

UNIVERSITY OF LIMERICK

RADIATION SAFETY PLAN

Revision 5. 11 March 2020

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**1. RADIATION SAFETY POLICY STATEMENT**

The University of Limerick is committed to protecting the health and safety of on-site personnel, students, the general public, and the environment, from hazards which may arise through the use of ionizing radiation. To this end, a Radiation Safety Committee has been appointed to advise on Radiation Safety Policy. Responsibility for implementing Radiation Safety Policy is vested in the Heads of Departments where Ionising Radiation is used.

The Radiation Safety Committee have approved this Radiation Safety Plan which defines the scope of work and identifies radiation hazards, recommends appropriate hazard controls, identifies responsibilities, and proposes continuous improvement measures. A Radiation Protection Officer (RPO) has been appointed to oversee the implementation of the plan and the implementation of departmental hazard controls (i.e. Radiation Safety Procedures). Department Heads will be assisted in discharging their responsibilities for Radiation Safety by the RPO, and by delegated Departmental Radiological Protection Supervisors. The following general principles will be observed when developing procedures and implementing hazard controls;

* All operations will be conducted such that exposure to ionizing radiation is maintained as low as reasonably achievable and shall be justified by the advantages which they produce.
* All applicable laws, regulations, dose limits, and best management practices will be observed.
* All employees will be appropriately trained and competent to perform their duties safely.
* Procedures will be put in place to anticipate future hazards (e.g. introduction of new practices) or to deal with emergencies.
* We will ensure that all relevant employees understand the content and importance of this Policy, and in turn, employees are responsible for integrating policy considerations into their own work activities.
* Employees have the authority and responsibility to stop, or not perform, any task when there is a reasonable belief that the task poses imminent risk of serious injury or unjustified radiation exposure. In such a case, the employee must report this to their supervisor immediately.

The need to learn from successes and deviations from expected outcomes is also recognized, and staff members are encouraged to both report these instances and provide feedback. The plan will be subject to review, based on the outcome of the audits, or in response to legislative changes or reports of oversights or hazardous situations.

This plan will be integrated into the overall health and safety plan for the institution

**2. SCOPE**

 This plan sets out the overall policy and methodology for radiation safety in the University of Limerick. The scope of the plan extends to all departments where ionizing radiation is used for educational or research purposes. The plan is approved by the Radiation Safety Committee, and will be subject to regular review and continuous improvement.

**3. RESPONSIBILITY**

**3.1. The Undertaking**

Radiation safety of staff, students, and members of the public, is the responsibility of the University of Limerick (henceforth referred to as the Undertaking). The Undertaking must ensure compliance with all applicable laws, regulations, and best management practices, including the conditions of the licence issued by the EPA Office of Radiological Protection & Environmental Monitoring (ORM), and where relevant, regulations issued by the Health Information & Quality Authority (HIQA). A local Radiation Safety Committee has been appointed to advise on policies to ensure compliance with statutory regulations and standards of best practice. Responsibility for implementation of policy, and ensuring the radiation safety at departmental level is vested in the Department Heads. A Radiation Protection Officer (RPO) has also been appointed to oversee implementation of the policy, and Departmental Radiological Protection Supervisors (DRPS) have been delegated to assist Department Heads in discharging their responsibilities.

An outline of the administration of radiation protection in the University is presented in Appendix A.

**3.2. The Radiation Safety Committee.**

The Radiation Safety Committee (RSC) is appointed by the Undertaking to direct radiation safety policy in line with all relevant laws and regulations, and best management practices. As such, the RSC is responsible for recommending and reviewing this plan. The scope of the committee also includes radiation safety of persons undergoing DEXA scans. The RSC will include a representative from each department where ionizing radiation is used (normally the DRPS). In addition, it includes the RPA and the RPO, who acts as chairperson. The RPO also acts as the Management and Health & Safety representative on the committee to maintain links with other health and safety groupings in the University. Clerical support should be provided to ensure that an appropriate record is maintained of all meetings.

The RSC will meet at least once per year, or as necessary, to discuss and issue guidelines on any issues arising under the standing agenda (appendix. B) or any other issues arising relating to radiation safety, including research proposals involving the use of ionizing radiation. The committees will also consider future hazards (e.g. introduction of new practices) and/or emergency procedures, as well as any relevant new or proposed legislation and guidelines.

