Environmental Protection Agency
An Ghníomhaireacht um Chaomhnú Comhshaoil

ORP Inspection and Licensing Activities and Annual Inspection Programme for 2015

ENVIRONMENTAL PROTECTION AGENCY

The Environmental Protection Agency (EPA) is responsible for protecting and improving the environment as a valuable asset for the people of Ireland. We are committed to protecting people and the environment from the harmful effects of radiation and pollution.

The work of the EPA can be divided into three main areas:

Regulation: *We implement effective regulation and environmental compliance systems to deliver good environmental outcomes and target those who don't comply.*

Knowledge: *We provide high quality, targeted and timely environmental data, information and assessment to inform decision making at all levels.*

Advocacy: *We work with others to advocate for a clean, productive and well protected environment and for sustainable environmental behaviour.*

Our Responsibilities

Licensing

We regulate the following activities so that they do not endanger human health or harm the environment:

- waste facilities *(e.g. landfills, incinerators, waste transfer stations)*;
- large scale industrial activities (*e.g. pharmaceutical, cement manufacturing, power plants)*;
- intensive agriculture *(e.g. pigs, poultry)*;
- the contained use and controlled release of Genetically Modified Organisms *(GMOs)*;
- sources of ionising radiation *(e.g. x-ray and radiotherapy equipment, industrial sources)*;
- large petrol storage facilities;
- waste water discharges;
- dumping at sea activities.

National Environmental Enforcement

- Conducting an annual programme of audits and inspections of EPA licensed facilities.
- Overseeing local authorities' environmental protection responsibilities.
- Supervising the supply of drinking water by public water suppliers.
- Working with local authorities and other agencies to tackle environmental crime by co-ordinating a national enforcement network, targeting offenders and overseeing remediation.
- Enforcing Regulations such as Waste Electrical and Electronic Equipment (WEEE), Restriction of Hazardous Substances (RoHS) and substances that deplete the ozone layer.
- Prosecuting those who flout environmental law and damage the environment.

Water Management

- Monitoring and reporting on the quality of rivers, lakes, transitional and coastal waters of Ireland and groundwaters; measuring water levels and river flows.
- National coordination and oversight of the Water Framework Directive.
- Monitoring and reporting on Bathing Water Quality.

Monitoring, Analysing and Reporting on the Environment

- Monitoring air quality and implementing the EU Clean Air for Europe (CAFÉ) Directive.
- Independent reporting to inform decision making by national and local government *(e.g. periodic reporting on the State of Ireland's Environment and Indicator Reports)*.

Regulating Ireland's Greenhouse Gas Emissions

- Preparing Ireland's greenhouse gas inventories and projections.
- Implementing the Emissions Trading Directive, for over 100 of the largest producers of carbon dioxide in Ireland.

Environmental Research and Development

- Funding environmental research to identify pressures, inform policy and provide solutions in the areas of climate, water and sustainability.

Strategic Environmental Assessment

- Assessing the impact of proposed plans and programmes on the Irish environment *(e.g. major development plans)*.

Radiological Protection

- Monitoring radiation levels, assessing exposure of people in Ireland to ionising radiation.
- Assisting in developing national plans for emergencies arising from nuclear accidents.
- Monitoring developments abroad relating to nuclear installations and radiological safety.
- Providing, or overseeing the provision of, specialist radiation protection services.

Guidance, Accessible Information and Education

- Providing advice and guidance to industry and the public on environmental and radiological protection topics.
- Providing timely and easily accessible environmental information to encourage public participation in environmental decision-making *(e.g. My Local Environment, Radon Maps)*.
- Advising Government on matters relating to radiological safety and emergency response.
- Developing a National Hazardous Waste Management Plan to prevent and manage hazardous waste.

Awareness Raising and Behavioural Change

- Generating greater environmental awareness and influencing positive behavioural change by supporting businesses, communities and householders to become more resource efficient.
- Promoting radon testing in homes and workplaces and encouraging remediation where necessary.

Management and structure of the EPA

The EPA is managed by a full time Board, consisting of a Director General and five Directors. The work is carried out across five Offices:

- Office of Environmental Sustainability
- Office of Environmental Enforcement
- Office of Evidence and Assessment
- Office of Radiological Protection
- Office of Communications and Corporate Services

The EPA is assisted by an Advisory Committee of twelve members who meet regularly to discuss issues of concern and provide advice to the Board.

ORP Inspection and Licensing Activities and Annual Inspection Programme for 2015

Prepared by
The Radiation Protection Regulation Programme

December 2015

EPA Mission

To protect and improve the environment as a valuable asset for the people of Ireland. To protect our people and the environment from the harmful effects of radiation and pollution

Contents

Foreword

The purpose of this document is to promote transparency in the activities of the EPA's Office of Radiological Protection (ORP). It explains aspects of the internal workings of the Radiation Protection Regulation programme within the ORP to aid understanding of its processes and decisions which may impact on licensees and other interested parties.

Every effort has been made to ensure the accuracy and completeness of information contained herein, but the EPA does not warrant such accuracy or completeness and lists of procedures and criteria may not be exhaustive. The reader should also bear in mind that the actual inspection programme and related procedures or criteria may be altered or revised in the course of the year in response to new developments.

This is a guidance and information document and, while the EPA is available to advise and assist generally with regulatory queries, the information so provided or contained in this document is of a general nature and is not intended to address the specific circumstances of any particular party. This document is not intended as a legal interpretation of the legislation that applies to the EPA or of the obligations of parties operating in spheres covered by that legislation. Parties wishing to be advised on such matters should consult their legal advisers.

1. Introduction

The Radiological Protection Act 1991, as amended by the Radiological Protection (Miscellaneous Provisions) Act, 2014, provides for the EPA to regulate, by licence, the custody, production, processing, handling, holding, storage, use, manufacture, importation, distribution, transportation, exportation or other disposal of radioactive substances, nuclear devices and irradiating apparatus. In particular, Section 28 allows the EPA to appoint inspectors and Section 29 sets out the powers of inspectors appointed under the Act.

The Radiological Protection Act, 1991 (Ionising Radiation) Order 2000 (S.I. No. 125 of 2000) implements Council Directive 96/29/Euratom and sets out basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation. The EPA's radiological licensing system is based upon these legal requirements and the day to day responsibility for implementing the system has been delegated to the Radiation Protection Regulation (RPR) programme within the Office of Radiological Protection (ORP). Inspections undertaken by the ORP are designed to ensure compliance with both the legislative requirements as set out in S.I. No. 125 of 2000, S.I. No. 875 of 2005 and licence conditions. It is also an objective of the programme to assess the level of radiation protection in place at each licensed facility and to encourage licensees to strive to attain best practice in relation to radiation protection.

The ORP's RPR programme is organised as set out in Figure 1. In addition, an external consultant and warranted inspector, Prof P. Horton, assists the ORP in carrying out inspections at radiotherapy facilities. It should be borne in mind when considering the resources available to the ORP that inspectors are engaged in a wider range of activities than inspections including licensing, drafting guidance documentation, accreditation activities, advice to Government, radioactive waste management, management of Radiation Protection Advisor (RPA) registers, approval of courses, international representation, regulator/stakeholder liaison, policy and legislation development as detailed in the strategy documents and annual work programmes for the EPA.

