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# INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

## MISSION

**TO**

# IRELAND

Dublin, Ireland

*30 August 2015 to 9 September 2015*

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

IAEA
Integrated Regulatory Review Service
IRRS

epa
Office of Radiological Protection

Integrated
Regulatory
Review Service

IAEA | IRRS

# REPORT OF THE
# INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
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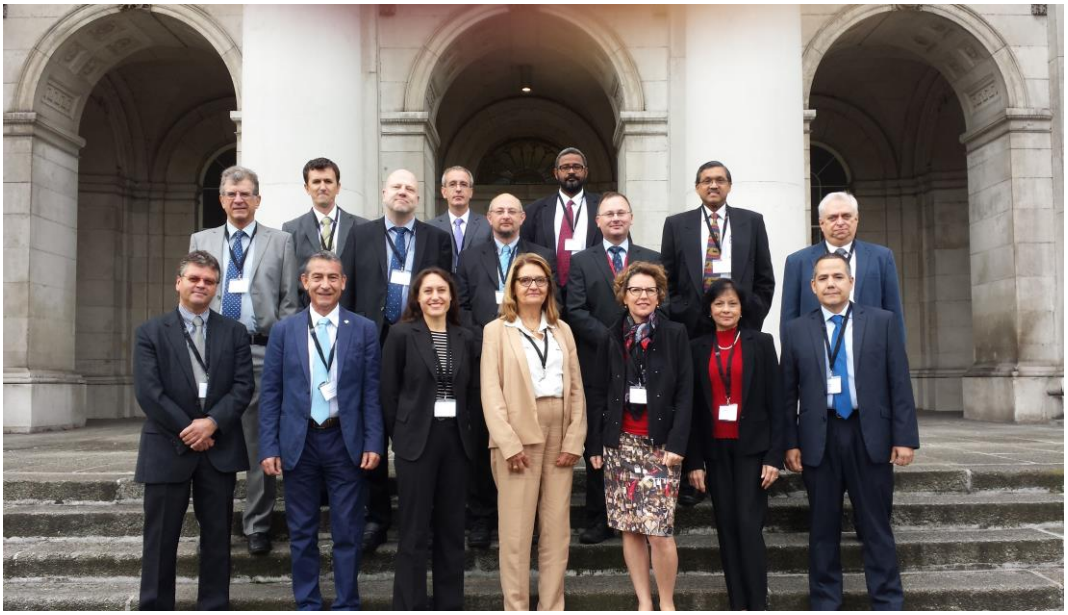

Integrated Regulatory Review Service

IAEA IRRS

# REPORT OF THE
# INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
# TO
# IRELAND

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| **Mission dates:** | *30 August 2015 to 9 September 2015* |
| **Regulatory body visited:** | *Environmental Protection Agency and Department of Health* |
| **Location:** | *Dublin, Ireland* |
| **Regulated facilities and activities in the mission scope:** | *Radiation sources in industrial and medical facilities, research facilities, emergency preparedness and response, medical exposure, occupational exposure and radon exposure* |
| **Organized by:** | *IAEA* |

| IRRS REVIEW TEAM | |
|---|---|
| TIRMARCHE Margot | Team Leader (France) |
| BOSNJAK Jovica | Reviewer (Bosnia and Herzegovina) |
| EBDON-JACKSON Steve | Reviewer (United Kingdom) |
| GARCIA LEIVA Manuel | Reviewer (Spain) |
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| HUNT John | Reviewer (Brazil) |
| MANICKAM Selva Kumar | Reviewer (Australia) |
| MARKKANEN Mika | Reviewer (Finland) |
| MURITH Christophe | Reviewer (Switzerland) |
| ROUSSE Carole | Reviewer (France) |
| SHADAD Ibrahim | IAEA Team Coordinator |
| BRUNO Gerard | IAEA Review Area Facilitator |
| JOVA SED Luis | IAEA Review Area Facilitator |
| SWOBODA Zumi | IAEA Administrative Assistant |

**The number of recommendations, suggestions and good practices is in no way a measure of the status of the national infrastructure for nuclear and radiation safety. Comparisons of such numbers between IRRS reports from different countries should not be attempted.**

## CONTENTS

## EXECUTIVE SUMMARY

At the request of the Government of Ireland, the IAEA convened an international team of senior safety experts to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the peer review was to review the Republic of Ireland's regulatory framework for radiation safety.

The review compared Ireland's regulatory framework for safety against IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS team members and Ireland's counterparts in the areas covered by the IRRS.

The IRRS team consisted of 10 senior regulatory experts from 9 IAEA Member States, 3 IAEA staff members and 1 IAEA administrative assistant. The IRRS review team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, patient protection, public and environmental exposure control including radon, transport, waste management and decommissioning.

In addition, policy issues were discussed, including: Radioactive waste management policy and the role of the Regulatory Body, and the Integration of radiation protection regulation with environmental protection regulation – the key considerations.

The IRRS review addressed all facilities and activities involving the use of ionizing radiation regulated by EPA and the Health Service Executive (HSE).

The mission included observations of regulatory activities and interviews and discussions with EPA staff, representatives from the Department of Environment, Community and Local Government, the Department of Health, HSE, Irish Aviation Authority, Marine Safety Directorate and the Office of Emergency Planning at the National Emergency Coordination Centre to help assess the effectiveness of the regulatory system. Visits were also made to: St James's Hospital, the Radiotherapy Department of the Beacon Hospital, Becton Dickenson Penel Ltd Industrial Sterilisation Facility, and the M2i Ltd Cyclotron Facility. The IRRS team observed the working practices during inspections and audits carried out by EPA and HSE, including discussions with the licensee personnel and management.

EPA and HSE provided the IRRS review team with advance reference material and documentation including the results of the self-assessment in all areas within the scope of the mission. Throughout the mission, the IRRS team was extended full cooperation in regulatory, technical, and policy issues by all parties; in particular, the staff of EPA and HSE provided the fullest practicable assistance and demonstrated extensive openness and transparency.

The IRRS review team made the following general observations:

- EPA is an effective and independent regulatory body;
- Ireland actively participates in the global safety regime;
- EPA benefits from experienced, technically competent and well-motivated staff.

An important observation of the IRRS review team is that Ireland needs to implement an effective and independent legal and regulatory framework for the regulation of patient protection. The Government should ensure effective coordination between the different authorities in regulating patient protection.

Also the radioactive waste management policy that has been approved by the Government should be fully implemented.

The IRRS team also believes that EPA has challenges and opportunities over the next few years, which include:

- Integration of radiation protection regulation with environmental protection regulation;
- Further development and implementation of its Management System to incorporate radiological protection;
- Development of a long term strategy for human resources with regard to its radiation safety functions, including knowledge management.

The IRRS review team identified a number of good practices and made recommendations and suggestions that indicate where improvements are necessary or desirable to continue enhancing the effectiveness of regulatory functions in line with the IAEA Safety Standards. The IRRS team recognized that the IRRS findings broadly correlated with the action plan prepared by EPA and HSE as a result of the self-assessment.

Among the good practices identified by the IRRS team are the following:

- EPA's radiation safety inspection activities are formally accredited to an ISO standard, which provides for openness and transparency, as well as, continuous assessment and improvement;
- EPA/ORP has established a web-based system which allows applying for a radiological license, for its renewing or amending by following clear step by step instructions on the information to be provided and documents to be uploaded in support of the application;
- The nuclear and radiological emergency plans are well integrated on the national and regional level in a framework for major emergency management system and a national emergency coordination system following the all hazards approach;
- Effectiveness of the national radon control strategy is maximized through this "top down" approach driven by Government, ensuring all stakeholders work together in a cohesive manner.

The IRRS team identified certain issues warranting attention or in need of improvement and believes that consideration of these would enhance the overall performance of the regulatory system:

- Implement an effective legal framework for the regulation of patient protection and urgently put in place arrangements to carry out inspections and enforcement to ensure patient protection;
- Ensure that the regulatory body for patient protection is independent and does not have responsibilities for, or interests in, providing medical exposure to ionizing radiation;
- Ensure effective coordination between the EPA and the regulatory body for patient protection;
- Complement the regulatory framework to include the predisposal management of radioactive waste and decommissioning of facilities;
- Establish policies and processes regarding development and updating of guidance documents and code of practice for radiation safety;
- Make a formal arrangement for the involvement of stakeholders as part of the emergency management system for radiation emergencies;

- Revise the legislative and regulatory framework for radiation safety to align it with the requirements of the Basic Safety Standards (GSR Part 3).

The IRRS review team findings are summarized in Appendix V.

An IAEA press release was issued at the end of the IRRS mission.

# I. INTRODUCTION

At the request of the Government of Ireland, an international team of senior safety experts met representatives of the Environmental Protection Agency (EPA) and the Health Service Executive (HSE) from 31 August to 9 September 2015 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review Ireland's regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Ireland in September 2010. A preparatory mission was conducted from 17 to 18 February 2015 at EPA Offices in Dublin to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in Ireland and their related safety aspects and to agree the scope of the IRRS mission.

The IRRS team consisted of 10 senior regulatory experts from 9 IAEA Member States, 3 IAEA staff members and 1 IAEA administrative assistant. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, radon, control of medical exposure, public and environmental exposure control, transport of radioactive material, waste management and decommissioning. In addition, policy issues were discussed, including: Radioactive waste management policy and the role of the Regulatory Body and Integration of radiation protection regulation with environmental protection regulation – the key considerations.

EPA, HSE and DECLG conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of Ireland's self-assessment and supporting documentation were provided to the IRRS review team as advance reference material for the mission. During the mission the IRRS review team performed a systematic review of all topics within the agreed scope through review of Ireland's advance reference material, conduct of interviews with management and staff from both the EPA and HSE, direct observation of EPA's regulatory activities at regulated facilities and an observation of a clinical audit at a medical facility carried out by the HSE. Meetings with the Department of Environment, Community and Local Government (DECLG), the Health Service Executive, the Office of Emergency Planning (OEP), the Irish Aviation Authority, the Marine Survey Office of the Department of Transport, Tourism and Sport and the Department of Health were also organized.

Throughout the mission the IRRS team received excellent support and cooperation from the Irish Authorities.

## II. OBJECTIVE AND SCOPE

The purpose of the IRRS mission was to review Ireland's radiation and nuclear safety regulatory framework and activities against the relevant IAEA safety standards to report on regulatory effectiveness and to exchange information and experience in the areas covered by the IRRS. The agreed scope of this IRRS review included all facilities and activities regulated in Ireland. It is expected that this IRRS mission will facilitate regulatory improvements in Ireland and other Member State, utilizing the knowledge gained and experiences shared between EPA and IRRS reviewers and the evaluation of the Ireland's regulatory framework for nuclear safety, including its good practices.

The key objectives of this mission were to enhance the national legal, governmental and regulatory framework for nuclear and radiation safety, and national arrangements for emergency preparedness and response through:

a) providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;

b) providing the host country (regulatory body and governmental authorities) with a review of its regulatory technical and policy issues;

c) providing the host country (regulatory body and governmental authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;

d) promoting the sharing of experience and exchange of lessons learned among senior regulators;

e) providing key staff in the host country with an opportunity to discuss regulatory practices with IRRS team members who have experience of other regulatory practices in the same field;

f) providing the host country with recommendations and suggestions for improvement;

g) providing other states with information regarding good practices identified in the course of the review;

h) providing reviewers from Member States and IAEA staff with opportunities to observe different approaches to regulatory oversight and to broaden knowledge in their own field (mutual learning process);

i) contributing to the harmonization of regulatory approaches among states;

j) promoting the application of IAEA Safety Requirements; and

k) providing feedback on the use and application IAEA safety standards.

## III. BASIS FOR THE REVIEW

### A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Ireland, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 17 to 18 February 2015. The preparatory meeting was carried out by the appointed Team Leader Ms Margot Tirmarche and the IRRS IAEA Team representative Mr Ahmad Al Khatibeh.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of EPA represented by Dr Ann McGarry, Director of the Office of Radiological Protection, other senior management and staff. It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides

- Radiation sources facilities and activities;
- Control of medical exposure;
- Occupational radiation protection;
- Chronic exposure to radon;
- Public and environmental exposure control;
- Control of radioactive discharge and materials for clearance;
- Emergency Preparedness and Response;
- Transport of radioactive materials.

Dr Tom Ryan made presentations on the national context, the current status of EPA and the self-assessment results to date.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in Ireland in August/September 2015.

The proposed composition of the IRRS Review team was discussed and tentatively confirmed. Logistics including meeting and work places, counterparts and Liaison Officer identification, proposed site visits, lodging and transportation arrangements were also addressed.

The EPA Liaison Officer for the IRRS mission was confirmed as Dr Tom Ryan.

EPA provided IAEA with the advance reference material (ARM) for the review at the end of June 2015. In preparation for the mission, the IAEA review team members reviewed Ireland's advance reference material and provided their initial impressions to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

### B) REFERENCES FOR THE REVIEW

The relevant IAEA safety standards and the Code of Conduct on the Safety and Security of Radioactive Sources, were used as review criteria. The complete list of IAEA publications used as the references for this mission is provided in Appendix VII.

### C) CONDUCT OF THE REVIEW

The initial IRRS Review team meeting took place on Sunday, 30 August, 2015 in Dublin, directed by the IRRS Team Leader and the IRRS IAEA Team Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the

background, context and objectives of the IRRS programme. The understanding of the methodology for review was reinforced. The agenda for the mission was presented to the team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

The host Liaison Officer was present at the initial IRRS team meeting, in accordance with the IRRS Guidelines, and presented logistical arrangements planned for the mission.

The IRRS entrance meeting was held on Monday, 31 August, 2015, with the participation of EPA and HSE senior management and staff and representatives from across the Irish Governement systems and the Radiation Protection Advisors (RPA) community. Opening remarks were made Ms Laura Burke, Director General EPA, Mr David Walsh, Assistant Secretary, Department Environment, Community and Local Government (DECLG) and Mr Patrick Lynch, National Director, Quality Assurance and Verification Division, Health Service Executive, Ms Margot Tirmarche IRRS Team Leader and Mr Ibrahim Shadad IRRS IAEA Team Coordinator. Dr Stephen Fennell gave an overview of the Ireland context, EPA and HSE activities and the action plan prepared as a result of the pre-mission self-assessment.

During the IRRS mission, a review was conducted for all review areas within the agreed scope with the objective of providing Ireland and EPA with recommendations and suggestions for improvement and where appropriate, identifying good practice. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations regarding the national legal, governmental and regulatory framework for safety.

The IRRS team performed its review according to the mission programme given in Appendix III.

The IRRS exit meeting was held on Wednesday, 9 September, 2015. The opening remarks at the exit meeting were presented by Mr Paul McDonald, Department of the Environment, Community and Local Government and were followed by presentations of the results of the mission by the IRRS Team Leader Ms Margot Tirmarche, and some initial reflections on the IRRS mission to Ireland by Dr Ann McGarry, Director of the Office of Radiological Protection, EPA. Closing remarks were made by Mr Ibrahim Shadad on behalf of the IAEA Deputy Director General, Department of Nuclear Safety and Security.

An IAEA press releases were issued at the end of the Mission.

# 1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

## 1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

The Irish Government has published a national policy and strategy for safety in the document titled *National Policy Position: Nuclear Safety and Radiation Protection (NPP2015)*. It was developed by the Department of Environment, Community and Local Government (DECLG), which is the lead Government agency for radiation protection in the area of occupational and public exposures. The policies in NPP2015 flow from the DECLG's strategy for 2015-17 to '*maintain public confidence in relation to nuclear safety and radiation protection*'. 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).

NPP2015 takes into account the safety objectives and principles in *the IAEA Safety Standards: Fundamental Safety Principles (SF-1)* and reflects the Government's long term commitment to safety by stressing that Ireland will comprehensively update the radiation protection framework while implementing the new Euratom Basic Safety Standards Directive.

The national policy document also notes the important role that ionizing radiation plays in the economic and social environment in Ireland through its use in the dental, medical, industrial, research, veterinary and educational sectors. It endorses the graded approach by setting out that the sources of ionizing 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. NPP2015 clearly and explicitly assigns the prime responsibility for the protection of people and the environment from the harmful effects of ionizing radiation to the license holder and makes a commitment that the DECLG and the EPA work with relevant stakeholders to ensure that this responsibility is met.

NPP2015 also describes specific priority policy issues for Ireland. These include national emergency preparedness arrangements, radioactive waste management policy and the national radon control strategy. The document also describes Ireland's strong commitment to the global safety regime through its membership and active participation in a broad range of international organizations and conventions dealing with nuclear safety and radiation protection.

Policy formation and legislative developments in relation to the protection of the patients being medically exposed to ionizing radiation lies outside the scope of NPP2015 as it comes within the remit of the Minister for Health and the Health Services Executive (HSE). There are issues in relation to the legal framework and regulatory independence in this area and these are covered in 1.2 and 1.3 below.

## 1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

A national framework for the protection of people from occupational and public exposure to radiation has been established. It consists of primary and secondary legislation. The primary legislation establishes a regulatory body and a licensing function and the secondary legislation provides the detailed requirements and processes. The principle Acts and Statutory instruments are:

- Radiological Protection Act, (No. 9 of 1991), 1991 [RPA91]
- Radiological Protection (Miscellaneous Provisions) Act, (No. 20 of 2014), 2014 [RPA14]
- Environmental Protection Act (No. 7 of 1992), 1992 [EPA92]

- S.I. No. 125 of 2000 Radiological Protection Act 1991 (Ionizing Radiation) Order, 2000 [SI125/00]

A framework to provide for the protection of individuals medically exposed to ionizing radiation is provided for in S.I. No. 478 of 2002 - European Communities (Medical Ionizing Radiation Protection) Regulations 2002 (SI478/02) (as amended).

There is no provision for radon in homes in legislation but a national plan (National Radon Control Strategy) covers this issue.

The framework for the protection of people from occupational and public exposure to radiation provided for under RPA91 and SI125/00 generally provides an effective governmental, legal and regulatory framework for safety. However, the legislative framework established by SI478/02 does not contain many of the elements necessary for an effective legal framework for the protection of individuals medically exposed to ionizing radiation (patient protection). This is because SI478/02 does not include provisions for inspection and has only limited enforcement provisions which makes it impossible for HSE to undertake its regulatory functions as it has a role in providing the use of ionizing radiation for medical purposes throughout Ireland. This represents a significant gap in Ireland's regulatory framework for the protection of individuals medically exposed to ionizing radiation. SI478/02 also does not include any provisions for a framework to license activities relating to patient protection.

For transport safety, there are national laws that set up the framework for the carriage of dangerous goods by various modes, namely, road, rail, sea and air. Although rail regulations are in place, transport of Class 7 goods by rail does not take place in practice. The national laws that set up the transport safety framework are:

- Carriage of Dangerous Goods by Road Act 1998 -Appointment of Competent Authorities- Order 2010;
- Irish Aviation Authority Act 1993;
- European Communities (Transport of Dangerous Goods by Rail) Regulations, 2010; and
- Merchant shipping (Dangerous Goods) Rules, 1992.

The IRRS team and Ireland's self assessment identified two issues which are not covered by the Irish legislation in regard to radiation safety. These are in relation to the requirement for legislation to explicitly provide for a graded approach and provisions for appeal against decisions of the regulatory body. For the government to establish an effective safety framework it is recommended that the missing requirements of the international standards should be covered in the national legislation.

In relation to the graded approach, it is implemented by the EPA in practice through risk-based licensing and inspection process. The EPA also has a new authorization model outlined in the document, "Proposals for a Graded Authorization Model for the use of Ionizing Radiation in Ireland" (GAAR12), which was approved by the Board of the RPII for implementation through legislative amendments that will be made in line with the implementation of the Euratom Basic Safety Standards by a planned completion date of February 2018. The implementation of GAAR12, which would require legislative amendments, would introduce a graded approach to authorization by providing for 'registration' and 'notifications' in addition to 'licenses'.

The legislation (RPA91) provides only a limited right of appeal against the decisions of the EPA (section 30(6)) for amendment to, or revocation of, a radiological protection license. There are also administrative provisions relating to appeals in relation to the appointment of Radiation Protection Advisers and a complaints mechanism against decisions of inspectors. However, RPA91 does not provide an explicit right of appeal against any decision of the EPA. Similarly, the legislation for patient protection (SI478/02) also does not contain appeal provisions.

The regulation (SI125/00) provides for the issuance of 'enforcement notices' under section 42 for minor non-compliances. However, the section 42 power to issue enforcement notices has never been used in practice as there is no provision that makes it an offence to not comply with such a notice.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** The legal framework (SI478/02) for the regulation of patient protection does not contain the necessary elements to empower the HSE to perform the full range of regulatory functions. Consequently, HSE is not performing its essential regulatory functions. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 2, Paras 2.5(2) (3) (6) (7) (8) (9) (10) (11) (15) (18) states that** *"The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:*<br>*(2) The types of facilities and activities that are included within the scope of the framework for safety;*<br>*(3) The type of authorization that is required for the operation of facilities and for the conduct of activities, in accordance with a graded approach;*<br>*(6) Provision for assigning legal responsibility for safety to the persons or organizations responsible for the facilities and activities, and for ensuring the continuity of responsibility where activities are carried out by several persons or organizations successively;*<br>*(7) The establishment of a regulatory body, as addressed in Requirements 3 and 4;*<br>*(8) Provision for the review and assessment of facilities and activities, in accordance with a graded approach;*<br>*(9) The authority and responsibility of the regulatory body for promulgating (or preparing for the enactment of) regulations and preparing guidance for their implementation;*<br>*(10) Provision for the inspection of facilities and activities, and for the enforcement of regulations, in accordance with a graded approach;*<br>*(11) Provision for appeals against decisions of the regulatory body;*<br>(*15) Provision for acquiring and maintaining the necessary competence nationally for ensuring safety;*<br>*(18) The specification of offences and the corresponding penalties;"* |
| **R1** | **Recommendation: The Government should implement an effective legal framework for the regulation of patient protection. Meanwhile, the Government should, as a matter of urgency, put in place arrangements to carry out inspections and enforcement to ensure patient protection.** |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** Two elements for an effective governmental and legal framework for safety are missing from the Irish legislation. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 1, paras. 2.5(3), (8), (10), (11) and (18) states that "***The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:* |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | *(3) The type of authorization that is required for the operation of facilities and for the conduct of activities, in accordance with a graded approach;*<br>*(8) Provision for the review and assessment of facilities and activities, in accordance with a graded approach;*<br>*(10) Provision for the inspection of facilities and activities, and for the enforcement of regulations, in accordance with a graded approach;*<br>*(11) Provision for appeals against decisions of the regulatory body;*<br>*(18) The specification of offences and the corresponding penalties."* |
| **R2** | **Recommendation: The government should ensure that the legislation explicitly addresses the following issues in accordance with GSR Part 1:**<br>**1. Use of a graded approach in all regulatory activities;**<br>**2. Ensure legislation provides for appeals against the decisions of the regulatory bodies in relation to radiation safety and patient protection.** |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** The 'Enforcement Notice' provisions in section 42 of the regulations (SI125/00) have never been used in practice as the non-compliance with an Enforcement Notice is not an offence. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 2, para. 2.5(10) and (18) states that** *"The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:*<br>*(10) Provision for …. the enforcement of regulations in accordance with a graded approach."*<br>*(18) The specification of offences and the corresponding penalties."* |
| **R3** | **Recommendation: The Government should make appropriate amendments to facilitate the effective use of the 'Enforcement Notice' provisions in SI125/00.** |

### 1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The EPA was established by the Environmental Protection Act, 1992 [EPA92] and the Radiological Protection Institute of Ireland (RPII) was established in primary legislation by the Radiological Protection Act 1991 [RPA91]. The EPA and the RPII were merged in 2014 and all of the RPII's radiation protection and safety regulation functions were transferred to the EPA. Conditions can be attached to EPA's licenses and the EPA has the power to prosecute for offences. The EPA also has the power to appoint inspectors who may, among others, require certain information and enter premises as part of their inspection and enforcement functions. The EPA is effectively independent with the capacity to make independent regulatory decisions.

There are a number of competent and independent authorities involved in the transport of dangerous goods by road, rail, sea and air. The EPA is the competent authority for matters relating to the carriage by road and rail of radioactive material (Class 7) only. The Department of Transport, Tourism and Sport is the competent authority for the carriage of dangerous goods by sea (including Class 7 radioactive

material). The Irish Aviation Authority is the competent authority for the carriage of dangerous goods by air (including Class 7 radioactive material). The EPA is the only competent authority that issues an authorization (license) for the transport of radioactive material.

The staff of the RPII was transferred to EPA upon the merger and provide the radiological protection and safety competence in that field in a dedicated Office (Office of Radiological Protection (ORP)) in the EPA. Staff competence within the EPA in radiological protection is maintained under a Performance Management and Development System (PMDS) and 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 organization as a whole are identified. The Director of the ORP is a member of the Board of the EPA.

The regulation of health protection of individuals against the dangers of ionizing radiation in relation to medical exposures (patient protection) is the responsibility of the Minister for Health and the oversight of those regulations is a separate function from EPA. Under SI478/02, the Minister for Health is the competent authority for the regulation of health protection of individuals against the dangers of ionizing radiation in relation to medical exposures (patient protection). The Minister for Health's regulatory responsibilities are exercised by the Director General of the HSE. In addition the Medical Council and the Dental Council have roles under SI478/02 to, among others, approve new medical procedures or medical exposure for biomedical and medical research using ionizing radiation. However, the legislative framework established by SI478/02 does not contain all the elements necessary to set an effective legal framework for the regulation of patient protection. This has led to a situation where the regulatory body for patient protection is not empowered to carry out the full range of regulatory functions to authorize, inspect, and enforce all parties involved in patient protection. The current competent authority (the Minister for Health) and the regulatory body comprising, HSE staff and the medical and dental councils are also not effectively independent as they are made up of persons or bodies who also have a role in the provision of the use of ionizing radiation for medical purposes.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** The HSE is not effectively independent as it has responsibilities for, or interests in, the provision of medical use of ionizing radiation. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 4 states that** *"The government shall ensure that the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making."* |
| **R4** | **Recommendation: The Government should ensure as a matter of urgency that the regulatory body for patient protection does not have responsibilities for or interests in providing medical exposure to ionizing radiation.** |

## 1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

The Government has not expressly assigned prime responsibility for safety to the person or organization responsible for a facility or an activity as it is considered that in the Irish legal system it is unwarranted due to the Law of Torts in Ireland. Nevertheless, the national policy document NPP2015 states that the "Primary responsibility for the protection of people and the environment from the harmful effects of ionizing radiation rests with the license holder of the radiation sources". In addition SI125/00 also assigns responsibility for assessing and implementing arrangements for the radiological protection of exposed workers to the undertaking (subsection 19(1)).

Responsibility for safety covers all stages in the lifetime of facilities through the authorization processes in SI125/00. While specific aspects such as 'siting' are not mentioned, where specific issues arise in relation to a particular facility such as closure of the facility, these are dealt with through the licensing process or license conditions. Facilities that generate radioactive waste such as hospitals are authorized using the procedure set out in SI125/00 and radioactive waste management issues are dealt with through specific license conditions imposing, for example, take-back arrangements with producers or suppliers.

There is, however, no explicit provision in legislation that places an obligation on the authorized party to verify that products and services that it uses to meet its expectations and comply with any relevant regulatory requirement. Arguably, the provision in subsection 19(1) of SI125/00 that assigns responsibility for implementing arrangements for the radiological protection of exposed workers may be used to enforce this obligation but a more specific imposition of this requirement may be made through license conditions.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** There is no explicit provision in legislation that the authorized party has the responsibility to verify that products and services meet its expectations and comply with any relevant regulatory requirement. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 6, para 2.14 states that** *"The authorized party has the responsibility for verifying that products and services meet its expectations (e.g., in terms of completeness, validity or robustness) and that they comply with regulatory requirements."* |
| **S1** | **Suggestion: The EPA should consider requiring authorized parties to verify that products and services meet the authorized party's expectations and comply with any relevant regulatory requirement.** |

## 1.5. COORDINATION OF AUTHORITIES WITH RESPONSIBILITIES FOR SAFETY WITHIN THE REGULATORY FRAMEWORK

Although EPA and HSE have primary responsibilities for the protection of workers and members of the public, and for 'patient protection' respectively, there are also other regulators or bodies with responsibilities. This includes the Health Safety Authority (HSA) for the licensing of drivers of various classes of materials and the Commission for Energy Regulation (CER) for the off shore industries (oil and gas). Coordination exists between the EPA and HSE, HSA and CER through Memoranda of Understanding. In addition, the Health Regulators Forum also provides an avenue for information exchange and practices among regulatory bodies and the EPA participates in this. In the area of emergency preparedness, the DECLG has a statutory requirement to coordinate with other Government departments. At the EU level, there is also coordination and cooperation among member states for the shipment of sealed sources under Council Regulation Euratom No 1493/93.

