Ireland's Report on the Implementation of Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community Framework for the Responsible and Safe Management of Spent Fuel and Radioactive Waste

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Introduction

Council Directive 2011/70/EURATOM of 19th July 2011 establishes a Community framework for the responsible and safe management of spent fuel and radioactive waste. It was required to be transposed into national legislation by 23rd August 2013 and Ireland completed its transposition on time with the enactment of the Radiological Protection Act 1991 (Responsible and Safe Management of Radioactive Waste) Order 2013 (S.I. No 320 of 2013). Article 15 (2) specifically exempts Ireland from obligations in respect of the transposition and implementation of those provisions in the Directive relating to spent fuel for as long as Ireland decides not to develop any activity related to nuclear fuel. Article 13 (1) provides that Member States shall notify the Commission of their national programmes and Article 14 sets out the reporting requirements to the Commission on the implementation of the Directive. This report is submitted in compliance with both the notification and reporting requirements of the Directive.

Overview

The primary law governing radiation protection in Ireland is the Radiological Protection Act, 1991 as amended. This Act repealed the Nuclear Energy Act, 1971. Under the 1991 Act, the Minister for the Environment, Community and Local Government has Ministerial responsibility in relation to nuclear safety and radiological protection matters. The Radiological Protection (Miscellaneous Provisions) Act, 2014 provided for the merger of the Environmental Protection Agency (EPA) and the Radiological Protection Institute of Ireland (RPII) essentially establishing the EPA as the national regulatory body, with the radiation protection functionality being exercised on a day to day basis by the Office of Radiological Protection (ORP).

The regulatory framework in Ireland with respect to ionising radiation, including radioactive waste, is based on the relevant EU Directives and Regulations. The Radiological Protection Act, 1991 (Ionising Radiation) Order, 2000 (S.I. No.125 of 2000) gives legal effect in Ireland to EU Council Directive 96/29/Euratom of 13 May 1996, which lays down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation, and EU Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas. Under S.I. No. 125 of 2000, all activities involving radioactive sources, including disused sources and waste, save those which meet the criteria for exemption specified in the S.I., require a licence from the EPA. In addition, the Radiological Protection Act 1991 (Control of High Activity Sealed Radioactive Sources) Order (S.I. No. 875 of 2005) gives effect to Council Directive 2003/122/EURATOM on the control of high activity sealed radioactive sources and orphan sources.

The European Communities (Medical Ionising Radiation Protection) Regulations 2002 (S.I. No. 478 of 2002), as amended by the European Communities (Medical Ionising Radiation Protection) (Amendment) Regulations (S.I. No. 303 of 2007), gives legal effect in Ireland to EU Council Directive 97/43/Euratom on the health protection of individuals against the

dangers of ionising radiation in relation to medical exposures. Under these regulations, the Minister for Health is defined as the Competent Authority and has Ministerial responsibility in relation to the radiological protection of patients. In addition to the Radiological Protection Act, 1991, S.I. No. 125 of 2000 and S.I. No. 478 of 2002, the principal Irish legislation directly or indirectly relating to nuclear matters and radiological protection is listed in Appendix 1.

Ireland currently meets its electricity requirements from a combination of thermal and renewable energy sources. Ireland has chosen not to develop a nuclear power industry and the Government has no plans for a change of policy in this respect. Factors informing the formation of this policy include concerns about public health and safety, environmental protection and security, as well as concern at the continued absence of an acceptable solution to the problem of the long-term management of the large quantities of radioactive waste produced by nuclear power stations.

Ireland has:

- No nuclear power stations.
- No defence reactors for research or other purposes.
- No spent nuclear reactor fuel in storage or awaiting treatment and no associated spent fuel reprocessing facilities of any sort.
- No trans-boundary movement of spent nuclear fuel from other countries across its territory, nor through its territorial waters.

However, like all modern societies, Ireland uses radioactive materials in the form of sealed and unsealed sources in support of its high technology industries and its medical and other societal infrastructure. These activities give rise to waste materials such as disused sealed sources. There are also small amounts of naturally occurring radioactive materials that are produced and also discharged as a result of Ireland's exploitation of natural resources.

Ireland, therefore, has a small but well-developed infrastructure to control and monitor these materials and to provide the necessary protection of public and workers health. This is exercised through the Environmental Protection Agency (EPA) which is the national competent authority and regulatory body for regulating, *inter alia*, the custody, use and disposal of radioactive substances and irradiating apparatus, operating independently from parliament or government departments.

The Irish Government has demonstrated its commitment to safety over many decades by providing the policy lead for radiation safety; the enactment of safety legislation; the establishment of an independent Regulatory Body and the resources (financial and human), to underpin and implement the safety framework. All of these commitments and provisions are now encapsulated in a National Policy Position document. It captures the current general policy position of Ireland in relation to nuclear safety and radiation protection including radioactive waste. It has been developed in line with current scientific evidence, Ireland's commitments due to its membership of the EU and other international organisations such as the International Atomic Energy Agency (IAEA) as well as the specific radiation protection

and nuclear safety issues of concern in Ireland and a commitment to the safety of people in Ireland.

In developing the National Policy Position, the following factors were also taken into account:

- The important role that ionising radiation plays in the economic and social environment in Ireland through its use in the dental, medical, industrial, veterinary and educational sectors.
- Existing national arrangements for safety, including strong independent regulatory control in relation to the use of ionising radiation.
- Specific priority policy issues for Ireland, including national emergency preparedness arrangements; radioactive waste management policy; national radon control strategy; the important bilateral UK-Ireland interactions on radiological matters and energy supply.
- Ireland's strong commitment to the global safety regime through its membership and active participation in the broad range of international organisations and conventions dealing with nuclear safety and radiation protection.

In particular, in late 2010 the Government adopted a policy outlining principles and key future steps to be taken with regard to Radioactive Waste Management in Ireland. The National Programme on radioactive waste is based on this policy. Significant progress has been made in the implementation of the policy and programme. The waste inventory which consists mainly of disused sealed sources has been reduced to a fraction of what it had been.

Reporting Article by Article

Article 4 General Principles

Article 4.1
Member States shall establish and maintain national policies on spent fuel and radioactive waste management. Without prejudice to Article 2(3), each Member State shall have ultimate responsibility for management of the spent fuel and radioactive waste generated in it.

Article 4.2
Where radioactive waste or spent fuel is shipped for processing or reprocessing to a Member State or a third country, the ultimate responsibility for the safe and responsible disposal of those materials, including any waste as a by-product, shall remain with the Member State or third country from which the radioactive material was shipped.

Article 4.3
National policies shall be based on all of the following principles:
(a) the generation of radioactive waste shall be kept to the minimum which is reasonably practicable, both in terms of activity and volume, by means of appropriate design measures and of operating and decommissioning practices, including the recycling and reuse of materials;
(b) the interdependencies between all steps in spent fuel and radioactive waste generation and management shall be taken into account;
(c) spent fuel and radioactive waste shall be safely managed, including in the long term with passive safety features;
(d) implementation of measures shall follow a graded approach;
(e) the costs for the management of spent fuel and radioactive waste shall be borne by those who generated those materials;
(f) an evidence-based and documented decision-making process shall be applied with regard to all stages of the management of spent fuel and radioactive waste.

Article 4.4
Radioactive waste shall be disposed of in the Member State in which it was generated, unless at the time of shipment an agreement, taking into account the criteria established by the Commission in accordance with Article 16(2) of Directive 2006/117/Euratom, has entered into force between the Member State concerned and another Member State or a third country to use a disposal facility in one of them.
Prior to a shipment to a third country, the exporting Member State shall inform the Commission of the content of any such agreement and take reasonable measures to be assured that:
(a) the country of destination has concluded an agreement with the Community covering spent fuel and radioactive waste management or is a party to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management ('the Joint Convention');
(b) the country of destination has radioactive waste management and disposal programmes with objectives representing a high level of safety equivalent to those established by this Directive; and
(c) the disposal facility in the country of destination is authorised for the radioactive waste to be shipped, is operating prior to the shipment, and is managed in accordance with the requirements set down in the radioactive waste management and disposal programme of that country of destination.

The Department of Environment, Community and Local Government (DECLG) has Government policy responsibility in the area of nuclear safety and radiological protection. These responsibilities include:

- implementing national policy in relation to nuclear matters,
- transposition into national legislation of all relevant EU and other international legal instruments,
- co-ordination of specific projects including the national emergency plan for nuclear accidents and the national radon control strategy, and

- representation at meetings of EU, IAEA and other international organisations.

DECLG's Statement of Strategy 2015-2017 tasks it with '*maintaining public confidence in relation to nuclear safety and radiation protection*'. The overall aim of the safety framework is to ensure that people in Ireland are protected from the harmful effects of ionising radiation, while facilitating the use of ionising radiation to the benefit of Irish society.

Any changes in national or international policy in this area require reliable scientific evidence and must be considered along with existing and future obligations of the State under the laws of the European Union and relevant international agreements, including membership of the IAEA and the fundamental safety principles. In addition, policy formation and legislative developments in relation to the protection of the patient from the dangers arising from the use of ionising radiation in medical treatment comes within the remit of the Minister for Health.
In carrying out its brief of maintaining public confidence in nuclear safety and radiation protection, DECLG is supported by the Environmental Protection Agency (EPA) through its Office of Radiological Protection (ORP). The EPA is an independent public body and the competent authority in Ireland with responsibility for ensuring that people and the environment in Ireland are protected from the harmful effects of ionising radiation. The national radiation protection framework provides the EPA with the necessary legislative basis to fulfil its role as a strong independent regulatory authority. While the EPA raises some of its annual financial requirements through its regulatory activities and service provision, it is substantially funded through various exchequer funding streams. The on-going financial, human resource, and research and development requirements of the EPA are ensured through the normal annual budgeting and workforce planning processes exercised between DECLG and agencies under its aegis. Appropriate co-ordination between DECLG and EPA is underpinned through a Service Level Agreement which is regularly reviewed and updated.

DECLG has set out the overall approach to safety in a document titled 'The National Policy Position for Nuclear Safety and Radiation Protection'. In framing the Policy, the Irish Government notes the important role that ionising radiation plays in the economic and social environment in Ireland through its use in the dental, medical, industrial, veterinary and educational sectors. It further endorses the graded approach by setting out that these sources of ionising radiation used in these activities have to be managed safely and securely at all times, in an appropriate manner commensurate with the radiation risks involved including best practice and the international safety standards.

Ireland's Radioactive Waste Policy
In late 2010 the Government adopted a policy outlining principles and key future steps to be taken with regard to Radioactive Waste Management in Ireland. Development of the policy was guided by the following principles:

- The need to address the storage and disposal of legacy and orphan sources into the future in a safe, secure and sustainable way that meets Ireland's international commitments and addresses domestic concerns.

- To aim to do this in a way that has the support of stakeholders (including those who hold and use radioactive sources, and relevant Government Departments and Agencies) and of the public.

- That the development and implementation of the policy needs a "whole of Government" approach, with a high level of inter-agency co-operation in a context of agreed and clearly defined demarcation of roles and responsibilities.

- There is no "one size fits all" solution to the variety of waste sources thereby requiring a number of parallel and complementary strands.

- The resource requirements of implementing the policy should be addressed, as far as possible, according to the "polluter pays" principle.

- The policy reflects the specific roles of key stakeholders including the role of the regulatory authority in terms of licensing and compliance monitoring.

- A National Radioactive Waste Storage Facility for disused radioactive sources is to be established. The Department of Environment, Community and Local Government (DECLG) and the Environmental Protection Agency (EPA) are to draw up a detailed specification for the facility and make recommendations on the siting, management and resourcing of the facility.

- The inventory of disused radioactive sources to be reduced through a co-ordinated and phased Inventory Reduction Programme.

- Interim centralisation of sources by sector in a small number of sector-specific existing storage facilities.

- Further consideration of options for the final disposal of Ireland's disused radioactive sources.

- Further updates to be provided to Government, as necessary, as this work progresses.

In implementing the Policy, Ireland follows the principles of;

- minimisation of the generation of radioactive waste in any form

- avoidance of the importation of radioactive waste in any form.

Article 5 National Framework

Article 5.1
Member States shall establish and maintain a national legislative, regulatory and organisational framework ('national framework') for spent fuel and radioactive waste management that allocates responsibility and provides for coordination between relevant competent bodies. The national framework shall provide for all of

the following:
(a) a national programme for the implementation of spent fuel and radioactive waste management policy;
(b) national arrangements for the safety of spent fuel and radioactive waste management. The determination of how those arrangements are to be adopted and through which instrument they are to be applied rests within the competence of the Member States;
(c) a system of licensing of spent fuel and radioactive waste management activities, facilities or both, including the prohibition of spent fuel or radioactive waste management activities, of the operation of a spent fuel or radioactive waste management facility without a licence or both and, if appropriate, prescribing conditions for further management of the activity, facility or both;
(d) a system of appropriate control, a management system, regulatory inspections, documentation and reporting obligations for radioactive waste and spent fuel management activities, facilities or both, including appropriate measures for the post-closure periods of disposal facilities;
(e) enforcement actions, including the suspension of activities and the modification, expiration or revocation of a licence together with requirements, if appropriate, for alternative solutions that lead to improved safety;
(f) the allocation of responsibility to the bodies involved in the different steps of spent fuel and radioactive waste management; in particular, the national framework shall give primary responsibility for the spent fuel and radioactive waste to their generators or, under specific circumstances, to a licence holder to whom this responsibility has been entrusted by competent bodies;
(g) national requirements for public information and participation;
(h) the financing scheme(s) for spent fuel and radioactive waste management in accordance with Article 9.

