Ionising Radiation Regulation

Key Findings from the 2016 Inspection and Enforcement Programme

October 2017

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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 2016 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 2016 Inspection Programme

One hundred and twenty two inspections, including three security surveys, carried out with the assistance of An Garda Síochána National Crime Prevention Unit, were undertaken in 2016 (Table 1). The completed Inspection schedule for 2016 is presented in the Appendix. The number of unannounced site visits was increased in line with the recommendations from the 2015 inspection programme. The number of site visits classified by risk category is shown in Table 1 and by site category in Table 2.

In 2016 the EPA expanded its Licensing and Enforcement Management Application (LEMA) to include a new radiation protection licensing module. 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 inspections findings for 2016 in this report. In is intended to further develop this quantitative analysis in future reports as experience is gained with LEMA.

Table 1: Completed Site Visits by Risk Category – 2016

Completed Site Visits by Risk Category - 2016		
Licensee Sector	**Risk Category**	**No. of Site Visits**
Dental	**Low**	4
Veterinary	**Low**	3
Industrial	**Medium/High**	63*
Medical	**Medium/High**	46
Education & Research	**Medium**	6
Total		122
* Three of these were security related		

Table 2: Site Visit Findings by Licence Category – 2016

Site Visits by Category - 2016			
Licence Category	**No. of Site Visit Findings**	**No. of Site Visits**	**Average Findings Per Site Visit**
Dental Level 1	8	4	2.0
Veterinary Level 1	9	3	3.0
Industrial Level 1	39	12	3.3
Industrial Level 3	138	27	5.1
Industrial Level 4	9	2	4.5
Industrial Level 5	13	1	13.0
Industrial Level 6	33	10	3.3
Industrial Level 8	43	8	5.4
Industrial Level 9	13	3	4.3
Hospital Level 2	20	5	4.0
Hospital Level 3	97	22	4.4
Hospital Level 4	4	1	4.0
Hospital Level 5	27	9	3.0
Hospital Level 6	33	9	3.7
Education Level 3	42	6	7.0
Total	**528**	**122**	**4.3**

3 Inspection Observations

Following the introduction of the new LEMA radiation protection module, on site visit findings have been classified according to action categories and subcategories. Examples of these include, administrative (authorisation, operational controls /administrative), practical radiation protection arrangements (operational controls, signage), radiation safety procedures (availability, implementation, adequacy), transportation (ADR equipment, driver training, transport documents), maintenance and operational controls (operational controls, servicing, QA/QC programme), radiation safety committee (ineffective, governance). The category and number of findings for the medical sector are presented in Figure 1.