The objective of this report is to provide an overview of inspection activities of the ORP, to examine the evolution in licensee numbers and to outline the rationale in developing annual inspection programmes. All inspection activities are now carried out within the framework of a quality management system including inspection planning, the training of inspectors, the conduct of inspections as well as post inspection follow up and review. This report also provides an overview of the main features of the quality system.

In addition, the report sets out the rationale used in devising the inspection programme for 2015 as well as the programme as approved by the Board of the EPA.

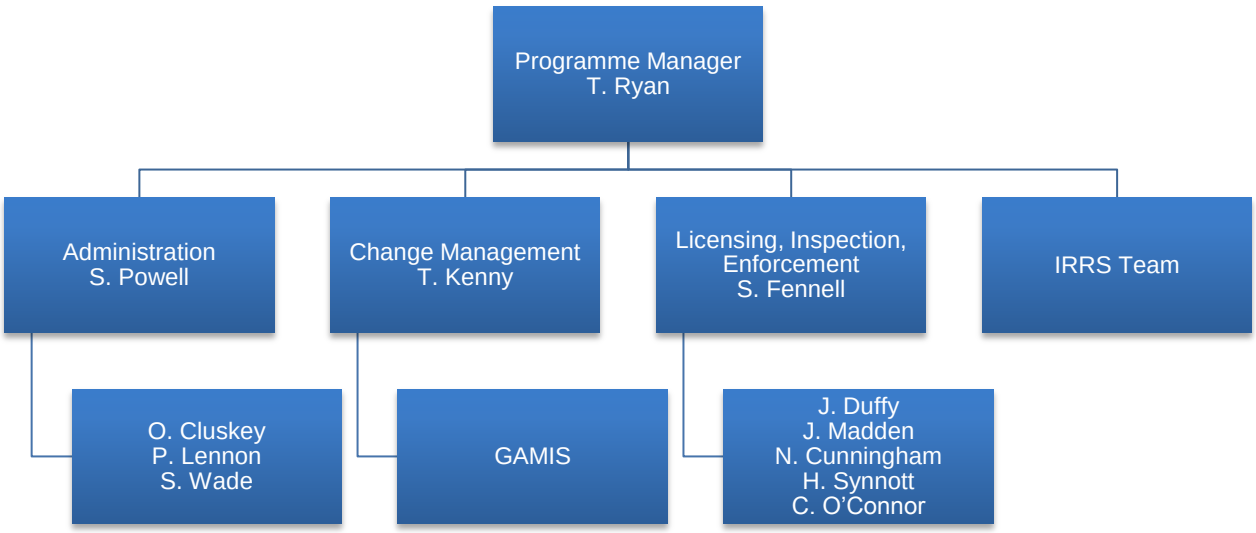

Figure 1: Radiation Protection Regulation Programme - Structure and Staff

2. The Licensees

The Irish licensing system was first established in 1977 with the passage of the Nuclear Energy (General Control of Fissile Materials, Radioactive Substances and Irradiating Apparatus) Order 1977. The current regulations are provided by S.I. No. 125 of 2000. The Nuclear Energy Board (NEB) commenced issuing licenses in 1977 and by 1985 there were 300 active licences in the medical and industrial sectors[a]. There was a significant increase in active licences 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 levelled off in recent years (Figure 2).

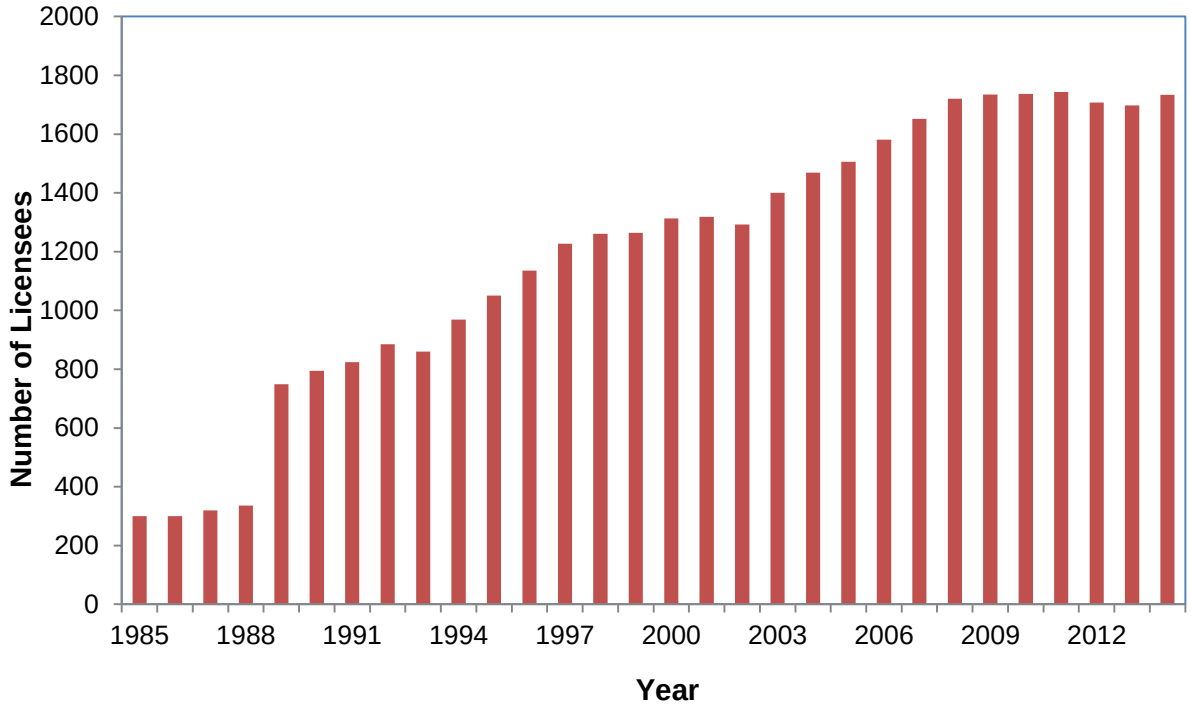

Figure 2: Licensee Numbers (1985 to 2014)

2.1. Licence Categorisation

In order to ensure the safety and security of all sources of ionising radiation held throughout Ireland the EPA operates a licensing system in accordance with its statutory obligations under the Radiological Protection Act, 1991. Prior to any individual or organisation acquiring either a radioactive source or an irradiating apparatus they must first obtain a licence from the EPA. On the 1st January 2015 there were 1734 active licences across six sectors, as illustrated in Figure 3. The dental sector makes up 55% of the licences issued, followed by

[a] While records show that licenses were issued in 1977, the data is incomplete. There were 150 licensees in 1979 and 200 in 1980.

