Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

LESSONS LEARNED

from receipt of statutory notifications of accidental and unintended medical exposures to ionising radiation in 2023

September 2024

Safer Better Care

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About the Health Information and Quality Authority (HIQA)

The Health Information and Quality Authority (HIQA) is an independent statutory body established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector of Social Services within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of permanent international protection accommodation service centres, health services and children's social services against the national standards. Where necessary, HIQA investigates serious concerns about the health and welfare of people who use health services and children's social services.
- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health and social care services, with the Department of Health and the HSE.

Introduction

The European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and amendments provide a framework for the regulation of medical exposure to ionising radiation in Ireland. The Health Information and Quality Authority (HIQA) is the competent authority under these regulations for regulating this area. Under these regulations, undertakings* have a responsibility to submit notifications to HIQA on significant events arising from accidental or unintended medical exposure to ionising radiation as they occur in their services. Under these regulations, HIQA is required to analyse the notifications that meet defined thresholds, and to share lessons learned from the associated incident investigations.

Between 1 January and 31 December 2023, HIQA received 143 significant event notifications. This report provides details on the 131 incidents which met the defined thresholds of notifiable significant events and were processed and completed by HIQA. As the remaining 12 notifications did not meet significant event thresholds, data from these notifications is excluded from this report. However, HIQA encourages undertakings to submit any notification that they believe meets reporting thresholds, and regards the submission of notifications as a demonstration of the undertakings' awareness of their regulatory responsibilities under Regulation 17: Accidental and unintended exposures and significant events.

Key findings

An analysis of the 131 notifications of significant events, processed by HIQA in 2023, identified a number of key findings. Firstly, the number of notifications continues to increase year-on-year, which is a positive finding. There was an 18% rise in the number reported to HIQA in 2023 from 2022, albeit from fewer services when compared with previous years. Despite the decrease in the number of services who submitted notifications, 2023 marked the first year in which a dental service submitted a notification. This is good practice, again demonstrating good awareness in the ionising radiation community of regulatory responsibilities in incident reporting. Secondly, human error, during local justification processes, was the most frequently reported root cause of significant events. Thirdly, where undertakings had identified other contributory factors to the significant event, these factors were not proactively addressed in all investigation reports submitted. Other factors identified in investigation reports from the undertakings were in line with findings from HIQA inspections performed in 2023. This is explored in the discussion of this report.

* Undertaking: a person or body who, in the course of a trade, business or other undertaking (other than as an employee), carries out, or engages others to carry out, a medical radiological procedure or the practical aspects of a medical radiological procedure.

Appendix 1 of this report provides a graphic summary of the findings from the significant events that met reportable thresholds from January to December 2023 and were managed by HIQA. Appendix 2 summarises the key messaging of this report in poster format, which undertakings can use to raise awareness of incident learning and outcomes in services where medical exposure to ionising radiation occurs.

Incident reporting by services

In 2023, HIQA saw an increase in notifications with 131 processed, compared to the 111 notifications processed in 2022. This is a welcome finding indicating that undertakings have increased awareness of their regulatory responsibilities and that incident reporting and management are increasingly prioritised during the delivery of ionising radiation exposures to people using services. It may also show that undertakings have enhanced the safety culture in their services, ensuring that staff are supported and encouraged to report incidents, as well as being assured that management teams are committed to implementing improvement initiatives based on the incidents identified and reported by staff.

While potential exists for all undertakings to submit notifications on significant events to HIQA, those providing higher radiation dose procedures are more likely to incur incidents that meet the reporting thresholds, as defined by HIQA. However, further analysis of the 131 incidents showed that fewer services submitted notifications to HIQA in 2023 (n=47) than in the preceding year (2022, n=50).

Considering that 74 services in Ireland deliver high radiation dose procedures, for example in radiotherapy, nuclear medicine, interventional and CT imaging services, it is notable that only 47 of these services submitted notifications in 2023. This disparity may suggest that incidents did not occur in the remaining 27 services, or that other factors may have contributed to low reporting rates in these services. For example, low reporting rates may be attributable to inadequate local incident reporting structures and resources, or to poor awareness of reporting thresholds by staff. Furthermore, staff may be hesitant to report incidents for various reasons, including the perception that routinely implemented corrective measures are ineffective, or that there is a lack of organisational learning from previously reported incidents. Therefore undertakings are encouraged to continuously review reporting structures and frequency of reporting within their services to ensure that incidents are identified and addressed appropriately.