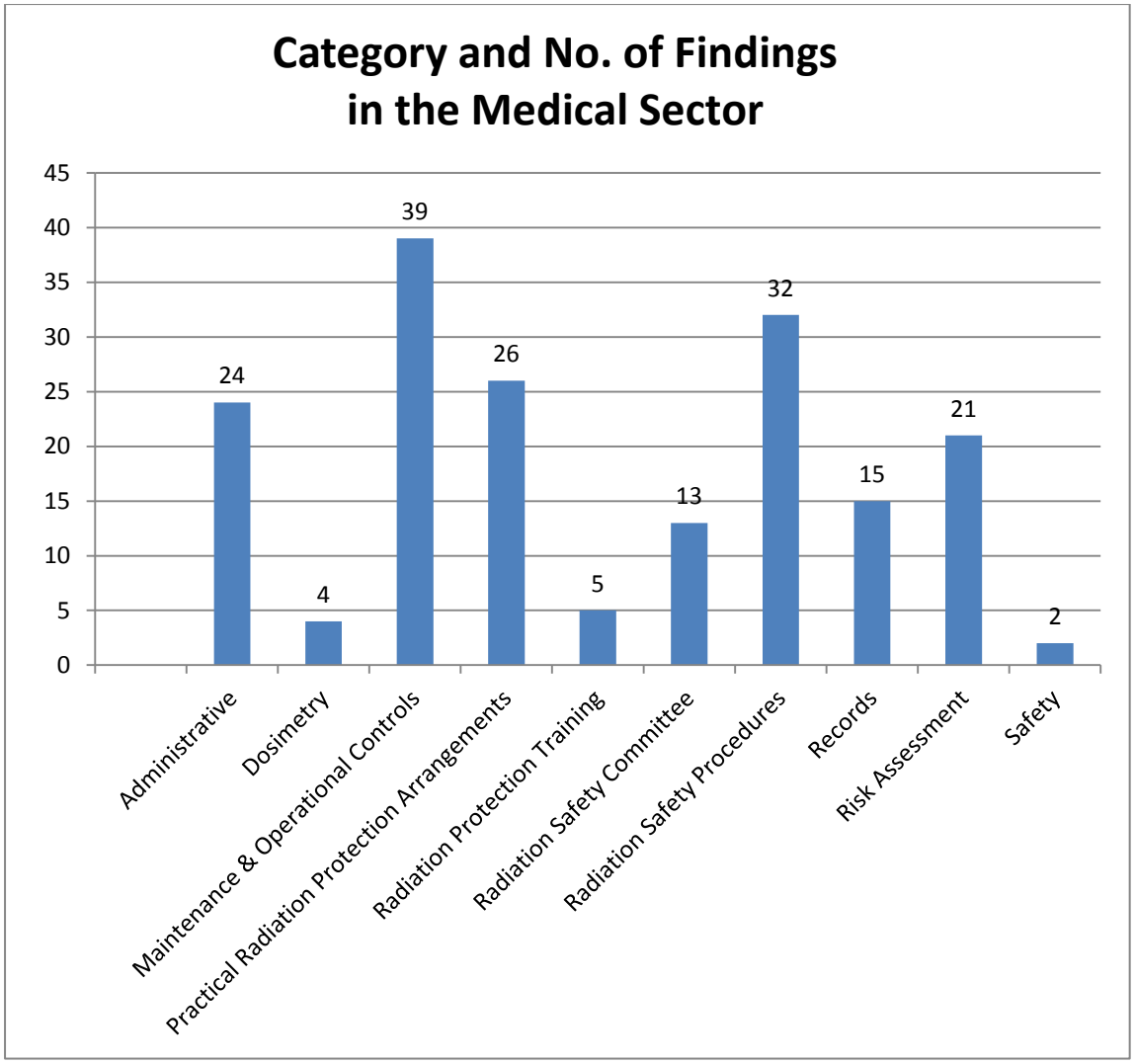

Figure 1. Category and Number of Findings in the Medical Sector for 2016.

The greatest number of findings in the medical sector was associated with maintenance and operational controls of irradiating apparatus. This category consists of three subcategories (Quality Assurance/Quality Control programme, servicing arrangements and operational controls). Thirty four of the thirty nine findings (87%) were associated with the Quality Assurance/Quality Control programme within the hospitals.

Radiation safety procedures were also high on the list of findings in the medical sector. Twenty four of the thirty two findings (75%) were associated with inadequate procedures (13) and lack of evidence of availability of procedures to staff (11).

The category and number of findings for the industrial sector are presented in Figure 2.

