Key Findings from the 2017 Radiation Protection Inspection and Enforcement Programme

August 2018

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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 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 2011 to 2017. 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. A quality management system has been developed for these inspection activities in line with ISO 17020, which is an international standard designed for inspection bodies.

This report which is for licensees, their Radiation Protection Advisers (RPA) and other relevant Competent Authorities sets out the key findings from the EPA's 2017 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 Site Visit Programme

In late 2016 the term ‘inspections’ was changed to ‘site visits’ to be consistent with the other EPA offices. One hundred and twenty-five site visits, including 8 security surveys in the industrial and medical sectors, carried out with the assistance of An Garda Síochána, Crime Prevention National Centre of Excellence, were undertaken in 2017 (Table 1). The completed site visit programme by Licence Category for 2017 is presented in the Appendix. Forty seven percent of the site visits were unannounced.

In 2015 the EPA expanded its Licensing and Enforcement Management Application (LEMA) to include a new radiation protection licensing module. In January 2016 LEMA was extended to include inspections. This new module allows for greater quantitative analysis of inspection findings than was possible in earlier years. This is reflected in the presentation of the findings for 2017 in this report. It is intended to further develop this quantitative analysis in future reports as experience is gained with LEMA.

The areas of focus included in the 2017 inspection programme included:

- Activities using sources of ionising radiation such as high dose rate radiotherapy, non-destructive testing (industrial radiography) and radiopharmaceutical production;
- Activities involving large numbers of, or high activity, sealed and unsealed radioactive sources;
- Unannounced or short notice inspections of non-destructive testing site work, particularly where licensees conduct these practices on third-party premises;
- The use of Cone Beam CT in the dental sector.
- Medical facilities, where RPA support is provided by an external, regional-based service;
- Follow up inspections of facilities within the medical sector that were placed on increased medical surveillance because of concerns noted or significant inspection findings in previous years.

Table 1: Completed Site Visit Programme by Sector for 2017

Regulated Facility Type	No. in Category	No. of Planned Site Visits	Site Visits undertaken
Hospital & Medical Facilities	139	47	38
Industrial & Commercial Licensees Including Source Distributors & Transport Companies	127	67	50
Education & Research Licensees	15	7	5
Other Licensees (low & medium risk Vets, Dentists, Industrial cabinet X-ray, distributors of X-ray units)	1475	22	32
Total	1756	143	125

66 of the 125 Site Visits were announced (30 were Medical and 36 were Industrial related)

3 Site Visit Findings

Site visit findings are classified according to categories and subcategories Table 2). Examples of these are given in Table 2.

Table 2: Categories of Site Visit Findings

Category	Subcategory
Administrative	Authorisation, operational controls administrative
Dosimetry	Inadequate dosimetry, incident investigation
High Activity Sealed Sources (HASS)	HASS Management Framework, HASS records
Maintenance & Operational Controls	Operational controls, servicing, Quality Assurance (QA) and Quality Control (QC) programme
Practical Radiation Protection Arrangements	Operational controls, security, signage
Radiation Protection Training	Implementation, training policy
Radiation Safety Committee	Ineffective, governance related
Radiation Safety Procedures	Availability, implementation, adequacy, review of procedures
Records	Availability, fire safety, security
Risk Assessment Safety	Availability, inadequate, omitted practices, review of risk assessment
Safety	Incidents, operational controls
Transportation	ADR equipment, driver training, operational controls, packaging and labelling, placarding, security, stowage and transport documents