There is, however, no formal arrangement for coordination among the competent authorities for sea (Maritime Safety Directorate) and air transport (Irish Aviation Authority) with the EPA in relation to any modifications to the IMDG Code, the requirements for the carriage of radioactive material Class 7 by sea, changes to the ICAO technical instructions or the Aeronautical Notices regarding the carriage of radioactive material by air. There is also no legal or formal agreement between the Maritime Safety Directorate, the Irish Aviation Authority and the EPA covering the responsibilities of each competent authority to ensure appropriate coordination of and liaison between the competent authorities.

The EPA and the HSE have a MoU covering many areas of cooperation. However, the coordination can be improved in areas covering patient protection. For example, in relation to ensuring quality control and acceptance testing of equipment both organizations have duties in legislation. This overlapping responsibility potentially causes confusion on the scope of the functions of the two regulators.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** There is no formal agreement for coordination between the EPA and the competent authorities for the carriage of radioactive material by sea and air. There are overlapping duties and responsibilities in the legislation in the area of patient protection between the EPA and the HSE, but these are not covered by a formal agreement. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 7 states that** "*Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties"*<br><br>**BASIS: GSR Part 1, Requirement 7, para 2.18, states that** *"This coordination and liaison can be achieved by means of memoranda of understanding, appropriate communication and regular meetings. Such coordination assists in achieving consistency and in enabling authorities to benefit from each other's experience*"<br><br>**BASIS: TS-G-1.5, para 2.7 states that** "*Where there are several responsible authorities, they should cooperate closely and there should be legal or formal agreements between them covering the responsibilities of each authority. Each competent authority is required to communicate with and provide information to other governmental and non-governmental organizations that have related responsibilities."*<br><br>**BASIS: TS-G-1.5, para. 4.120, states that** *"One of the aims of such meetings is to ensure the consistent application of inspection and enforcement measures relating to compliance assurance…"; **and**, "…The regulations and inspection criteria for the transport of radioactive material should be understood and applied by inspectors of such agencies in a manner similar to that in which other regulations and inspection criteria are applied, such as those relating to maritime safety or road traffic."* |
| **R5** | **Recommendation: The Government should make formal provision for effective coordination among the EPA, the Irish Aviation Authority, and the Maritime Safety Directorate and between the EPA and the HSE.** |

## 1.6. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE EXISTING OR UNREGULATED RADIATION RISKS

Where an unregulated activity is discovered, the situation is managed under procedures specified in the Enforcement Policy referred to as the EPPDA. Where possible, the issue would be regularized through the normal licensing process as set out in SI125/00. Orphan sources are dealt in accordance with Directive 2003/122/Euratom on the control of high activity sealed radioactive sources and orphan sources, which is transposed into Irish law by Statutory Instrument SI875/05. The operational procedures for dealing with orphan sources involve an interdepartmental agreement called 'The Temporary Operational Protocol'

(TOP) which sets out the procedure for dealing with the safe management, storage and disposal of the orphan source.

SI125 of 2000 deals with the issue of the control of contamination from past events (and possible future emergencies) though there is also no specific mention of remediation of radiological contaminated sites in Irish law. There is, however, one facility where there is radium contamination within the facility and the contaminated area is isolated and occasionally monitored. The EPA has the power to deal with any remedial action through the normal authorization process including consultation with the licensee's Radiation Protection Advisor and the development of a risk assessment and a work plan. However, there is scope for the legislation to provide specifically for the regulatory control and remediation of contaminated sites.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** Legislation does not provide for a specific regulatory framework for the remediation of contamination from past activities or events. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 9 states that** *"The government shall establish an effective system for protective actions to reduce undue radiation risks associated with contamination from past activities or events, consistent with the principles of justification and optimization."* |
| **S2** | **Suggestion: The Government should consider implementing a legislative framework for the remediation of any contamination from past activities or events.** |

## 1.7. PROVISIONS FOR THE MANAGEMENT OF RADIOACTIVE WASTE

Ireland has a partial legal framework for decommissioning and radioactive waste management in SI125/00 as amended by SI320/13. In the context of radioactive waste management in Ireland, relevant waste streams relate to low activity short lived radioactive waste produced in medical and research facilities as well as legacy disused sealed sources and possible future decommissioning and remediation activities.

In exercising that regulatory control, the Irish Government at a cabinet meeting on the 21st December 2010 agreed a policy framework in relation to radioactive waste management. One of the key elements of that policy is the adoption of the following principles:

- The inventory of disused radioactive sources currently stored in Ireland should be reduced through a co-ordinated and phased Inventory Reduction Programme;
- A National Interim Storage Facility for disused radioactive sources should be established;
- 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, and
- There should be further consideration to options for the final disposal of Ireland's disused radioactive sources. As part of this work there would be consideration of the re-export of sources to elsewhere inside or outside the EU, by prior agreement, with one or more states.

Another principle stated in the policy is the management of all sealed sources from "cradle to grave". EPA implements a 'take back' agreement requirement which requires at the point of authorization a facility to make provision for the repatriation of the source or its disposal at the end of its useful life and, in the case of High Activity Sealed Sources (HASS), to ensure that financial provisions are in place to

implement that agreement.

The implementation of the Government's policy would be contingent on making available sufficient financial resources for its implementation. As far as possible, these resources' requirements should adhere to the "polluter pays" principle but a more robust funding mechanism or framework needs to be put in place in order to provide for potential decommissioning or remediation projects not planned in advance or the recovery and disposal of orphan or other disused sealed sources.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** The national policy and supporting legal framework on radioactive waste management does not consider the establishment of a funding mechanism for the financial insurance of unforeseen remediation, decommissioning and radioactive waste management including disposal. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 2, para. 2.5(16) states that** *"The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:*<br>*(16) Responsibilities and obligations in respect of financial provision for the management of radioactive waste and of spent fuel, and for decommissioning of facilities and termination of activities."*<br>**BASIS: GSR Part 1 Requirement 10, paras. 2.33 states that** *"Appropriate financial provision shall be made for:*<br>*(a) Decommissioning of facilities;*<br>*(b) Management of radioactive waste, including its storage and disposal;*<br>*(c) Management of disused radioactive sources and radiation generators;*<br>*(d) Management of spent fuel.*<br>**BASIS: GSR Part 6 Requirement 4, states that** *"The government shall establish and maintain a governmental, legal and regulatory framework within which all aspects of decommissioning, including management of the resulting radioactive waste, can be planned and carried out safely. This framework shall include a clear allocation of responsibilities, provision of independent regulatory functions, and requirements in respect of financial assurance for decommissioning."*<br>**BASIS: SSR-5 Requirement 1, states that** *"The government is required to establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities shall be clearly allocated for disposal facilities for radioactive waste to be sited, designed, constructed, operated and closed. This shall include: … securing of financial and other resources, and provision of independent regulatory functions relating to a planned disposal facility."* |
| **R6** | **Recommendation: The Government should ensure that the radioactive waste management strategy including both short and long term storage of radioactive waste, unforeseen decommissioning, remediation and disposal of radioactive waste includes provisions for financial support.** |

## 1.8. COMPETENCE FOR SAFETY

As Ireland has no nuclear installations the strategy to ensure the assurance of competence for safety is commensurate with the activities in Ireland involving the use of ionizing radiation. The capacity and resources of EPA are generally negotiated with the Government on an annual basis through the standard

budgeting process, with room for requests for additional resources on a case by case basis. EPA also undergoes a periodic 'work force planning' to map resource and competency requirements against new and on-going work requirements and these needs are negotiated with Government. At the individual level, staff competencies in EPA are developed and maintained through a formal performance management system.

The competence of certain health care professionals such as doctors, dentists, nurses and radiographers are assured through registration requirements (e.g., the Medical Council and Dental Council, and the Radiographers Registration Board).

The competence of the staff of authorized parties are also assessed when the EPA authorizes a license for a facility. For example, when licensing a Non Destructive Testing applicant, proof of relevant qualifications, training and experience is sought. The competence is then routinely discussed and checked during inspections.

Training courses are also organized by the sectors themselves particularly in relation to medical physics activities and the EPA occasionally approves courses when requested 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.

The EPA also ensures competence for safety through stringent selection processes for the register of Radiation Protection Advisers (RPA), who perform an important role in providing comprehensive advice to licensees, who are required by law to appoint a RPA. Applicants are required to submit a portfolio of documents that demonstrate compliance with certain criteria and a syllabus based on European Commission guidelines. An Assessment Panel is formed that involves experts from both within the EPA as well as external independent experts and an assessment is made against the requirements. Approval is for 5 years.

## 1.9. PROVISION OF TECHNICAL SERVICES

The main requirements for technical services within Ireland are personal dosimetry services, instrument calibration services and environmental monitoring (including measurement of radon in buildings). The RPA91 requires the EPA to monitor levels of ionizing radiation in the State as well as the exposure of individuals and does not preclude the calibration of monitoring instruments. In practice the EPA filled a void in the market by providing all three services. However, following a market review in 2010 the EPA made a phased withdrawal from the dosimetry service market and now provides regulatory oversight for external dosimetry services.

## 1.10. SUMMARY

The Irish Government has published a national policy and strategy for safety in the National Policy Position: Nuclear Safety and Radiation Protection (NPP2015). A national legislative framework for the protection of people from occupational and public exposure to radiation has been established (RPA91). There is also a framework for the protection of individuals medically exposed to ionizing radiation (patient protection). However, the latter does not contain many elements necessary for an effective legal framework. For transport safety, there are effective laws for the carriage of dangerous goods by road, rail, sea and air. Although there is no mention of the graded approach in legislation, in practice the graded approach is implemented through risk-based processes. RPA91 provides only a limited right of appeal against the decisions of the EPA in relation to radiological protection licenses but there is an inherent right to seek judicial review in the courts.

The Radiological Protection Institute of Ireland (RPII) was established in 1991 and was merged with the EPA in August 2014. All of RPII's radiation protection regulation functions were transferred to the EPA.

The competent authority for the protection of individuals medically exposed to ionizing radiation is the Minister for Health, who is assisted by the HSE and the Medical and Dental Councils. Collectively, they comprise the regulatory body for patient protection but are not effectively independent as they also have a role in promoting the use of ionizing radiation for medical purposes.

The Government has not expressly assigned in legislation the prime responsibility for safety to the person or organization responsible for a facility or an activity as it considers it unnecessary within the Irish legal system. Nevertheless, the national policy document, NPP2015, does so. Although there is good coordination between EPA and a range of other agencies and departments, there is no formal arrangement for coordination among the EPA and the competent authorities for road, rail, sea and air transport. There is also no legal or formal agreement between the Maritime Safety Directorate, the Irish Aviation Authority and the EPA.

The EPA and the HSE have a MoU covering many areas of cooperation. However, the coordination can be improved where there are overlapping regulatory responsibilities in their respective legislation.

The EPA has powers to regulate decommissioning and radioactive waste management and there is an agreed national policy framework in relation to radioactive waste management that leans towards long-term storage while working on a disposal solution. However, the implementation of the Government's policy is contingent on making available sufficient financial resources.

The EPA has comprehensive arrangements to maintain competence for safety and is providing services to fill any gap in the quantity or quality of those services. These are in the areas of instrument calibration and radon measurement.

# 2. THE GLOBAL SAFETY REGIME

## 2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Ireland is a contracting party to a range of nuclear safety related international conventions and Agreements, including the:

- Convention on Early Notification of a Nuclear Accident;
- Convention on Assistance in Case of a Nuclear Accident or Radiological Emergency;
- Convention on the Physical Protection of Nuclear Material;
- Convention on Nuclear Safety;
- Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management;
- Comprehensive Nuclear Test Ban Treaty; and
- The Treaty on the Non-Proliferation of Nuclear Weapons.

Ireland has also expressed support for the 'Code of Conduct on the Safety and Security of Radioactive Sources' and implements the associated Guidance on the Import and Export of radioactive sources in practice. Ireland is also a party to European Commission agreements and implements Euratom Directives.

The EPA has a number of bilateral agreements in place that enhances safety, particularly through harmonized approaches and increased quality and effectiveness of safety reviews and inspections. The agreements are with French Nuclear Safety Authority (ASN) and the UK's Office for Nuclear Regulation (ONR) and the Canadian Nuclear Safety Commission (CNSC). Annual bilateral meetings have also been held with the Norwegian Radiation Protection Authority (NRPA) since 2010.

## 2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

EPA staff represent Ireland at a wide variety of international fora including the institutions of the European Union (EU), the IAEA, the Nuclear Energy Agency (NEA) of the OECD, the Heads of the European Radiological Protection Competent Authorities (HERCA), the International Commission on Radiological Protection (ICRP) and the Western Nuclear Regulators' Association (WENRA).

EPA also receives relevant information from other States and from authorized parties through its participation in, among others, the European ALARA network, IRRS peer review missions, the review meetings of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, and the Convention on Nuclear Safety, the European Nuclear Safety Regulators Group (ENSREG) and the IAEA RASSC & TRANSSC meetings.

## 2.3. SUMMARY

Ireland is a contracting party to a range of nuclear safety related international conventions and Agreements. The EPA has a number of bilateral agreements in place that enhances safety, particularly through harmonized approaches and increased quality and effectiveness of safety reviews and inspections. EPA staff represent Ireland at a wide variety of international fora. EPA also receives relevant information from other States and from authorized parties through its participation in a wide variety of regional and international meetings.

# 3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

## 3.1. ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND ALLOCATION OF RESOURCES

The EPA is an independent public body established in July 1993 under the Environmental Protection Agency Act, 1992 [EPA92] coming under the Department of Environment, Community and Local Government (DECLG). The responsibilities of the EPA were extended in August 2014 following its merger with the Radiological Protection Institute of Ireland (RPII). The merger dissolved the RPII - the body previously responsible for all matters pertaining to ionizing radiation - and transferred all of RPII's functions, assets, liabilities and staff to the EPA.

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, the EPA is divided into five offices: the Office of Communications and Corporate Services; the Office of Environmental Enforcement; the Office of Climate, Licensing, Resources and Research; the Office of Environmental Assessment, and the Office of Radiological Protection (ORP). The ORP has functional responsibility for, among others, radiation safety regulation, radioactive waste regulation and radiation emergency preparedness.

The regulation, i.e., licensing, inspection and enforcement activities, of facilities and activities involving sources of ionizing radiation throughout Ireland is managed by the ORP's Radiation Protection Regulation work programme. The structure of this section can be modified, as and when needed, to reflect changing business needs following consultation between the Director of ORP and Programme Managers.

The ORP's annual work programme sets the priorities for the EPA each year in relation to the regulation of facilities and activities using ionizing radiation in accordance with a graded approach. The graded approach is reflected in how inspection priorities are established, in the periodicity of license renewal and the extent of licensing requirements, in the guidance provided and in the approach to enforcement. All of these activities are included in the annual work plan and are resourced through the budgetary process.

## 3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

The EPA was established as an independent statutory body under an Act of Parliament (EPA92). In August 2014 its statutory responsibilities were extended to include ionizing radiation. In terms of specific radiation protection regulatory activities, the EPA ensures its effective independence in a number of ways.

All decisions on radiological license applications or amendments to existing licenses have been delegated by the EPA Board to, and are made solely by, staff from the ORP's Radiation Protection Regulation programme who report monthly to the Board on these activities. There is no requirement to consult with any external bodies, thus eliminating the possibility of any external influences on the licensing decisions. Where applications are received for new technologies or a previously unlicensed activity which is new or novel, the ORP may set up a licensing review panel comprising of staff from Radiation Protection Regulation, to review the application and make a recommendation on whether a license can be issued. This ensures that licensing decisions are not made on the basis of just one individual's review of the application.

For inspection activities, the EPA ensures independence through accreditation as a Type A inspection body to ISO 17020:2012. As part of this standard, the ORP must be independent of those organizations being inspected and all inspected related activities cannot be influenced by any stakeholders. For inspections of radiotherapy facilities the EPA/ORP does not have the necessary in-house technical

expertise for all items covered within the scope of the inspection. In order to address this skill deficit it engages the services of a UK-based expert in radiotherapy who must comply with the requirements of the ISO 17020 standard in terms of training, independence and impartiality. The use of a technical expert, who is not associated with any licensable activities in Ireland, rather than an Irish-based expert, ensures that there are no conflicts of interest in relation to any inspection findings.

EPA has developed an enforcement policy, approved by the Board, which sets out the procedures for determining which enforcement actions are followed in various situations where serious non-compliances are identified during the course of inspections or other regulatory activities. By adhering to the procedures set out in this policy, the EPA ensures that all enforcement decisions taken by staff within ORP are objective in nature. While ORP will make a recommendation as to whether a particular enforcement action is taken, the final decision is a matter reserved for the EPA Board. In addition, ORP has contracted an external solicitor, who is not associated with any activities involving ionizing radiation, to provide legal advice on matters relating to licensing and inspection. This ensures that all legal advice obtained by ORP is independent and cannot be influenced by anyone with a vested interest.

The ORP has a number of measures in place to minimize possible occurrences of conflicts of interest. These include the following:

- All inspectors are required to adhere to an inspector's code of conduct;
- All staff are required to adhere to the EPA's Code of Conduct for Directors and Staff of the EPA which explicitly deals with potential conflicts of interest;
- Sections 37 and 38 of the EPA Act, 1992 [EPA92] explicitly requires Directors and Staff of the EPA to declare and disclose any interests that could be likely to influence them in relation to any matter coming before the Agency or in the exercise of any function of the Agency and;
- The EPA maintains a Risk Register which is used to manage risk in areas where there may be potential conflicts of interest.

### 3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

The ORP has a current staff complement of 35, divided across the three programme areas as follows:

- Director of ORP: One staff member;
- Radiation Protection Regulation: One Programme Manager, one Technical Manager, five and a half 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, and
- Radiation monitoring & Emergency Preparedness: One Programme Manager, two Technical Managers, five and a half scientific staff and four technical staff.

The ORP has confirmed that staff numbers are constrained by general public sector employment policies. Nevertheless, more recently a submission has been made for one additional scientific staff member to assist in the transposition of the Euratom BSS.

The EPA operates a Performance Management Development System (PMDS) for all staff to manage their contribution to the delivery of the annual work programmes and the EPA's strategic plan. This ensures that the work of all staff is strategically aligned to the overarching aims of the organization. As part of the PMDS programme, all staff meet with their line manager at the start of the year to agree and document their individual work programme for the year. Half way through the year a mid-year review meeting is held between the staff member and their manager where progress on both the agreed work plan and the training and development programme are reviewed. Towards the end of the year, an end of year review

meeting is held to review whether the objectives of both the work and training and development plans were met during the year.

The ORP's ISO 17020 quality management system allows for some flexibility when drawing up a training programme for a new inspector, as he or she will have different skills and experience. For a newly recruited inspector a formal training and development plan is drawn up. As well as focusing on the skills required to carry out inspections the training also looks at wider training requirements, particularly the soft skills necessary to become a competent and effective inspector.

With regard to the transport of radioactive material training, the EPA ensures its inspectors are trained in the area of transport of radioactive materials through its Quality Management System, inspector participation in transport related seminars, in-house workshops and completion of ADR exams.

While there is a workforce plan in place for ORP that identifies future staff needs the plan does not address a strategy for succession planning.

For patient protection matters, it is the HSE that is responsible for the delivery of health services in Ireland. The HSE has delegated the function of patient protection during medical radiation exposures to the National Director of the Quality Assurance and Verification Division (QAVD). Within the QAVD, the Medical Exposure Radiation Unit (MERU) supports the regulatory functions of the HSE in relation to protection of the patient from the medical use of ionizing radiation. It has been established to provide operational functions associated with the assessment and control of medical exposures. MERU, as part of QAVD, has access to healthcare audit and incident management expertise and other services as required. Expertise is contracted on a part-time or voluntary basis. The current staff complement of MERU is 1.6 WTE (1 WTE administrator, 0.4 WTE Radiographic Adviser, and 0.2 WTE Medical Physics Adviser) under the direct management of the assistant national director QAVD. There is currently a deficit in the administration team. MERU currently does not have any full-time technical staff and instead relies on contracted advisors acting on a part-time basis and, if required, voluntary support as and when required for matters relating to radiotherapy.

| **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES** | |
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| **Observation:** The ORP does not have a plan to manage staff succession. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 18, para. 4.12 states that** *"The human resources plan for the regulatory body shall cover recruitment and, where relevant, rotation of staff in order to obtain staff with appropriate competence and skills, and shall include a strategy to compensate for the departure of qualified staff."* |
| **R7** | **Recommendation: The EPA should develop a strategic plan for ORP's staff succession management.** |

| **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES** | |
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| **Observation:** The current provision of resources for the regulation of patient exposure is insufficient. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 16, para. 4.4 states that** *"….the government shall be responsible for ensuring that the regulatory body has sufficient resources to fulfil its statutory obligations."* |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **R8** | **Recommendation: The Government should urgently ensure that the regulatory body that is responsible for patient protection is adequately resourced.** |

### 3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

A new high level scientific advisory body, the Radiological Protection Advisory Committee (RPAC), has been established to advise the EPA in the carrying out of its functions on matters concerning ionizing radiation, with particular emphasis on public health matters. The committee includes experts from both France and the UK who offer a broader international radiological protection perspective to issues under consideration.

From time to time, the ORP also obtains support from other organizations for technical or other expert professional advice or services. For example, engaging external consultants to review best international practice and assist with the development of new or revised regulatory requirements. In addition to IRRS missions, the ORP has also received peer reviews to review specific work programmes and engages in bilateral arrangements, including annual meetings and exchanges of information, with other European regulatory authorities.

Section 38 of the Environmental Protection Act, 1992 [EPA92] requires members of any committee established by the EPA, including the RPAC, and consultants engaged by the Agency to disclose any conflicts of interests in matters being considered or advised upon.

The ORP also has a long term arrangement with an external legal firm for all legal advice relating to radiation protection activities and an external medical physicist to advice on the licensing and inspection of radiotherapy facilities. However, in these two cases only the arrangements are informal and not by way of a formal written agreement.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** There is no formal written agreement in place with two long-term external advisers to the EPA's Office of Radiological Protection on legal matters and radiotherapy matters respectively. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 20, para. 4.18 states that** *"The regulatory body may decide to give formal status to the processes by which it is provided with expert opinion and advice. If the establishment of advisory bodies, whether on a temporary or a permanent basis, is considered necessary, it is essential that such bodies provide independent advice, whether technical or non-technical in nature."* |
| **(2)** | **BASIS: GSR Part 1 Requirement 20, para. 4.20 states that** *"Arrangements shall be made to ensure that there is no conflict of interest for those organizations that provide the regulatory body with advice or services."* |
| **S3** | **Suggestion: The regulatory body should consider entering into written agreements with any external adviser to formalize the arrangements and to facilitate the management of any potential conflict of interest.** |

## 3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

The EPA has several mechanisms, both formal and informal, to ensure that it continually communicates with authorized parties. A significant and important mechanism is the use of Radiation Protection Advisers (RPA). For all radiological licensees, with the exception of those using veterinary X-ray units, the requirement to appoint and consult with an EPA approved (RPA) in relation to all matters concerning compliance with the EPA's license conditions and the relevant legislation is enforced. The EPA works closely with RPAs to ensure that they are kept up to date on all new developments and changes to the EPA's licensing requirements, including the justification for these changes. They in turn are then able to offer up-to-date and appropriate advice and support to licensees. The EPA routinely emails all RPAs to advise them of safety alerts, recent incidents and lessons learned, upcoming conferences and meetings and other matters that may be of interest to them and their clients (licensees) and organizes an annual RPA liaison meeting.

The EPA meets from time to time with professional bodies representing licensees such as the Irish Dental Association and bodies who have a regulatory oversight role with licensees such as the Dental Council and Veterinary Council of Ireland. For specific issues relevant to a particular sector, the EPA will write to all licensees in that sector to alert them to new or changed licensing requirements. The EPA also uses its inspections as an opportunity to build and maintain relationships with licensees.

## 3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

The EPA performs all radiation protection regulation activities under the provisions of the RPA91 and SI125/00. The process of licensing has been mapped and a new information management system (GAMIS) has been developed to support the processes. The inspection processes are controlled and developed in a formal quality management system that is accredited to ISO 17020:2012. The enforcement process is set out in an 'Enforcement Policy and Procedures' document.

There are also technical projects on going following the merger between the EPA and the RPII that are examining functions and processes that are similar between radiation protection and other activities of the EPA. These include projects in authorization; inspection/enforcement; emergency preparedness; environmental monitoring; environmental data and reporting and quality management.

However the ORP has not documented its process and procedures for review and assessment of license applications and amendments and for the authorization of transport activities.

**Refer to Recommendation 10 in Chapter 4.4.**

## 3.7. SAFETY RELATED RECORDS

The ORP has developed processes for establishing and maintaining adequate and retrievable records relating to the safety of facilities and activities. All safety related records pertaining to licenses issued before 2015 are stored in hard copy on individual licensee files in fire-proof cabinets. In addition, any communication issued by ORP to licensees is also filed on the relevant licensee's file. In accordance with the record management policy, files are routinely culled and extracted records are stored off-site. These records can be retrieved following a 24 hour notice [RMH]. All records relating to facilities that no longer require a license are similarly archived off-site once the relevant files are closed.

In October 2014 ORP commenced development on a new information management system to support its regulatory activities. The new system, GAMIS (Graded Authorization Information Management System), is being developed on a CRM platform in-house and will replace the existing regulatory database. The licensing modules were the first to be developed and these were launched in March 2015. Currently several hundred licensees are using GAMIS, accessing it through the EPA's EDEN on-line portal, and are

able to manage their own licenses on-line, including submitting requests for license amendments and applications to renew their license. For those licensees using GAMIS, all safety related records are now stored electronically in Share Point and the hard copy licensee files for those licensee are no longer used. It is expected that all licensees will be transferred over to GAMIS by the end of in 2016, by which time functionality relating to ORP's inspection activities will have been developed and launched, thereby removing the current reliance on paper-based records and files.

The ORP is responsible for maintaining the National Dose Register for all occupational doses received by monitored workers in Ireland. A database was developed in-house for this register using a Laboratory Information Management (LIMS) system. Approved dosimetry service providers are required to upload details of all occupational doses measured to the National Dose Register for the preceding year by 31 July each year.

## 3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

The EPA has developed a communications plan for 2015 [CP2015] which is informed by the priorities set out in the current Strategic Plan 2013 – 2015. This Communications Plan acts as a framework to highlight the main communications activities planned for the year ahead while also allowing for a degree of flexibility to accommodate changes that may occur throughout the year. The Plan identifies key communication actions for the EPA when dealing with the public, media and external agencies and organizations.

The EPA has many communication channels with Interested Parties, including licensees, public bodies and private organizations. These include MoUs, bi-laterals meetings and participation on national committees. An annual one-day liaison meeting is also organized with all approved Radiation Protection Advisors (RPAs) and information updates and alerts to RPAs and licensees are sent using email.

There are several direct lines of communication that the EPA has with governmental authorities including appearing before the Joint Parliamentary Committee on the Environment each year where it has to account for, and respond to questions on, its annual programmes of work. The EPA also has to submit its Annual Report to a meeting of the Government Cabinet each year. For specific programmes, staff of the EPA participate on Inter-Departmental working groups and taskforces that are chaired by Government Ministers or Senior Officials from DECLG and other Government Departments and Agencies e.g. the working group on radioactive waste.

