Radiological Protection Institute of Ireland

An Institiúid Éireannach um Chosaint Raideolaíoch

RPII Inspection and Licensing Activities and Annual Inspection Programme for 2014

Prepared by

The Regulation and Information Management Division

RPII 14/01

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Foreword

The purpose of this document is to promote transparency in the activities of the Radiological Protection Institute of Ireland (RPII) discussed herein. It explains aspects of the internal workings of the Regulation and Information Management Division (RIMD) of the RPII to aid understanding of the processes and decisions of that Division 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 RPII 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 RPII 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 RPII 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 provides for the RPII 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 RPII to appoint inspectors and Section 29 sets out the powers of inspectors appointed under the Act.

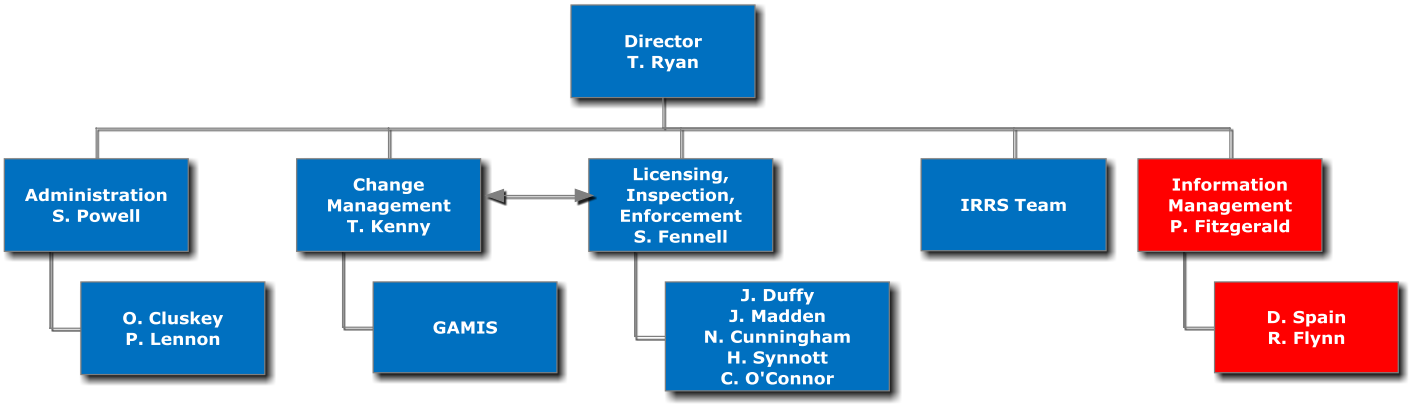
The Radiological Protection Act, 1991 (Ionising Radiation) Order 2000 (S.I. No. 125 of 2000) implements Council Directive 96/29/Euratom and sets out basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation. The RPII's licensing system is based upon these legal requirements and the day to day responsibility for implementing the system has been delegated to the Regulation and Information Management Division (RIMD). Inspections undertaken by the RIMD 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 regulatory function is organised as set out in Figure 1. In addition, an external consultant and warranted inspector, Prof Pat Horton, assists the RIMD in carrying out inspections at radiotherapy facilities. It should be borne in mind when considering the resources available to the RIMD 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 business plans for RPII.

The objective of this report is to provide an overview of inspection activities of the RPII, 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 2014 as well as the programme as approved by the Board of the RPII.

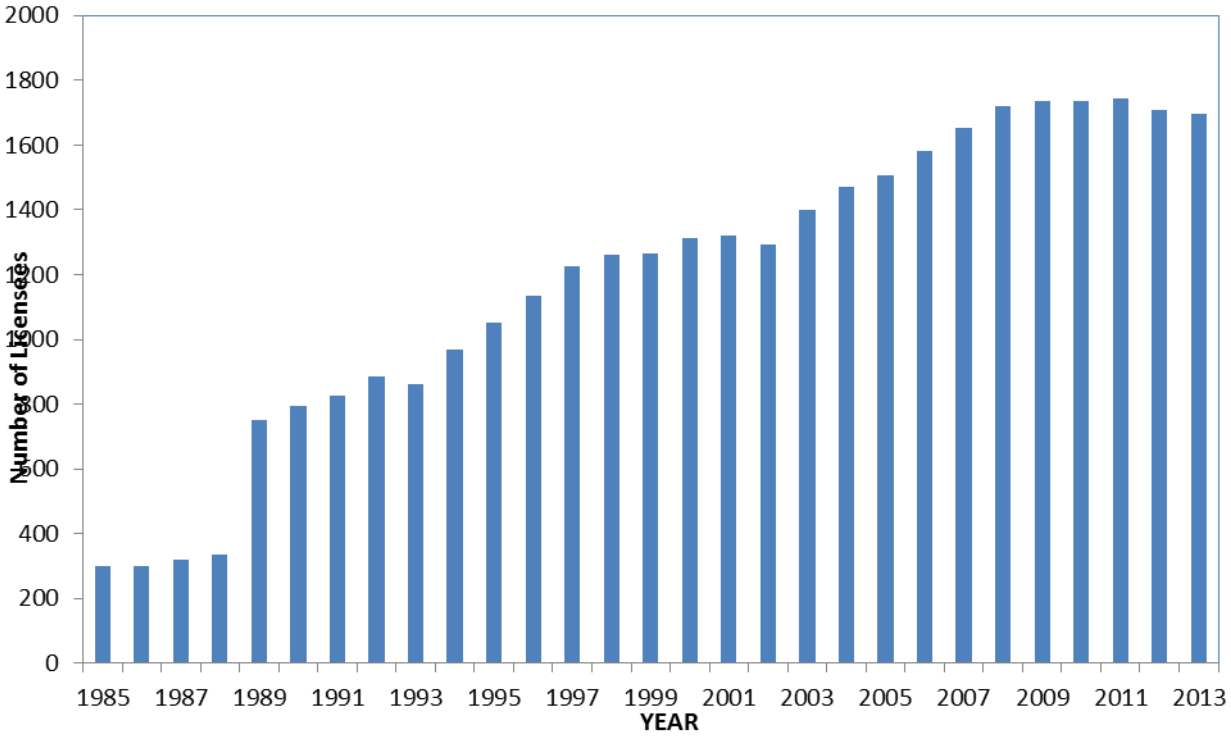
Figure 1: Regulation and Information Management Division Structure and Staff



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[1]. 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 dropped off slightly in recent years (Figure 2). On the 1st January 2014 there were 1698 active licences.