Article 5.2
Member States shall ensure that the national framework is improved where appropriate, taking into account operating experience, insights gained from the decision-making process referred to in Article 4(3)(f), and the development of relevant technology and research.

The primary law governing radiation protection in Ireland is the Radiological Protection Act, 1991 as amended. This Act repealed the Nuclear Energy Act, 1971. Under the 1991 Act, the Minister for the Environment, Community and Local Government has Ministerial responsibility in relation to nuclear safety and radiological protection matters. The Radiological Protection (Miscellaneous Provisions) Act, 2014 provides for the merger of the Environmental Protection Agency (EPA) and the Radiological Protection Institute of Ireland (RPII) essentially establishing the EPA as an independent national regulatory body with the radiation protection functionality being exercised on a day to day basis by the Office of Radiological Protection (ORP).

The Radiological Protection Act, 1991 (Ionising Radiation) Order, 2000 (S.I. No.125 of 2000), which was made under Section 30 of the Radiological Protection Act of 1991, gives legal effect in Ireland to EU Council Directive 96/29/Euratom of 13 May 1996, which lays down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation, and EU Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas. Under S.I. No. 125 of 2000, all activities involving radioactive sources, including disused sources and waste, save those which meet the criteria for exemption specified in the S.I., require a licence from the EPA. In addition, the Radiological Protection Act 1991 (Control of High Activity Sealed Radioactive Sources) Order (S.I. No. 875 of 2005) gives effect to Council Directive 2003/122/EURATOM on the control of high activity sealed radioactive sources and orphan sources.

The Radiological Protection Act, 1991 (as amended) sets out the functions of the EPA as well as the legislative powers of the Minister for the Environment, Community and Local Government in the areas of nuclear safety and radiological protection. It also sets out specific responsibilities of other Government Ministers and functions of the Food Safety Authority of Ireland, principally in regard to the protection of individuals from radiological hazards in food.

The Radiological Protection Act, 1991 (Ionising Radiation) Order, 2000 (S.I. No. 125 of 2000) is divided into a number of sections and areas, which include the following:

- Regulation of practices and work activities
- Justification, optimisation and dose limitation
- Estimation of effective dose
- Protection of exposed workers, apprentices and students
- Radiation protection of the population for practices in normal circumstances.
- Intervention and Emergency Preparedness
- Enforcement

In addition to the Radiological Protection Act, 1991 and S.I. No. 125 of 2000, the principal Irish legislation directly or indirectly relating to nuclear matters and radiological protection includes the following:

- Radiological Protection (Miscellaneous Provisions) Act, 2014 (No. 20 of 2014)
- Radiological Protection Act 1991 (Responsible and Safe Management of Radioactive Waste) Order 2013 (S.I. No. 320 of 2013)
- Radiological Protection Act, 1991 (Nuclear Safety) Order, 2011 (S.I. No. 390 of 2011)
- European Communities (Supervision and Control of Certain Shipments of Radioactive Waste and Spent Fuel) Order, 2009 (S.I. No. 86 of 2009)
- Radiological Protection Act 1991 (Control of high-activity sealed radioactive sources) Order 2005 (S.I. No. 875 of 2005)
- Radiological Protection Act, 1991 (Licensing Application and Fees) Regulations, 2007 (S.I. No. 654 of 2007)
- Health Act, 1953 (No. 26 of 1953)
- Safety, Health & Welfare at Work Act, 2005 (No. 10 of 2005)
- Dumping at Sea Act, 1996 (No. 14 of 1996)
- Harbours Act, 1996 (No. 11 of 1996), as amended by the Harbours (Amendment) Act 2000 (No. 21 of 2000)
- Containment of Nuclear Weapons Act 2003 (No. 35 of 2003).
- Nuclear Test Ban Act 2008 (No. 16 of 2008)
- European Communities (Radiological Emergency Warning to Public) Regulations 1993 (S.I. No. 209 of 1993)
- Electricity Regulation Act 1999 (No. 23 of 1999)
- Environmental Protection Act 1992 (Number 7 of 1992)

In terms of the types of facilities and activities included within the scope of the framework for safety, Section 30 of the Radiological Protection Act of 1991 sets out a list of practices that are prohibited save under licence issued by the EPA and these include: the custody, production, processing, handling, holding, storage, use, manufacture, importation, distribution, transportation, exportation or other disposal of such radioactive substances, nuclear devices, or irradiating apparatus.

Authorisation

The Radiological Protection Act, 1991 provides for

- authorisation, including practices involving radioactive waste, by means of a licensing system (Section 30)
- the appointment of inspectors with specific powers (Section 29)
- enforcement and penalties (Section 40).

The expectation is that in exercising these powers and procedures the regulatory body would use a graded approach in line with 'international standards'. In practice this is achieved in terms of authorisation, inspection and enforcement through written and agreed protocols and procedures.

As part of the authorisation process, where radioactive sources are being acquired for use, the applicant has to provide proof that they have arrangements in place to deal with the source at the end of its use. This is achieved primarily through entering 'take back' arrangements with the supplier of the source. In the case of HASS sources, the associated costs must be identified and the applicant is required to make provision for those costs in their business accounts. There are no specific legislative provisions providing for release from regulatory control. However, in practice licence conditions attaching to authorisations set out the criteria for releasing wastes out of regulatory control.

Licensees are divided into different bands which are further sub-divided into categories or 'levels'. The band divisions represent a broad categorisation and the sub-divisions reflect a 'judgement of risk'. Over the years the bands and categories have been extended to track the tailoring of licence conditions to new types of practices. It should be noted that from the point of view of an applicant to the EPA, applicants are only categorised as 'Low', 'Medium' or 'High'. This reflects a re-grouping of the existing licensees across the bands to reflect the 'risk and effort' profile for each and this was carried out as part of the financial review to determine the revised licence fee schedule introduced in October 2007.

While this is not an exhaustive list, the current principle operational bands and sub-categories are:

- Industrial (Sub Categories: Level 1–9)
- Medical (Sub Categories: Level 1–6)
- Educational/Research and Laboratories (Sub categories: Level 1–3)
- Distributor (Sub Categories: Level 1–2)
- Dental (Sub Categories: Level 1–3)
- Veterinary (Sub Categories: Level 1–2)

- Transport services

In the main, the sub-categories reflect the differing levels of 'risk' where such risk has been equated with the complexity of the process and the number and activity of sources and irradiating apparatus being held and/or used. An example of this is a hospital offering radiotherapy services which is categorised as 'Medical – Level 6' while a process irradiation facility is categorised as 'Industrial – Level 9'. In contrast, a small hospital providing X-ray services with only one unit and without other diagnostic or therapeutic facilities such as CT, mammography or fluoroscopy is 'Medical – Level 1'. On the industrial side, a company that has custody and use of a simple cabinet X-ray machine is categorised as 'Industrial – Level 1'.

The authorisation process is carried out by the EPA at various stages in the lifetime of a facility or a practice, that is, at the application stage prior to issuing a licence, upon receipt of a request for an amendment to a licence and at the licence renewal stage. The specific information, set out in the legislation, to be included in a licence application to the EPA includes a radiological risk assessment, radiation safety procedures and details of the practice for which a licence is required and applicant, and premises details. A statement setting out the grounds for justification may also be required for practices that have not been previously approved in writing by the EPA, that is, for the introduction of new practices or significant changes to existing practices. For example, the recent regulatory decision, by an ORP licensing panel, to authorise by licence the introduction of the Nomad Hand-held dental X-ray unit, following a review of the submitted application and supporting documentation.

As part of the licensing process, applicants may also be required to produce security plans (where relevant) to support licence applications and these, together with their risk assessments and radiation safety procedures must be reviewed by the licensee during the term of the licence. Licence applicants in preparing a set of radiation safety procedures must describe in detail, or refer to supporting documentation, how safety is assured in the use of the sources for both the user and members of the public. The radiation safety procedures should be based on the outcome of an assessment of the risks to workers and members of the public associated with the radiation sources and the measures required to mitigate those risks.

The risk assessment prepared by the applicant should demonstrate a safety case which is a document or set of documents that describes risk in terms of the hazards presented by the facility or the practice under normal modes of operation, including reasonably foreseeable incident situations and those radiation protection measures that need to be implemented in order to prevent or minimise the harm.

The licence applicant must also demonstrate that locations where radiation sources are used or stored shall be designed so that the dose to all persons, other than exposed workers, is less than 0.3 mSv per year. In practice, the applicant submits a shielding assessment to demonstrate this and includes details of the assumptions used (occupancy factors, size and nature of source) in determining the shielding requirements. Furthermore, Article 6(4) of S.I No 125 of 2000 provides for the EPA to seek any additional relevant information that in its opinion is necessary for the licence application.

Licence Conditions and Controls

Regulatory requirements for all holders and users [licensees] of ionising radiation are set out in the legislation (S.I. No 125 of 2000), with additional requirements set out in conditions attaching to the relevant licence. Limits, conditions and controls on the authorised party's subsequent activities are controlled by these licence conditions as provided for in Section 30 of the Radiological Protection Act 1991 which may be amended by the EPA for a safety or related purpose. In addition, failure to comply with a licence condition is deemed an offence in accordance with the Radiological Protection (Amendment) Act, 2002.

Authorisation is carried out in stages in the medical sector to ensure all equipment is commissioned prior to first use on patients. In these cases, the EPA firstly issues or amends a licence to allow the commissioning of a new piece of equipment. Once a satisfactory commissioning report has been provided by the applicant and the approved Radiation Protection Adviser (RPA) is satisfied for the unit to be used clinically the EPA can amend the licence to allow for use of the equipment.

Assessment

As part of the regulatory process an applicant for a licence is required to submit documentation to the EPA that includes Facility Design Plans, Risk Assessments, and Radiation Safety Procedures before construction of any new facility or commencement of any licensable practice. Collectively, this documentation submitted by the applicant can be taken to be a safety case. These documents are produced by the applicant in conjunction with a Qualified Expert/Radiation Protection Advisor (RPA) to ensure their completeness for review and assessment by the EPA. The EPA does not provide prescriptive advice to licensees or applicants on how to comply with its regulatory requirements. Instead, licensees are required to appoint and consult with an approved RPA who provides advice to licensees on how to meet both legislative and licensing requirements. As part of the regulatory process, the RPA must sign off on behalf of the applicant on all radiation protection matters pertinent to the issuing of a licence.

The EPA has a statutory responsibility for approving Radiation Protection Advisors (RPA) and for maintaining an RPA register. Within the EPA the ORP approves and maintains a register of Radiation Protection Advisors and requests that licensees appoint an approved RPA to advise them "in order to ensure effective protection of individuals and the correct operation of protective equipment". This is outlined in Article 19 of S.I. No. 125 of 2000.

The role of the RPA is central to the review and assessment process and one of their principal responsibilities is to ensure that the information provided to the EPA as part of the licensing process is sufficient and accurate. In order for a practice or a facility to be approved by the EPA, it must be convinced the practice is justified by the applicant. The RPA on behalf of the applicant or licensee will also need to assess the risk to workers, staff and members of the public from normal operations and from reasonably foreseeable accident and incident situations during operation. Risks unrelated to radiation are not taken into consideration in the regulatory decision making process.

Licence applicants in preparing a set of radiation safety procedures should describe in detail or refer to supporting documentation as to how safety is assured in the use of the sources for both the user and members of the public. The radiation safety procedures should be based on the outcome of undertaking an assessment of the risks to workers and members of the public associated with the radiation sources and the measures required to mitigate those risks. The risk assessment should demonstrate a safety case which is a logical and hierarchical set of documents that describes risk in terms of the hazards presented by the facility or the practice under normal modes of operation, including reasonably foreseeable accident and incident situations and those radiation protection measures that need to be implemented in order to prevent or minimise the harm.

The applicant is required to submit an adequate demonstration of safety in support of an application. The scope and content of the safety case required is commensurate with the radiation risk associated with facilities and activities, in accordance with a graded approach. It will be expected to cover aspects such as: the legal person with prime responsibility for safety for the practice; the management structure within the applicant company with responsibility for managing radiation protection; radiation protection must be consistent with ALARA; and the arrangements in place for dealing with accident and incidents (emergency and intervention plans).