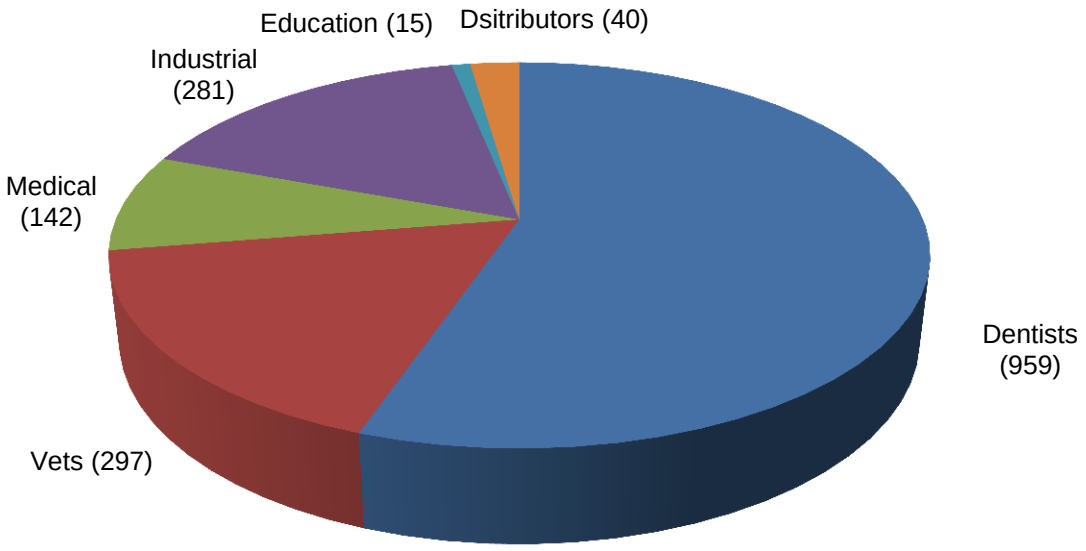

Figure 3: Licensees by Sector (1st January 2015)

the veterinary and industrial sectors at 17% and 16% respectively. From a radiological risk point of view licensees can be grouped into one of three categories – High, Medium and Low. In accordance with S.I. No. 654 of 2007, the criteria which determine the category a licensee falls into, reflecting the level of risk associated with the activities carried out, are based upon consideration of the following:

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

Table 1 provides example of the types of licensable activities that would fall into each of the three risk categories.

Table 1: Examples of licensable activities

Risk Category	Example activities
High	Radiotherapy; non-destructive testing - industrial radiography; use of HASS sources; product sterilisation; radiopharmaceutical manufacturing.
Medium	Nuclear medicine; medical diagnostic X-ray services; use of fixed and portable gauges (sealed sources); distribution of radioactive sources; educational & research purposes.
Low	Dental radiography; veterinary radiography; cabinet X-ray (security screening & quality control testing); bone densitometry; laboratory-based gas chromatography.

Table 2 details the breakdown of licensees within each of the three categories for each licensing sector. The only sectors which have licensees in the High risk category are the industrial and medical sectors.

Table 2: Distribution of licensees by risk category

Sector	Low	Medium	High
Dental	959	0	0
Distribution	28	12	0
Education & Research	0	15	0
Industrial	162	92	27
Medical	26	100	16
Veterinary	296	1	0
Total	1471	220	43

Currently all users of sources of ionising radiation must hold a licence from the EPA. While ORP adopts a graded approach in terms of reviewing and assessing different types of licence applications, and applying licensing conditions that reflect the nature and risk of the licensed activities, in practice the current licensing system is a one size fits all. However, for new licence applications that fall into the High risk category, ORP will usually carry out a site visit at some stage of the building process in advance of issuing a new licence.

In the coming years a new graded authorisation system will be introduced which will allow for different types of authorisation such as notification, registration and licensing to be used.

This new tiered system of authorisation will better reflect the risk associated with different uses of ionising radiation throughout Ireland without compromising on radiation safety. For example, it is expected that low risk activities such as dental radiography or the use of cabinet X-ray units will move to a more simplified registration system, whereas high risk activities such as radiotherapy and non-destructing testing will remain at licensing.

3. Inspections

The ORP has the resources to undertake typically 150 – 220 inspections per year and the number of inspections undertaken in a given year is based upon a risk analysis. Figure 4 illustrates the number of inspections undertake in the years 1985 – 2014.

In accordance with the strategic objectives set out in the RPII's Strategic Plan for 2014 – 2015, the ORP commenced work on two major new projects during 2014. The first of these was the development of a new information management system, GAMIS (Graded Authorisation Management Information System), which will allow licensees to manage their own licences on-line as well as eventually providing for alternative types of authorisation to licensing, such as registration and notification, which will be introduced with the new European Basic Safety Standards Directive. The second project relates to the IAEA's IRRS[b] peer review of Ireland, which will be undertaken in September 2015, and required the self-assessment preparatory work to be undertaken during 2014. Both of these projects required significant inspector resources during 2014, and again in 2015, and for that reason a reduced inspection programme will be undertaken in 2015. However, with the completion of the IRRS review mission in 2015, the inspection programme for 2016 will see the numbers of inspections increase significantly.

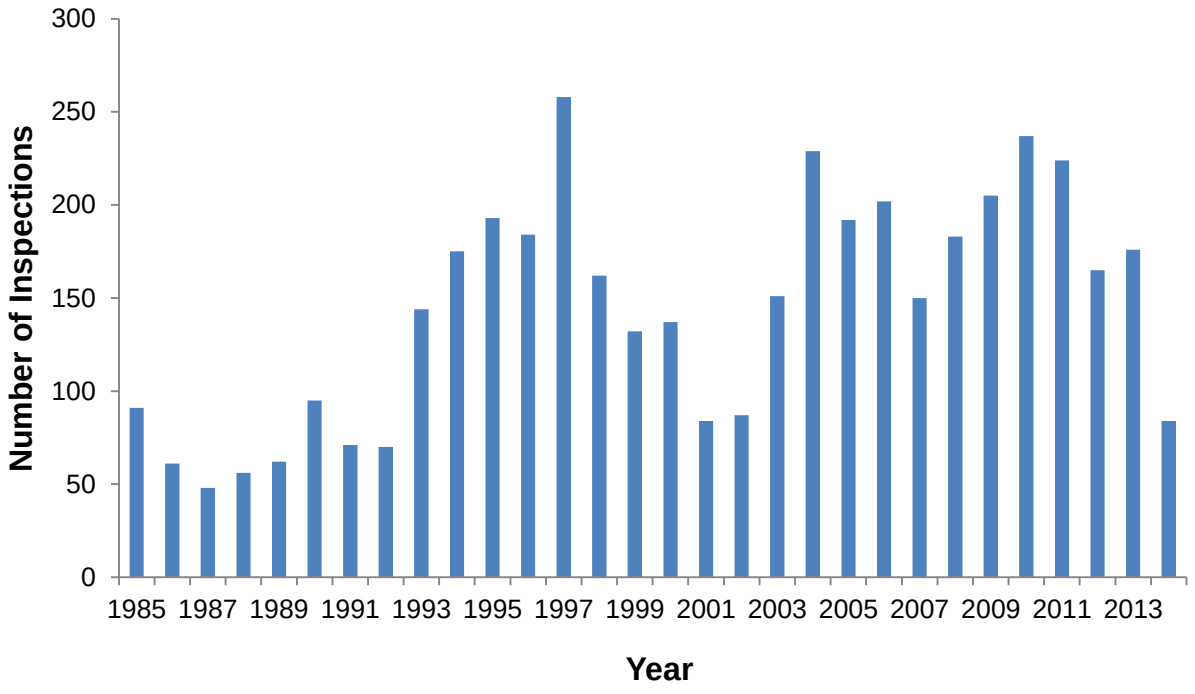

Figure 4: Inspections undertaken from 1985 to 2014

[b] Integrated Regulatory Review Service

The primary focus for ORP inspections is of those licensees who fall into either the High or Medium risk categories. ORP has determined target inspection frequencies for various activities which take account of the associated risks (Table 3). The dental and veterinary sectors are omitted from this table as licensees in these sectors are not subject to routine, frequency-based inspections - instead specific inspection projects are undertaken periodically within these sectors.

