Ionising Radiation Regulation

Key Findings from the 2015 Inspection and Enforcement Programme

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1. Introduction

The Radiological Protection Act 1991, as amended by the Radiological Protection (Miscellaneous Provisions) Act, 2014, provides for the EPA 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"*. Section 28 of the Act covers the appointment of 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 setting out basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation. Inspections undertaken by the EPA are designed to ensure compliance with the legislative requirements set out in S.I. No. 125 of 2000 and other relevant legislation including S.I. No. 875 of 2005 (High Activity Sealed Sources) and the Carriage of Dangerous Goods by Road Regulations.

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.

This report sets out the key findings from the EPA's 2015 programme of inspection for facilities regulated under the Radiological Protection Act, 1991.

Details of the EPA's system of regulation for ionising radiation can be found on the EPA website www.epa.ie.

2 Inspection Programme

The areas of particular focus included in the 2015 inspection programme included:

- High risk activities using sources of ionising radiation such as radiotherapy, non-destructive testing and radiopharmaceutical production;
- Activities involving large numbers of, or high activity, sealed and unsealed radioactive sources;
- Unannounced inspections of non-destructive testing site work, particularly where licensees conduct these practices on third-party premises;
- A focus on hospitals' pregnancy determination protocols for patients undergoing diagnostic or therapeutic medical procedures;
- Radiation protection standards in the medical sector, particularly where RPA support is provided by an external, regional-based service;
- Follow up inspections of hospitals where concerns were noted in relation to quality assurance programmes during 2014.

The completed Inspection schedule for 2015 is presented in the Appendix. The number of radiation protection focused inspections of licensed facilities carried out in 2015 was 73. This number includes six visits to sites suspected of having historic lightning preventors dating back to the 1970s. Taken together with similar visits in 2014, this resulted in the identification of eight premises with such lightning preventors.

3 Inspection Observations

- Eight radiotherapy inspections were undertaken during the year which focused on a combination of administrative and practical aspects of radiation protection. No radiation protection/safety concerns were noted in this sector and the standard of radiation protection remains high. The main findings raised during the inspections included issues with non-working warning lights, inadequate signs and notices, risk assessment and radiation safety procedures not being regularly reviewed and updated where necessary. The availability of risk assessments from third party organisations responsible for the service and maintenance of equipment in radiotherapy therapy departments was also an issue.
- Non-destructive industrial radiography is an activity where workers can potentially record significant doses on their personal dosimeters and accordingly the EPA carries out unannounced inspections whenever practicable. During 2015 nine unannounced inspections were carried out in this sector. In general the standards of radiation protection demonstrated at each inspection were good. As in all sectors

there is always room for improvement as evidenced by one inspection where the radiographers were relying on their alarming Electronic Personal Dosimeters, rather than a survey meter, to confirm that source had properly retracted to their shielded position. In another inspection of NDT work being performed on the third level of a multi-storey facility the inspectors judged that the exclusion barriers were not adequately patrolled and the warning notices provided were inadequate. This demonstrates that continued vigilance is required for what is a high risk sector.

- With the possible exception of licensees involved in the distribution of radioactive sources, industrial radiographers are one of the most frequent transporters of radioactive sources. Accordingly they are required to comply with the relevant requirements of the ADR whenever radioactive sources are moved on public roads. A number of breaches of the ADR by licensees in this sector were noted during the year. These were mainly issues regarding vehicle placarding and documentation. In recent times inspections of licensees involved in the practice of transportation have placed a greater emphasis on assessing compliance with the ADR. It was recommended that the EPA continue to focus on compliance with the ADR in subsequent years with a view to reducing the number of non-compliances.

- Building upon the area of focus initiated in 2014, inspectors continued work to ensure that appropriate pregnancy determination protocols were available in all relevant facilities. The EPA recognises this is a very complex area and where appropriate a number of hospitals were requested to review their procedures to ensure that they were sufficiently robust and fit for purpose. The EPA was made aware by the medical physics professional body that there are multiple challenges posed to hospitals in this particular area. It was recommended that this issue be further addressed in 2016.