Figure 2: RPII Licensee Numbers (1985 to 2013)



2.1. Licence Categorisation

Licensees are divided into different bands which are further sub-divided into categories or 'levels'. The band divisions represent a broad categorisation and the sub-divisions reflect a 'judgement of risk'.

Over the years the bands and categories have been extended to track the tailoring of licence conditions to new types of practices. The result is the division of licensees into nine bands which are further divided into approximately 24 different categories or levels. While seemingly complicated, this system has served the RPII well over many years.

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

It should be noted that from the point of view of an applicant to the RPII, applicants are only categorised as 'Low', 'Medium' or 'High'. This reflects a re-grouping of the existing licensees across the bands to reflect the 'risk and effort' profile for each and this was carried out as part of the financial review to determine the revised licence fee schedule introduced in October 2007.

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

i. Industrial (Sub Categories: Level 1–7)
ii. Medical (Sub Categories: Level 1–5)
iii. Educational/Research and Laboratories (Sub categories: Level 1–3)
iv. Distributor (Sub Categories: Level 1–3)
v. Dental (Sub Categories: Level 1–3)
vi. Veterinary (Sub Categories: Level 1–2)
vii. Custody Only

In the main, the sub-categories reflect the differing levels of 'risk' where such risk has been equated with the complexity of the process and the number and activity of sources and irradiating apparatus being held and/or used. An example of this is a hospital offering radiotherapy services which is categorised as 'Medical – Level 5' while a process irradiation facility is categorised as 'Industrial – Level 7'. In contrast, a small hospital providing X-ray services with only one unit and without other diagnostic or therapeutic facilities such as CT, mammography or fluoroscopy is 'Medical – Level 1'. On the industrial side, a company that has custody and use of a simple cabinet X-ray machine is categorised as 'Industrial – Level 1'.

2.2. The Licensees

On the 1st January 2014 there were 1698 active licences as presented in Figure 3. The dental sector makes up 55% of these followed by the veterinary and industrial sectors at 17% and 16% respectively.

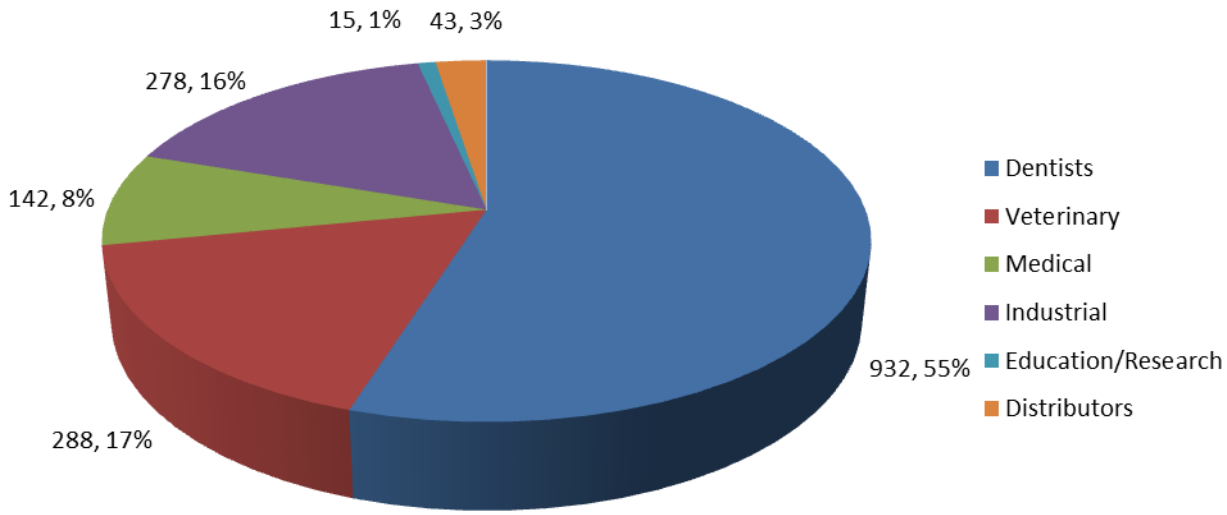
2.2.1. Dental

There are currently 932 licensees in this band and for the most part they comprise private dental surgeries with a single X-ray unit. Increasingly there are dental practices using more complex procedures with ten licensees currently employing dental cone beam CT. In addition seven licensees are licensed for the use of a hand-held dental X-ray unit.

2.2.2. Veterinary

There are currently 288 licensees in this band and for the most part they comprise private veterinary surgeries with a single portable X-ray unit used in a fixed location. Some of these licensees also use their portable units in the field, particularly those associated with large animal practices including the equine industry. Horse sales are included in this sector and there is also one nuclear medicine facility catering exclusively for the thoroughbred industry.

Figure 3: Licensees by Sector 1st January 2014



2.2.3. Medical

There are currently 142 licences active under the broad 'Medical' band. This is made up of seven sub-categories as set out in Figure 4. Ninety six (68%) of these licensees fall into Levels 1–3 and comprise facilities ranging from those using one simple X-ray unit, to those using unsealed sources for limited in-vitro applications. The remaining 46 licensees comprise chiropractors (15) and those medical facilities engaged in nuclear medicine and radiotherapy - typically providing a combination of complex services.

