



Radiological Protection Institute of Ireland
An Institiúid Éireannach um Chosaint Raideolaíoch

RPII Inspection and Licensing Activities and Annual Inspection Programme for 2013

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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 comprises 9.6 whole time equivalent (WTE) members of staff. It is currently 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 2013 as well as the programme as approved by the Board of the RPII.

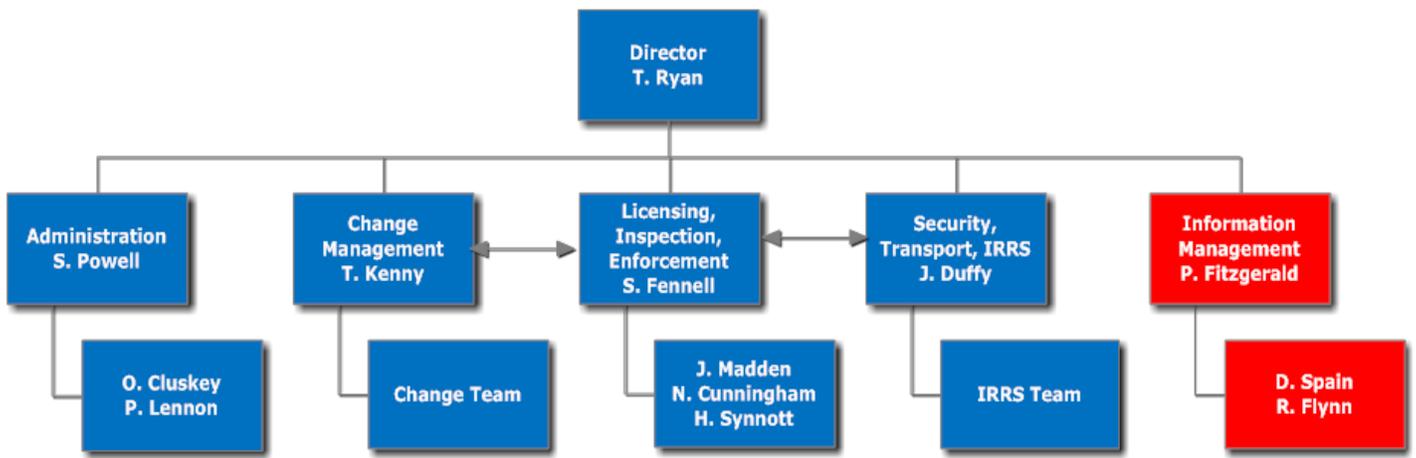


Figure 1^a: Regulation and Information Management Division Structure and Staff

^a From January 1st to 30th June 2013, Stephen Fennell will take over the role of Director of the Regulatory function of the RIMD, Tanya Kenny will take over the role of management of Licensing, Inspection and Enforcement. Dermot Howett retired in February 2012.

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^b. There was a significant increase in active licences in 1989 when the dental sector was brought within the licensing system and since then there has been a steady increase in new licensees, though the total number has levelled off in recent years (Figure 2). On the 1st January 2013 there were 1707 active licences.

