An Overview of the Inspection Programme in Ireland.

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Abstract

The Radiological Protection Institute of Ireland (RPII) is the national authority with responsibility for the licensing and inspection of all users of sources of ionising radiation throughout the Republic of Ireland. The Institute's Regulatory Service currently licenses approximately 1400 licensees in the medical, research, educational, and industrial sectors.

Licensees are inspected by the Regulatory Service to ensure compliance with the requirements of their licence and to assess the overall level of radiation protection provided. At the end of each year individual licensees are selected for inspection during the coming year; this selection process takes into account the potential risk associated with each licensee's activity and the time elapsed since the last inspection. Inspections are carried out using standard audit forms to ensure that each inspection is conducted to a uniform set of criteria. Options available to the Regulatory Service for dealing with non-compliances identified during inspections include directing the licensee to carry out specified improvements within a prescribed time-scale, formal enforcement notices, which may include a requirement that the licensee ceases carrying on the practice, prosecution and licence suspension or withdrawal. The option decided upon will reflect the seriousness of the non-compliance.

The Regulatory Service is continually seeking to improve its procedures and the service it provides to its licensees. As part of this process a peer review mission was carried out by the International Atomic Energy Agency (IAEA) in 2000 which examined the functions of the Regulatory Service including its inspection programme. In addition, work is currently under way to accredit the Regulatory Service to EN 45004: *General criteria for the operation of various types of bodies performing inspection* [1].

The Radiological Protection Act

The primary Irish legislation governing safety in the uses of ionising radiation is the Radiological Protection Act, 1991 [2]. The Act gives the Radiological Protection Institute of Ireland (hereafter called the Institute) the functions and powers which enable it to be the regulatory body for the control of sources of ionising radiation and radioactive materials in Ireland. In particular, Section 8 of the Act requires the Institute "*to carry out a licensing system relating to the custody, use, manufacture, importation, distribution, transportation, exportation or other disposal of radioactive substances, nuclear devices or irradiating apparatus*". Section 30 of the Act elaborates the framework for the licensing system; in particular, it provides for conditions to be attached to licences issued by the Institute, for the amendment or revocation of licences and for the charging of licence fees. Sections 28 and 29 of the Act deal with the appointment and powers of inspectors, while Sections 40 and 41 deal with offences and prosecutions.

The Ionising Radiation Order

A Ministerial Order (The Radiological Protection Act, 1991 (Ionising Radiation) Order, 2000 (S.I. No. 125 of 2000)) [3], made under the Act in May of 2000, consolidates previous regulations. In particular, it provides for the implementation in Irish law of the 1996 European Union Directive [4] laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation. This legislation designates the Institute as the competent authority.

The Order requires all practices, including the custody, production, processing, handling, holding, storage, use, manufacture, importing into and exporting from the European Union, distribution, transportation, recycling, re-

use or other disposal of radioactive substances and nuclear devices, to be licensed by the Institute unless the exemption conditions are met. The exemption levels do not apply to disposal, recycling or re-use of radioactive substances arising from a licensed practice.

Inventory of Radiation Sources and Radioactive Materials

The Institute currently licenses approximately 1400 licensees in the medical, research, educational, and industrial sectors. Licences and conditions attached thereto are based on the type of source to be used and the nature of the use. The category and number of licensees are given in Table I. Approximately 950 of these licences relate solely to irradiating apparatus and are issued principally to dentists and veterinary surgeons. The remaining licences involve either sealed sources, unsealed radioactive substances, irradiating apparatus or a combination thereof, and are used primarily in medicine, industry or education/research.

Table I: Breakdown of Licensees by Category

Licence Category	Number in Category
Process Irradiators and Cyclotron	5
Industrial Radiography	20
Lightning Preventors	7
Manufactures of Devices	2
Industrial Users	222
Education & Research	18
Government Departments & State Run Services	7
Hospitals/Medical	124
Custody Only	33
Distributors	50
Veterinary Surgeons	155
Chiropractors	9
Dental Surgeons	794
Contaminated Scrap Metal	2
Total	**1448**

IAEA Peer Review Mission

In November 2000, the International Atomic Energy Agency (IAEA) was invited to undertake a peer review of the Regulatory Service and to assess the effectiveness and efficiency of the regulatory infrastructure in Ireland. The review team spent a week with staff of the Regulatory Service during which time they carried out a comprehensive assessment of the relevant legislation and of licensing and enforcement procedures, as well as accompanying inspectors on several inspections.