- Not all licensees have an in-house RPA and many source their RPA support from external regional-based services. Inspections of hospitals that depend on external RPA services focussed closely on the level of support provided by the RPA. A number of the findings raised during these inspections identified short-comings in the implementation of the hospital's quality assurance programme, as drawn up by the external RPA. The most significant being a mobile C-arm fluoroscopy X-ray unit used in an operating theatre setting, which had not undergone QA testing for three years despite the RPA's QA programme requiring testing on an annual basis. This resulted in a direction being given by the inspector to the hospital to cease its use (see Section 5). In addition, it was noted on several occasions that risk assessments were not being reviewed during the period of the licence.

- It was noted that hospitals were still facing challenges with respect to resource constraints. This was reflected in a significant number of findings being reported with respect to inadequate levels of Radiation Protection Adviser (RPA) and medical physics support. These support levels are an essential requirement for hospitals in order that they meet all of their licensing and statutory obligations and maintain high radiation protection standards. It was recommended that the EPA continue to closely

monitor this in subsequent years to ensure that it is not adversely affecting radiation safety standards.

- During a small number of hospital inspections inspectors noted multiple issues such as incomplete QA records, poor communication, lack of management commitment to radiation protection and insufficient medical physics/RPA input. Collectively these issues raise concerns in relation to the overall commitment to safety culture within the hospitals. This commitment to safety culture must come from senior management. Furthermore, these issues also raised concerns with respect to the advocacy and the ownership of radiation protection in these facilities. In these cases the CEO/General Manager of the hospitals concerned were advised that these issues must be addressed as a matter of urgency and to review their governance arrangements to ensure appropriate structures were in place to ensure all radiation protection regulatory requirements were being met. Follow-up inspections were undertaken to determine whether these issues had been closed out to the satisfaction of the EPA, and further surveillance was recommended for 2016.

4 High Level Observations

- During the year inspectors noticed an increasing number of recurring findings among licensees. Examples of such findings included, in the medical sector, shortcomings in the documentation and implementation of appropriate QA programme, pregnancy determination and patient identification audits. Findings from previous inspections where manifesting themselves again, leading inspectors to the conclusion that licensees were often just addressing the actual individual findings rather than addressing the underlying causes which led to the findings occurring in the first place. On other occasions there was evidence in some facilities of licensing requirements being addressed just prior to the inspection indicating a reactive approach to radiation protection. This raises concerns that items are only being addressed as a result of a pending inspection. As a result it was recommended that an increased number of unannounced inspections be scheduled for 2016.

- In 2015 the EPA started to promote the concept whereby licensees were encouraged to develop and implement an effective radiation safety culture within their organisations – this concept is well embedded in the nuclear industry and has been shown to contribute significantly to maintaining high standards of radiation safety. While it is not straightforward to assess whether an organisation has a good radiation safety culture, a large number of significant inspection findings can often indicate a poor radiation safety culture. During the year, based on evidence from inspection findings it was reported, to a number of licensees that the radiation safety culture was poor and that senior management needed to improve on their approach to radiation safety.

- Two pre-licensing security surveys of new licence applicants were carried out during the year with the assistance of An Garda Síochána's National Crime Prevention Unit. These surveys assess the security arrangements in place at applicant/licensees' facilities against international best security practice for those wishing to store and use high activity sealed sources, in advance of a licence being granted. Recommendations for increased security measures were made to both licensees relating to issues such as CCTV monitoring, physical and electronic security and documented security plans.

- Fourteen licensees involved in the transport of radioactive material were inspected during the year. These included hospitals (as consignors), industry, industrial radiography companies and distributors. Some of the key ADR issues identified during these inspections included inadequate or incorrect labelling and/or marking of the package or vehicle, vehicles not fully equipped as required under the ADR and ADR training certificates not being available where required. None of these findings presented a high level of risk but the sector warrants on-going vigilance though both announced and unannounced inspections. Where required, licensees in the medical sector were requested to update their Radiation Safety Procedures and associated documentation to take account of their obligations under the ADR.