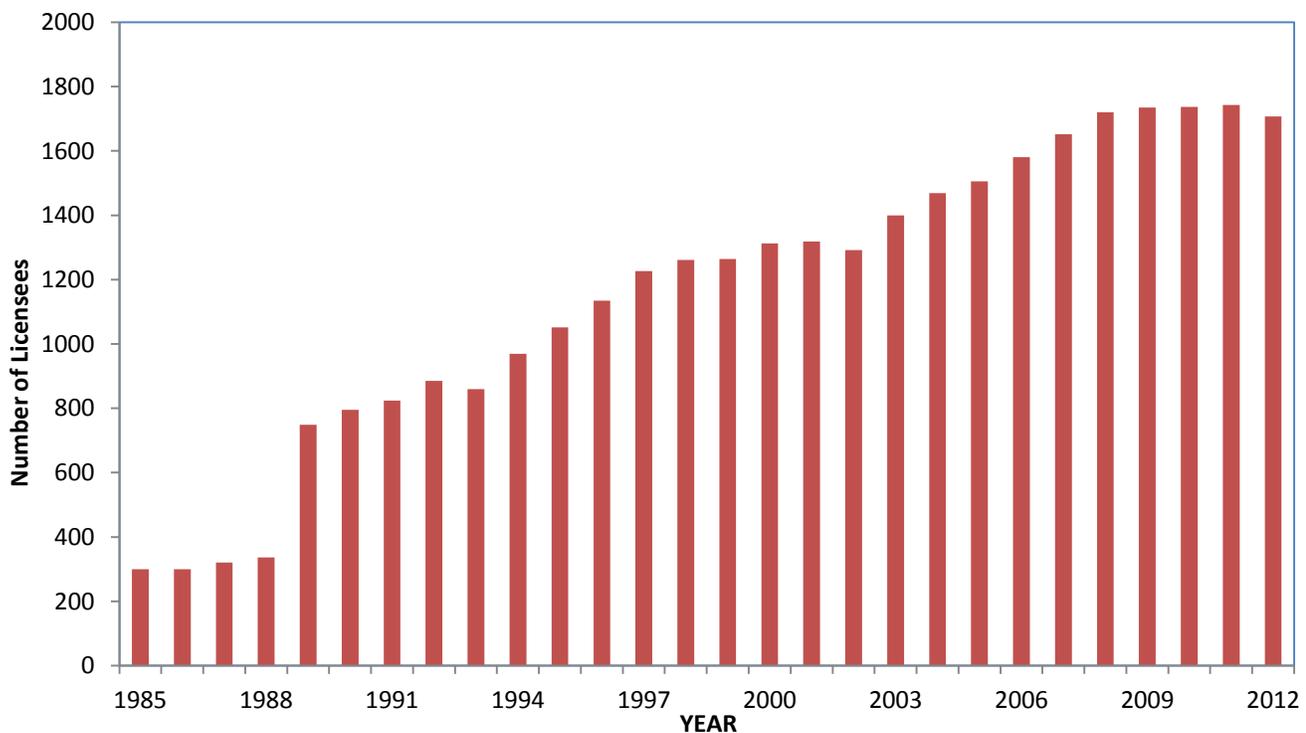


Figure 2: RPII Licensee Numbers (1985 to 2012)

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'.

The bands and categories have also been extended to track the tailoring of licence conditions to new types of practices. The result is the division of licensees into 9 bands which are further divided into approximately 24 different categories or levels. While seemingly complicated, this system has served the

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

RPII well over many years.

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 2013 there were 1707 active licences as presented in Figure 3. The dental sector makes up 55% of these followed by the industrial and the veterinary sectors at 16% each.

2.2.1 Dental

There are currently 946 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 nine licensees currently employing dental cone beam CT.

2.2.2 Veterinary

There are currently 265 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.

