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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<td>1/8/2013</td>
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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 S1 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 measureable 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

Basic Safety Standard
BSS 96/26/EURATOM

Medical Exposure Directive 97/43/EURATOM

Patients

Transposed into Irish Legislation

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

Protection of Workers and the Public


Dept of Health/HSE

Protection of the Patient

Patient Radiation Protection Manual

Radiation Protection Legislation Structure
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:

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.
4. 2010 Guidelines for reporting patient safety incidents from medical ionising radiation (Section 3 of this manual).
5. 2011 Population Dose from CT Scanning 17.
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.
4. 2008 Radiation Doses Received by the Irish Population (RPII) 25.
6. 2009 Guidelines for reporting incidents to the RPII 27.
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

Accessed 6th August 2013,
http://www.rpii.ie/Licensing/Licensing-%E2%80%93-what-you-need-to-know.aspx

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>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
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<tr>
<td>Hospital Level 1 (HL1)</td>
<td>Licensee with only one simple (general, mobile, chest, mammography etc) X-ray unit. Non-simple X-ray units would include CT, interventional, fluoroscopy etc – these would be covered in HL2.</td>
</tr>
<tr>
<td>Hospital Level 1 – Bone Densitometer</td>
<td>Licences who use DXA units only</td>
</tr>
<tr>
<td>Hospital Level 2 (HL2)</td>
<td>Licensee with either one non simple X-ray units (CT, fluoroscopy) or multiple X-ray units (e.g. multi room hospital, clinic etc).</td>
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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>
</tr>
<tr>
<td>Hospital Level 3 (HL3)</td>
<td>Licensee who uses unsealed radioactive sources for in-vitro application only. These licensees may also have diagnostic X-ray units</td>
</tr>
<tr>
<td>Hospital Level 3 – Transportation</td>
<td>A HL3 hospital who is additionally licensed for the transport of radioactive sources</td>
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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>
</tr>
<tr>
<td>Hospital Level 4 Transportation</td>
<td>A HL4 hospital who is additionally licensed for the transport of radioactive sources</td>
</tr>
<tr>
<td>Hospital Level 5 (HL5)</td>
<td>Licensee who uses radiotherapy equipment e.g. linear accelerator, Co-60, brachytherapy etc. These licensees may also have diagnostic and nuclear medicine facilities.</td>
</tr>
<tr>
<td>Hospital Level 5 – Transportation</td>
<td>A HL5 hospital who is licensed for the transport of radioactive sources</td>
</tr>
<tr>
<td>Chiropractor</td>
<td>Licensee uses one or more X-ray units for diagnostic procedures</td>
</tr>
<tr>
<td>Cyclotron Radiopharmaceutical Production</td>
<td>Licensee uses a cyclotron for the manufacturer 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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</table>

#### BAND - Dental

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental Level 1</td>
<td>Dentists in private practice (no limit on number of X-ray units)</td>
</tr>
<tr>
<td>Dental Level 2</td>
<td>Government Departments (Defence and Justice)</td>
</tr>
<tr>
<td>Dental Level 2– Dublin Dental Hospital</td>
<td>Third level teaching hospital</td>
</tr>
<tr>
<td>Dental Level 3</td>
<td>HSE Dental Clinics.</td>
</tr>
</tbody>
</table>