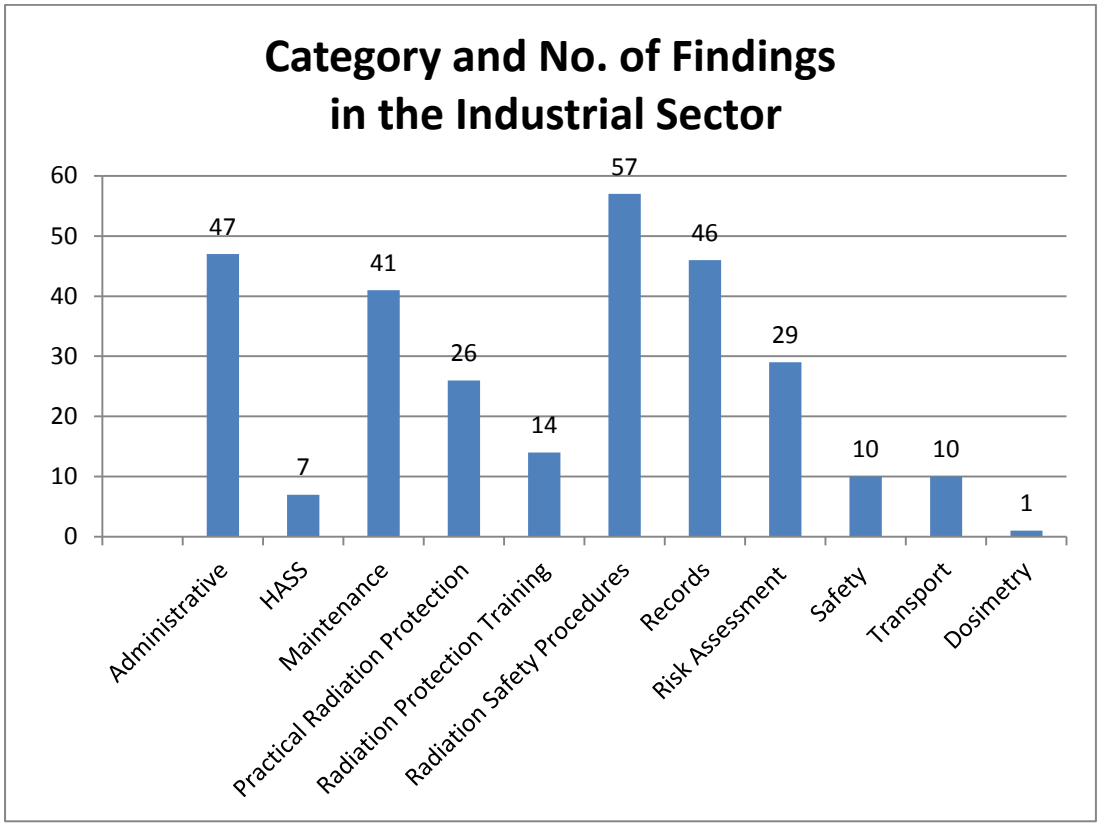

Figure 2. Category and Number of Findings in the Industrial Sector 2016.

The greatest number of findings in the industrial sector was associated with radiation safety procedures. Thirty one of the 57 findings (54%) were associated with the review of the procedures within the licence period (16) and lack of evidence of availability of procedures to staff (15). Administrative findings were also high on the list of findings in the industrial sector. Thirty seven of the 47 findings (78%) were associated with authorisation (changes to inventory and personnel (RPO/RPA) and the remainder were related to administrative operational controls such as display of the licence (10).

4 High Level Observations

- Radiotherapy. While 9 hospitals providing a radiotherapy service were inspected in 2016, five inspections were specifically focused on radiotherapy, while the other inspections addressed nuclear medicine and diagnostic radiology. The radiotherapy inspections focused on a combination of administrative and practical aspects of radiation protection. The standard of radiation protection remains high. The medical physics staffing for radiotherapy is currently satisfactory and there is in general a good commitment to radiotherapy staff training.

- Industrial Radiography. Eight inspections of non-destructive testing site work were undertaken in 2016. Twenty one of the forty three findings (49%) were associated with administrative matters (7), practical radiation protection (7) and records (7). Findings on maintenance and operational controls (6) as well as transport of radioactive material (ADR) (6) also featured. Continued vigilance is required in this sector.

- Unannounced inspections of licensees in the medical sector. Forty four percent of site visits in the medical sector were unannounced in 2016. These short and focused visits were welcomed by the sector and provided an opportunity for the EPA to get a more accurate assessment of the management of radiation protection in practice in this sector.

- Regional based Radiation Protection Advisor Services. Not all licensees have an in-house RPA and many source their RPA support from external regional-based services. Inspections of hospitals that depend upon 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.

- Follow-up inspection of hospitals. While significant progress has been made by the relevant licensees, it was noted that some hospitals are still facing challenges with respect to resource constraints. The EPA will continue to closely monitor this to ensure that it is not adversely affecting radiation safety standards.

- Use of X-ray equipment in hospital locations outside the main radiology department. The use of X-ray equipment or sources in theatres was observed and generally found to be in compliance with the Regulations. However, the EPA will continue to monitor this area of use particularly around the governance of radiation protection in these areas.

