Radiological Protection Institute of Ireland
An Institiúid Éireannach um Chosaint Raideolaíoch

RPII Inspection and Licensing Activities and Annual Inspection Programme for 2011

Prepared by
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FOREWORD

The purpose of this document is to promote transparency in the activities of the RPII discussed herein. It explains aspects of the internal workings of the Regulation and Information Management Division 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 10.6 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 in 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 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 2011 as well as the programme as approved by the Board of the RPII.

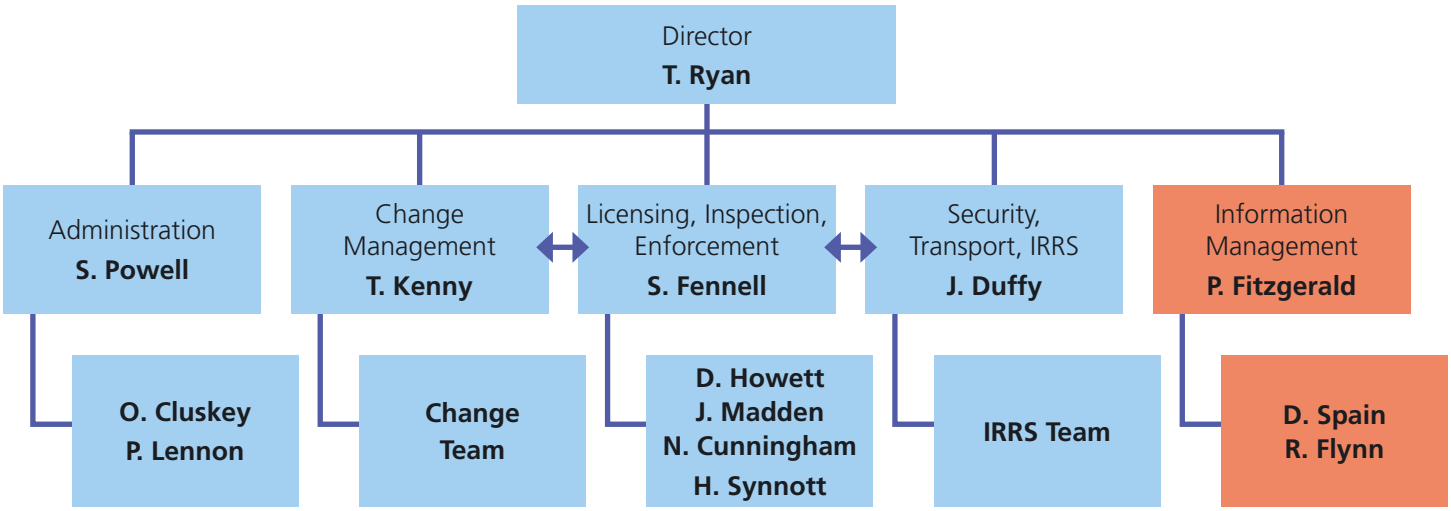

Figure 1: Regulation and Information Management Division Structure and Staff

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 and there has been a steady increase in new licensees to the present day (Figure 2). On the 1st January 2011 there were 1737 active licences.

