XA0102995 IAEA-CN-84/39

REGULATORY CONTROL OF RADIATION SOURCES AND RADIOACTIVE MATERIALS IN IRELAND

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Abstract. The primary legislation governing safety in uses of ionizing radiation in Ireland is the Radiological Protection Act, 1991. This Act provided for the establishment in 1992 of the Radiological Protection Institute of Ireland, and gives the Institute the functions and powers which enable it to be the regulatory body for all matters relating to ionizing radiation. A Ministerial Order made under the Act in 2000 consolidates previous regulations and, in particular, provides for the implementation in Irish law of the 1996 European Union Directive which lays down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation.

Under the legislation, the custody, use and a number of other activities involving radioactive substances and irradiating apparatus require a licence issued by the Institute. Currently some 1260 licences are in force. Of these, some 850 are in respect of irradiating apparatus only and are issued principally to dentists and veterinary surgeons. The remaining licences involve sealed radiation sources and/or unsealed radioactive substances used in medicine, industry or education.

A schedule attached to each licence fully lists the sealed sources to which the licence applies, and also the quantities of radioactive substances which may be acquired or held under the licence. It is an offence to dispose of, or otherwise relinquish possession of, any licensable material other than in accordance with terms and conditions of the licence. Disused sources are returned to the original supplier or, where this is not possible, stored under licence by the licensee who used them.

Enforcement of the licensing provisions relies primarily on the programme of inspection of licensees, carried out by the Institute's inspectors. The Institute's Regulatory Service has a complement of four inspectors, one of whom is the Manager of the Service. The Manager reports to one of the Institute's Principal Scientific Officers, who in turn reports to the Chief Executive.

The Institute's licensing system and inspection programme constitute the principal means of ensuring safety and security of radiation sources and radioactive materials. They are backed by powers of prosecution which the Institute typically uses a few times each year.

The management of abnormal events and of orphan sources, education and training, and the dissemination of information to the public are also considered in the paper.

REGULATORY INFRASTRUCTURE

The Radiological Protection Act

The primary legislation governing safety in the uses of ionizing radiation in Ireland is the Radiological Protection Act, 1991 [1]. This Act provided for the establishment in 1992 of the Radiological Protection Institute of Ireland, and Section 7 of the Act lists the general functions of the Institute. These include:

- monitoring radiation levels in the environment;
- monitoring the exposure of individuals;
- advising the Government on measures for the protection of individuals from radiological hazards, and in relation to relevant international standards;
- assisting in the planning and implementation of measures to deal with radiological emergencies; and
- providing information to the public on matters relating to radiological safety.

The Institute is under the aegis of the Department of Public Enterprise, the Government department dealing with energy and transport.

The Act gives the Institute the functions and powers which enable it to be the regulatory body for the control of radiation sources 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 deal with the appointment and powers of inspectors, while Sections 40 and 41 deal with offences and prosecutions.

The Ionizing Radiation Order

A Ministerial Order (The Radiological Protection Act, 1991 (Ionizing Radiation) Order, 2000) [2] made under the Act in May of 2000 consolidates previous regulations and, in particular, provides for the implementation in Irish law of the 1996 European Union Directive laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation. This legislation designates the Institute as the competent authority.

It 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 and, at present, there is no provision for clearance of contaminated material.

The principles of justification and optimization are included in the legislation and the annual effective dose limits are 20 mSv and 1mSv for exposed workers and members of the public, respectively. Other requirements include those relating to classification of areas (controlled and supervised), radiation safety procedures (written statement of procedures to be followed to minimize risk of exposure), appointment of a Radiation Protection Adviser (qualified expert), dose monitoring, and information and training to be provided for exposed workers. With regard to the control of radioactive substances, nuclear devices and irradiating apparatus, Article 28 of the Order requires that an up-to-date inventory of the locations and quantities of all sources of radiation be maintained by the licensee and that these sources be clearly labelled and kept in secure and safe storage when not in use. In the case of unsealed radioactive substances, the licensee is required to maintain records of the quantities used and the dates and method of disposal.