Review of incident investigation reports

The 131 investigation reports for the submitted notifications were examined to learn the cause and contributory factors for these incidents, as identified by investigation teams in undertakings.

Causes

While some undertakings reported that process errors (n= 15) and system errors (n=11) such as the work environment, poor communication and inadequate staff training were the root cause of the notifiable incidents, the majority of investigation reports received in 2023 cited human error (n=74) as the root cause. This is in line with investigation reports received from 2019 to 2022, in which human error was also identified as the root cause in the majority of incidents reported each year.

Corrective actions

HIQA also examined the corrective actions undertakings took to prevent similar incidents from happening again in their services.

In the 131 investigation reports reviewed, the undertaking had implemented one or more corrective actions to address the root cause of the incident. The most common corrective action involved staff education and information (n=57), followed by the implementation of reminders, checklists and double checks (n=21). Other actions implemented included automation and computerisation, preventative measures such as forcing functions, as well as reviewing processes and documentation.

Discussion

Throughout the inspection programme in 2023, HIQA observed that many undertakings had implemented systems and processes for justification, optimisation and dose limitation, which are the three basic principles of radiation protection. [1] Inspectors noted that these systems and processes aimed to support staff in delivering safe and appropriate medical exposures, and thereby prevent incidents that could lead to accidental and unintended exposures. Additionally, inspectors were informed that delivering medical exposures requires considerable human effort, and therefore staff are strongly relied upon to follow these systems and processes.

The analysis of investigation reports showed that gaps and non-adherence in the justification process contributed to 48 significant events, as reported by 27 services to HIQA in 2023. For example, staff had not identified that the patient was referred for an incorrect procedure, or that the incorrect patient was referred for a procedure, or staff had not sought or reviewed previous recent imaging, as required by the regulations. In other incidents, staff had not completed the local patient identification procedure, or had completed it incorrectly prior to delivering the

exposure. The process of justification relies firstly on the input of the appropriate and complete information by the referrer requesting the medical exposure and secondly by the practitioner, who must assess, based on the information provided, if the requested examination is justified. The potential for human error increases as multiple inputs are made by different staff members.

HIQA's analysis also revealed that in 14 of the 27 services which reported gaps in justification practices, two or more incidents around justification practices had occurred in these services. This raises the question of whether the corrective actions implemented following the first incident were sufficiently effective to prevent similar incidents occurring.

The analysis of the 47 incident reports relating to justification showed that corrective actions implemented were mainly limited to staff education and information sessions (n=19) and reminders and checklists (n=12). These corrective measures rely on staff action and memory, to perform the justification process correctly and do not consider any weaknesses or gaps in the justification process itself. It is generally accepted that staff do not intend to cause an incident and that staff reminders to follow processes are regarded as the least effective strategy in bringing about change. Focusing on the 'what', 'how' and 'why' an incident occurred rather than 'who' was involved, provides a broader perspective and considers any weaknesses or gaps in the process itself. This approach also considers other factors, such as the environment and work-related factors, which may have affected adherence to the established justification practices.

Some investigation teams also identified other factors that contributed to the incident occurring, such as workloads and busy work environments. However, corrective actions to address these factors were not implemented in the majority of reports viewed, with greater emphasis on addressing only human behaviour noted in these investigation reports. However, this approach does not have the necessary impact to prevent similar significant events recurring, as discussed above.

Inspection findings

In 2023, of the 55 services inspected, 17 services were assessed as substantially compliant or not compliant with Regulation 8: Justification of medical exposure. Under this regulation, inspectors found gaps in documenting justification in advance and other gaps in adherence to local justification processes. This demonstrates similarities between inspection findings and what undertakings identified during the investigation of significant events in their services.

Compliance with Regulation 17: Accidental and unintended exposures and significant events was also assessed in 45 of the 55 services inspected in 2023. Of these 45

services, four were assessed as substantially compliant or not compliant with this regulation, with gaps in the undertakings' systems to identify, report and analyse potential incidents most frequently identified by inspectors.