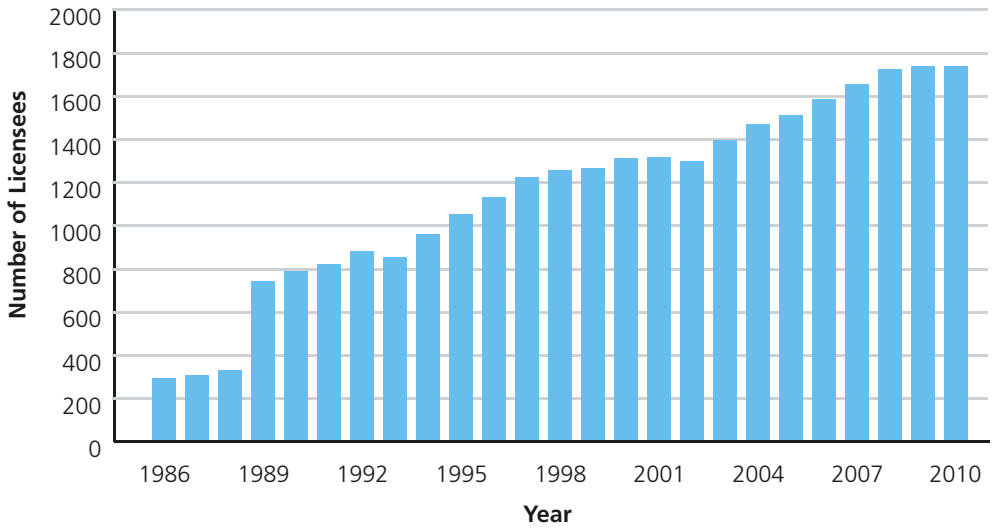

Figure 2: RPII Licensee Numbers (1985 to 2010)

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' - very often corresponding to the number of sources used and the complexity of the activity.

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

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 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' and 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 Category: Level 1–3)
v. Dental (Sub Category: Level 1–3)
vi. Veterinary (Sub Category: 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 2011 there were 1737 active licences as presented in Figure 3. The dental sector makes up 54% of these followed by the Industrial Sector at 17% and the veterinary sector at 15%.

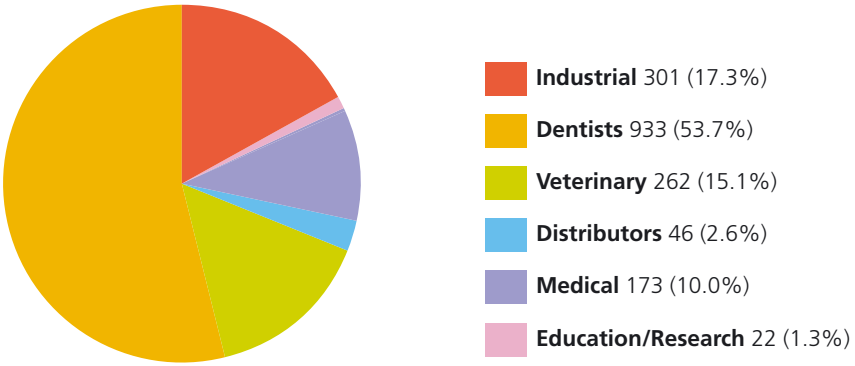

Figure 3: Licensees by Sector 1st January 2011

Dental

There are currently 933 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 10 licensees currently employing dental CT.

Veterinary

There are currently 262 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.

Medical

There are currently 173 licences active under the broad 'Medical' band. This is made up of seven sub-categories as set out in Figure 4. 122 (71%) of these licensees fall into Levels 1–3 and comprise facilities that use one simple X-ray unit to those with additional facilities using unsealed sources for limited in-vitro applications. The remaining 51 licensees comprise chiropractors (19), a blood irradiation facility, a manufacturer of PET radiopharmaceuticals and those medical facilities engaged in nuclear medicine and radiotherapy - typically providing a combination of complex services.

Industrial

There are currently 301 licences active under the broad 'Industrial' band. This is made up of seven sub-categories as set out in Figure 5. 242 (82%) 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 lightening 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.

Education/Research

There are 22 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.

Distributor

There are currently 46 licensees holding licences for distribution of radioactive material and or irradiating apparatus supplying services across all of the sectors.