The review team recommended that a set of documented procedures should be drawn up for each existing licensing procedure and that these procedures should be reviewed with a focus on radiation safety. This work is currently underway with the intention of seeking accreditation to an ISO quality management system. Initially the Regulatory Service began working towards certification to the ISO 9000 standard however, after discussions with other regulatory authorities and the Irish National Accreditation Board, it was decided that EN 45004: *General criteria for the operation of various types of bodies performing inspection* would be a more appropriate standard for the Regulatory Service. Accreditation to this standard would demonstrate an assurance of the

technical competence of the personnel and the technical robustness of the Institute's Regulatory Service. This is especially important given that many of the licensees are already accredited to various ISO standards.

The review team considered that the regulatory programme in Ireland is effective, and that the Institute is well placed to implement the regulatory infrastructure. However, the team felt that the Regulatory Service would benefit from a thorough review of its licensing and inspection procedures. A comprehensive review of the licensing procedures has recently been completed. The review highlighted the fact that too much time was being spent pursuing administrative paperwork which, at licence renewal times, was resulting in delays in the issuing of renewed licences. While the administrative aspects of the licensing system play an important role, it is now recognised that real improvements in radiation safety are effected through a comprehensive and targeted inspection programme. In addition the review has resulted in the extension of many of the licence durations and the introduction of phased licence expiry dates throughout the year.

Licensees in the medical sector represent approximately 8% of the total number of licensees. However a considerable amount of time is devoted to dealing with licensing issues in this sector. This is in large part due to the continual advances in both medical procedures and equipment. At the time of the review the Regulatory Service lacked the specialised expertise required to assess the technical issues involved in this particular area. The review team recommended that consideration should be given to further strengthening the expertise of the existing staff or to the use of specialised external consultants to ensure that the Regulatory Service had the necessary expertise to regulate this sector.

Licensing

The procedures for assessing a licence application and for issuing a licence are set out in the Regulatory Service's Quality Manual. With the introduction of EN 45004 these procedures will be audited, both internally and externally, on a regular basis. Where weaknesses in the procedures are identified, corrective measures will be introduced to address them.

Under current regulations (S.I. No 125) all practices involving radioactive sources (other than exempt sources) require prior authorisation in the form of a licence issued by the Institute. A completed application form for a licence must be received and a licence issued by the Institute prior to taking possession of a source. The application must include all relevant documentation, e.g. risk assessment, radiation safety procedures, and, in the case of sealed sources, written assurance that the supplier will accept the return of the source when no longer required by the applicant. An application for the renewal of a licence must be submitted to the Institute 30 days prior to the expiry date of the licence. At the time of renewal, the licensee must ensure that the inventory of sources is up-to-date and that their radiation safety procedures have been reviewed.

A licence amendment process allows licensees to request changes to their authorisation and other licence conditions as required. Supporting documentation for amendment applications must be provided. In some instances, e.g. the purchase of a new source or a change in work practice, the risk assessment and radiation safety procedures would require revision and these must be forwarded to the Institute in support of the amendment application within 30 days of the proposed date of the licence amendment.

The Institute attaches a schedule of conditions to each licence issued. These conditions are reviewed at the renewal time for each category of licensee, or when a licensee applies for a new practice or amendment to their licence. The Radiological Protection Act, 1991 was amended in 2002 to make failure to comply with a licence condition a prosecutable offence

The Regulatory Service has recently reviewed the duration of licences issued and will now issue licences for durations of 5 years or, in the case of low risk activities such as the use of cabinet X-ray equipment, for ten years. For industrial radiography licences a licence will be valid for two years and for dental and veterinary practices the licence will be valid for four years. In circumstances where the Regulatory Service is concerned about the standards of radiation protection, it may revoke or suspend the licence or restrict the practices that may be carried out thereunder.

Inspectors

Sections 28 and 29 of the Radiological Protection Act, 1991 provides for the Institute to appoint inspectors and confers on inspectors so appointed wide-ranging powers. Warrants of appointment are approved by the Board of the Institute and issued to the inspectors. The powers of inspectors include the power to seize and detain any radioactive substances or irradiating apparatus and to undertake or arrange for their safe disposal. The powers also include right of entry, the power to order an evacuation and the power to order persons to perform or refrain from performing any act that might prevent or reduce the danger arising from ionising radiation.

New inspectors are trained on the job by accompanying an experienced inspector for two to three months before undertaking inspections alone. Where suitable training courses are identified these are used to supplement the on the job training both for new and existing inspectors. In addition to training courses in radiological protection inspectors also undertake training in health and safety awareness, courtroom skills, report writing and presentation skills.