INVENTORY OF RADIATION SOURCES AND RADIOACTIVE MATERIALS

Currently, there are approximately 1260 licences in force. The Institute issues licences based on the type of source to be used and the nature of the use. The number of licensees by category is given in the table below. Of the total number of licences, some 850 are in respect of irradiating apparatus only and are issued principally to dentists and veterinary surgeons. The remaining licences involve sealed radiation sources and/or unsealed radioactive substances, which are used in medicine, industry or education.

Band	Licence Category	Number in Category
Industrial	Level 7 -process irradiation facility	3
	Level 6 - industrial radiography using X rays and/or sealed sources, gauge manufacture	25
	Level 5 - 20 or more sources (X ray sets or sealed sources other than for use in industrial radiography)	9
	Level 4 - 6-19 sources (X ray sets or sealed sources other than for use in industrial radiography)	9
	Level 3 - 1-5 sources (X ray sets or sealed sources other than for use in industrial radiography)	83
	Level 2 - sealed sources with activity < 10 MBq	9
	Level 1 - cabinet type X ray set	63
	Lightening preventors	11
	Static controllers	8
	Logging	2
	Gaseous Tritium	1
	Custody Only	15
Medical	Level 5 - hospital with radiotherapy facilities	4
	Level 4 - hospital with radiology and nuclear medicine facilities	15
	Level 3 - hospital with X ray facilities which also uses unsealed sources for in-vitro application only	6
	Level 2 - hospital with X ray facilities only	57
	Level 1 - hospital with one simple X ray set (i.e. not CT, mammography or fluoroscopy)	21
Education,	Level 3 - more than 5 sealed sources, at least one of which has activity >1 MBq, and/or unsealed sources	28
Research &	Level 2 - 1 - 5 sealed sources (1 with activity > 1 MBq), or >5 sealed sources of activity <1MBq, or unsealed sources	1
Labs	Level 1 - < 6 sealed sources of activity < 1MBq and/or simple X ray sets	1
Distribution	Level 2 - distributor of sources other than Ionisation chamber smoke detectors (ICSD's)	40
	Level 1 - distributor of ICSD's only	11
Others	Dental surgeons	713
	Veterinary surgeons	119
	Chiropractors	5
	Miscellaneous	3
Total		**1258**

LICENSING

Application for a licence to the Institute must be made before possession of the source can occur and must include all relevant documentation (i.e. 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 it is no longer required by the applicant). Depending on the licence category, licences are issued for terms of between one and four years, with shorter terms for more hazardous activities. An application for renewal of a licence must be submitted to the Institute by the licensee 30 days prior to the expiration date of the licence. At the time of renewal, the licensee must ensure that the inventory of sources is up-to-date and that the radiation safety procedures have been reviewed.

A licence amendment process allows licensees to request changes to their authorization and other licence conditions as required. Supporting documentation for amendment applications must be provided. In some instances, i.e. purchase of a new source or change in work practice, modification of the risk assessment and radiation safety procedures may be required and any revisions must be forwarded to the Institute within 30 days of the date of licence amendment.

INSPECTION

A routine announced inspection programme based on the licence band (industrial, medical, education/research, distribution and others) is drawn up at the beginning of each year. As a guideline, the Institute aims to inspect each licensee (with the exception of dentists and veterinary surgeons) at least once during the licence period. In the first place, the programme is designed to ensure that those licensees where the greatest potential radiological risks exist are inspected. Priority is then given to those licensees who have not been visited by Institute inspectors or who were last inspected outside the current licence period. In 1999, a total of 132 inspections were undertaken, while in 2000, the programme identifies 135 licensees due for inspection. In advance of the inspection, the licence, 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 document the inspection details. Approximately five to ten days following the inspection, a summary letter specifying the required actions is forwarded to the licensee with a response deadline of four to six weeks.