2.2.4. Industrial

There are currently 278 licences active under the broad 'Industrial' band. This is made up of seven sub-categories as set out in Figure 5. Two hundred and twenty four (81%) of these licensees fall into Levels 1 -3 and comprise facilities that use one simple cabinet X-ray unit or line baggage inspection unit, to those holding lightning preventors or those that use unsealed sources and portable gauges such as nuclear moisture density gauges as well as sources held for storage until a disposal route is identified. The remaining 54 licensees comprise those with more than six sources, or those engaged in significant transport activities, non-destructive testing, process irradiation and custody of sources.

2.2.5. Education/Research

There are 15 licensees in the category of education and research. These typically include the use of both sealed and unsealed sources for teaching and research purposes and licences could include transportation and disposal within their scope.

2.2.6. Distributor

There are currently 43 licensees holding licences for distribution of radioactive material and or irradiating apparatus supplying services across all of the sectors.

Figure 4: Medical Band by Level, 1st January 2014

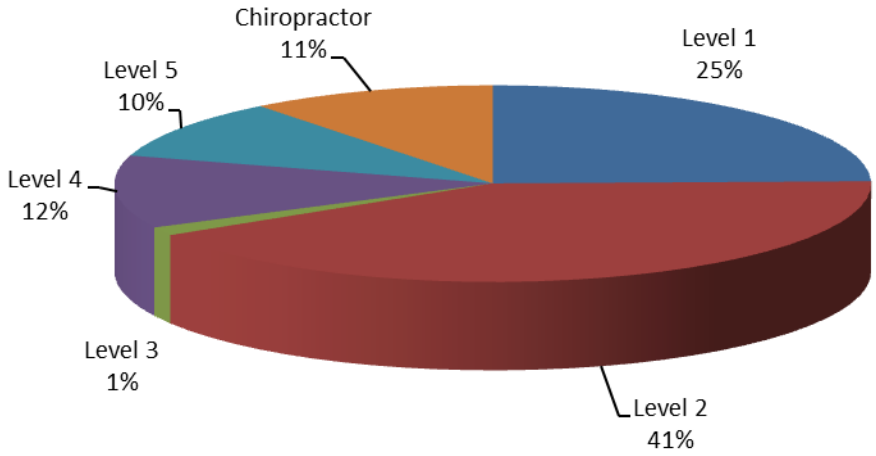
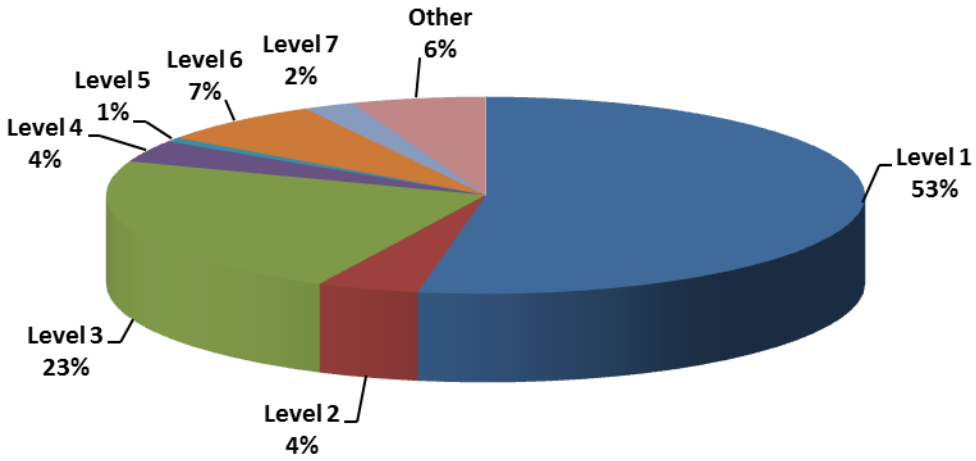


Figure 5: Industrial Band by Level, 1st January 2014



3. Inspections

While the formal licensing system commenced in 1977, the available records show that 59 inspections were carried out in 1983[2], though it is likely that inspections had taken place in the previous years. Figure 6 illustrates the number of inspections undertaken in the years 1985 to 2013, ranging from 56 in 1988 to a peak of 256 in 1997. The number of radiation protection focused inspections of licensed facilities carried out in 2013 was 173. In addition, one security audit[3] was carried out in conjunction with An Garda Síochána during the year.

The RPII 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. In accordance with the strategic objectives set out in the RPII's new Strategic Plan for 2014 – 2015, the RIMD will commence work on two major new projects during 2014. The first of these is 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 providing for alternative types of authorisation to licensing, such as registration and notification, which will be required under the new European Basic Safety Standards Directive. The second project relates to the IAEA's IRRS[4] peer review of Ireland, to be undertaken in 2015, which requires the self-assessment preparatory work to be undertaken during 2014. Both of these projects will require significant inspector resources during the year and for that reason a reduced inspection programme will be undertaken in 2014.

While the number of inspections planned for 2014 will be significantly lower than in previous years, RIMD will continue to undertake inspections of licensees engaged in the highest risk activities. Table 1 details the 80 inspections planned for 2014. Hidden within the numbers are differences in type and scope of inspections. For example, a hospital providing a broad range of services such as diagnostic, nuclear medicine and radiotherapy may be inspected with the scope of the inspection 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 arise outside of the normal annual programme where incidents are investigated.

