td>D009</td>
</tr>
<tr>
<td>Inadvertent dose to foetus &lt; 1mSv</td>
<td>tba</td>
</tr>
<tr>
<td>Dose to the breastfed child over 1mSv</td>
<td>D011</td>
</tr>
<tr>
<td>Therapeutic N Med - Administered activity different by 20% of intended</td>
<td>D012</td>
</tr>
<tr>
<td>Therapeutic N Med - Administered activity different by 10% to 20% of intended</td>
<td>D013</td>
</tr>
<tr>
<td>Therapeutic N Med dose given instead of diagnostic dose e.g. radioiodine</td>
<td>D014</td>
</tr>
<tr>
<td>Radiotherapy Dose or volume variation from the total prescribed of less than 5%</td>
<td>tba</td>
</tr>
<tr>
<td>Radiotherapy Dose or volume variation from the total prescribed - 5% to 10%</td>
<td>D018</td>
</tr>
<tr>
<td>Radiotherapy Dose or volume variation from the total prescribed of greater than 10%</td>
<td>D015</td>
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<tr>
<td>Radiotherapy Dose or volume variation from the fraction prescribed - 10% to 20%</td>
<td>D017</td>
</tr>
<tr>
<td>Radiotherapy Dose or volume variation from the fraction prescribed of greater than 20%</td>
<td>D016</td>
</tr>
<tr>
<td>Deterministic effects</td>
<td>D021</td>
</tr>
<tr>
<td>Dose given to carers without consent greater than medical council guidelines</td>
<td>D022</td>
</tr>
<tr>
<td>Any other radiation exposure incident to patient</td>
<td>D023</td>
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</table>
Appendix 2

Guide to “Greater than Intended” definition for non-notifiable incidents

<table>
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<th>Diagnostic Procedures</th>
<th>Dose multiples greater than intended</th>
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<tr>
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<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>
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</table>
Appendix 3
TEMPLATE FOR REPORT OF INVESTIGATION AND FINDINGS OF PATIENT RADIATION INCIDENT.

Additional information or local reports may also be attached 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>
</table>

<table>
<thead>
<tr>
<th>Patient age:</th>
<th>Patient sex:</th>
<th>M □</th>
<th>F □</th>
<th>MERU Incident definition</th>
</tr>
</thead>
</table>

What speciality was patient admitted under / referred from? NEAR MISS? YES □ NO □

Incident description: (Accurately describe, in chronological order, the relevant details of what happened leading up to, 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 (include referring clinician where applicable)?</th>
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</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 practitioner 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:
3. **Cause of Incident**

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

Which of these 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.

What is the likelihood of a similar incident occurring?

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., what is the learning for this and/or other locations?

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

Reported completed by: Role: Email:

Signed: Date: Tel:

Please return signed copy to: Private and Confidential, Medical Exposure Radiation Unit, HSE, Mill Lane, Palmerstown, Dublin 20
### Appendix 4
**RADIOTherapy Patient Radiation Incident Form**

**Patient Details:**

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Name</td>
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</tr>
<tr>
<td>Date of Birth</td>
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<tr>
<td>Treating Physician</td>
<td></td>
</tr>
<tr>
<td>Prescription, Fractionation &amp; Phase (I, II, III):</td>
<td></td>
</tr>
<tr>
<td>Patient Identification NO:</td>
<td></td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
</tr>
</tbody>
</table>

**Incident Details:**

<table>
<thead>
<tr>
<th>Incident Details</th>
<th>Area of Discovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time and Date of Incident</td>
<td>CT – Sim</td>
</tr>
<tr>
<td>No. Fields/Fractions Involved</td>
<td>Planning</td>
</tr>
<tr>
<td>Radical</td>
<td>Simulator</td>
</tr>
<tr>
<td>Palliative</td>
<td>Treatment Unit</td>
</tr>
</tbody>
</table>

Incident Discovered by: ___________________ (Name, title) ______________________ (signature) _________ Date _______

Details of Incident: _______________________

Action taken to prevent recurrence/ Comments:

### Radiation Dose (To Be Completed by Physicist):

<table>
<thead>
<tr>
<th>Dose Variation</th>
<th>Incidence Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;5% in total dose</td>
<td>□</td>
</tr>
<tr>
<td>≥5% &lt;10% in total dose</td>
<td>□</td>
</tr>
<tr>
<td>Set up variation (cm)</td>
<td>□</td>
</tr>
</tbody>
</table>

Recoverable should this be correctable? Yes □ No □

### Incident Categorisation (STARSWeb codes in Brackets):

**NOTIFICATION TO MERU - NOT REQUIRED**

- Dose or volume variation in one fraction 10 - 20 % wrt fraction dose (D017)
- Total Dose or volume variation 5 – 10 % wrt total prescribed dose (D018)
- Total Dose or volume variation < 5% wrt total prescribed dose (tba)
- Wrong Patient <1mSv (tba)

**MERU NOTIFIABLE INCIDENTS:**

- Total Dose or volume variation > 10 % wrt total prescribed dose (D015)
- Total Dose or volume variation > 20 % wrt total prescribed dose (D016)
- Other Notifiable Incidents:
  - Wrong Procedure/Anatomy (D003)
  - Deterministic Effects (D021)
  - Dose given to carers without consent greater than medical council guidelines (D022)
  - Wrong Patient > 1mSv(D001)
  - Inadvertent foetal dose > 1mSv (D009)
  - Any other incident (D023) (notification depends on dose)
INCIDENT SEVERITY and RATING (CHECK CLASSIFICATION APPENDIX 1):

<table>
<thead>
<tr>
<th>Minor Incident (level 1): ☐</th>
<th>Serious Incident (level 2): ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Incident (level 3): ☐</td>
<td>Critical Incident (level 4): ☐</td>
</tr>
</tbody>
</table>

What is the RISK RATING number? Refer to table below:

<table>
<thead>
<tr>
<th>Probability Consequences</th>
<th>Rare</th>
<th>Unlikely</th>
<th>Possible</th>
<th>Likely</th>
<th>Almost Certain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insignificant - level 1</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Minor - level 1</td>
<td>2</td>
<td>4</td>
<td>6</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>Moderate - level 2</td>
<td>3</td>
<td>6</td>
<td>9</td>
<td>12</td>
<td>15</td>
</tr>
<tr>
<td>Major - level 3</td>
<td>4</td>
<td>8</td>
<td>12</td>
<td>16</td>
<td>20</td>
</tr>
<tr>
<td>Catastrophic - level 4</td>
<td>5</td>
<td>10</td>
<td>15</td>
<td>20</td>
<td>25</td>
</tr>
</tbody>
</table>

Low Risk: [ ] Medium Risk: [ ] High Risk: [ ]

NOTIFICATIONS

<table>
<thead>
<tr>
<th>Patient Informed</th>
<th>Yes/no</th>
<th>Date</th>
<th>Initial</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>☐ No</td>
<td>☐</td>
</tr>
<tr>
<td>Reported to Local Radiation Safety/Risk Committee</td>
<td>Yes</td>
<td>☐ No</td>
<td>☐</td>
</tr>
<tr>
<td>Reported to Chief Executive/Hospital Manager (HSE)</td>
<td>Yes</td>
<td>☐ No</td>
<td>☐</td>
</tr>
<tr>
<td>STARSWEB Data submitted (public hospitals only)</td>
<td>Yes</td>
<td>☐ No</td>
<td>☐</td>
</tr>
<tr>
<td>Radiological Protection Institute Ireland Informed</td>
<td>Yes</td>
<td>☐ No</td>
<td>☐</td>
</tr>
<tr>
<td>Medical Exposure Radiation Unit informed</td>
<td>Yes</td>
<td>☐ No</td>
<td>☐</td>
</tr>
<tr>
<td>Action taken if required</td>
<td>Yes</td>
<td>☐ No</td>
<td>☐</td>
</tr>
</tbody>
</table>