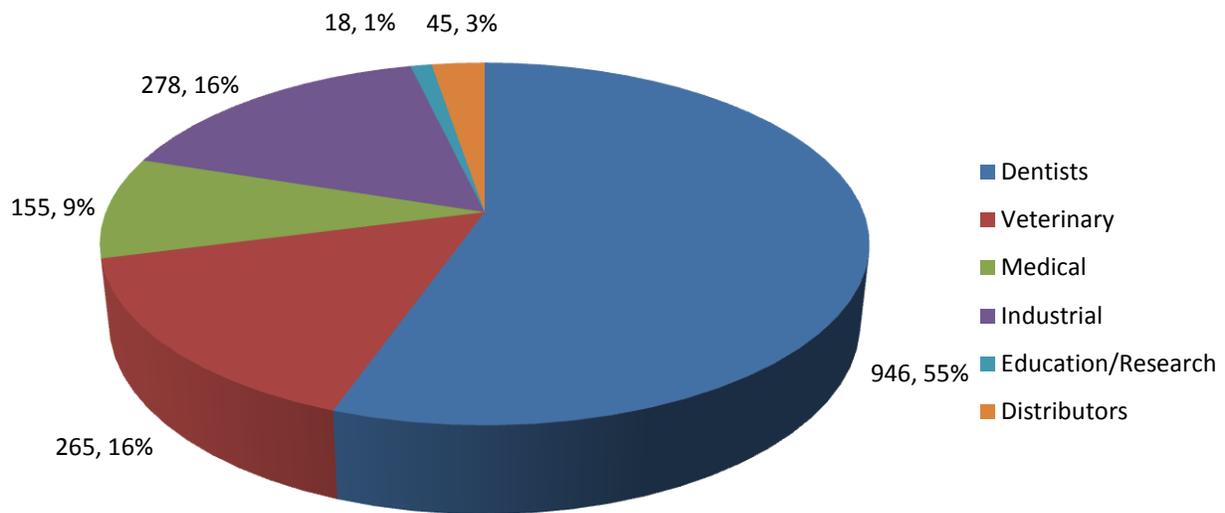


Figure 3: Licensees by Sector 1st January 2013

2.2.3 Medical

There are currently 155 licences active under the broad ‘Medical’ band. This is made up of seven sub-categories as set out in Figure 4. One hundred and eight (70%) of these licensees fall into Levels 1–3 and comprise facilities that use a range of facilities from one simple X-ray unit, to those with additional facilities using unsealed sources for limited in-vitro applications. The remaining 47 licensees comprise chiropractors (16) 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 fifteen (77%) 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 63 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 18 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 45 licensees holding licences for distribution of radioactive material and or irradiating apparatus supplying services across all of the sectors.

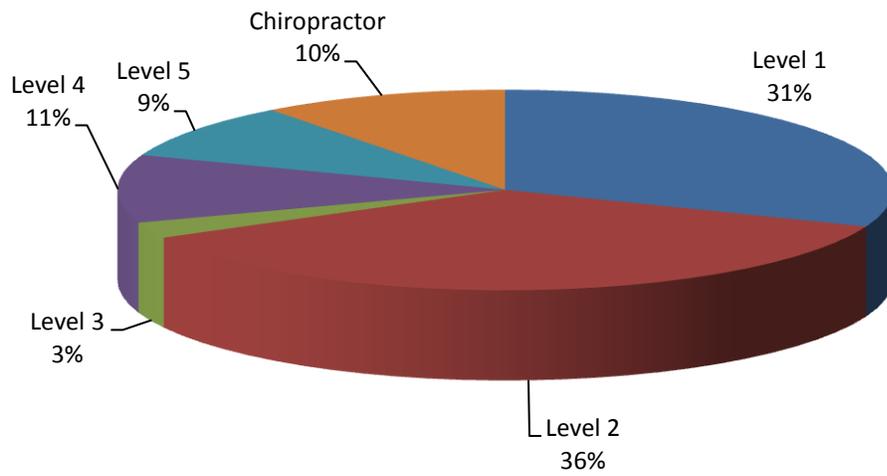


Figure 4: Medical Band by Level, 1st January 2013

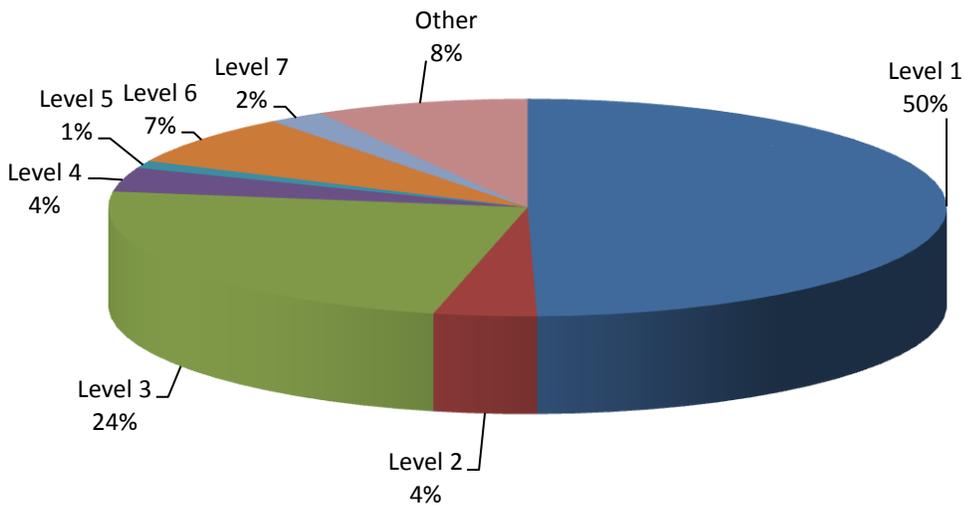


Figure 5: Industrial Band by Level, 1st January 2013

3. Inspections

While the formal licensing system commenced in 1977, the available records show that 59 inspections were carried out in 1983^c, 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 2012, 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 2012 was 162 with three additional security audits^d carried out in conjunction with An Garda Síochána. While this is 59 inspections fewer than 2011, this was due to the retirement of an inspector at the start of the year.