**3.3. The Radiation Protection Adviser & The Medical Physics Expert**

The Holder is required to appoint a Radiation Protection Adviser (RPA) (from the ORM register of RPA’s) as a condition of the EPA licence, and a Medical Physics Expert (MPE) as a requirement of S.I. 256 of 2018 in relation to DEXA scanning. The roles of the RPA and MPE are generally assumed by an appropriately qualified medical physicist. The RPA has specific responsibilities in relation to risk assessment, commissioning, and advising on the use or modification of licensable items or practices. Further details on these various roles can be found in the EPA licence conditions. The MPE must advise the holder on dose optimization and suitability of irradiating equipment for exposing individuals for research purposes, as set out in S.I. 256 of 2018.

**3.4.** **The Radiation Protection Officer**

 The Radiation Protection Officer has an oversight role in ensuring that the University Radiation Safety Plan and local Radiation Safety Procedures are implemented. The Role of the RPO is normally be assumed by a member of the Health & Safety Department, who will also act as Chairperson of the Radiation Safety Committee. The RPO is authorized to enforce radiation safety procedures, and has the authority to temporarily suspend activities involving ionizing radiation deemed to be unsafe, pending consideration by the Radiation Safety Committee.

**3.5. Heads of Departments.**

The responsibility for the radiological safety of employees, students and visitors within the agreed boundaries of departments is vested with the Heads of Departments.

The Heads of Departments must ensure that their Departments comply with the legal obligations set out in the Radiological Protection Act, 1991 (Ionising Radiation) Order, 2019 (SI No 30 of 2019) and the EPA licence. Heads of Departments must also ensure that their staff and students adhere to the University of Limerick Radiation Safety Plan, as well as all Radiation Safety Procedures relevant to their departments

**3.6. Departmental Radiological Protection Supervisors**

A senior member of the Departmental staff with the appropriate experience and/or training is delegated as Departmental Radiological Protection Supervisor (DRPS) to assist the Department Head in discharging his/her responsibilities for radiation safety. He/she should exercise close supervision to ensure that the work is done in accordance with the local radiation safety procedures, though he/she need not be present all the time. The DRPS should;

(a) know and understand the requirements of the regulations, licence and local rules as they affect the work he/she supervises;

(b) commands sufficient respect from the people doing the work as will allow him/her to exercise supervision of radiation protection and;

(c) understands the necessary precautions to be taken in the work that is being done and the extent to which these precautions will restrict exposures.

 (d) ensure that radiation safety policies and documentation are distributed to relevant staff and implemented.

**3.7. Users of Irradiating Apparatus or Radioactive Sources.**

In addition to the general responsibilities of workers under the Safety, Health & Welfare at Work Act 2005, users of irradiating apparatus have specific responsibilities as set out in the Radiation Safety Procedures and Working Instructions for the department concerned (section 6). Irradiating apparatus or radioactive sources may only be used by persons, or under the direct supervision of persons, who have been so authorized by the DRPS. All researchers and lecturers/demonstrators using ionizing radiation must read the radiation safety plan and the radiation safety procedures and sign/date a declaration that they have done so. This declaration will be held by the DRPS.

In addition to the departmental Radiation Safety Procedures, all radioactive sources or irradiating apparatus used for demonstration purposes must be used in accordance with a Standard Operating Procedure which includes details on safe use/handling of the specific source/apparatus. The custodian of the source (e.g. lecturer, course leader, or principal investigator) is responsible for identifying the hazards associated with the experiment/demonstration, and for preparing a suitable SOP to minimize the risk, where one does not already exist. In the case of radioactive sources, the lecturer or course leader must formally take custody of the source from the DRPS and accept responsibility for ensuring that procedures are followed to ensure the safety of other staff, students, and members of the public. He/She must also accept responsibility for the security of the source and its safe return to the custody of the DRPS.

**3.8.** **Users of Irradiating Apparatus for Medical or Research Exposures.**

Radiation protection of persons receiving medical exposures is the responsibility of the Governing Authority as the Undertaking. Regulations in S.I. 256 of 2018 must be implemented, and any relevant guidelines issued by the Health Information & Quality Authority (HIQA), as the competent authority, must be observed. A declaration of undertaking form has been sent to HIQA identifying the undertaking representative, as well as a Designated Manager for liaising with HIQA on day to day regulatory matters.

 A list must me maintained by the undertaking of all qualified Practitioners, who are authorized to take clinical responsibility for exposures, as well as appropriately qualified persons who are delegated to carry out the practical aspects of exposures.