INCIDENT REVIEW BY LOCAL RADIATION INCIDENT PANEL

Review Date: [ ]

Recommendations of Radiation Incident Panel:

Investigation required? (Yes if notifiable to RPII/MERU) Yes ☐ No ☐

SIGNATURES:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiation Therapist:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiation Oncologist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treating Radiation Oncologist: (severity level 2 or above)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiation Incident Panel Chair:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: Severity Incident Type 1 - sign off by incident committee will suffice
## Classification of Patient Incidents in Radiotherapy

<table>
<thead>
<tr>
<th>Incident Severity</th>
<th>Examples</th>
<th>Individuals to Be Notified</th>
<th>Time Scale</th>
</tr>
</thead>
</table>
| Minor Incident    | • Dose or volume variation from prescribed total dose of <5% and fractional dose of 10 – 20%  
• Near miss or unsafe condition which could potentially cause a treatment error. | Clinical Specialist or Senior RT  
RTSM,  
Treating Consultant only if actual patient impact Committee Chairperson | Within 24hrs |
| Serious Incident  | • Dose or volume variation from prescribed total dose of 5-10% and fractional dose of greater than 20%.  
• Radiation dose or medication error causing side effects requiring minor treatment or ongoing monitoring and assessment.  
• Setup variation > 1cm - no critical structures included. | RTSM,  
Head of Physics,  
Treating Radiation Oncologist | Within 24 hrs |
| Potential Serious Incident | • A near miss that could have been a serious incident. | Clinical Specialist or Senior RT  
Committee Chairperson | Within 24 hrs |
| Major Incident    | • Dose or volume variation from prescribed total dose of 10 - 20%.  
• Radiation dose or medication error causing side effects requiring major treatment and intervention or hospitalisation.  
• Setup variation that will/could impact on normal tissue effects (e.g. Heart, lung, eyes, kidney etc.). | CEO,  
RTSM,  
Head of Physics,  
Director of Nursing,  
Treating Radiation Oncologist | Immediate |
| Potential Major Incident | • A near miss that could have been a major incident. | CEO,  
RTSM,  
Head of Physics,  
Director of Nursing,  
Treating Radiation Oncologist | Within 24 hrs |
| Critical Incident | • Radiation dose or medication error causing death or disability.  
• Dose or volume variation from prescribed total dose of >20%.  
• Completely incorrect volume. | CEO/Clinical Director,  
Radiotherapy Service Manager (RTSM),  
Head of Physics,  
Director of Nursing,  
Treating Radiation Oncologist | Immediate |

### Major and Critical Incident Escalation Process

1. **Treatment is to cease immediately and no further treatment is to take place without the approval of the patient's consultant or the consultant on call.**
2. **The consultant is to be informed of the incident. If the consultant is not available, the covering consultant, or the consultant on call, is to be informed.**
3. **The consultant is to inform the patient.**
4. **The staff member who discovers the error is to immediately inform their head of section/department.**
5. **The head of department is to inform the chief executive-clinical director and if he/she is unavailable at least one member of the executive management team is to be informed. The heads of departments/sections of radiation therapy, physics and nursing are to be informed.**
6. **The head of physics will direct a senior member of his/her staff to undertake a preliminary physics incident report.**
7. **A review of all patients receiving similar treatment protocols is to be undertaken.**
8. **An emergency meeting of the radiotherapy risk management committee/radiation incident panel is to be held which the patient's consultant will also attend.**
9. **The radiation risk management committee will consider the preliminary incident report and determine what action should be taken.**
# Appendix 5

## DIAGNOSTIC IMAGING PATIENT RADIATION INCIDENT FORM

### PATIENT DETAILS:

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>Patient Identification NO:</th>
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<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of Birth</th>
<th>NEAR MISS?</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Referring Clinician</th>
<th>Modality:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Investigation:**

**Modality:**

### INCIDENT DETAILS:

<table>
<thead>
<tr>
<th>Incident Details</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time and Date of Incident</th>
<th>Estimated Effective Dose in mSv:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Incident Discovered by: ___________________  (Name, title) ______________________  (signature)  _________Date _______

**Details of Incident:**

Action taken to prevent recurrence/ Comments:

### INCIDENT CATEGORISATION (STARSWeb codes in Brackets):

#### NOTIFICATION TO MERU NOT REQUIRED

<table>
<thead>
<tr>
<th>Minor Incident (level 1):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect patient (&lt; 1mSv)</td>
</tr>
<tr>
<td>Dose greater than intended</td>
</tr>
<tr>
<td>(below notifiable levels) (D006)</td>
</tr>
<tr>
<td>Inadvertent foetal dose &lt; 1mSv (tba)</td>
</tr>
</tbody>
</table>

#### MERU NOTIFIABLE INCIDENTS (INVESTIGATION WILL BE REQUIRED):

<table>
<thead>
<tr>
<th>Serious Incident (level 2) (unless dose is in excess of 100mSv):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect Patient (&gt; 1mSv) (D001)</td>
</tr>
<tr>
<td>Incorrect Anatomy (D003)</td>
</tr>
<tr>
<td>Inadvertent foetal dose &gt; 1mSv (D009)</td>
</tr>
<tr>
<td>Adult: diagnostic overexposure (&gt; twice) of 10 mSv or 20 times dose intended (D007)</td>
</tr>
<tr>
<td>Dose given to carers without consent greater than medical council guidelines (D022)</td>
</tr>
</tbody>
</table>

### NOTIFICATIONS

<table>
<thead>
<tr>
<th>Yes/no</th>
<th>Date</th>
<th>Initial</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>

- Patient Informed
- Report to Local Radiation Safety/Risk Committee
- Reported to Chief Executive/Hospital Manager (HSE)
- STARSWEB Data submitted (public hospitals only)
- Radiological Protection Institute Ireland Informed
- Medical Exposure Radiation Unit informed

### SIGNATURES:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Name/Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Referring clinician</td>
<td>Practitioner</td>
</tr>
<tr>
<td>Radiographer</td>
<td>Physicist</td>
</tr>
</tbody>
</table>

Date: ________________________

---

### Section 3 Incident Reporting and Learning
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.
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? [_________]

* STARSweb 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> <em>(D006)</em></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;1mSv (D009)</td>
<td></td>
</tr>
<tr>
<td>Incorrect 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. radioiodine (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 a fractional 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
Local Documentation for Section 3 Incident Reporting

**Insert:**
Local incident protocols and templates
Annual record of Incident numbers
Incident reports and investigation reports
Documentation of improvements made resulting from incident investigation or Incident review
Record of staff briefings and communications on incidents

**NOTE:**
If the local documentation is not held in this file please indicate where it is held and ensure that it can be easily accessed upon request and readily available to the relevant personnel.

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Location Held</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
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<td></td>
</tr>
</tbody>
</table>
Section 4
Patient Pregnancy Protocols

Contents
Legislation governing special protection of females of childbearing age
Protection of the unborn child during diagnostic medical exposures

Local documentation to be added to this section:
Pregnancy protocols for patients
Pregnancy Waiver Form
Protocols for Comforters and Carers

Key Performance Indicators for this section;
Record kept of pregnancy status of females of childbearing age for all relevant procedures
Evidence of decision to proceed with imaging a pregnant patient
Record of incidents where foetus inadvertently received a radiation dose and appropriate action taken.
Evidence of waiver form and procedure

Relevant National Healthcare Standards;
Standards 2.1, 2.5 (Effective Care and Support)
Standard 3 (Safe Care and Support)
Section 4 Patient Pregnancy Protocols

The service should actively support and promote the safety of pregnant patients as part of a wider culture of quality and safety.