The RPII has the resources to undertake typically 150 – 220 inspections per year and that the number of inspections undertaken in a given year is based upon a risk analysis. For 2013 it is intended to undertake 161 inspections as detailed in Table 1. 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 only one of these areas examined during a given inspection. 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 2012. 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 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 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/m³, averaged over a period of three months. The legislation states that all underground workplaces, including mines and show caves should be measured for radon gas on being directed to do so by the RPII. There are currently two

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

^d This type of audit is outside the scope of the accreditation.

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^e during 2007. Follow-up work was carried out in 2008 and there were six repeat inspections in underground workplaces in 2010. In 2012 three show caves were visited by inspectors to assess radiation protection measures.

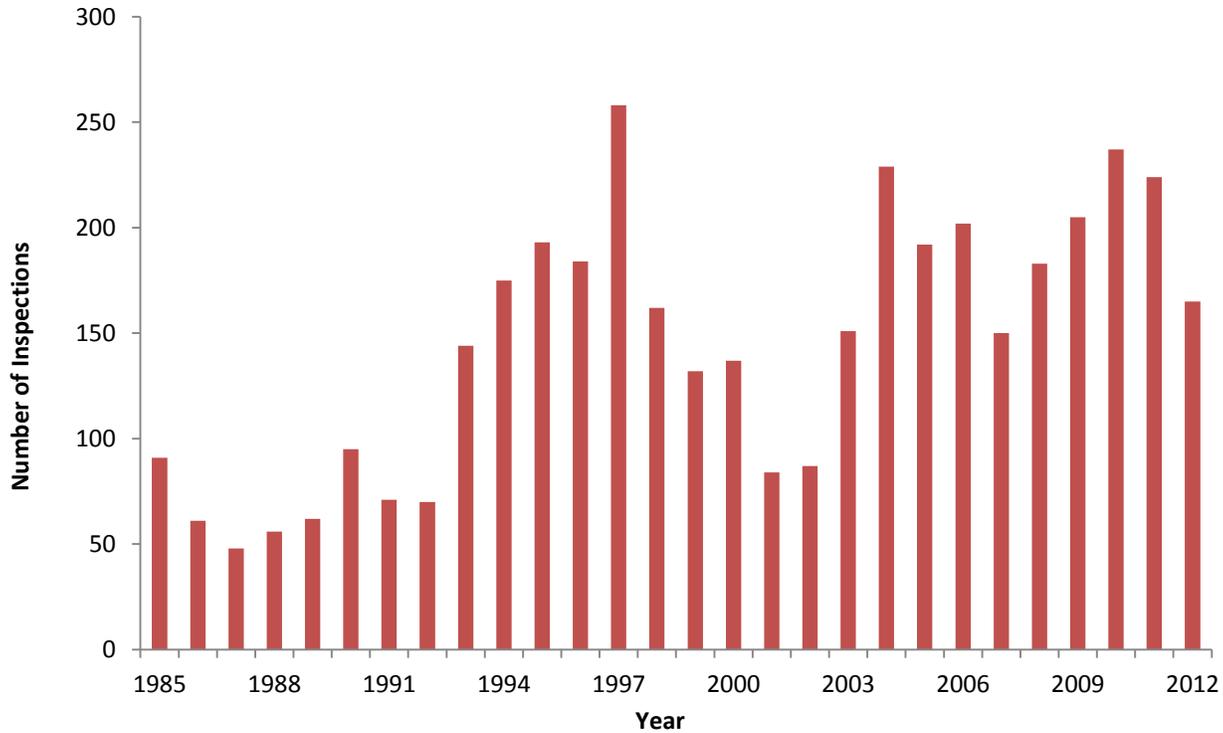


Figure 6: Inspections Undertaken by RPII/NEB (1985 to 2012)