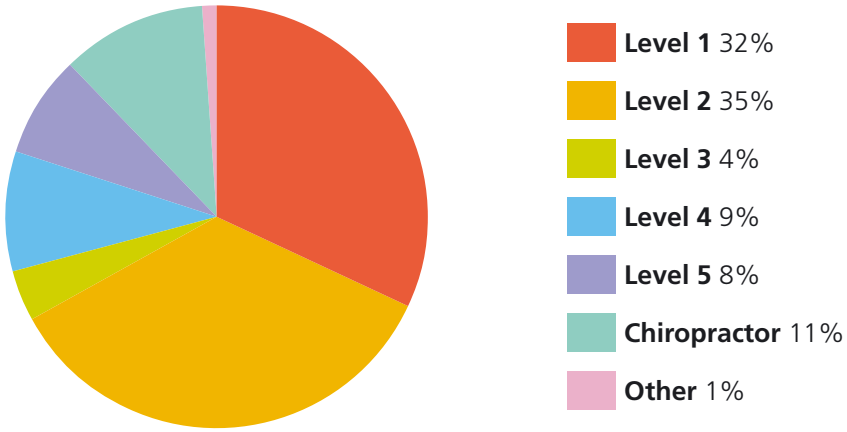

Figure 4: Medical Band by Level, 1st January 2011

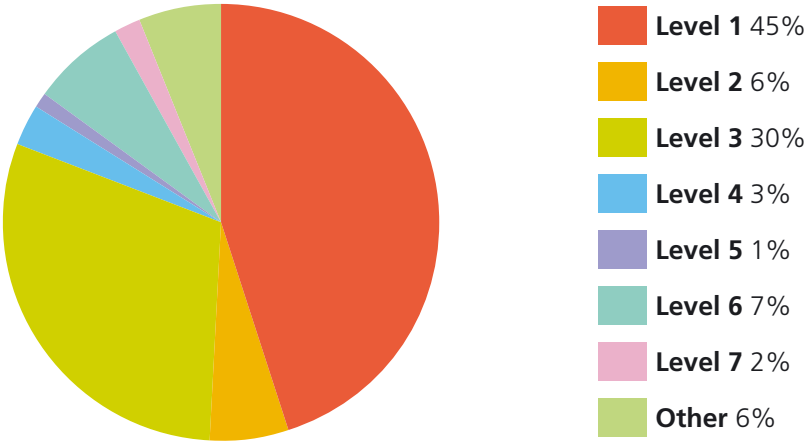

Figure 5: Industrial Band by Level, 1st January 2011

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 2010 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 2010 was 222 with an additional 4 air operators, 6 underground workplaces and 3 security audits[3] where the latter were carried out in conjunction with An Garda Síochána.

The total number of inspections undertaken in a given year broadly reflects the staff resources available and the priorities identified at any given time. 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 well in advance but occasionally unannounced inspections take place. Inspections can arise outside of the normal annual programme where incidents are investigated or occasionally where the licensee invites an inspection.

Figure 7 illustrates the focus of inspections in the period between 2003 and 2010. It is evident that the inspection numbers have been weighted towards the medical and industrial areas and 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.

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 accreditation

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 should 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 has been issued to an underground workplace, all underground workplaces were inspected[4] during 2007. Follow-up work was carried out in 2008 and there were six repeat inspections in underground workplaces in 2010.

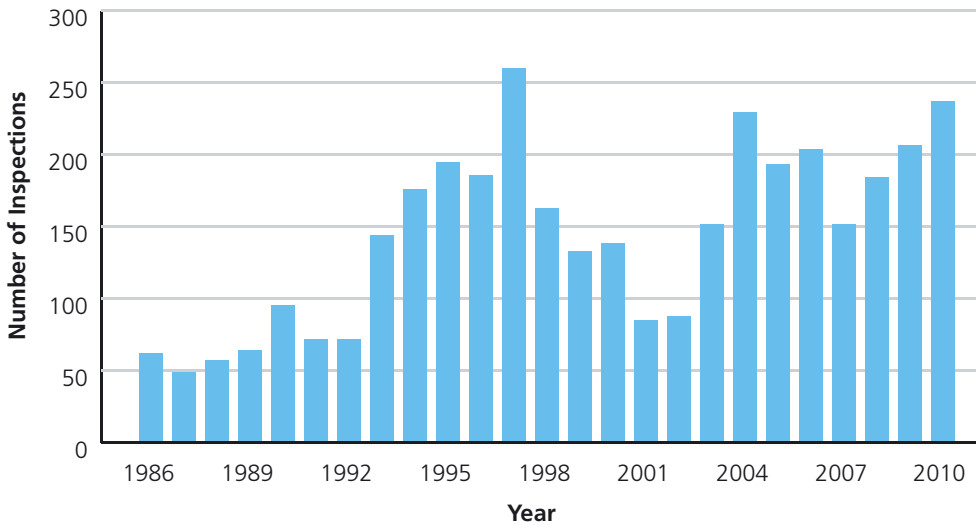

Figure 6: Inspections Undertaken by RPII/NEB (1985 to 2010)