Figure 7 illustrates the focus of inspections in the period between 2003 and 2013. It is evident that the inspection numbers have been weighted towards the medical and industrial areas. A more detailed analysis demonstrates that the primary focus is on the higher level categories within the bands representing a general 'risk' based approach to setting the inspection programme. It should be noted that inspections are not viewed as the only means of enforcement. In particular, the RPII 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

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2 Data is taken from annual reports, where systematic records of inspection numbers only commenced in 1985

3 This type of audit is outside the scope of the RIMD's ISO 17020 accreditation

4 Integrated Regulatory Review Service

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 RPII 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 RPII. 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 to date no formal direction to measure radon has been issued to an underground workplace, all underground workplaces have carried out radon monitoring and were inspected[5] 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.

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

Figure 6: Inspections Undertaken by RPII/NEB (1985 to 2013)

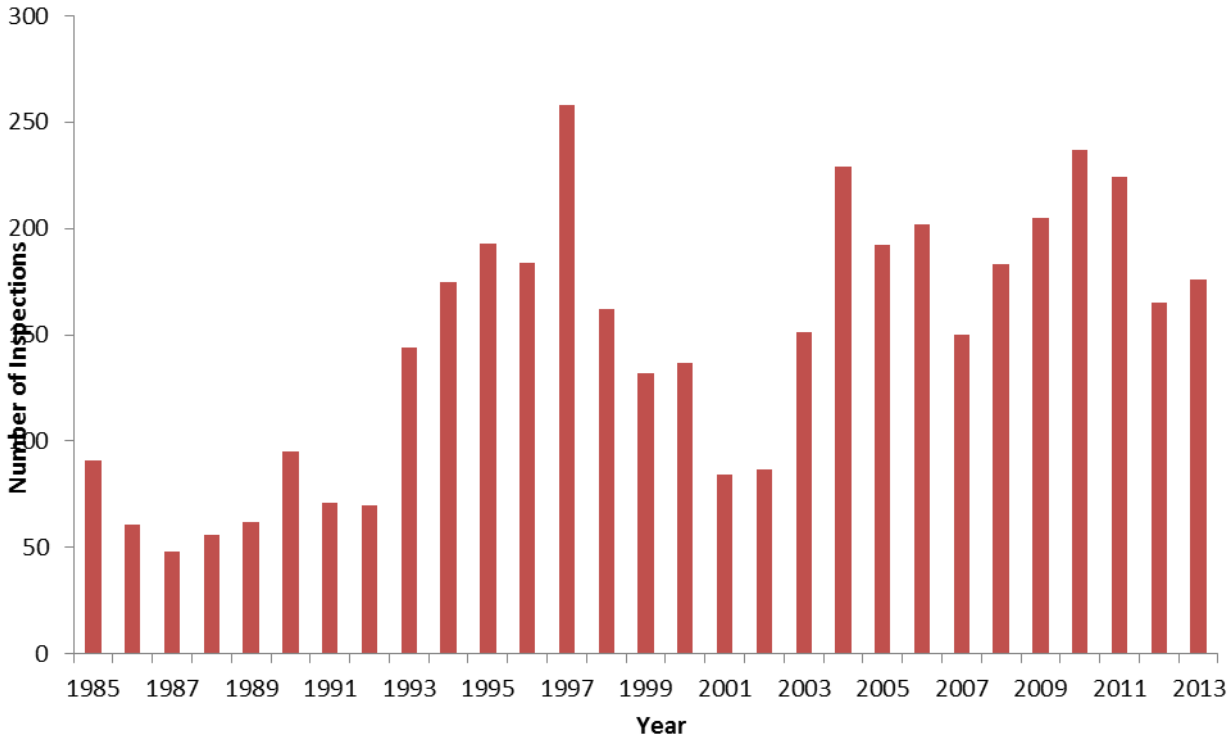
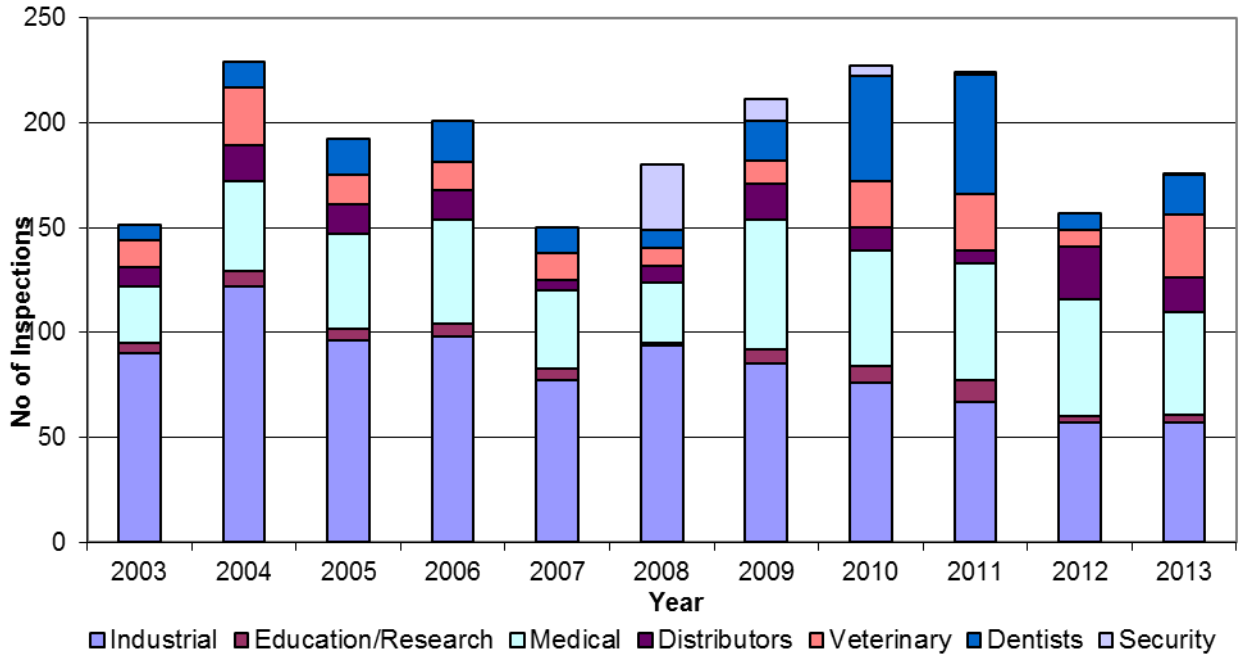


Figure 7: Inspection Focus (2003 to 2013)



4. Development of the 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 and the broader provisions of the quality system are described in Section 5. For the purposes of this report it is appropriate to describe in detail the procedure used and considerations that are currently taken into account in devising and agreeing the annual inspection programme.