 All referrals for medical exposures must be from a qualified medical practitioner, and all exposures for biomedical research must have been approved by an ethics committee established or recognised under the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (S.I. No. 190 of 2004).

**3.9. Outside Workers**

Under IIR19, the undertaking has a duty of care for the radiation protection of Outside Workers. Employers of service engineers who perform annual preventative maintenance on irradiating apparatus should therefore be requested to confirm that all service engineers have received appropriate radiation safety training, and that they will not be exposed to primary or unshielded scattered radiation while performing any maintenance work on site. Service companies must also be Registered with the EPA for the practice of Installation/servicing of radiological equipment.

**4. STRUCTURE OF THE RADIATION SAFETY PLAN**

 There are five steps which are central to the Radiation Safety Plan, as shown in Figure 1. These five steps should be followed by the Radiation Safety Committee where unmitigated hazards or oversights are identified in the Feedback & Improvement step, where new practices are proposed or introduced, or where changes are made to standards and legislation. These steps include hazard identification (Section 5), control development and implementation (Section 6), as well as feedback and continuous improvement (section 7).

Definition of Policy & Scope

Hazard Identification & Analysis

Development of Controls

Implementation

Feedback & Continuous Improvement

Figure 1. The 5 steps in the radiation Safety Plan

**5. Hazard Identification & Analysis**

Hazards are broadly identified as including the areas of work where ionizing radiation is used for demonstration or research purposes. These practices currently include;

1. Use of Sealed Radioactive Sources (Department of Physics & Energy),

2. Use of Laboratory X-ray Equipment (MABE,CEMS, P&E, MSSI)

3. DEXA, (Physical Education & Sports Science)

 For the purposes of defining legal dose limits, all persons are designated as members of the public, and these dose limits are detailed further in Section 8.4. Special dose limits are also specified for students or apprentices aged 16-18 years, and for pregnant exposed workers.

Risk assessments should be prepared by the various departments in relation to all licensed sources and irradiating apparatus.. The risks associated with the different hazards are assessed as High, Medium, or Low Risk, according to the following criteria.

**H (High).** Unacceptably high exposure risk. Risk of exceeding Occupational dose limits. Hazard must be avoided or level of risk reduced significantly by reliable controls.

**M. (Medium).**  Risk of regulatory non-compliance or requirement to designate workers as Exposed Workers. Should aim to reduce the exposure risk further to As Low As Reasonably Achievable (ALARA).

**L. (Low).** Acceptable exposure risk. Existing controls adequate but should be monitored to ensure ALARA.

 As a guideline, the risk rating can be evaluated in terms of Probability x Consequences, in accordance with the methodology outlined in Appendix C.

**6. ESTABLISHMENT & IMPLEMENTATION OF CONTROLS**

**6.1. Procedures and Working Instructions**

For each of the hazardous practices which give rise to identified radiation risks (see risk assessment, Appendix C), a set of controls, in the form of written Departmental Radiation Safety Procedures and Working Instructions, have been established to address these risks.

The Radiation Safety Procedures contain general controls and policies, as well as Working Instructions which address individual hazards. Temporary controls may be put in place by the Radiation Safety Committee or the RPO where oversights or hazardous situations are identified.

 In addition, Standard Operating Procedures (SOPs) may be produced within individual departments detailing the methodology and hazards associated with specific uses of the apparatus or sources, or for routine or repetitive tasks such as QA or safety monitoring.

**6.2. Hierarchy of Controls for Risk Mitigation**

Where controls need to be put in place following a review of hazards, or in an emergency situation, the hierarchy of controls for risk mitigation should be as follows;

1. Strict observance of all applicable laws, regulations, and best practices. These are detailed in section 8.

2. Elimination of the hazard where feasible and appropriate (e.g. identification and elimination of un-justified practices leading to unnecessary exposures).

3. Use of engineering controls where feasible and appropriate (e.g. use of structural shielding to ensure exposures are as low as reasonably achievable (ALARA)).

4. Specification of work practices and procedures which limit exposure in a SOP (e.g. distance and exposure time).

5. Use of Personal Protective Equipment to limit exposure.

**6.3. Document Control**

 The DRPSs and Heads of Department are responsible for ensuring that all relevant documentation is distributed to relevant staff, new staff, and visitors (including outside contractors) and that they understand their responsibilities as regards radiation safety. They must also ensure that documentation is up to date. Controlled versions of this plan, and the Departmental Radiation Safety Procedures, will be maintained by the RPO.