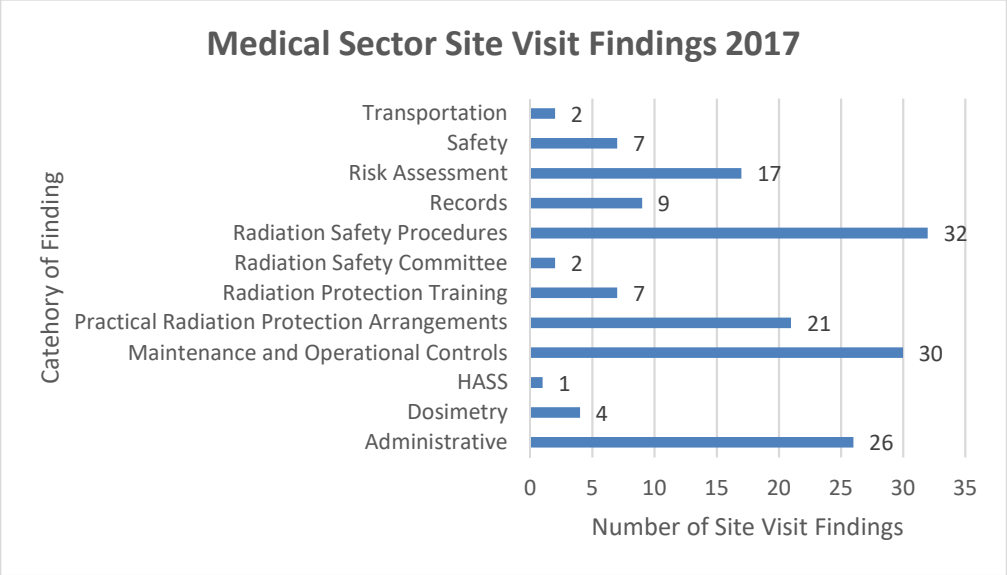

Figure 1. Category and Number of Findings in the Medical Sector for 2017.

The category and number of findings for the medical sector are presented in Figure 1. The greatest number of findings (20%) was associated with radiation safety procedures. Eleven of the 32 findings (34%) were associated with the availability of procedures within the hospitals and 10 out of the 32 (31%) were associated with inadequate procedures. Five of the 32 findings were associated with implementation of radiation safety procedures (for example, inadequate compliance with the established dosimetry monitoring programme, incorrect procedures for dealing with spills in the nuclear medicine department and lack of or insufficient emergency exercises, procedures for storing and disposal of decayed waste not being fully implemented and the pregnancy awareness protocol not being fully implemented, prior to x-ray examination)

Maintenance and operational controls were also high on the list of findings in the medical sector. Twenty four of the 30 findings (80%) were associated with the QA /QC programme.

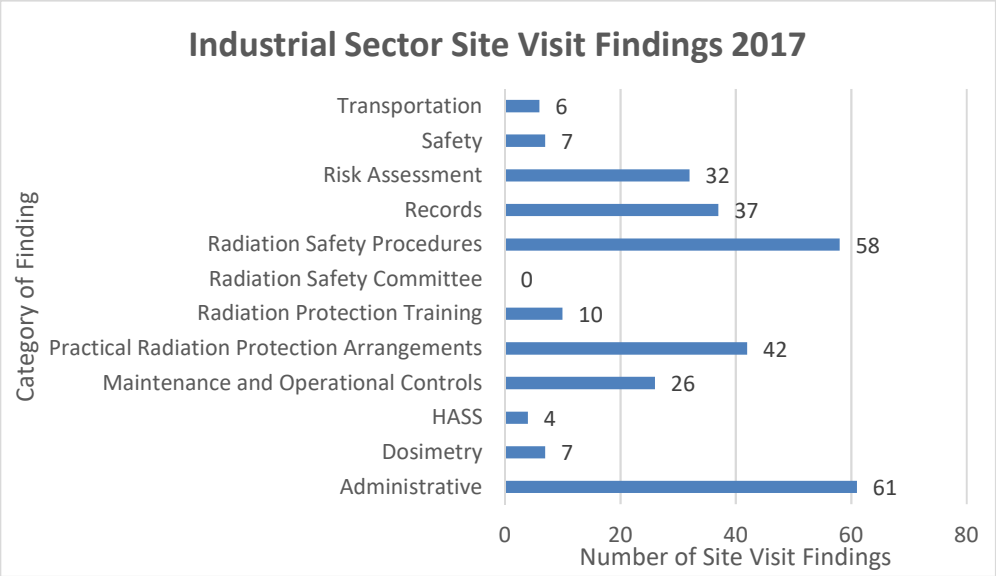

Figure 2. Category and Number of Findings in the Industrial Sector 2017.