Regulation 6: Undertaking was assessed in all inspections in 2023. Gaps in the clear allocation of roles and responsibilities regarding local incident management systems were identified in several services. For example, inspectors found that although incidents involving medical exposures of ionising radiation were discussed at appropriate governance and management level, these discussions were limited and did not include the learning or recommendations from the incident investigation reports.

With the publication of the *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation* by HIQA in November 2023, undertakings must now implement clinical audits in accordance with these procedures. The clinical audit strategy should be developed by local management teams to help identify areas for improvement within services, and reduce the risk of incidents occurring. Undertakings should also consider the outcomes of investigation reports as future topics for clinical audits. Clinical audit is an important tool in systematically reviewing radiological practices and providing assurances to undertakings that they are not only meeting the basic standard as outlined in the regulations, but also continuously improving the delivery of appropriate procedures involving medical exposures to all people using services.

Conclusion

The reporting of significant events to HIQA increased in 2023 and included the first time a notification was submitted by a dental service. This shows good awareness by some undertakings of their regulatory responsibilities under Regulation 17. However, the decrease in the number of services who reported significant events in 2023 indicates that improvements are required in other services to assist in identifying and reporting notifiable significant events to HIQA as required by the regulations.

In many reported incidents, human error was identified as the root cause. In response to such incidents, education and information sessions, reminders and checklists were the most common actions implemented by investigation teams in line with actions taken in previous years. As some services reported multiple similar incidents, evidence suggests that these actions were only partially effective in preventing incidents recurring. When investigating new incidents, undertakings should consider past incidents and the effectiveness of the corrective actions taken.

While it is widely acknowledged that human error can play a role in a large number of incidents, an effective incident investigation process should not focus solely on an individual's actions. Instead, investigation teams should consider focusing on the

'what', 'how' and 'why' during the incident management process. Investigations should be completed with a systematic approach, which includes examining the human and organisational factors involved, such as training, procedures and work systems, and how they influence staff performance in decision-making and completing key radiation protection measures. This approach to incident management would likely lead to the implementation of effective corrective actions that can prevent similar incidents occurring in the future.

References

1. International Commission on Radiological Protection in medicine. ICRP Publication 105. *Ann ICRP.* 2007;37:1–63. Available online from: https://www.icrp.org/publication.asp?id=ICRP%20Publication%20105. Accessed 28 June 2024

Appendices

Appendix 1 Summary of findings from significant event notifications January-December 2023

Figures 1-5 provide details on the significant events in ionising radiation services which were reported to HIQA between 2019-2023 and met the defined thresholds. The figures highlight the number of notifications processed annually, the submission methods used and the notification type. Information is also provided on the modalities where the events occurred and the categories under which they were reported.

Figure 1. Number of incidents reported to HIQA (2019-2023)