**6.4. Emergency Intervention**

 Local radiation safety procedures must include steps to be carried out in the event of a radiation emergency. These should take account of potential incident scenarios identified by the RPO in a radiation interventional plan.

**7. FEEDBACK & CONTINUOUS IMPROVEMENT**

**7.1. Feedback Mechanisms.**

Periodic assessment and review of the plan is necessary to ensure that safety procedures and practices keep pace with relevant legislation and standards, and also to measure the effectiveness of the plan. This involves the collection of feedback information, identifying opportunities for improvement, making changes to improve, and communicating those changes to relevant staff by updating documentation, etc. The key feedback mechanisms are;

* Incident/Accident Reporting
* Staff & Line Manager Feedback
* Monitoring
* External Audit

All feedback will be collated by the RSC and taken into consideration when reviewing the procedures, or recommending additional controls (see RSC standing agenda, Appendix B). The hazard/risk assessments will also be reviewed as part of this process, which will dictate the urgency in relation to consideration of additional controls (taking time, resources, etc, into consideration) or procedures.

**7.2. Incident/Accident Reporting.**

Reporting of radiation related accidents/incidents will be in accordance with the normal health & safety procedures for the institution, as referenced in the appendices to the local Radiation Safety Procedures. However, department heads or DRPS’s are required to forward relevant reports to the Radiation Safety Committee, consideration of which will be included in the standing agenda for the committee (Appendix B). They must also be forwarded to the RPA and a Clinical Incident Report must be completed where the incident involves overexposure of a DEXA subject. A separate investigation may be conducted by the RPA where warranted and a copy of the report forwarded to the EPA Office of Radiological Protection & Environmental Monitoring where necessary, in accordance with the RPII guidelines for reporting exposure incidents of August 2013.

In the case of DEXA subject over-exposures, a clinical incident report must be completed. Clinical incidents which are notifiable to the HIQA, in accordance with their guidelines of January 2019, will be further investigated by the RPO, in co-operation with the Department Head, the persons directly involved or affected, and where necessary, the RPA.

**7.3. Staff/Line Manager Feedback.**

Staff and students are expected to raise any oversights or immediate radiation safety concerns to the RPO, the DRPS, or the department head, again for consideration by the RSC. However, reported hazards which are an immediate risk to health must be dealt with immediately by the head of department.

**7.4. Monitoring.**

Appropriate radiation safety monitoring programmes, as may be advised by the RPA, will be conducted periodically by the RPO or the DRPS in specific areas. These should be detailed in the Radiation Safety Procedures.

**7.5. External Audit.**

 External Audit mechanisms include the ORM Inspection Programme, and Clinical Audit under S.I. 256. Radiation safety may also be reviewed by the RPA at appropriate intervals.

ORM inspections involve visits by inspectors to specific institutions or departments within institutions where licensed items are used. There is no specified frequency but an inspection should be expected (at relatively short notice) during the issue period of a licence.

Clinical audit may be required for DEXA scanning, in accordance with criteria set out by the Minister for Health & Children, under S.I. 256 of 2018, and in accordance with any guidelines issued by the HIQA. HIQA commenced a programme of inspections in 2019 to assess compliance and a guide to the inspection of services providing medical exposures was issued by HIQA in 2020.

**8. LAWS & REGULATIONS.**

**8.1. Regulatory Framework.**

 While all controls are intended to address specific hazards/risks, they must take account of all laws and regulations. Irish laws (Statutory Instruments) relating to Radiation Safety are transposed from European Directives, which are generally guided by the recommendations of the International Commission on Radiological Protection (ICRP). These recommendations form the conceptual framework of radiation protection, and are based on the key principles of;

* 1. **Justification** - the process of showing that a particular use of ionising radiation produces sufficient benefit to the exposed individuals or society to offset the radiation detriment it causes;
	2. **Optimisation** - the process of keeping all exposures as low as reasonably achievable, economic and social factors being taken into account; and
	3. **Dose limitation** - the process of keeping the sum total of all relevant doses received, whether by workers or members of the public, within specified limits.

All relevant laws, regulations, and guidelines are listed in Appendix C. There are two Statutory Instruments in particular which separately regulate radiation safety of staff and the public (S.I. 30 of 2019), and safety of patients (S.I. 256 of 2018). These are detailed below.