4 This type of inspection is outside the scope of the accreditation

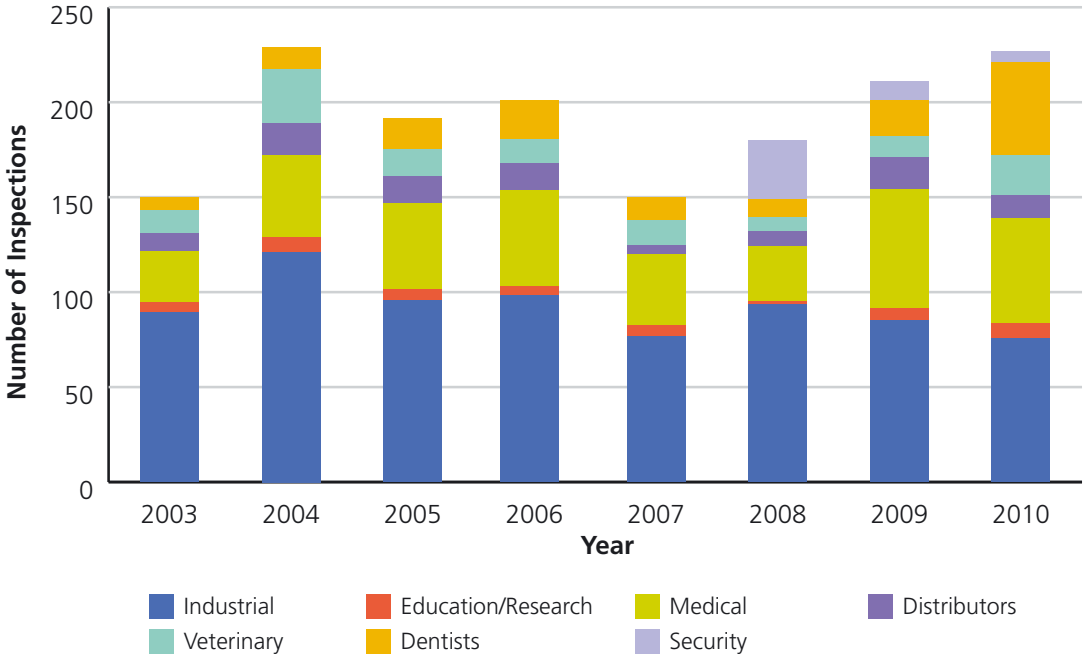

Figure 7: Inspection Focus (2003 to 2010)

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. The responsible section is tasked with drawing up a draft inspection schedule 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 schedules identify most individual licensees to be inspected as well as the scope of the inspections. However, for some categories it is not generally efficient or necessary to identify the individual licensee that will be inspected given the nature of the practices involved. For these categories the inspection schedules identify the number of licensees within these categories that will be inspected. When the draft Schedules have 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(s) to devise the final version of the inspection programme for the forthcoming calendar year and the discussions are based on the draft schedules. The Director reviews the criteria used to compile each schedule and the number of planned inspections and may suggest modifications. Once the programme and its associated schedules have been signed off by the RIMD it is forwarded to the Board for 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 relevant Technical Manager. At the end of each year the Technical Manager(s), 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 obviously 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(s) 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. This may only be done with the authorisation of the Technical Manager(s) 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, for 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 of the Radiological Protection Institute of Ireland, hereafter referred to as the RPII, 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[5]:

1. *Complete all scheduled inspections as defined in the Inspection Programme for 2011;*
2. *Issue all Inspection Reports within 28 days of the inspection date;*
3. *Systematically and periodically identify 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.*

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.

5 Quality objectives are updated annually

The Director of the RIMD has ultimate responsibility for both Quality Assurance and Quality Control in the Division. The Technical Managers are 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 this 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(s) and in his/her absence they report to the Director. In particular, Inspectors, under the direction of the manager(s), 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(s) 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(s) 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, Managers 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. Identifying common/frequent findings.

5.4. Inspection Procedure

The 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 will 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 representative 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 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(s) 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 issues and defects noted
- 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 such as 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 appropriate Technical Manager.