While the EPA has a comprehensive public information system, it does not have a system of consulting with the local population before an authorization relating to ionizing radiation is granted, but this is not considered to be an omission as Ireland does not have nuclear facilities and authorizations are generally for relatively low risk undertakings.

## 3.9. SUMMARY

The EPA is an independent public body established in July 1993. It comes under the Department of Environment, Community and Local Government. The responsibilities of the EPA were extended in August 2014 following its merger with the Radiological Protection Institute of Ireland (RPII).

All decisions on radiological license applications or amendments to existing licenses are made solely by staff from the EPA's Office of Radiological Protection through a delegation from the Board of the EPA. The ORP ensures independence in its inspection activities through accreditation to ISO 17020:2012. The ORP has also developed an enforcement policy, approved by the Board, which sets out the procedures for determining enforcement actions. The ORP also has a number of measures in place to minimize possible occurrences of conflicts of interest, including requirements to declare conflicts of interest.

The ORP has a current staff number of 35, divided across three programme areas. Staff numbers are constrained by general public sector employment policies but a recent submission has been made for one additional scientific staff member to assist in the transposition of the Euratom BSS. However there is a severe shortage of staff in the regulatory body (HSE) that carries out regulatory activities for patient protection.

A new high level scientific advisory body, the Radiological Protection Advisory Committee (RPAC), has been established to advise the EPA in the carrying out of its functions. The EPA also has several mechanisms, both formal and informal; to ensure that it continually communicates with authorized parties. A significant and important mechanism is the use of EPA-approved Radiation Protection Advisers (RPA). For all radiological licensees, with the exception of those using veterinary X-ray units, the requirement to appoint and consult with an approved RPA in relation to all matters concerning compliance with the EPA's license conditions and the relevant legislation is enforced.

The ORP has developed processes for establishing and maintaining adequate and retrievable records relating to the safety of facilities and activities. It also operates a web-based portal for license administration called GAMIS, which is a good practice.

The EPA has a communications plan and many communication channels with interested parties. These include MoUs, bi-laterals meetings, participation on national committees, an annual one-day liaison meeting with RPAs and information updates and alerts to RPAs and licensees. While the EPA has a comprehensive public information system, it does not have a system of consulting with the local population before an authorization relating to ionizing radiation is granted, but this is not considered to be an omission as Ireland does not have nuclear facilities and authorizations are generally for relatively low risk undertakings.

# 4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

## 4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

The merger of the Environmental Protection Agency (EPA) and the Radiological Protection Institute of Ireland (RPII), based on the 2014 Act, had a significant impact on the management system framework. The merged organization adopted the management system, structure, governance policies and practices of the EPA with the creation of an additional Director position. A fifth office, the Office of Radiological Protection (ORP), was established to carry out the operational tasks of the former RPII including radiation protection regulation, radiation emergency preparedness, radiation protection service provision and environmental monitoring for radioactivity. Leadership in terms of corporate issues including financial planning, governance and communications were integrated into the EPA's Office of Communications and Corporate Services (OCCS).

The management framework comprising the elements of (a) Organizational Statements of Strategy, (b) Business (Work programme) Planning and (c) Performance Management and Development System (PMDS), provides a means of developing and monitoring achievement at the level of the organization, the Office and the individual respectively. The overall management policy objectives and processes are set out in the EPA's statement of Corporate Strategy [EPACS], which is approved by the Board. Currently, there are two strategies operating, one governing the work of the ORP and the other for the pre-merger EPA offices. A new corporate strategy for the whole EPA is under development. The IRRS team was informed that it will be in force from 2016. The annual Work Programme [EPAWP] has been developed to achieve the objectives of the strategy. The Annual Work Programme is linked to each staff member of EPA by developing on an annual basis a Performance Management and Development System (PMDS) role profile that reflects both the operational tasks and goals of each individual. PMDS is an integral part of the management systems operating in the Public Service in Ireland and provides for performance review as well as providing a system for managing and coordinating staff development.

Another important document for the management system is the Corporate Governance Manual (CGM), updated in 2014. This manual is a key document underpinning the overall management of processes and activities, but currently does not cover radiological protection functions and is due to be updated in 2015. This document forms a formal link between the mandate set down in legislation and the systems and processes by which the organization is managed, roles and responsibilities are defined, outcomes and risks are reviewed, assessed, and reported. The CGM provides a description of the responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work. This manual is based on a code of governance provided by central government as a basis for the governance of all state funded agencies such as the EPA. Most of the key documents of the Management System are managed and maintained on the corporate intranet and they include: Corporate Governance [EPACGM]; Delegations [EPADD]; Risk [EPARR]; Audit [EPAAS]; Human Resources [EEH]; Accredited Quality Management Systems [ISO 17025; ISO 17020; ISO 14001]; Safety [OHSAS equivalent]; and Enforcement [EPAEP, EPABR].

To ensure best practice, some quality systems have independent external accreditation by the Irish National Accreditation Board. The analytical laboratories including the radiation protection related laboratories are accredited to ISO/IEC 17025:2005 (General requirements for the competence of testing and calibration laboratories). The EPA complies with ISO 14001 standard, which relates primarily to environmental objectives, and this will be rolled out in due course to the ORP. From a radiation protection point of view, the most important external accreditation is that the inspection activities of the ORP are

accredited to ISO 17020:2012 (Conformity assessment– Requirements for the operation of various types of bodies performing inspections) with very broad scope of accreditation. Through external accreditation, procedures and practices are regularly reviewed and assessed and any required improvements are addressed in a timely manner.

The IAEA Safety Standards require that safety culture should be explicitly addressed to ensure that all staff give appropriate attention to safety culture in their roles and tasks. The IRRS team was informed by the Irish counterpart that safety culture is increasingly becoming part of the operational considerations of ORP with a growing focus on safety culture assessment during inspections and regular engagement with RPAs on safety issues. However it is acknowledged that there is scope to enhance the safety culture in the organization and do more to influence safety culture in regulated facilities. The ORP has an OHSAS 18001 equivalent safety management system including a safety manual [ORPSM]. An EPA Board sub-committee is in place to oversee health and safety and the safety management system is currently being updated for the whole organization.

Although existing legislation does not address specifically a graded approach with regard to radiological protection licenses, it is taken into account in practice. It is the intention of ORP that a more formalized graded authorization system will be implemented in the near future. ORP has analyzed the licensing system and has published a revised authorization process that would more explicitly differentiate on the basis of risk. Additionally, the planning and execution of the annual inspection programme is carried out as part of quality management system. The generation of an inspection programme is based on documented criteria including risk, available resources, target inspection periodicity and issues arising in a particular sector.

While the existing management system is based on that designed primarily for the EPA, it is broadly consistent with that which applied in the RPII pre-merger. However, there are a number of ongoing areas for integration, since the operational tasks of the ORP, including radiation protection regulation, radiation emergency preparedness, radiation protection service provision and environmental monitoring of radiation are new to the EPA. Within ORP and the Radiation Protection Regulation (RPR) programme there is significant change taking place, and a number of the processes covered by the management system are yet to be mapped and documented for example the radiation safety authorization procedures. A new information management system (GAMIS) is under development to support the management of the regulatory processes including external interaction with licensees through a WEB portal (EDEN), and many other activities are in progress.

| **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES** | |
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| **Observation:** Existing post-merger EPA's management system does not fully reflect all the requirements for a radiation safety regulatory body. | |
| **(1)** | **BASIS: GS-R-3 para. 2.1 states that** *"A management system shall be established, implemented, assessed and continually improved. It shall be aligned with the goals of the organization and shall contribute to their achievement. The main aim of the management system shall be to achieve and enhance safety by:*<br>– *Bringing together in a coherent manner all the requirements for managing the organization;*<br>– *Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied;*<br>– *Ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative* |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | *impact on safety."* |
| **R9** | **Recommendation: The EPA should assess gaps in the management system with regard to radiation safety due to the merger of RPII with the EPA, and prioritize actions to develop the management system further in line with GS-R-3 where appropriate.** |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** EPA's radiation safety inspection activities are accredited by the Irish National Accreditation Board (INAB) to the ISO 17020:2012 standard for inspection bodies "General Criteria for the Operation of Various Types of Bodies Performing Inspections." | |
| **(1)** | **BASIS: GSR Part 1 Requirement 19, para. 4.14 states that** *"The regulatory body shall establish and implement a management system whose processes are open and transparent. The management system of the regulatory body shall be continuously assessed and improved."* |
| **GP1** | **Good practice: EPA's radiation safety inspection activities are formally accredited to an ISO standard, which provides for openness and transparency, as well as, continuous assessment and improvement.** |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** The EPA has a management framework comprising (a) Organizational Statements of Strategy, (b) Work programme and (c) Performance Management and Development (PMDS) as well as the Corporate Governance Manual. Through these elements there is clear connection between the legislation that establishes the mandate of the EPA and the role of the individual staff member. Roles and responsibilities are defined, reporting and review arrangements specified, and corporate values and behavioural expectations are established. | |
| **(1)** | **BASIS: GS-R-3 para. 3.3 states that** *"Management at all levels shall communicate to individuals the need to adopt these individual values, institutional values and behavioural expectations as well as to comply with the requirements of the management system."* |
| **GP2** | **Good practice: There is a documented system providing a link between the legislation mandating the organization and individual contribution to delivery of goals, including corporate values and behavioural expectations.** |

### 4.2. MANAGEMENT RESPONSIBILITY

Management responsibility is primarily set out in the Corporate Governance Manual [EPACGM], reviewed in 2014, before the merger of RPII with EPA. The Manual provides a clear summary of the principal aspect of corporate governance for the Directors and senior managers. Leadership development is the responsibility of senior management and a number of initiatives in terms of developing leadership within the EPA have been on-going. The updated version of the Manual will fully incorporate the ORP.

The Director General has, with the Board, the overall responsibility for the management and leadership of the EPA and in that respect has responsibility for the management system. Key documents in the management system such as the Statement of Corporate Strategy; the Work Plan; the Corporate Governance Manual and the List of Delegations can only be revised and amended with the approval of the Board. However, day-to-day responsibilities have been assigned for the management of these documents to staff within the OCCS and in particular the Corporate Governance Section. Each of the ISO accredited systems have specifically appointed Quality managers and deputy quality managers/quality representatives to manage the systems. Other key positions or job holder descriptions have been designated such as the chief financial officer (DG); head of internal audit, and the chief risk officer.

### 4.3. RESOURCE MANAGEMENT

The Board of the EPA is ultimately responsible for resource management. At an operational level, the Human Resources (HR) and Finance Work Programmes, together with the Programme Managers, manage human resource issues for the EPA. This involves managing the process of resource allocation across the organization and the recruitment of staff. They also have responsibility for the management of the work force planning process where activities are mapped against capacity and a work force plan is developed for discussion with the parent department, DECLG on an annual basis. Each of the quality systems and the safety management system also take account of resource management as a consideration particularly as a standing item on the Annual Management Review Meeting with regard to radiological protection. The team notes that individual role descriptions are documented for EPA staff through the PMDS system.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** Individual role descriptions have been documented for EPA staff but are not yet in place for ORP staff. It is noted that a skills mapping exercise is planned for all staff roles in 2016. | |
| **(1)** | **BASIS: GS-R-3 para. 4.3 states that** *"Senior management shall determine the competence requirements for individuals at all levels."* |
| **(2)** | **BASIS: GS-G-3.1 para. 2.61 states that** *"Job descriptions should be developed for the different competences or types of work to define the total scope of each individual's job. Job descriptions should be used to establish baselines for identifying training and competence needs."* |
| **S4** | **Suggestion: The EPA should consider assessing and documenting the competence requirements for individual roles in the ORP structure through the planned skills mapping exercise.** |

### 4.4. PROCESS IMPLEMENTATION

Based on IAEA safety standard GS-R-3 and supporting safety guide GS-G 3.1, identification and development of processes, documentation of processes, process maps and the scope of process owner responsibility, control of records are all elements of a Management System. Process development is managed in a decentralized manner in the EPA with each office responsible for the development and management of processes relevant to its functions. The main processes of relevance to radiation safety have been identified and the majority are supported by documented procedures. There are ten key processes: licensing, inspection and enforcement, guidance development, radioactivity measurement and certification service, calibration service, advice services to government and public, radiation emergency preparedness, and research.

The IRRS team was informed that some of the identified processes are undergoing further development. The process of licensing has been mapped and has been coded into an on-line information management system (GAMIS). The inspection processes are controlled and developed in a formal accredited quality management system ISO 17020. The enforcement process is set out in an 'Enforcement Policy including Procedures and a Decision Architecture' [EPPDA] that is maintained under review. There is a current external consultation process on 'Enforcement' and 'Better Regulation' incorporating all relevant EPA activities including those within ORP.

Generic management system processes such as Control of products, Control of records, Purchasing, Communication, Managing organizational change, HR and Internal Audit are well developed under the management system of EPA and the ORP falls fully within the scope of these processes. The ORP is already integrated in the majority of these systems or is currently involved in an ongoing integration process.

The IRRS team noted that the Irish counterpart is aware that not all systems are fully integrated at present but as integration following the merger is more fully progressed this will be addressed in due course. Examples of active areas of cross organization integration include (a) the area of IM&T where a subcommittee of the Board has been established ensuring an integrated systems approach to information management and development needs; (b) the EPA wide Safety Management System which is being developed in line with OHSAS 18001 and will be ready to roll out in 2016; (c) centralization of the laboratory accreditation systems for the whole of the EPA.

Additionally, there are on-going technical projects to support the merger between the EPA and the RPII. These projects are oriented to the examination of functions and processes that are similar between radiation protection and other activities of the EPA. These include projects in authorization; inspection/enforcement; emergency preparedness; environmental monitoring; and environmental data and reporting and quality management.

| **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES** | |
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| **Observation:** Process development is managed in a decentralised manner within the EPA offices. Ten key processes of relevance to radiation safety have been identified but development and management of processes and procedures are not fully implemented. | |
| **(1)** | **BASIS: GS-R-3 para. 5.1 states that** *"The processes of the management system that are needed to achieve the goals, provide the means to meet all requirements and deliver the products of the organization shall be identified, and their development shall be planned, implemented, assessed and continually improved."* |
| **R10** | **Recommendation: The EPA should further develop and document those processes and procedures relevant to radiation safety not already addressed.** |

### 4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

The EPA management system is reviewed and monitored in the first instance by the Board. In particular the Board monitors progress on the Work Programme monthly with comprehensive reviews from each Office three times per year.

ISO accredited quality management systems have review and improvement mechanisms built into the system of monitoring and measurement which occur on a cyclical basis aimed at the continual improvement of the management system.

The IRRS team was informed that independent assessments from a corporate governance perspective in the EPA is the primary responsibility of the Internal Audit function where there are clearly defined roles and responsibilities. The internal audit committee comprises external members with a range of expertise including radiological protection expertise. A Board risk committee is in place and both corporate and office risk registers are maintained. An audit schedule is prepared each year and approved by the Board and can entail an examination of any aspect of the EPA's activities including radiation protection; safety; effectiveness; leadership; quality as well as identifying opportunities for improvement. On the financial side, the Comptroller and Auditor General reviews the financial arrangements of the EPA on an annual basis. While the ORP is fully within the scope of the Internal Audit function, including within the corporate risk register an office risk register so far post-merger the ORP technical radiation protection functions have not been scheduled for audit.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** There is a centralized process of review and improvement of the management system in EPA through the process of internal audit. So far, radiation safety activities have not been scheduled for internal audit. | |
| **(1)** | **BASIS: GS-R-3 para. 6.3 states that** *"Independent assessments shall be conducted regularly on behalf of senior management:*<br>– *To evaluate the effectiveness of processes in meeting and fulfilling goals, strategies, plans and objectives:*<br>– *To determine the adequacy of work performance and leadership;*<br>– *To evaluate the organization's safety culture;*<br>– *To monitor product quality;*<br>– *To identify opportunity for improvement."* |
| **S5** | **Suggestion: The EPA should consider ensuring that post-merger ORP functions continue to be taken into account when establishing the audit schedule in the same way as other technical areas of the EPA.** |

### 4.6. SUMMARY

The Environmental Protection Agency (EPA) as a national competent authority for regulating, inter alia, radiation protection issues, has a management system that is not yet completely integrated. In August 2014, RPII merged with EPA and consequently, an existing Management System had to be reviewed and upgraded to meet the needs of newly established Office of Radiological Protection (ORP).

The majority of the elements of the Management System are already in place. This includes description of the tasks and responsibilities of all organizational units and persons, as well as management practices and internal communication at all levels, all of which are well defined. However, there are elements and requirements from IAEA safety standards and guides that are not currently met in the EPA management system, such as some processes and procedures not being documented, currency of job descriptions for ORP staff and, lack of internal audits of radiation protection activities.

The IRRS team also noted good practices such as EPA's inspection activities being formally accredited to an ISO standard and the existence of a documented system that provides a link between the legislation mandating the organization and individual contribution to delivery of goals.

EPA is currently implementing a set of actions for improvement of its management system and expressed its commitment to a continuous improvement programme. Therefore, further development and reviews are necessary to fully satisfy the requirements set out in the IAEA safety standards.

# 5. AUTHORIZATION

## 5.1. GENERIC ISSUES

The Radiological Protection Act 1991, as amended by the Radiological Protection (Miscellaneous Provisions) Act, 2014, provides for the EPA to regulate, by license, the custody, production, processing, handling, holding, storage, use, manufacture, importation, distribution, transportation, exportation or other disposal of radioactive substances, nuclear devices and irradiating apparatus.

The practices associated with ionizing radiation to be licensed and those to be exempted are detailed in S.I. No. 125 of 2000.

Within EPA, the Office of Radiological Protection (ORP) has the delegated responsibility for the radiological licensing function. The authority to issue a license is delegated to individual inspectors. In some cases, for example, when new a type of practice is introduced which requires justification considerations or in the case of a high risk practice to be licensed, a licensing panel comprising typically three inspectors is formed to assess the application.

Authorization of facilities and activities is through a one-level authorization system of licensing. The applicant is required to submit documentation to the EPA that includes facility design plans, risk assessment and radiation safety procedures one month before commencement of any licensable practice.

The legislation does not provide for different types of authorization at different stages in the lifetime of a facility or the duration of an activity. However, as a non-nuclear country the need for such a provision is rather limited and some examples given (e.g. establishment of a radiotherapy department) demonstrate that the current legislation provides sufficient flexibility to the same effect on case by case basis where needed.

Licenses are issued for periods ranging from one to four years, depending on the activities carried out and the risks involved. There are typically up to 60 applications for new licenses each year. In addition, there are approximately 800 license amendment applications each year.

The legislation as such does not provide for a graded approach for regulation. This is addressed in Recommendation 2 in Chapter 1.2. However, EPA implements a graded approach to its regulatory functions, including authorization and inspections, utilizing risk based categorization of practices and sources. However, the implementation of a graded approach is currently under further development, for example, a more formal graded approach to authorization, including licensing, registration and notification processes, is foreseen in the near future due to the implementation of the new Euratom BSS directive.

The implementation of a graded approach could be further improved by considering the different interacting regulatory processes such as the frequency of inspection and the duration of the license. It was noted that EPA has already looked at license durations in its development of a graded model for authorization.

Once a license has been granted, any modifications to practices, equipment or facilities require the licensee to seek authorization from the EPA in the form of an amendment (change) request to the license.

A license is closed when the licensee informs the EPA of the cessation of the practice and provides evidence that sources and radioactive waste have been appropriately transferred out of its jurisdiction.

EPA/ORP has recently introduced a computerized system, Graded Authorization Management Information System (GAMIS) that was developed through the EPA's Licensing Enforcement and Monitoring Application (LEMA). The system provides for online license applications, as well as,

amendments and renewal of licenses through an online web portal EDEN (Environmental Data Exchange Network).

The authorization process, which is now being implemented to large extent by applying the GAMIS system, is not yet prescribed in EPA's written procedures, nor is there in place written procedures for the review and assessment of license applications. The lack of these written procedures is addressed in **Recommendation 10 in Chapter 4.4**.

In establishing the written procedures for the authorization process, consideration should be given to include, for example, (1) the involvement of relevant interested parties in the justification of new types of practices; (2) a mechanism to appeal against a regulatory decision relating to an authorization or a condition attached to an authorization (as required in GSR Part 1 Requirement 24, para. 4.32). The latter matter is addressed in **Recommendation 2 in Chapter 1.2**.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** EPA/ORP has developed and established a web-based system (GAMIS) which allows applications for new licenses to be made on-line and for a licensee to make requests to amend and renew an existing license. The system guides the user step by step on the information to be provided and on the documents supporting the application to be uploaded electronically. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 24, para. 4.33 states that** *"The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization."* |
| **GP3** | **Good Practice: The EPA/ORP has established a web-based system that allows applications for a new radiological license to be made and for existing licenses to be renewed or amended by following clear step by step instructions on the information to be provided and documents to be uploaded in support of the application.** |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** EPA has taken major steps in implementing a graded approach to regulatory control. However, the implementation can be further improved by considering the different interacting regulatory processes such as the frequency of inspection and the duration of the license. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 24, para. 4.33 states that** *"The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."* |
| **S6** | **Suggestion: The EPA should consider developing further its graded approach by taking into account the interaction between all the elements of the regulatory control.** |

## 5.2. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

There are no dedicated facilities devoted to radioactive waste management in Ireland. The waste management is performed in research and medical facilities where the waste is generated. As the majority of the radioactive wastes are short lived, the management relies on interim storage for decay, control,

clearance and release as common waste. The review, assessment and authorization of the radioactive waste management activities is performed within the authorization process of the facilities.

## 5.3. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

Prior authorization is required from the EPA before a radiation source is acquired. The applicants are required to submit risk assessments and radiation safety procedures to support license applications. An agreement from the supplier to take back the source at the end of its useful life must be in place prior to issuing a license for a sealed radioactive source.

There was a significant increase in licenses in 1989 when the dental sector was brought within the licensing system. Since then there has been a steady increase in new licensees, though the total number has leveled off in recent years. In the beginning of 2015 there were 1732 active licenses of which dentist represent 959, veterinary 297, medical 140, industrial 281, education 15 and distributors 40.

The license duration varies from 1 year, for high risk practice, to 4 years for low risk practices.

The GAMIS system provides also for a national register for radiation sources. It contains relevant information on all sources attached to licenses. Regarding radioactive sealed sources the register contains details of all sources exceeding the exemption level.

Licensees are encouraged to hold the minimum number of sources, necessary for their business. Recent campaigns in this respect have significantly reduced the number of disused sources stored at licensees' premises.

Radioactive sources may be exported for recycling by transferring the sources to a licensed waste management contractor who arranges for them to be shipped overseas to facilities authorized to accept sources for recycling/reuse purposes. There are no facilities in Ireland that recycle or recondition sources.

The Order SI 875/05 transposes the requirements of the Council Directive 2003/122/Euratom (HASS directive). These requirements provide for a comprehensive set of requirements for high-activity sealed sources (HASS) which are more stringent compared to those for other sealed sources. They also provide for a financial security arrangement to cover disposal costs at the end of their life-cycle and measures concerning site security. EPA has entered into arrangements with the National Crime Prevention Unit of An Garda Síochána (Irish National Police) where a security audit of the premises/site by the Irish National Police must be submitted to the EPA for consideration together with any HASS license application or amendment. Audit findings need to be appropriately addressed prior to issuing a license.

EPA itself uses radiation sources within its own activities. These include high activity sealed sources for calibration purposes. These practices have been regulated (licensed and regularly inspected) as they would be for any licensee with similar sources. However, it was observed that, at the moment, the regulatory control of EPA's own use of radiation is also in a transition phase due to the merger of EPA and RPII and due to the transition from paper based authorization process to the internet based GAMIS system.

In the case of import or export of sources, EPA follows the IAEA Import and Export Guidance, for example, through an administrative arrangement with the Canadian Nuclear Safety Commission (CNSC) based on the said guidance.

Ireland has not yet notified the Director General of the IAEA of its intention to act in accordance with the IAEA Guidance on the Import and Export of Radiation Sources. However, it was noted that the EPA has already taken measures to this effect and that, as described above, in practice Ireland is acting in accordance with the guide.

Transfers of sources from or to other EU Member States are regulated in accordance with the EU Council Regulation 1493/93.

There is no legal requirement for the Customs to verify that the consignee of an imported radiation source is authorized to take custody of the source.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** There is no legal requirement for the Customs to verify that the consignee of an imported radiation source is authorized to take custody of the source. | |
| **(1)** | **BASIS GS-G-1.5, para. 2.21 states that** *"For example, this link could extend to customs authorities to ensure that there is adequate regulatory control over the import and export of radiation sources, and that the persons importing or receiving the sources are identified and authorized."* |
| **S7** | **Suggestion: EPA should consider assessing the current provisions and co-operation arrangements regarding the import of radioactive sources and to make appropriate proposals, if needed, for establishing arrangements which provide for the Customs to verify systematically that the imported sources are appropriately licensed by the EPA.** |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** EPA co-operates with the National Crime Prevention Unit of the Garda Síochána (Irish National Police ) so that the police performs a security audit of the premises/site where any HASS source is employed. Audit findings need to be appropriately addressed prior to issuing a license. In addition, EPA and the police conduct regularly joint inspections covering relevant safety and security aspects simultaneously. | |
| **(1)** | **BASIS: GSR Part 3, para. 1.37 states that** *"Security infrastructure and safety infrastructure need to be developed, as far as possible, in a well coordinated manner. All the organizations involved need to be made aware of the commonalities and the differences between safety and security so as to be able to factor both into development plans. The synergies between safety and security have to be developed so that safety and security complement and enhance one another."* |
| **(2)** | **BASIS: COC para. 20 states that** "*Every State should ensure that the regulatory body established by its legislation has the authority to:*<br>*..(m) liaise and co-ordinate with other governmental bodies and with relevant non-governmental bodies in all areas relating to the safety and security of radioactive sources."* |
| **GP4** | **Good practice: The systematic co-operation between the EPA and the police significantly supports EPA in the implementation of an integrated approach to safety and security of radiation sources.** |

## 5.4. AUTHORIZATION OF TRANSPORT

The authorization of some facilities includes, where relevant, aspects related to the transportation of

radioactive material. Compliance with IAEA "*Regulation for the Safe Transport of Radioactive Material*" is included, as well as the modal transport regulations (ADR, RID, IMDG code and TI-ICAO), as a reference in the Authorization's condition. The carriers are also approved by the EPA. The license duration of these Authorizations (licenses) ranges from 1 to 3 years.

The EPA is the competent authority in respect of matters relating to the carriage by road of Class 7 radioactive materials, including, among others, the approval of specialization courses for the training of drivers of vehicles carrying radioactive material of ADR Class 7 and the examination of persons who have participated in those courses required under the relevant road transport statutory provisions.

Regarding road transport, the requirements concerning the training of the vehicle crew (drivers) is function specific and the training requirements and structure of the training is provided in Chapter 8.2 of the ADR for basic and specialization training. Basic courses are approved by the Health and Safety Authority and run by the Chartered Institute of Logistics and Transport. The one day Class 7 specialization course is run by a training company approved by the EPA.

For the approvals required by the SSR-6 para. 802 (and the modal transport regulations) the IAEA regulation includes a graded approach to safety by the application of activity limits for the content, dose rate limits for packages and conveyances, requirements on the design, operation and on the package maintenance, and the required administrative controls (e.g. the need for package design approval, inspections before each transport).

The functions of the EPA include issuing approvals; however, in practice the items listed in para. 802 of the IAEA Regulations are not currently applicable to Ireland. Only Shipment Approval Certificates are issued for Type B packages where required and where valid Competent Authority Certificates of Design (from the country of origin) are available.

Special form radioactive material, low dispersible radioactive material, fissile material, packages containing 0.1 kg or more of uranium hexafluoride, Type B(U), Type B(M) packages or Type C packages are not currently designed or manufactured in Ireland.

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 TI-ICAO), the EPA is the only Competent Authority that issues an Authorization for the transport of radioactive material. No applications for approvals for certain shipments, radiation protection programmes for special use vessels, approval for calculation of radionuclide values not listed in Table 2 (Section VIII of the IAEA SSR-6 Regulation) or approval for calculation of alternative activity limits for an exempt consignment of instruments or articles have been received to date.