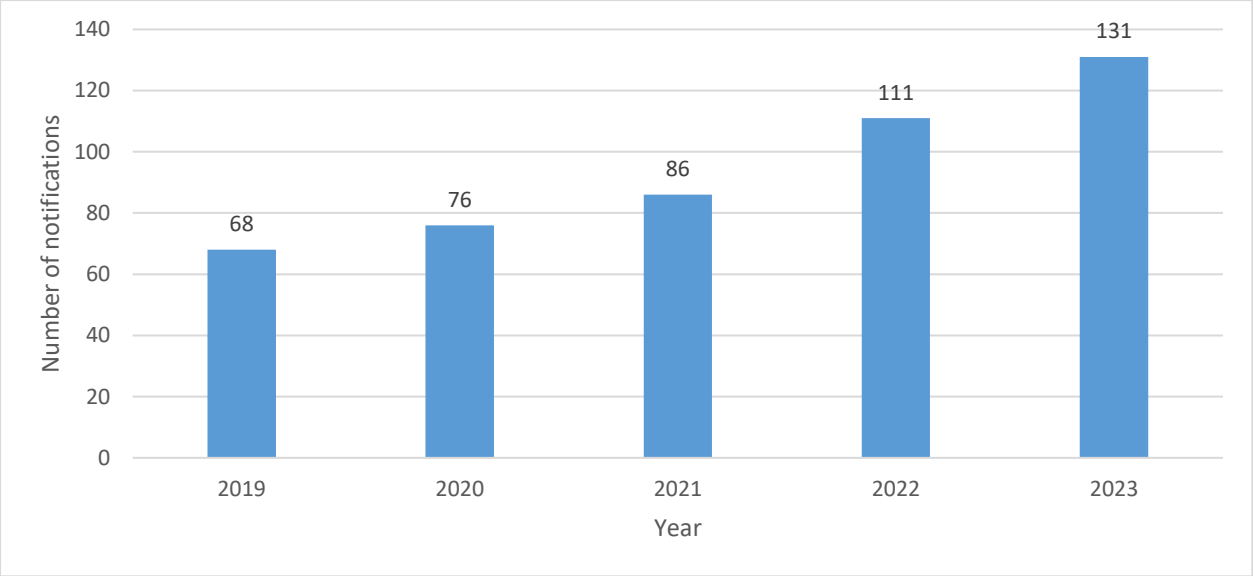


Figure 2. Methods used to submit notifications to HIQA (2019-2023)

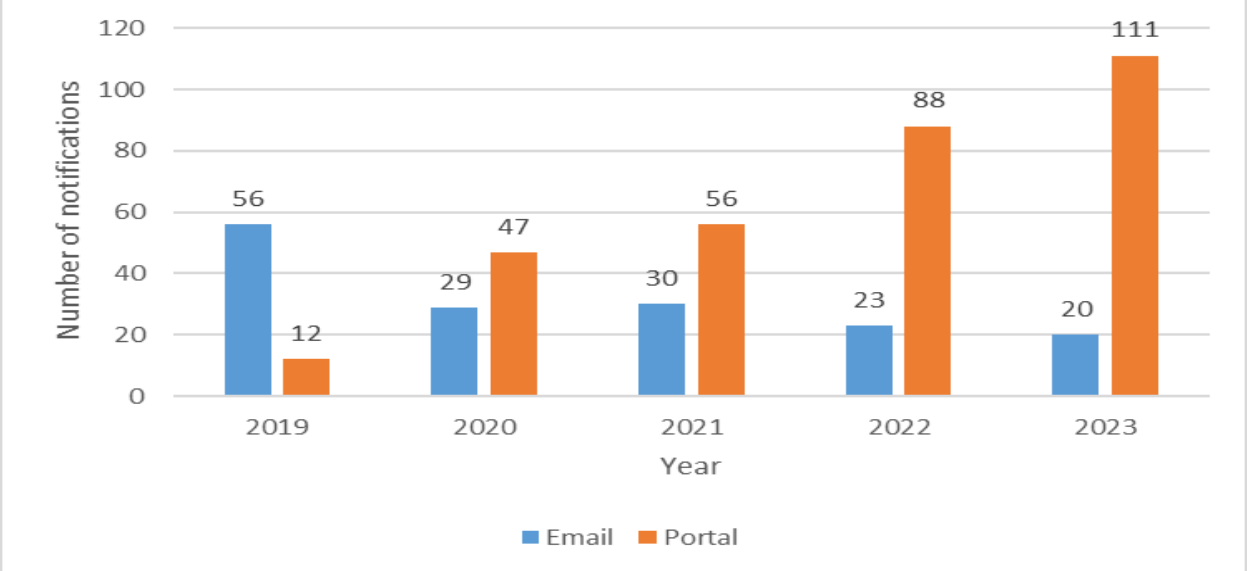


Figure 3. Notification type (2019-2023)

Undertakings were asked to assign each accidental and unintended exposure or significant event to one of the following categories at the initial notification stage:

- NF211A – Diagnostic Imaging (Dental/Radiology/Nuclear Medicine)
- NF211B – Radiotherapy
- NF211C – Significant event notification - Other