Inspection

The EPA devises and implements an annual inspection programme of licensees engaged in practices involving ionising radiation including radioactive waste. Towards the end of each year work begins at EPA on compiling the inspection programme for the forthcoming year. All inspectors are involved in compiling the inspection programme. A draft inspection schedule is drawn up, taking account of the following factors and available staff resources:

- Radiological risk associated with each category of licensee;
- Date of most recent inspection for each licensee;
- Number of licensees within each category;
- Reported incidents during the year;
- Issues related to individual licensees;
- Matters that may have arisen during the year;
- Deferred inspections from previous years, where relevant;
- Recommendations from all inspectors or other relevant personnel;
- A policy direction from the Board of the EPA.

The inspection programme is approved by the Board of the EPA and monitored and reviewed continuously throughout the year at inspectors' meetings of which at least two are held each year. Modifications to the inspection schedules and ultimately the annual inspection programme may be made at any stage during the year. At the end of each year a review of the number of completed inspections is carried out with respect to the approved schedule where trends or recurring issues are identified for action. The EPA's inspection activities are accredited by the Irish National Accreditation Board (INAB) to the ISO17020:2012 standard for inspection bodies "*General Criteria for the Operation of Various Types of Bodies*

Performing Inspection". A requirement of this standard is to have an Annual Management Review Meeting to cover all aspects of the Quality System including inspections activities and during this meeting the previous year's inspection programme is reviewed.

The annual inspection programme approved by the Board of the EPA at the beginning of the year can only include those inspections which were foreseen at the time the programme was compiled. There may be occasions during the year when it is necessary to include additional inspections in the programme. Typical events that may warrant this action can include:

- Where a concern in relation to a source of ionising radiation is brought to the attention of the Radiation Protection Regulation (RPR), see ORP Organisational Chart on page 20) by any individual;
- The reporting of an incident involving a licensable item to the RPR in compliance with licensing conditions;
- Where the RPR is notified of a dose recorded on a personal dosemeter which exceeds the reporting levels as defined in the licence conditions.

The EPA has the resources to undertake typically 150 – 220 inspections per year. Most inspections are planned in advance but a number of unannounced, proactive and reactive inspections also take place each year. Inspections can arise outside of the normal annual programme where incidents are investigated.

All of the inspections carried out by the EPA require the presence of representatives of the licensee. Licensee representatives would typically include the Radiation Protection Officer and the licensee's Radiation Protection Adviser. It is also expected that a senior management representative is also available for at least part of the inspection typically the introduction and close out meetings. This demonstrates the licensee's commitment to radiation protection at the highest level.

In the case of licensees holding large quantities of disused radioactive sources, the EPA carries out specific audits of on-going site security arrangements in conjunction with the National Crime Prevention Office of An Garda Síochána (Irish police force).

Enforcement

Section 28 of the Radiological Protection Act, 1991 provides for the appointment of inspectors and Section 29 provides those inspectors with considerable powers to inspect; to access information; to take samples; to take control; to seize; to enter and by 'direction' to evacuate or to cease an activity. Offences and penalties are set out in Sections 38, 39 and 40 of the Act, with prosecution provisions provided for in Section 41 in relation to individuals and corporate bodies. Additional enforcement powers are set out in Article 42 of S.I. No 125 of 2000 in the form of 'Enforcement Notices.

Offences and penalties are set out in the Radiological Protection Act, 1991, Section 38 (Offences relating to Nuclear Material) and Section 40 which states that a "person who contravenes a provision of an order made under section 30 or a regulation or order made

under Section 32 of this Act shall be guilty of an offence under this Act" and sets out the various conditions under which a person could be become liable. It also provides for offences committed by corporate bodies. Any breach of a licence condition or legislative requirement is potentially a prosecutable offence. In addition, Section 38 of the 1991 Act was subsequently amended by Section 42 of the Radiological Protection (Miscellaneous Provisions) Act, 2014 to extend the range of offences in line with the 2005 amendment of the Convention on the Physical Protection of Nuclear Material (CPPNM). There are other provisions for 'on the spot fines' in relation to transport of Class 7 materials in associated legislation. Section 23.1 of S.I. No. 478 of 2002 provides for offences in relation to protection of the patient regulations with subsequent provisions providing for the means whereby prosecutions can be taken.

The EPA has established and implemented an enforcement policy within its legal framework for responding to non-compliances by licensees with respect to regulatory requirements or licence conditions. The primary purpose of the EPA's enforcement programme is to foster compliance with the Regulations rather than to carry out punitive action. This philosophy is the basis of the guiding principles outlined in the EPA Enforcement Policy. The objective of the policy is "to have a shared understanding of the principles and procedures governing decisions to take enforcement actions and to ensure and to demonstrate that in taking such decisions there is proportionality of action, consistency of approach and transparency of process". The Enforcement Policy sets out the procedures to be followed where activities or incidents have been identified that may require an enforcement decision. Each of these procedures sets out the appropriate action to be taken and a series of escalated actions to be taken in the event that the licensee fails to comply with regulatory requirements. Enforcement is undertaken on a graded approach.

The EPA and its warranted inspectors have various enforcement powers under Sections 29, 30, 38, 40 and 41 of the Radiological Protection Act 1991. EPA inspectors also have powers under the European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) Regulations 2011 to 2015 to issue fixed penalty notices for various offences under the ADR as specified in the regulations.

In accordance with Sections 29(2) and 29(3) of the Radiological Protection Act, 1991 where an Inspector is of the opinion that there is or may be a danger to any individual, land, building or other property arising from a radioactive substance, nuclear device or irradiating apparatus or arising from levels of activity or ionising radiation in excess of the specified levels the Inspector shall have the power by direction, to order persons to perform or refrain performing any act if, in his/her opinion, the performance of such act (as the case may be) is necessary in order to prevent or alleviate the escalation of the danger.

Regarding implementation of corrective actions to address the findings of an inspection, an Inspection Report is issued to licensee management within four weeks of the date of the inspection and this includes a response date of four weeks by which the licensee must provide a written response to the report. If this is not provided then the inspectors follow up in accordance with the enforcement policy (correspondence, solicitor's letter as required). Once the actions have been implemented this is confirmed in writing by the EPA inspector.

There is a range of enforcement instruments available to the EPA inspectorate from 'soft' actions to 'hard' actions including:

- Raising non compliances during routine inspections and follow up until there is satisfactory closure
- Letter of censure/warning letter
- Issuing a direction
- Issuing an enforcement notice
- On the spot fines in relation to certain transport matters
- Seizure of relevant items such as radioactive sources/orphan sources
- Revocation of a licence
- Prosecution (and subsequent penalties/fines)

More than 50 prosecutions have been taken by the Regulatory Body in relation to contravention of the radiation protection regulations since 1991.

Prime Responsibility for Safety

The principle of prime responsibility of the licence holder is met by a sum of regulatory requirements including justification and adherence to specific licence conditions set down by the Competent Authority (EPA).

Responsibility for safety covers all stages in the lifetime of facilities through the authorisation process as provided for in Article 6 of S.I. No. 125 of 2000. While specific aspects such as 'siting' are not specifically mentioned in the legislation, where specific issues arise in relation to a particular facility such as the need for decommissioning, then these are dealt with either through licence conditions as provided for in Section 6 (5) or as part of the regulatory process towards the closure of a licence.

Facilities that generate radioactive waste such as hospitals are authorised using the procedure set out in Article 6 of S.I. No. 125 of 2000 and radioactive waste management issues are deal with through specific licence conditions. The combination of regulations and licensing conditions ensures that the responsibility for waste management is clear and enforceable. In addition, S.I. No. 320 of 2013 deals specifically with radioactive waste management and sets out general principles.

Article 6 Competent Regulatory Authority

Article 6.1
Each Member State shall establish and maintain a competent regulatory authority in the field of safety of spent fuel and radioactive waste management.

Article 6.2
Member States shall ensure that the competent regulatory authority is functionally separate from any other body or organisation concerned with the promotion or utilisation of nuclear energy or radioactive material, including electricity production and radioisotope applications, or with the management of spent fuel and radioactive waste, in order to ensure effective independence from undue influence on its regulatory function.

Article 6.3
Member States shall ensure that the competent regulatory authority is given the legal powers and human and financial resources necessary to fulfil its obligations in connection with the national framework as described in Article 5(1) (b), (c), (d) and (e).

The EPA was established in primary legislation by the Environmental Protection Act, 1992 and the RPII was established in primary legislation by the Radiological Protection Act 1991. In 2014 the EPA and the RPII were merged in primary legislation by the Radiological Protection (Miscellaneous Provisions) Act, 2014. All of the general and particular functions in relation to radiation protection safety regulation were transferred to the EPA and are set out in Sections 7 and 8 of the Radiological Protection Act, 1991 and in detail in a suite of secondary legislation all of which transferred to the EPA in the merger. With regard to patient protection the Minster for Health is the designated competent authority as provided for in S.I. No. 478 of 2002.

The EPA is empowered to regulate radioactive material including practices involving radioactive waste, and radiation sources through a licensing system established by Order (primarily S. I. No. 125 of 2000) under Section 30 of the Radiological Protection Act 1991. Conditions can be attached to the licence as provided for in Section 30(4) of the 1991 Act. The EPA has the power to prosecute offences in contravention of the licensing order (Section 40). In addition, Section 28 provides for the appointment of inspectors for the purposes of the Act and regulations and orders made under it. Section 29 of the Act sets out the powers of inspectors which provide, *inter alia*, that they are empowered to demand certain information and to enter premises.

The establishment of the Regulatory Authority as an independent public body in primary legislation is the main national commitment to making provision for acquiring and maintaining the necessary competence for ensuring safety. The staff of the RPII transferred to the EPA in the recent merger and provide the radiological protection and safety competence in that field in a dedicated Office (Office of Radiological Protection (ORP)) in the EPA. In addition, the Radiological Protection (Miscellaneous Provisions) Act, 2014 provides for a 'person having relevant experience in relation to radiological protection' to be appointed to the Board of the EPA. Staff competence within the EPA in radiological protection is maintained by the usual corporate processes such as Performance Management and Development (PMDS), annual Work Programme planning where competence and capacity is taken into account. In addition, there is a process of 'Workforce Planning' where competency and capacity needs for the organisation as a whole are identified particularly where there are new responsibilities being taken on by the EPA and these needs are then negotiated with the DECLG.

The EPA has a number of different funding streams including central Government funds and this is negotiated on an annual basis through budgetary submissions and business plans but those discussions do not touch on regulatory decisions. However, the actual radiation protection regulatory function of the EPA currently operates on a full cost recovery basis by charging for licences but these monies go directly into the central agency fund. Staff of the

EPA have no direct or indirect interest in facilities and activities of authorised parties and this is provided for in the Code of Conduct for inspectors.

The EPA has the following duties and responsibilities in respect of radiation protection, nuclear safety and waste management:

- To provide advice to the Government, the Minister for Environment, Community and Local Government and other Ministers on matters relating to radiological safety.
- To provide information to the public on any matters relating to radiological safety.
- To maintain and develop a national laboratory for the measurement of levels of radioactivity in the environment and to assess the significance of these levels for the Irish population.
- To control by licence the custody, use, manufacture, importation, transportation, distribution, exportation and disposal of radioactive substances, irradiating apparatus and other sources of ionising radiation.
- To assist in the development of national plans for emergencies arising from nuclear accidents and to act in support of such plans.
- To carry out or promote research in relevant fields.
- To monitor developments abroad relating to nuclear installations and radiological safety generally and to keep the Government informed of their implications for Ireland.
- To co-operate with the relevant authorities in other states and with appropriate international organisations.
- To represent the State on international bodies.
- To be the competent authority under international conventions on nuclear matters.
- Where appropriate, to provide, or oversee the provision of, specialist radiation protection services such as personal dosimetry, radioactivity measurement, instrument calibration, radon measurements and product certification.

The EPA has also been designated the national competent authority for the purposes of the IAEA Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency and the Convention on Early Notification of a Nuclear Accident and is the National Authority responsible for the physical protection of nuclear material.

Structure, Organisation and Staffing

The EPA is managed by a full-time Executive Board consisting of a Director General and five Directors. Each Director is responsible for an Office within the Agency. In addition to the Office of the Director General (ODG), the EPA is divided into five offices: the Office of Communications and Corporate Services (OCCS); the Office of Environmental Enforcement (OEE); the Office of Climate, Licensing, Resources and Research (OCLRR); the Office of Environmental Assessment (OEA), and the Office of Radiological Protection (ORP) (Figure 1).