Prior to the recruitment of a medical physicist in late 2003 the Regulatory Service did not have the necessary in-house expertise to undertake comprehensive inspections of medical facilities with radiotherapy or nuclear medicine departments. To address this issue the Regulatory Service contracted the services of a consultant, who is the Chief Physicist in a major UK hospital, to assist its own inspectors in performing inspections of these facilities. It should be noted that it was decided to contract someone located outside the State to avoid a possible conflict of interest. The consultant was subsequently appointed as an inspector by the Institute's Board which afforded him the powers to conduct inspections. All inspections by the consultant were performed in conjunction with staff of the Regulatory Service. Following the inspection he provided the Regulatory Service with a report of his findings which formed the basis of the inspection report issued by the Regulatory Service.

At the end of 2003 the Regulatory Service recruited a medical physicist, with several years experience of working in a major Irish hospital. This medical physicist is now responsible for all licensing and inspection matters in relation to the medical sector. However, one of the difficulties facing any medical physicist once he or she is removed from the environments of a busy hospital is that it becomes increasingly difficult for that person to keep up-to-date with new advances in medical procedures and equipment. For that reason the Institute ensures that adequate resources are made available for this person's knowledge and training to be kept up-to-date through attendance at professional meetings, conferences and training courses.

Inspection Programme

An inspection programme is drawn up at the beginning of each year. As a guideline, the Institute aims to perform a full inspection of each licensee (with the exception of dentists and veterinary surgeons) at least once during each licence period. Partial inspections of the major sources of radiation are performed approximately mid-way between full inspections. For the majority of licensees this implies a full inspection every five years with a partial inspection approximately mid-way. Licensees involved in potentially hazardous practices such as process irradiation and industrial radiography are inspected more frequently. The frequency of inspection of a particular category of licensee may be varied to reflect the incidence of reported non-compliances and equipment faults associated with the practice in question.

In order to complete the inspection programme two and a half inspectors are required; this is the basis of an inspector, working full time on inspections, being able to undertake approximately 80 inspections per year. During 2003, two inspectors working full time carried out a total of 151 inspections. In addition to the planned inspections, inspections are also undertaken by the Regulatory Service where:

- It has received a complaint in relation to a licensee;
- A radiation incident has come to its attention;
- It suspects that a source of ionising radiation is being held and/or used without a licence;
- Concerns have arisen with regard to documents supporting licence application/amendment.

The breakdown of the inspections during 2003, by licensee category, is given in Table II.

Table II: Inspections undertaken in 2003

Licence Category	Licensees	Inspections
Process Irradiators and Cyclotron	5	5
Industrial Radiography	20	11
Lightning Preventors	7	1
Manufactures of Devices	2	1
Industrial Users	222	47
Education & Research	18	5
Government Departments & State Run Services	7	4
Hospitals/Medical	124	24
Custody Only	33	20
Distributors	50	9
Veterinary Surgeons	155	13
Chiropractors	9	3
Dental Surgeons	794	7
Contaminated Scrap Metal	2	1
Total	**1448**	**151**

Inspections

In advance of an inspection, the licence, recent correspondence, radiation safety procedures, previous inspection reports and incident or event reports are reviewed. Standard inspection audit forms (based on the category of licence) are used to guide the inspector and record the inspection details.

The inspection is generally divided into two parts: an audit of the administrative aspects of the licence and an inspection of the licensed item(s) and the facility. During the administrative part of the inspection the inspector will review all documentation relating to the licence, personal dosimetry, disposals, acquisitions, quality assurance testing, servicing etc. In addition, the inspector will also review the availability of suitable trained personnel and the appropriateness of their on-going training. In the case of licensees in the medical sector the Institute assess staffing levels against the European Federation of Organisations for Medical Physics (EFOMP) staffing model [5]. The second part of the inspection includes a physical or visual examination of the licensed item(s) and protective equipment, an assessment of the radiation protection shielding and engineering controls, storage arrangements etc. The inspector may also make some dose rate measurements, in the case of radioactive sources, or kV and timer and other equipment performance measurement in the case of X-ray units. However, it is important to note that these performance measurements are just spot checks rather than a full QA assessment, which is the responsibility of the licensee to perform.

A number of licensees use licensed items at locations off-site to the licensee's administrative base e.g. industrial radiography equipment, portable veterinary X-ray units and trailer based mobile mammography and PET units. In these cases an off-site inspection would be arranged to enable the inspectors to observe these items in operation.