- Radiation Protection Safety Culture in the Medical Sector. In May 2016 the RPA hosted a workshop for Radiation Protection Advisers (Medical and Industrial) to explore the concepts of radiation protection safety culture. It is clear that gaps in in-house quality control programmes, recurring site visit findings, Radiation Safety Committee's not meeting as required, risk assessments not being reviewed, poor

advocacy of radiation protection, insufficient management commitment to and failure to integrate radiation protection as part of the health and safety programme is a challenge for licensees, RPAs and the EPA.

- Security of radioactive material. Three security surveys were carried out during the year with the assistance of An Garda Síochána National Crime Prevention Unit (NCPU). Training in radiation protection was also provided by EPA to members of the NCPU and specific Crime Prevention Officers in February 2016. Two surveys were undertaken at industrial sterilisation facilities as part of planned follow-up visits. The third was undertaken at road construction site where it was proposed to use and store a nuclear moisture density gauge during the project. 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 or portable gauges, in advance of a licence being granted. Recommendations for increased security measures were made to the licensees relating to issues such as CCTV monitoring, physical and electronic security measures and documented security plans.

5 Enforcement Activities in 2016

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 2016, directions issued to licensees included:

- Due to concerns site radiography was stopped by the inspector as continuation would pose a danger to the Radiographers and other individuals on the site. The direction remained in place for all site work for approximately one month until the observed breaches of licence conditions and Radiation Safety Procedures were addressed by the licensee. A prosecution is currently pending.
- During the course of an inspection in a hospital, a direction was issued to cease use of an x-ray unit, as no request had been made to include it on the schedule of the licence, nor was a commissioning report made available on the day of the site visit. Both the licence change request and the commissioning report were made available following the site visit.
- During the course of a site visit in a hospital, a licence restriction was imposed limiting the use of an X-ray C-arm (fluoroscopy) to a specific theatre, pending the installation of appropriate lead shielding in the other theatres.
- During the course of a site visit in a hospital, a licence restriction was imposed to cease the use of an X-ray C-arm for particular high risk interventional procedures, pending the submission of an appropriate risk assessment.
- During an inspection of a medical licensee a direction was issued to cease use of a CT unit pending the submission of a complete licence application.

- During an inspection of a medical licensee a direction was issued to cease use of a general X-ray unit pending the submission of a complete licence application.

Additionally, site visits were arranged with a Dental and a Veterinary Practice to encourage them to fully complete the licence renewal process for x-ray equipment held. Both Practices renewed and subsequently addressed the inspector's findings.

Appendix – Completed Inspection Schedule for 2016

Licence Category	Risk Category	No. in Category	No. of Planned Inspections	Completed inspections
Chiropractors	Medium	14	5	4
Distributors & transport (sources)	Medium	27	1	0
Hospital Level 2 (1 X-ray unit)	Medium	13	1	1
Hospital Level 3 (> 1 X-ray unit)	Medium	56	23	22
Hospital Level 4 (Diagnostic X-ray + sealed sources)	Medium	2	1	1
Education and Research	Medium	15	8	6
Industrial level 3 (sources, transport)	Medium	60	25	27
Industrial level 4 (> 6 sources)	Medium	13	2	2
Industrial level 5 (ICSD Assembly)	Medium	1	1	1
Industrial level 6 (NDT fixed sources)	Medium	11	8	9
Hospital level 5 (nuclear medicine)	Medium	18	10	9
Veterinary Equine Nuclear Medicine	Medium	1	0	0
Hospital level 6 (radiotherapy)	High	13	9	9
Industrial level 7 (Oil & Gas exploration)	High	3	1	1
Industrial level 8 (NDT site work)	High	8	9	8
Industrial Level 9 (irradiation, e-beam, cyclotron & mobile container scanner)	High	6	4	3
Total		261	108	103
Licensees from the Low risk category (e.g. dentists, vets, X-ray Distributors & cabinet X-ray units)	Low	-	17	19
Total (including inspections from the Low risk category)			125	122*

*Three of these were security related in the industrial sector.