The category and number of findings for the industrial sector are presented in Figure 2. The greatest number of findings was associated with administrative issues. Forty three of the 61 findings (70%) were associated with authorisation (schedule amendments – changes to inventory and personnel such as the Radiation Protection Officer) and the remainder were associated with operational controls such as display of the licence and site radiography notifications.

Radiation safety procedures were also high on the list of findings in the industrial sector. Twenty three of the 58 findings (40%) were associated with the review of procedures not being undertaken within the licence period. Additionally, twenty five percent of procedures needed to be updated and a further twenty four percent, there was no or insufficient evidence that the procedures had been made available to staff.

4 Observations on Site Visit Findings

Medical Sector - General

- Risk assessments for CT (Computed Tomography) rooms in Nuclear Medicine Departments in some hospitals need to consider the potential dose to service engineers who may have to work in adjacent rooms or on the roof adjacent to the CT room during its operation. It was observed that in some cases, Risk Assessments were not being reviewed within the licence period. Hazards and associated risks including reasonably foreseeable incidents and accidents for each step where radiopharmaceuticals are used/stored/manipulated in the Nuclear Medicine Department were not fully assessed and documented.
- Some Hospitals failed to have documented policies in place for ordering and delivery of radiopharmaceuticals and to provide evidence that distributors and carriers transporting radioactive material are aware of the policies and procedures. Maintaining a record of the date on which the Radiation Safety Procedures were made available to the staff concerned and other persons who may be affected by the Procedures is still a challenge for some hospitals.
- The long-term storage of disused sources is not regarded as good practice from a radiation safety or security perspective. Short-term storage and demarcation of radioactive sources in nuclear medicine departments needs some improvement. Security obligations are applicable to low and high activity sources.
- In some hospitals, the annual quality assurance assessment of x-ray equipment by the Radiation Protection Adviser (RPA) was not up to date. In some cases, records requested by the inspectors were not available to review as they were locked in a staff member's office. Inadequate RPA and Medical Physics support to meet licensing obligations is an ongoing challenge.
- It was noted during some site visits that radiation protection training of ancillary staff such as cleaners, porters and security personnel was overdue.
- The Chief Fire Officer of the Local Authority must be informed annually of the locations of all radioactive substances held by the licensee. In some cases, this had not been completed. Radiation warning signs need to be placed on entrance doors to the screening and injection rooms that are classified as radiation controlled areas.
- Licence amendments - changes to inventory and personnel, were not being kept up to date in several cases.

Medical Sector – Radiotherapy

- Seven radiotherapy inspections were undertaken during the year which focused on a combination of administrative and practical aspects of radiation protection. No particular radiation protection/safety concerns were noted in this sector and the standard of radiation protection remains high. The findings raised during the site visits included matters concerning transport documentation. As these licensees are consignors under the Carriage of Dangerous Goods by Road Regulations for the return of sources, the standard Consignors Note/Dangerous Goods Note must be completed for every shipment, copies kept and provided to the licensed transport carrier. In addition, the Type A package certification for the high dose rate iridium sources and the low dose rate iodine-125 sources were not always available.

- While noting that the Quality Control programme for the Linear accelerators was being implemented, it was observed that the Quality Control programme for the CT Simulators was not always current.

- Annual Training of exposed workers in the safe management of High Activity Sealed Sources was not specifically provided.

- The medical physics staffing for radiotherapy is currently satisfactory and in general there is a good commitment to radiotherapy staff training. Contingency arrangements are in place to provide full Radiation Protection Adviser cover for radiotherapy.