At the end of the inspection the inspector presents a summary of his/her findings to the licensee's radiation protection officer and a member of the senior management, where available. The licensee is verbally directed (under section 29 of the Act) to undertake corrective actions, usually within four to six weeks, regarding any non-compliances identified during the inspection; for serious non-compliances, where there may be safety implications, a shorter deadline may be given. The licensee is asked to sign the inspection summary report form acknowledging that they understand the verbal direction that they have received. The licensee is given the

option of making a copy of the summary of non-compliances. Shortly after the inspection the inspector writes to the licensee summarising the details of the direction previously given, restating the deadline by which the non-compliances shall be addressed.

The Regulatory Service undertakes specific targeted inspection programmes on a regular basis. In the late 1990's a comprehensive programme of dental inspections was undertaken with the objective of removing from use dental X-ray equipment which did not comply with the Institute's Code of Practice for Radiological Protection in Dentistry [6]. Common equipment non-compliances identified during the programme included dental X-ray units using mechanical timers, short pointer cones (resulting in an insufficient skin to focal spot distance), low generating voltages and the absence of appropriate warning lights. Where units were identified that could not be brought into compliance with the Code the dentist was directed to decommission these units thereby rendering them incapable of producing ionising radiation. This programme successfully resulted in the removal of sub-standard dental X-ray equipment from Ireland which has resulted in a reduction in the mean patient skin doses and an improvement in radiation protection generally.

Recently the Regulatory Service investigated an incident where a stud farm assistant received a significant radiation dose while assisting a veterinary surgeon in the X-raying of horses. Although the exact cause of the dose received could not be established the veterinary surgeon was found to have been at fault for not providing long-handled cassette holders to the individuals assisting him as required in the Institute's code of practice for veterinary surgeons [7]. As a follow-up to this incident the Regulatory Service currently has a specific programme targeting veterinary surgeons, especially those using portable X-ray units in the field, with the objective of increasing the awareness of the requirements contained in the Institute's code of practice.

Enforcement

There are a number of options available to the Regulatory Service for dealing with non-compliances. These include issuing a verbal direction during the course of an inspection instructing the licensee to carryout specified improvements within a prescribed time-scale, formal enforcement notices, which may include a requirement that the licensee ceases carrying on the practice, prosecution and licence suspension or withdrawal. The option decided upon will reflect the seriousness of the non-compliance.

Since the Institute was established in 1992, 34 prosecutions have been undertaken for various offences - the majority of these were in respect of the failure to hold the appropriate licence. A summary of these prosecutions is given in Table III. .

Table III: Summary of Prosecutions

Category	No.	Offence(s)
Industrial	16	Unlicensed custody/use/disposal Failure to calibrate a survey meter & keep records of calibration Failure to carry out wipe tests
Dental	8	Unlicensed custody/obstruction of an inspector
Distribution	5	Unlicensed distribution/custody
Medical	3	Unlicensed exportation/custody
Education	1	Unlicensed custody
Vet	1	Unlicensed custody
Total	**34**	

According to Section 40 of the Radiological Protection Act, 1991, the maximum fine on summary conviction for an offence involving a radioactive source that a district court may impose is €1269. However in the event of a prosecution following a serious incident the case may be heard in a higher court where the maximum penalty on indictment is €126,900 and/or imprisonment for a term not exceeding ten years. In practice almost all the cases taken by the Institute have been heard in a district court where the fines that have been handed down are usually of the order of several hundred euros. However, of more concern to the licensees than the size of the fine is the potential for the case to be reported in the media and the associated negative publicity for the licensee. All prosecutions are reported on an annual basis in the Institute's annual report, though the names of the licensees are withheld

Conclusions

The responses from licensees to inspections carried out by the Regulatory Service are usually very positive. For licensees in the industrial sector, where the responsible staff would not have the same level of expertise as a medical physicist, the inspection is welcomed and is viewed as part of their overall health and safety audit/programme. Furthermore, several of the Regulatory Service's licensees actually request an inspection of their facilities in order to fulfil their requirements for an annual independent radiation survey as part of their quality assurance programme – in these instances the Institute would charge the licensee for the cost of the requested inspection.

The Institute has in recent years modified its approach to the undertaking of inspections of large facilities such as a university or major hospital. In the past a comprehensive inspection of these facilities would have been carried out over a number of days, auditing every aspect of the licence and inspecting each department/section of the facility. Experience has shown that it is preferable to undertaken shorter duration inspections more frequently, typically half a day in duration, and to target specific activities or departments each year. This affords the Institute a greater presence on-site which increases the radiation protection awareness and the implementation of safeguards.

The Institute believes that real improvements in radiation safety can only be effected through a well structured and comprehensive inspection programme. This provides the licensee and inspectors an opportunity to meet face to face and experience has shown that this encourages the licensees to make contact with the Regulatory Service whenever guidance or assistance is required.

References

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