More information was required during the IRRS mission in regard to the relationships between the different Competent Authorities. A meeting was organized by the EPA with representatives of the Maritime Safety Directorate, the Irish Aviation Authority and the EPA. Issues in relation to the process of authorization, assessment, inspection and enforcement actions were discussed at this meeting and these issues are included in chapters 6.4, 7.4 and chapter 8.

The Maritime Safety Directorate stated that they do not issue Authorizations.

The Irish Aviation Authority (IAA) issues approvals and undertakes on-going surveillance of compliance by airlines and organizations involved in the carriage of dangerous goods, including radioactive material, by air. IAA also issues the approval for training companies to conduct dangerous goods training in accordance with the requirement of the ICAO Technical Instructions.

## 5.5. SUMMARY

The Radiological Protection Act 1991, provides for the EPA to license facilities and practices. Within the EPA, the ORP has the delegated responsibility for the radiological licensing function.

Authorization of facilities and activities is through a one-level authorization system of licensing. The applicant is required to submit documentation to the EPA that includes Facility Design Plans, Risk Assessments, and Radiation Safety Procedures one month before commencement of any licensable practice.

The legislation does not provide for different types of authorization at different stages in the lifetime of a facility or the duration of an activity. Licenses are issued for periods ranging from one to four years, depending upon the activities carried out and risks involved.

The legislation as such does not provide for a graded approach for regulation. However, EPA implements a graded approach to its regulatory functions, including authorization and inspections, utilizing risk based categorization of practices and sources. Once a license has been granted, any modifications to practices, equipment or facilities require the licensee to seek authorization from the EPA in the form of an amendment (change) request to the license.

In regards to the transport of radioactive material, the Irish Aviation authority also issues approvals and undertakes on-going surveillance of compliance by Airlines and organizations involved in the carriage of dangerous goods by air.

EPA/ORP has recently introduced a computerized system, Graded Authorization Management Information System (GAMIS) that was developed through the EPA's Licensing Enforcement and Monitoring Application (LEMA). The system provides for online license applications, as well as, amendments and renewal of licenses through an online web portal EDEN (Environmental Data Exchange Network). However, written procedures for the authorization, review and assessment of license applications are not in place.

# 6. REVIEW AND ASSESSMENT

## 6.1. GENERIC ISSUES

### 6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

An applicant for a license is required to submit documentation to the EPA that includes Facility Design Plans, Risk Assessments, and Radiation Safety Procedures. The EPA reviews and assesses this information to determine whether the facilities and activities comply with the regulatory requirements.

Based on the outcome of the review and assessment, EPA may set conditions to the license. However, there is no mechanism in place to appeal against a regulatory decision relating to an authorization or a condition attached to an authorization. This is addressed in **Recommendation 2 in Chapter 1.2**.

A graded approach to review and assessment is implicitly built into the process by the fact that the contents of the risk assessment and radiation safety procedures are expected to be more rigorous and comprehensive for high risk practices than for lower risk practices.

Review and assessment is carried out before issuing a license, upon receipt of a request for an amendment to a license and at the license renewal stage.

### 6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

Usually review and assessment is carried out by an individual inspector but in case of a high risk practice, or a new type of practice, a license review panel, comprising of several inspectors is established to review the application. Advice from an external independent expert may also be sought during this process. Normally, an inspection is not conducted as part of the review and assessment but is carried out in case of some high risk practice.

The documents sent to EPA in support of the application are produced by the applicant in conjunction with a Radiation Protection Adviser (RPA). Especially in the case of high risk practices the comprehensiveness, quality and completeness of the documents for review and assessment by the EPA relies heavily on the expertise provided to the licensees by the RPAs.

### 6.1.3. BASES FOR REVIEW AND ASSESSMENT

Review and assessment is based primarily on the information submitted by applicant. These include Design Plans, Risk Assessments and Radiation Safety Procedures. Collectively, this can be taken as the safety assessment which forms the basis for EPA's review and assessment. The safety assessment is expected to demonstrate the implementation of fundamental safety principles including the optimization of protection.

The new computerized GAMIS system provides for a process and procedure for the review and assessment. However, these are not yet documented.

### 6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

The inspectors performing a review and assessment are highly experienced and familiar with safety and protection principles, regulatory requirements and various safety aspects of the regulated practices. The comprehensive expertise arise mainly from the fact that in a relatively small unit most inspectors need to be continuously involved in various regulatory functions including authorization, review and assessment,

inspection and enforcement, as well as, other functions of the EPA such as emergency preparedness or environmental monitoring.

## 6.2. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

The review and assessment of the radioactive waste management activities is performed within the authorization of the practice.

## 6.3. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The paragraph 6.1 above essentially covers the review and assessment for radiation sources facilities and activities and is thus not repeated in this paragraph.

The new Euratom BSS directive provides for a graded approach to regulation, for example, by establishing a framework for different levels of authorization i.e. registration and licensing. EPA has prepared generic safety assessments for specific types of practices in order to assess the possibility to authorize them by registration rather than the current licensing approach.

## 6.4. REVIEW AND ASSESSMENT FOR TRANSPORT

With regard to the transport of radioactive material by road, the review and assessment is undertaken by the EPA and includes both radiation protection and transport matters. The licensee is required to ensure that all the activities associated with the transport of radioactive material shall be conducted in accordance with the IAEA's regulation for the Safe Transport of Radioactive Material, the Modal Instrument and national transport regulations.

The Quality Management system for ORP inspection activities is accredited to the international standard ISO 17020 and relates to inspection activities with regard to radiological protection. However, there are no documented procedures regarding the assessment of applications for authorizations in relation to the transport of radioactive material. This is addressed in **Recommendation 10 in Section 4.4**.

A meeting was organized during the IRRS mission by the EPA with representatives of the Maritime Safety Directorate, the Irish Aviation Authority and the EPA. The Irish Aviation Authority indicated during this meeting that the review and assessments of airlines to transport dangerous goods (including Class 7) are undertaken using standard forms.

## 6.5. SUMMARY

An applicant for a license is required to submit documentation to the EPA that includes Facility Design Plans, Risk Assessments, and Radiation Safety Procedures. The EPA reviews and assesses this information to determine whether the facilities and activities comply with the regulatory requirements.

A graded approach to review and assessment is implicitly built into the process by the fact that the contents of the risk assessment and radiation safety procedures are expected to be more rigorous and comprehensive for high risk practices than for lower risk practices.

Review and assessment is carried out before issuing a license, upon receipt of a request for an amendment to a license, during regulatory inspections and at the license renewal stage. Usually review and assessment is carried out by an individual inspector but in the case of a high risk practice, or a new type of practice, a license review panel is established to assess the application. Advice may also be obtained from external independent experts during the review and assessment process.

The documents sent to EPA in support of the application are produced by the applicant in conjunction with a Radiation Protection Adviser (RPA). Especially in the case of high risk practices the comprehensiveness, quality and completeness of the documents for review and assessment by the EPA is highly reliant on the expertise provided to the licensees by the RPAs.

EPA has prepared generic safety assessments for specific types of practices in order to assess the possibility of authorizing them by registration, rather than by license which will be provided for with the implementation of the new EU BSS directive.

With regard to the transport of radioactive material by road, the review and assessment is undertaken by the EPA. The Irish Aviation undertakes the assessments of airlines to transport dangerous goods by air (including Class 7).

# 7. INSPECTION

## 7.1. GENERIC ISSUES

### 7.1.1. INSPECTION PROGRAMME

Section 28 of the Radiological Protection Act 1991 empowers the EPA to appoint inspectors for the purpose of the Act and section 29 assigns a very comprehensive set of powers to the inspectors. EPA's inspection activities are accredited by the Irish National Accreditation Board (INAB) to the ISO 17020:2012 standard for inspection bodies "*General Criteria for the Operation of Various Types of Bodies Performing Inspections.*"

Towards the end of each year EPA develops an inspection programme for the forthcoming year. All inspectors are involved in compiling the inspection programme and it is finally approved by the Board of EPA. The inspection programme takes into account various factors including target inspection frequencies, reported incidents during the year, issues related to individual licensees, matters that may have arisen during the year and the available staff resources.

The target inspection frequency varies between 1 – 6 years depending on the type of practice and risks involved. During the year the programme may be adjusted, where appropriate, to consider for example reactive inspections due to an accident or incident. In some cases newly introduced practices may need to be inspected before the license is issued, however, most new practices are not inspected at the licensing phase but at a later date when they are incorporated into an annual inspection plan. No separate time frame has been defined before which a practice should be inspected for the first time.

Typically EPA conducts 150 – 220 radiological inspections per year. The number of inspections (56) planned for 2015 is significantly lower than in previous years due to other priority work commitments. This reduction in the number of inspections scheduled for 2015 was previously planned for and it is anticipated that up to 170 inspections will be completed in 2016 as resources are reprioritized.

Inspector's meetings are convened at least twice a year to, for example, review the inspections carried out and the inspection schedule and to discuss and assess issues arising from inspections completed. A review of the findings is published annually in a report titled "*Inspection and Licensing Activities and Inspection Programme."*

### 7.1.2. INSPECTION PROCESS AND PRACTICE

As the inspection activities are formally accredited, relevant written procedures including a comprehensive set of audit forms for different types of inspected practices have been established and included in the Quality Manual System.

An inspection is normally conducted by one inspector but in the case of a complex facility more than one inspector may be involved.

An inspection commences with an entrance meeting at which the inspector advises the licensee of the purpose of the inspection, the areas to be inspected and the structure/format of the inspection. Where possible, a representative from licensee's senior management is expected to be present.

Inspections are carried out utilizing practice specific inspection audit forms that are followed during the whole inspection. Each audit form asks questions on operational activities in place for assessing the maintenance, quality control, dosimetry, safety and security of the licensed items. These include routine

radiation surveys and wipe testing as well as the designation of controlled and supervised areas, radiation warning signs and barriers and testing and calibration of radiation measurement or monitoring equipment.

Once the entrance meeting has been satisfactorily completed, an inspection of the licensee's facilities and premises is undertaken. This involves visiting the areas where ionizing radiation is used and/or stored appropriate to the scope of the inspection.

On completing the site inspection the inspector reviews the findings of the inspection in private and prepares a written summary detailing the inspection findings and any recommendations for improving radiation safety. This list is recorded on the audit form. To conclude the inspection an exit meeting is convened between the inspector and the licensee's representatives during which the summary of the inspection findings is presented verbally. A formal report of the inspection findings is forwarded within four weeks.

The licensee is required to forward to the EPA a written response to the inspection report within four weeks of the date of issue, or sooner if so directed.

### 7.1.3. INSPECTORS

The majority of staff recruited to EPA/ORP to date have come directly from universities or technical colleges. On a few occasions staff who had previously worked as medical physicists in hospitals within Ireland have been recruited. Inspectors are, in addition to conducting inspections, involved in other functions of the EPA/ORP.

Staffing and training of inspectors is addressed further in Chapter 3.3

## 7.2. INSPECTION OF WASTE MANAGEMENT FACILITIES

The IRRS team noted through the review of inspection reports that the inspection of radioactive waste management activities and stored radioactive waste is performed as part of the inspection programme of the facilities that generate the waste and the license conditions are controlled and enforced accordingly.

## 7.3. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The main purpose of inspections is to check the licensee's compliance with license conditions and relevant legislation and, while not yet incorporated into the audit form, to assess the licensee's safety culture.

In general, the inspection programme, processes and practices are discussed in Chapter 7.1 above and is thus not repeated here.

Most planned inspections are announced but some unannounced inspections are also conducted, for example, in case of industrial radiography (NDT). This is facilitated by the fact the EPA receives from the licensee four day advance notice of any site radiography work.

In addition, peer reviews of inspections of various sectors with HASS i.e. Radiotherapy (HPA2007), Industrial Radiography (HPA2007) and Process Irradiation facilities (HPA2008A) have been carried out by the UK Health Protection Agency (HPA), the predecessor to Public Health England.

## 7.4. INSPECTION OF TRANSPORT

The EPA is responsible for the inspection of radioactive material transported by road and rail (although in Ireland there is currently no transport of radioactive material by rail).

The frequency of the transportation of radioactive material by road within Ireland is currently approximately 5000 transports per year.

The vast majority of the packages transported are Excepted or Type A packages (mainly for medical uses). A small proportion of the packages are Type B packages (mainly cobalt radioactive sources used in industrial sterilization and iridium sources for industrial radiography). The number of inspections undertaken of radioactive material transported by road in a given year is based upon a risk analysis.

All inspection activities undertaken by the EPA are carried out within the framework of a Quality Management System [QM17020] This issue is addressed in Good Practice 1 in Chapter 4.1. The Quality Procedures Manual includes a set of forms where transport is considered. Nevertheless, audits to verify the user's management system of transport organizations are not currently implemented.

| **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES** | |
|---|---|
| **Observation:** Transport organization's management systems are not included in the Inspection Programme. | |
| **(1)** | **BASIS: SSR-6, para 306 states that** "*A management system based on international, national or other standards acceptable to the competent authority shall be established and implemented for all activities within the scope of the Regulations.*"<br>**SSR-6, para 307 states that** "*The competent authority shall assure compliance with these Regulations.*"<br>**Safety Guide TS-G-1.5 para 4.58 states that** "*The competent authority should put in place an auditing programme to verify that the user's management system is implemented and followed correctly…*" **and** *"…However, the competent authority should also ensure by means of an ongoing audit or inspection programme that suitable management systems are implemented in the transport of packages of other types*" |
| **R11** | **Recommendation: The EPA inspection program should be extended to verify that the user's management system relating to the transport of radioactive material is implemented and followed correctly.** |

With regard to the transport of radioactive material by sea, the number of transportations is significantly less than by road and it is undertaken infrequently. There are no transports of packages that require notification or multilateral approval on the territorial Sea in Ireland. Transport of radioactive material by sea utilizes the road-sea-road interface. The consignors and consignees involved in the transportation of radioactive material by sea are licensed by the EPA.

A meeting was organized during the IRRS mission by the EPA with representatives of the Maritime Safety Directorate, the Irish Aviation Authority and the EPA. The Maritime Safety Directorate representative stated that there is no specific programme for the inspection of radioactive materials. Furthermore, the training, in relation to IMDG Code, provided for inspectors does not include specific training in relation to radioactive material (Class 7). See **Recommendation 5 in Chapter 1.5**.

The majority of the radioactive sources transported by air are used for medical purposes. They are shipped from, or are delivered to, EPA licensed facilities within Ireland by road. Some of these radioactive sources are transported to Northern Ireland as transit shipments by road.

The Irish Aviation Authority representative stated that the inspections are performed based on an annual inspection programme and that the IAA inspectorate has dangerous goods training that meets the requirements of the ICAO Technical Instruction.

## 7.5. SITE VISITS

**Observations of inspections conducted:**

**Industrial Facilities**

The IRRS team members observed an inspection by the EPA at an industrial irradiator facility (Becton Dickinson Penel Ltd) and a cyclotron facility at M2i Ltd. Both inspections started with an entrance meeting with the Radiation Protection Officer (RPO) and other representatives of the facility. In case of the irradiator facility, the site manager participated and in the case of cyclotron facility the RPA was also present.

The inspection included the checking of documents required by EPA including the risk assessment and safety procedures. Other documents and records were also checked by the inspector. The inspectors then proceeded to the location where the practice is conducted to conduct a visual and other checks.

Both inspections were conducted in a systematic manner following comprehensive inspection audit forms.

After the walk around of the facility the inspectors compiled their findings in private and presented them in an exit meeting.

While the inspectors were compiling their findings the IRRS team had an opportunity to discuss in private with the representatives of the licensee. In both cases the licensee expressed their sincere appreciation of how the EPA conducts its regulatory functions. There seemed to be a very open relationship between the EPA inspectors and the licensee which is driven by mutual respect and a desire to improve safety.

As a whole, the inspection concentrated on matters relevant to safety and was conducted in a very professional manner and the IRRS Team was convinced that the inspections contribute significantly to the improvement of safety and enhancing further the safety culture at the regulated facilities.

**Beacon Private Hospital:**

In contrast with the HSE clinical audit at St James's Hospital (see section 11.1), the visit to the Radiotherapy Department at Beacon Hospital with EPA staff and an external advisor was very obviously an inspection. The introductions by EPA staff were formal, and the legal basis, purpose and scope of the inspection made clear. The inspection considered the impact of recent ownership changes on licensing requirements, commitment to radiation safety and structures, workload and case mix, techniques in use, staffing levels and the use of electronic data transfer facilities. The external EPA advisor on radiotherapy examined in detail measurement records and the there was a visit to one of the linear accelerators and the sealed sources laboratory. The inspection concluded with an exit meeting involving the hospital's CEO, the RPAs and clinical and management staff. Issues highlighted included licensing requirements and conditions as a consequence of the cessation of a prostate treatment service using sealed sources, training of ancillary staff, handling of incidents related to inappropriate patient exposures, the activities of the Radiation Safety Committee and subsequent actions. Following this, the IRRS team were allocated time to discuss the hospital's views of its interactions with EPA. These were largely satisfactory and communication with the EPA was viewed to be appropriate, timely and helpful although they expressed a hope that new licensing systems would reduce times taken to address licensing issues.

The inspection provided opportunities to discuss with EPA staff their use of powers under the Radiological Act 1991. In particular, the provisions under Regulation 7(2)(b)(ii) are used to address equipment QA and how this relates to patient exposure. Similar powers are not included in SI 125. This

could be considered to be an inappropriate use of these powers, given the existence of SI 478 which includes similar requirements and is expressly intended to address patient exposure, rather than occupational and public exposure that is the primary remit of EPA. The IRRS team is of the view that EPA staff are aware of the possible duplication but that their motivation is to fill the void that is a consequence of the lack of inspection powers and activity under SI 478. This should not be criticized.

## 7.6. SUMMARY

The Radiological Protection Act empowers the EPA to appoint inspectors for the purpose of the Act and assigns a comprehensive set of powers to the inspectors.

EPA's inspection activities are accredited by the Irish National Accreditation Board (INAB) to the ISO 17020:2012 standard for inspection bodies.

EPA sets up an annual inspection programme which is approved by the Board of EPA. The inspection programme takes into account various factors including the target inspection frequency, reported incidents during the year, issues related to individual licensees, matters that may have arisen during the year and the available staff resources. During the year the programme may be adjusted, when deemed necessary. Inspection findings are reviewed regularly and the main findings are published annually.

The main purpose of inspections is to check the licensee's compliance with license conditions and relevant legislation and, while not yet incorporated into the audit form, to assess the licensee's safety culture.

With regard to the transport of radioactive material, the EPA is responsible for the inspection of radioactive material only by road and rail, though in practice no transport by rail takes place. Inspection of radioactive material by sea and air is the responsibility of the Marine Survey Office and the Irish Aviation Authority, respectively.

An inspection is normally conducted by one inspector but in the case of a complex facility more than one inspector may be involved. Inspections are carried out utilizing practice specific inspection audit forms that are followed during the whole inspection. A formal report of the inspection findings is forwarded within four weeks.

Most planned inspections are announced but some unannounced inspections are also conducted, for example, in the case of industrial radiography (NDT). This is facilitated by the fact the EPA receives from the licensee advance notices of any site radiography work. The programme includes also joint security inspections with An Garda Síochána, Ireland's national police.

The IRRS team followed the conduction of several inspections. The IRRS team observed that the EPA inspections are comprehensive, concentrated in matters relevant to safety and were conducted in a very professional manner. The IRRS team was convinced that the inspections contribute significantly to the improvement of safety and enhancing the safety culture at the regulated facilities.

# 8. ENFORCEMENT

## 8.1. ENFORCEMENT POLICY AND PROCESS

EPA has a comprehensive set of powers under Sections 29, 30, 38, 40 and 41 of the Radiological Protection Act 1991 to enforce regulatory requirements. The range of enforcement instruments available to the inspectorate range 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 license, and
- Prosecution with (and subsequent penalties/fines)

However, the "enforcement notice" is not in effect because of legal aspects which are discussed further in in **Recommendation 3 in Chapter 1.2**.

EPA has developed an enforcement policy, for radiation safety activities, (EPPDA) setting out how it responds to non-compliances by licensees with respect to regulatory requirements or license conditions. This policy applies to all licensed practices.

The primary purpose of the EPA's enforcement programme is to foster compliance with the regulatory requirements rather than to carry out punitive action. This philosophy is the basis of the guiding principles outlined in the EPA Enforcement Policy.

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.

Enforcement in relation to the transport of radioactive material in Ireland depends on the mode of transport. For road and rail, the competent authority is the EPA. For sea transport, the competent authority is the Marine Survey Office and for air transport the competent authority is the Irish Aviation Authority.

While each of the three aforementioned competent authorities has its own enforcement policy, there are no formal provisions for the effective coordination of the competent authorities to achieve consistency and exchange information in the application of enforcement actions. See **Recommendation 5 in Chapter 1.5.**

## 8.2. ENFORCEMENT IMPLEMENTATIONS

During the conduct of an inspection, where an inspector is of the opinion that there is or may be an immediate danger on site he/she has the power, to order persons to perform or refrain from performing any act if, in his or her opinion, the performance of such an act (as the case may be) is necessary in order to prevent or alleviate the escalation of the danger.

Regarding implementation of corrective actions, an inspection report is issued to the licensee 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 (e.g. correspondence, solicitor's letter). If the licensee still doesn't respond, then the licensee may be subject to prosecution under the Radiological Protection Act 1991 (RPA91). Once the actions have been implemented this is confirmed in writing by the EPA inspector.

No license has been revoked to date.

The RPII has undertaken more than 50 prosecutions since its establishment in 1991. The results of these and other enforcement matters are published in the Annual Report. To date there have been no significant transport matters that have warranted the RPII, and more recently the EPA, undertaking a prosecution in this sector.

### 8.3. SUMMARY

The Radiological Protection Act assigns a comprehensive set of powers to the EPA to enforce regulatory requirements.

EPA has developed an enforcement policy for responding to non-compliances by licensees with respect to regulatory requirements or license conditions. This policy applies to all licensed practices.

The primary purpose of the EPA's enforcement programme is to foster compliance with the regulatory requirements rather than to carry out punitive action. The Enforcement Policy sets out the procedures to be followed where activities or incidents have been identified that may require an enforcement decision.

During the conduct of an inspection, the inspector has the power to order persons to perform or refrain from performing any act if the performance of such an act is necessary in order to ensure radiation safety.

No license has been revoked so far. However, over 50 prosecutions have taken place since the establishment of the regulatory body. The results of enforcement matters are published in the Annual Report.

Enforcement in relation to the transport of radioactive material in Ireland is undertaken depending on the mode of transport. For road and rail transport the competent authority is the EPA. For sea transport the competent authority is the Marine Survey Office and for air transport the competent authority is the Irish Aviation Authority

# 9. REGULATIONS AND GUIDES

## 9.1. GENERIC ISSUES

The set of legally binding regulations setting out the basic criteria for regulatory compliance are established through the Orders issued by the Minister implementing the European Directives namely:

- S.I. No. 125 of 2000 implementing the Euratom BSS 1996 directive
- S.I. No 875 of 2005 implementing the Euratom HASS 2003 directive
- S.I. No 478 of 2002 implementing the Euratom MED directive

Current regulations will be reviewed in line with the new Council Directive 2013/59/Euratom when transposing it into Irish legislation.

EPA does not have the power to issue legally binding regulations. In accordance with Section 8 of the Radiological Protection Act, 1991, EPA's functions include the preparation and issuance of codes of practice dealing with radiological safety, radioactive substances, nuclear devices or irradiating apparatus, taking into account relevant standards recommended by relevant international bodies.

ORP has established a set of codes of practice and guidance covering some safety aspects of regulated practices, as well as, prescribing some regulatory processes. However, these sets of codes of practices and guides do not provide for a systematic set of codes and guides covering all types of regulated practices but are rather set up as and when required. There are no established policies and processes regarding establishing and amending guidance documents and codes of practice.

The EPA can impose additional regulatory requirements on licensees by the inclusion of specific conditions in the licenses granted. These conditions supplement legislative requirements and in many cases make explicit reference to the EPA's codes of practice and guidance documents. The license conditions were given additional legal standing by the enactment of the Radiological Protection (Amendment) Act, 2002 [RPA02] which made it an offence not to comply with license conditions.

EPA has developed comprehensive sets of standard license conditions to be attached to all licenses, as well as, practice specific license conditions for certain types of practice. In this way, the EPA establishes many of its safety principles, requirements and associated criteria for safety as license conditions instead of establishing regulations, codes of practice and guides.

All the EPA issued guidance documents and Codes of Practice are accessible to interested parties through the EPA website.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** EPA has not established policies and processes regarding establishing and amending guidance documents and code of practices relating to radiation safety. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 32 states that** *"The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."* |
| **(2)** | **BASIS: GSR Part 1 Requirement 32, para. 4.61 states that** *"The government or the regulatory body shall establish, within the legal framework, processes for establishing or adopting, promoting and amending regulations and guides."* |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **R12** | **Recommendation: The regulatory body should establish policies and processes regarding establishing and amending guidance documents and code of practices relating to radiation safety.** |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** EPA establishes some of its safety principles, requirements and associated criteria for safety as radiological license conditions instead of regulations, code of practice and guides relating to radiation safety. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 32 states that** *"The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."* |
| **(2)** | **BASIS: GSR Part 1 Requirement 32, para. 4.62 states that** *"The regulations and guides shall provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization. They shall also establish the criteria to be used for assessing compliance."* |
| **(3)** | **BASIS: GSR Part 1 Requirement 32, para. 4.28 states that** *"There shall be consistency in the decision making process of the regulatory body and in the regulatory requirements themselves, to build confidence among interested parties."* |
| **S8** | **Suggestion: The EPA should consider the review, and revision if appropriate, of the means (radiological license condition, regulations or guides) of establishing its safety principles, requirements and associated criteria for radiation safety.** |

## 9.2. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE

### 9.2.1. CONTROL OF RADIOACTIVE DISCHARGES

The IRRS team noted that radionuclide-specific conditions and limits (including authorized limits for discharges) are set by ORP as conditions attached to each license where the practice of discharge of radioactive materials into the environment is included in the authorization. All licensees must comply with these conditions. Failure to comply is an offence. Discharges of radionuclides contained in patient excreta (predominantly Tc-99m and I-131) are regulated by specifying the maximum activities of individual radionuclides that facilities are authorized to use and discharge each year, with licensees required to record all activities administered to patients or discharged to the sewers.

Art. 9 of SI125/00 states that "for the purpose of identifying the protective measures needed to restrict exposures to ionizing radiation, the undertaking shall, before commencing a practice, make an assessment acceptable to the Institute [EPA] of the risks of exposure to ionizing radiation arising from the practice or from reasonably foreseeable accidents resulting from the practice for workers and members of the public who may be affected". It is a condition of each license to review this risk assessment periodically and when the circumstances change in relation to the licensed activities.

The regulations only make one reference to radioactive discharges, namely in Part 7, 34 (4) c of SI 125/00 which states: "Where relevant to a practice, the Institute [EPA] shall, before granting a license in respect of the practice or amending any condition attached to such a license and as a condition for doing either of those things - (c) require the undertaking to submit to the Institute for examination and approval plans for the discharge of radioactive effluents." This means that the regulation currently in place does not cover all the requirements on discharge assessment, control and records established in the GSR Part 3. While Article 35(1)(b) of SI125/00 allows the EPA to direct licensees to estimate the doses to the public, workers, and reference groups as a result of any practice carried out, including routine discharges, there is no specific requirements for licensees to make specific measurements as part of these estimates. In addition, there is no current requirement for radiological environmental impacts to be considered in an integrated manner with features of the system of protection and safety.