Legislation governing special protection of females of childbearing age

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.

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.
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.

INTRODUCTION
Under S.I. No. 478 (2002)1 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
Local Documentation for Section 4
Patient Pregnancy Protocols

Insert:
Pregnancy protocols for patients
Protocols for the protection of the unborn child during diagnostic medical exposures
Protocols for comforters and carers

NOTE:
If the local documentation is not held in this file please indicate where it is held and ensure that it can be easily accessed upon request and readily available to the relevant personnel.

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Location Held</th>
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<tbody>
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</tr>
</tbody>
</table>
Section 5
Patient Protocols

Contents
Referral Criteria
Patient Identification check
Procedure Matching
Patient Information
Justification
Patient consent
Optimisation
Imaging Protocols
Bio-Medical and Medical Research Projects
Health Screening

Local documentation to be added to this section:
Referral criteria
All patient protocols including;
Patient ID protocols
Procedure matching protocols
Patient Information leaflets
Justification protocols
Patient consent protocols
Optimisation protocols
Imaging Protocols
Bio-Medical and Medical Research Protocols, if applicable

Key Performance Indicators for this section;
Evidence of application of referral criteria
Evidence of patient identification and procedure matching checks
Evidence that valid consent was obtained from patient

Relevant National Healthcare Standards;
Standards 2.1, 2.5 (Effective Care and Support)
Standard 3 (Safe Care and Support)
Section 5 Protocols and Standards

The service should actively support and promote the safety of patients as part of a wider culture of quality and safety.

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, Independent Nurse Referrers etc.

The Royal College of Radiologists (UK) produced referral criteria guidelines (iRefer 2012). The NRSC and the Faculty of Radiologists have endorsed the use of these criteria "Making the best use of clinical radiology". The HSE has purchased on-line access (iRefer) for all facilities and staff involved in prescribing and using ionising radiation. (www.irefer.org.uk - Making the best use of Clinical Radiology).

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 is required where the patient is 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. For children under 16 years, the responsible parent or guardian should verify their identity.
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.

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 and that the completed image is recorded against the correct patient. 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](http://www.nrls.npsa.nhs.uk/resources/?EntryId45=73612)

Patient Information

Patients and other individuals involved should be given information on the risk of ionising radiation. Leaflets should be made available to patients about all radiological procedures and this information should be sufficient to enable the patient to make an informed decision balancing benefits and risks.

Justification

Justification is defined in the context of medical ionising radiation as:

**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”.

In Ireland, the practitioner and the prescriber have responsibility for justification.

**SI 478 (2002), Article 2 (Definitions)**

"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 prescribers, as required; giving information on the risk of ionising radiation to patients and other individuals involved, as appropriate.
Article 7

7.11. A prescriber shall state in writing on each individual prescription his or her reason for requesting the particular procedure and the practitioner shall make arrangements to satisfy himself or herself that the procedure as prescribed is justified.

7.12. The prescriber and 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.

So while the practitioner is clearly assigned clinical responsibility for the medical exposure, which includes justification, the prescriber does have some responsibilities in this area (Articles 7.11 and 7.12).

Guidance for Referrers for radiological investigations

The following prompt questions are recommended to be considered by Referrers for each radiological investigation using ionising radiation.

Is this the best investigation? - Imaging techniques undergo rapid change; it is often helpful to discuss an investigation with a radiologist before it is requested. The RCR Referral Criteria “iRefer” provide the basis for decision making for all radiological referrals. These guidelines have been recommended for use in Ireland by the Faculty of Radiologists and the National Radiation Safety Committee. It is also prudent to consider other non-ionising radiation imaging modalities such as ultrasound and magnetic resonance imaging.

Does the patient need the procedure? - Undertaking investigations when the results are unlikely to affect patient management should be avoided.

Have I outlined the clinical problem to the radiologist? - The best patient outcomes occur when Referrers provide appropriate clinical information. This allows the radiologist to focus on the clinical problem and write a targeted report.

Has the investigation been done recently? - Every attempt should be made to obtain previous images or reports which will help avoid repeat investigations.

Does the patient need it now? - Avoid undertaking investigations too early. Sometimes clinicians order tests prematurely or before the disease has progressed or before the results could influence treatment. Interval follow-up, whether short term or long term (whereby clinical assessment is repeated after a designated period) can, in some circumstances, establish the diagnosis without the need for radiology investigations. This can also be particularly relevant where the patient may be pregnant.

Have I sought consent from the patient or the guardian? - It is important to discuss the risks and benefits of the investigation with the patient and/or the parents of a child prior to ordering the investigation.

Is there a possibility that the patient could be pregnant? – It is important to ensure that pregnancy status is established and taken into account, given the benefits and risks to the unborn child.
Patient Consent

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

The National Consent Policy requires that the patient is informed, understands the risks and benefits and is given time to enable them to exercise the right to make an informed decision about their investigations and treatment.

“Consent is the giving of permission or agreement for an intervention, receipt or use of a service or participation in research following a process of communication about the proposed intervention. Consent must be obtained before starting a treatment or investigation. The need for consent is recognised in Irish and International law.

For the consent to be valid the service user must:
Have received sufficient information in a comprehensible manner about the nature; purpose and risks of an intervention / service or research project; 
Not to be acting under duress; and
Have the capacity to make the particular decision”

National Consent Policy37, HSE 2013, 

The amount of information to be provided about an intervention will depend on the urgency, complexity, nature and level of risk associated with the intervention and on the preferences of the person. Many decisions require the person to balance potential risks and benefits of the intervention and, in order to do so; he or she will need adequate information about:

- Their diagnosis and prognosis
- Options for treating or managing the condition, including the option not to treat
- The purpose of any proposed intervention and what it will involve
- The potential benefits, risks and the likelihood of success of any proposed intervention, as well as that of any available alternative

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 the near future.

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.

**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 exposure charts should be available for each piece of equipment, as appropriate. Protocols for local techniques should be available in close proximity to each X-ray machine.

**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”.

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 therapeutic benefit from this practice, the target levels of doses shall be planned on an individual basis by the practitioner”.

**Health Screening**

SI 459 (2010) outlines procedures to be followed when providing a health screening programme.
Local documentation for Section 5 Patient Protocols

Insert:
Referral criteria
All Patient Protocols including;
Patient ID Protocols
Procedure matching protocols
Patient Information leaflets
Justification protocols
Patient consent protocols
Optimisation protocols
Imaging Protocols
Bio-Medical and Medical Research Protocols, if applicable

NOTE:
If the local documentation is not held in this file please indicate where it is held and ensure that it can be easily accessed upon request and readily available to the relevant personnel.

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Section 6
Clinical Audit

Contents
Requirements for Clinical Audit in Medical Radiological Practices (Diagnostic Radiology, Radiotherapy and Nuclear Medicine)

Local documentation to be added to this section:
Table to Record Audit Activity
Audit tools
Minutes and actions taken of audit group
List of Audits Completed and Audit related reports, and changes implemented

Key Performance Indicators for this section;
Terms of Reference and membership of radiological clinical audit group available
Minutes of audit group available
Evidence that audits completed and evidence of action taken as a result of audit

Relevant National Healthcare Standards;
Standards 2.8 (Effective Care and Support)
Requirements for Clinical Audit in Medical Radiological Practices (Diagnostic Radiology, Radiotherapy and Nuclear Medicine)\textsuperscript{38}

Health Service Executive
Faculty of Radiologists

January 2011
Foreword

All health service providers and employees have a responsibility regularly to audit the clinical quality of the service they provide. A significant number of publications and requirements have been introduced, some specific to radiological practices. Providers and employees have requested guidelines on practical and effective ways of meeting this requirement. The HSE and the Faculty of Radiologists consulted with stakeholders to develop this guide which provides a summary of the relevant requirements, guidance on local structures and governance to enable providers. We, the undersigned, hope that its publication will serve to focus attention on what is a critical element in the safe and effective governance of any radiological health service.