Guidelines or regulations are also issued by the competent authorities specified in the Statutory Instruments, and other guidelines are recommended by international bodies, such as the European Commission, to reflect what is considered best practice in particular areas. All relevant documents which should be available in an individual departments should be listed in the Radiation Safety Procedures for that department.

**8.2. S.I. No. 30 of 2019 and the EPA Office of Radiological Protection & Environmental Monitoring.**

 The Radiological Protection Act, 1991 (Ionising Radiation) Order, 2019 (S.I. No. 30 of 2019), gives effect to the relevant sections of Council Directive 2013/59/Euratom, also known as the Basic Safety Standards Directive. The competent authority for implementing this legislation is the Office of Radiological Protection & Environmental Monitoring of the Environmental Protection Agency, as set up under the radiological protection Act (1991-2014). This S.I. provides the framework for the ORM’s authorisation system and details the general radiation protection requirements for all users of ionising radiation. For the University sector, the law is enforced by means of licensing and the conditions applied to that licence, as set out in Schedule 1 of the licence for each institution. These conditions are specific to the type of institution licensed, but are generally considered under the headings of;

A. General Conditions.

B. Acquisition.

C. Dosimetry and Reporting Levels.

D. Design of New Installations

E. Maintenance and Quality Control.

F. Safety and Security.

G. Return or Other Disposal.

H. Records.

I. Disposal of Unsealed radioactive Substances.

J. Transportation.

**8.3. S.I. No. 256 of 2018 & HIQA.**

The European Communities (Medical Ionising Radiation Protection) Regulations, 2018 (S.I. No. 256 of 2018), gives effect to the relevant sections of Council Directive 2013/59/ Euratom dealing with health protection of individuals against the dangers of ionising radiation in relation to medical exposures. Certain aspects of this legislation will apply where persons are exposed for medical or research purposes. The competent authority is the Health Information & Quality Authority (HIQA) who have issues various guidelines to ensure compliance (Appendix D).

**8.4. Dose Limits & Worker Classification**

Annual dose limits are specified in Section 2 of S.I. 30 of 2019 for; 1. Exposed Workers (including Outside Workers), 2. Apprentices and Students, and 3. Members of the Public. In each case annual dose limits are specified for Effective Dose (1mSv for a member of the public), Equivalent Dose to the eyes, and Equivalent Dose to the skin. The EPA licence conditions (Section C: Dosimetry & Reporting levels) also specify that an investigation must be carried out where these doses for an exposed worker exceed 2mSv, 15mSv, and 50mSv respectively, in any 16 week period.

An Exposed Worker is a worker whose annual exposure is likely to result in a dose exceeding any of the dose limits specified for a member of the public (1mSv Effective Dose). Exposed workers are further classified as Category A or B (Ref. Regulation 39). An exposed worker must be classified as category A where he/she is liable to receive an Effective Dose of >6mSv per annum. In an educational environment, it would be unusuail for anyone to be classified as an exposed worker. Therefore, dose limits for members of the public should be observed for everyone.

**8.5. Classification of Areas under S.I. 30 of 2019**

 Under Regulation 36 of S.I. 30 of 2019, the Undertaking (i.e.the manager) is required to classify as a Controlled Area any area where an exposed worker is liable to receive an Effective dose greater than 6 mSv in a period of 12 months or an equivalent dose greater than 15 mSv per year for the lens of the eye or greater than 150 mSv per year for skin and extremities . Similarly, areas where a worker is liable to receive an effective dose greater than 1 mSv in a period of 12 months or an equivalent dose not greater than 15 mSv per year for the lens of the eye or greater than 50 mSv per year for skin and extremities must be classified as a Supervised Area.

 Under Regulation 37, controlled areas must be delineated and subject to restricted access and radiological surveillance. Supervised areas must also be delineated where appropriate and subject to radiological surveillance, depending on the risk. Limits on radioactive contamination in controlled and supervised areas are also specified in the EPA licence conditions (Section C: Dosimetry & Reporting Levels).

 The radioactive source stores, and the DEXA scan room (while exposing), are designated as controlled areas. These areas should have warning signs indicating that they are controlled areas, and access to these areas is strictly restricted to personnel authorised by the RPO, and with appropriate training.