The IRRS team was informed that in June 2007, an external consultant was contracted to assist the regulatory body in evaluating the need to install iodine holding tanks in both existing and future iodine ablation facilities. The final report (RBPIAD2010) showed that Ireland´s position with regards to iodine-131 discharges was consistent with international recommendations and best practice worldwide and made a number of recommendations in relation to Ireland´s approach for ablation waste management. The IRRS team was informed that as part of Ireland's policy on best practice for the management of liquid wastes arising from thyroid ablation that are discharged to the sewer, the following recommendations were adopted in 2009 (RBPIAD2010):

- Licensees with existing ablation facilities are required to undertake both on and off site monitoring to validate the assumptions and calculations used in their risk assessments when first applying for a license for ablation therapies; and
- License applications for new ablation facilities are assessed on a case by case basis to determine whether holding tanks are required.

In practice, licensees have not been directed to carry out measurements to date. However, the IRRS team was informed that previous studies by Akinmboni (2004) have shown that iodine levels in the waste water treatment facility and the marine environment as a direct result of radioactive waste discharges from authorized practices were of no significance from a radiological point of view.

The IRRS team was also informed that licensees must keep a record of their discharges to the sewer (GNDUS, TCL1). These records are examined during inspections. Furthermore, it is a condition of EPA licenses authorizing the discharge of unsealed sources that there is annual reporting of the quantities discharged (medical sector: I-131; education and research sectors: H-3, C-14, P-32, S-35, Cr-51, I-125). This data is collated annually by ORP and provided to the OSPAR Commission as part of Ireland´s reporting requirements under the OSPAR Convention (OSPAGR2013-11).

As part of the authorization process, licensees must demonstrate how they meet the design dose constraint of 300 μSv $y^{-1}$. In cases where this constraint cannot be met, they must implement best available technology (BAT) e.g. in the case of an application which involves the discharge of I-131 this could include consideration of iodine holding tanks. Art 9(5) of SI125/00 requires applicants to use dose constraints to ensure that all exposures and work activities under its control are kept as low as reasonably achievable. EPA has issued guidelines on design dose constraints for occupationally exposed workers and members of the public (DDMFCOP_09).

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | **Observation:** The EPA has adopted a regulatory position for the management of liquid |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | wastes arising from thyroid ablation with I-131 that are discharged to sewer. |
| **(1)** | **BASIS: GSR Part 3 Requirement 31, para. 3.132 states that** *"Registrants and licensees, in cooperation with suppliers, in applying for an authorization for discharges, as appropriate:*<br>*(a) Shall determine the characteristics and activity of the material to be discharged, and the possible points and methods of discharge;*<br>*(b) Shall determine by an appropriate pre-operational study all significant exposure pathways by which discharged radionuclides could give rise to exposure of members of the public;*<br>*(c) Shall assess the doses to the representative person due to the planned discharges;*<br>*(d) Shall consider the radiological environmental impacts in an integrated manner with features of the system of protection and safety, as required by the regulatory body;*<br>*(e) Shall submit to the regulatory body the findings of (a)–(d) above as an input to the establishment by the regulatory body, in accordance with para. 3.123, of authorized limits on discharges and conditions for their implementation."* |
| **(2)** | **BASIS: GSR Part 3 Requirement 31, para. 3.133 states that** *"Registrants and licensees shall ensure that operational limits and conditions relating to public exposure are met in accordance with paras 3.123and 3.124."* |
| **(3)** | **BASIS: GSR Part 3 Requirement 31, para. 3.134 states that** *"Registrants and licensees shall review and modify their discharge control measures, as appropriate and in agreement with the regulatory body, taking into account:*<br>*(a) Operating experience;*<br>*(b) Any changes in exposure pathways or in the characteristics of the representative person that could affect the assessment of doses due to the discharges."* |
| **GP5** | **Good Practice: EPA took the initiative to evaluate at the national level the need to install iodine holding tanks in both existing and future iodine ablation facilities. The evaluation reviewed existing practices in Ireland in relation to iodine-131 ablation discharges to the sewers (discharges leading to the highest potential dose) and made recommendations for a regulatory policy, based on international best practice and forecasts of future activity.** |

### 9.2.2. EXEMPTION AND CLEARANCE

The concept of "clearance" is not specified in Irish legislation. The decision was made to not include "clearance" in the transposition of the 1996 Euratom BSS by SI125/00 on the basis that it was not applicable to the Irish situation as there are no decommissioning activities in Ireland (Para 4.7 IAEAWS-R-5).

The IRRS team was informed and noted from the evidence that so far, situations where management of materials arising from regulated practices with radioactivity sufficiently low as not to warrant regulatory control have been dealt with on a case by case basis by the ORP. For example, exemption levels, as set in Schedule 5 of SI125/00 are currently used to "clear" previously licensed quantities of unsealed radioactive sources used in the research/academic sector, on the basis that activities have decayed to

levels that are below the exempted activity. In this case, discharge to the sewer is authorized, providing also that records are kept of the date, type of radionuclide(s) and quantities involved. In practice this means that clearance is applied.

It was noticed in the discussions that despite the use that clearance levels may have in the decommissioning process, this concept, together with "exemption", defines the radiation safety regulatory framework considering that:

- **Exemption -** Is the determination by a regulatory body that a source or practice need not be subject to some or all aspects of regulatory control on the basis that the exposure and the potential exposure due to the source or practice are too small to warrant the application of those aspects or that this is the optimum option for protection irrespective of the actual level of the doses or risks; while
- **Clearance -** Defines the removal of regulatory control by the regulatory body from radioactive material or radioactive objects within notified or authorized practices. Removal of regulatory control in this context refers to regulatory control applied for radiation protection purposes.

### 9.2.3. ENVIRONMENTAL MONITORING ASSOCIATED WITH AUTHORIZED PRACTICES FOR PUBLIC RADIATION PROTECTION PURPOSES

Ireland has no nuclear power plants, no fuel cycle facilities and no waste management facilities. While no specific environmental monitoring programmes to assess public exposure associated with discharges from planned exposure situations have been implemented, the EPA routinely measures the levels of radioactivity in the environment in compliance with its statutory obligations. The results of the monitoring programme are publicly available on the EPA website. The IRRS team was informed that the approach taken to date is deemed appropriate for Ireland. This approach was also supported by independent experts' report. "Peer review of the RPII Environmental Monitoring Programme" that was organized in 2009 and presented to the IRRS team.

SI125/00 does not address safety requirements for environmental monitoring associated with discharges arising from planned exposure situations. The only references to monitoring in SI125/00 relate to the Monitoring of Working Environments (Article 21) and Dose Monitoring of Persons (Article 22).

The IRRS team was informed that the EPA has a central role in ensuring Ireland's emergency preparedness in the event of a nuclear accident abroad and is responsible for monitoring developments in relation to nuclear installations abroad. Monitoring of radioactivity in the environment is a core activity of the ORP. The IRSS team was informed that the objectives of the monitoring programme are, among others, to:

- Assess doses to individuals and the population from radionuclides in the environment;
- Assess the temporal and geographical distributions of concentrations of artificial and natural radionuclides in the environment; and
- Maintain the systems, procedures and expertise necessary to facilitate a rapid assessment of environmental contamination in the event of a nuclear or radiological incident, so that effective countermeasures to protect the Irish public can be implemented.

The programme combines round-the-clock measurements from the permanent monitoring network and a programme of sampling, followed by laboratory testing. A range of radionuclides is assessed as part of the monitoring programme. Those routinely assessed are caesium-137; caesium-134, potassium-40; beryllium-7; iodine-131; tritium; strontium-90; gross alpha and gross beta; gamma dose rate; technetium-99; plutonium-238, plutonium-239, plutonium-240 and americium 241. Analytical techniques include

gamma spectrometry; alpha spectrometry; gas proportional counting and liquid scintillation counting. In some cases, radiochemical separation is required.

This information confirms the compliance with GSR Part 3 (Para 2.23), which provides that "The government shall ensure that arrangements are in place for the provision of technical services relating to protection and safety, such as services for personal dosimetry, environmental monitoring and the calibration of monitoring and measuring equipment." However, the regulatory framework does not address the responsibilities of the licensees to establish environmental monitoring programmes. However, Art 35(1)(b) of SI 125/00 provides for the EPA to direct licensees to estimate doses received by the population arising from practices carried out.

### 9.2.4. SAFETY REQUIREMENTS FOR EXISTING EXPOSURE SITUATIONS AND REMEDIATION

In relation to existing exposure situations SI125/00 addresses only identification of work activities involving significant exposure to radon; remedial measures when radon exceeds the established reference levels; identification of work activities involving significant exposure to natural radiation sources other than radon and protection of air crew against exposure to cosmic radiation.

The IRRS team was informed that, based on studies carried out in 2004 and 2006, the normal use of building material in Ireland would not give rise to radiation doses in excess of 1 mSv per year, with the majority of doses anticipated to be less than 0.3 mSv per year. Exposure to natural radiation sources other than radon is dealt with in Part 6 Section 32 of S.I. No. 125/00. EPA has assessed doses arising from NORM industries in Ireland (NORM2008). The study concluded that it was very unlikely that activities carried out by these industries would give rise to doses in excess of 1 mSv/ per year.

The efforts for the monitoring and assessing of doses received by the population and workers in Ireland is commendable and is described in Chapter 9.2.3.

The safety requirements for existing exposure situations are mainly related to the exposure situations originating from radon in working places.

The IRRS team was informed that the EPA's monitoring programme measures radioactivity in air, mixed diet, drinking water, milk and cereals and ambient radiation levels to ensure compliance with EU standards, in accordance with Art. 35 and 36 of the EURATOM Treaty, and in the marine environment to allay public concerns on nuclear discharges. In addition, the EPA works closely with other agencies such as the Department of Agriculture, Food and the Marine (DAFM), the Health Service Executive (HSE), the Food Safety Authority of Ireland (FSAI) and the Irish Customs to monitor levels of radionuclides in commodities including food and feedstuffs produced in Ireland and products imported from third countries.

Article 40 of SI 125 of 2000 applies to situations leading to lasting exposure resulting from the after-effects of a radiological emergency or practice which has ceased to be carried out. However the regulations do not address remediation requirements for these situations. These will need to be considered when the new Eurotom BSS transposed. Therefore:

1. There is no legal or regulatory framework to ensure that provision is made for identifying those persons or organizations responsible for areas with residual radioactive material; for establishing and implementing remediation programmes and post-remediation control measures, if appropriate; and for putting in place an appropriate strategy for radioactive waste management. (GSR Part 3 Requirement 49)

2. There is no legal or regulatory framework for the remediation of areas with residual radioactive material deriving from past activities or from a nuclear or radiological emergency and for this reason there are no provision made in the framework for protection and safety for among others:
    a. The identification of those persons or organizations responsible for the contamination of areas and those responsible for financing the remediation programme, and the determination of appropriate arrangements for alternative sources of funding if such persons or organizations are no longer present or are unable to meet their liabilities;
    b. The designation of persons or organizations responsible for planning, implementing and verifying the results of remedial actions;
    c. An appropriate system for maintaining, retrieval and amendment of records that cover the nature and the extent of contamination; the decisions made before, during and after remediation; and information on verification of the results of remedial actions, including the results of all monitoring programmes after completion of the remedial actions;
    d. Monitoring the area regularly during the remediation so as to verify levels of contamination, to verify compliance with the requirements for radioactive waste management, and to enable any unexpected levels of radiation to be detected and the remedial action plan to be modified accordingly, subject to approval by the regulatory body or other relevant Authority;
    e. Review, amend as necessary and formalize the type, extent and duration of any post-remediation control measures already identified in the remedial action plan, with due consideration of the residual radiation risks;
    f. The identification of the person or organization responsible for any post-remediation control measures.

The identification of the person or organization responsible for post-remediation control measures need to establish and maintain, for as long as required by the regulatory body or other relevant authority, an appropriate programme, including any necessary provision for monitoring, to verify the long term effectiveness of the completed remedial actions for areas in which controls are required after remediation.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | **Observation:** The concept of "clearance" and derived clearance levels are not defined in Irish regulatory framework. Current regulations do not address all the safety requirements in relation to radioactive discharges, environmental monitoring, existing exposure situations and remediation. |
| **(1)** | **BASIS: GSR Part 3 Requirement 8, states that** *"The regulatory body shall approve which sources, including materials and objects, within notified practices or authorized practices may be cleared from regulatory control."* |
| **(2)** | **BASIS: GSR Part 3 Requirement 8, para. 3.12 states that** *"The regulatory body shall approve which sources, including materials and objects, within notified or authorized practices may be cleared from regulatory control, using as the basis for such approval the criteria for clearance specified in Schedule I or any clearance levels specified by the regulatory body on the basis of these criteria. By means of this approval, the regulatory body shall ensure that sources that have been cleared from regulatory control do not again become subject to the requirements for notification, registration or licensing unless it so specifies."* |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **(3)** | **BASIS: GSR Part 3 Requirement 31, para. 3.132 states that** *"Registrants and licensees, in cooperation with suppliers, in applying for an authorization for discharges, as appropriate:*<br>*(d) Shall consider the radiological environmental impacts in an integrated manner with features of the system of protection and safety, as required by the regulatory body;*<br>*(e) Shall submit to the regulatory body the findings of …(d) above as an input to the establishment by the regulatory body, in accordance with para. 3.123, of authorized limits on discharges and conditions for their implementation."* |
| **(4)** | **BASIS: GSR Part 3 Requirement 32, para. 3.135 states that** *"The regulatory body shall be responsible, as appropriate, for:*<br>*(a) Review and approval of monitoring programmes of registrants and licensees, which shall be sufficient for:*<br>*(i) Verifying compliance with the requirements of these Standards in respect of public exposure in planned exposure situations;*<br>*(ii) Assessing doses from public exposure."* |
| **(5)** | **BASIS: GSR Part 3 Requirement 32, para. 3.137 states that** *"Registrants and licensees shall, as appropriate:*<br>*(a) Establish and implement monitoring programmes to ensure that public exposure due to sources under their responsibility is adequately assessed and that the assessment is sufficient to verify and demonstrate compliance with the authorization. These programmes shall include monitoring of the following, as appropriate:*<br>*(i) External exposure due to such sources;*<br>*(ii) Discharges;*<br>*(iii) Radioactivity in the environment;*<br>*(iv) Other parameters important for the assessment of public exposure."* |
| **(6)** | **BASIS: GSR Part 3 Requirement 47 states that** *"The government shall ensure that existing exposure situations that have been identified are evaluated to determine which occupational exposures and public exposures are of concern from the point of view of radiation protection."* |
| **(7)** | **BASIS: GSR Part 3 Requirement 48 states that** *"The government and the regulatory body or other relevant authority shall ensure that remedial actions and protective actions are justified and that protection and safety is optimized."* |
| **(8)** | **BASIS: GSR Part 3 Requirement 49 states that** *"The government shall ensure that provision is made for identifying those persons or organizations responsible for areas with residual radioactive material; for establishing and implementing remediation programmes and post-remediation control measures, if appropriate; and for putting in place an appropriate strategy for radioactive waste management."* |
| **R13** | **Recommendation: The Government should review the radiological protection regulations to ensure that all the requirements related to public exposure control are in compliance with GSR Part 3.** |

## 9.3. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES AND DECOMMISSIONING

### 9.3.1. SAFETY REQUIREMENTS FOR PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE

The IRRS team noted that the radioactive waste generated by different licensees in the research or medical areas are mainly short lived radioactive waste which need to be managed safely and stored for decay and release or clearance from the regulatory control. The IRRS team noted that while the radiation protection framework is adequately covered under both SI125/00 and license conditions, currently there is no regulatory framework in place for the regulation and control of safe radioactive waste management including disused sealed sources and potential radioactive waste produced in any abnormal situation. The regulation, review, assessment and control of the radioactive waste predisposal management activities is performed on a case by case basis in accordance with the regulatory body's license´ conditions.

The IRRS team was informed also that in late 2010 the Government adopted a policy outlining principles and key 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.
- 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.

The key elements of the policy are:

- A National Radioactive Waste Storage Facility for disused radioactive sources is to be established. A National Implementation Committee, comprising of the Environmental Protection Agency (EPA) and Department of Environment, Community and Local Government (DECLG) has been constituted to draw up a detailed specification for the facility and make recommendations on the siting, management and resourcing of the facility.
- The current inventory of disused radioactive sources is to be reduced through a coordinated and phased Inventory Reduction Programme.
- Interim centralization of sources by sector in a small number of sector-specific existing storage facilities.
- A High Level Interdepartmental Group on Radioactive Waste has been mandated to give further consideration to options for the final disposal of Ireland's disused radioactive sources.
- Further updates to be provided to Government, as necessary, as this work progresses.

One of the key initiatives under this policy was the reduction of Ireland's inventory of radioactive waste through a coordinated and phased Inventory Reduction Programme. This programme commenced in 2011

with lead agencies and government departments tasked with driving source disposal programmes within their respective sectors. Between 2011 and 2013 over 6500 disused source, including approximately 99% of all disused sources with half-lives greater than ten years, were successfully exported out of Ireland to disposal and recycling facilities in Europe and the USA. With the successful implementation of the national Inventory Reduction Programme there now remain approximately 30 disused sealed sources (T½ >10 yrs) held at 14 licensees' premises.

In addition the IRRS team was informed that Ireland follows the principles of;

- minimization of the generation of radioactive waste in any form; and
- 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 supplier of the sources.

The disposal limits in license conditions relating to the disposal of radioactive waste in Ireland are generally set at levels such that it can be demonstrated that doses to the public will be very low and typically less than 10 μSv/year.

During the IRRS mission discussions took place on the possible scope of an ARTEMIS Mission (integrated peer review on radioactive waste management) in Ireland taking into consideration the findings provided by the IRRS mission. As per prior discussions with the IAEA the organization of an ARTEMIS mission, proportional to the amount of waste in the country, will be performed in parallel to the IRRS follow up mission. The outcomes of the IRRS mission would be used as necessary for the ARTEMIS mission.

### 9.3.2. SAFETY REQUIREMENTS FOR DECOMMISSIONING OF NUCLEAR AND OTHER FACILITIES CONTAINING RADIOACTIVE MATERIALS

The terms 'siting', 'design', 'construction', 'commissioning', 'operation' and 'decommissioning' are normally used to delineate the six major stages in the lifetime of an authorized facility and of the associated licensing process. The term 'decommissioning' refers to the administrative and technical actions taken to allow the removal of some or all of the regulatory controls from a facility (except for the part of a disposal facility in which the radioactive waste is emplaced, for which the term 'closure' instead of 'decommissioning' is used). Aspects of decommissioning have to be considered throughout the other five major stages.

Decommissioning is performed using a graded approach to achieve a progressive and systematic reduction in radiological hazards. Decommissioning is undertaken on the basis of planning and assessment to ensure safety, protection of workers and the public, and protection of the environment.

Planning for decommissioning begins at the design stage and continues throughout the lifetime of the facility. It includes: preparation of an initial decommissioning plan; collection of relevant information and data to facilitate future decommissioning; selection of a decommissioning strategy; radiological characterization of the facility; preparation of a final decommissioning plan; estimation of costs; identification of the provision of financial resources for the decommissioning project; submission of the plan to the regulatory body for review and approval; and any activities for public consultation in accordance with national requirements.

The IAEA Safety Requirement GSR Part 6 on Decommissioning of Facilities applies to all facilities, including predisposal waste management facilities, facilities for processing naturally occurring radioactive material (NORM), former military sites, and relevant medical facilities, industrial facilities, and research and development facilities. The IAEA Safety Guide WS-G-2.2 on Decommissioning of Medical, Industrial and Research Facilities provides guidance to national authorities, including regulatory

bodies, and operators to ensure that the decommissioning process for medical, industrial and research facilities where radioactive materials and sources are produced, received, used and stored is managed in a safe and environmentally acceptable manner. The current regulatory framework in Ireland does not include safety provisions for the decommissioning of different facilities with a graded approach.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** While SI125/00 and license conditions provide an appropriate radiation protection framework for the management of radioactive waste including disused sealed sources, it does not provide for its predisposal management of radioactive waste. Currently the predisposal management is regulated through license conditions. Similarly, there is no regulatory framework for the decommissioning of facilities. | |
| **(1)** | **BASIS: GSR Part 1 Requirement 10, states that** *"The government shall make provision for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities."* |
| **(2)** | **BASIS: GSR Part 5 Requirement 1, states that** *"The government shall provide for an appropriate national legal and regulatory framework within which radioactive waste management activities can be planned and safely carried out. This shall include the clear and unequivocal allocation of responsibilities, the securing of financial and other resources, and the provision of independent regulatory functions. Protection shall also be provided beyond national borders as appropriate and necessary for neighbouring States that may be affected."* |
| **(3)** | **BASIS: GSR Part 5 Requirement 3, states that** *"The regulatory body shall establish the requirements for the development of radioactive waste management facilities and activities and shall set out procedures for meeting the requirements for the various stages of the licensing process."* |
| **(4)** | **BASIS: GSR Part 3 Requirement 2, para. 2.24 states that** *"The government shall ensure that arrangements are in place for the safe decommissioning of facilities, the safe management of radioactive waste."* |
| **(5)** | **BASIS: GSR Part 6 Requirement 4, states that** *"The government shall establish and maintain a governmental, legal and regulatory framework within which all aspects of decommissioning, including management of the resulting radioactive waste, can be planned and carried out safely. This framework shall include a clear allocation of responsibilities, provision of independent regulatory functions, and requirements in respect of financial assurance for decommissioning."* |
| **R14** | **Recommendation: The Government should complement the regulatory framework regarding the :**<br>- **predisposal management of radioactive waste activities and facilities should be planned and safely carried out, including the radioactive waste produced during remediation and disused sealed sources, and**<br>- **all aspects of decommissioning of facilities, including the safe management of the resulting radioactive waste should be planned and carried out.** |

## 9.4. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The EPA has issued a large number of guidance documents and Codes of Practice that relevant licensees must comply with. These include:

Codes of Practice

- Code of Practice for Radiation Protection in Veterinary Medicine
- Code of Practice for Radiological Protection in Dentistry
- The Design of Diagnostic Medical Facilities where Ionizing Radiation is used

Guidance Note:

- Guidance Note on High Activity Sealed Sources (GNHASS)
- Guidance notes for the disposal of decayed sealed sources to landfill facilities
- Guidance Note on the Disposal of Prepared Uranium/Thorium Compounds
- Guidance notes on the disposal of unsealed radionuclides discharges to the sewer
- Guidance Note: Management of X-ray Units at End of Life (RPDX)

Guidance or Guidelines:

- Guidance for licensees on the regulatory requirements regarding the disposal of unsealed radionuclides discharges to the sewer
- Management of Waste Ionization Chamber Smoke Detectors (ICSDs)
- RPII Guidance for the Handling of Cadavers Containing Significant Quantities of Iodine-131
- Guidance Notes for the Compilation of Radiation Safety Manual
- Guidance Notes on Radiation Risk Assessment (GNRRA)
- Guidance for licensees on how to compile a Radiation Risk Assessment
- Guidance notes on training of persons involved in the carriage of radioactive materials (Class 7) by road
- Patient radiation protection manual, 2013, HSE
- National Audit of medical radiological and radiotherapy practices, 2012, Patient Radiation Protection, HSE.

National Protocols

- Temporary Operational Protocol for making safe and managing orphaned or seized radioactive sources (TOP).

## 9.5. REGULATIONS AND GUIDES FOR TRANSPORT

The EPA is not responsible for the publication and periodic review and revision of national regulations for the safe transport of radioactive material. Each mode of transport regulation is maintained by the relevant government departments that initiate national legislation that give effect to the Modal Instrument (ADR, RID, IMDG Code and ICAO TI). Nevertheless, the requirements regarding the transport of radioactive material, that are included in the modal instruments, comes from the IAEA SSR-6 Regulation. The modification of SSR-6 comes from the IAEA-TRANSSC committee in which the EPA is the representative of Ireland.

The EPA has a set of guides and protocols available in its website in which the transport activities are included. There are also some guides that are not yet published but they are available on request. Nevertheless, there is no formal policy in place regarding a review and revision of these guides, see **Recommendation 12 in Chapter 9.1**.

## 9.6. SUMMARY

The legally binding regulations setting out the basic criteria for regulatory compliance are established through the Orders issued by the Minister implementing the European Directives. It was noticed that the radiation protection regulations need to be updated in accordance with the latest IAEA safety requirements. It is expected that this will happen when the country implements the Euratom Basic Safety Standards Directive in 2018. In addition the regulatory framework for decommissioning and safe radioactive waste management needs to be developed.

EPA does not have the power to issued legally binding regulations. However, its functions prescribed in the Radiological Protection Act include the preparation and issuance of codes of practice dealing with radiation safety.

EPA has established a set of codes of practice and guidance. However, these do not provide for a systematic set of codes and guides covering all types of regulated practices but are rather set up for certain topical needs. There are no established policies and processes regarding establishing and amending guidance documents and codes of practice.

The EPA can impose additional regulatory requirements on licensees by the inclusion of specific conditions in the licenses granted. These conditions supplement legislative requirements and in many cases make explicit reference to the EPA's codes of practice and guidance documents.

EPA has developed comprehensive sets of standard license conditions to be attached to all licenses. In this way, the EPA establishes many of its safety principles, requirements and associated criteria for safety as license conditions instead of establishing regulations, codes of practice and guides.

All the EPA issued guidance documents and Codes of Practice are accessible to interested parties through the EPA website.

# 10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

## 10.1. GENERAL EPR REGULATORY REQUIREMENTS

The Nuclear and radiological emergency management system in Ireland has the following structure:

- **Licensee level:** Emergency Preparedness and Response (EPR) for the different practices of licensees in Ireland in the field of industry, research and medicine overseen by the regulatory body.
- **Local/Regional level:** EPR for major emergencies for different hazards including radiological and nuclear emergencies at the local and regional level by the emergency services and local authorities.
- **National level:** EPR for emergencies with wide spread contamination mainly after a severe nuclear accident abroad. Certain elements of the national emergency response would also come into play in the case of a local/regional emergency depending on the extent of the emergency.

**Basic responsibilities:**

- Licensees have the main responsibility for on-site EPR. According to legislation licensees have to coordinate with the local authority and also submit their plans to the EPA for approval. If necessary in case of an emergency, licensees will be supported by the local authority together with its emergency service the Fire Service.
- The current Framework for Major Emergency Management, launched by the Irish government in 2006, is a system for standardized response to different major emergencies such as fires, transport accidents, hazardous substance incidents including radiological emergencies and severe weather. Multi-agency arrangements, e.g. the Protocol for a Multi-Agency Response to Radiological Emergencies, enable co-ordination between different response organizations including Garda Síochána, the local and national authorities. Within this framework a harmonized approach at different levels is achieved, including a consistent risk assessment methodology for different hazards, coordination of the response, and common information systems for different emergencies.
- At the national level the Emergency Response Coordination Committee (ERCC) has been established for a coordinated response in case of a widespread contamination in Ireland after a radiation accident. The ERCC, chaired by the Department of Environment, Community and Local Government, consists of and coordinates all relevant Government Departments and Agencies at state level. It will make the relevant decisions in case of a nuclear emergency. The ERCC meets in a dedicated centre, the National Emergency Coordination Centre, (NECC), which has been specifically equipped to coordinate any national response. The National Emergency Plan for Nuclear Accidents (NEPNA) assigns roles and responsibilities to all relevant Departments and Agencies. The EPA has a key role in the ERCC providing technical advice and counter measures recommendations.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES |
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| **Observation:** Ireland´s EPR system for off-site response is well integrated and coordinated at the national and regional level. EPA plays a key role in providing technical advice and counter measures recommendations. |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **(1)** | **BASIS:GSR-2, 3.11 para. states that** *"The national co-ordinating authority and the response organizations shall ensure that the arrangements for response to a nuclear or radiological emergency are co-ordinated with the arrangements for response to conventional emergencies."*<br><br>**GSR-2, 5.11 para. states that** *"When several different organizations or other States are expected to have or to develop tools, procedures or criteria for use in responding to the same emergency, coordination arrangements shall be put in place to harmonize the results of assessments of contamination, doses and health effects and of any other appropriate assessments made in the event of a nuclear or radiological emergency in order not to give rise to inconsistency and confusion."* |
| **GP6** | **Good Practice: The nuclear and radiological emergencies are well integrated on national and regional levels in a framework for major emergency management system and a national emergency coordination system following the all hazards approach. EPA has a key role if a radiation emergency occurs.** |

**The role of the EPA:**

- The EPA is responsible for the regulatory oversight of the EPR of the licensee. Only in the case of an emergency overexposure of patients is the Health Service Executive (HSE) under the Department of Health responsible.
- The role of the EPA as response organization to radiation emergencies is discussed in chapter 10.4.