This guide is the first in what its authors anticipate will be an iterative process. The more widely the guide is used, the more we will all learn about the most effective ways of conducting audits of this kind, and the better subsequent versions of the guide and related documents will be.

We would like to thank the team of the Medical Exposures Radiation Unit, HSE and the Faculty of Radiologists for the production of this publication and the National Radiation Safety Committee for their guidance. We are convinced that rigorous and effective clinical audit represents one of the most powerful tools at our disposal to improve the quality of the service we provide to patients, and we would urge all those who provide radiological health services to implement the recommendations within.

Dr Joe Devlin, Director, Quality Safety and Risk, HSE

Dr Risteard O’Laoide, Radiology Clinical Lead, HSE

Dr Adrian Brady, Dean, Faculty of Radiologists

Dr Sheelah Ryan, Chairman, National Radiation Safety Committee
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1. Introduction

This document outlines a summary of the requirements for Clinical Audit in Radiological Practice and a guide to the implementation of structures and processes for an effective audit cycle (appendix 4).

Clinical audit is “a systematic examination or review of medical Radiological procedures. It 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. Modifications of the practices are implemented where indicated and new standards applied if necessary.” (EC Directive 97/43 EURATOM (MED))

By comparing the practice of the service against the standards of good practice, clinical audits can inform the staff of the health care service and all other stakeholders about the essential elements of quality and the weak points of the overall clinical service. The audits will indicate areas for improvement and provide reassurance on issues such as safety and efficacy, all of which are essential to creating an environment of continuous development. In a blame-free environment, this can lead to an improved and more content situation for patients, staff and referring physicians.

The report of the Commission (2008) on Patient Safety and Quality Assurance “Building a Culture of Patient Safety” 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.”
Clinical Audit is a professional and organisational responsibility. E.U. Member States are required to implement Clinical Audit in Radiology “in accordance with national procedures” (EC Directive 97/43 Euratom (MED)). Statutory Instrument 478 (2002) and its amendments transposed the EU Directive into Irish law. This currently places a requirement on organisations to engage an external auditor, appointed by the HSE, to audit radiological practice every five years. The next audit is due to be completed by 2012.

As part of the enactment of Section 11 of the Medical Practitioner Act 2007, participation in clinical audit is now required for all registered medical practitioners. By May 2011, medical practitioners must enrol in a professional competence scheme and engage in professional competence activities. It is proposed in the Act that all Doctors should engage in clinical audit, and at a minimum participate in one audit exercise annually. The Act recommends that doctors spend a minimum one hour per month in audit activity.


The European Commission subsequently published Guidelines on Clinical Audit for Medical Radiological Practices (Diagnostic Radiology, Nuclear Medicine and Radiotherapy) in 2009 (RP 159) and these have been accepted by the Medical Council, the Faculty of Radiologists, the National Radiation Safety Committee and the HSE as best practice and are recommended for use in all Radiology departments. It is recognised that time and resources will need to be managed to ensure that performing clinical audit is part of normal daily activity in a radiology patient service. Clinical audit will highlight if the service provided is actually safe and effective and which issues need to be addressed at the Radiation Safety Committee meetings.

These guidelines state that clinical audit should be conducted in all aspects of Radiological services covering structure, process and outcomes. It should be a systematic and continuing activity with multidisciplinary involvement. EU Commission guidelines should guide all clinical audits within radiology departments. A document is attached which aims to summarise the European Commission Guidelines on Clinical Audit for Medical Radiological Practices (Diagnostic Radiology, Nuclear Medicine and Radiotherapy), 2009 (Appendix 1).

Guidelines on clinical audit for Radiologists have recently been issued by the Faculty of Radiologists as part of its Quality Assurance Programme. An excerpt from these guidelines is listed in Appendix 3.

The introduction of the proposed Health Information Bill and other national developments in clinical audit will further influence the requirement for audit. The HSE with the Faculty of Radiologists has set a date of review for this document for December 2012, or earlier if required.
3. Clinical Audit Structures, Processes and Accountability

The Clinical Audit Criteria of the Medical Council (2004) states that:

‘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.’

Since the publication of the Clinical Audit Criteria in 2004, there have been a number of developments in the implementation of clinical audit nationally. The first HSE National Baseline Audit of Radiological Practices (2008) made a set of recommendations concerning the structures and governance necessary to support a process of effective audit in this area. The EU Commission Guidelines on Clinical Audit for Medical Radiological Practices (Diagnostic Radiology, Nuclear Medicine and Radiotherapy), 2009, have been accepted for use in Ireland. In addition, the HSE has produced the document Excellence in Clinical Governance (2010). Specific recommendations on clinical audit have been made in the Building a Culture of Patient Safety - Report of the Commission on Patient Safety and Quality Assurance, 2008.

These documents, recommendations and implementations have been reviewed and the National Radiation Safety Committee (NRSC) has produced the following recommendations:

3.1 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 Appendix 5.

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 radiological 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. Each individual, both professionals and administrators, also has 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.

3.2 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.

3.2.1 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 (appendix 4) 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.
3.2.2 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.

3.3 Audit of Dental Practices

Dental practitioners and Holders should audit their practice in accordance with the Clinical Audit Criteria produced by the Dental Council. Where dental clinical audit committees exist in the public sector, it is recommended that their terms of reference are extended to include radiation issues. Their membership will differ to the above but should be reviewed and modified, where appropriate, in accordance with clinical governance criteria as established by the HSE.

In all other cases, Practitioners and Holder should implement a regular process of clinical audit in accordance with the criteria and guidelines as approved by professional guidelines. Reference can be made to the European Commission Guidelines on Clinical Audit for Medical Radiological Practices (Diagnostic Radiology, Nuclear Medicine and Radiotherapy), 200947.

3.4 Audit of Small Radiological Practices

It is recommended that small radiological practices link in with a local Radiation Safety Committee where possible. Where a practice does not have access to a Radiation Safety Committee or a Clinical Audit Committee, a process of regular clinical audit should be implemented, following the criteria and guidelines as approved by professional guidelines. The clinical audits will be available for review, as requested, by the HSE, as outlined in guidance to Holders issued in March 2010.

In addition to the ongoing programme for clinical audit, the CEO/Hospital Manager is required, in Statutory Instrument 478 (2002), 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 next external audits will commence in 2011 and are to be completed by 2012. A schedule of audits and chosen topics will be issued to all locations in advance of commencement of audit. Audits will be conducted by a multidisciplinary team appointed by the HSE, led by a Radiologist / Radiation Oncologist or Dentist.

The external audit topic chosen will be in accordance with the Clinical Audit Criteria. The team will also take into account priority areas such as:

- high dose/high risk/high volume procedures
- potential for benefit to practice and patient
- economic and efficient use of resources
- evidence of variation in current treatment approaches
- outcomes and feasibility of implementation

The external audit will check for evidence that there is an ongoing, effective cycle of clinical audit in place in the radiological facility (appendix 4).

5. How to Audit

The Royal College of Radiologists (UK) has an extensive list of audit recipes which could assist radiology departments in the selection of audits, “Clinical Audit in Radiology: 100 + Recipes” (1996) and Audit Live is available on its website www.rcr.ac.uk.

The following is a bibliography of documents providing guidance on clinical audit:


Section 6 Clinical Audit


5.1 Useful References


### 5.2 Websites

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Appendix 1
European Commission Guidelines on Clinical Audit

European Society of Radiologists’ summary:

Background
In October 2009, the European Commission published guidelines relating to clinical audit for radiological practice, including all investigations and therapies involving ionising radiation.