^e This type of inspection is outside the scope of the accreditation

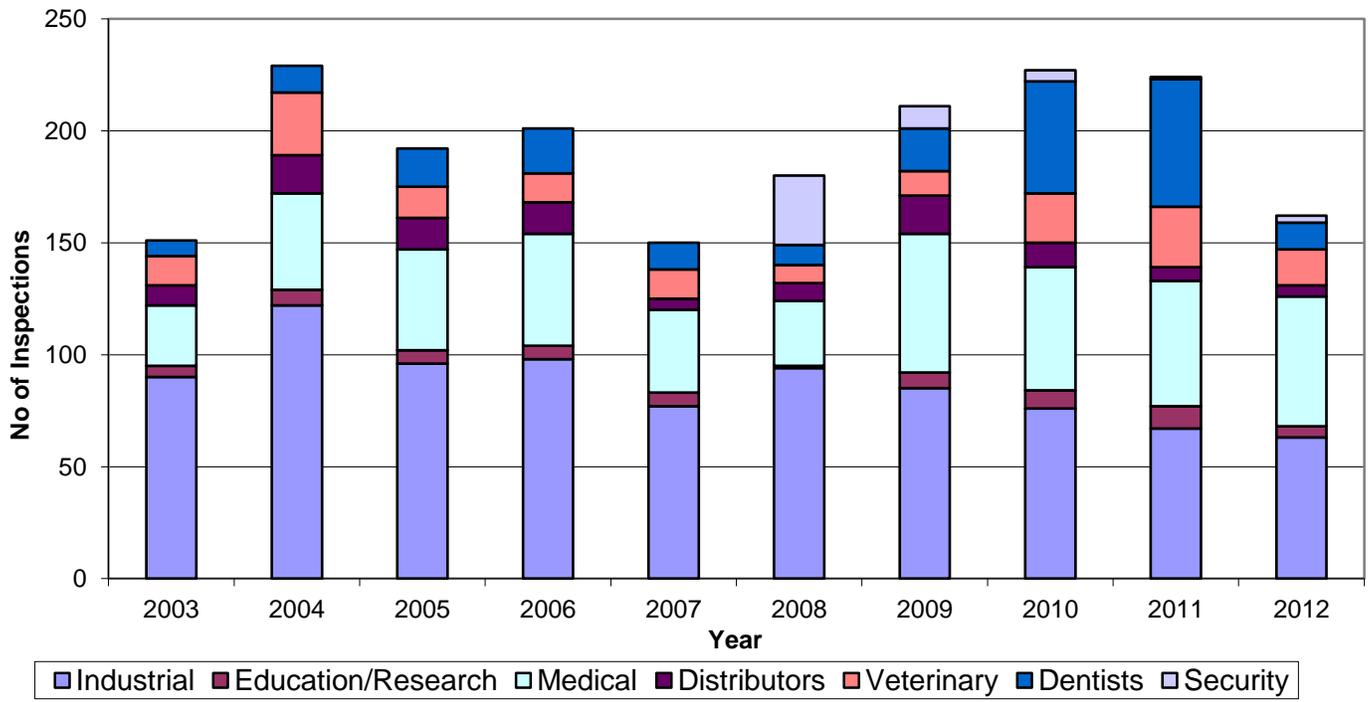


Figure 7: Inspection Focus (2003 to 2012)

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 these reviews 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 dosimeter 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.

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:

- 1. Complete all scheduled inspections as defined in the Inspection Programme for 2013;*
- 2. Issue all Inspection Reports within 28 days of the inspection date;*
- 3. Systematically and periodically collate elements of good practice for dissemination to licensees;*
- 4. Analyse recurring non-compliances identified at inspection to determine specific actions required to address them within specific licensee categories;*
- 5. Document and publish the Inspection Programme.*

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 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

^f Quality objectives are updated annually

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 2012 – Main Findings

6.1. Main Inspection Findings for 2012

The 2012 inspection programme was developed with a particular focus on the following:

- Holders of radioactive waste and disused sources in the private sector with a view to ensuring that all such materials were being maintained in a safe and secure manner and that all steps were being pursued for the return or authorised disposal of such material.
- Holders of nuclear moisture density gauges. As the use of these gauges had significantly decreased due to the completion of road building projects, they were no longer in routine use and particular attention was paid during the inspections to their storage and security arrangements as well as plans for the final disposal of these items.
- Holders of lightning preventors to determine whether the on-going safety and security arrangements were appropriate. This is a sector with a poor safety history and the disposal of such instruments has proven both problematic and costly.
- Raising awareness of the new, more stringent, International Commission on Radiological Protection (ICRP) dose limits for the lens of the eye, and associated implications for the revision of the European Basic Safety Standards Directive (BSS), for relevant licensees e.g. those involved in interventional radiology and PET studies.
- Pre-licensing inspections for licence applications received during the year for hand held dental radiography units. Approval in principle has been given by RPII to the licensing of these instruments and the inspection would allow the protective measures that would be in place to be evaluated.
- The non destructive sector, particularly those companies that carry out field work. These inspections were warranted due to the potentially hazardous nature of the activities particularly when performed in the field, the difficulty in arranging field inspections and due to the persistent occurrence of reportable doses in the sector.
- Underground show caves where exposure to elevated levels of radon may be of concern. This sector had not been inspected at all in recent years and the exposure of staff in certain facilities remains an issue of concern.

The completed Inspection schedules for 2012 are presented in Appendix 1. The number of radiation protection focused inspections of licensed facilities carried out in 2012 was 162 with three additional security audits^g carried out in conjunction with An Garda Síochána. The inspection programme outcome for 2012 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 2012 there was a significant reduction in the amount of radioactive waste and disused

^g This type of audit is outside the scope of the accreditation

radioactive sources held in third level institutes resulting from the availability of funding for this initiative becoming available from the Higher Education Authority. Holders of radioactive waste and disused sources that were inspected were encouraged to explore all available options to reduce or preferably eliminate their inventories of radioactive sources. Such options included exercising take back agreements with suppliers, using authorised source disposal facilitators to dispose of sources and using protocols for source disposal developed jointly by the RPII/EPA.

- Six exclusive holders of nuclear moisture density gauges were inspected due to concerns in relation to safety and security in the context of the downturn in construction. 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.
- Five holders of lightning preventors were inspected. During these inspections, licensees were advised of a recently identified disposal route for these items and were encouraged to avail of it. While the preventors remained secure, the licensees did not avail of the disposal options due to the significant costs involved. The annual requirement to notify the Chief Fire Officer of the Local Authority of the location, nature and amount of all radioactive substance was not implemented by three of the five licensees inspected.
- Inspectors raised awareness of the new ICRP dose limits for the lens of the eye during all relevant inspections of hospitals undertaking interventional and cardiac catheterisation work in Diagnostic Imaging Departments. It was noted in particular that many hospitals had commenced a dose reduction programme taking into account stakeholder consultation with cardiologists and radiographers, raising awareness of the new dose limits, education activities, use of more accurate dosimeters to give a good insight into the dose levels at the level of the eye, provision of specific personal protective equipment and collaboration with national and international colleagues.

In hospitals where such work had not commenced, the licensees were requested by the inspectors to undertake a Risk Assessment to identify and quantify those workers and activities likely to be affected by the proposed new dose limit. The Risk Assessment would also have to give consideration to the categorisation of workers.

- There are currently four hand held dental radiography units licensed in Ireland. Pre-licence inspections were not undertaken as these particular units were not present on-site in advance of a new licence being issued. The holders of these hand held dental radiography units will be inspected in 2013.
- A downturn in work in the non-destructive testing (NDT) sector was again noted during 2012 resulting in fewer notifications of intended site radiography work during the year. However, based upon those received, three site radiography inspections were carried out during the year. The issues found were largely of an administrative nature and no significant safety or transport related findings were observed during the unannounced site visits.
- There are five show caves in Ireland where exposure to elevated levels of radon may be of concern. In 2012 inspectors visited three of these caves to review the arrangements in place for radiation protection. The remaining two caves will be visited in 2013 after which a review of the findings from all visits will be undertaken to determine whether any additional measures need to be put in place.

- In 2012 an analysis was carried out of the inspection findings of 50 private and 35 public sector dental licensees undertaken in 2010 and 2011. This analysis looked at the commissioning, quality assurance testing of dental X-ray units, issues outstanding from QA tests, servicing arrangements/policies for dental X-ray units, availability of local rules and issues arising from RPII inspections. In general, compliance with licence conditions and relevant radiation protection legislation was good within the sector and RPII inspectors were satisfied with the overall standard of radiation protection in 95% of the dental practices inspected. For the remaining 5% of practices the licensees were required to address issues such as modifying radiation safety procedures and improving record keeping.