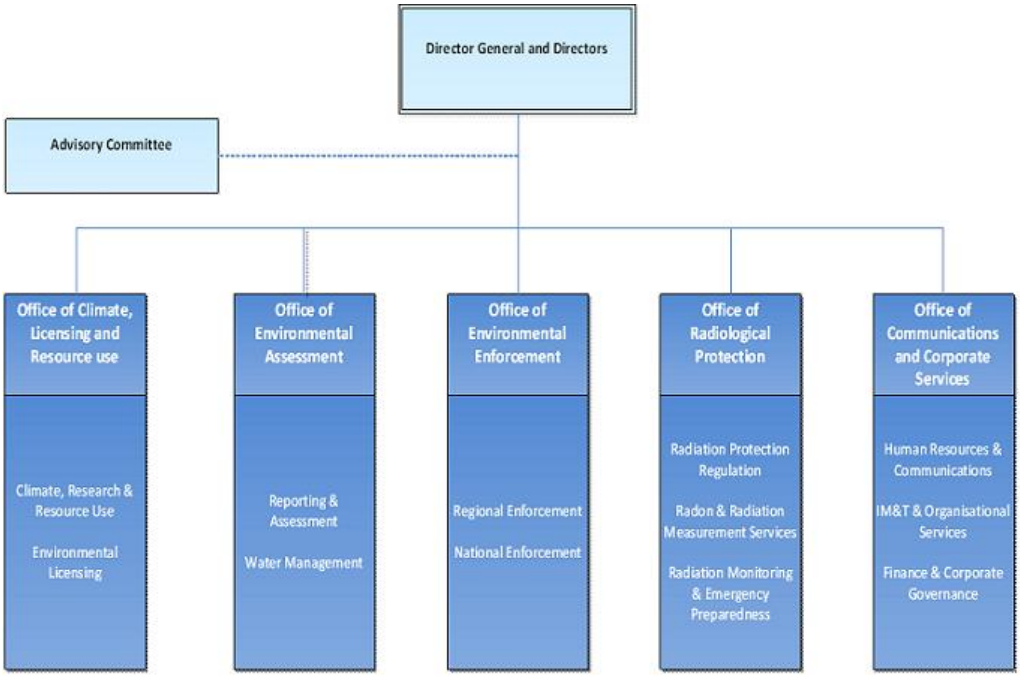

Figure 1: Environmental Protection Agency Organisational Chart

ORP has a current staff complement of 34, divided across three work programme areas as follows (Figure 2):

- Director of ORP: One staff member
- Radiation Protection Regulation: One Programme Manager, one Technical Manager, five scientific staff and four admin staff
- Radon & Measurement Service: One Programme Manager, one Technical Manager, two scientific staff , two technical staff and four admin staff
- Radiation monitoring & Emergency Preparedness: One Programme Manager, two Technical Managers, five scientific staff and four technical staff

ORP is supported in its work, in particular, by the Office of Communication and Corporate Service (OCCS). Within this office essential support is provided for non-scientific work areas including finance, human resources, information management & technology, building maintenance, corporate governance and communications.

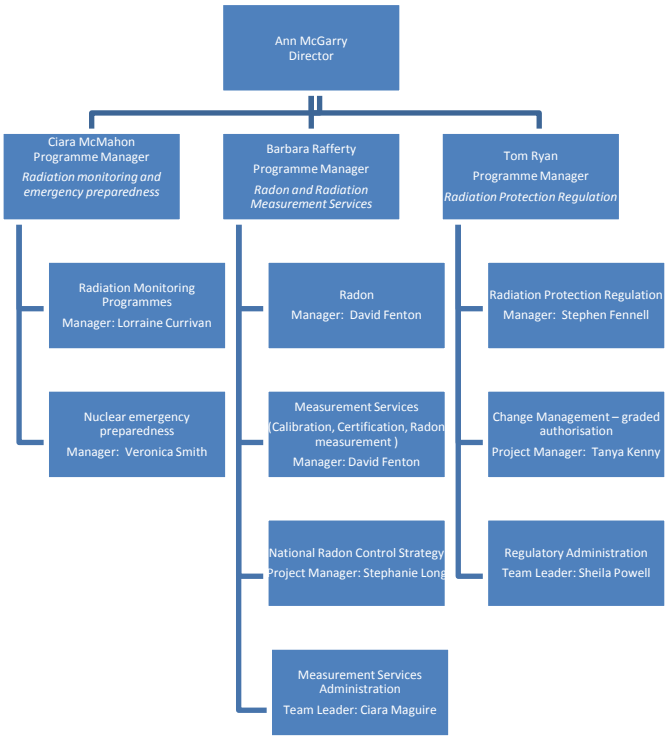

Figure 2: Office of Radiological Protection Organisational Chart

The distribution of licensees and licensed facilities in Ireland in relation to ionising radiation (as of January 2015) is as follows:

- **12 radiotherapy facilities** including 33 Linear Accelerators, five High Dose Rate brachytherapy systems, eight Low Dose Rate brachytherapy systems, three radiotherapy x-ray units, 6 ^{131}I ablation suites, 27 CT Simulators and one Cyberknife Unit. There are no ^{60}Co Teletherapy units in Ireland.
- **19 nuclear medicine facilities** with 8 PET/CT units
- **144 diagnostic/interventional facilities** including 536 conventional x-ray systems, 62 interventional radiology systems, 77 CT scanners, 61 mammography units and 85 bone densitometer units
- **959 dental licensees**
- **295 veterinary licensees** including one equine nuclear medicine facility
- **15 education and research facilities**
- **274 industrial facilities** including one radiopharmaceutical manufacturer, three irradiation facilities and 18 facilities carrying out industrial radiography
- **40 licensed distributors** of radioactive sources and X-ray equipment.

The breakdown of licensees by sector is shown in Figure 3.

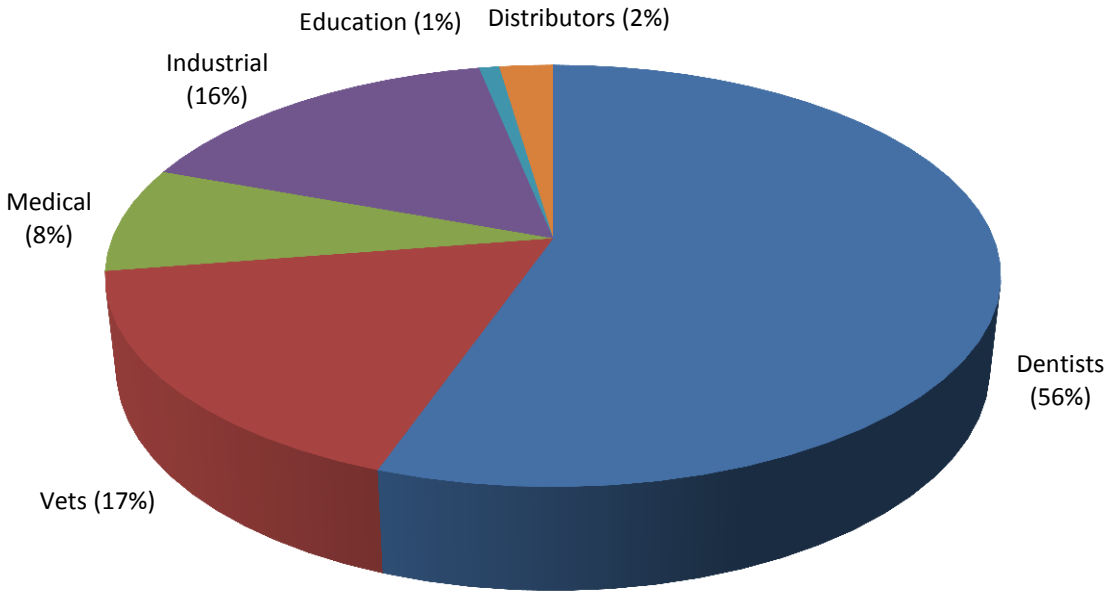

Figure 3: Licensees by Sector 1st January 2015

Ireland has:

- No nuclear power stations.
- No defence reactors for research or other purposes.
- No spent nuclear reactor fuel in storage or awaiting treatment and no associated spent fuel reprocessing facilities of any sort.
- No trans-boundary movement of spent nuclear fuel from other countries across its territory, nor through its territorial waters.

Under the Radiological Protection Act of 1991, the EPA regulates the custody, use and disposal of radioactive materials in Ireland through a licensing scheme, the terms and conditions of which are set out under S.I. No.125 of 2000. In addition to providing for the licensing scheme, it also transposes Council Directive 96/29 Euratom of 13 May 1996, referred to earlier, into national legislation. The EPA publishes a report each year of its regulatory activities including the focus of inspections and an outline inspection plan for the following year.

EPA provides services such as instrument calibration, food certification and radon measurement and all money collected for services and licences goes to a central fund. As budget allocations are made from the central fund there is no financial incentives within the business function to promote any of the EPA's services.

Other authorities may have an interest in the licensing process. For example in relation to the regulation of the medical sector, patient protection is the responsibility of the Minister for Health and the oversight of those regulations is a separate function from EPA. While EPA

staff provide support and advice through participation on committees there is no formal authorisation process in relation to patient protection.

While there are a number of Competent Authorities involved in the transport of Dangerous Goods by Road, Rail, Sea and Air with respect to the implementation of the Modal Instruments (ADR, RID, IMDG, and ICAO respectively) the EPA is the only competent authority that issues an authorisation (licence) for the transport of radioactive material. A Memorandum of Understanding has been established with the Health and Safety Authority (HSA) regarding transport by Road and an inter-Government Department/Agency Working Group on ADR has been established to ensure consistency of approach in the sector. Similar but less formal arrangements are in place for the other modes. The IMDG Code (sea) and the ICAO (air) modal instruments replicate the requirements of the IAEA Regulations for the Safe Transport of Radioactive Material. The licence conditions issued by the EPA reference the current Modal Instruments.

Article 7 Licence holders

Article 7.1
Member States shall ensure that the prime responsibility for the safety of spent fuel and radioactive waste management facilities and/or activities rest with the licence holder. That responsibility cannot be delegated.

Article 7.2
Member States shall ensure that the national framework in place require licence holders, under the regulatory control of the competent regulatory authority, to regularly assess, verify and continuously improve, as far as is reasonably achievable, the safety of the radioactive waste and spent fuel management facility or activity in a systematic and verifiable manner. This shall be achieved through an appropriate safety assessment, other arguments and evidence.

Article 7.3
As part of the licensing of a facility or activity the safety demonstration shall cover the development and operation of an activity and the development, operation and decommissioning of a facility or closure of a disposal facility as well as the post- closure phase of a disposal facility. The extent of the safety demonstration shall be commensurate with the complexity of the operation and the magnitude of the hazards associated with the radioactive waste and spent fuel, and the facility or activity. The licensing process shall contribute to safety in the facility or activity during normal operating conditions, anticipated operational occurrences and design basis accidents It shall provide the required assurance of safety in the facility or activity. Measures shall be in place to prevent accidents and mitigate the consequences of accidents, including verification of physical barriers and the licence holder's administrative protection procedures that would have to fail before workers and the general public would be significantly affected by ionising radiation. That approach shall identify and reduce uncertainties.

Article 7.4
Member States shall ensure that the national framework require licence holders to establish and implement integrated management systems, including quality assurance, which give due priority to safety and are regularly verified by the competent regulatory authority.

Article 7.5
Member States shall ensure that the national framework require licence holders to provide for and maintain adequate financial and human resources to fulfil their obligations with respect to the safety of spent fuel and radioactive waste management as laid down in paragraphs 1 to 4.

Duties and responsibilities of licence holders in Ireland are described in the licence conditions and in S.I. No. 125 of 2000. The principle of prime responsibility of the licence

holder is met by a sum of regulatory requirements including justification and adherence to specific licence conditions set down by the Competent Authority (EPA).

Ireland operates a Common Law legal system in which the law comprises a combination of principles adopted and developed by the courts through successive precedent cases and primary and secondary legislation passed by the legislature and government. In summary, the vesting of primary safety responsibility in the person carrying out an activity in Ireland derives from both principles of law developed by the courts and from legislation.

In Ireland primary responsibility for the safety of an installation would rest with the person or body owning and/or operating that installation. Such an allocation of responsibility would derive primarily from legal principles developed by the courts in the area of tortuous liability (i.e. negligence, occupier's and employer's liability). The imposition of such primary responsibility on the party carrying out an activity has been reinforced through primary legislation such as the health and safety legislation and miscellaneous secondary legislation such as S.I. No. 125 of 2000.

Article 8 Expertise and skills

Article 8
Member States shall ensure that the national framework require all parties to make arrangements for education and training for their staff, as well as research and development activities to cover the needs of the national programme for spent fuel and radioactive waste management in order to obtain, maintain and to further develop necessary expertise and skills.

Ireland has no nuclear industries and Government pursues an appropriate strategy and policy in terms of ensuring assurance of competence and capacity commensurate with the activities perused in Ireland involving the use of ionising radiation. With regard to the regulatory body, capacity and resources are negotiated with Government on an annual basis through the standard budgeting process. Where additional resources are required outside of this annual process these are pursued on a case by case basis. In addition, the regulatory body undergoes a periodic 'work force planning' exercise where there is a mapping of resources and required competencies against new and on-going work requirements and these needs are negotiated with Government. Within the regulatory body itself staff competences are considered at the individual level through a performance management system where individual training and competency requirements are considered in detail.