This is in line with the European Atomic Energy Community’s remit to establish uniform safety standards to protect workers and the general public from the dangers of ionising radiation. The relevant pre-existing Council Directives are 96/29 Euratom and 97/43/Euratom. The latter introduced the requirement for clinical audit of diagnostic radiology, nuclear medicine and radiotherapy. Article 6.4 in the section on procedures states that ‘Clinical audits shall be carried out in accordance with national procedures’. Clinical audit of procedures is therefore mandatory. The guideline gives recommendations and suggestions for the implementation of clinical audit in member states, taking a wide interpretation of the procedures/processes which should be audited. MRI and ultrasound imaging are not included, as the guideline covers only ionising radiation, although the same principles can be applied to these modalities.

This ESR document aims to summarise the guideline, but the EC document is 110 pages long, and the interested reader is referred to the original publication.

Definitions
Clinical audit in the document is defined as a ‘systematic examination or review of medical radiological procedures. It seeks to improve the quality and outcome of patient care through structured review whereby radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures. Modifications of practices are implemented where indicated and new standards applied if necessary.’

It emphasises that clinical audit is not research, quality system audit, accreditation or a regulatory activity but a multi-professional activity which is both scheduled and systematic, carried out by auditors with knowledge of the procedures, combine internal assessment of performance with external review, and identify areas for future improvement. All those involved in audit should respect the confidentiality of patient data, staff discussions, audit reports and other performance data. Much emphasis is placed on the difference between clinical audit and other quality systems and regulatory inspections, there being clear differences in the purpose, focus, scope, methods and the consequences of the results of the observations, their impact and use. Regulatory bodies should neither carry out clinical audits directly nor exclusively set up the criteria for the audits.
**Scope of clinical audit**

The document recommends that the whole patient pathway should be subject to clinical audit, under the categories of structure, process and outcome and that it should address both radiation protection for the patient and key components of the overall quality system, which are enumerated in the guidance. Under structure; lines of authority, radiation safety responsibilities, staff issues, premises and equipment are included. In process, justification and referral processes, protocol and process availability, optimisation procedures, patient dose, image quality, emergency incident procedures, and reliability of information transfer are key themes. Outcome audit includes methods for follow up of the outcome of examinations both short and longer term. This is acknowledged as providing the greatest challenge, particularly in relation to diagnostic accuracy.

The process is one of sampling of performance and comparing the results with a pre-selected standard of good practice. If the standard is not met, reasons for this are sought, changes implemented and a re-audit carried out to ensure improvement.

Standards may come from various sources, which are enumerated in the document.

**Internal vs. external audit**

Internal assessment within units or departments, which should employ standard audit methodology, is recommended as a systematic and continuing activity with a significant annual output of departmental audit data.

Emphasis is however placed on external clinical audit whereby an external auditing body or auditors carry out the audit. A cycle of external audit, carried out every 5 years is recommended. The guideline recommends the development of special auditing organisations to carry this out. These should preferably be non-profit organisations, if possible, supported by professional and/or scientific societies. These auditing organisations should be accredited by a national accreditation body. International audit services may be exploited where no national systems exist. Auditors would require a suitable professional background and would comprise a multidisciplinary team which could include radiologists, radiographers and medical physicists. They should have received specific training in audit and should be independent of the process/unit being audited.

The costs of the external audit process should be borne directly by the radiological unit unless the organisation of audits is carried out through a directly funded government body. The unit to be audited should foster an open and constructive atmosphere amongst its staff towards the process. Emphasis should be placed on avoiding misunderstanding, or confusion with other quality assessment activities.

The guideline suggests that a special national or regional advisory group, or steering committee of clinical experts, independent of the auditing organisations, may prove useful in the overall coordination and development of clinical audit implementation, criteria and procedures. The group should preferably be established by the Health Ministry or other government organisation, in order to ensure appropriate authority and financing. The role of professional/scientific societies, it is suggested, can be of great value in developing standards of good practice and in providing practical advice, stimulus and support for the establishment of appropriate clinical audit organisations.

**Conclusions**

For many, clinical audit will be a relatively new concept. This guideline reinforces EC support for the concept, and suggests how it may be developed nationally within member states.
Appendix 239

Criteria for Clinical Audit

Prepared by:
Faculty of Radiologists, Royal College of Surgeons in Ireland

Submitted to Council by:
Medical Ionising Radiation Committee on 7 October 2004

Adopted by Council on 11 October 2004

Available from:
Office of Education and Training
Medical Council of Ireland
Lynn House
Portobello Court
Lower Rathmines Road
Dublin
Criteria for Clinical Audit

SI 478 of 2002 European Communities (Medical Ionising Radiation) Regulations states:

15.1. The Medical and Dental Councils shall, within two years of the making of these regulations and in consultation with the Faculty of Radiologists of the Royal College of Surgeons of Ireland (RCSI), adopt criteria for clinical audit.

Clinical Audit is a quality improvement process that seeks to improve patient care and outcome through systematic review of care and comparison with explicit criteria followed by the implementation of change. Aspects of the structure, processes and outcomes of care are selected and systematically evaluated against explicit criteria. Improvements are then instituted and the process re-evaluated, thus completing the audit cycle.

This paper explains and sets out the criteria for clinical audit in relation to statutory instrument number SI 478 of 2002. This SI transposes the European Union Council Directive 1997/43/Euroatom of the 30th June 1997, on the health protection of individuals against the dangers of ionising radiation in relation to medical exposure and repealing directive 84/466/Euratom.

The specific section of SI 478 dealt with in this paper is Article 15. This process of audit is instituted to ensure that all installations and the professionals and staff who work in them conform to the EU Directive. In interpreting the regulations, accepted clinical practice is considered to be that course of action or opinion that the general body of the speciality of diagnostic radiology, and radiation oncology in Ireland would consider proper. The basic criterion of Clinical Audit is that the standard of practice in the installation under scrutiny should equate to what is regarded as reasonable practice by the general body of practitioners (as defined in the SI 478) in the country.

While conducting audit activities at an installation, due regard would be paid to the quantity and quality of the equipment, resources and staff which is available. Assessment of the clinical practice of radiology will be led by clinical radiologists, nuclear medicine physicians and radiation oncologists who are engaged in full time or nearly full time clinical practice, similar to the installations being audited. The advice of a radiography service manager, the medical physicist/radiation protection adviser or the radiation safety officer may be appropriate.

Clinical Audit shall be conducted, firstly to confirm conformity to the various sections of SI 478, as follows

7:1 Justification of each individual medical exposure is a clinical decision to be made by the practitioner. Published guidelines of indications for various examinations from UK, Europe and North America are not criteria and do not override the responsibility of the radiologist to make this decision.

7.3. High risk or high dose procedures in diagnostic radiology require particular attention, including interventional procedures, CT scanning, pregnancy and Paediatric Radiology

7.6. “Health screening programmes shall be undertaken only with a prior consent of the Minister, which he may refuse to give, and in accordance with such criteria as he or such persons that he might nominate may specify”.
As of this date, the only programme meeting these criteria is the Breast Check Programme.

7.7 New medical practices involving radiation exposure must have professional acceptance by the specialty or sub-specialty body within whose province they lie.

7.11 Requests for radiological exposure require a formal authorisation and appropriate clinical information, with previous records as appropriate.

8.9 Examinations shall conform to these regulations concerning medico legal practice, occupational health and research.

13 Individuals performing medical radiological procedures shall be appropriately trained and qualified under the regulations. Certification of continuing medical education will be sought when the national regulations have so provided.

NB Important to reflect this in the earlier sections 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. Does the committee meet on a regular basis with minutes of meeting? Have audit projects been conceived and carried through to conclusion with application of results to improve practice?