The analysis further indicated that 90% of licensees inspected had the correct inventory of X-ray units on their licence and that 80% of licensees had carried out QA testing within the previous 2 years. It was found however that approximately 10% of licensees inspected had one or units that required commissioning testing. The findings of this project were presented to the RPII/RPA liaison meeting in March 2012 and it is planned to publish these findings in 2013.

6.1.2 Additional High Level Observations

- Standards of radiation protection across the medical sector remain high, with a significant commitment from hospital management evident from the inspections carried out during the year. However it is anticipated that there will be challenges to maintain these standards with the increased pressures on budgetary and resource constraints. The main findings related to the revision of procedures and risk assessments and managing the administrative aspects of the licence requirements. In addition, findings with regard to the classification of areas and exposed workers in accordance with the provisions of SI No. 125 of 2000, personal dosimetry of exposed workers and the issue of Outside Workers in the Control Areas of licensees were also noted.
- Radiation protection standards across the industrial sector remain high. The most recurring finding noted during inspections was that of licensees holding radiation sources failing to notify the Chief Fire Officer of the location and nature of these sources. In addition, the need to provide refresher training for appointed Radiation Protection Officers was also identified and revisions to security arrangements had to be implemented in some instances.
- Selected licensees involved in the transport of radioactive material were inspected throughout the year. The key ADR (transport) related issues noted were failure to provide a consignment note; inadequate or incorrect labelling or marking of the package or placarding of the vehicle and vehicles not carrying the equipment required in the ADR.
- During the 165 inspections carried out in 2012, 174 non-compliances were raised. A significant proportion of these non-compliances related to record keeping requirements. As part of the RIMD's quality procedures the status of these non-compliances is reviewed on a monthly basis and the vast majority of these have already been closed out by the licensees to the satisfaction of the RIMD.
- It was evident that recommendations made by inspectors in previous inspections are being implemented by licensees and these have led to improvements in radiation safety. Examples include audits of patient identification protocols being undertaken and analysis of these audits being carried out.

- Inspectors noted several good practice observations during inspections which are documented and discussed collectively at the inspectors meetings. These good practices are then shared with licensees during inspections where applicable. Examples of good practices include licensees performing internal radiation protection audits and retaining photographs of radiation sources at the location of storage.

6.2. Enforcement Activities in 2012

- The RPII did not undertake any prosecutions in 2012.
- There were five solicitor's letters issued to licensees during 2012 mainly in relation to licence renewal matters. 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 2012, four occasions arose where a direction had to be issued. One direction was given in the case of a company in liquidation where, based upon the advice of An Garda Síochána security aspects of the premises had to be strengthened to secure the storage location of lightning preventors. The remaining three directions were given to three separate dental licensees where equipment did not meet the criteria of acceptability set out in the Dental Code of Practice^h. Specifically, one of these directions concerned a handheld dental X-ray unit, purchased via the internet, which was the subject of a report from the Health Protection Agency (HPA) in the UK questioning its safety. The licensee was directed to return the unit to the supplier and immediately complied with the direction.

^h The Code of Practice for Radiological Protection in Dentistry, RPII/96/2.

7. Priority setting and programme planning for 2013

In line with RIMD's procedures a draft inspection schedule proposal was agreed for 2013 on 18th January and approved by the Board at its meeting on 31st January. 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 1707 licensees across the dental, veterinary, medical, industrial, educational and distributor sectors. Excluding the veterinary and dental sectors 42 of these licensees have not yet had an inspection, though some of these were only issued with licences recently. It should be noted that 31 of the 42 are in the very low risk cabinet X-ray category. The inspection programme for 2013 proposes to carry out inspections of 15 licensees who have never had an inspection.