ENFORCEMENT

The Ionizing Radiation Order, which came into force in May 2000, contains provisions for the issuance of enforcement notices, but these provisions have yet to be used. The enforcement notice may require the licensee to cease performing the practice. The existing legislation provides for the prosecution of an undertaking for failure to fulfil the licensing requirements or for failure to observe the conditions attached to a licence. Since the Institute was established in 1992, 17 prosecutions have been undertaken for various offences, the majority in respect of failure to hold the appropriate licence.

THE MANAGEMENT OF DISUSED SOURCES

Currently, there is no waste repository in Ireland, but consideration is being given to establishing a national centralized storage facility for disused sealed sources. Consequently, unless provision has been made to return disused sources to the supplier, sources must be stored by the licensee in a safe and secure location. The Institute's inspectors have the power

to take custody of sources, but these powers have not been exercised because of the lack of a suitable store. Altogether, approximately 7550 sources are in store in 70 different locations around the country, with a nominal total activity of 14 375 GBq. Approximately 7000 of these are the Mo-99 cores of Tc-99m generators. The database operated by the Institute's Regulatory Service contains records of all sources held for custody only, i.e. in storage.

EMERGENCY RESPONSE

In 1998, the Irish Government approved a revised National Emergency Plan for Nuclear Accidents, which details the response of the various government agencies and departments to accidents in other countries involving the release or potential release of radioactive substances into the environment. Under the plan, the Institute has significant responsibilities, principally with regard to the assessment of the consequences of an accident and the provision of advice and information to the public and others. The Institute has established a number of communication pathways with international agencies and provides an on-call service for the receipt of messages giving early notification of any radiological incident. It also operates a gamma dose-rate monitoring network and a country-wide system for air sampling and rainwater collection. Exercises of various aspects of the plan have been conducted over the last number of years and a full scale exercise is due to take place in 2001.

With regard to incidents or accidents occurring in Ireland, it is a condition of licence that the Institute be notified as soon as possible and, at the latest, within 24 hours. Outside office hours, the Institute's on-call duty officer can be contacted and a member of the Regulatory Service alerted. Since 1990, over 60 incidents involving ionizing radiation have been reported to and investigated by the Institute's Regulatory Service. The incidents have principally involved industrial users, distributors and hospitals. In most cases, the radiological consequences were low. Details of incidents are published in the Institute's annual report.

ORPHAN SOURCES

To date, there have been three discoveries of orphan sources in Ireland. In one case, the source was hidden in a consignment of scrap steel and was inadvertently melted down. The resulting contaminated material was shipped back to the supplying country. In the second case, the country of origin of a source concealed in a consignment of scrap metal could not be determined and the source is now held, under licence, by the steel recycling plant. In the third case, the source was discovered by a member of the public and it is now held, under licence, by an existing licensee (a hospital).

LOST SOURCES

Incidents involving the loss of sources have occurred mainly during the transport of the source from supplier to customer. In general, the Institute has adopted a policy of alerting all those who might come in contact with the source to the potential hazard. For example, when a source was lost in transit at an airport, all airport personnel, the airport police and the Gardai (national police) were notified. In cases where a source has been stolen, the public at large are alerted through the issue of a press release to the media.

EDUCATION AND TRAINING

The Ionizing Radiation Order requires all employers using ionizing radiation to provide appropriate information and training in radiation protection to exposed workers. It also requires that adequate information is given to other persons directly involved with the work with ionizing radiation to ensure their health and safety. Training courses in radiation protection are provided both in Ireland and in the UK and the staff of the Regulatory Service give lectures and presentations on a number of Irish training courses.

REFERENCES

[1] Radiological Protection Act, 1991 (Number 9 of 1991), The Stationery Office, Dublin.
[2] Radiological Protection Act 1991 (Ionizing Radiation) Order, 2000 (S.I. No. 125 of 2000), The Stationery Office, Dublin.