The emphasis should be on leadership, teamwork and support. The services of a permanent secretary are essential. Access to statistical, technical and information technology assistance may be required.

The auditors will give due notice of intention to audit the installation and will arrange to meet the practitioner in charge and members of the audit committee.

Audit activities are grouped as follows.

1. Structures - equipment and staffing levels
2. Processes, including quality assurance - how well do departmental processes work?
3. Outcomes - clinical outcomes are the best standard but are difficult to measure
4. Audit of doses and compliance with dose reference levels

There are very many specific criteria that may be evaluated and some are listed below:

A. Key indicators in radiological installations

1. Work Load
2. Access-waiting times and cancellations
3. Time from attendance for procedure to delivery of report to prescriber.
4. Time from dictation of report to delivery of report to prescriber.
5. Justification for prescribing procedures
6. Records – Delay or failure to obtain records
B. Critical events in diagnostic radiology

1. Films per examination, film reject rate.
2. Lost films, reports
3. Unplanned repeat films
4. Diagnostic accuracy
5. Complications of invasive procedures
6. Reactions to contrast media

C. Criterion based audit.

A specific topic may be selected in a particular installation. Items here are any areas of local concerns, areas of variation from usual practice, areas of perceived high risk. Information provided for audit purposes should be confidential and used only for the purposes of audit.

Perhaps the most important resource required for audit is time. Workloads continue to rise inexorably and administration, teaching and research compete for audit time. In the UK the equivalent of one half session per week (around one and a half hours) was suggested as an appropriate amount of protected time for audit.

One of the causes of failure of the audit process is the absence of a clear standard against which to audit. Standard may be based on local agreement, consensus statements, results of research and recommendations from learned societies.

The role of the Faculty of Radiologists in audit is the promotion of standards e.g. referral criteria, training guidelines, quality and management guidelines against which audit projects can be measured. In addition the Faculty promotes audit by supporting the provision of adequate resources and as a requirement for training and for CME/CPD. Ultimately the aim is to improve Irish radiological services by comparing actual practice with generally agreed standards and to bring the two as close together as possible.

The process of Clinical Audit under current regulations is developing and the Medical Ionising Radiation Committee with the Faculty of Radiologists is willing to revisit this document when criteria for clinical audit are adopted.
Appendix 3

Faculty of Radiologists (2010)

‘Guidelines for the Implementation of a National Quality Assurance Programme in Radiology - Version 1.0’

Extract on Clinical Audit:

Clinical Audit
As part of the enactment of Section 11 of the Medical Practitioner Act 2007, participation in clinical audit is now required for all registered medical practitioners. By May 2011, medical practitioners must enrol in a professional competence scheme and engage in professional competence activities. It is proposed in the Act that all Doctors should engage in clinical audit, and at a minimum participate in one audit exercise annually. The Act recommends that doctors spend a minimum one hour per month in audit activity.

The Faculty of Radiologists, RCSI, will facilitate the formalisation of audit activities for Radiology by:

a) Including regular audit activity as part of the Radiology Registrar Training Programme
b) Encouraging health service providers to resource the audit process with both personnel and time
c) Encouraging Radiology departments to undertake standard radiology audit cycle menus annually (e.g. Royal College of Radiologists Audit Live) and
d) Organising national audits as necessary

Clinical audit is a quality improvement process and this document recommends a number of clinical audit activities in which a Radiology Department should be engaged.

1.5 Focused Audit
Currently ad hoc audit is a frequent activity in many Radiology Departments but may not be recorded in a formalised manner or credit given for participation. As part of the enactment of Section 11 of the Medical Practitioner Act 2007, participation in clinical audit is now required for all registered medical practitioners. Clinical audit should be conducted in all aspects of Radiology services covering structure, process and outcomes. Routine focused audit of report turnaround time and report completeness should be conducted. Local protocol will determine what other audit(s) to conduct, frequency of audit(s) and number of cases to be considered. As far as possible the audit cycle should be completed through the implementation of change and the assessment of improvements made.
The Royal College of Radiologists (UK) has an extensive list of audit recipes which could assist radiology departments in the selection of audits.

**Key Quality Indicators**
- Number of Audits
- Audit Type

Individual can be divided into the following categories:
- Structure
- Process
- Outcome
- % of Audits with Audit Cycle complete

### 2.4 Focused Audit, Interventional Radiology
Audit should be used by all practitioners of radiology be it basic biopsy and drainage work or more complex embolisation work. For interventional Radiologists these audits should be steered towards patient outcome, procedure success, complication rate and patient experience.

Within the Royal College of Radiologists (UK) list of audit recipes there is a category for audits which are applicable to Interventional Radiology which could assist radiology departments in the selection of audits. Link to RCR Audit Live - Intervention Audits

**Key Quality Indicators**
- Number of Audits performed
- Number of Audits where the audit cycle is completed
- Audit Type: audits can be based on any aspect of interventional practice including,
  - Indications for procedures
  - Patient (and procedure) outcomes
  - Radiation exposure
  - Equipment and disposable usage
  - Procedure success
  - Complication rate
  - Peri-procedural care
  - Patient experience
Appendix 4

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
Appendix 5

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.

Diagram showing the relationship between CEO, Hospital Board, Clinical Director, Practitioner in Charge, Clinical Lead for Radiology Audit, Radiation Safety Officer, Individual Clinician, Clinical Governance Committee and/or Hospital Clinical Audit / Risk / Patient Safety Committee, Radiation Safety Committee, Radiology Clinical Audit Working Group.
Local Documentation for Section 6 Clinical Audit

**Insert:**
Audit tools
Minutes and actions taken of audit group
List of Audits Completed and Audit related reports, and changes implemented

**NOTE:**
If the local documentation is not held in this file please indicate where it is held and ensure that it can be easily accessed upon request and readily available to the relevant personnel.

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<th>Location Held</th>
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</tbody>
</table>
SAMPLE TABLE TO RECORD AUDIT ACTIVITY:

### 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.

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<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>
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<td>Justification/ referral criteria</td>
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<td>Patient Dose / Diagnostic Reference Levels</td>
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<td>Treatment preparation/verification</td>
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<tr>
<td>Treatment prescription</td>
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<td>Planning procedures</td>
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<tr>
<td>Treatment delivery</td>
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<td>In vivo Dosimetry</td>
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<td>Record and Verify</td>
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<td>Imaging for treatment verification (image guided RT)</td>
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Section 7

Diagnostic Reference Levels (DRLs)

Contents

Establishment and Use of Diagnostic Reference Levels (DRLs)
Review of DRLs
Definition of DRL
National, European and International DRLs
Irish Paediatric DRLs.
Information on Patient Radiation Doses, Ireland
Band Classification of the Typical Doses of Ionising Radiation from Common Imaging Procedures

Local documentation to be added to this section:
Local DRLs for each procedure (sample template enclosed)

Key Performance Indicators for this section;
Evidence that local DRLS have been set and reviewed annually against the national / other benchmarks
Evidence of action taken to improve DRLs

Relevant National Healthcare Standards;
Standard 2 (Effective Care and Support)
Section 7 Diagnostic Reference Levels (DRLs)

Establishment and Use of Diagnostic Reference Levels (DRLs)

Diagnostic Reference Levels (DRLs) have been established for the most common Irish procedures. The DRL is generally determined as the 75th percentile of the average relevant dose measure for that procedure.

Service providers are required to establish and use DRLs for each of their routine procedures.

Review of DRLs

DRLs should be reviewed annually or when there is a significant change in protocol or where they are consistently exceeded. The review of DRLs should compare local with national or referenced averages and a note made of any significant variances to these averages and the justification for it. The local DRLs can be higher or lower than the national DRLs depending on the imaging equipment available to them or the patient casemix of that location. This regular review provides opportunity to provide feedback to ensure good practice in medical exposures is maintained.

