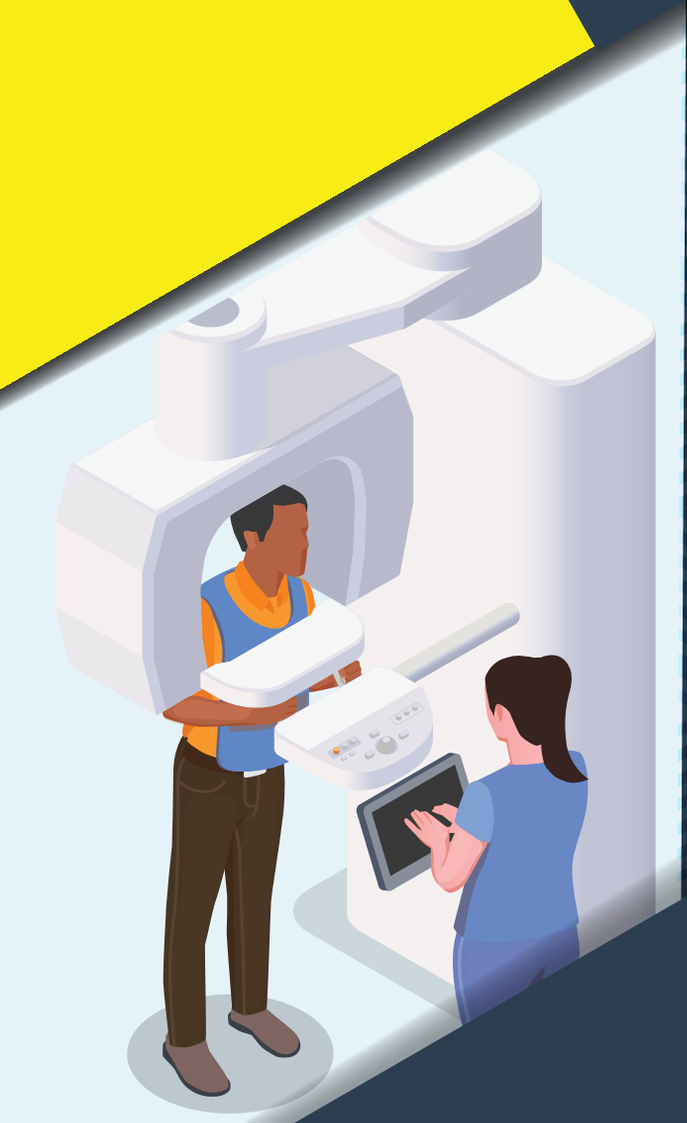
Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Overview Report
Medical exposure to ionising radiation

September 2022

Lessons learned from receipt of statutory notifications of accidental and unintended exposures in 2021



About the Health Information and Quality Authority (HIQA)

The Health Information and Quality Authority (HIQA) is an independent statutory authority 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.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. 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 Office of the Chief Inspector 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 health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these 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 services, in conjunction with the Department of Health and the HSE.

Contents

Executive summary

This is the third overview report from the Health Information and Quality Authority (HIQA) of lessons learned from the receipt of statutory notifications of significant events of accidental and unintended medical exposures to ionising radiation.

This report summarises the notifications reported to HIQA in 2021 and considers data from 2019 and 2020 for trending purposes. Statutory reporting has seen an upward trend in the annual number of accidental and unintended exposures and significant events reported to HIQA since it began receiving notifications in January 2019. It is HIQA's view that this is a positive indicator of an improving patient safety culture in medical exposure to ionising radiation.

All data reported since 2019 indicates that accidental and unintended exposures and significant events predominantly occurred in computed tomography (CT) departments and in the vast majority of cases, involved an additional radiation dose in the range of 1 to 5 millisieverts (mSv). This amount of radiation is associated with minimal risk to the service user. Since 2019, the majority of notifications each year are related to an incorrect service user being exposed to a dose greater than 1 mSv.

Trends were also seen in the main cause of events, with human error attributed as the main cause of incidents in over half of the notifications received in 2020 and 2021. Similarly, education and information were predominantly relied on as the corrective action for staff involved in accidental and unintended exposures or significant events. It was noted that corrective actions could be improved by relying on more effective system-focused changes rather than people-focused interventions such as education and information.

While the overall number of notifications increased, it was highlighted that some medical radiological facilities with high levels of activity, across a range of imaging modalities and providing complex medical exposures, did not report any or only reported a single event during 2021. Low rates of reporting may indicate that systems and processes are inadequate in identifying and subsequently reporting incidents. Therefore, facilities with low reporting rates will be considered in HIQA's ongoing risk-based approach to inspection to determine compliance with the regulations, to promote radiation protection and improve the quality and safety of medical exposures for service users.

1. Introduction

The European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019 provide a framework for the regulation of medical exposure to ionising radiation in Ireland.[1] These regulations define the Health Information and Quality Authority (HIQA) as the competent authority for regulating medical exposure to ionising radiation in Ireland.

The regulations extended HIQA's role and regulatory powers to include public and private radiological, radiotherapy, nuclear medicine and dental services. Each service provider, known as an undertaking*, has a responsibility to submit notifications of significant events arising from an accidental or unintended medical exposure to ionising radiation to HIQA. It should be noted that a single undertaking can operate multiple medical radiological facilities, known as facilities for the remainder of this report.

HIQA began receiving and reviewing notifications of significant events arising from an accidental or unintended medical exposure to ionising radiation in January 2019. Subsequently, HIQA has published an annual overview report which has quantified the numbers and types of accidental or unintended medical exposure to ionising radiation which occur and which shares the lessons learned from the investigation and outcomes of these events. These annual reports are available online.