Towards the end of each year, work begins on compiling the inspection programme for the forthcoming year. A draft inspection schedule is drawn up, taking account of the following factors and available staff resources:

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

The draft inspection schedule identifies most individual licensees to be inspected as well as the scope of the inspections. However, for some categories it is generally not necessary to identify the individual licensee that will be inspected given the nature of the practices involved. For these categories the inspection schedule identifies the number of licensees within these categories that will be inspected. When the draft schedule has been compiled, the inspection team meets to review the selection criteria used, the number of planned inspections, the licensees to be inspected, the scope of the inspections and any requirements to use the services of external consultants. The draft schedule is amended accordingly.

A meeting is held between the Director and the Technical Manager to devise the final version of the inspection programme for the forthcoming calendar year and the discussions are based on the draft schedule. The Director reviews the criteria used to compile the schedule and the number of planned inspections and may suggest modifications. Once the programme and its associated schedule have been signed off by the RIMD it is presented to the Board for its consideration and approval.

The inspection programme is monitored and reviewed continuously throughout the year at the inspectors' meetings. Modifications to the inspection schedules and ultimately the annual inspection programme may be made at any stage during the year with the approval of the Technical Manager. At the end of each year the Technical Manager, or a delegated inspector, undertakes a review of the number of completed inspections carried out with respect to the approved schedule. A summary of this review is discussed at the Annual Management Review Meeting and is maintained on the inspection programme file.

While the annual inspection programme is approved by the Board 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 RIMD by any individual;
- The reporting of an incident involving a licensable item to the RIMD in compliance with licensing conditions;
- Where the RIMD is notified of a dose recorded on a personal dosemeter which exceeds the reporting levels as defined in the licence conditions.

Where the RIMD is informed of any such event the details are immediately brought to the attention of the Director. The Director and Technical Manager discuss the circumstances, severity and possible implications of the notified events and where an inspection is warranted the details of the inspection to be undertaken are included on the inspection programme. In addition, the RIMD is open to requests from licensees to perform inspections. The Director will review all requests for inspections and where appropriate the inspection programme is updated accordingly.

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. This may only be done with the authorisation of the Technical Manager following discussion with the Director.

5. Accreditation

The RIMD has developed a quality system for its inspection activities in line with ISO 17020 which is an international standard specifically designed for inspection bodies. Accreditation for the full scope sought was achieved in December 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. While the arrangements for developing an annual inspection programme were detailed in Section 4, it is instructive to summarise the other relevant procedures in the quality system such as those governing inspectors, inspectors' meetings, inspector training, inspection, and post inspection activities.

During 2013, the RIMD 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 RIMD assesses the competency of its inspectors through an annual inspection witnessing programme where each inspector is witnessed at least once a year carrying out an inspection by the Technical Manager.

5.1. 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 RIMD:

'It is the policy of the Regulation and Information Management Division (RIMD) of the Radiological Protection Institute of Ireland, to achieve and maintain a standard of quality which is consistent with client and regulatory requirements of the inspection work it carries out. Therefore, as a Type A Inspection Body it is committed to maintaining its status as an ISO 17020 Inspection Body.

To attain this level of excellence the RIMD will aspire to achieve the following objectives[6]:

1. *Complete all scheduled inspections as defined in the Inspection Programme for 2014;*
2. *Issue all Inspection Reports within 28 days of the inspection date;*
3. *Systematically and periodically collate elements of good practice for dissemination to relevant parties;*
4. *Undertake an analysis of the inspection findings annually and present the outcome of the analysis, including any resulting actions identified, at the Annual Inspection Review Meeting;*
5. *Document and publish the RPII Annual Inspection Activity Programme;*
6. *Undertake targeted inspections to address specific issues within particular sectors or to identify issues where further regulatory action is required within the sector.*

The RIMD is also committed to the continuous improvement of the effectiveness of its quality management system. It aims to provide all licensees, at all times, with a service complying with the

[6] Quality objectives are updated annually

Irish National Accreditation Board (INAB) accreditation standard for all the work for which it has been accredited.

The Director of the RIMD has ultimate responsibility for both Quality Assurance and Quality Control in the Division. 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 the ISO 17020 Standard.

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

5.2. Inspectors' Responsibilities

All Inspectors report directly to the Technical Manager and in his/her absence, to the Director. In particular, Inspectors, under the direction of the Technical Manager, have responsibility, inter alia, to:

- Plan and arrange inspections of licensee facilities in accordance with the approved annual inspection programme;
- Communicate the rationale, purpose and objectives of each inspection to the licensee;
- Undertake inspections using the appropriate Audit Form and accurately record the findings;
- Be familiar with the relevant legislation and licence conditions pertaining to the particular categories of inspection;
- Apply technical knowledge and professional judgement to interpreting the findings of an inspection;
- Report on the findings of an inspection in the form of a written report which is issued to the licensee;
- Liaise with the appropriate Technical Manager and/or Director regarding the findings of an inspection and agreeing appropriate action to be undertaken, where relevant;
- Issue recommendations, directions and enforcement notices, as required;
- Follow-up inspections as appropriate;
- Attend and participate in inspectors' meetings;
- Ensure that the calibration and maintenance of test/measurement equipment is carried out in accordance with the equipment schedule;
- Adhere to and ensure that all work is performed in accordance with the agreed Quality Procedures;
- Carry out their work in a courteous and professional manner;
- Adhere to all health and safety requirements of both the RPII and the licensee, where appropriate, and without prejudice to statutory powers.