Certain Health care professionals such as doctors, dentists, nurses and radiographers are regulated through the establishment of statutory regulatory bodies (Medical Council, Dental Council, An Board Altranais, Radiographers Registration Board). In addition, veterinary surgeons are governed by the Veterinary Council. In addition, when the EPA authorise a licence for a facility, where appropriate assurance with regard to professional training is primarily assessed during the licensing process. For example, when licensing a Non Destructive Testing facility proof of relevant qualifications, training and experience of radiographers is sought. These issues are routinely discussed and checked during inspections.

The national infrastructure provides for such facilities and access according to the needs of various sectors. For example, in the medical sector there are five academic facilities involved in the training of medical doctors, two in the training of dentists and three in the training of veterinary surgeons. Several universities have research programmes in the area of radioactivity in the environment as well as research into radioactivity in building materials. There are training facilities for radiologists, radiographers and radiotherapists.

Training courses are organised by the regulated sectors themselves particularly in relation to medical physics activities and the EPA has the authority to approve courses and has endorsed an awareness course for the transport of Class 7 substances. In practice where there are gaps, the general practice has been for professionals to look abroad and particularly to the UK for training opportunities. Competence for certain professionals that are statutorily regulated are set by those regulatory bodies (e.g. Medical Council, Dental Council, Radiographers Registration Board). Other competencies are dealt with on a case by case basis and as part of the licensing and authorisation process.

Ensuring the availability of sufficient radiation protection professionals is a challenge both for the competent authority and for the regulated community. In particular, Ireland has established a formal competence based system of recognition for Radiation Protection Advisors and the current register of RPAs is well populated. RPAs have an important role in terms of advising on the management of the small inventory of radioactive material in Ireland.

There are no specific actions taken by Government with regard to competency building beyond providing adequate funding and legislative authority to the Regulatory Body which in turn provides oversight of the operators. Government also funds to a large extent the third level institutions which provide training in certain related disciplines. Given the range of activities involving the use of ionising radiation in Ireland and in particular the absence of a nuclear programme, such training arrangements are made as the need arises and are done locally by the interested party or regulated sector and there is no central coordination.

Article 9 Financial resources

Article 9
Member States shall ensure that the national framework require that adequate financial resources be available when needed for the implementation of national programmes referred to in Article 11, especially for the management of spent fuel and radioactive waste, taking due account of the responsibility of spent fuel and radioactive waste generators.

Prior to the merger of the RPII with the EPA, the RPII's income was made up of a grant from the Exchequer and earnings from licence charges and commercial measurement services. In 2012, the RPII's income was made up of a grant of €3.499m from the Exchequer and earnings of €1.679m from licence charges and dosimetry, product certification, radon measurement and other services. From 2015 the ORP will be allocated a budget within the EPA.

In 2005 the regulatory authority, with the assistance of an external accounting and consultancy firm, carried out a comprehensive review of all its licence fees. The revised schedule of fees, which provide for full cost recovery of the costs associated with running the Regulatory Service, was approved by the Minister of the Environment, Community & Local Government in 2007 and introduced by way of Regulations (Radiological Protection Act, 1991 (Licensing Application and Fees) Regulations, 2007 (S.I. No. 654 of 2007). The Regulations provide for a once-off application fee for new licence applications and an annual licence fee. Licensees fall into one of three fee categories depending upon:

- the number of practices to be licensed and the level of complexity of the practice(s)
- the type, size, number and complexity of the radioactive source or irradiating apparatus
- the security and safety measures
- the complexity of radiation protective measures required
- potential for doses arising to workers and members of the public
- consequences of an accident.

While there is no specific budget for radioactive waste management, related regulatory activities are funded through annual provision in the budgetary process. Extraordinary issues that arise from time to time are dealt with by DECLG on a case by case basis.

Article 10 Transparency

Article 10.1
Member States shall ensure that necessary information on the management of spent fuel and radioactive waste be made available to workers and the general public. This obligation includes ensuring that the competent regulatory authority inform the public in the fields of its competence. Information shall be made available to the public in accordance with national legislation and international obligations, provided that this does not jeopardise other interests such as, inter alia, security, recognised in national legislation or international obligations.

Article 10.2
Member States shall ensure that the public be given the necessary opportunities to participate effectively in the decision- making process regarding spent fuel and radioactive waste management in accordance with national legislation and international obligations.

One of the key strategic goals for the EPA is to provide information on radiation protection, in a readily accessible and understandable format, so that the public has the necessary information to protect themselves from the harmful effects of exposure to radiation. In particular, the EPA publishes an annual report on its regulatory activities and includes issues dealing with radioactive waste. A range of communication activities are undertaken each year to meet this objective and to promote the work of the EPA through the media, events, advertising, the EPA website, free phone call centre for radon advice, presentations and publications.

The media play a significant role in disseminating information and in reporting on radiological protection issues of public concern. Press releases are issued to coincide with the EPA's major events and media interest in EPA activities is strong with staff participating in many television and radio programmes on an annual basis. The print media also have a keen

interest in EPA activities. Feature articles have also been placed in publications which assist in highlighting the array of activities that the EPA is responsible for. The EPA ensures that all public communications are focused and use the media to target various groups in the community and continuously develops their existing relationships with the media.

Each year the EPA hosts a number of events including report launches, seminars and presentations with the objective of disseminating information to targeted groups. The EPA's website, www.epa.ie, is a valuable source of key information. Each year, the EPA produce a number of publications, including reports, guidance notes, codes of practice, information leaflets and posters – all of which are available free of charge on www.epa.ie.

Article 11 National Programmes

Article 11.1
Each Member State shall ensure the implementation of its national programme for the management of spent fuel and radioactive waste ('national programme'), covering all types of spent fuel and radioactive waste under its jurisdiction and all stages of spent fuel and radioactive waste management from generation to disposal.

Article 11.2
Each Member State shall regularly review and update its national programme, taking into account technical and scientific progress as appropriate as well as recommendations, lessons learned and good practices from peer reviews.

The key element of Ireland's policy and implementation programme is the adoption of the following activities:

- The inventory of disused radioactive sources currently stored in Ireland should be reduced through a co-ordinated and phased Inventory Reduction Programme.

- A National Radioactive Waste Storage Facility for disused radioactive sources is to be established. The Department of Environment, Community and Local Government (DECLG) and the Environmental Protection Agency (EPA) are to draw up a detailed specification for the facility and make recommendations on the siting, management and resourcing of the facility.

- Arrangements for the short term Emergency Storage of orphan or seized radioactive sources in an existing facility should be put in place as a matter of urgency until such time as the National Storage Facility is available to meet this requirement.

- Further consideration to be given to options for the final disposal of Ireland's disused radioactive sources. As part of this work should be consideration of the re-export of sources to elsewhere inside or outside the EU, by prior agreement, with one or more States, and under proper license agreement.

In implementing the Policy, Ireland follows the principles of;

- minimisation of the generation of radioactive waste in any form

- avoidance of the importation of radioactive waste in any form.

Another principle is the management of all sealed sources from "cradle to grave". This includes a licensing system and take-back arrangements with the original overseas supplier of the sources. If available, the practice of replacement of radioactive sources by non-radioactive alternatives is applied. This includes, for example, prohibiting the import and use of lightning conductors that employ radioactive sources or of radium used in luminescing materials. Ireland, in its transposition of the Directive, provided specifically for certain restrictions in relation to the importation and exportation of radioactive waste and these are enforced by the EPA, the Competent Authority for the Directive.

Key aspects of licensing central to implementing the overall policy on radioactive waste are as follows (it also covers aspects of the responsibilities of licence holders):-

- The licensing system in Ireland for sealed and unsealed sources has been in operation since 1977. As part of that system, information has been gathered and maintained on all such sources. This database provides a useful tool in the "cradle to grave" management of sources.
- Holders of disused sources are required to verify their holdings at specific periods which are set out in their licences and to report any anomalies to the EPA. Sealed sources, whether in use or not, must be leak tested not less than once every two years or as recommended by the manufacturers and reported to the EPA.
- Licence conditions include requirements for the management of radioactive waste.
- Licensees are required, as a prerequisite to licence issue, to have an agreement with the source supplier or manufacturer to take back sources ("take back agreement") when they become disused. The EPA looks for written evidence from the supplier or manufacturer that the source will be accepted back when no longer required before issuing a licence.
- Many categories of licensees are required to appoint a Radiation Protection Adviser (RPA). Furthermore the EPA maintains a Register of all persons approved to act as RPAs to undertakings in the medical, dental, educational and veterinary sectors. In assessing an application for RPA approval, one of the areas in which an applicant must demonstrate their competency is their knowledge of waste management principles.
- Licensees wishing to transfer sources between sites must comply with the international transport regulations and any licence conditions that the EPA may consider important to impose. A specialised training course for those involved in the transport of relevant radioactive consignments was first approved by the EPA in 2007 and has been re-evaluated on an annual basis since then. Similar arrangements apply to transboundary shipments. Transboundary shipments of sources within the EU are governed by specific pieces of European Community legislation.
- General requirements of the licence include a duty on licensees to keep records, to ensure proper labelling of sources and containers, to provide training and to arrange for the appointment of responsible persons by the licensees. Licensees are obliged to inform the EPA of any changes in the inventory of radioactive waste for which they are responsible and to have their licence amended accordingly.

- Inspectors from the EPA carry out inspections to assess compliance with the licence conditions. Information on the number of inspections carried out in 2014 is presented in Appendix 3.
- Members of An Garda Síochána's (national police force) Crime Prevention Office have undertaken security audits of facilities holding large numbers of disused radioactive sources and where necessary improved security measures have been implemented.

As part of the licensing process all licensees are obligated to carry out a risk assessment in relation to all sources in their custody and use including waste management at hospitals for example. Such licensees are also obligated to develop safety procedures to manage the risks identified and to keep doses as low as reasonably achievable. Such risk assessments and safety procedures have to be reviewed and updated periodically.

As a result of a combination of a well-established licensing system, take back arrangements and a comprehensive inventory of sources, there have been very few incidents involving orphan sources. The number of such sources that have been discovered is very low and the EPA has dealt with them in consultation with the Department of Environment, Community and Local Government on a case-by-case basis. Where orphan sources have been identified and seized they have been taken into the safe custody of existing licensees. There is now an operational protocol, mandated by Government, in place to deal with the management of such sources.

The licence conditions specify that adequate provision must be made, by way of a financial security or any other equivalent means appropriate to high activity sealed sources (HASS), for the safe management of HASS when they become disused sources. A documented financial costing for the safe management of HASS is required with all licence applications/amendments for HASS. This costing shall be signed by the General Manager or equivalent of the company concerned. In addition, a written guarantee from the General Manager or equivalent of the company concerned to cover the cost of management/disposal is required to accompany all licence applications/amendments. This guarantee covers the return or disposal of HASS, including all packaging, transport and return fees even in the event of the applicant/licensee becoming insolvent or going out of business. Any changes in the financial arrangements have to be confirmed in writing to the EPA on an annual basis.

The status of licence conditions is laid down in the Radiological Protection (Amendment) Act 2002 (Article 3 (1B)). This article states that *inter alia* that a person who fails to comply with a condition, or any provision of such condition, that is attached to a licence granted pursuant to an order or regulations made under Section 30 of the Radiological Protection Act, 1991 shall be guilty of an offence.

Article 12 Contents of national programmes

Article 12.1
The national programmes shall set out how the Member States intend to implement their national policies referred to in Article 4 for the responsible and safe management of spent fuel and radioactive waste to secure the aims of this Directive, and shall include all of the following:
(a) the overall objectives of the Member State's national policy in respect of spent fuel and radioactive waste

management;
(b) the significant milestones and clear timeframes for the achievement of those milestones in light of the over-arching objectives of the n ational programme;
(c)an inventory of all spent fuel and radioactive waste and estimates for future quantities, including those from decommissioning, clearly indicating the location and amount of the radioactive waste and spent fuel in accordance with appropriate classification of the radioactive waste;
(d) the concepts or plans and technical solutions for spent fuel and radioactive waste management from generation to disposal;
(e) the concepts or plans for the post-closure period of a disposal facility's lifetime, including the period during which appropriate controls are retained and the means to be employed to preserve knowledge of that facility in the longer term;
(f) the research, development and demonstration activities that are needed in order to implement solutions for the management of spent fuel and radioactive waste;
(g) the responsibility for the implementation of the national programme and the key performance indicators to monitor progress towards implementation;
(h) an assessment of the national programme costs and the underlying basis and hypotheses for that assessment, which must include a profile over time;
(i) the financing scheme(s) in force;
(j) a transparency policy or process as referred to in Article 10;
(k) if any, the agreement(s) concluded with a Member State or a third country on management of spent fuel or radioactive waste, including on the use of disposal facilities.