**APPENDIX A**

**OUTLINE OF ADMINISTRATION FOR RADIOLOGICAL PROTECTION AT THE UNIVERSITY OF LIMERICK**

**Governing Authority**

**President**

**Director HR**

**Deans of the Faculties S&E and E&HS**

**Heads of Department**

**CEMS, PESS, CES , MSSI, MABE, P&E**

**RPO - Mr. P. Thornton**

**RPA – Mr. John Upton**

**Departmental Radiological Protection Supervisors**

**Ms. M. Munroe**

**Prof. P. Jakeman**

**Mr. N. Coleman**

**Ms. M. Quinn**

**Dr. J. Leen**

**Dr. G. Armstrong**

**RADIATION PROTECTION COMMITTEE**

**(Chair - Mr. P. Thornton)**

**APPENDIX B**

**Radiation Safety Committee**

**STANDING AGENDA**

**Date:**

**Venue:**

**Time:**

*Attendance: Chairperson, RPA, RPO, Heads of Departments and/or departmental representatives, General Manager and/or H&S representative, Secretary.*

1. **Minutes of last Meeting:**
* **Proposal/Adoption of Minutes**
* **Matters Arising**

1. **EPA & Licence**
* **Licence Status (current licence on display, all sources/equipment listed etc.)**
* **Correspondence**
* **Inspections**
* **Dosimetry/Monitoring**
* **Emergency Planning**
* **Staff Radiation Safety Awareness**
* **Test/Monitoring Equipment**
1. **HIQA and S.I.256 of 2018 Issues (DEXA)**
2. **New Practices/Risk Assessments.**
3. **Review**
* **Incident/Accident Reports**
* **Issues raised by staff or heads of departments.**
* **Documentation/Procedures.**
* **Audit**

**6. Any Other Business**

**7. Next Meeting**

**APPENDIX C**

Risk Assessment Methodology

 **Risk Rating = Probability x Consequences**

**Decision Matrix**

|  |  |  |
| --- | --- | --- |
| **SCORE** | **CONSEQUENCES** | **PROBABILITY** |
| **1** | **Minor:** An Effective Dose to an individual exceeding a dose constraint of 1mSv, but less than 20mSv | **Unlikely:** Exposure unlikely |
| **2** | **Significant:** An Effective Dose to an individual exceeding a dose constraint of 20mSv, but less than 100mSv. | **Possible:** Occasional exposure possible but not expected. |
| **3** | **Serious:** An Effective or Equivalent Dose to an individual exceeding a dose constraint of 100mSv | **Likely:** Continuous or repeated exposures likely. |

**Scoring Matrix**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Likely (3)** | **Possible (2)** | **Unlikely (1)** |
| **Serious (3)** | **9** | **6** | **3** |
| **Significant (2)** | **6** | **4** | **2** |
| **Minor (1)** | **3** | **2** | **1** |

**APPENDIC C (Continued)**

**Risk Rating Categories**

|  |  |  |
| --- | --- | --- |
| **Rating** | **Description** | **Score Threshold** |
| **LOW** | Acceptable exposure risk. Existing controls adequate but should be monitored to ensure ALARA. | **< 3** |
| **MEDIUM** | Risk of regulatory non-compliance or requirement to designate workers as Exposed Workers. Should aim to reduce the exposure risk further to As Low As Reasonably Achievable (ALARA) | **≥3, <6** |
| **HIGH** | Unacceptably high exposure risk. Risk of exceeding Occupational dose limits. Hazard must be avoided or level of risk reduced significantly by reliable controls. | **≥ 6** |