Table 3: Target inspection frequencies

Activity	Risk	Target Inspection Frequency (yrs)
Industrial Radiography	High	1
Irradiators - industrial	High	1-2
Radiotherapy	High	2
Gauges – fixed & portable	Medium	2-3
Transport related	Medium	2-3
Nuclear Medicine	Medium	3
Diagnostic Radiology	Medium	3
Education & Research	Medium	3
Chiropractors	Medium	3
Distributors (sources)	Medium	3 - 4
Single X-ray unit (medical)	Medium	5
Cabinet X-ray/Security Screening	Low	5
Distributor (X-ray)	Low	5
Bone densitometry	Low	6

This setting of target inspection frequency represents a graded, risk-based approach to planning the annual inspection programme, where those licensees engaged in higher risk activities are inspected more frequently. However the frequencies have been generalised across all licensees carrying out similar type activities and do not take account of specific licensee's circumstances. For some licensees, who may have excellent radiation safety cultures, it will not always be necessary to carry out an inspection in accordance with the target frequency. In contrast, there will be other licensees who will require more frequent inspections than the targets would suggest. While ORP strives to meet these target frequencies, account must be taken of available inspector resources when planning the annual inspection programme and the frequencies may have to be temporarily adjusted from

time to time. It should be noted that inspections are not viewed as the only means of enforcement. In particular, the ORP has incorporated the statutory Radiation Protection Advisor (RPA) requirement into its licensing requirements on a phased basis and this is seen as a significant step forward in enhancing radiation safety and compliance in all relevant sectors.

The exposure of aircrew to cosmic radiation is subject to regulation under S.I. No 125 of 2000. The holder of an air operator's certificate is required to evaluate the doses received by its aircrew to determine if measures to control exposure to cosmic radiation are warranted. The legislation applies to those air operators whose crew are potentially liable to receive an annual dose greater than 1 millisievert (mSv), which effectively applies only to those airlines flying above 8000 metres. An evaluation of doses to aircrew must be submitted to the ORP within three months of the end of the calendar year. Doses are estimated using software produced by the Civil Aeromedical Institute in the United States (CARI-6) and a European route dose calculation code (EPCARD). This information is combined with details of an individual's flying hours in order to assess radiation doses. There are currently eight air operators that come under these requirements and all of these have been inspected in recent years.

Radon in workplaces is subject to regulatory control as S.I. No. 125 of 2000 applies to work activities which take place in workplaces having radon concentrations in excess of 400 Bq/m^3, averaged over a period of three months. The legislation states that all underground workplaces, including mines and show caves shall be measured for radon gas on being directed to do so by the EPA. There are currently two commercial mines, two show mines, five show caves and two adventure centres in Ireland that are relevant in this context.

While no formal direction to measure radon has been issued to an underground workplace to date, all underground workplaces have carried out radon monitoring and were inspected[c] during 2007. Follow-up work was carried out in 2008 and there were six repeat inspections in underground workplaces in 2010. In 2013 two show caves were visited by inspectors to assess radiation protection measures in place. There are no plans to undertake specific inspections of show caves during 2015, but this may change on review during the year.

[c] This type of inspection is outside the scope of the accreditation

3.1. Annual Inspection Programme

The development of the annual inspection programme is now formally embedded in a Quality System that has been accredited to the international standard for inspection bodies ISO 17020 (*Requirements for the operation of various types of bodies performing inspection*) and the broader provisions of the quality system are described in Section 4.

The annual inspection programme sets out the list of licensees that will be inspected each year. The programme, which is approved by the Board of the EPA, takes account of available staff resources and is based upon the following factors:

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

The inspection programme identifies individual licensees to be inspected as well as the scope of the inspections. However, for some sectors it is generally not necessary to identify the individual licensee that will be inspected given the nature of the practices involved. For these sectors the inspection schedule identifies the number of licensees within these categories that will be inspected.

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

- Where a concern in relation to a source of ionising radiation is brought to the attention of the ORP by any individual;

- The reporting of an incident involving a licensable item to the ORP in compliance with licensing conditions;
- Where the ORP is notified of a dose recorded on a personal dosemeter which exceeds the reporting levels as defined in the licence conditions.

From time to time it may not be possible to complete all inspections as set out in the inspection programme and it may then be necessary to postpone inspections. In such circumstances, these inspections will be included in the following year's programme, where possible.

4. Accreditation

The ORP has developed a quality system for its inspection activities in line with ISO 17020, which is an international standard specifically designed for inspection bodies, and has been accredited to this standard since 2008. The quality system provides a framework for planning and reviewing the annual inspection programme, the conduct of inspections, the follow up of inspections and the training of inspectors. Continual improvement is facilitated through a system of document management and periodic system audits involving all staff.

During 2013, the ORP was successfully re-accredited to the new ISO 17020:2012 standard for a further five years. One of the requirements of the new standard is an increased emphasis on assessing the competency of inspectors, rather than simply ensuring that they are trained. The ORP assesses the competency of its inspectors through an annual inspection witnessing programme where each inspector is witnessed at least once every two years carrying out an inspection by the Technical Manager.

4.1. Quality Policy Statement

A policy statement with measurable objectives is a fundamental part of the accreditation process and the following has been adopted by the ORP:

> *"It is the policy of the Office of Radiological Protection to achieve and maintain a standard of quality of its inspection work which is consistent with its status as a Type A Inspection Body under ISO 17020:2012 Standard. The ORP is committed to maintaining its status as an ISO 17020:2012 Inspection Body. The ORP is also committed to ensuring that people in Ireland are protected from the harmful effects of radiation.*
>
> *To attain this level of excellence the ORP will aspire to achieve the following objectives:-*
>
> - *Complete all scheduled inspections as defined in the Inspection Programme;*
> - *Issue all Inspection Reports within 28 days of the inspection date;*
> - *Systematically and periodically collate elements of new good practice for dissemination to relevant parties;*
> - *Undertake a review of the inspection findings annually and present the outcome of this review, including any resulting actions identified, at the Annual Inspection Review Meeting;*
> - *Document and publish the EPA's Office of Radiological Protection (ORP) Annual Inspection Programme;*

- *Undertake targeted inspections to address specific issues within particular sectors or to identify issues where further regulatory action is required within the sector.*

ORP is also committed to the continuous improvement of the effectiveness of its Quality Management System (QMS). It aims to provide all licensees, at all times, with a service complying with the Irish National Accreditation Board (INAB) accreditation standard for all the work for which it is accredited.