Article 12.2
The national programme together with the national policy may be contained in a single document or in a number of documents.

Ireland uses radioactive materials in the form of sealed and unsealed sources in support of its high technology industries and its medical and other societal infrastructure. These activities give rise to waste materials such as disused sealed sources. There are also small amounts of naturally occurring radioactive materials that are produced and also discharged as a result of Ireland's exploitation of natural resources. These are the radioactive wastes that are the subject of Irish Government policy and programmes. All such wastes are regulated by licence and overseen by the EPA and as provided for by the Radiological Protection Act, 1991 and subsidiary legislation. In practice, existing licences are not closed until all activities have been ceased, decommissioned or disposed of in a manner approved by the Regulatory Body or a successor licensee has been established. In this way continuity of responsibility is enforced by Government through the operational activities of the Regulatory Body.

With regard to radioactive sources, the EPA implements a 'take back' agreement requirement which requires at the point of authorisation a facility to make provision for the repatriation of the source or its disposal at the end of its useful life and to ensure that financial provisions are in place to implement that agreement.

Where wastes are held by an authorised party, the conditions under which these wastes are maintained are set out in licence conditions by the EPA. As Ireland has no nuclear facilities by definition all of the waste arising would fall into the IAEA's low level waste category and no formal waste categorisation process beyond that was deemed of value in that context. In practice however, during the surplus sources reduction programme that was undertaken following the Government Decision in December 2010, it proved useful to class sources in terms of 'half-life bands' for management purposes (Towards a Radioactive Waste Policy for Ireland, 2006). In addition High Activity Sealed Sources (HASS) have a particular definition in legislation and where they occur in waste, they are specifically identified as HASS.

There is also in place a Temporary Operational Protocol (TOP) for dealing with orphan sources and sources that are seized by the Regulatory Body. In these cases, where the responsible parties cannot be identified then the DECLG will step in to consider funding issues in the management and disposal of sources on a case by case basis.

In practice, radioactive waste in unsealed form arises from the use of radionuclides mainly in hospitals and in a few educational and research establishments. The sources are either imported from the relevant overseas suppliers or short-lived ones generated on the main hospital sites.

Requirements for the licensing of the use and disposal of unsealed sources, or exemption from such requirements, are established by Article 5 of S.I. No. 125 of 2000. Quantities or concentrations requiring licensing under S.I. No. 125 of 2000 are based on Annex I of the EU Council Directive 96/29/Euratom. Normal practice in regard to requirements for licensing is to apply the limits or concentrations used on a daily basis.

The main aspects of the safety and management of unsealed sources in Ireland are as follows:

- The generator cores that produce Tc-99 are returned to the supplier. Most are being imported from Holland or the UK. Transport to and from Ireland is in accordance with the appropriate Transport Regulations.

- The practice of liquid radioactive waste disposal relates mainly to the medical sector in Ireland. It is a condition of licences granted in the medical sector, where unsealed sources are used, that there is annual recording of the quantities discharged. This data is now collated annually by the EPA and is available to the OSPAR Commission as part of Ireland's reporting requirements under the OSPAR Convention. In addition, recent assessments have shown that the maximum dose to the critical public group (sewer workers) from such disposals is less than 10 µSv/year.

- Solid waste materials from hospitals that contain residual activity are segregated and controlled at source. In particular, they are isolated and stored until the levels of radioactivity are such that disposal is permitted under the conditions set out in the hospitals' licence.

- Licensees are obliged to report the quantities which are actually disposed of to sewers in the case of specific radionuclides.

- Licence conditions on hospitals include requirements to ensure that precautions are taken to prevent radioactive contamination, including contamination in the form of excreta from patients.

- The licence condition places an obligation on hospitals and clinics to keep records of radionuclide administrations to patients which will enable estimates of the quantities excreted to the sewers to be made, using established excretion factors.

- The EPA also requires that any licence application to use unsealed radionuclides for medical purposes be accompanied by an estimation of doses to critical groups. In the case of disposal to sewers, the licensee must demonstrate that doses to sewer workers, who are taken as the critical group, will be below 300 µSv/year. In practice such doses will be below 10 µSv/year.

Use and Potential use of Holding Tanks for Discharges from Hospitals

There are currently five hospitals in Ireland, which are involved in radioiodine thyroid ablation treatments and therefore use significant amounts of radioiodine (~3-5 GBq/patient). In this regard, the doses to critical groups averted by decay tanks must be balanced against the potential radiation doses to workers involved in their maintenance and risks from bacteriological hazards. All hospitals in Ireland that use significant amounts of radionuclides for therapeutic purpose are situated close to the sea. This means that discharges to sewers pass into treatment works and then via a normally short route to the sea where dilution takes place quickly. There are no discharges from such facilities into fresh water that may be used for human consumption.

Following a review of iodine ablation therapy practices in Ireland, particularly in relation to the possible use of holding tanks for the decay of Iodine-131, the following regulatory position was adopted and remains valid in 2015:

- In the case of existing iodine ablation facilities licensees will not be required to retro-fit iodine holding tanks.
- Licensees with existing ablation facilities will be required to undertake both on- and off-site monitoring to validate the assumptions and calculations in their risk assessments.
- Licence applications for new ablation facilities will continue to be assessed on a case-by-case basis to determine whether holding tanks are required.
- New and existing licensees will be required to undertake appropriate on- and off-site monitoring of discharges to validate the assumptions and calculations in their risk assessments during the operation of their facilities.

Inventory of Sealed Sources

In accordance with the priorities identified in Ireland's 2010 national policy on radioactive waste, a programme commenced in 2011 to reduce the inventory of disused radioactive sources held by licensees across Ireland. This programme has resulted in a very significant reduction the national inventory of disused sealed sources, reducing it to a very small fraction of the inventory that existed in the years prior to 2011 (Figure 4).

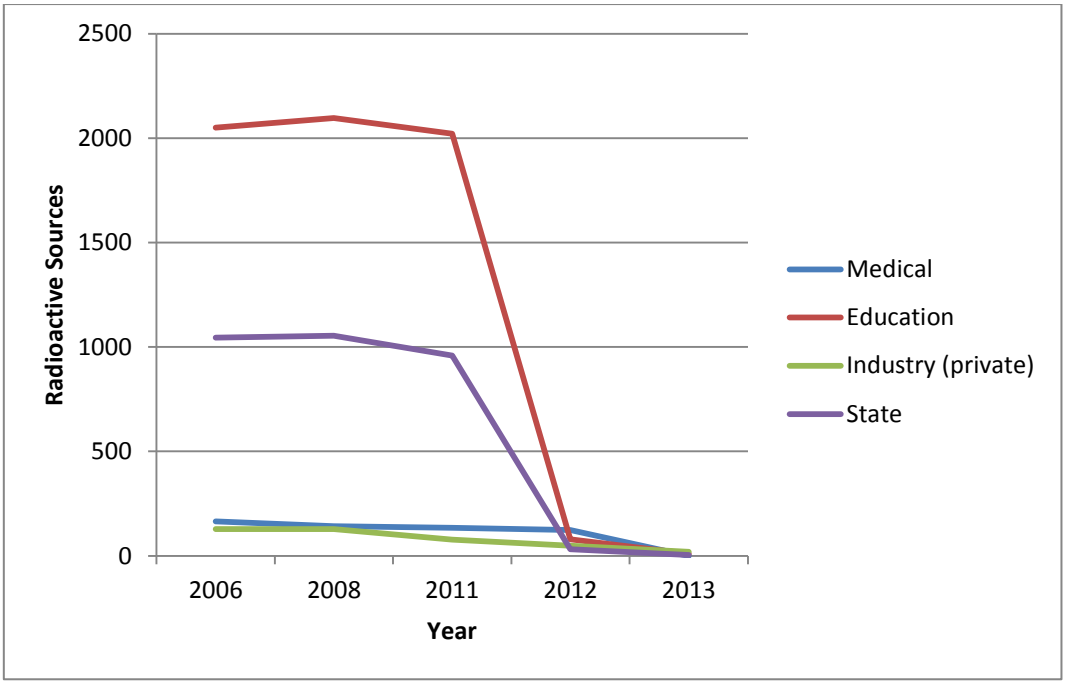

Figure 4: Disused source inventory reduction in all sectors (half-life >10 years)

The few sources that comprise the current disused source inventory arise from acquisitions made prior to the introduction of take-back agreements into normal regulatory practice and so the waste issue in Ireland is substantially a legacy issue. The inventory is comprised of items containing such radioisotopes as Cs-137, Co-60, Am-241 and Sr-90. These are detailed in Appendix 2.

Natural Uranium Rods in a Sub-critical Assembly

Until recently, Ireland had in storage 2.5 tonnes of uranium metal in the form of rods that were originally supplied as an experimental sub-critical assembly to a University Department from the United States under the "Atoms For Peace" programme. The sub-critical assembly was used for student experiments until the 1980s after which it was disassembled. The neutron fluxes and consequent build-up of fission products was considered negligible. The rods were stored in boxes and had been declared as radioactive waste. They were maintained in single secure store fitted with CCTV cameras and were the subject of inspections and quarterly reports under the Safeguards Agreement with the International Atomic Energy Agency (IAEA) (INFCIRC/263) and the European Atomic Energy Community (EURATOM).

The sub-critical assembly essentially consisted of an array of uranium in a water-filled steel tank in which fission reactions were initiated by neutrons from an appropriate source. Given its sub-critical nature, a neutron source was required to initiate fission and also to maintain a measurable neutron flux. To that end, a neutron source, made of a quarter gram of Plutonium and Beryllium, was also supplied to the university under the Atoms for Peace Program.

The safe repatriation of all nuclear material was achieved thanks to the financial support of the Higher Education Authorities in Ireland and the facility was officially decommissioned by the IAEA as a storage facility for nuclear materials in 2013.

Iodine-125 Sources

There was a practice in hospitals whereby Iodine-125 seeds used in brachytherapy were recorded as waste. However, there is now a procedure in place for the return of seeds to the supplier. On occasion, issues can arise with the return of individual seeds, and currently one hospital holds a small number of biologically contaminated seeds. These issues are dealt with on a case by case basis.

Radium Sources

In common with all countries, Ireland historically (from about 1900 to 1980) used radium in medical applications and some other applications but has replaced this with safer, more efficient and easier to use radioisotopes. All legacy disused radium sources have now been disposed of abroad as part of the source reduction programme in line with Government policy.

Lightning Preventors Incorporating Radium

In the 1970s a number of lightning preventors incorporating radium in semi-sealed sources were imported and used on a number of buildings in Ireland. They are no longer considered to provide any benefit over conventional lightning conductors and the EPA does not authorise their importation. There was a concerted effort in particular to have these removed from buildings and disposed of and this proved to be very successful. With the exception of a few recently discovered preventors heads, all known lightning preventors were successfully disposed of to authorised overseas facilities.

Technetium 99 (Tc-99)

Until recently there was an estimated 7000 older Tc-99m (t½ ~6 hours) generator cores, which were acquired prior to the introduction of the practice of requiring take-back agreements, held in storage. While, strictly speaking, they were not sealed sources they were included under this heading for the purposes of this Report. The generator cores contained the very long-lived and hence low specific activity Tc-99 daughter. All legacy disused Technetium-99 generator cores have now been disposed of abroad as part of the source reduction programme in line with Government policy.

Disused Educational Sources

Until recently, there was an estimated 475 small teaching sources held by post primary schools that were no longer in use and were awaiting disposal. In addition, there was an estimated 9 kg of thorium and uranium components (unsealed) also awaiting disposal. These figures had been extrapolated from a survey of schools undertaken in 2000.

In terms of the disposal programme for disused sources held by secondary schools, a tender seeking specialist waste disposal contractors to dispose of all unwanted schools sources was issued in 2013. Following a successful tender process, a source disposal programme

commenced in June 2013. By 2014 1066 disused radioactive sources had been removed from 201 schools. Approximately 42 schools still retain radioactive source which continue to be used for demonstration purposes.

Implementation in Ireland of the HASS Directive

The purpose of the HASS Directive (2003/122/EURATOM) is to prevent exposure of workers and the public to ionising radiation arising from inadequate control of high activity sealed radioactive sources and orphan sources and to harmonise controls in place in the Member States by defining specific requirements ensuring that each such source is kept under control. The Directive was transposed into Irish Law in December 2005 as the Radiological Protection Act 1991 (Control of high-activity sealed radioactive sources) Order 2005 (S.I. No. 875 of 2005). The EPA is designated as the Competent Authority for the purposes of the Legislation and the Directive.