Dental Sector - Cone Beam CT

- Eight site visits to specialist Dentists using Cone Beam CT indicated that in general, compliance with radiation protection legislation and licence conditions was mixed. The following findings were noted; the Code of Practice for Radiological Protection in Dentistry was not always available in the surgery or made available to staff; in some cases, there were no warning notices or signs outside the cone beam CT room or on the x-ray units indicating the potential ionising radiation hazard associated with the equipment. In one case, there were no records pertaining to the licence available on the day of the site visit. In three separate dental practices, the licensees were in possession of intra-oral / hand-held x-ray units without the authorisation of the EPA (all issues were immediately addressed following the site visits). Schedule amendments were required in some practices. In one premises, personal dosimetry was not in place for staff, in accordance with the risk assessment. In some practices the quality assurance testing was overdue.

Industrial Sector – General

- Some risk assessments and radiation safety procedures are not being reviewed and revised, where appropriate, within the licence period. While routine testing of X-ray equipment prior to use was ongoing, servicing and annual maintenance checks are not always current. Refresher radiation safety training needs to be provided for Radiation Protection Officers and exposed workers at intervals of approximately 3 years. Records pertaining to the licence were not always readily available for the inspector. On some site visits, leak testing of sealed radioactive sources and correspondence with the Chief Fire Officer of the Local Authority were not up to date. Licence amendments - changes to inventory and personnel, were not being kept up to date in several cases.

Industrial Radiography

- Industrial radiography is an activity where workers can potentially record significant doses on their personal dosimeters and accordingly the EPA carries out short notice or unannounced site visits whenever practicable. During 2017 sixteen site visits (6 of which were security related) were carried out in this sector. As in all sectors there is always room for improvement as evidenced by one site visit where the radiographers were primarily relying on their Electronic Personal Dosimeters, rather than a radiation survey meter, to confirm that source had properly retracted to their shielded position. Other findings in the sector indicated that while generic risk assessments were present, site specific risk assessments were not always available. Dose rates at the temporary barriers were not always being checked. Correspondence to the Chief Fire Officer of the Local Authority regarding the presence and location of the sources was not always up to date. The emergency procedures for source retrieval need to be tested more frequently. From an administrative perspective, the licence Schedule needs to reflect the inventory and the annual reporting requirements for safeguards and the safe management of High Activity Sealed Sources needs to be up to date. This demonstrates that continued vigilance is required for what is a higher risk sector.

Transport of Radioactive Material

- Carriers, industrial radiography companies and users of density gauges transporting radioactive material as well as Hospitals, Industry and Universities returning sources have obligations under the Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment Regulations 2011-2017. During 2017, 22 site visits covered various elements relating to the transport of radioactive material (ADR). The programme included a combination of road checks and company visits. Typical findings included partially damaged/torn labelling on packages, the vehicle

did not carry the full equipment required in the ADR or in the instructions in writing, there were no instructions in writing conforming to the ADR, the vehicle and equipment used regularly for the carriage of radioactive material was not periodically checked to determine the level of contamination, the standard Consignors Note/Dangerous Goods Note was not completed for every shipment, there was no specific transport security document available (at the consignors office). The EPA continues to focus on compliance with the ADR across all sectors and imposes conditions in the relevant licenses issued.

Security of Radioactive Material.

- Eight security surveys were carried out during the year with the assistance of An Garda Síochána, Crime Prevention National Centre of Excellence, Garda Bureau of Community Engagement. These ongoing surveys were undertaken in the industrial medical sectors to assess the security arrangements in place at licensees' facilities against international best security practice for those using high activity sealed sources. Recommendations for enhancing security measures were made to the licensees relating to CCTV monitoring, lighting, physical and electronic security measures and documented security plans.