The Programme Manger has ultimate responsibility for both Quality Assurance and Quality Control. The Technical Manager is responsible for the implementation of the procedures, as set out in the Quality Manual, in order to ensure that the quality standard meets the requirements of INAB and ISO 17020:2012 Standard.

It is the responsibility of all staff to understand the contents of this Quality Manual and to comply with the policies and procedures laid down in this manual and associated documentation at all times."

4.2. Inspection Procedure

All announced inspections are arranged in advance with the licensee either by telephone or e-mail. The structure and format of the inspection will be outlined to the licensee and any relevant documentation pertaining to the scope of the inspection may be requested in advance of the inspection. For unannounced inspections no prior contact or arrangement is made with the licensee in advance of the inspection.

Each inspection commences with an entrance meeting at which the Lead Inspector advises the licensee or licensee's representative of the purpose of the inspection, the areas to be inspected and the structure/format of the inspection. Where possible, the licensee's representatives should include a representative from senior management.

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

Inspections are carried out using specifically designed inspection audit forms relating to the types of activities carried out by the licensee and the nature of the sources held. The inspection also includes the examination of all relevant documents and records appropriate to the scope of the inspection.

To conclude the inspection an exit meeting is convened between the inspector(s) and the licensee's representatives during which the summary of the inspection findings is presented verbally. Where an inspector is of the opinion that there is or may be an immediate danger on site he/she has the power by direction, to order persons to perform or refrain from performing any act if, in his/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.

Following the inspection an Inspection Report is issued to the licensee within 28 days. The report includes a list of inspection findings and recommendations for improvement. Licensees are required to respond to the inspection findings within four weeks of the date of issue of the report or as appropriate to the circumstances.

4.3. Inspector Training

For staff members involved in inspection the key competencies required to perform the different types of inspections have been defined, including knowledge of legislative and licensing requirements, shielding considerations, conduct of inspections and report writing. Training to attain these competencies takes the form of on-the job training and external training where appropriate. The competence of these personnel is appraised by a trained member of staff who is assigned responsibility by the Technical Manager.

Competence is evaluated on the basis of skill, underpinned by technical knowledge and demonstrated capability.

For each area of competence, the following training and mentoring process is implemented:

- An induction period, whereby the trainee observes inspections and reviews the relevant literature;
- A supervised working period with experienced inspectors, where the trainee is observed and mentored against specific inspection audit protocols;
- Competence assessment of the trainee against the relevant inspection audit forms.

During 2014 a new inspector joined the ORP on a half time basis. This inspector had previously worked for five years as a medical physicist in an Irish hospital and brought with her practical experience of working in both a nuclear medicine and a diagnostic X-ray department. She was warranted as an inspector by the RPII Board in April 2014 and following the completion of her training programme she was signed off as an inspector in December.

5. Inspection Programme 2014 – Main Findings

5.1. Main Inspection Findings for 2014

During 2014, ORP inspectors became involved in two major new work projects – preparatory work for the 2015 IAEA's IRRS peer review mission to Ireland and the development and testing of the new Regulatory IT system, GAMIS. Accordingly, a reduced inspection programme was undertaken in 2014 compared to previous years.

The areas of particular focus during the 2014 inspection programme included:

- Licensees who predominantly use sealed and unsealed radioactive sources, especially those with large numbers of, or high activity, sources;
- Licensees involved in the transport of radioactive sources with a particular focus on assessing compliance against the ADR requirements;
- The use of brachytherapy equipment in hospitals providing radiotherapy services
- Witnessing non-destructive testing activities in the field, particularly where licensees conduct these practices on third-party premises;
- The use of veterinary X-ray equipment at horse shows and sales venues where members of the public could have access to stables and other areas where horses might be examined.

In recent years, specific inspection projects have been undertaken in the dental and veterinary sectors. Between 2010 and 2013, 126 dental and 79 veterinary inspections were carried out. Similarly, the chiropractic sector has been the focus of targeted inspections each year, with each chiropractor licensee having been inspected within the past three years. For 2014 these sectors were not focussed on.

The completed Inspection schedule for 2014 is presented in Appendix I. The number of radiation protection focused inspections of licensed facilities carried out in 2014 was 103. This number includes 14 visits to sites suspected of having a historic lightning preventors dating back to the 1970s (these visits were outside the scope of the accreditation system). Ninety three per cent of inspection reports were issued within 28 days of the inspection date. The inspection programme outcome for 2014 was reviewed and issues arising from the particular areas of focus were noted together with additional high level observations.

5.1.1 Observations from Areas of Focus

- Nineteen licensees involved in the transport of radioactive material were inspected during the year. These included hospitals (as consignors), industry, industrial radiography companies and distributors. Some of the key ADR (transport) issues

identified during these inspections included inadequate or incorrect labelling and/or marking of the package or vehicle, vehicles not fully equipped as required under the ADR and ADR training certificates not being available where required. Where required, licences in the medical sector were requested to update their Radiation Safety Procedures and associated documentation to take into account of their obligations under the ADR.

- There was a significant increase in the number of inspections carried out in the Non Destructive Testing (NDT) sector in 2014. Nineteen inspections were carried out during the year – 14 administrative and five involving witnessing of NDT site work. The issues found were largely of an administrative nature and no significant radiation safety or transport related findings were observed during these inspections. While this sector has demonstrated good adherence to radiation safety principles, continued vigilance is required to ensure that this is maintained.

- Three radiotherapy inspections were undertaken which focused on a combination of administrative and practical aspects of radiation protection. The focus on brachytherapy applications which commenced in 2013 was continued during 2014. It was found in some cases that the tracking of iodine seeds during brachytherapy procedures and the detection of missing seeds were not fully addressed in Risk Assessments and Radiation Safety Procedures. Inspectors recommended that licensees perform an exercise simulating a lost seed to ensure they are adequately prepared for such an event. The focus on brachytherapy applications will continue in 2015 with a view to ensuring all facilities will have been inspected by the end of the year

- Following a concern expressed by a member of the public in 2013, in relation to the use of X-ray units at RDS Dublin Horse Show, an inspection of the arrangements for X-raying horses at the RDS was carried out during the 2014 horse show. The inspectors noted that a designated stable had been made available for veterinary radiography procedures and that it was suitable for mobile veterinary radiography procedures in line with the requirements of the RPII's Code of Practice for Radiation Protection in Veterinary Medicine. In contrast to the use of mobile X-ray units at horse sales venues, veterinary radiography procedures occur very infrequently at the show as injured horses are generally stabilised and transferred by ambulance to nearby UCD for treatment.

5.1.2 Additional High Level Observations

- Radiation protection standards across the industrial sector remain high. However, from an administrative point of view good record keeping and associated document management practices continues to be a challenge for licensees in this sector. This is evident during inspections where on occasion licensees were unable to produce documented risk assessments or copies of notification letters to the Chief Fire Officer

as required under the conditions of their licence. In addition, inspectors noted on occasions that refresher training for appointed Radiation Protection Officers was not being provided by employers.