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

For each unit 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, whereby 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 2010 – MAIN FINDINGS

6.1. Main Inspection Findings for 2010

The inspection programme outcome for 2010 was reviewed and the high level issues arising were noted:

- The appointment of Radiation Protection Advisers by licensees in both the higher risk industrial sectors and the dental sector has resulted in general improvements in radiation awareness and radiation protection practice.
- The introduction of a notification scheme for licensees prior to their undertaking site radiography is facilitating inspections of such practices.
- There was a significant decrease in the number of reportable doses to RPII, particularly in the NDT sector, and this may be correlated with the appointment of RPAs though the down turn in contract work may also be a factor – this will be kept under review.
- Raising the awareness of radon in the workplace was introduced into the scope of inspections during the year with inspectors providing information on the potential risks from radon to workers and recommending that the licensee considers carrying out radon measurements if they haven't already done so.
- Inspectors encouraged licensees holding custody only sources to reduce their inventories, where appropriate by utilising protocols developed by the RPII in conjunction with the EPA on the disposal of radioactive sources.
- Compliance with the requirements of the High Activity Sealed Sources (HASS) Directive remains good among those licensees inspected during the year.
- The main findings from inspections that continue to present challenges for licensees include updating safety procedures, providing personal dosimeters to staff, undertaking and reviewing risk assessments, ensuring licence schedules are kept up to date, maintaining on-site inspection logs and annually notifying the Chief Fire Officer of the presence of radioactive sources.

The completed Inspection schedules for 2010 are presented in Appendix 1. Between both schedules the number of radiation protection focused inspections of licensed facilities carried out in 2010 was 222 with an additional four air operators and six underground workplaces visited and three security audits[6] carried out in conjunction with An Garda Síochána.

6 This type of audit is outside the scope of the accreditation

6.2. Non-Compliances Detected

During the inspections carried out in 2010, 291 non-compliances were raised. As part of the 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.

6.3. Enforcement Activities in 2010

- One prosecution was initiated in 2010 which was successfully concluded in January 2011.
- There were 27 solicitor's letters issued during 2010 mainly in relation to licence renewal matters.
- There were no directions issued during 2010.

7. PRIORITY SETTING AND PROGRAMME PLANNING FOR 2011

In line with procedures a draft inspection schedule proposal was agreed for 2011 on 15th February and approved by the Board at its meeting on 2nd March. It should be noted that the inspection programme agreed is a working plan that may be modified during the year in line with procedures should priorities change.

7.1. General Industrial, Educational and Veterinary Licensee Information

There are currently 610 licensees in these categories. 34 new licences were issued in the sector in the two year period 2009 – 2010. Excluding veterinary practices, 15 licensees have not yet had an inspection and a further 60 (39 of which are in the very low risk Industrial Level 1 cabinet X-ray category) have not been inspected within the last four years. In the veterinary sector 132 of the 262 licensees have been the subject of an inspection to date.

7.2. Industrial, Educational and Veterinary Sectors Priorities for 2011

The inspection programme will focus on:

- Holders of radioactive waste and disused sources with a view to ensuring that all such materials are being maintained in a safe and secure manner and that all steps are being pursued for the return or authorised disposal of such material.
- The veterinary sector with particular attention to the use of mobile X-ray units in large-animal practices.
- Holders of nuclear moisture density gauges. With the collapse in the construction industry it is anticipated that these devices are not being used as frequently and it will be important to establish that they are being maintained in a safe and secure manner or if no longer required, arrangements are being made for their return.
- Non destructive testing companies.
- Licensees deemed to warrant a routine inspection, consistent with the general risk based approach to inspection planning, based on the date of their last inspection.

The inspection schedule for these sectors is summarised in Table 7A.

Table 7A: Proposed Industrial, Educational and Veterinary Inspection Schedule for 2011

Licence Category	No. in Category	Number of Inspections Proposed
Distribution [level 1 and 2]	25	8
Education and Research	22	10
Industrial level 1 [cabinet style X-ray]	134	13
Industrial level 2 [ECDs, custody only]	19	6
Industrial level 3 [sources, transport]	89	30
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	7
Industrial level 7 [irradiation, e-beam and mobile container scanner]	5	2
Others [e.g. scrap, lightning preventors.]	22	4
Vets	262	30
Air Operators	8	0
Underground	11	0
Total	**629**	**110**

7.3. General Medical and Dental Licensee Information

There are currently 1127 licensees including 933 dental practices in these categories.