5.3. Inspectors' Meetings

Inspectors' meetings are convened by the Technical Manager or delegated inspector at least twice annually. The inspectors' meetings provide a forum for systematically and periodically identifying elements of good practice for dissemination to licensees and the analysis of non-conformances identified at inspection to determine specific actions required to address them.

At a minimum this meeting has the following agenda items:

i. Review of inspections carried out;
ii. Issues arising (corrective actions/good practice);
iii. Forthcoming inspections/allocation of inspections;
iv. Inspection audit forms;
v. Review of the inspection schedule;
vi. Close out of inspections.

The Technical Manager or delegated inspector circulates a summary of actions and decisions of the meeting to the attendees. Additionally, a divisional inspectors' meeting is held annually to review the inspection programme for the previous year. This meeting is attended by the Director, Technical Manager and all inspectors. The Chief Executive is also invited. This meeting provides a formal opportunity to share experiences relating to inspection work and will typically include discussion of the following:

i. Inspections undertaken during the year;
ii. Lessons learned;
iii. Observations of interest;
iv. Identification of common/frequent findings.

5.4. Inspection Procedure

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. This is formally recorded on the inspection audit form. Where possible, the licensee's representatives should include a representative from senior management. The meeting is chaired by the Lead Inspector. The inspector will have his/her warrant available for examination.

Inspections are carried out using specifically designed inspection audit forms. Each item on the form is addressed during the inspection and a record made of the responses obtained. For items that are not relevant, or applicable, that particular section of the form is marked to clearly indicate this.

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 ionising radiation is used and/or stored appropriate to the scope of the inspection. The audit form provides an inspection trail for the inspector in completing this process. Any items requiring attention, as well as observations are noted.

Where an inspector observes a situation which compromises radiation safety and which in the opinion

of the inspector, poses a serious hazard to workers or members of the public the licensee or representative is advised of this issue immediately. A decision on any actions required by the licensee to address the issue is made by the inspector after consultation with the Technical Manager and Director, if appropriate. This decision is communicated to the licensee and recorded on the inspection audit form. The inspection also includes the examination of all relevant documents and records appropriate to the scope of the inspection.

On completing the site inspection the inspector(s) reviews the findings of the inspection in private and prepares a written summary detailing the non-compliances observed, items requiring attention 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(s) and the licensee's representatives at which the summary of the inspection findings is presented verbally. The licensee is informed that a formal report of the inspection findings will be forwarded within four weeks and that a written response to the inspection report must be forwarded to the RPII within four weeks of the date of issue of the report or as appropriate to the circumstances. Where an inspector is of the opinion that there is or may be an immediate danger on site s/he 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.

5.5. Post Inspection Follow up

The RIMD issues an 'Inspection Report' to the licensee following an inspection. The inspection report includes a list of the non-compliances observed, as measured against the licence conditions and relevant legislation, items requiring attention and recommendations for improvement/best practice. The RIMD does not issue Certificates of Conformance following an inspection.

Detailed inspection records are maintained on licensee files including the completed inspection audit form and a copy of the inspection report. The inspection report is sent to the licensee.

The inspection report which is issued on RPII headed paper includes the following information:

- Date of issue;
- Unique identification in the form of licence number and date of inspection;
- Identification of the issuing body and the licensee;
- The date the inspection was undertaken and the location of the inspection;
- The scope of the inspection undertaken stating the particular aspect of the facility and licensed item(s) which was inspected and any areas that were omitted;
- Identification of the regulations and procedures against which the inspection was performed;
- Identification of test equipment used or samples taken, where applicable;
- A summary of the inspection findings requiring action;
- Recommendations for good practice;
- A date by which a written response to the actions is required;

- The signature of the inspector who performed the inspection;
- The names of the licensee's representatives who were in attendance during the inspection;
- A statement that the inspection report and its findings only relate to the scope of the inspection as identified therein.

5.6. 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.

6. Inspection Programme 2013 – Main Findings

6.1. Main Inspection Findings for 2013

The 2013 inspection programme was developed with a particular focus on the following:

- The use and application of radioactive sources for brachytherapy treatments within radiotherapy departments of hospital licensees. The radioactive sources used for these procedures, typically iodine-125 seeds and iridium-192, pose certain specific challenges to staff delivering this treatment due to the nature of the high activities involved.
- The use of complex X-ray systems for interventional procedures such as cardiac catheterisation and vascular procedures. These procedures are carried out in dedicated X-ray interventional laboratories within imaging departments of licensed hospitals requiring hospital staff to be within the controlled area while X-rays are being generated.
- The use of medical mobile X-ray units in areas outside the main hospital radiology department such as mortuaries and specialist equipment such as O-arm X-ray units for use in operating theatres.
- Activities associated with the distribution and transport of radioactive sources to ensure that the delivery and receipt of radioactive sources is carried out in accordance with licence conditions and that documented protocols exist in the event of scheduled deliveries being altered.
- Dental facilities holding a licence for custody and use of hand held dental radiography units.
- Holders of radioactive waste and disused sources in the private sector with a view to ensuring that all such materials continue to be maintained in a safe and secure manner and that all steps are being pursued for the return or authorised disposal of such material.
- Holders of lightning preventers to determine whether the on-going safety and security arrangements are appropriate.
- The security and storage arrangements for nuclear moisture density gauges.
- The continuing work of ensuring safety in underground workplaces.