At present there are approximately 1132 licensed sealed sources in Ireland, which have activities that would bring them under the control of the HASS Directive. Most of these are used in the irradiation cells of two sterilisation plants. The majority of the remaining sources coming within the scope of the HASS Directive are held by industrial radiography companies, universities, and hospitals and by a manufacturer of radioactive gauges. All legacy HASS sources, that were no longer required, were disposed of abroad as part of the source reduction programme in line with Government policy.

Progress on Inventory Reduction

As can be seen from Appendix 2 (Table 1.1 – 1.17), initiatives taken by the EPA and other actors in line with Government policy during the reporting period have resulted in almost the elimination of the legacy sources in all categories. These initiatives included encouraging holders through the inspection process to pursue disposal options available from specialist waste management companies. A particularly successful initiative in the educational sector saw monies made available for the disposal of sources in that sector. They also included the development of a number of waste related regulatory guidance documents aimed at assisting holders to manage and dispose of certain categories of sources. Guidance included:

- A Guidance Note on the Management of Waste Ionisation Chamber Smoke Detectors (ICSDs)
- A Guidance Note for the Disposal of Decayed Sources to Landfill Facilities
- A Guidance Note for the Disposal of Prepared Uranium and Thorium Compounds

In 2011 there were 50 holders of sources across a range of half-lives and management requirements. At the time of reporting in 2015 this number had reduced to 15 but holding only 43 sources (Table 1.17).

The EPA continually reviews its licensing and inspection system to ensure that it remains focused on ensuring a high level of safety and security and takes account of developments in

radiation protection philosophy and radiation safety standards. Recently implemented or planned activities to that form the national programme and improve safety include:-

- The establishment of a National Radioactive Waste Storage Facility for disused radioactive sources. The Department of Environment, Community and Local Government (DECLG) and the Environmental Protection Agency (EPA) are to draw up a detailed specification for the facility and make recommendations on the siting, management and resourcing of the facility.

- Further consideration will be given to options for the final disposal of Ireland's small inventory of disused radioactive sources.

- To continue to work with other interested Government Departments and organisations towards implementing national policy for the safe long-term management and ultimate disposal of Ireland's radioactive waste materials.

- Ireland has requested an Integrated Regulatory Review Service (IRRS) mission from the IAEA which is scheduled to take place in September 2015.

- A new Radiation Protection Advisory Committee has been established to advise the EPA in all issues relation to radiation protection including radioactive waste issues.

In addition the EPA will take the following specific regulatory actions:

- Continue to target holders of radioactive waste in the annual inspection programme bringing pressure to bear to explore disposal options. To date the pressure has been in the form of focusing on waste disposal during inspection and through sectoral pressure in the health and education sectors by respective ministries. Ultimately, where routes are identified and there are no compelling reasons for not exercising them particularly where there are existing 'take back' agreements in place then licences can be revoked and prosecutions can be contemplated though this has not been tested to date. The current strategy is to strongly encourage compliance and there is some evidence that this is working.

- Engage with the Radiation Protection Advisors (RPA) in a future workshops to outline the issues and objectives of the inventory reduction programme and to encourage their active participation in source disposal initiatives.

- Establish the regulatory licensing criteria for the design, construction and operation of a National Waste Management Storage facility.

- Introduce a more graded approach to authorisation and to increase to the maximum extent possible, taking full cognisant of safety and security issues, the transparency of the regulatory process

- The introduction of a modern information management system to replace the current system to provide a greater degree of functionality and data management.

Table of Acronyms

ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road

CPPNM - Convention on the Physical Protection of Nuclear Material

DECLG - Department of Environment, Community and Local Government

EPA - Environmental Protection Agency

EURATOM - European Atomic Energy Community

HASS - High Activity Sealed Sources

HSA - Health and Safety Authority

IAEA - International Atomic Energy Agency

ICAO – International Civil Aviation Organization

ICSD - Ionisation Chamber Smoke Detectors

IMDG - International Maritime Code for Dangerous Goods

INAB - Irish National Accreditation Board

IRRS - Integrated Regulatory Review Service

OCCS - Office of Communications and Corporate Services

OCLRR - Office of Climate, Licensing, Resources and Research

ODG - Office of the Director General

OEA - Office of Environmental Assessment

OEE - Office of Environmental Enforcement

ORP - Office of Radiological Protection

OSPAR – Convention for the Protection of the Marine Environment of the North-East Atlantic

RID – Regulations Concerning the International Carriage of Dangerous Goods by Rail

RPA - Radiation Protection Adviser

RPII – Radiological Protection Institute of Ireland

RPR - Radiation Protection Regulation

S.I. - Statutory Instrument (secondary legislation)

TOP - Temporary Operational Protocol

Appendix 1: Relevant National Laws, Regulations and Requirements

Primary Legislation

Radiological Protection Act, 1991 (No. 9 of 1991)

The Act establishes the Radiological Protection Institute of Ireland (RPII), and defines its functions. It sets out the appointment and powers of inspectors (Articles 28 and 29 of the 1991 Act) and the framework for the ORP licensing system (Article 30 of the 1991 Act as amended).

Environmental Protection Agency Act, 1992 (No. 7 of 1992)

The Act establishes the Environmental Protection Agency (EPA) and defines its functions.

Energy (Miscellaneous Provisions) Act, 1995 (No. 35 of 1995)

Section 26 – provides for regulation of use of radioactive material in medical and dental apparatus.

Food Safety Authority Act, 1998 (No. 29 of 1998)

Section 65 provides for the inclusion of Food Safety Authority in the Radiological Protection Act, 1991.

Carriage of Dangerous Goods by Road Act, 1998 (Number 43 of 1998)

This Act enables effect to be given to the ADR agreement.

Electricity Regulation Act, 1999 (No. 23 of 1999)

Section 18 – (6) An order under this section shall not provide for the use of nuclear fission for the generation of electricity.

Radiological Protection (Amendment) Act, 2002 (No.3 of 2002)

Amends the Radiological Protection Acts, 1991 and 1995, and provides for the making of grants out of funds provided by the Oireachtas.

Containment of Nuclear Weapons Act, 2003 (No. 35 of 2003)

This Act provides the legislative basis for the implementation of Ireland's obligations under the 1998 Protocol to the 1973 Agreement between the European Atomic Energy Community (EURATOM); the non-nuclear weapons States of EURATOM and the International Atomic Energy Agency.

Nuclear Test Ban Act, 2008 (No. 16 of 2008)

This Act provides the legislation needed to enable Ireland to implement its obligations under the Comprehensive Nuclear Test Ban Treaty.

Radiological Protection (Miscellaneous Provisions) Act, 2014 (No. 20 of 2014)
Provides for dissolution of the Radiological Protection Institute of Ireland and the transfer of all its functions, assets, liabilities and staff to the Environmental Protection Agency and gives effect to the amendment to the Convention on the Physical Protection of Nuclear Material done at Vienna on 8 July 2005.

Secondary Legislation

European Communities (Radiological Emergency Warning to Public) Regulations, 1993 (S.I. No. 209 of 1993)
This statutory instrument gives effect to Council Directive 89/618/Euratom on informing the general public about the health protection measures to be applied and the steps to be taken in the event of a radiological emergency.

Council Regulation (Euratom) No. 1493/93 on shipments of radioactive substances between Member States.
This regulation sets out the procedure to be followed when shipping sealed sources to Member States of the European Union.

European Communities (Supervision and Control of Certain Shipments of Radioactive Waste) Regulations, 1994 (S.I. No. 276 of 1994)
This statutory instrument gives effect to Council Directive 92/3/Euratom on the shipment of radioactive waste.

Radiological Protection Act, 1991 (Ionising Radiation) Order, 2000 (S.I. No. 125 of 2000)
This statutory instrument gives effect to Council Directive 96/29/Euratom (Basic Safety Standards Directive) and to Council Directive 90/641/Euratom (Outside Workers Directive).

European Communities (Safety Advisors for the Transport of Dangerous Goods by Road and Rail) Regulations, 2001 (S.I. No 6 of 2001)
This statutory instrument gives effect to Directive No. 96/35/EC and Directive 2001/18/EC.

Carriage of Dangerous Goods by Road Regulations, 2001 (S.I. No. 492 of 2001)
This statutory instrument gives effect to Council Directives 94/55/EC as amended by Directive 2000/61/EC and Directives 96/86/EC and Directive 1999/47/EC and Directive 95/50/EC as amended by Directive 2001/26/EC on the carriage of dangerous goods by road; including the loading and unloading of the dangerous goods in relation to their carriage.

European Communities (Medical Ionising Radiation Protection) Regulations, 2002 (S.I. No. 478 of 2002)
This statutory instrument gives effect to Council Directive 97/43/ Euratom on the health protection of individuals against the dangers of ionising radiation in relation to medical exposures.

Containment of Nuclear Weapons Act, 2003 Regulations, 2004 (S.I. 123 of 2004)

This Regulation provides the regulatory basis to enable Ireland to implement its obligations under the Protocol Additional to the 1973 Agreement.

Radiological Protection Act, 1991 (Control of high-activity sealed radioactive sources) Order 2005 (S.I. No. 875 of 2005)

This statutory instrument gives effect to Directive No. 2003/122/EURATOM and sets out some of the specific requirements of authorisation to hold and use the types of sources that come within the scope of the Directive.

Radiological Protection Act, 1991 (Licensing Application and Fees) Regulations, 2007 (S.I. No. 654 of 2007)

This statutory instrument sets out the information to be supplied in a licence application, licence categories and fees as well as the criteria applied by the ORP in determining the category of licence required.

European Communities (Supervision and Control of Certain Shipments of Radioactive Waste and Spent Fuel) Order, 2009 (S.I. No 86 of 2009)

This statutory instrument gives effect to Directive No. 2006/17/EURATOM laying down conditions for the supervision and control of shipments of radioactive waste and spent fuel.

Radiological Protection Act, 1991 (Responsible and Safe Management of Radioactive Waste) Order 2013 (S.I. No. 320 of 2013)

This Order transposes Ireland's obligations in relation to Directive 2011/70/EURATOM.

Appendix 2: Data for disused sources in Ireland (Sorted by Half-life and Sector)

Table 1.1: Medical Sector 'Custody Only' Sources – half-life > 10 y

Licensee Code	Nuclide	No of Sources (2008)	No of Sources (2011)	No of Sources (2014)
LM1	AM-241	1	1	0
	CS-137	1	1	0
	U-238		4	0
LM2	CS-137	1	0	1
	U-238		1	0
LM4	CS-137	1	1	0
	BA-133	1	1	0
	AM-241	1	1	0
	RA-226	1	1	0
LM5	PU-238	1	1	0
LM6	AM-241	1	1	0
LM8	CS-137	1	0	0
	RA-226	2	0	0
LM9	Sealed/unsealed	109	105	0
	(Misc)		1	0
	SR-90		1	0
	BA-133/CS-137			
LM10	AM-241	2	3	0
	CS-137	10	2	0
	RA-226	2	2	0
LM12	CS-137	5	5	4
	NI-63	1	1	0
	SR-90	1	1	1
	Total	**142**	**134**	**6**

Table 1.2: Medical Sector 'Custody Only' Sources – half-life 5 - 10 y

Licensee	Nuclide	No of Sources (2008)	No of Sources (2011)	No of Sources (2014)
None				
	Total	**0**	**0**	**0**

Table 1.3: Medical Sector 'Custody Only' Sources – half-life 1 - 5 y

Licensee	Nuclide	No of Sources (2008)	No of Sources (2011)	No of Sources (2014)
None				
	Total	**0**	**0**	**0**

Table 1.4: Medical Sector 'Custody Only' Sources – half-life <1 y

Licensee	Nuclide	No of Sources (2008)	No of Sources (2011)	No of Sources (2014)
LM2	CO-57 IR192 Ge-68	3	0 1	0 0 1
LM4	CO-57		1	0
LM6	CO-57	10	10	0
LM7	CO-57	2	0	0
LM15	GD-153	1	0	0
LM16	CO-57	7	7	0
LM17	I-125 CO-57	1 1	0 0	0 0
LM8	CO-57	26	0	0
	GD-153	2	0	0
LM11	CO-57	1	0	0
LM12	CO-57	6	6	6
LM 100	CO-57	1	1	0
	Total	**61**	**26**	**7**