- In general radiation protection standards across the industrial sector remain high. However, from an administrative point of view, good record keeping and associated document management practices continue to be a challenge for licensees in this sector. This is evident during inspections where on occasion licensees were unable to produce documented risk assessments or copies of notification letters to the Chief Fire Officer as required under the conditions of their licence. Some minor findings regarding the training of relevant staff in radiation safety/awareness and the review of Radiation Safety Procedures (mainly administrative) were the most significant issues of note. It is noted that in the NDT sector the EPA is not always aware of when site radiography work, using either X-ray or sealed sources, is to be undertaken.

5 Enforcement Activities in 2015

If 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, in accordance with Article 29 (3) of the Radiological Protection Act, 1991, 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 2015, directions had to be issued to three separate licensees:

- Due to concerns that EPA inspectors had in relation to the shielding of a general medical X-ray room, a direction was issued to a hospital ordering it to refrain from using X-ray equipment in the room. The hospital was directed to carry out a new risk assessment for the room in conjunction with its RPA, review the shielding integrity of

the entrance doors and all boundaries of the room, and provide for increased shielding where necessary.

- During the course of an inspection of a hospital inspectors discovered that a mobile C-arm fluoroscopy X-ray unit, which was in routine use, had not had any QA testing for the previous three years in contravention of the hospital's annual QA programme. A direction was issued to a hospital ordering it to immediately cease operation of the unit until it had been fully tested and the results approved by the RPA.

- A direction was issued to two industrial radiographers about to commence NDT work, ordering them not to proceed with their work as they were not in possession of a sufficient number of personal dosimeters or Electronic Personal Dosimeters (EPD) as required under the conditions of their licence. The radiographers had to return to their headquarters to retrieve the relevant items before being allowed to return and commence their work.

In addition to the three directions issued, a licensing embargo was placed on a hospital preventing it from acquiring any new licensable items until such time as significant concerns that the EPA had in relation to its existing radiation protection programme were addressed. These concerns included incomplete QA records, lack of management commitment to radiation protection and insufficient medical physics/RPA input. This embargo ensured that a new CT Unit was not introduced to the facility until the hospital had regularised their significant radiation protection shortcomings.

In general licensees respond to inspection findings in a timely manner. While it may not always be possible to fully implement improvements in a short time frame, nevertheless the EPA would expect the licensee's senior management to commit to a plan of action with tangible deliverables. However, on occasion licensees do not address the inspection findings to the satisfaction of the EPA. In such situations EPA can increase its regulatory surveillance by undertaking more frequent inspections, often returning to a licensee for a follow-up inspection within several months. During 2015 the EPA had to place three licensees under increased surveillance.

Appendix – Completed Inspection Schedule for 2015

Licence Category	Risk Category	No. in Category	No. of Planned Inspections	Completed inspections
Chiropractors	Medium	13	1	0
Others [e.g. scrap industry, lightning preventors]	Medium	13	0	6[a]
Distributors (sources)	Medium	12	1	2
Hospital Level 1 (1 X-ray unit)	Medium	12	0	2
Hospital Level 2 (>1 X-ray unit)	Medium	58	8	7
Hospital Level 3 (Diagnostic X-ray + unsealed sources)	Medium	2	0	0
Education and Research	Medium	15	2	0
Industrial level 3 (sources, transport)	Medium	69	3	7
Industrial level 4 (> 6 sources)	Medium	9	3	6
Industrial level 5 (> 20 sources)	Medium	2	1	0
Vet (X-ray + equine nuclear medicine)	Medium	1	1	1
Industrial level 6 (fixed X-ray, sources, transport, ICSD assembly)	Medium/High	20	8	16
Hospital Level 4 (nuclear medicine)	Medium/High	17	6	2
Hospital Level 5 (radiotherapy)	High	14	10	9[b]
Industrial level 7 (irradiation, e-beam, cyclotron and mobile container scanner)	High	6	2	2
Total		263	46	60
Licensees from the Low risk category (e.g. dentists, vets, DXA & cabinet X-ray units)	Low	-	10	13
Security inspections			0	2[c]
Total (including inspections from the Low risk category)			56	75

[a] Outside the scope of ISO 17020
[b] Eight inspections were radiotherapy and one was diagnostic X-ray
[c] Outside the scope of ISO 17020