- It was noted during the year that hospitals are now facing increased challenges to ensure that sufficient resources are made available to fully implement quality assurance (QA) testing programmes for licensed equipment.
- During a small, but important, number of hospital inspections inspectors found significant gaps in the QA records; poor communication and management issues relating to radiation protection; concerns in relation to the commitment to safety culture within the hospitals; inadequate RPA support and inadequate Medical Physics staffing levels. In all cases these issues were brought to the attention of the CEO/General Manager of the hospital who was advised that there issues must be addressed as a matter of urgency. Follow-up inspections were undertaken to determine whether these issues had been closed out to the satisfaction of the ORP.
- The installation and commissioning of a new CT scanner was halted by ORP Inspectors during an inspection of a hospital until safety concerns had been addressed. Once the safety concerns had been appropriately addressed the ORP was then in a position to authorise the installation and commissioning of the unit.
- Inadvertent exposures due to incorrect patient identification remain the most frequently reported incident to ORP. However it is evident from inspections carried out in 2014 that hospitals are working to improve their patient identification procedures to ensure that the right patient undergoes the right diagnostic or therapeutic procedure at all times. Further work is required by hospital staff to ensure that appropriate records are kept to verify that these identification procedures are being carried out.
- Inspectors focussed on the area of pregnancy determination protocols prior to medical diagnostic or therapeutic procedures during the latter half of 2014. A large variation in procedures and forms within hospitals was found, with some hospitals found not to have developed any in-house documented pregnancy determination procedures, instead relying on generic external procedures, while others had procedures which inspectors deemed were not sufficiently robust. Audits of records and discussions with clinical staff on the ground during inspections revealed inadequate documentation and misalignment between documented procedures and what happens in practice. The ORP will work with hospitals during 2015 to ensure that appropriate pregnancy determination protocols are available in all facilities.
- Three radiotherapy inspections were undertaken which focused on a combination of administrative and practical aspects of radiation protection. Risk assessments undertaken by the hospitals clearly show that doses to staff working in radiotherapy are as low as reasonably achievable. While personnel monitoring continues to be undertaken it is widely recognised that this is for reassurance purposes only.

- Several cardiac catheterisation, vascular and interventional procedures were witnessed during inspections of hospitals throughout the year. Inspectors focussed on observing operational radiation protection measures in practice by staff. Many licensees continue to implement eye dose monitoring programmes and are ensuring that the necessary personal protective equipment is available for relevant staff.
- Following a review of archive documentation relating to the use of lightning preventors containing radioactive sources in Ireland in the 1970s, 14 potential sites were identified where lightning preventors may have been in use. These were all visited during the year and seven preventors were duly discovered. The owners of the buildings where these preventors were located have all been advised that they must arrange for them to be removed and sent overseas for recycling as their continued use is no longer justified.

5.2. Enforcement Activities in 2014

- The ORP did not undertake any prosecutions in 2014.
- If during an inspection an inspector comes across a situation where there is a danger to persons arising from a source of ionising radiation they may issue a direction to the licensee ordering them to either cease carrying out an activity or alternatively to put measures in place to prevent or alleviate the danger. During 2014, there were no requirements for a direction to be issued.

6. Priority setting and programme planning for 2015

In line with EPA's procedures, a draft inspection schedule proposal was agreed for 2015 on 20th March and approved by the Board at its meeting on 31st March. It should be noted that the inspection programme agreed is a working plan that may be modified during the year in line with procedures should priorities change.

6.1. General Licensee Information

There are currently 1734 licensees across the dental, veterinary, medical, industrial, educational and distributor sectors. Of these, 263 fall within either the High or Medium risk categories. In taking a risk based approach to its inspection activities, ORP priorities those licensees in the High and Medium risk categories for inspections. A very small number of licensees in Low risk category will also be inspected, but these numbers are not considered to be statistically significant in terms of assessing general compliance within this category.

Within the High risk categories, there are four licensees who have not been inspected. One licensee currently doesn't have any licensable items, having recently returned them to the UK while the remaining three are based in the UK and involved from time to time in off-shore oil and gas exploration activities off the coast of Ireland. These may or may not undertake activities in Irish water in a given year, however where possible the ORP endeavours to carry out inspections of these licensees subject to scheduling considerations and being able to gain access to the off-shore platforms.

Within the Medium risk category there are 12 licensees who haven't been inspected, four of which are based in the UK. The inspection programme for 2015 proposes to carry out inspections of four of the remaining eight licensees.

6.2. Inspection Priorities for 2015

The general criteria that are used to develop the annual inspection programme are set out in Section 3. For 2015, inspectors will again be involved in two major projects – preparatory work for the IAEA's IRRS peer review mission of Ireland to be carried out in September 2015 and the development and testing of the new Regulatory IT system, GAMIS. Accordingly there are fewer resources available for the 2015 inspection programme compared to previous years and the inspection programme has been compiled taking this into account. However the advantages of a new IT systems and the outcome of the IAEA's peer review will contribute significantly to supporting future improvement in the ORP's regulatory approach. For 2016 it is expected that the numbers of inspections undertaken will substantially increase.

The areas of particular focus that inform the 2015 inspection programme include:

- Licensees engaged in high risk activities such as radiotherapy, non-destructive testing and radiopharmaceutical production;
- Licensees who predominantly use sealed and unsealed radioactive sources, especially those with large numbers of, or high activity, sources;
- Witnessing non-destructive testing activities in the field, particularly where licensees conduct these practices on third-party premises;
- A focus on hospitals' pregnancy determination protocols for patients undergoing diagnostic or therapeutic medical procedures;
- Medical facilities where RPA support is provided by an external, regional-based service;
- Follow up inspections of hospitals were concerns were noted in relation to quality assurance programmes during 2014;
- Three inspections (a hospital, industrial irradiation facility and a manufacturer of radiopharmaceuticals) will be undertaken during the IRRS mission where IAEA technical experts will witness how ORP performs its inspections to assess the EPA's competency and effectiveness in the field of radiation protection.

Table 4 details the breakdown of inspections planned for 2015 within the different risk categories. It is clear from the table that the High risk category has been prioritised, with 51% of licensees within this category scheduled to be inspected in 2015. For the Medium and Low risk categories the percentage of licensees that will be inspected in 2015 are 11% and 0.7% respectively.

Table 4: Inspections planned for 2015

Risk Category	No. of Licensees	No. of Inspections Planned
High	43	22
Medium	220	24
Low	1471	10
Total	1734	56

Table 5 details the breakdown of the 56 inspections planned for 2015. Over 70% of the planned inspections will be of licensees in either the High or Medium risk categories. Hidden within the numbers are differences in type and scope of inspections. For example, while a

hospital providing a broad range of services such as diagnostic, nuclear medicine and radiotherapy may be inspected, the scope of the inspection may be limited to only one of these areas. Most inspections are planned in advance but a number of unannounced inspections also take place each year. Inspections can also arise outside of the normal annual programme in response to an incidents or where a complaint has been received.