5 High Level Observations

- With the increase in more focused short notice or unannounced site visits, it is evident that some licensees are not prepared for inspections. This is clearly prevalent in the availability of documentation requested by the inspectors. However, these short focused visits provide an opportunity for the EPA and the licensee to get a more accurate assessment of the management of radiation protection in practice.
- Not all licensees are fully aware of their legal requirements with respect to legislation (radiological and transport) and the specific conditions of the EPA radiological licence. Some licensees have now commenced internal audits of their licence conditions to enhance understanding and compliance.
- Licensees in the medical sector need to assess the level of medical physics/RPA support to ensure that the hospital can meet their licensing obligations for all X-ray, radiotherapy and Nuclear Medicine equipment across the hospital or hospital group.
- While Quality Assurance (QA) programmes for irradiating apparatus are in place, in hospitals, there are still resource challenges in ensuring that the documented QA programme is fully implemented in practice. This is still evident in hospitals that depend upon external Radiation Protection Adviser services.
- While many hospitals aspire to having and promoting a positive radiation safety culture, few have the topic included on the agenda of the Radiation Safety Committee Meetings. The EPA still has some concerns with respect to radiation safety culture in areas outside of Radiology, particularly in theatres, which needs to be improved.
- Hazards and associated risks (risk assessments) are not always being fully assessed and documented particularly in Nuclear Medicine Departments. Similar findings were noted for work in Cardiac Catheterisation Laboratories.
- More concrete evidence such as internal audits of procedures need to be undertaken by licensees to ensure that the provisions of the Radiation Safety Procedures are being implemented in practice.

6 Enforcement Activities

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 2017, the following directions or licence restrictions were issued to licensees:

- During a site visit in a hospital, a licence restriction was imposed limiting the use of a mobile X-ray unit for which a commissioning report was not available. Both the licence change request and the commissioning report were made available following the site visit and the restriction was removed.
- During a site visit to a Dental Surgery, the dentist was directed to cease use of an intra-oral X-ray unit. The dentist had acquired the unit in 2015 and there was no documented evidence that the unit had been serviced, commissioned or undergone Quality Assurance testing. Furthermore, there was no documented risk assessment or a shielding assessment. All matters were subsequently addressed following the site visit.

7 Key Messages

If you have a query about a specific matter, contact staff in the Radiation Protection Regulation Unit (EPA Office of Radiation Protection and Environmental Monitoring), Dublin 01 268 0100.

- Make sure that the correct legal entity is licensed and inform the EPA of any changes.
- Ensure there are sufficient human and financial resources to undertake the work associated with the licensed items (for example - use, maintenance, ongoing quality assurance and testing, security arrangements, training, money set aside for the return of sources, recycling of equipment etc.).
- Review the inventory of licensed items to ensure it is current and identified correctly on the licence.
- Undertake an internal audit of the licence conditions on an ongoing basis, to promote better understanding and compliance.
- Maintain relevant records and make sure they are readily available for inspection.
- Use the knowledge, training and experience of your Radiation Protection Officer and Radiation Protection Adviser, regarding radiation protection in practice and compliance with the Regulations.

Appendix – Completed Site Visit Programme by Licence Category for 2017

Licence Category	Risk Category	No. in Category	No. of Planned Site Visits	Completed Site Visits
Chiropractors	Medium	12	6	5
Distributors (sources)	Medium	13	4	1
Hospital Level 2 (1 X-ray unit)	Medium	13	0	0
Hospital Level 3 (> 1 X-ray unit)	Medium	56	7	6
Hospital Level 4 (Diagnostic X-ray + sealed sources)	Medium	2	0	0
Education and Research	Medium	15	7	5
Industrial level 3 (sources, transport)	Medium	63	17	14
Industrial level 4 (> 6 sources)	Medium	13	8	7
Industrial level 5 (ICSD Assembly)	Medium	1	0	0
Industrial level 6 (NDT fixed sources)	Medium	10	5	3
Hospital level 5 (nuclear medicine)	Medium	18	16	11
Veterinary Equine Nuclear Medicine	Medium	1	0	1
Transport Services	Medium	10	9	5
Hospital level 6 (radiotherapy)	High	14	18	16
Industrial level 7 (Oil & Gas exploration)	High	3	0	0
Industrial level 8 (NDT site work)	High	8	20	16
Industrial Level 9 (irradiation, e-beam, cyclotron & mobile container scanner)	High	6	4	4
Licensees from the Low risk category (e.g. dentists (14), vets (7), X-ray distributors (1) & cabinet X-ray units (9))	Low	1475	22	31*
Total			143	125

*This figure is higher than last year due to the sectoral analysis of dental cone beam CT and the number of licensees inspected with cabinet style x-ray, as part of an inspectors training programme.