As part of the requirement to promote international cooperation and enhance safety globally, EPA staff engage actively in relevant international fora in EPR at IAEA, OECD-NEA, EU, ICRP and HERCA, as well as providing experts for peer review and other international missions. These activities are a positive and important contribution to improving standards and arrangements in EPR.

**Legal requirements**

The Irish government has enacted legislation for EPR for nuclear and radiological accidents. Ireland has bilateral agreements on information exchange and cooperation in the field of nuclear and radiation safety with the UK. Additional agreements between the EPA and Competent Authorities of the UK and France are in place. Ireland is party to the Convention on Early Notification of a Nuclear Accident and to the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency.

EPR legislation for radiation emergencies is based on the Radiological Protection Act, 1991 (Ionizing Radiation) Order 2000 (S.I. No. 125/2000). In addition, the EPA has developed multiple guidance documents addressing EPR at licensee level. Ireland is yet to implement the new Euratom-Basic Safety Standards Directive (Council Directive 2013/59/Euratom).

**Assessment of threats**

Within the licensing system the practices in Ireland are categorized according to a national threat categorization system reflecting the level of risk. This threat categorization is not in line with the threat categorization of GSR-2. A separate threat assessment has been prepared specifically for emergency preparedness purposes using the threat categorization of GS-R-2. This EPR threat assessment [THREAT]

was prepared by the EPA, discussed within the NEPNA Review Group before being finalized and delivered to the Department of the Environment, Community and Local Government for use as a basis for the current revision of the National Emergency Plan for Nuclear Accidents (NEPNA). A draft of the revised NEPNA plan was provided to the IRRS team and includes the EPR threat assessment as a chapter. It is intended that the NEPNA revision will be finalized by the end of 2015. This issue is addressed in **Suggestion S12 in Chapter 10.2**.

Based on the EPA threat assessment in line with GSR-2 the following threat categories exist in Ireland:

- About 15 threat category III facilities: wet/dry cell irradiators for sterilization, irradiation of blood and plasma, research and development, industrial radiography (on-site) and hospitals with HDR brachytherapy;
- Threat category IV: mobile sources and transport of sources; and
- Threat category V: nuclear accidents abroad.

The updating of threat assessments is implemented in conjunction with the updating of emergency plans at different levels or when new threats are identified. EPA guidance requires licensees to review their intervention plans after exercises and as part of their licensing renewal process.

## 10.2. FUNCTIONAL REGULATORY REQUIREMENTS

### Establishing emergency management and operations

As required by SI125/00 the licensee has to prepare a risk assessment for all reasonably foreseeable accidents and Radiation Safety Procedures for the practice to be licensed. Both have to be approved by the EPA. In addition, the licensee has to evaluate if a radiological emergency resulting from the practice would give rise to significant hazards to members of the public and the likely spatial and temporal distribution of the radioactive substances dispersed in the event of such an emergency and the corresponding potential exposures.

Based on this evaluation the EPA may request an intervention plan from the licensee in addition to emergency procedures as part of the Radiation Safety Procedures. This intervention plan is prepared after consultation with the EPA and the local authority within whose functional area the licensee carries out the practice.

For the preparation of an intervention plan the EPA has prepared Guidance Notes on Intervention Planning and Emergency Preparedness for Radiological Accidents (GNIPEP) which determine the general content of an intervention plan such as:

- Responsibilities for activating and coordinating the plan;
- Procedures for assessing the seriousness of the situation;
- Notification procedures for informing EPA, emergency services and the relevant local authority;
- Circumstances in which the emergency services should be involved and the arrangements for medical assistance for dealing with conventional and radiation induced injuries;
- Immediate mitigating actions to be taken;
- Organization of intervention and the assessment of its effectiveness;
- Information that should be given to the public and/or the media; and
- Emergency equipment and dosimetry for an emergency.

Finally the intervention plan has to be approved by the EPA. After approving the plan GNIPEP requires, among others, training to implement the plan, exercises at appropriate intervals to test the implementation of the intervention plan and periodic reviews and, where necessary, updating of the plan.

**Identifying, notifying and activating**

Licensees are required to identify, promptly report and assess emergency situations but are not required to classify them. First notification will normally be given to the EPA by phone. The inspectors or the on-call duty officer uses an incident notification form to ask for all relevant information. Classification of the emergency is done by the EPA.

Under SI125/00, licensees are required to immediately report emergencies and then submit an initial assessment of the event not later than 24 hours to the EPA. But there is no clear definition in place when an emergency starts and how it is categorized.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** An immediate notification of a radiological emergency by the licensee to the EPA is required by legislation and by EPA Guidance documents. But there is no clear definition in place when an emergency starts and how it is categorized. | |
| **(1)** | **BASIS: GS-R-2 para. 4.7 states that** *"For facilities in threat category I, II or III the transition from normal to emergency operations shall be clearly defined and shall be effectively made without jeopardizing safety."*<br><br>**GS-G-2.1 para. 4.2 states that** *"Consequently, the Requirements (para. 4.19) require the operator of a facility or practice in threat category I, II, III or IV to make arrangements for the prompt identification of an actual or potential nuclear or radiological emergency and determination of the appropriate level of response.*<br>*Furthermore, the Requirements (para. 4.20) require that the criteria for classification be "predefined emergency action levels (EALs) that relate to abnormal conditions for the facility or practice concerned, security related concerns, releases of radioactive material, environmental measurements and other observable indications."*<br>*The Requirements (para. 4.25) also require that declaration of a particular class of emergency "shall promptly initiate the appropriate level of co-ordinated and preplanned emergency response on and off the site."* |
| **R15** | **Recommendation: The EPA should establish criteria for the radiological licensees of threat category III facilities for a clear definition and categorization of emergencies. This should also be reflected in the reporting requirements of the licensee.** |

**Taking mitigatory actions**

SI125/00 and the EPA Guidance Notes on Intervention Planning and Emergency Preparedness for Radiological Accidents require that the intervention plan or the emergency procedures of the licensee should include the immediate mitigatory actions to be taken. In addition the licensee is required to coordinate with the relevant local authority in preparation for intervention plans and in implementing mitigatory actions. The necessary mitigatory actions are identified within the risk assessment.

**Taking urgent protective action**

In case of a nuclear or major radiological accident the EPA, as a response organization, is responsible for advising the Government and the public on protective measures, including urgent protective actions. EPA also assists in the planning and implementation of these measures.

The EPA currently recommends the following intervention levels (based on averted dose) for protective measures for all age groups of the population:

- 10 mSv (2 day integration period) for sheltering
- 50 mSv (Thyroid dose) for Iodine Blocking

A comprehensive consequence assessment on the impact on Ireland of a range of potential nuclear accidents in the UK (the closest NPP is just over 100 km from the east coast of Ireland) is the basis of the protection strategy of the EPA for a nuclear accident abroad: Evacuation is not necessary for Ireland, Iodine Blocking is very unlikely to be justified due to the distance from any NPP, though the consequence assessment is that population sheltering could be justified in case of a very severe accident combined with unfavourable weather.

Operational Intervention Levels (OILs) for nuclear and radiological emergencies are defined for emergency worker protection and for the maximum permitted levels of radioactivity in drinking water, food and feedstuff. OILs for protective measures such as Sheltering and Iodine Blocking will be part of the revised National Emergency Plan for Nuclear Accidents.

The new Euratom Basic Safety Standards (Council Directive 2013/59/Euratom), which has to be transposed by 2018, will require the definition of OILs for protective measures for the public and a review of intervention levels.

| **RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES** | |
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| **Observation:** Operational Intervention Levels (OILs) for nuclear and radiological emergencies are presently defined in the field of emergency workers protection and for contamination of drinking water, food and feedstuff. OILs are missing for protective measures such as sheltering and Iodine Blocking. | |
| **(1)** | **BASIS: GSR Part 3, 4.8 para. states that** *"Development of a protection strategy shall include, but shall not be limited to, the following three successive steps:*<br>*(3) Once the protection strategy has been optimized and a set of generic criteria has been developed, pre-established default triggers for initiating the different parts of an emergency plan, primarily for the initial phase, shall be derived from the generic criteria. Default triggers, such as on-scene conditions, operational intervention levels and emergency action levels, shall be expressed in terms of parameters or observable conditions. Arrangements shall be established in advance to revise these triggers, as appropriate, in an emergency exposure situation, with account taken of the prevailing conditions as these evolve."* |
| **S9** | **Suggestion: The EPA in its role as governmental advisor for protective measures for the public should consider defining Operational Intervention Levels for protective measures in radiation emergencies.** |

**Providing information and issuing instructions**

Information on nuclear and radiological emergency planning is widely distributed among the population of Ireland. This includes the following:

- A booklet on emergency management for different disasters including nuclear and radiological emergencies was sent to all households;
- Information on emergency plans has been made available in five languages, different formats/media, including braille, large-print, audio recordings and an easy-read style;
- A booklet on the NEPNA that summarises background information on nuclear emergencies and the arrangements in Ireland has been distributed to public libraries and citizens advice bureaux;
- Text templates for a public "dark" homepage of the dedicated website on the NEPNA which could handle very massive access are prepared;
- Arrangements for TV and Radio Broadcasts in an emergency are in place;
- Social media will be used.

A subgroup of the Emergency Response Coordination Committee (ERCC), which is the national body for coordinating emergency/crisis, is responsible for the coordination of information to the public between the relevant organizations (such as the Department of Environment, Community and Local Government, the Department of Health, the Government Information Service, and the EPA) in case of nuclear or radiological emergency. This coordination mechanism ensures that information provided to the public is consistent.

Requirements concerning information to the public prior to and in case of a radiation emergency are currently required under SI209 of 1993 and are also part of the new Euratom Basic Safety Standards (Council Directive 2013/59/Euratom).

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** Information on nuclear and radiological emergency planning is widely distributed and well known by the population in Ireland. In addition a national coordination group to inform the public has been established to ensure consistent information in case of an emergency. | |
| **(1)** | **BASIS: GSR-2, 4.83 para. states that** *"Arrangements shall be made for: providing useful, timely, truthful, consistent and appropriate information to the public in the event of a nuclear or radiological emergency; responding to incorrect information and rumours; and responding to requests for information from the public and from the news and information media."*<br>**4.84 para. states that** *"The operator, the response organizations, other States and the IAEA shall make arrangements for co-ordinating the provision of information to the public and to the news and information media in the event of a nuclear or radiological emergency."* |
| **GP7** | **Good Practice: The information to the public on emergency planning prior to an emergency is very efficient in reaching all sectors of the population in Ireland. In addition a coordination mechanism to inform the public in case an emergency has been established under the national emergency coordination group of the government. The EPA has an important role in these activities for the information of the public.** |

**Protecting emergency workers**

The first responders to radiation emergencies in Ireland are Fire Service personnel, who are not considered radiation workers and are therefore subject to a dose limit of 1 mSv. Only in life-saving situations, may firefighters be permitted to receive doses in excess of 1 mSv, in accordance with the national guidance (SOG7.07). This guidance also requires that those involved in the taking of such measures should be provided with radiological monitoring and medical surveillance.

**Assessing the initial phase**

The Ionizing Radiation Order and the EPA Guidance Notes on Intervention Planning and Emergency Preparedness for Radiological Accidents require licensees´ intervention plans to include procedures for assessing the seriousness of a situation.

**Managing the medical response**

If the risk assessment, which is a pre-condition for licensing, identifies a potential need for medical response, the licensee has to make sure that the medical treatment of victims is part of the emergency preparedness arrangements. Medical response is also required by the intervention plan of those licensees where, depending on the risk assessment, an intervention plan is needed.

In the case of a major radiological emergency, the activities of the responding organizations on scene including life-saving actions and emergency decontamination up to the transport to designated hospitals is based on the Multi-Agency Protocol on Response to Radiological and Nuclear Accidents in the Framework of the Major Emergency Management.

At a national level the Health Service Executive is responsible for organizing medical treatment in designated hospitals. There are two such hospitals in Ireland. These hospitals, together with HSE, have developed emergency plans for radiation emergencies including the decontamination, diagnosis and treatment of contaminated and/or overexposed persons in the hospitals. For serious internally contaminated or irradiated persons international assistance will be requested (see also chapter 11.2). The Percy military hospital in Clamart near Paris has a specialist centre for radiation injuries and works with IRSN. Discussions have started between HSE and the Percy hospital on formalizing arrangements for treatment.

**Other activities in emergency preparedness**

*Agricultural countermeasures*

EU regulations regarding the maximum permitted levels (MPLs) of radioactive contamination of foodstuffs and of feeds apply to Ireland. Agricultural counter measures after a wide spread contamination are very important because ingestion of food has been identified as the main potential pathway for radiation doses after a nuclear accident. Also Ireland is a large exporter of foodstuff. A handbook of agricultural counter measures has been developed and a Plan & Prepare booklet aimed at farmers and food producers is also under development. The handbook in line with GSR Part 3 as well as the Euratom Basic Safety Standards approach for developing integrated protective measures strategies.

Within the NEPNA plan and at the level of the Government Taskforce on Emergency Planning, which meets every six to eight weeks, all relevant governmental stakeholders are involved in preparedness and response. In terms of non-governmental stakeholders, an Irish stakeholder panel for food counter measures including representatives from consumers, retailers, farming organizations, and food processing organizations, was established as part of the European PREPARE project. There is a plan to maintain this

panel after the project is completed. The outcome of the panel's discussions will be reflected in the review of the NEPNA plan.

GSR Part 3 as well as the new Euratom Basic Safety Standards (Council Directive 2013/59/Euratom) include requirements for arrangements to be made for Stakeholder Involvement as part of the Emergency Management System.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** Stakeholder involvement is practiced in different areas of EPR. However, there is no formal arrangement to include stakeholder involvement in the emergency management system. | |
| **(1)** | **BASIS: GSR Part 3:4.5 para. states that** "*The emergency management system shall provide for essential elements at the scene, and at the local, national and international level, as appropriate, including the following:*<br>*(a) to (k)…*<br>*(l) Involvement of relevant parties and interested parties."* |
| **R16** | **Recommendation: The Government should make a formal arrangement for the involvement of stakeholders as part of the emergency management system.** |

The EPA laboratory is the only accredited laboratory for radioactivity monitoring in food- and feedstuff in Ireland. According to the EPA Sub-plan under the NEPNA, the small laboratory team will be supplemented with additional staff from other areas within ORP to ensure personnel resources in the laboratory are sufficient for measurements relevant for decisions on health protection actions related to air, drinking water and food in the early phase of a nuclear emergency. The personnel resources are however not sufficient for measurements beyond this, such as to enable the resumption of normal economic activities in the area of food/feed exports or to sustain the long-term monitoring of the environment after a wide spread contamination. The draft report of the recent EURATOM Art. 35 verification visit to Ireland had a similar observation.

The EPA has in place coordinated arrangements with other national organizations (such as the Department of Agriculture, Food and the Marine Civil Defence, and Met Éireann (the Irish Meteorological Service)) for the collection of environmental, food and feed samples in an emergency. In order to optimize the use of limited resources for measurement in Ireland, a more detailed, pre-agreed nation-wide sampling plan for environmental, food and feed samples and use of mobile teams for in-situ gamma spectrometry measurements could additionally be considered.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** The EPA laboratory is the only accredited laboratory for radioactivity monitoring in food and feed in Ireland. The staff resources are not sufficient for measurements to enable the resumption of normal economic activities in the area of food/feed export in case of widespread contamination | |
| **(1)** | **BASIS: GSR-2, 4.89 para. states that** "*For areas with activities in threat category V arrangements shall be made for taking effective agricultural countermeasures, including restriction of the consumption, distribution and sale of locally produced foods and agricultural produce following a release of radioactive material. These arrangements shall include: default OILs for environmental measurements (such as dose rates due to deposition and deposition densities) and food concentrations; the means to revise the OILs; timely*

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | *monitoring for ground contamination in the field; the sampling and analysis of food and water; and the means to enforce agricultural countermeasures."* |
| **S10** | **Suggestion: The Government should consider mechanisms for increasing national measurement capacity to cope with a widespread, long-lasting contamination.** |
| **S11** | **Suggestion: The EPA should consider finalizing the extension of its NEPNA sub plan to take account of the full resources of the EPA.** |

*Non-radiological consequences*

Dealing with the psycho-sociological consequences of emergencies:

- Emergency workers (mainly fire services) obtain psychological support as part of their hot debriefing after incidents. If needed, they will get additional psychological support by psychologists after a second debriefing.
- A guidance document for managing the response to psychosocial impact on the population was developed within the framework of major emergencies management.

*Recovery operations*

The transition from an Emergency Exposure Situation to an Existing Exposure Situation is currently not defined in the Irish legislation or in regulatory requirements although criteria for the termination of an emergency have been prepared in a separate chapter on recovery in the draft revision of the National Emergency Plan for Nuclear Accidents in a very sound and comprehensive way.

The definition of this transition is also required by the new Euratom Basic Safety Standards (Council Directive 2013/59/Euratom). This issue was also identified by EPA in its Action Plan.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** A draft version of the revised National Emergency Plan for Nuclear Accidents includes criteria for the transition from an Emergency Exposure Situation to an Existing Exposure Situation in line with GSR-2 and GSR Part 3. | |
| **(1)** | **GSR-2, 4.97 para. states that** *"The transition from the emergency phase to long term recovery operations and the resumption of normal social and economic activity shall be planned and made in an orderly manner and in accordance with international standards and guidance."*<br><br>**GSR Part 3, 4.20 para. states that** "*The government shall ensure that, as part of its overall emergency preparedness, arrangements are in place for the transition from an emergency exposure situation to an existing exposure situation. The arrangements shall take into account that different geographic areas may undergo the transition at different times. The responsible authority shall take the decision to make the transition to an existing exposure situation. The transition shall be made in a coordinated and orderly manner, by making any necessary transfer of responsibilities between organizations, with the involvement of relevant authorities and interested parties."* |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **S12** | **Suggestion: The Government should consider finalizing the revision of the National Emergency Plan for Nuclear Accidents as soon as possible to bring arrangements for the transition from an Emergency Exposure Situation to an Existing Exposure Situation in line with GS-R-2.** |

In case of a widespread contamination in Ireland (after a nuclear accident or a radiological malicious incident) a fraction of radioactive waste will also arise among large amounts of conventional waste. This has to be managed in the later phases of a nuclear emergency. The handbook of agricultural counter measures provides for a strategy of waste minimization. However, the treatment and management of radioactive waste in the recovery phase requires further consideration by EPA (see chapter 9).

## 10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE

### Authority and organization

EPA's personnel resources in EPR are as follows:

- The ORP has 35 staff members including administrative staff. Out of these, 28 persons are scientific/technical staff in the field of radiation protection. From these 20 persons 2.5 whole-time equivalent staff are dedicated to the area of EPR preparedness.
- In case of a nuclear emergency, the EPA-NEPNA sub plan envisages a response structure based around pre-assigned functional teams. The heads of these teams, under the director of operations, the Director of ORP or their deputy, will form an EPA coordination committee.
- According to the nuclear emergency subplan for the EPA (NEPNA subplan) every member of the ORP (plus other EPA staff that previously worked in RPII) has an assigned role in the EPA response in the case of an emergency. The assigned role was chosen based on their normal work assignments and on a skills/experience questionnaire. The ORP has prepared an aide-memoire for staff for their role in case of an emergency, as well as providing all response staff with a summary document on the sub-plan as part of their training on response roles. Due to the merger of the RPII and the EPA this has to be updated. This update has begun with relevant EPA, IT and communications staff, with scope for future inclusion of staff from other (non-radioactivity related) EPA laboratories.
- Four persons are available for the EPA on-call duty service with one duty officer in service at all times.

### Plans and procedures

Emergency plans at different levels are in place. These areas are as follows:-

- At the licensee level: Intervention plans/Emergency Procedures of the licensee
- At local/regional level: The Protocol for a Multi-Agency Response to Radiological Emergencies within the Framework for Major Emergency Management. These plans relate to the response to major emergencies. In addition, an emergency plan for local incidents is under development by EPA
- At national level: The National Emergency Plan for Nuclear Accidents (NEPNA) for a widely dispersed radiation emergency, together with NEPNA sub plans required for all organizations involved in nuclear emergencies in Ireland, including an EPA subplan.

In addition there is a national protocol that defines the responsibilities of involved organizations in case of CBRN incidents and plans at the designated hospitals for dealing with victims of radiation accidents.

**Logistical support and facilities**

The EPA Guidance Notes on Intervention Planning and Emergency Preparedness for Radiological Accidents requires each licensee to have a list of emergency equipment and review the provision of the emergency equipment on an annual basis.

**Training, drills and exercises**

Articles in SI125/00 concerning intervention plans of the licensee require the licensee to carry out drills and exercises to test the intervention plan at regular intervals. Reports on these drills and exercises are considered during inspections.

Systematic review by the EPA of the licensee's exercise programme and observation/evaluation of these exercises, taking into account the graded approach, is not in place as required by GSR-2. This was identified by the EPA in the Action Plan.

The EPA participates in internal, national and international level exercises for threat category IV and V and has a multi-year exercise strategy to cover such exercises.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** EPA has presently no systematic oversight of emergency exercises undertaken by relevant radiological licensees. The requirement for an exercise plan developed by the licensee and evaluated by EPA does not exist. | |
| **(1)** | **BASIS: GSR-2, 5.33 para. states that** "*Exercise programmes shall be conducted to ensure that all specified functions required to be performed for emergency response and all organizational interfaces for facilities in threat category I, II or III and the national level programmes for threat category IV or V are tested at suitable intervals. These programmes shall include the participation in some exercises of as many as possible of the organizations concerned. The exercises shall be systematically evaluated and some exercises shall be evaluated by the regulatory body. The programme shall be subject to review and updating in the light of experience gained."* |
| **R17** | **Recommendation: The EPA should establish a systematic oversight on emergency exercises of licensees in threat category III as appropriate including the requirement for the licensee to establish emergency exercise plans which will be evaluated by the EPA.** |

**Quality assurance programme**

The IRRS team was informed that many licensees have QA systems and the licensees are required to maintain the calibration of radiation monitoring equipment, but there is no requirement for a quality assurance programme in the field of emergency preparedness and response for licensees.

Some areas of EPA's EPR are covered under ISO accreditation but a systematic QA programme covering all areas of EPR is presently not implemented.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** A systematic QA programme covering all areas of EPR is presently not implemented at EPA. Requirements for the licensees for QA programmes in the field of EPR are not in place. | |
| **(1)** | **BASIS: GSR-2, 5.37 para. states that** *"The operator of a facility, practice or source in threat category I, II, III or IV and the off-site response organizations shall establish a quality assurance programme, in accordance with international standards, to ensure a high degree of availability and reliability of all the supplies, equipment, communication systems and facilities necessary to perform the functions specified in Section 4 in an emergency. This programme shall include arrangements for inventories, resupply, tests and calibrations, made to ensure that these items and facilities are continuously available and functional for use in an emergency. Arrangements shall be made to maintain, review and update emergency plans, procedures and other arrangements and to incorporate lessons learned from research, operating experience (such as the response to emergencies) and emergency drills and exercises."* |
| **R18** | **Recommendation: The EPA should establish a QA programme in the field of its EPR covering the areas not currently covered, and also the requirements for QA for the licensees in the field of EPR in line with a graded approach.** |

## 10.4. ROLE OF REGULATORY BODY DURING RESPONSE

The EPA has a major role in the response to nuclear and radiological accidents. According to the National Emergency Plan for Nuclear Accidents (NEPNA), the EPA's responsibilities in emergency response include the following:

- On-call duty officer service for the receipt and rapid assessment of information on a nuclear accident
- Competent authority according to international conventions and ECURIE
- Advice on the potential consequences and protective measures to the Government and the Emergency Response Co-ordination Committee (ERCC).
- Operation of the national radioactivity monitoring network.
- Organization of the collection and analysis of samples (e.g. environmental and foodstuffs, etc.) by appropriate national organizations.
- Organization in conjunction with the Department of the Environment, Community and Local Government of emergency exercises
- Provision for the certification of radioactivity levels in foodstuffs and other products.
- Assist the Government Information Services and ERCC in providing information to the public and media.

A specific EPA-sub plan of the NEPNA provides for the roles, functions, and procedures of EPA in EPR.

## 10.5. SUMMARY

In Ireland, radiation emergency planning and coordination systems are well integrated at the national and regional levels in "following the all hazards" approach. This is also reflected in the off-site emergency plans at local, regional and national level. The EPA has a key role if a radiation emergency occurs and has the necessary plans in place for this role.

The information for the public on emergency planning prior to an emergency is very efficient. In addition a coordination mechanism for informing the public in case an emergency has been established.

It needs to be mentioned that there are some elements of EPR that are not fully in line with the IAEA's GS-R-2 requirements. Specifically this applies to the definition and categorization of emergencies, formalization of the involvement of stakeholders as part of the emergency management system, and formal adoption of the criteria for the transition from an Emergency Exposure Situation to an Existing Exposure Situation.

EPA should also improve the QA programme in the field of EPR and QA requirements for licensees, and establish a systematic oversight on emergency exercises of licensees in threat category III.

In the response phase of nuclear or radiological emergencies, the EPA will among others advise on the potential consequences and protective measures to the Government organize sampling and measurement and assist in provision of information to public.

# 11. ADDITIONAL AREAS

## 11.1. CONTROL OF MEDICAL EXPOSURES

### Responsibilities

The regulatory framework for medical exposure is covered by the Regulation S.I. No. 478 of 2002 (which is based on the European Directive 97/43/Euratom) which has been amended on two occasions - firstly by S.I. No. 303 of 2007 and again by S.I. No. 459 of 2010. Nevertheless currently these regulations are not consistent with the latest international recommendations in the field of medical exposure provided in the GSR Part 3. There are in place however, a number of guidance documents relating to patient radiation protection and incident reporting.

The competent authority for control of medical exposures is the Minister for Health. The Department of Health is responsible for overall organizational, legislative, policy and financial accountability of the public health sector and supports the Minister for Health, in his parliamentary responsibilities.

Specific responsibilities in relation to regulation are vested by the Minister of Health to the Director General of the Health Service Executive (HSE). The HSE is responsible for the delivery of health and personal social services in Ireland. HSE has delegated the function to the National Director of the Quality Assurance and Verification Division (QAVD). Within the QAVD the Medical Exposure Radiation Unit (MERU) supports the regulatory functions of the HSE in relation to protection of the patient in the medical use of ionizing radiation.

The role of the Medical Exposure Radiation Unit includes:

- To conduct/oversee clinical audit in radiation facilities.
- To manage the statutory incident reporting system.
- To develop and provide guidance and direction to holders, practitioners, other staff and statutory bodies on relevant matters as guided by the National Radiation Safety Committee (NRSC).
- To ensure quality assurance programmes are in place.
- To maintain a register of installations.
- To support and manage the work of the NRSC and the subcommittees.

EPA has responsibility in relation to the protection of workers and members of the public with respect to ionizing radiation (primarily RPA91 (as amended) and SI125). With regard to specific members of the public SI 125 is applicable to the unborn child, whereas SI 478 applies to both the unborn child and comforters and carers.

The HSE, as an executive arm of the Department of Health, has a direct relationship to the Minister of Health and as such undertakes delegated responsibilities as the institution with the legal responsibility for radiological installations (i.e. the holder) and the employment of hospital staff within the public sector (including voluntary hospitals). As such it is the provider undertaking the majority of medical exposures in the diagnostic specialties and a significant proportion of radiotherapy exposures. It can also be considered as the body which acts as the Competent Authority for the purposes of SI 478. This dual role has been identified by HSE itself as a failing with regard to the requirement that a regulatory body should be independent of the organizations it regulates. During the Mission, the IRRS team was informed that in principal, it has been agreed that the functions of the regulatory body should be transferred to the Health and Information Quality Authority (HIQA) but no timetable for this is available. HSE staff at all levels are supportive of this transfer.