7.2. Inspection Priorities for 2013

The general criteria that are used to develop the annual inspection programme are set out in Section 4. In addition, a number of particular areas of focus have been identified. The areas of particular focus that inform the 2013 inspection programme include:

- A specific focus on 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. It is also noted that there is an increase in the number of brachytherapy procedures being performed internationally. Control of these radiation sources and the strict adherence to safety procedures are therefore extremely important to ensure all doses to staff and members of the public are as low as reasonably achievable. It is proposed that these inspections would focus on the practical elements of dealing with and handling these sources to ensure procedures are being followed and documentation relating to the sources is being maintained.
- A specific focus on 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. These procedures require workers to be within the controlled area while X-rays are being generated. It is therefore important to ensure strict adherence to radiation safety procedures. It is also important to continue to focus on promoting the regulatory position of the RPII of the new proposed ICRP dose limits for the lens of the eye, and the associated implications for the revision of the European Basic Safety Standards Directive (BSS), for relevant licensees.
- It is noted that there are several licensees involved in the distribution and transport of radioactive sources. For the safe control of these sources it is important 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. It is proposed that there will be a

focus on the practical aspects of these source deliveries which will incorporate inspectors accompanying transporters as radioactive sources are delivered and collected to ensure protocols are being followed and radiation sources are tracked appropriately.

- The RIMD has recently become aware of regulatory counterparts in other European countries focusing on some specific applications of medical X-ray units which include the use of mobile radiography in mortuaries and the use of mobile O-arm fluoroscopy units which are used in a theatre setting. It is proposed that inspections will focus on these areas where applicable.
- Inspections of dental facilities who have acquired a licence for hand held dental radiography units. It is recognised that these units have only recently been introduced to Ireland and therefore it will be important to evaluate the protective measures during the early phases of their introduction.

In addition to the particular areas of focus outlined above there are also continued priorities from the 2012 inspection programme which include the following:

- Continuing attention to the 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.
- Continuing attention to holders of nuclear moisture density gauges. As the use of these gauges has significantly decreased due to the completion of road building projects, they are no longer in routine use and particular attention will be paid during the inspections to their storage and security arrangements as well as plans for the final disposal of these items.
- Holders of lightning preventors to determine whether the on-going safety and security arrangements are appropriate. This is a sector with a poor safety history and the disposal of such instruments has proven both problematic and costly.
- Continued attention to the non destructive sector particularly those companies that carryout field work due to the potentially hazardous nature of the activities particularly when performed in the field, the difficulty in arranging field inspections and due to the persistent occurrence of reportable doses in the sector.
- Inspections of all five underground show caves commenced in 2012 and will also continue in 2013.

The inspection schedule is summarised in Table 1

Table 1: Proposed Inspection Schedule for 2013

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

ⁱ Six of these inspections will be of radiotherapy departments, two will be nuclear medicine departments and one will be a diagnostic X-ray department.

^j Outside scope of accreditation

Appendix I

Summary Table of Completed Inspection Schedule for 2012

Table A: Inspection Schedule for 2012

Licence Category	No. in Category	Number of Inspections Proposed	Number of completed inspections
Chiropractors	20	6	5
Dentists	947	10	12
Distributors (sources & X-ray)	44	5	5
Hospital Level 1 (1 X-ray unit)	22	7	7
Hospital Level 1 (bone densitometer)	28	3	3
Hospital Level 2 (>1 X-ray unit)	63	24	23
Hospital Level 3 (as level 2 + unsealed sources for in-vitro)	4	2	2
Hospital Level 4 (nuclear medicine)	15	7	8
Hospital Level 5 (radiotherapy)	14	10 ^k	10
Education and Research	19	5	5
Industrial level 1 [cabinet style X-ray unit]	136	3	2
Industrial level 2 [electron capture devices, custody only]	10	2	2
Industrial level 3 [sources, transport]	72	31	33
Industrial level 4 [> 6 sources]	10	2	2
Industrial level 5 [> 20 sources]	3	0	0
Industrial level 6 [fixed X-ray, sources, transport, ICSD assembly]	20	17	17
Industrial level 7 [irradiation, e-beam, cyclotron and mobile container scanner]	6	3	3
Others [e.g. scrap, lightning preventors]	26	6	4
Vets	284	15	16
Non-licensees (e.g. air operators and underground workplaces)	19	3	3
Security surveys ^l (in conjunction with An Garda Síochána)	-	tbd	3
Total excluding non-licensees	1743	158	162
Total	1762	161	165

^k Six of these inspections were of radiotherapy departments, two were nuclear medicine departments and two were diagnostic X-ray departments.

^l 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 Éireannach um Chosaint Raideolaíoch

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