A sample template to record and review CT DRLs for locations is under local documentation in this section. This template can be adapted to set DRLs for locations for all diagnostic procedures.

Locations should keep a record of their average doses, their DRLs and annual figures on patient activity. This information will be requested from locations to assist in determining medical ionising radiation doses received by the Irish population.

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.

National, European and International DRLs

The Medical Council is required to promote the establishment of DRLs and has published a position paper on DRLs in 2004 outlining DRLs for use; [http://www.medicalcouncil.ie/About-Us/Legislation/Medical-Ionising-Radiation/Diagnostic-Referance-Levels-03-12-2004.pdf](http://www.medicalcouncil.ie/About-Us/Legislation/Medical-Ionising-Radiation/Diagnostic-Referance-Levels-03-12-2004.pdf).

Since then, national surveys have produced average doses and from these, more recent DRLs can be established and are outlined below. These are the national benchmarks against which local DRLs can be compared. As new surveys are produced, these national DRLs will be reviewed.
### Section 7 Diagnostic Reference Levels (DRLs)

<table>
<thead>
<tr>
<th>Diagnostic Procedure</th>
<th>Entrance Surface Dose mGy</th>
<th>75&lt;sup&gt;th&lt;/sup&gt; Percentile DAP Gycm2</th>
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<tr>
<td>DENTAL&lt;sup&gt;1&lt;/sup&gt;</td>
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<td>Intra-Oral</td>
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<td>GENERAL XRAY&lt;sup&gt;2&lt;/sup&gt;</td>
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<td>75&lt;sup&gt;th&lt;/sup&gt; Percentile Activity (MBq)</td>
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<td>Chest PA</td>
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<td>Lumbar Spine Lat</td>
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<td>Lumbar Sacral Junction</td>
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<td>Full Spine (C+T+L)</td>
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<td>Skeletal Survey</td>
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<td>Abdominal AP</td>
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<td>Pelvic AP</td>
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<td>Femur AP</td>
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<td>Femur Lat</td>
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<td>Knees AP/Lateral</td>
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<td>NUCLEAR MEDICINE&lt;sup&gt;2&lt;/sup&gt;</td>
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<td>75&lt;sup&gt;th&lt;/sup&gt; Percentile Activity (MBq)</td>
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<td>131-I Thyroid metastases</td>
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<td>123-I DAT Scan</td>
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<td>123-I MIBG Scan</td>
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<td>111-In OctreoScan</td>
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<td>99mTc Myocardial Scan</td>
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<tr>
<td>99mTc Cerebral blood flow</td>
<td>800</td>
<td></td>
</tr>
</tbody>
</table>
### References

1) Diagnostic Reference Levels. Dental Council  
4) Preliminary results, Population Dose from PET_CT. HSE MERU 2013\(^{40}\)  
5) Preliminary results, Population Dose from Interventional Radiology. HSE MERU 2013\(^{41}\)

European DRLs were established by the Dose Datamed II project undertaken by the European Commission. The results were published in 2013 and are available here;  

Guidance on diagnostic reference levels in Nuclear Medicine is available from ARSAC. Administration of Radioactive Substances Advisory Committee (ARSAC); [www.arsac.org.uk/\(^{42}\)](http://www.arsac.org.uk/)

### Table: Diagnostic Reference Levels (DRLs)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>75(^{th}) Percentile Activity (MBq) / DLP (mGy.cm)</th>
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</thead>
<tbody>
<tr>
<td><strong>PET/CT</strong></td>
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<tr>
<td>Whole Body</td>
<td>375 MBq / 800 mGy.cm</td>
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<td>Brain</td>
<td>290 MBq / 290 mGy.cm</td>
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<tr>
<td><strong>CT</strong></td>
<td>75(^{th}) Percentile DLP (mGy.cm)</td>
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<tr>
<td>Brain</td>
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<tr>
<td>Cervical Spine</td>
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<td>Abdomen/Pelvis</td>
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<td>Thorax/Abdomen/Pelvis</td>
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<td><strong>FLUOROSCOPY &amp; INTERVENTIONAL</strong></td>
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<td>Orthopaedics</td>
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<td>Oesoph &amp; Stomach &amp; small intestine</td>
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<td>Colon</td>
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<td>Biliary tract</td>
<td>16.4</td>
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<tr>
<td>Cerebral procedures</td>
<td>56.0</td>
</tr>
<tr>
<td>All IV lines, e.g. Hickman</td>
<td>2.76</td>
</tr>
<tr>
<td>TIPS</td>
<td>144.4</td>
</tr>
<tr>
<td>All Thoracic procedures</td>
<td>7.80</td>
</tr>
<tr>
<td>All Abdominal procedures</td>
<td>51.6</td>
</tr>
<tr>
<td>All Pelvic procedures</td>
<td>79.0</td>
</tr>
<tr>
<td>All Peripheral procedures</td>
<td>29.1</td>
</tr>
<tr>
<td>Cardiac studies</td>
<td>53.1</td>
</tr>
<tr>
<td>PTCA</td>
<td>62.0</td>
</tr>
<tr>
<td>Pacemaker</td>
<td>2.76</td>
</tr>
</tbody>
</table>
Paediatric DRLs

Particular attention needs to be given to establish separate DRLs for paediatrics for different ages. Below are recommended DRLs for paediatric CT. There are a number of published research articles on paediatric DRLs available in Ireland or internationally which should be taken in to account when setting a benchmark from which to compare local DRLs.

<table>
<thead>
<tr>
<th>Diagnostic Procedure</th>
<th>Age</th>
<th>75th Percentile DLP (mGy.cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT</td>
<td>Age</td>
<td>75th Percentile DLP (mGy.cm)</td>
</tr>
<tr>
<td>Brain</td>
<td>Newborn</td>
<td>340</td>
</tr>
<tr>
<td></td>
<td>1-4 years</td>
<td>470</td>
</tr>
<tr>
<td></td>
<td>5-9 years</td>
<td>620</td>
</tr>
<tr>
<td></td>
<td>10-15 years</td>
<td>850</td>
</tr>
<tr>
<td></td>
<td>Adult</td>
<td>950</td>
</tr>
<tr>
<td>Abdomen/Pelvis</td>
<td>Newborn</td>
<td>130</td>
</tr>
<tr>
<td></td>
<td>1-4 years</td>
<td>160</td>
</tr>
<tr>
<td></td>
<td>5-9 years</td>
<td>230</td>
</tr>
<tr>
<td></td>
<td>10-15 years</td>
<td>400</td>
</tr>
<tr>
<td></td>
<td>Adult</td>
<td>640</td>
</tr>
</tbody>
</table>