Within the QAVD, the Medical Exposure Radiation Unit (MERU) supports the regulatory functions of the HSE in relation to protection of the patient from the medical use of ionizing radiation. It has been established to provide operational functions associated with the assessment and control of medical exposures – MERU, as part of QAVD, has access to healthcare audit and incident management expertise and other services as required.

Expertise is contracted on a part-time or voluntary basis. The current staff complement of MERU is 1.6 WTE (1 WTE administrator, 0.4 WTE Radiographic Adviser, and 0.2 WTE Physics Adviser), under the direct management of the assistant national director QAVD. There is currently a deficit in administration team but an additional, post has been advertised. MERU currently does not have any full-time staff and instead relies on contracted advisors acting on a part-time basis and, if required, voluntary support as and when required for matters relating to radiotherapy.

At present, SI 478 does not include provisions for inspection and effective enforcement, a requirement of the Euratom Directive it is intended to transpose and the International Basic Safety Standards Directive. It is impossible therefore for the Competent Authority to undertake its regulatory functions. Audit has been used by HSE to address this in part, but this represents a significant gap in Ireland's regulatory framework. Other aspects of the Regulations are broadly in place to satisfy the requirements of 97/43/Euratom and in turn the International Basic safety Standards Directive. It should be noted however that many of the requirements of the Regulations are directed towards external bodies (e.g. the Medical and Dental Councils) and to doctors within an installation, rather than to the local legal entity. This is not consistent with the view, held by the HSE and in line with HSE governance arrangements that the CEO of the Local Legal Entity carries significant responsibilities as a duty holder. A secondary consequence of this overall approach is that to some degree, this shifts the focus of the Regulations away from the justification and optimization of individual exposures at a local level.

The SI does not include requirements for authorization, including licensing where required, of installations with regard to those undergoing medical exposure. This is being considered under separate legislation, but the primary consideration of this is general patient safety rather than radiation protection. This should be addressed.

Responsibilities for the justification of new types or classes of practice involving medical exposures and review of existing practices are attributed to the Medical and Dental Councils. Processes for these are not specified in SI 478 and it is understood that a generic approach has been taken in the past. No evidence was presented of this process being undertaken more recently. The justification process at the individual level is well understood and responsibilities attributed to the referrer and the practitioner appropriately. It should be noted however that under current arrangements, the ability to act as a practitioner relates to requirements established within the Medical Practitioners Act 1978 and by the Medical Council and the Dentist Act 1985 and the Dental Council and is restricted to radiologists and radiation oncologists and dentists. The Regulations themselves do not include requirements for training relating to the scope of practice of practitioners or other medical specialists to whom practical aspects of a radiological procedure can be delegated, or for referrers (with the exception of nurse referrers). The IRRS team was informed that the structure of the medical exposure regulations will be reviewed during the transposition process for 2013/59/Euratom and it is expected that the subsequent SI will be formatted to be consistent with the model for healthcare delivery in Ireland.

Requirements relating to optimization are broadly in place, although some appear to duplicate requirements in SI 125 and others rely on activities of external bodies rather than on internal duty holders. There are clear requirements for medical physicists, in accordance with 97/43/Euratom, but as support to the practitioner rather than as defined duty holder. No system for national recognition exists or is imminent.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** The regulatory framework (SI478/02) for the regulation of patient protection is not consistent with the latest IAEA Safety Requirements in GSR Part 3. | |
| (1) | **BASIS: GSR Part 3 Requirement 36, states that** *"Registrants and licensees shall ensure that no person incurs a medical exposure unless there has been an appropriate referral, responsibility has been assumed for ensuring protection and safety, and the person subject to exposure has been informed as appropriate of the expected benefits and risks."* |
| (2) | **BASIS: GSR Part 3 Requirement 37, states that** *"Relevant parties shall ensure that medical exposures are justified."* |
| (3) | **BASIS: GSR Part 3 Requirement 38, states that** *"Registrants and licensees and radiological medical practitioners shall ensure that protection and safety is optimized for each medical exposure."* |
| (4) | **BASIS: GSR Part 3 Requirement 39, states that***: "Registrants and licensees shall ensure that there are arrangements in place for appropriate radiation protection in cases where a female patient is or might be pregnant or is breast-feeding."* |
| (6) | **BASIS: GSR Part 3 Requirement 41, states that** "*Registrants and licensees shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures. Registrants and licensees shall promptly investigate unintended or accidental medical exposures and, if appropriate, shall implement corrective actions."* |
| (7) | **BASIS: GSR Part 3 Requirement 42, states that** *"Registrants and licensees shall ensure that radiological reviews are performed periodically at medical radiation facilities and that records are Maintained."* |
| **R19** | **Recommendation: The Government should revise the current regulatory framework to bring it in accordance with GSR Part 3 for the regulation of patient protection.** |

**St James's Hospital (public)**

At St James's Hospital the audit addressed incident reporting. It involved two external auditors and an HSE advisor. The hospital system for all incident reporting was demonstrated and its use in relation to incidents involving inappropriate exposure of patients discussed. There was a strong drive to promote responsibility of all involved in the patient care, coupled with a "no-blame" approach. This was considered to be the best way of generating an appropriate safety culture. Discussions highlighted apparent contradictions with drug administration policies, where only one person was deemed responsible. There may also be issues around the demonstration of accountability. This may be important when considering the regulatory structure required for radiation protection. As part of the visit, the HSE advisor was accompanied on a visit to the Radiology Department to discuss recent incident reports. This demonstrated clearly that the HSE were undertaking audit activities rather than attempting to undertake an inspection. Questioning related to clarification of numbers and types of incident that had been reported, but not to processes that might have been put in place to minimize future occurrence. During the visit, the

hospital's RPA expressed a strong view that rationalization of reporting of unintended exposures of patients was a priority, either by having a single Regulatory authority or a single reporting mechanism.

**Meeting with HSE**

The IRRS team were able to meet with the Director General of HSE and the Chair of the National Radiation Safety Committee. These senior officials expressed openly that they did not believe HSE was an appropriate body to be the regulator for patient exposures and agreed with the views expressed by other HSE staff in earlier meetings. They were clear that activities as a regulator could influence negatively their other functions relating to quality and improvement. They provided further information about intentions to introduce a licensing scheme for healthcare facilities and the transfer of regulatory activities and were of the view that HIQA had a strong mandate and track record as a regulator for patient safety.

**Meeting with the Department of Health**

The IRRS team was also able to meet with Chief Medical Officer (CMO) and senior Department of Health officials. This provided an opportunity to discuss the main findings of the mission. These were that the inspection and enforcement powers required for patient exposures were not included within SI 478, that the body charged with regulatory functions was not independent and that co-ordination was required between the bodies charged with the regulation of all exposures relating to medical practices. The CMO was able to accept and agree with these findings and to outline a vision for future regulation of medical exposures, within the context of healthcare provision in general. Options for future regulatory control were discussed. The meeting was considered to be positive with clear commitment for appropriate action on the part of the Department of Health.

## 11.2. OCCUPATIONAL RADIATION PROTECTION

### LEGAL / REGULATORY FRAMEWORK

The regulatory work of EPA's Office of Radiological Protection (ORP) is established through a series of Acts and Statutory Instruments derived from European Regulations and Directives. The Irish radiation protection legislation is listed on and accessible from the EPA site.

The main legislation in the area of occupational radiation protection is the Statutory Instrument No. 125/2000 - Radiological Protection Act, 1991 (Ionizing Radiation) Order, 2000. SI 125 applies to workplaces where there may be exposure to ionizing radiation. It is the main piece of legislation specifically dealing with the obligations of employers and the protection of workers and members of the public. It gives effect in Ireland to two European Directives: Council Directive 96/29/EURATOM (Basic Safety Standards Directive), and Council Directive 90/641/Euratom (Outside Workers Directive).

The European directives have recently been up-dated in the Council Directive 2013/59/EURATOM of the 5$^{th}$ of December 2013. Ireland has four years to implement the changes into the national legislation.

The 2013/59 Council Directive:

- Promotes a more graded authorization process (licensing, registration and notification);
- Reduces the annual limit for the lens of the eye dose;
- Mentions the education, training and re-training, the activities and the recognition (where appropriate) of Radiation Protection Officers (RPOs).

Dose limits consistent with the IAEA BSS Standard (GSR Part 3) are in place for occupational exposure of workers, members of the public, persons undergoing training or education for working with sources of

ionizing radiation, emergency interventions and for supervised and controlled areas. The dose limit for the lens of the eye will be revised in line with the IAEA BSS Standard as part of the transposition of the new EC Directive 2013/59. Ireland also employs a rolling 12 month effective dose limit for workers of 20 mSv which is more conservative than GSR Part 3.

The EPA has been pro-active in relation to the reduced dose to the lens of the eye in advance of the implementation into Irish law of the 2013/59/EURATOM directive. Starting from 2013, the relevant licensees were identified and discussions were held so that surveys and studies could be conducted by the licensees. The studies would establish the potential impact of the proposed reduction and to whether additional protection measures would be required.

A positive point is that EPA is the sole authority responsible for occupational radiation protection in Ireland. A second good point is the information available in the report "Radiation Doses Received by the Irish Population 2014" which shows that the dose levels in the Irish Republic are low.

A further good practice is the establishment of a system of Radiation Protection Advisers (RPAs). SI 125 establishes that every licensee has to appoint and consult with an approved RPA. 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 Radiation Protection Adviser (RPA) who provides advice to licensees on how to meet both legislative and the licensing requirements.

The EPA has two RPA Assessment Committees that consider all applications for inclusion on either, or both, of its RPA registers. An external expert in radiation protection chairs both RPA Assessment Committees and membership of the committees includes both EPA staff and external UK based experts in radiation protection. All decisions on whether an applicant has met the RPA approval criteria for inclusion on the RPA register are made by the Director of ORP, taking account the recommendations of the Assessment Committees, which in turn take account of external, independent opinions.

The EPA has developed guidance on the required experience and qualifications of RPAs and on the re-approval criteria for RPAs. The re-approval guide establishes the requirement for continuous professional development (CPD). The EPA also organizes a yearly workshop (Annual Liaison Meeting) of the RPAs where experience and feedback from regulatory activities such as inspections and licensing. are shared and any 'good practices' identified during inspections are highlighted. The EPA maintains an up-to-date registry of the authorized RPAs on the EPA website.

## GENERAL RESPONSIBILITIES OF REGISTRANTS, LICENSEES AND EMPLOYERS

Only licenses are issued under the Irish regulatory system - there is no registration process in place. SI 125 states, "The undertaking shall be responsible for assessing and implementing arrangements for the radiological protection of exposed workers." The undertaking (employer) shall ensure that protection and safety is optimized and that the dose limits for occupational exposure are not exceeded. SI 125 establishes that each licensee (including dentists) has to appoint a Radiation Protection Adviser (RPA). There is no legislative requirement for the licensee to appoint an RPO; however, license conditions for industrial applications require the appointment of an RPO. EPA has published a guidance document on the functions and role of the RPO; however, the criteria for RPO education, training, qualification and competence have not been established in legislation.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES |
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| **Observation:** The license conditions for medical licensees do not include a requirement to nominate an RPO and the regulations do not include minimum education, qualification, training and experience |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| requirements for RPOs. | |
| **(1)** | **BASIS: GSR Part 3 para. 2.21 states that** *"The government shall ensure that requirements are established for:*<br>*(a) Education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety;*<br>**In addition, GSR part 3 para. 3.94 states that** *Employers, registrants and licensees, in consultation with workers, or through their representatives where appropriate:*<br>*(e) Shall designate, as appropriate, a radiation protection officer in accordance with criteria established by the regulatory body.***"** |
| **S13** | **Suggestion: EPA should consider reviewing its requirements in relation to nomination and qualification of RPOs.** |

## GENERAL RESPONSIBILITIES OF WORKERS

SI 125 establishes the obligations and responsibilities of workers in terms of occupational radiation protection. Workers must fulfil their obligations and carry out their duties for protection and safety. Occupationally exposed workers must implement all radiation protection and safety measures to protect both themselves and report unsafe conditions.

## REQUIREMENTS FOR RADIATION PROTECTION PROGRAMMES

Licensees and users must implement a radiation protection and safety programme based on a risk analysis and apply radiation protection and safety measures commensurate with the risks associated with the practice or activity. With the exception of the medical sector, licensees must also appoint a Radiation Protection Officer (RPO) with responsibility for implementing the radiation protection and safety measures and an approved RPA who provides advice to licensees on how to meet both legislative and the licensing requirements.

Licensees and users must establish and maintain organizational, procedural and technical arrangements for the designation of controlled areas and supervised areas consistent with the SI 125 and GSR Part 3 and they must establish local rules, written instructions and radiation safety procedures.

Licensees and users are responsible for making arrangements for the assessment and recording of occupational exposures, workplace monitoring and for workers' health surveillance, and they must provide workers with adequate information, instruction and training in radiation protection and safety.

In terms of existing exposure situations, EPA has in place a regulatory strategy for cosmic radiation exposure of aircrew and for exposure to radon in workplaces.

The licensee, based on the risk assessment, classifies the occupationally exposed workers into "category A" or "category B". The great majority of workers are classified as "category B". Both category A and B workers are individually monitored. There are no regulations which establish the wear period for personal dosimetry, though guidance is provided for specific sectors in a number of codes of practices. It is considered an improvement possibility to establish guidelines on the wear period for all workers.

## MONITORING PROGRAMMES AND TECHNICAL SERVICES

With reference to external monitoring, a number of external monitoring service providers (OSL and TLD) offer services in Ireland. All the services are accredited under the ISO 17025 system or equivalent. A guidance document "Approval of dosimetry services in Ireland – Guidance for applicants" was published in 2012. The document establishes the initial EPA requirements and the annual follow-up of the dosimetry services. Neutron and beta dosimetry is also available from the external dosimetry services; however, the number of users is very low. Extremity dosimetry is also available.

With reference to internal monitoring, Ireland has the capability of in vivo and in vitro bioassay, with lung and thyroid counting systems and urine and faeces analysis for the more commonly found radionuclides. However, considering the licensed practices in Ireland, there is a low risk of a significant internal intake.

With reference to workplace monitoring, licensees carry out their own workplace monitoring, under the supervision of the RPA and RPO. The EPA operates a portable dose rate and surface contamination calibration service which is ISO 17025 accredited. The EPA also operates an accredited radon-in-air monitoring service and a wipe test service. The EPA charges for these services.

With reference to the national dose register, EPA operates a national dose register that receives the annual dose of all occupationally exposed workers in Ireland. The register is used by the EPA to produce statistical reports on doses and could be used to help regulatory optimization processes. However, in the register the workers are not uniquely identified which means that the register cannot be used to retain individual dose records.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** Licensees are responsible for maintaining dose records for individually monitored occupationally exposed workers. However, the Irish national dose register exists for statistical and other purposes, and so the workers are not individually identified and therefore access to individual dose records is not possible through the register. | |
| **(1)** | **BASIS: GSR part 3 para. 3.107 states that** *"If employers, registrants and licensees cease to conduct activities in which workers are subject to occupational exposure, they shall make arrangements for the retention of workers' records of occupational exposure by the regulatory body or a State registry, or by a relevant employer, registrant or licensee, as appropriate.* |
| **S14** | **Suggestion: The EPA should consider extending the scope of the national dose register to enable individually monitored occupationally exposed workers to be unambiguously identified.** |

## 11.3. CONTROL OF CHRONIC EXPOSURE RADON

### Introduction

The regulation currently in force in Ireland "S.I. No 125 of 2000 - Radiological Protection Act 1991 (Ionizing Radiation) Order 2000" governs exposure due to radon at workplaces.

The Radiological Protection (Miscellaneous Provisions) Act 2014 transfers to the EPA the responsibility for giving advice on radiation to the public and Government. This includes advice on radon. Recognizing the scale of the radon problem in Ireland (about 250 lung cancer cases attributable to radon each year), an

interagency Group was tasked in 2011 to develop a strategy, which would comprehensively address radon exposure in Ireland. In 2014 the group published the "National Radon Control Strategy (NRCS)" which co-ordinates the actions needed to manage the radon problem.

The NRCS is the vehicle to implement into practice the legislation concerning the radon area, and to inform the development of the Euratom BSS. The national radon control strategy is monitored and evaluated, and progress reports are published annually. Its content and achieved goals are discussed in more detail in the following paragraphs.

**National Radon Control Strategy**

EPA is the principal authority for the radon issue. The NRCS recommends a broad range of measures aimed at reducing the risk from radon to people living in Ireland. The NRCS is in line with the IAEA Safety Guide SSG-32 (2015) that provides recommendations and guidance on how to meet the requirements of GSR Part 3 for protection of the public against indoor exposure to radon.

The NRCS gives an overview of the current radon situation and helps to identify the significant challenges to improve the effectiveness of the national radon strategy for the protection of the public in Ireland. The strategy is based on 48 recommendations that are grouped into six thematic areas listed below:

- Radon prevention in new buildings;
- Use of property transactions (sales and rental) to drive action on radon;
- Raising radon awareness and encouraging individual action on radon;
- Advice and guidance for individual householders and employers with high radon results;
- Promoting confidence in radon services, and
- Addressing radon in workplaces and public buildings.

The strength of this strategy is that implementation of the action plan is coordinated and monitored by a Government-led inter agency working group. The working group represents five key Government Departments and six key Government agencies, as listed below:

1. The Department of Environment, Community and Local Government (DECLG)
2. The Department of Health (DOH)
3. The Department of Jobs, Enterprise and Innovation
4. The Department of Communications, Energy and Natural Resources
5. The Department of Education and Skills (DES)
6. The Environmental Protection Agency (EPA)
7. The Health Services Executive (HSE)
8. The Health and Safety Authority
9. The Sustainable Energy Authority of Ireland
10. The Geological Survey of Ireland
11. The City and County Management Association

The active participation of these bodies has united the main stakeholders involved in a practicable and effective response to the radon problem. This has resulted in the active engagement of not only government agencies, but also the relevant professional representative bodies and the radon industry in the implementation of the action plan. Examples of significant progress which can be attributed to the work of this inter-agency working group include:

- the inclusion of radon in the conveyancing process through the Law Society of Ireland;
- the enhancement of building regulations and their implementation through the DECLG;
- the continuation of the measurement and remediation of social housing through the DECLG;

- the coordination with the smoking cessation program (QUIT) through the HSE;
- the continuation of the measurement and remediation of radon in schools, funded and facilitated through the DES;
- the promotion of confidence in radon services through the DECLG, professional bodies and the radon industry, and
- the facilitation of research that will support the implementation of the strategy through the EPA research programme STRIVE.

Between 1998 and 2004 every school in Ireland was tested for radon and all schools with high radon levels have been remediated by the DES. The DES continues its commitment to fund on-going measurements and remedial work as required in schools. In addition, radon preventive measures in newly built schools go beyond the requirements of the current Building Regulations. The DES require a radon barrier in all newly built schools while Building Regulations only require this in High Radon Areas (HRAs). The DES also require a radon test following occupation of the building. Research to establish the long term effectiveness of remedial work in schools between 1998 and 2004 is on-going.

In addition, most local authorities in High Radon Areas have made very significant progress in testing their social housing inventory. To date, approximately 21,500 local authority homes have been measured and, where necessary, remediated.

Despite the significant progress already made in Ireland in some areas such as schools and social housing, significant challenges remain. The rate of remediation in private homes, for example, is low at about one in four, although this is consistent with progress in other countries. Both stakeholder consultation and EPA householder surveys have identified cost as a significant disincentive to carrying out remediation. The NRCS recommends consideration be given to financial assistance for remediation. This recommendation is supported by IAEA SSG-32 para 3.50.

**Radon Measurement Services (RMS)**

The EPA provides services for radon measurement in homes and workplaces but it also has certain regulatory functions, including the power to direct employers to carry out radon measurement and to prosecute employers who do not do so. There is potentially a conflict of interest between these functions.

There are now eight companies (including the EPA) offering a radon measurement service in Ireland. The EPA is the only service that is accredited to ISO 17025 therefore the quality of its service is independently audited. One other service meets the certification system operated by Public Health England in the UK. The remaining six RMS do not operate to any specific criteria. Currently there is no recognized system that assures the quality of the RMS operating in Ireland. The absence of such a system undermines confidence in the quality of these services. This is recognized by the NRCS recommendation 38 that calls for the setting up of such a certification system for RMS. Work is currently on-going on this task. In the interim, the NRCS called for the EPA to maintain the ISO17025 accreditation for its RMS.

The establishment of a registration scheme by EPA presents a potential conflict of interest, which should be considered and managed. A comparison can be made with the external dosimetry service operated previously by the RPII. In early 1990s the RPII was the only external dosimetry service operating in Ireland. Over time, as other Approved Dosimetry Services were established, it was seen as no longer necessary (or in the national interest) for the RPII to maintain its dosimetry service. A phased closure of the service was undertaken and a national registration system established in its place.

If the same process were to be followed with radon measurements, by setting up a registration or certification requirement for all RMS in Ireland, the EPA could then reconsider its own RMS. Another factor to consider in such a move would be the EPA's continued access to radon measurement data to

support its research needs. In the interim the EPA should remain committed to managing its RMS and its radon regulatory functions in line with the principles outlined above.

Nevertheless, the administration of the radon measurement service should be functionally separated from both the regulation of radon and the registration scheme for other RMS in Ireland.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** There is a comprehensive Government-led National Radon Control Strategy (NRCS) addressing radon exposure to the public and to the workers. There is strong active contribution to address the problem, e.g. the DES approach in schools. | |
| **(1)** | **BASIS: GSR Part 3 Requirement 47 states that** *"The government shall ensure that existing exposure situations that have been identified are evaluated to determine which occupational exposures and public exposures are of concern from the point of view of radiation protection."* |
| **(2)** | **BASIS: GSR Part 3 Requirement 50 states that** *"The government shall provide information on levels of radon indoors and the associated health risks and, if appropriate, shall establish and implement an action plan for controlling public exposure due to radon indoors."* |
| **GP8** | **Good Practice: The effectiveness of the national radon control strategy is maximized through this "top down" approach driven by Government, ensuring all stakeholders work together in a cohesive manner.** |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** Measurement and remediation rates are low in private homes. It is recognized that for some individuals cost is a genuine disincentive to remediating high radon levels. | |
| **(1)** | **BASIS: GSR Part 3 Requirement 50 para. 5.20 (b) (c) and (d) states that** *"Where activity concentrations of radon that are of concern for public health are identified on the basis of the information gathered as required in para. 5.19(a), the government shall ensure that an action plan is established comprising coordinated actions to reduce activity concentrations of radon in existing buildings and in future buildings, which includes:*<br>*(b) Reducing activity concentrations of 222Rn and consequent exposures to levels at which protection is optimized;*<br>*(c) Giving priority to actions to reduce activity concentrations of 222Rn in those situations for which such action is likely to be most effective;*<br>*(d) Including in building codes appropriate preventive measures and corrective actions to prevent the ingress of 222Rn and to facilitate further actions wherever necessary."* |
| **(2)** | **BASIS: SSG-32 para. 3.50 states that** *"The government may consider the possibility of reimbursing the owners of dwellings for part or all of the costs of corrective actions, in particular owners of those dwellings with very high activity concentrations of $^{222}$Rn."* |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **S15** | **Suggestion: The Government should consider provisions to support remediation by owners of homes with high radon levels.** |

Radon exposure at workplaces

Progress in addressing radon in workplaces has been mixed. Since 2004, for example, the State Claims Agency has been proactive in advising government employers to measure radon in their premises and this has resulted in over 500 government workplaces being tested and remediated as appropriate. This is in addition to nearly 4,000 schools that have been tested. A number of large private sector employers have taken a similar approach. However, despite this, the vast majority of Irish workplaces remain untested and the number of radon measurements made in small businesses remains relatively low.

An effective strategy for dealing with radon in workplaces will include both regulatory and enforcement type actions and implementing awareness or educational measures. The existing legislation addressing radon at workplaces has clear gaps. EPA has attempted to address those gaps through a suite of non binding guidance materials. In line with best practices, both in radiation protection and occupational health and safety, the strategy for dealing with radon in workplaces should involve a graded approach to risk and a careful targeting of resources. While efforts to address radon focus on HRAs, there are gaps in the specific provisions in relation to the duties of employers (e.g. testing, remediation and, ongoing risk assessment), issuing directions, enforcement, penalties and underground workplaces. It is noted that through implementation of the new Euratom BSS and in line with NRCS, consideration should be given to the development of an enforcement strategy in workplaces that addresses these deficiencies. A targeted and risk-based programme should be implemented to specifically address radon in workplaces particularly those that are vulnerable to high levels of radon, such as underground workplaces.

It would be beneficial to consider extending the collaboration between the Health and Safety Authority (HSA) and the EPA to other relevant inspectorates to implement an enforcement strategy in relation to radon in workplaces.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** While Articles 30 and 31 of SI 125 of 2000 deal with radon in workplaces these regulations do not fully meet all the requirements of GSR Part 3. | |
| **(1)** | **BASIS: GSR Part 3 Requirement 47 states that** *"The government shall ensure that existing exposure situations that have been identified are evaluated to determine which occupational exposures and public exposures are of concern from the point of view of radiation protection."* |
| **(2)** | **BASIS: GSR Part 3 Requirement 48 states that** *"The government and the regulatory body or other relevant authority shall ensure that the protection strategy for the management of existing exposure situations, established in accordance with paras 5.2 and 5.4, is commensurate with the radiation risks associated with the existing exposure situation;"* |
| **(3)** | **BASIS: GSR part 3 para. 5.29 states that** *"If, despite all reasonable efforts by the employer to reduce activity concentrations of radon, the activity concentration of $^{222}$Rn in workplaces remains above the reference level established in accordance with para. 5.27* |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | *(1000 Bq/m$^3$) the relevant requirements for occupational exposure in planned exposure situations as stated in Section 3 shall apply."* |
| | **BASIS: GSR Part 3 Requirement 50 para. 5.21 (b) states that** "*The government shall assign responsibility for:*<br>*(b) Determining the circumstances under which actions are to be mandatory or are to be voluntary, with account taken of legal requirements and of the prevailing social and economic circumstances.***"** |
| **R20** | **Recommendation: The Government should review and revise the specific regulations addressing radon in workplaces to enhance their effectiveness.** |
| **S16** | **Suggestion: The regulatory body should consider a plan of how to determine the workplaces with the highest radon levels.** |

## 11.4. SUMMARY

SI 478 is intended to transpose EC Directive 97/43/Euratom and includes much of the text of that Directive. It does not however reflect the importance of the local legal entity as intended within European and international Basic Safety Standards. In addition, it does not provide a regulatory framework consistent with that expected currently in healthcare facilities in Ireland. It does not include requirements for training of staff and places undue reliance and responsibilities on radiologists, rather than a range of healthcare professionals. Most importantly, it does not provide for inspection and effective enforcement by the regulatory body. SI 478 does however provide a clear understanding of the justification process.

The SI will need comprehensive revision to successfully transpose EC Directive 2013/59/Euratom and to meet requirements of the international Basic Safety Standards.

General observations and recommendations on medical exposure relating to regulatory framework independence, coordination issues and staffing are provided at sections 1.2, 1.3, 1.5 and 3.3.

The occupational radiation protection regulatory framework in Ireland is based on Euratom directives, and is under review at present, to be up-dated in 2018. The regulatory framework is well established and has been successfully applied to workplaces in Ireland. The occupational radiation protection infrastructure is well developed and all services providers have ISO 17025 accreditation or similar.

Based on the National Radon Control Strategy - a document mutually agreed among all the relevant ministries and agencies, we can state that the Irish radon control strategy is exemplary, sustainable and efficient. This good practice represents a model to other countries to emulate. Although much has been achieved in the radon area compared to other countries, the strategy acknowledges the need to enhance the legislation to strengthen the enforcement of measurement and remediation actions, particularly in the control of radon exposure at workplaces. These legal instruments will help to implement more comprehensively the GSR Part 3 requirements and IAEA SSG-32 guidance.