Table 1.5: Educational Sector 'Custody Only' Sources Half-Life >10 y

Licensee	Nuclide	No of Sources (2008)	No of Sources (2011)	No of Sources (2014
LE1	AM-241	1	0	0
	RA-226	3	3	0
	SR-90	1	1	0
	NI-63		1	1
	Th-232	5	3	0
	U-238+	5	7	0
	Misc	2	3	0
LE2	CS-137	2	1	0
	Ra-226	2	0	0
	SR-90	5	5	0
	Th-232	8	8	0
	Misc	10	10	0
LE3	SR-90	1	1	1
	AM-241		1	0
	AM/BE		1	0
	Th-232	16	3	0
	TH-232NAT	1	0	0
	U-238+	3	3	0
LE4	RA-226	1	0	0
LE5	Am 241	16	8	0
	SR-90	14	0	0
	H3	10	14	0
	Cs137	12	4	0
	C-14	8	6	0
	TH 232	16	9	0
	U-238	53	36	0
	Ra-226	6	1	0
	PU-239	1	1	0
	I-129	3	0	0
	Ni-63		1	0
	CS-137/BA-137		1	0
	Misc	13	12	0
LE6	SR-90	7	3	0
	Thorium-232	9	8	0
	U-238+	14	13	0
LE7	Th-232	10	10	0
	U-238+	20	20	0
	Misc	3	3	0
LE8	RA-226	1	1	0
	RN-222+	1	1	0
	NI-63		2	0
	SR-90	2	2	0
	SR-90+	3	0	0
	TH-232NAT	3	3	0
	U-238+	7	7	0
LE9	AM-241	2	2	0
	AM-241/BE	2	2	0

Licensee	Nuclide	No of Sources (2008)	No of Sources (2011)	No of Sources (2014
	CS-137	2	2	0
	RA-226	3	7	0
	KR-85		3	0
	U-238	1	1	0
	Th-232	1	1	0
	TH-232N	1	0	0
LE10	AM-241	3	0	0
	C-14	1	0	1
	RA-226	4	2	0
	SR-90	5	0	0
	TH-232NAT	4	0	0
	U-238	25	1	0
	Sealed/unsealed (Misc)	210	188	0
LE11	CS-137	3	3	4
	AM-241	1	1	0
	PU-238/Beryllium	1	1	0
	NI-63	2	2	0
	RA-226	2	2	0
	SM-151	3	3	0
	SR-90	2	2	0
	TH-232N	1	1	0
	U-238	1401	1401	0
LE12	Am-241	6	6	0
	Bi-207	1	1	0
	Pb-210	3	3	0
	Ra-226	10	10	0
	Cs-137	3	3	0
	C-14	2	2	0
	H-3	7	7	0
	Ni-63	3	3	0
	Sr-90	1	1	0
	Th-232	2	4	0
	MISC	9	5	0
	U-238	17	39	0
	Sealed/unsealed Misc	8	10	0
LE13	AM-241	4	4	0
	NI-63	1	1	0
	Th-232	3	1	0
	U-238	3	7	0
				0
LE14	SR-90		4	0
	AM-241		2	0
	RA-226		3	0
	Th-232	4	4	0
LE100	Th-232	1	0	0
LE101	U-238		8	0
	TH-232		6	0
	Misc	4	4	0

Licensee	Nuclide	No of Sources (2008)	No of Sources (2011)	No of Sources (2014
LE102	Ra-226	1	3	1
	Ni-63	1	1	0
	SR-90	1	9	0
	AM-241		4	0
	U-238	13	13	0
	TH-232	10	11	0
LE500	Cs-137/Ba-137			4
	U/TH			2
	Total	**2096**	**2021**	**14**

Table 1.6: Educational Sector 'Custody Only' Sources Half-Life 5 - 10 y

Licensee	Nuclide	No of Sources (2008)	No of Sources (2011)	No of Sources (2014)
LE1	CO-60	4	5	0
LE2	CO-60	3	3	0
LE3	CO-60	1	1	1
LE5	CO-60	9	0	0
LE9	CO-60	1	1	1
LE10	CO-60	3	0	0
LE11	CO-60	4	3	0
LE12	C0-60		4	0
	Total	**25**	**17**	**2**

Table 1.7: Educational Sector 'Custody Only' Sources Half-Life 1 -5 y

Licensee	Nuclide	No of Sources (2008)	No of Sources (2011)	No of Sources (2014)
LE14	CD-109	1	1	0
	FE-55	1	1	0
LE5	NA-22	3	1	0
	TL-204	4	2	0
	CS-134	2	0	0
LE12	FE-55		1	0
	TL-204		2	0
	CS-134/TL-204		1	0
	NA-22		1	0
	Total	**11**	**10**	**0**

Table 1.8: Educational Sector 'Custody Only' Sources Half-Life < 1 y

Licensee	Nuclide	No of Sources (2008)	No of Sources (2011)	No of Sources (2014)
LE9	C0-57	1	1	0
	CO/FE	0	2	0
	SN-119	6	6	0
LE15	CO-57	4	4	
LE5	C0-58	1	1	0
	P-32	6	4	0
	P-33	2	1	0
	S-35	1	1	0
	I-131	0	1	0
	CR-51	1	1	0
	PO-210	1	0	0
LE11	CO-57	8	8	0
	FE-59	1	1	0
LE2	I-125	1	0	0
LE3	PO-210	1	1	1
	Total	**34**	**32**	**1**

Table 1.9: Industrial Sector 'Custody Only' Sources Half-Life > 10 y

Licensee	Nuclide	No of Sources (2008)	No of Sources (2011)	No of Sources (2014)
LI1	TH-232NAT	1	0	0
LI100	TH-232	1	0	0
LI2	AM-241/BE	1	0	0
	CS-137	1	0	0
	Cm-244	1	0	0
LI3	AM-241	3	2	2
	SR-90	1	1	1
LI4	AM-241	1	0	0
LI5	U-238+	1	0	0
	Ni-63	3	0	0
LI6				0
	AM-241/BE	1	0	0
	NI-63	27	0	0
LI101	U-238	3	3	0
LI102	Am-241	1	0	0
LI7	CS-137	2	0	0
LI103	Cs137	1	0	0
LI11	RA-226	1	0	0
LI12	NI-63	3	1	0
LI104	U-238	1	1	0
LI13	AM-241	7	0	0
LI105	u-238	1	18	0
	TH-232		10	0
	MISC		3	0
LI16	CS-137	1	0	0
LI106	Am-241/Be	1	0	0
LI107	U-238	2	0	0
LI108	Am-241/Be	3	0	0
	Cs-137	3	0	0
LI109	KR-85	1	0	0
LI20	Am-241	3	3	0
	Ra-226	4	4	0
LI110	Ni-63	8	16	0
LI23	Am-241/Berylium	1	0	0
	Cs-137	1	0	0
LI24	NI-63	1	0	0
LI25	AM-241/BE	1	0	0
	CS-137	1	0	0
LI26	RA-226	1	0	0
LI28	AM-241/BE	2	0	0
LI30	CS-137	1	1	0
LI40	USN&A	1	1	0
LI41	CU-244	2	0	0
LI42	NI-63	1	0	0
LI43	RA-226	1	1	0
	TH-232N	1	1	0

	U-238	1	1	0
	URYLATE	2	1	0
LI111	U-238	1	0	0
LI44	AM-241	1	0	0
LI46	AM-241/BE	1	0	0
	CS-137	1	0	0
LI112	Am-241/Be	1	0	0
	Cs-137	1	0	0
LI48	CS-137	1	0	0
LI49	AM-241		0	0
LI113	AM-241	1	1	0
LI114	U-238	3	0	0
LI52	SR-90	6	6	0
LI53	CS-137	2	2	0
LI54	CS-137	1	0	0
LI115	Cs-137	1	0	0
LI55	RA-226	1	1	0
	Am-241/Be	0	0	3
LI600	Cs-137	0	0	3
LI601	NI-63	0	0	1
LI602	AM-241	0	0	1
LI603	AM-241	0	0	1
LI604	NI-63	0	0	1
	Total	**128**	**78**	**13**

Table 1.10: Industrial Sector 'Custody Only' Sources Half-Life 5 - 10 y

Licensee	Nuclide	No of Sources (2008)	No of Sources (2011)	No of Sources (2014)
LI116	CO-60	1	1	0
	Total	**1**	**1**	**0**

Table 1.11: Industrial Sector 'Custody Only' Sources Half-Life 1 - 5 y

Licensee	Nuclide	No of Sources (2008)	No of Sources (2011)	No of Sources (2014)
LI117	Tl-204	1	0	0
LI118	TI-204	1	0	0
LI119	PM-147	1	1	0
LI120	CD-109	1	0	0
LI40	PM-147		0	0
	TI-204		0	0
LI113	PM-147	2	2	0
	TI-204	1	1	0
LI43	TI-204	7	7	0
	Total	**14**	**11**	**0**

Table 1.12: Industrial Sector 'Custody Only' Sources Half-Life < 1 y

Licensee	Nuclide	No of Sources (2008)	No of Sources (2011)	No of Sources (2014)
LI48	Co-57	5	0	0
LI121	Po-210	1	0	0
	Total	**6**	**0**	**0**

Table 1.13: State (other) Sector 'Custody Only' Sources Half-Life > 10 y

Licensee	Nuclide	No of Sources (2008)	No of Sources (2011)	No of Sources (2014)
LSO1	AM-241	2	2	0
	CS-137+	3	3	0
LSO100	Th-232	1	1	0
LSO101	TH-232	1	1	0
	U-238	1	1	0
LSO2	CL-36	1	0	0
	NI-63	1	0	0
	Ra-226	1	0	0
LSO4	H-3	1	0	0
	NI-63	3	0	0
LSO6	Am-241	1	0	0
	H-3	33	0	0
	Misc	3	0	0
	U-238+	3	0	0
LSO7	Am-241/Beryl	1	0	0
	Cs-137	1	0	0
LSO8	AM-241/BE	2	0	0
	CS-137	2	0	0
LSO10	C-14	65	40	0
	Cs-137	1	0	0
	Sr-90	1	0	0
	Ra-226	877	877	0
LSO102	Ni-63	1	1	0
LSO12	Am-241	2	0	0
	CS-137	7	5	0
	Sr-90	7	5	0
	Th-232	1	1	0
	U-232/Th-232	1	1	0
	U-238+	7	0	0
	Ra-226	8	8	0
LSO103	Ni-63	4	4	0
	U-238	2	4	0
LSO13	AM-241/BE	2	2	0
	CS-137	3	1	0
	NI-63	2	0	0
	U-238	2	2	0
				0
	Total	**1054**	**959**	**0**

Table 1.14: State (Other) Sector 'Custody Only' Sources Half-Life 5 – 10 y

Licensee	Nuclide	No of Sources (2008)	No of Sources (2011)	No of Sources (2014)
LSO12	CO-60	1	1	0
LSO2	BA-133	1	0	0
	Total	**2**	**1**	**0**

Table 1.15: State (Other) Sector 'Custody Only' Sources Half-Life 1 - 5 y

Licensee	Nuclide	No of Sources (2008)	No of Sources (2011)	No of Sources (2014)
LSO6	Cd-109 Fe-55		0 0	0 0
LSO4	TI-204 PM-147	1 2	0 0	0 0
	Total	**3**	**0**	**0**

Table 1.16: State (Other) Sector 'Custody Only' Sources Half-Life <1 y

Licensee	Nuclide	No of Sources (2008)	No of Sources (2011)	No of Sources (2014)
LSO12	Co-57	1	1	0
LSO13	I-125	2	2	0
	Total	**3**	**3**	**0**

Table 1.17: Summary 'Custody Only' sources September 2014

	No of Licensees	No of sources half-life >10 yrs	No of Sources half-life <10 yrs	Total no Sources
Medical	*2*	6	7	13
Industry	*6*	13	0	13
Education	*7*	14	3	17
State/Other	*0*	0	0	0
	15	33	10	**43**

Appendix 3: Summary Table of Completed Inspection Schedule for 2014

Licence Category	No. in Category	Number of Inspections Proposed	Number of Inspections Completed
Chiropractors	15	1	1
Dentists	932	5	6
Distributors (sources & X-ray)	43	3	1
Hospital Level 1 (1 X-ray unit)	11	0	0
Hospital Level 1 (bone densitometer)	24	1	1
Hospital Level 2 (>1 X-ray unit)	59	8	10
Hospital Level 3 (as level 2 + unsealed sources for in-vitro)	2	1	1
Hospital Level 4 (nuclear medicine)	17	12	10[1]
Hospital Level 5 (radiotherapy)	14	11	7[2]
Education and Research	15	4	3
Industrial level 1 [cabinet style X-ray unit]	147	0	7
Industrial level 2 [electron capture devices, custody only]	12	1	1
Industrial level 3 [sources, transport]	65	6	6
Industrial level 4 [> 6 sources]	10	0	1
Industrial level 5 [> 20 sources]	2	0	0
Industrial level 6 [fixed X-ray, sources, transport, ICSD assembly]	20	14	18

[1] Seven of these inspections were of nuclear medicine departments and three were diagnostic X-ray departments

[2] Three of these inspections were of radiotherapy departments, two were of nuclear medicine departments and two were of diagnostic X-ray departments

Industrial level 7 [irradiation, e-beam, cyclotron and mobile container scanner]	6	1	3
Others [e.g. scrap, lightning preventors]	16	7	0
Vets	288	3	8
Non-licensees (e.g. air operators and underground workplaces)	19	2	0
Security surveys (in conjunction with An Garda Siochána)	-	0	0
Total excluding non-licensees	1698	78	84
Total	1717	80	84