The completed Inspection schedule for 2013 is presented in Appendix 1. The number of radiation protection focused inspections of licensed facilities carried out in 2013 was 173 with one additional security audit[7] carried out in conjunction with An Garda Síochána. The inspection programme outcome for 2013 was reviewed and issues arising from the particular areas of focus were noted together with additional high level observations.

6.1.1. Observations from Areas of Focus

- In advance of the enactment of the Euratom Waste Directive in August 2013, particular focus

[7] This type of audit is outside the scope of the accreditation

was given to the inspection of licensees that had not yet disposed of their legacy radioactive waste under the National Inventory Reduction Programme approved by Government in 2010. Inspections of licensees holding disused sources and radioactive waste, including lightning preventors, were carried out across the medical, industrial, educational and state sectors. These inspections, in conjunction with other regulatory initiatives, resulted in a 99% reduction in the national inventory of disused sources with $T_{½}$ > 10 yrs between 2010 and 2013.

- Six radiotherapy inspections were undertaken which focused on a combination of administrative and practical aspects of radiation protection. A number of specific brachytherapy treatments were also observed during these inspections. While risk assessments had been undertaken by licensees, in some cases the documented assessments did not adequately address all the risks or include the basis for categorisation of relevant staff as exposed workers. The focus on brachytherapy applications will continue in 2014 with a view to ensuring all facilities will have been inspected in the period 2013-2014.

- Several cardiac catheterisation, vascular and interventional procedures were witnessed during inspections of hospitals. Inspectors focussed on observing operational radiation protection measures in practice by staff. It is reassuring to note that there has been an increased awareness of both the proposed new ICRP dose limits for the lens of the eye and the necessary protection measures needed to ensure that eye doses are kept as low as reasonably achievable. Many licensees have already implemented eye dose monitoring programmes and are ensuring that the necessary personal protective equipment is available for relevant staff.

- The RIMD reviewed the use of mobile X-ray units in hospital mortuaries for post mortem examinations to determine whether additional radiation protection measures were required. Inspectors noted that mobile X-ray units are seldom used in mortuaries with the vast majority of such procedures taking place in hospital X-ray departments after hours. Inspectors also looked at the use of mobile O-arm fluoroscopy units in theatres, which are a relatively new type of unit in Ireland, and found it to be infrequent. In all cases inspectors were satisfied with the radiation protection arrangements that relate to the use of these types of units.

- Eighteen dental practices licensed for either hand-held intra-oral units or cone beam CT systems were inspected during the year. Some of the areas identified for improvement include better record keeping and ensuring that quality assurance (QA) testing programmes for the X-ray equipment are fully implemented.

- Three holders of nuclear moisture density gauges were inspected to ensure that appropriate safety and security provisions remain in place for these sources following the dramatic downturn in the construction sector in recent years. During the course of the inspections, licence holders were strongly encouraged to exercise take back agreements for those gauges that are no longer required for use. No issues of concern relating to safety and security arrangements were identified during these inspections.

- Thirteen licensees involved in the transport of radioactive material were inspected during the year. Some of the key ADR (transport) non-compliance issues identified during these inspections include 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.

- A downturn in work in the non-destructive testing (NDT) sector was again noted during 2013 resulting in fewer notifications of intended site radiography work during the year. Eight inspections were carried out during the year – six administrative and two involving witnessing of NDT site work. While the issues found were largely of an administrative nature no significant radiation safety or transport related findings were observed during these inspections.

- There are five show caves in Ireland where exposure to elevated levels of radon may be of concern. Inspectors visited two of these caves in 2013 to review the arrangements in place for radiation protection. All show caves have now been visited over the period 2012-2013. A review of the findings from all visits will be undertaken in 2014 to determine whether any additional measures need to be put in place.

- In 2013, the RIMD initiated a project to follow up on licence application forms previously issued within the veterinary sector, where these applications were never submitted to the Institute for processing. Thirty inspections were undertaken as part of this project which included short notice or unannounced inspections of small animal, mixed practices and those with multiple premises across the country. It was noted in the majority of cases, there was compliance for the most part with the Code of Practice for Radiation Protection in Veterinary Medicine.

- The RIMD also carried out several site visits during the construction phase of Ireland's first Cyberknife Robotic Radiosurgery System which was followed up with an inspection once it was licensed for full clinical use.

- An acute hospital where a major flood caused an entire X-ray department to be closed, requiring the establishment of a new temporary X-ray department on the hospital grounds, was also inspected to ensure that the new temporary arrangements provided for the required radiation protection arrangements.

6.1.2. Additional High Level Observations

- Standards of radiation protection across the medical sector remain high with many examples of good radiation protection practice observed during the year. Hospitals continue to face challenges to ensure that sufficient resources are available to fully implement quality assurance (QA) testing programmes for licensed equipment and the RIMD will continue to monitor this closely in the coming years. It is also evident from the inspections carried out, that hospitals are improving their patient identification procedures to ensure that the right patient always undergoes the right diagnostic or therapeutic procedure, though further work is required by hospital staff to ensure that appropriate records are kept to verify that these procedure are being carried out. Inspectors have also noted that staff in many hospitals have been incorrectly classified as exposed workers, with additional, sometimes unnecessary, legal responsibilities being placed on the employer. RIMD inspectors will follow this up in future inspections to ensure that all staff are appropriately classified and that hospitals are meeting their legal requirements.

- Radiation protection standards across the industrial sector remain high. However, from an administrative point of view good record keeping and associated document management practices continue 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 several occasions that refresher training for appointed Radiation Protection Officers was not being provided by employers.