19 new licences were issued in the medical sector (excluding dentists) in the two year period 2009 – 2010.

Excluding dentists and new licensees, all other licensees in these categories have been inspected within the last four years, with the exception of one licensee engaged in low risk bone densitometry services.

7.4. Medical and Dental Sectors Priorities for 2011

The inspection programme will focus on:

- Holders of radioactive waste and disused sources with a view to ensuring that all such materials are being maintained in a safe and secure manner and that all steps are being pursued for the return or authorised disposal of such material.
- The Dental sector with particular emphasis in 2011 on practices in the public sector.
- A number of inspections will take place as follow up to incidents involving reported doses to staff to close out investigations and to ensure that improved practices are in place where appropriate.
- Licensees deemed to warrant a routine inspection, consistent with the general risk based approach to inspection planning, based on the date of their last inspection.

The inspection schedule for the Medical and Dental Sectors is summarised in Table 7B

Table 7B: Proposed Medical and Dental Inspection Schedule for 2011

Licence Category	No. in Category	Number of inspections proposed
Chiropractors	19	7
Cyclotron Radiopharmaceutical Production	1	0
Dentists	933	34
Medical Distributors (sources & X-ray)	21	4
Hospital Level 1 (1 X-ray unit)	26	5
Hospital Level 1 (Bone Densitometer)	29	5
Hospital Level 2 (>1 X-ray unit)	61	13
Hospital Level 3 (as level 2 + unsealed sources for in-vitro)	6	1
Hospital Level 4 (nuclear medicine)	16	15[7]
Hospital Level 5 (radiotherapy)	14	11[8]
Irradiating Blood and Blood Products	1	0
Total	**1127**	**95**

7 Four of these inspections will be of nuclear medicine department and 11 will be of diagnostic X-ray departments

8 Four of these inspections will be of radiotherapy departments, four of diagnostic X-ray and three of nuclear medicine departments

APPENDIX I

Summary Tables of Completed Inspection Schedules for 2010

Table A: Industrial, Educational and Veterinary Inspection Schedule for 2010

Licence Category	No. in Category	Number of Inspections Proposed	Inspections completed
Distribution [level 1 and 2]	24	8	4
Education and Research	22	7	8
Industrial level 1 [cabinet style X-ray]	133	9	11
Industrial level 2 [ECDs, custody only]	25	8	7
Industrial level 3 [sources, transport]	97	21	26
Industrial level 4 [> 6 sources]	12	3	2
Industrial level 5 [> 20 sources]	2	2	2
Industrial level 6 [fixed X-ray, sources, transport, ICSD assembly]	22	18	19
Industrial level 7 [irradiation, e-beam and mobile container scanner]	5	5	5
Others [e.g. scrap, lightning preventors.]	14	5	4
Vets	268	14	22
Air Operators	7	4	4
Underground	11	6	6
Security Surveys[9]		1	1
Total excluding underground workplaces and air operators	624	101	111
TOTAL	**642**	**111**	**121**

9 Outside scope of accreditation

Table B: Medical and Dental Inspection Schedule for 2010

Licence Category	No. in Category	Number of inspections proposed	Inspections completed
Chiropractors	17	6	7
Cyclotron Radiopharmaceutical Production	1	1	1
Dentists	913	50	50
Medical Distributors (sources & X-ray)	27	7	7
Hospital Level 1 (1 X-ray unit)	28	3	1
Hospital Level 1 (Bone Densitometer)	28	4	3
Hospital Level 2 (>1 X-ray unit)	62	24	24
Hospital Level 3 (as level 2 + unsealed sources for in-vitro)	6	2	2
Hospital Level 4 (X-ray & nuclear medicine)[10]	16	15	8
Hospital Level 5 (X-ray, nuclear medicine & radiotherapy)[11]	12	9	8
Irradiating Blood and Blood Products	1	0	1
Security Surveys[12]	-	2	2
Total	**1111**	**123**	**114**

10 Of the seven inspections not completed, three were nuclear medicine and four were diagnostic radiology
11 There were two outstanding inspections - one diagnostic and one nuclear medicine. All planned radiotherapy inspections were completed
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 Éireannach um Chosaint Raideolaíoch

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