References

### Information on Patient Radiation Doses, Ireland

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

<table>
<thead>
<tr>
<th>Ionising Radiation</th>
<th>Typical Effective Dose* in millisieverts²</th>
<th>Equivalent Period of Natural Background Radiation¹</th>
<th>Lifetime Additional Risk of Fatal Cancer per Single Examination³#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limbs and joints (excluding hip)</td>
<td>&lt;0.01mSv</td>
<td>one hour</td>
<td>&lt;1 in 100 million</td>
</tr>
<tr>
<td>Teeth, intra-oral</td>
<td>0.05mSv</td>
<td>&lt;1 day</td>
<td>1 in 4 million</td>
</tr>
<tr>
<td>Teeth, panoramic</td>
<td>0.02mSv</td>
<td>2 days</td>
<td>1 in 1 million</td>
</tr>
<tr>
<td>Chest PA x-ray</td>
<td>0.02mSv</td>
<td>2 days</td>
<td>1 in 1 million</td>
</tr>
<tr>
<td><strong>Return airplane flight Dublin – Rome</strong></td>
<td><strong>0.027mSv</strong></td>
<td><strong>2 days</strong></td>
<td>1 in 750,000</td>
</tr>
<tr>
<td>Cervical spine AP&amp; Lat. x-ray</td>
<td>0.07mSv</td>
<td>1 week</td>
<td>1 in 300,000</td>
</tr>
<tr>
<td>Hip x-ray</td>
<td>0.2mSv</td>
<td>3 weeks</td>
<td>1 in 100,000</td>
</tr>
<tr>
<td>Pelvis AP x-ray</td>
<td>0.3mSv</td>
<td>1 month</td>
<td>1 in 70,000</td>
</tr>
<tr>
<td>Thoracic Spine AP&amp; Lat x-ray</td>
<td>0.4mSv</td>
<td>1.5 months</td>
<td>1 in 50,000</td>
</tr>
<tr>
<td>Abdomen AP x-ray</td>
<td>0.4mSv</td>
<td>1.5 months</td>
<td>1 in 50,000</td>
</tr>
<tr>
<td>Lumbar Spine AP&amp; Lat x-ray</td>
<td>0.6mSv</td>
<td>2 months</td>
<td>1 in 35,000</td>
</tr>
<tr>
<td>Barium follow-through</td>
<td>1.2mSv</td>
<td>4 months</td>
<td>1 in 17,000</td>
</tr>
<tr>
<td>NM 99mTc Thyroid Scan</td>
<td>1.3mSv</td>
<td>5 months</td>
<td>1 in 15,000</td>
</tr>
<tr>
<td>NM 99mTc Renogram</td>
<td>1.3mSv</td>
<td>5 months</td>
<td>1 in 15,000</td>
</tr>
<tr>
<td>CT Brain / Head</td>
<td>1.7mSv</td>
<td>6 months</td>
<td>1 in 12,000</td>
</tr>
<tr>
<td>NM 99mTc Ventilation/Perfusion</td>
<td>3.22mSv</td>
<td>1 year</td>
<td>1 in 6,200</td>
</tr>
<tr>
<td><strong>One year’s natural background radiation Ireland</strong></td>
<td><strong>3.4mSv</strong></td>
<td><strong>1 year</strong></td>
<td><strong>1 in 5,900</strong></td>
</tr>
<tr>
<td>NM 99mTc Bone Scan</td>
<td>3.5mSv</td>
<td>1 year</td>
<td>1 in 5,700</td>
</tr>
<tr>
<td>Barium enema</td>
<td>3.6mSv</td>
<td>1 years</td>
<td>1 in 5,500</td>
</tr>
<tr>
<td>PTCA</td>
<td>7mSv</td>
<td>2 years</td>
<td>1 in 3,000</td>
</tr>
<tr>
<td>CT of Chest / Thorax</td>
<td>7mSv</td>
<td>2 years</td>
<td>1 in 3,000</td>
</tr>
<tr>
<td>CT of Abdomen and Pelvis</td>
<td>8mSv</td>
<td>2.4 years</td>
<td>1 in 2,500</td>
</tr>
<tr>
<td>Interventional Radiology (abdominal)</td>
<td>8.5mSv</td>
<td>2.5 years</td>
<td>1 in 2,500</td>
</tr>
<tr>
<td>Interventional Cardiac</td>
<td>11mSv</td>
<td>3.2 years</td>
<td>1 in 2,000</td>
</tr>
<tr>
<td>CT of Chest, Abdomen and Pelvis</td>
<td>13mSv</td>
<td>3.8 years</td>
<td>1 in 1,500</td>
</tr>
<tr>
<td>NM 131-I Thyroid Uptake Scan</td>
<td>47mSv</td>
<td>14 years</td>
<td>1 in 425</td>
</tr>
</tbody>
</table>

* where Irish data is not available reference data from the UK⁴ has been used
#based on 5% per Sv within age group 18-64years

1) Radiation Doses Received by the Irish Population, RPII, 2008.
2) Medical Exposure Radiation Unit Publications on CT, Dental, General and Nuclear Medicine Patient Radiation Doses, 2009 – 2013;
3) National Cancer Registry of Ireland (NCRI) (www.ncri.ie)
4) 2007 recommendations of the International Commission on Radiological Protection ICRP Publication 103, Annals of the ICRP vol 37¹⁴
5) Patient Dose Information, Public Health England website⁴⁵,
Band Classification of the Typical Doses of Ionising Radiation from Common Imaging Procedures

Typical effective doses for radiological examinations and associated risks as presented in “iRefer Making the Best us of Clinical Radiology” V 7.0.1. Royal College of Radiologists.

<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 (e.g., 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 (e.g., 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 (e.g., 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.]
Local Documentation for Section 7 Diagnostic Reference Levels (DRLs)

Insert:
Local DRLs for every procedure
Annual number of patients per common procedures for all modalities.

NOTE:
If the local documentation is not held in this file please indicate where it is held and ensure that it can be easily accessed upon request and readily available to the relevant personnel.

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Location Held</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Sample Template to record and monitor local DRLs (can be adapted for all exams)

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>CT Procedures</th>
<th>Reference (^1) DLP mGy.cm</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

Reference
1 Population Dose from CT Scanning 2009. HSE report 2011
The accuracy, quality and relevance of these works are 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.

2. Recommendations of International Commission for Radiological Protection (ICRP 60), 1990
10. SI 218 Pregnant Employees Regulations, 2000
11. Radiological Protection (Amendment) Act No 3 of 2002
20. Requirements for Clinical Audit in Medical Radiological Practices (Diagnostic Radiology, Radiotherapy and Nuclear Medicine), HSE and Faculty of Radiologists, 2011
21. The Use of Lead Aprons in Dental Radiology - Joint position statement by the RPII and HSE., 2011
22. Guidelines on the protection of the unborn child during diagnostic medical exposures (RPII), 2010
25. Radiation Doses Received by the Irish Population (RPII), 2008
26. Code of Practice on the Design of Diagnostic Medical Facilities where Ionising Radiation is used (RPII), 2009
27. Guidelines for reporting incidents to the RPII – Document no 13/03 RPII, 2003
30. Licensing requirements for ionising radiation equipment, RPII
33. Guidelines for Reporting and Learning from Patient Safety Incidents from Medical Ionising Radiation. HSE, NRSC, 2010
34. Root causes Analysis Fishbone Diagram Tool. NHS, 2010
38. Requirements for Clinical Audit in Medical Radiological Practices (Diagnostic Radiology, Radiotherapy and Nuclear Medicine) HSE And Faculty of Radiologists, 2011
40. Preliminary Results, Population Dose PET_CT. HSE MERU, 2013
42. Guidance on Diagnostic Reference Levels in Nuclear Medicine. ARSAC.
43. Information on Patient Radiation doses Ireland HSE. MERU 2013
44. Recommendations of the ICRP, Publication 103, 2007
45. Patient Dose Information, Public Health England
APPENDIX I

List of stakeholders consulted with on the Patient Radiation Protection Manual and members of the Medical Exposure Radiation Unit

Stakeholders:

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Role</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>
</tbody>
</table>

Members of the Medical Exposure Radiation Unit developed the guidance document and the National Radiation Safety Committee provided advice and direction.

Membership, Medical Exposure Radiation Unit:

<table>
<thead>
<tr>
<th>Member</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<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>
<tr>
<td>Dr Peter Finnegan</td>
<td>Specialist Public Health Medicine</td>
</tr>
<tr>
<td>Mr Martin Sheridan</td>
<td>Radiotherapy Medical Physics Advisor</td>
</tr>
</tbody>
</table>
APPENDIX II

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.

• **Medico legal 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
  - a person whose name is entered on the register established under Section 26 of the Dentists Act, 1985; 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 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.