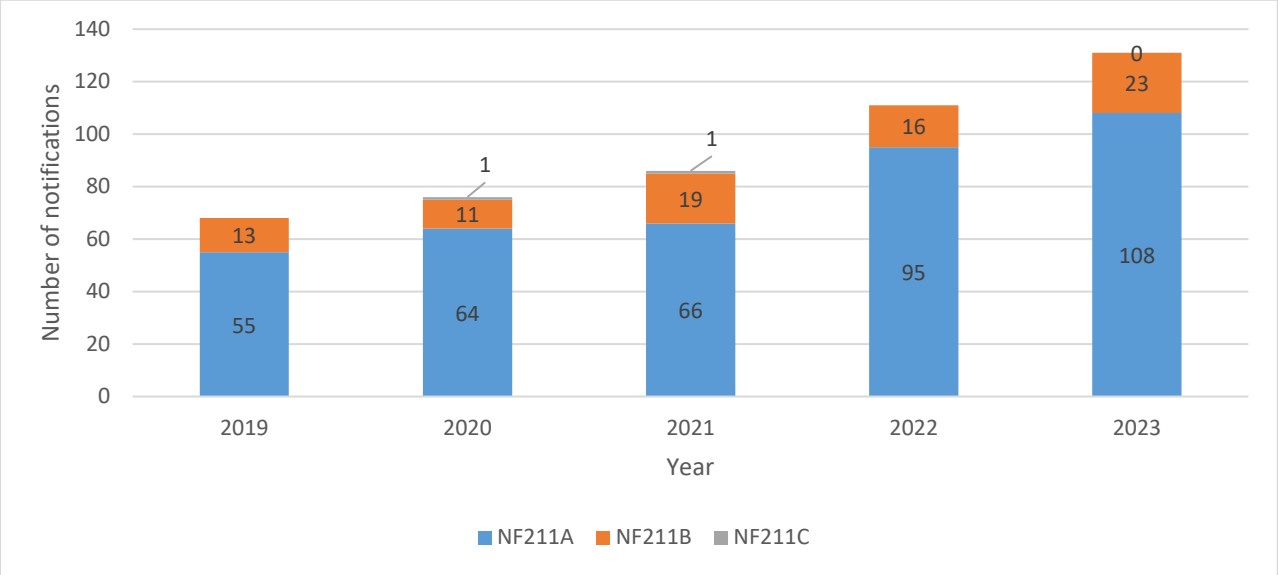


Figure 4. Modality type where the event occurred 2023

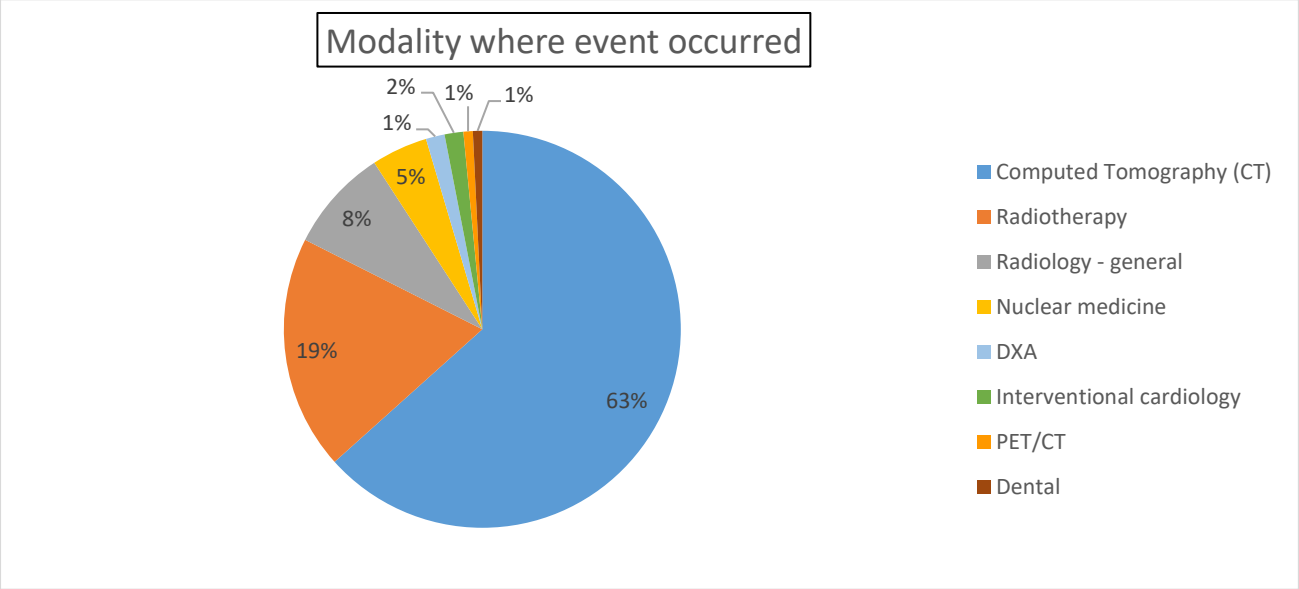
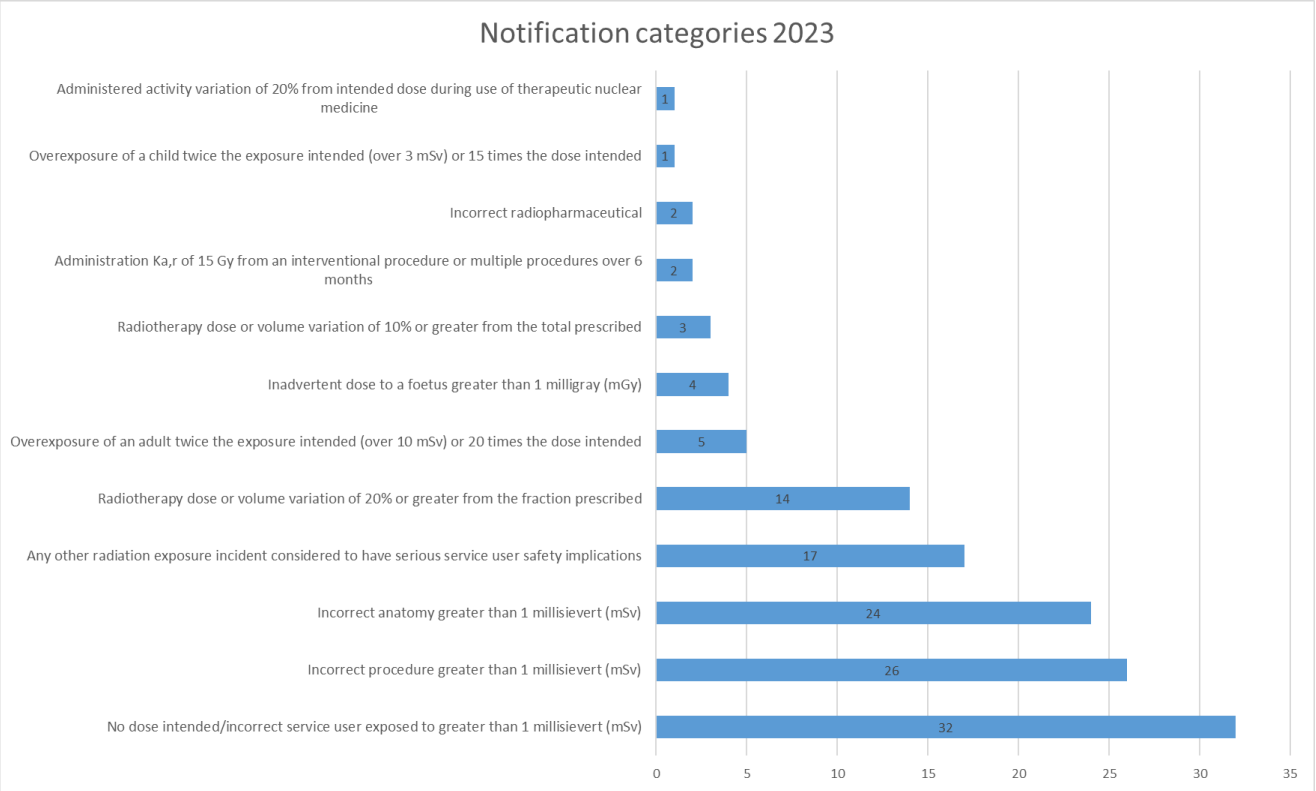


Figure 5. Notification categories of reported incidents



Appendix 2 Focus of Ionising Radiation Incident Investigations

The following poster presents the key messages derived from this report. Undertakings are encouraged to use the poster to raise awareness of incident learning and outcomes in services where medical exposure to ionising radiation occurs.

IONISING RADIATION
Incident investigations should focus on:

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WHAT happened?

Consider:

- incident details
- complete review of patient's journey by investigation team
- additional dose and patient risk

HOW did it happen?

Consider:

- impact of existing systems and processes
- contribution of organisational decisions, cultural or environmental factors
- any previous similar incidents and or effective actions

WHY did it happen?

Consider:

- adherence to and strength of systems and processes
- appropriate and current knowledge, skills and training for radiation protection

Rather than focusing on the actions of staff

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