## 12. POLICY DISCUSSIONS

### 1. *Integration of radiation protection regulation with environmental protection regulation – the key considerations*"

The policy discussion was chaired by IRRS Team Leader Margot Tirmarche and attended by the IRRS team, EPA staff, DECLG staff, and Ms Laura Burke, Director General of the EPA. A brief presentation was made by the Director of the EPA's Office of Radiological Protection, Dr Ann McGarry on the efforts to exploit the synergies between EPA and the RPII following their merger last year on the integration of licensing administration systems; on dealing with licensees who hold both industrial emissions and radiological protection licenses; and identifying cross-cutting issues, such as, radiation detection systems at licensed incineration facilities and the environmental issues of disposing of exempted radiation sources.

The floor was then open for comments on the experiences of licensing and inspecting a facility from both environmental and radiological protection perspectives. Several IRRS team members offered views based on experiences in their respective countries but no majority view emerged on any particular model.

One view was that notwithstanding the structural separation of regulatory responsibilities for environmental and radiation protection in most countries, close cooperation was still possible. Finland, for example, does not have joint environmental/radiological protection licenses because the roles of the respective regulators arise out of separate legislation. However, there is cooperation between the agencies on waste with radioactive contamination and on NORM issues from mining activities. For waste created from any emergency, both sets of regulators would be involved.

Another example of how environmental issues are integrated with radiation protection is Australia. Like Finland, jurisdiction and responsibilities for radiation and environment protection arise out of different legislation in Australia. In fact, for certain 'nuclear actions' the Federal Environment Minister's approval is a threshold requirement before a license application may be made to the nuclear regulator. Even so, every license application to the nuclear regulator would also have to be accompanied by, among others, an environmental protection plan and a radioactive waste management plan.

The discussion also heard that it is possible to have a single license for both radiation and environmental protection. For example, Switzerland has a single license for incineration facilities issued by the radiation protection regulator (Federal Office of Public Health), which is also responsible for the environmental radioactivity monitoring. This is facilitated by the fact that both radiation and environmental regulation come under the Public Health office. As part of the implementation of the Euratom BSS, Switzerland is amending its legislation to accommodate common interests between the two areas in relation to waste and Radon. There is also a requirement in Switzerland to install portal monitors at incinerator facilities and notify radiation authorities when there is an alarm – the regulatory authority will then work with the facility to manage the issue.

The joint license is also a feature in Brazil where, notwithstanding the existence of separate authorities for radiation and environment regulation, one license is issued for installations with foreseen environmental impact. A single license covering radiation protection, nuclear safety and environmental protection is also a feature in France but this is limited to the authorization of nuclear power plants and other nuclear installations.

There was also a call for caution based on the Cuban experience. The meeting heard that while there are strengths and opportunities from radiation and environmental issues being handled by the same organization, it may not necessarily be beneficial to merge the licensing and inspection functions of the two areas. This is because the organizational cultures in the two areas are different. This observation was supported by the Bosnian and Herzegovina experience where radiation and environmental protection fall under different government bodies. The view was expressed that the skills required by inspectors for radiation protection and environmental protection are not the same.

### *2. "Radioactive Waste Management Policy and the role of the Regulatory Body"*

The policy discussion was chaired by IRRS Team Leader Margot Tirmarche and attended by the IRRS team, EPA staff, DECLG staff , and Ms Laura Burke, Director General of the EPA. A brief presentation was made by Dr Stephen Fennell (EPA) on the Radioactive Waste Management Policy adopted by the Government in Ireland in 2010. Radioactive waste in Ireland mainly includes disused sealed sources in storage/custody and unsealed radioactive material arising from medical, research and cyclotron facilities. The Guiding Principles for Ireland's Radioactive Waste Management Policy are minimisation of waste generation; avoidance of waste importation; 'Cradle to Grave' management of disused sealed sources; requirement for "take back agreements" and adherence to the 'polluter pays' principle. A co-ordinated and phased disused radioactive source inventory reduction programme was carried out in Ireland.

The policy notes the need to address the management of legacy and orphan sources in a safe, secure and sustainable way. It aims to ensure the support of stakeholders (holders of sources, Government Departments and Agencies and the public). It includes Inter-agency co-operation with clearly defined roles and responsibilities ("whole of Government" approach). There is no "one size fits all" solution. According to the policy a national centralized waste storage facility should be established. To this end, a National Implementation Committee has been set up to develop specifications for facility and make recommendations on siting, management and resourcing of the facility.

The challenges of the implementation of the radioactive waste management policy include the identification of a suitable potential co-location site (with other hazardous waste), addressing public concerns/ facilitating public consultation re siting of national storage facility, the funding models for waste store, the lack of central funds for the management of orphan sources/legacy items and the prohibition on sending sources to overseas facilities for disposal, except where there are intergovernmental arrangements in place and in accordance with the Euratom Directive on radioactive waste.

IRRS team offered views based on experiences in their respective countries. A similar situation for sources exists in Switzerland where finding a site for storage remains an issue and end storage and public consultation so far were not successful. As well, there is concern for radium contamination in houses and each Canton in Switzerland has been asked to establish a temporary storage for radium wastes. In France the national funds has to pay for remediation of sites contaminated by radium.

It was stressed by some participants that storage should be considered as an interim step in a waste management strategy, with disposal as the end point. The Irish waste policy which is currently mainly focused on storage should be further developed to address implementation of the policy including the disposal of radioactive waste as the end point. The conditions of the establishment of the storage facility should also be further specified in particular to indicate the duration of storage, the steps of development (milestones, deadline) and the corresponding licensing process. DECLG indicated that disposal is part of the 2010 government plan and that the further specification of the waste management strategy, including disposal, is being considered.

Bosnia and Herzegovina who faces similar challenges, benefited from a close cooperation with the IAEA to prepare a comprehensive strategy. Sources have been sent for recycling and financial issues for orphan sources have been agreed by the Government. A storage facility is not considered appropriate at this point and the way to proceed is still under discussion. In Finland orphan sources mostly come from the scrap metal industry where operators pay for their disposal and reclaim the bill from their suppliers.

The 2013 deadline for the transposition of the EURATOM radioactive "waste directive" in Irish law was seen as one of the drivers for ensuring the success of the source reduction programme as it encouraged licensees to export disused sources for disposal while disposal routes were still available. Licensees were advised that disposal costs to overseas facilities would be far cheaper than the costs associated with the long term disposal of the same sources within Ireland upon the establishment of the national storage facility.

The IAEA indicated that, as regulator, EPA should not also be the operator of the waste facility according to the IAEA Safety Standards and the Joint Convention. The policy needs to specify the roles and responsibilities of all the actors in the implementation of the waste management strategy and the funding mechanisms. The strategy should be periodically reviewed by the Government.

According to EPA representative the current option under consideration is to co-locate the storage facility with an existing hazardous waste facility. Considering the level of the hazard involved (~30 sources), a graded approach has to be applied in their safe management. The co-location of hazardous and radioactive waste might however raise issues regarding the potential combination of chemical and radiation risks and the potential consequences from the safety and the public points of view. Communication with the public is a topic of concern.

The Finnish representative noted that in combining radiation and environmental regulation, due attention should be paid to the fundamental difference between radiation safety regulations, where the optimization of protection is a balance considering workers, patients and members of the public, and environmental regulations where the emphasis is mainly on the members of the public.

## APPENDIX 1 LIST OF PARTICIPANTS

| INTERNATIONAL EXPERTS | | | |
|---|---|---|---|
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| 4. | GARCIA LEIVA Manuel | Consejo de Seguridad Nuclear (CSN) | mgl@csn.es |
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| **LIAISON OFFICER** | | | |
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## APPENDIX II LIST OF COUNTERPARTS

| IRRS EXPERTS | COUNTERPART |
|---|---|
| **RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT** | |
| Jovica Bosnjak<br>Selva-Kumar Manickam | Ann McGarry<br>Paul McDonald<br>Tom Ryan<br>Stephen Fennell<br>Kilian Smith |
| **GLOBAL SAFETY REGIME** | |
| Jovica Bosnjak<br>Selva-Kumar Manickam | Ann McGarry<br>Paul McDonald<br>Tom Ryan<br>Stephen Fennell<br>Kilian Smith |
| **RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY** | |
| Jovica Bosnjak<br>Selva-Kumar Manickam | Ann McGarry<br>Paul McDonald<br>Tom Ryan<br>Stephen Fennell<br>Kilian Smith |
| **MANAGEMENT SYSTEM** | |
| Jovica Bosnjak<br>Selva-Kumar Manickam<br>Luis Jova Sed | Barbara Rafferty<br>Bernard Browne<br>Sheila Powell<br>Marie Kelly<br>Geraldine Ruane |
| **AUTHORIZATION** | |
| Steve Ebdon-Jackson<br>Mika Markkanen<br>Carole Rousse<br><br>Manuel Garcia Leiva | Tanya Kenny<br>Jack Madden<br>Hugh Synnott<br>Kevin Kelleher<br>Paul McGinnity<br><br>Jarlath Duffy<br>Noeleen Cunningham |

| IRRS EXPERTS | COUNTERPART |
|---|---|
| Luis Jova Sed | Stephen Fennell<br>Catherine Organo |
| **REVIEW AND ASSESSMENT** | |
| Steve Ebdon-Jackson<br>Mika Markkanen<br>Carole Rousse | Tanya Kenny<br>Jack Madden<br>Hugh Synnott<br>Kevin Kelleher<br>Paul McGinnity |
| Manuel Garcia Leiva | Jarlath Duffy<br>Noeleen Cunningham |
| Luis Jova Sed | Stephen Fennell<br>Catherine Organo |
| **INSPECTION** | |
| Steve Ebdon-Jackson<br>Mika Markkanen<br>Carole Rousse | Tanya Kenny<br>Jack Madden<br>Hugh Synnott<br>Kevin Kelleher<br>Paul McGinnity |
| Manuel Garcia Leiva | Jarlath Duffy<br>Noeleen Cunningham |
| Luis Jova Sed | Stephen Fennell<br>Catherine Organo |
| **ENFORCEMENT** | |
| Steve Ebdon-Jackson<br>Mika Markkanen<br>Carole Rousse | Tanya Kenny<br>Jack Madden<br>Hugh Synnott<br>Kevin Kelleher<br>Paul McGinnity |
| Manuel Garcia Leiva | Jarlath Duffy<br>Noeleen Cunningham |
| Luis Jova Sed | Stephen Fennell<br>Catherine Organo |

| REGULATIONS AND GUIDES | |
|---|---|
| Steve Ebdon-Jackson<br>Mika Markkanen<br>Carole Rousse<br><br><br>Manuel Garcia Leiva<br><br><br>Luis Jova Sed | Tanya Kenny<br>Jack Madden<br>Hugh Synnott<br>Kevin Kelleher<br>Paul McGinnity<br><br>Jarlath Duffy<br>Noeleen Cunningham<br><br>Stephen Fennell<br>Catherine Organo |
| **EMERGENCY PREPAREDESS AND RESPONSE** | |
| Peter Hofer | Ciara McMahon<br>Veronica Smith<br>Keith Leonard |
| **ADDITIONAL AREAS - Medical Exposure** | |
| Steve Ebdon-Jackson<br>Carole Rousse | Mandy Lewis<br>Bernadette Moran<br>Tanya Kenny<br>Collette O'Connor |
| **ADDITIONAL AREAS - Occupational Exposure** | |
| John Hunt<br>Mika Markkanen | Jack Madden<br>Lorraine Currivan<br>Leo Mckittrick |
| **Control of chronic exposures Radon** | |
| Christophe Murith | David Fenton<br>Stephanie Long<br>Alison Dowdall |

## APPENDIX III MISSION PROGRAMME

## IRELAND IRRS MISSION PROGRAMME, 30 August - 9 September 2015

| IRRS MISSION PROGRAMME | | |
|---|---|---|
| **Sunday, 30 August 2015** | | |
| **Initial IRRS Review Team Meeting** | | |
| 13:30 - 17:30 | Opening remarks by the IRRS Team Leader<br>Introduction by IAEA<br>Self-introduction of all attendees<br>IRRS Process (IAEA)<br>Report writing (IAEA)<br>Schedule (TL, IAEA)<br>First impression from experts arising from the Advanced Reference Material (ARM) (All Experts)<br>Administrative arrangements (EPA and IRRS LO, IAEA): Detailed Mission Programme | Venue: Camden Court Hotel<br><br>Participants:<br>the IRRS Team + the LO |
| **Monday, 31 August 2015** | | |
| **IRRS Entrance Meeting** | | |
| 09:00 – 12.30 | 09:30 Arrival and Registration<br>10:00 Welcome Address:<br>Ms Laura Burke, Director General EPA<br>Mr David Walsh, Assistant Secretary, Department Environment, Community and Local Government (DECLG) and Mr Patrick Lynch, National Director, Quality Assurance and Verification Division, Health Service Executive<br>10:15 IRRS Coordinator –IRRS programme<br>11:00 IRRS Team Leader – Expectations for the Mission and introduction of the IRRS Team<br>11:30 Coffee<br>12:00 EPA/HSE – Regulatory Overview, SARIS results (strength, challenges, action plan)<br>12:30 Questions | Venue: Custom House, Dublin<br><br>Participants:<br>High Level Government Officials<br>EPA Management and staff<br>HSE Management and staff<br>Official from relevant organizations<br>IRRS Team + the LO |
| 12:45 – 13:30 | Lunch | Venue: Custom House |
| 14:00 – 14:30 | Safety briefing/Administrative issues | Venue: EPA/ORP Boardroom Block 3 |
| 14:30 – 17:00 | Interviews and Discussions with Counterparts (parallel discussions) | Venue: EPA/ORP Offices<br>Participants: IRRS Reviewers and Ireland Counterparts |

| IRRS MISSION PROGRAMME | | |
|---|---|---|
| 17:30 | Daily IRRS Review Team meeting | Venue: Camden Court Hotel<br>Participants: IRRS team and LO. |
| **Tuesday, 1 September 2015** | | |
| **Daily Discussions / Interviews** | | |
| 09:00 – 17:00 | Interviews and discussions with Counterparts (parallel discussions) | Venue: EPA/ORP Offices<br>Participants: IRRS Reviewers and Ireland Counterparts |
| 13:00 – 14:00 | Lunch | |
| 14:00 | Visit Ministry – Department of Environment, Community and Local Government (DECLG)* | Participants: TL, DTL, TC, Reviewer Modules 1,2 and 3+ EPA |
| 17:30 | Daily IRRS Review Team meeting | Venue: Camden Court Hotel<br>Participants: IRRS team and LO. |
| **Wednesday, 2 September 2015** | | |
| **Daily Discussions / Interviews** | | |
| 09:00 – 17:00 | Follow-up interviews and discussions with counterparts for all modules | Venue: EPA/ORP Offices<br>Participants: IRRS Reviewers and Ireland Counterparts (TBD) |
| 08:30 – 13:30 | Visit to St James's Hospital (public), patient protection focus | Dublin |
| 08:00 – 13:30 | Visit to Industrial facility – Becton Dickenson – Industrial Sterilisation Plant | Dublin |
| 13:00 – 14:00 | Lunch | |
| 14:00 – 17:00 | Writing first draft of preliminary findings (Rs, Ss and GPs) | |
| 17:30 | Daily IRRS Review Team meeting | Venue: Camden Court Hotel<br>Participants: IRRS team and LO. |
| **Thursday, 3 September 2015** | | |
| **Daily Discussions / Interviews** | | |
| 08:30 – 13:30 | Visit to Beacon (private) Hospital: Radiotherapy inspection | Dublin |
| 08:00 – 13:30 | Visit to M2I – F18 Production facility | Dublin |
| 09:00 – 17:00 | Follow-up Interviews and discussions with counterparts (parallel discussions) | Venue: EPA/ORP Offices<br>Participants: IRRS Reviewers and Ireland Counterparts (TBD) |
| 14:00 | Visit with Officials of the Ministry of Health (MoH) | Venue: Hawkins House<br>Participants: TL, DTL, TC, Reviewer Modules 1,2 and 3+ EPA, HSE |
| 17:30 | Daily IRRS Review Team Meeting: recommendations, suggestions and good practices | Venue: Camden Court Hotel<br>Participants: IRRS team and LO. |
| **Friday, 4 September 2015** | | |
| **Daily Discussions / Interviews** | | |

| IRRS MISSION PROGRAMME | | |
|---|---|---|
| 09:30 – 17:00 | Team members write draft report. Finalize Observations, Recommendations, Suggestions and Good Practices | |
| 14:00 – 16:30 | Policy issue discussion:<br>1. Radioactive waste management policy and the role of the Regulatory Body<br>2. Patient protection regulation – the role of the Regulatory Body<br>3. Integration of radiation protection regulation with environmental protection regulation – the key considerations | Venue : EPA/ORP Boardroom Block 1<br>Participants: TL, TC and Reviewers |
| 17:30 | Daily IRRS Review Team meeting | Venue: Camden Court Hotel<br>Participants: IRRS team and LO. |
| **Saturday, 5 September 2015** | | |
| **Daily Discussions/ Interviews (if needed)** | | |
| 09:00 – 10:30 | Cross reading | |
| 10:30 – 16:00 | Finalizing draft - to be sent to EPA by 16:00 | |
| **Sunday, 6 September 2015** | | |
| | | |
| 09:00 – | EPA review the draft report | |
| 8:00 – 16:00 | Cultural event for IRRS Team | |
| **Monday, 7 September2015** | | |
| **Daily Discussions** | | |
| 12:00 | EPA submit comments | |
| 12:00 – 17:00 | Team review comments | |
| **Tuesday, 8 September 2015** | | |
| **Daily Discussions** | | |
| 09:00 – 17:00 | Discussion with counterparts for any clarification | |
| | Team finalize report | |
| 18:00 – 22:00 | Official dinner | |
| **Wednesday, 9 September 2015** | | |
| | | |

| IRRS MISSION PROGRAMME | | |
|---|---|---|
| 09:00 – 11:00 | IRRS Exit meeting, opening remarks by IAEA Official (TBD)<br><br>Main findings of the IRRS mission (Team Leader)<br><br>Closing Remarks by EPA and response to the Mission findings. | Venue: Custom House, Dublin<br><br>Participants:<br>High Level Government Officials<br>EPA Management and staff<br>HSE Management and staff<br>Official from relevant organizations<br>IRRS Team + the LO |

## APPENDIX IV SITE VISITS

1. St James's Hospital (public)
2. Becton Dickenson – Industrial Sterilisation Plant
3. Beacon Hospital (private)
4. M2I – F18 Production facility
5. National Emergency Coordination Centre

## APPENDIX V RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

| Area | | R: Recommendations<br>S: Suggestions<br>G: Good Practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| **1.** | **RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT** | R1 | The Government should implement an effective legal framework for the regulation of patient protection. Meanwhile, the Government should, as a matter of urgency, put in place arrangements to carry out inspections and enforcement to ensure patient protection. |
| | | R2 | The government should ensure that the legislation explicitly addresses the following issues in accordance with GSR Part 1:<br>1. Use of a graded approach in all regulatory activities;<br>2. Ensure legislation provides for appeals against the decisions of the regulatory bodies in relation to radiation safety and patient protection. |
| | | R3 | The Government should make appropriate amendments to facilitate the effective use of the 'Enforcement Notice' provisions in SI125/00. |
| | | R4 | The Government should ensure as a matter of urgency that the regulatory body for patient protection does not have responsibilities for or interests in providing medical exposure to ionizing radiation. |
| | | S1 | The EPA should consider requiring authorized parties to verify that products and services meet the authorized party's expectations and comply with any relevant regulatory requirement. |
| | | R5 | The Government should make formal provision for effective coordination among the EPA, the Irish Aviation Authority, and the Maritime Safety Directorate and between the EPA and the HSE. |
| | | S2 | The Government should consider implementing a legislative framework for the remediation of any contamination from past activities or events. |
| | | R6 | The Government should ensure that the radioactive waste management |

| Area | | R: Recommendations<br>S: Suggestions<br>G: Good Practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| | | | strategy including both short and long term storage of radioactive waste, unforeseen decommissioning, remediation and disposal of radioactive waste includes provisions for financial support. |
| **2.** | **RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY** | R7 | The EPA should develop a strategic plan for ORP's staff succession management. |
| | | R8 | The Government should urgently ensure that the regulatory body that is responsible for patient protection is adequately resourced. |
| | | S3 | The regulatory body should consider entering into written agreements with any external adviser to formalize the arrangements and to facilitate the management of any potential conflict of interest. |
| **3.** | **MANAGEMENT SYSTEM OF THE REGULATORY BODY** | R9 | The EPA should assess gaps in the management system with regard to radiation safety due to the merger of RPII with the EPA, and prioritize actions to develop the management system further in line with GS-R-3 where appropriate. |
| | | GP1 | EPA's radiation safety inspection activities are formally accredited to an ISO standard, which provides for openness and transparency, as well as, continuous assessment and improvement. |
| | | GP2 | There is a documented system providing a link between the legislation mandating the organization and individual contribution to delivery of goals, including corporate values and behavioural expectations. |
| | | S4 | The EPA should consider assessing and documenting the competence requirements for individual roles in the ORP structure through the planned skills mapping exercise. |
| | | R10 | The EPA should further develop and document those processes and |

| Area | | R: Recommendations<br>S: Suggestions<br>G: Good Practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| | | | procedures relevant to radiation safety not already addressed. |
| | | S5 | The EPA should consider ensuring that post-merger ORP functions continue to be taken into account when establishing the audit schedule in the same way as other technical areas of the EPA. |
| **4.** | **AUTHORIZATION** | GP3 | The EPA/ORP has established a web-based system that allows applications for a new radiological license to be made and for existing licenses to be renewed or amended by following clear step by step instructions on the information to be provided and documents to be uploaded in support of the application. |
| | | S6 | The EPA should consider developing further its graded approach by taking into account the interaction between all the elements of the regulatory control. |
| | | S7 | EPA should consider assessing the current provisions and co-operation arrangements regarding the import of radioactive sources and to make appropriate proposals, if needed, for establishing arrangements which provide for the Customs to verify systematically that the imported sources are appropriately licensed by the EPA. |
| | | GP4 | The systematic co-operation between the EPA and the police significantly supports EPA in the implementation of an integrated approach to safety and security of radiation sources. |
| **5.** | **INSPECTION** | R11 | The EPA inspection program should be extended to verify that the user's management system relating to the transport of radioactive material is implemented and followed correctly. |
| **6.** | **REGULATION AND GUIDES** | R12 | The regulatory body should establish policies and processes regarding establishing and amending guidance documents and code of practices |

| Area | | R: Recommendations<br>S: Suggestions<br>G: Good Practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| | | | relating to radiation safety. |
| | | S8 | The EPA should consider the review, and revision if appropriate, of the means (radiological license condition, regulations or guides) of establishing its safety principles, requirements and associated criteria for radiation safety. |
| | | R13 | The Government should review the radiological protection regulations to ensure that all the requirements related to public exposure control are in compliance with GSR Part 3. |
| | | GP5 | EPA took the initiative to evaluate at the national level the need to install iodine holding tanks in both existing and future iodine ablation facilities. The evaluation reviewed existing practices in Ireland in relation to iodine-131 ablation discharges to the sewers (discharges leading to the highest potential dose) and made recommendations for a regulatory policy, based on international best practice and forecasts of future activity. |
| | | R14 | The Government should complement the regulatory framework regarding the :<br>- predisposal management of radioactive waste activities and facilities should be planned and safely carried out, including the radioactive waste produced during remediation and disused sealed sources, and<br>all aspects of decommissioning of facilities, including the safe management of the resulting radioactive waste should be planned and carried out. |

| Area | | R: Recommendations<br>S: Suggestions<br>G: Good Practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| 7. | **EMERGENCY PREPAREDNESS AND RESPONSE** | GP6 | The nuclear and radiological emergencies are well integrated on national and regional levels in a framework for major emergency management system and a national emergency coordination system following the all hazards approach. EPA has a key role if a radiation emergency occurs. |
| | | R15 | The EPA should establish criteria for the radiological licensees of threat category III facilities for a clear definition and categorization of emergencies. This should also be reflected in the reporting requirements of the licensee. |
| | | S9 | The EPA in its role as governmental advisor for protective measures for the public should consider defining Operational Intervention Levels for protective measures in radiation emergencies. |
| | | GP7 | The information to the public on emergency planning prior to an emergency is very efficient in reaching all sectors of the population in Ireland. In addition a coordination mechanism to inform the public in case an emergency has been established under the national emergency coordination group of the government. The EPA has an important role in these activities for the information of the public. |
| | | R16 | The Government should make a formal arrangement for the involvement of stakeholders as part of the emergency management system. |
| | | S10 | The Government should consider mechanisms for increasing national measurement capacity to cope with a widespread, long-lasting contamination. |
| | | S11 | The EPA should consider finalizing the extension of its NEPNA sub plan to take account of the full resources of the EPA. |

| Area | | R: Recommendations<br>S: Suggestions<br>G: Good Practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| | | S12 | The Government should consider finalizing the revision of the National Emergency Plan for Nuclear Accidents as soon as possible to bring arrangements for the transition from an Emergency Exposure Situation to an Existing Exposure Situation in line with GS-R-2. |
| | | R17 | The EPA should establish a systematic oversight on emergency exercises of licensees in threat category III as appropriate including the requirement for the licensee to establish emergency exercise plans which will be evaluated by the EPA. |
| | | R18 | The EPA should establish a QA programme in the field of its EPR covering the areas not currently covered, and also the requirements for QA for the licensees in the field of EPR in line with a graded approach. |
| **8.** | **CONTROL OF MEDICAL EXPOSURES** | R19 | The Government should revise the current regulatory framework to bring it in accordance with GSR Part 3 for the regulation of patient protection. |
| **9.** | **OCCUPTIONAL RADIATION PROTECTION** | S13 | EPA should consider reviewing its requirements in relation to nomination and qualification of RPOs. |
| | | S14 | The EPA should consider extending the scope of the national dose register to enable individually monitored occupationally exposed workers to be unambiguously identified. |
| **10.** | **CONTROL OF CHRONIC EXPOSURES RADON** | GP8 | The effectiveness of the national radon control strategy is maximized through this "top down" approach driven by Government, ensuring all stakeholders work together in a cohesive manner. |
| | | S15 | The Government should consider provisions to support remediation by owners of homes with high radon levels. |
| | | S16 | The regulatory body should consider a plan of how to determine the |

| Area | | R: Recommendations<br>S: Suggestions<br>G: Good Practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| | | | workplaces with the highest radon levels. |

## APPENDIX VI REFERENCE MATERIAL USED FOR THE REVIEW

| DOCUMENTS |
|---|
| 001 Abbreviation List - Referenced Documents.pdf |
| 003A - Management of Comforters and Carers in relation to Ionizing Radiation. Version 2.pdf |
| 006A - Recommended Instructions of Care of Patients following Diagnostic Nuclear Medicine Examinations. Version 2.pdf |
| 009 - Recommended Instructions for Care of Patients following Diagnostic Nuclear Med Exams.pdf |
| 009A - Mandatory Training in Radiation Safety - Matters for Consideration.pdf |
| 014 VHRMF - Recom. Standard Operating Proc for Handling Cadavers containing Significant Quantities of Radioactive Iodine.pdf |
| 341_5 - Guidelines for the Implementation of a National Quality Assurance Prog in GI Endoscopy.pdf |
| ADR2015 - European Agreement Concerning the International Carriage of Dangerous Good by Road (2015) UNECE.pdf |
| ADSG - Approval of Dosimetry Services in Ireland - Guidelines for Applicants (2015).pdf |
| AEINE HSERPII - Arrangements for the exchange of info on reg of safe nuclear energy between HSE_UK and RPII.pdf |
| AIIFNA2012 - Assessment of the Impact on Ireland of the 2011 Fukushima Nuclear Accident (2012).pdf |
| Air Operators - Guidance Notes for Air Operators.pdf |
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## APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW


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4. INTERNATIONAL ATOMIC ENERGY AGENCY The Management System for Facilities and Activities. Safety Requirement Series No. GS-R-3 IAEA, Vienna (2006)
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## APPENDIX VIII ORGANIZATION CHART