- Across all sectors, the findings of most concern related to licensees failing to ensure that risk assessments and the associated radiation safety procedures were periodically reviewed and revised where necessary. To address this, the conditions of the licences were updated in 2013 to ensure greater clarity on the requirement to undertake a revision of risk assessments. There was also evidence of challenges related to managing the administrative aspects of the licence requirements and the classification of controlled areas and exposed workers.
- During the year a total of 173 inspections, focussing on radiation protection, and an additional security inspection were carried out. An analysis of the findings identified during these inspections will be undertaken later in the year to identify trends or areas of concern for RIMD. The results of this analysis, as well as good practices observed during the year, will be fed back to relevant stakeholder groups through correspondence or at meeting platforms such as the annual RPA/RPII Liaison meeting.

6.2. Enforcement Activities in 2013

- The RPII did not undertake any prosecutions in 2013.
- There were 100 solicitor's letters issued to licensees during 2013 mainly in relation to licence renewal matters. Eighty three letters were sent to dental licensees in January 2013 due to their failure to apply for the renewal of their previous licence which had expired in September 2012. An additional 17 letters were issued in August as a follow up to the March licence renewal programme. Some of these required an inspection follow-up in order that the licensees completed their licence renewal obligations.
- 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 2013, there were no requirements for a direction to be issued.

7. Priority setting and programme planning for 2014

In line with RIMD's procedures a draft inspection schedule proposal was agreed for 2014 on 4th February and approved by the Board at its meeting on 12th February. 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.

7.1. General Licensee Information

There are currently 1698 licensees across the dental, veterinary, medical, industrial, educational and distributor sectors. Excluding the veterinary and dental sectors, 61 of these licensees have not yet had an inspection, though 24 of these were only issued with licences within the past two years. None of the 61 licensees are engaged in high risk activities and in fact 43 of them are in the very low risk cabinet X-ray category. The inspection programme for 2014 proposes to carry out inspections of three licensees who have never had an inspection.

7.2. Inspection Priorities for 2014

The general criteria that are used to develop the annual inspection programme are set out in Section 4. For 2014, inspectors will be involved in two major new projects – preparatory work for the 2015 IAEA's IRRS peer review mission of Ireland and the development and testing of the new Regulatory IT system, GAMIS. Accordingly there are fewer resources available for the 2014 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 RPII's regulatory approach.

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 licensee having been inspected within the past three years. For 2014 it is not proposed to focus on these sectors. The areas of particular focus that inform the 2014 inspection programme include:

- 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.

The inspection schedule is summarised in Table 1.

Table 1: Proposed Inspection Schedule for 2014

Licence Category	No. in Category	Number of Inspections Proposed
Chiropractors	15	1
Dentists	932	5
Distributors (sources & X-ray)	43	3
Hospital Level 1 (1 X-ray unit)	11	0
Hospital Level 1 (bone densitometer)	24	1
Hospital Level 2 (>1 X-ray unit)	59	8
Hospital Level 3 (as level 2 + unsealed sources for in-vitro)	2	1
Hospital Level 4 (nuclear medicine)	17	12[8]
Hospital Level 5 (radiotherapy)	14	11[9]
Education and Research	15	4
Industrial level 1 [cabinet style X-ray unit]	147	0
Industrial level 2 [electron capture devices, custody only]	12	1
Industrial level 3 [sources, transport]	65	6
Industrial level 4 [> 6 sources]	10	0
Industrial level 5 [> 20 sources]	2	0
Industrial level 6 [fixed X-ray, sources, transport, ICSD assembly]	20	14
Industrial level 7 [irradiation, e-beam, cyclotron and mobile container scanner]	6	1
Others [e.g. scrap, lightning preventors]	16	7
Vets	288	3
Non-licensees (e.g. air operators and underground workplaces)	19	2
Security surveys (in conjunction with An Garda Siochána)[10]	-	0
Total excluding non-licensees	1698	78
Total	1717	80

[8] Eight of these inspections will of nuclear medicine departments and two will be diagnostic X-ray departments.

9 Five of these inspections will be of radiotherapy departments, two will be nuclear medicine departments and four will be diagnostic X-ray departments

[10] Outside scope of accreditation

8. Appendix I - Summary Table of Completed Inspection Schedule for 2013

Table A 1: Inspection Schedule for 2013

Licence Category	No. in Category	Number of Inspections Proposed	Number of completed inspections
Chiropractors	16	6	8
Dentists	946	11	19
Distributors (sources & X-ray)	45	25	16
Hospital Level 1 (1 X-ray unit)	20	2	3
Hospital Level 1 (bone densitometer)	28	2	3
Hospital Level 2 (>1 X-ray unit)	56	24	18
Hospital Level 3 (as level 2 + unsealed sources for in-vitro)	4	2	0
Hospital Level 4 (nuclear medicine)	17	11	9
Hospital Level 5 (radiotherapy)	14	9	8[11]
Education and Research	18	3	4
Industrial level 1 [cabinet style X-ray unit]	138	7	9
Industrial level 2 [electron capture devices, custody only]	11	3	3
Industrial level 3 [sources, transport]	66	12	17
Industrial level 4 [> 6 sources]	10	2	3
Industrial level 5 [> 20 sources]	3	3	2
Industrial level 6 [fixed X-ray, sources, transport, ICSD assembly]	20	12	11
Industrial level 7 [irradiation, e-beam, cyclotron and mobile container scanner]	7	3	2
Others [e.g. scrap, lightning preventors]	23	11	8
Vets	265	10	30
Non-licensees (e.g. air operators and underground workplaces)	19	3	2
Security surveys (in conjunction with An Garda Siochána)[12]	-	-	1
Total excluding non-licensees	1707	157	174
Total	1726	161	176

[11] Six of these inspections were of radiotherapy departments and two were nuclear medicine departments.
[12] Outside scope of accreditation

Mission Statement

To ensure that people in Ireland are protected from the harmful effects of radiation

Radiological Protection Institute of Ireland

An Institiúid Fireannach um Chosaint Raideolaíoch

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