Table 5: Proposed Inspection Schedule for 2015

Licence Category	Risk Category	No. in Category	No. of Planned Inspections
Chiropractors	Medium	13	1
Others [e.g. scrap, lightning preventors]	Medium	13	0
Distributors (sources)	Medium	12	1
Hospital Level 1 (1 X-ray unit)	Medium	12	0
Hospital Level 2 (>1 X-ray unit)	Medium	58	8
Hospital Level 3 (Diagnostic X-ray + unsealed sources)	Medium	2	0
Education and Research	Medium	15	2
Industrial level 3 (sources, transport)	Medium	69	3
Industrial level 4 (> 6 sources)	Medium	9	3
Industrial level 5 (> 20 sources)	Medium	2	1
Vet (X-ray + equine nuclear medicine)	Medium	1	1
Industrial level 6 (fixed X-ray, sources, transport, ICSD assembly)	Medium/High	20	8
Hospital Level 4 (nuclear medicine)	Medium/High	17	6[d]
Hospital Level 5 (radiotherapy)	High	14	10[e]
Industrial level 7 (irradiation, e-beam, cyclotron and mobile container scanner)	High	6	2
Total		263	46
Licensees from the Low risk category (e.g. dentists, vets, DXA & cabinet X-ray units)	Low	-	10
Total (including inspections from the Low risk category)			56

[d] Two of these inspections will of nuclear medicine departments and four will be diagnostic X-ray departments
[e] Seven of these inspections will be of radiotherapy departments and three will be diagnostic X-ray departments

7. Radiation Protection Advisers

In accordance with Article 19 of S.I. No 125 of 2000, the EPA is required to establish and maintain a register containing the names of persons and corporate bodies approved as persons or bodies who may be appointed to act as Radiation Protection Advisers (RPA). During 2014 three new applications for RPA approval were received - one of these was approved in 2014, while consideration of the remaining two was carried over to 2015. Four applications for re-approval from the Category I register (medical, dental and veterinary) were also received during the year. Three of the re-approval applications were successful while the remaining one was requested to submit additional information in order that the reassessment could be completed. At the end of 2014, there were 36 individuals on the EPA's RPA register in addition to nine corporate body RPAs.

Each year all approved RPAs on the EPA's Category I and II RPA registers are invited to attend an annual RPA Liaison Meeting. The aim of this meeting is to provide updates to the RPAs on recent regulatory changes and developments, new issues that may affect them in the coming year(s) and to provide them an opportunity to raise any topical issues with the regulator. The fourth RPA meeting was held in April this year and was attended by 32 RPAs. This year's meeting included, for the first time, an external guest speaker to address the group on a topical issue – a representative of An Garda Síochána's National Crime Prevention Unit spoke about security considerations in the context of radioactive sources. A dedicated session on RPA challenges featured presentations from individual RPAs including challenges facing a medical facility after a major incident, challenges in the industrial radiography sector and high dose alerts in medical personnel dosimetry. Presentations were also made by ORP staff on issues such as the IAEA Integrated Regulatory Review Service Mission, development of the EU Basic Safety Standards, incidents involving the theft of radioactive sources and inspection findings during 2013. The agenda for the meeting is given in Appendix II.

Appendix I - Summary Table of Completed Inspection Schedule for 2014

Licence Category	No. in Category	Number of Inspections Proposed	Number of Inspections Completed
Chiropractors	15	1	1
Dentists	932	5	8
Distributors (sources & X-ray)	43	3	1
Hospital Level 1 (1 X-ray unit)	11	0	0
Hospital Level 1 (bone densitometer)	24	1	1
Hospital Level 2 (>1 X-ray unit)	59	8	10
Hospital Level 3 (as level 2 + unsealed sources for in-vitro)	2	1	1
Hospital Level 4 (nuclear medicine)	17	12	10[f]
Hospital Level 5 (radiotherapy)	14	11	8[g]
Education and Research	15	4	3
Industrial level 1 (cabinet style X-ray unit)	147	0	7
Industrial level 2 (electron capture devices, custody only)	12	1	1
Industrial level 3 (sources, transport)	65	6	6
Industrial level 4 (> 6 sources)	10	0	1
Industrial level 5 (> 20 sources)	2	0	0
Industrial level 6 (fixed X-ray, sources, transport, ICSD assembly)	20	14	20
Industrial level 7 (irradiation, e-beam, cyclotron and mobile container scanner)	6	1	3
Others (e.g. scrap, lightning preventors)	16	7	0
Vets	288	3	8
Non-licensees (e.g. air operators and underground workplaces)	19	2	14[h]

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

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

[h] Outside scope of accreditation

Security surveys (in conjunction with An Garda Síochána)	-	0	0
Total excluding non-licensees	1698	78	89
Total	1717	80	103

Appendix II - Agenda for 2014 RPA Liaison Day

09.30 – 10:00	Registration	
Session 1	Introductory Session	
10:00 – 10:05	Welcome Address	Ann McGarry
10:05 – 10:20	RPII/EPA Merger: The Office of Radiological Protection (ORP)	Ann McGarry
10:20 – 10:50	European and International updates (BSS & IRRS)	Tom Ryan
11:00 – 11:20	Coffee break	
Session 2	Inspection and Licensing	
11:20 – 11:40	Significant Inspection Findings	Jarlath Dufy
12:00 – 12:20	Quality Assurance Programmes	Hugh Synnott
12:20 – 12:40	Incidents – Response to Stolen Lightening Conductors	Jack Madden
12:40 – 13:45	Lunch	
Session 3	Guest Speaker:	
13:45 - 14:15	Good Security with regard to Radioactive Sources	Sgt Aidan Donnelly, An Garda Síochána
Session 4	RPA Challenges	
14:15 – 14:30	Industrial Radiography	Estelle Walker
14:30 – 14:45	“Flood! Challenge to Radiological protection as a result of a major incident.”	Wil van der Putten
14:45 – 15:00	Cardiologist Doses	Paddy Gilligan
15:00 – 15:20	Coffee	
Session 5	Regulatory Update	
15:20 – 15:50	What is coming down the line.....Graded Authorisation, New Regulations, RPAs and Whistle blowing, Prime Responsibility, Population Dose	Stephen Fennell
15:50 – 16:00	Discussion: - Issues from the floor	
16:00	Meeting Close	

AN GHNÍOMHAIREACHT UM CHAOMHNÚ COMHSHAOIL
Tá an Ghníomhaireacht um Chaomhnú Comhshaoil (GCC) freagrach as an gcomhshaol a chaomhnú agus a fheabhsú mar shócmhainn luachmhar do mhuintir na hÉireann. Táimid tiomanta do dhaoine agus don chomhshaol a chosaint ó éifeachtaí díobhálacha na radaíochta agus an truaillithe.