**Risk Assessment Example**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Hazard Description** | **Consequences & Probability (Initial)** | **Persons at Risk** | **Initial Risk** | **Control measures or Mitigating Factors** | **Residual Risk** |
| External Irradiation by X-rays or gamma rays during normal use  | Leakage continuous depending on workload but consequences typically Minor | Lab. StaffStudents | Medium3 | Nominal Leakage at surface of enclosure < 0.1uSv/hr.Annual Compliance audit of regulatory controls. System of governance and radiation safety plan.Maintenance contract. Routine checks. Installation report.. Low workload/throughput. Exposure possible rather than likely.No category B workers identified and no requirement for personal monitoring. | Low2 |
| Exposure due to airbourne or surface contamination by Radioactive materials | No radioactive sources. | - | Low 1 | - | Low1 |
| Exposure due to equipment fault | Failure of an enclosure interlock possible and consequences of exposure to scatter could be significant | Lab. StaffStudents | Medium4 | Engineering controls include warning light, door interlock, emergency stop. Maintenance contract. Routine checks. Installation report. Engineering controls make exposure unlikely.Emergency procedures included in radiation safety Procedures.  | Low2 |
| Exposure due to failure to follow proper procedure | As for equipment fault | Lab. StaffStudents | Medium4 | Radiation safety procedures reviewed and updated annually. Record of date procedures read by relevant personnel.Appropriate training. Standard operating procedures/written operating instructions available.No necessity to designate controlled or supervised areas. Controls make exposure unlikely. | Low2 |
| Exposure due to theft or unauthorised use of a source or other licensed apparatus. | Improper use possible and could have serious consequences. | Lab. StaffStudentsPublic | High6 | Radiation warning signs. Lab security. Authorised users designated by RPS. Incident reporting procedures. Key control/security. Warning signs. Security controls make theft or unauthorized use unlikely. Exposure times unlikely to cause serious consequences. | Low2 |
| Exposure due to fire or other emergency | Damage to shielding possible. Could have significant consequences. | Lab. StaffStudentsPublic | Medium4 | Emergency procedures included in radiation safety Procedures. Standard fire orders, Electronic apparatus unlikely to survive a fire. | Low2 |

**APPENDIX D.**

**RELEVANT LAWS, REGULATIONS, AND GUIDELINES**

**Laws, regulations and guidelines relating to radiation safety of staff and the general public.**

1). Radiological Protection Act, 1991 (1991-2014).

2). Radiological Protection Act, 1991 (Ionising Radiation) Order, 2019 (S.I. No. 30 of 2019).

3). Conditions of EPA Licences (Schedule 1).

4). Radiological Protection Institute of Ireland. Guidelines for reporting radiological Incidents to the RPII (August 2013).

5). Radiological Protection Institute of Ireland.Guidance Notes on Risk Assessment (October 2004).

6). Radiological Protection Institute of Ireland. Guidance Notes on Intervention Planning and Emergency Preparedness for Radiological Accidents (June 2004).

7). Radiological Protection Institute of Ireland (March 2003). Notes for Drivers and Others Involved in Road Transport of Radioactive Materials.

8). Radiological Protection Institute of Ireland (October 2004). Protocol for Radioactive Source Wipe Tests.

9). Radiological Protection Institute of Ireland (February 2001). The Radiological Protection Officer.

10). Safety, Health and Welfare at Work Act 2005 (No. 10 of 2005).

11). ICRP Publication 103: 2007 Recommendations of the International Commission on Radiological Protection, 103

12). Council Regulation (Euratom) No 1493/93 on shipments of radioactive substances between Member States.

13). Radiological Protection Institute of Ireland (March 2004). Recording and reporting of the disposal of unsealed radionuclides discharged to the sewers.

**Laws, regulations and guidelines relating to radiation safety of Patients/Subjects.**

14) European Communities (Medical Ionising Radiation Protection) Regulations, 2018 (S.I. No. 256 of 2018).

15). Radiological Protection Institute of Ireland (May 2010). Guidelines on the protection of the unborn child during diagnostic medical exposures

16). Royal College of Physicians of London. Osteoporosis: clinical guidelines for prevention and treatment. London: Royal College of Physicians, 1999.

17). HIQA (January 2019), Guidance on Radiation Incident Notifications.

18). Guidance on Criteria for the Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy (HIQA, 2020).

19). Guidance on the establishment, use and review of diagnostic reference levels for medical exposure to ionising radiation (HIQA, 2020).

20). Guidance on Dose Constraints for Carers and Comforters and Individuals Participating in Medical and Biomedical Research Involving Medical Exposures to Ionising Radiation (HIQA, 2020).

21). A guide to the inspection of services providing medical exposure to ionising radiation (HIQA, 2019).

22). Guidance - assessing compliance in ionising radiation (HIQA, 2019).

23). Providers (undertakings) information handbook (HIQA, 2019).

24). Regulatory notice - definition of undertaking in the Medical Exposures Regulations. (HIQA, 2019).

**APPENDIX E – REVISION HISTORY**

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| **Version** | **Revision** |
| V3. March 2016 | Appendix A - List of DRPSs updated. |
| V4. March 2019 | References to S.I. 130 of 2019, and S.I. 256 of 2018. |
| V5. March 2020 | Updates further to HIQA guidelines, and in relation to outside workers. |