Is féidir obair na Gníomhaireachta a roinnt ina trí phríomhréimse:

Rialú: *Déanaimid córais éifeachtacha rialaithe agus comhlíonta comhshaoil a chur i bhfeidhm chun torthaí maithe comhshaoil a sholáthar agus chun díriú orthu siúd nach gcloíonn leis na córais sin.*

Eolas: *Soláthraímid sonraí, faisnéis agus measúnú comhshaoil atá ar ardchaighdeán, spriocdhírithe agus tráthúil chun bonn eolais a chur faoin gcinnteoireacht ar gach leibhéal.*

Tacaíocht: *Bímid ag saothrú i gcomhar le grúpaí eile chun tacú le comhshaol atá glan, táirgiúil agus cosanta go maith, agus le hiompar a chuirfidh le comhshaol inbhuanaithe.*

Ár bhFreagrachtaí

Ceadúnú
Déanaimid na gníomhaíochtaí seo a leanas a rialú ionas nach ndéanann siad dochar do shláinte an phobail ná don chomhshaol:
- saoráidí dramhaíola *(m.sh. láithreáin líonta talún, loisceoirí, stáisiúin aistrithe dramhaíola)*;
- gníomhaíochtaí tionsclaíocha ar scála mór *(m.sh. déantúsaíocht cógaisíochta, déantúsaíocht stroighne, stáisiúin chumhachta)*;
- an diantalmhaíocht *(m.sh. muca, éanlaith)*;
- úsáid shrianta agus scaoileadh rialaithe Orgánach Géinmhodhnaithe *(OGM)*;
- foinsí radaíochta ianúcháin *(m.sh. trealamh x-gha agus radaiteiripe, foinsí tionsclaíocha)*;
- áiseanna móra stórála peitril;
- scardadh dramhuisce;
- gníomhaíochtaí dumpála ar farraige.

Forfheidhmiú Náisiúnta i leith Cúrsaí Comhshaoil
- Clár náisiúnta iniúchtaí agus cigireachtaí a dhéanamh gach bliain ar shaoráidí a bhfuil ceadúnas ón nGníomhaireacht acu.
- Maoirseacht a dhéanamh ar fhreagrachtaí cosanta comhshaoil na n-údarás áitiúil.
- Caighdeán an uisce óil, arna sholáthar ag soláthraithe uisce phoiblí, a mhaoirsiú.
- Obair le húdaráis áitiúla agus le gníomhaireachtaí eile chun dul i ngleic le coireanna comhshaoil trí chomhordú a dhéanamh ar líonra forfheidhmiúcháin náisiúnta, trí dhíriú ar chiontóirí, agus trí mhaoirsiú a dhéanamh ar leasúchán.
- Cur i bhfeidhm rialachán ar nós na Rialachán um Dhramhthrealamh Leictreach agus Leictreonach (DTLL), um Shrian ar Shubstaintí Guaiseacha agus na Rialachán um rialú ar shubstaintí a ídíonn an ciseal ózóin.
- An dlí a chur orthu siúd a bhriseann dlí an chomhshaoil agus a dhéanann dochar don chomhshaol.

Bainistíocht Uisce
- Monatóireacht agus tuairisciú a dhéanamh ar cháilíocht aibhneacha, lochanna, uiscí idirchriosacha agus cósta na hÉireann, agus screamhuiscí; leibhéil uisce agus sruthanna aibhneacha a thomhas.
- Comhordú náisiúnta agus maoirsiú a dhéanamh ar an gCreat-Treoir Uisce.
- Monatóireacht agus tuairisciú a dhéanamh ar Cháilíocht an Uisce Snámha.

Monatóireacht, Anailís agus Tuairisciú ar an gComhshaol
- Monatóireacht a dhéanamh ar cháilíocht an aeir agus Treoir an AE maidir le hAer Glan don Eoraip (CAFÉ) a chur chun feidhme.
- Tuairisciú neamhspleách le cabhrú le cinnteoireacht an rialtais náisiúnta agus na n-údarás áitiúil *(m.sh. tuairisciú tréimhsiúil ar staid Chomhshaol na hÉireann agus Tuarascálacha ar Thascairí)*.

Rialú Astaíochtaí na nGás Ceaptha Teasa in Éirinn
- Fardail agus réamh-mheastacháin na hÉireann maidir le gáis cheaptha teasa a ullmhú.
- An Treoir maidir le Trádáil Astaíochtaí a chur chun feidhme i gcomhair breis agus 100 de na táirgeoirí dé-ocsaíde carbóin is mó in Éirinn.

Taighde agus Forbairt Comhshaoil
- Taighde comhshaoil a chistiú chun brúnna a shainaithint, bonn eolais a chur faoi bheartais, agus réitigh a sholáthar i réimsí na haeráide, an uisce agus na hinbhuanaitheachta.

Measúnacht Straitéiseach Timpeallachta
- Measúnacht a dhéanamh ar thionchar pleananna agus clár beartaithe ar an gcomhshaol in Éirinn *(m.sh. mórphleananna forbartha)*.

Cosaint Raideolaíoch
- Monatóireacht a dhéanamh ar leibhéil radaíochta, measúnacht a dhéanamh ar nochtadh mhuintir na hÉireann don radaíocht ianúcháin.
- Cabhrú le pleananna náisiúnta a fhorbairt le haghaidh éigeandálaí ag eascairt as taismí núicléacha.
- Monatóireacht a dhéanamh ar fhorbairtí thar lear a bhaineann le saoráidí núicléacha agus leis an tsábháilteacht raideolaíochta.
- Sainseirbhísí cosanta ar an radaíocht a sholáthar, nó maoirsiú a dhéanamh ar sholáthar na seirbhísí sin.

Treoir, Faisnéis Inrochtana agus Oideachas
- Comhairle agus treoir a chur ar fáil d'earnáil na tionsclaíochta agus don phobal maidir le hábhair a bhaineann le caomhnú an chomhshaoil agus leis an gcosaint raideolaíoch.
- Faisnéis thráthúil ar an gcomhshaol ar a bhfuil fáil éasca a chur ar fáil chun rannpháirtíocht an phobail a spreagadh sa chinnteoireacht i ndáil leis an gcomhshaol *(m.sh. Timpeall an Tí, léarscáileanna radóin)*.
- Comhairle a chur ar fáil don Rialtas maidir le hábhair a bhaineann leis an tsábháilteacht raideolaíoch agus le cúrsaí práinnfhreagartha.
- Plean Náisiúnta Bainistíochta Dramhaíola Guaisí a fhorbairt chun dramhaíl ghuaiseach a chosc agus a bhainistiú.

Múscailt Feasachta agus Athrú Iompraíochta
- Feasacht chomhshaoil níos fearr a ghiniúint agus dul i bhfeidhm ar athrú iompraíochta dearfach trí thacú le gnóthais, le pobail agus le teaghlaigh a bheith níos éifeachtúla ar acmhainní.
- Tástáil le haghaidh radóin a chur chun cinn i dtithe agus in ionaid oibre, agus gníomhartha leasúcháin a spreagadh nuair is gá.

Bainistíocht agus struchtúr na Gníomhaireachta um Chaomhnú Comhshaoil
Tá an ghníomhaíocht á bainistiú ag Bord lánaimseartha, ar a bhfuil Ard-Stiúrthóir agus cúigear Stiúrthóirí. Déantar an obair ar fud cúig cinn d'Oifigí:
• An Oifig um Inmharthanacht Comhshaoil
• An Oifig Forfheidhmithe i leith cúrsaí Comhshaoil
• An Oifig um Fianaise is Measúnú
• An Oifig um Cosaint Raideolaíoch
• An Oifig Cumarsáide agus Seirbhísí Corparáideacha
Tá Coiste Comhairleach ag an nGníomhaireacht le cabhrú léi. Tá dáréag comhaltaí air agus tagann siad le chéile go rialta le plé a dhéanamh ar ábhair imní agus le comhairle a chur ar an mBord.

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