This 2021 overview report, the third produced, provides an opportunity to establish a year-on-year analysis of the numbers and types of incidents reported to HIQA over a three year period. The aim of this report is to share the learning with service users† and undertakings on the circumstances that may contribute to a radiation incident and how such events may be prevented from happening again. The primary focus is to protect persons using the services from the unwanted and unintended effects resulting from accidental or unintended exposures to ionising radiation.

* An undertaking is the legal entity responsible for medical exposures to ionising radiation, for example, a company or sole trader.

† Service user is a person or persons who attends an undertaking for the purpose of undergoing a medical exposure. This includes a patient, comforters and carers and volunteers participating in research. The terms 'service user' and 'patient' are used interchangeably within this report.

2. What undertakings reported to HIQA from 2019 to 2021

Undertakings are required to provide an initial notification and a subsequent investigation report for each accidental and unintended exposure or significant event[‡].

This section takes a closer look at the number of notifications received, the location in which the accidental and unintended exposure or significant event occurred and the categorisation of the incident. This information is routinely requested as part of the initial notification allowing HIQA to review and risk assess each individual accidental and unintended exposure or significant event.

Information on causative factors and corrective measures taken by undertakings to minimise the probability of similar accidental and unintended exposures or significant events occurring again is also considered. This information is detailed within the investigation report that the undertaking submits after a full investigation of the incident has been completed.

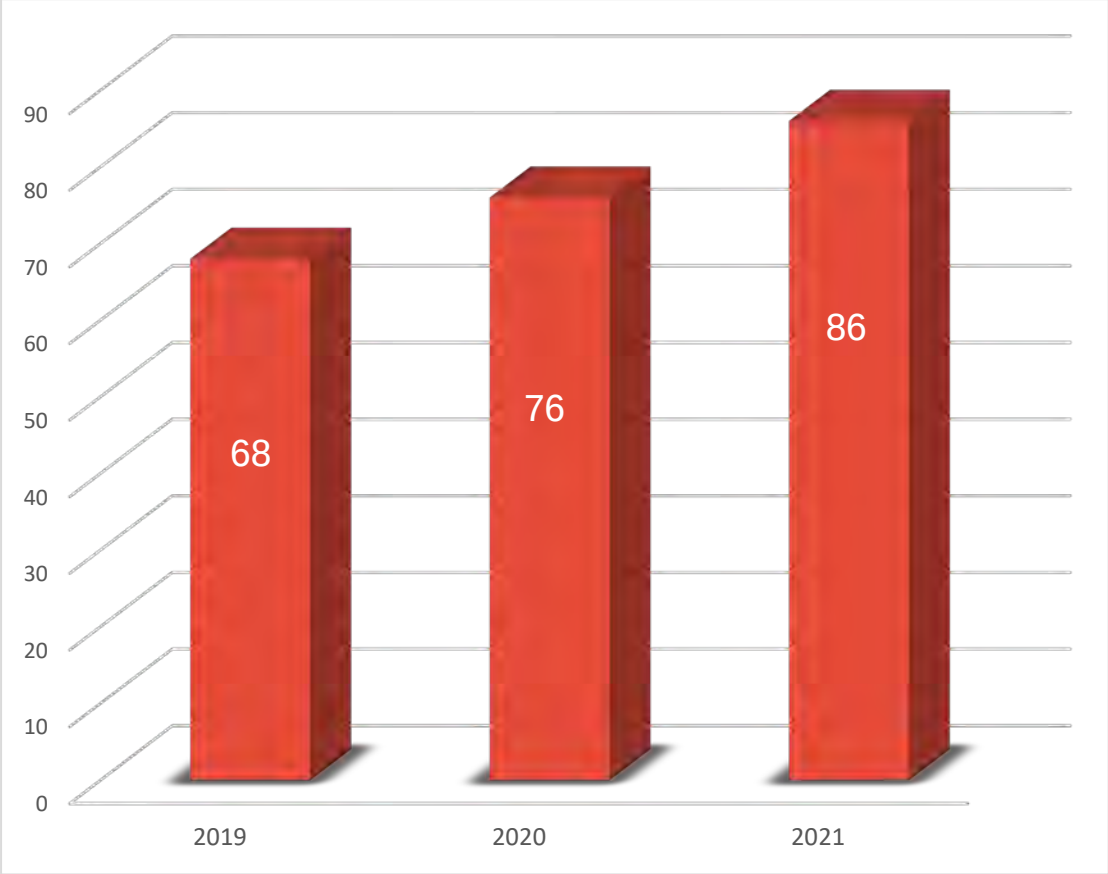
Undertakings compliance in respect of reporting in line with the time frames specified by HIQA, as well as the method of communication with HIQA, is reviewed. Finally, the radiation dose received by service users as a result of accidental and unintended exposures or significant events is also considered in this report.

2.1 Number of notifications submitted

In total, between 1 January 2021 and 31 December 2021, HIQA received 86 notifications which met the defined thresholds of reportable significant events (Appendix A). This number has risen every year since 2019 and the number reported to HIQA in 2021 represented a 26% increase in notifications submitted compared with notifications received in 2019 (Figure 1).

[‡] A significant event is an incident involving medical exposures that are deemed to be above or below an acceptable threshold and have the potential to cause harm.

Figure 1: Number of accidental or unintended medical exposure to ionising radiation incidents reported to HIQA (2019-2021).



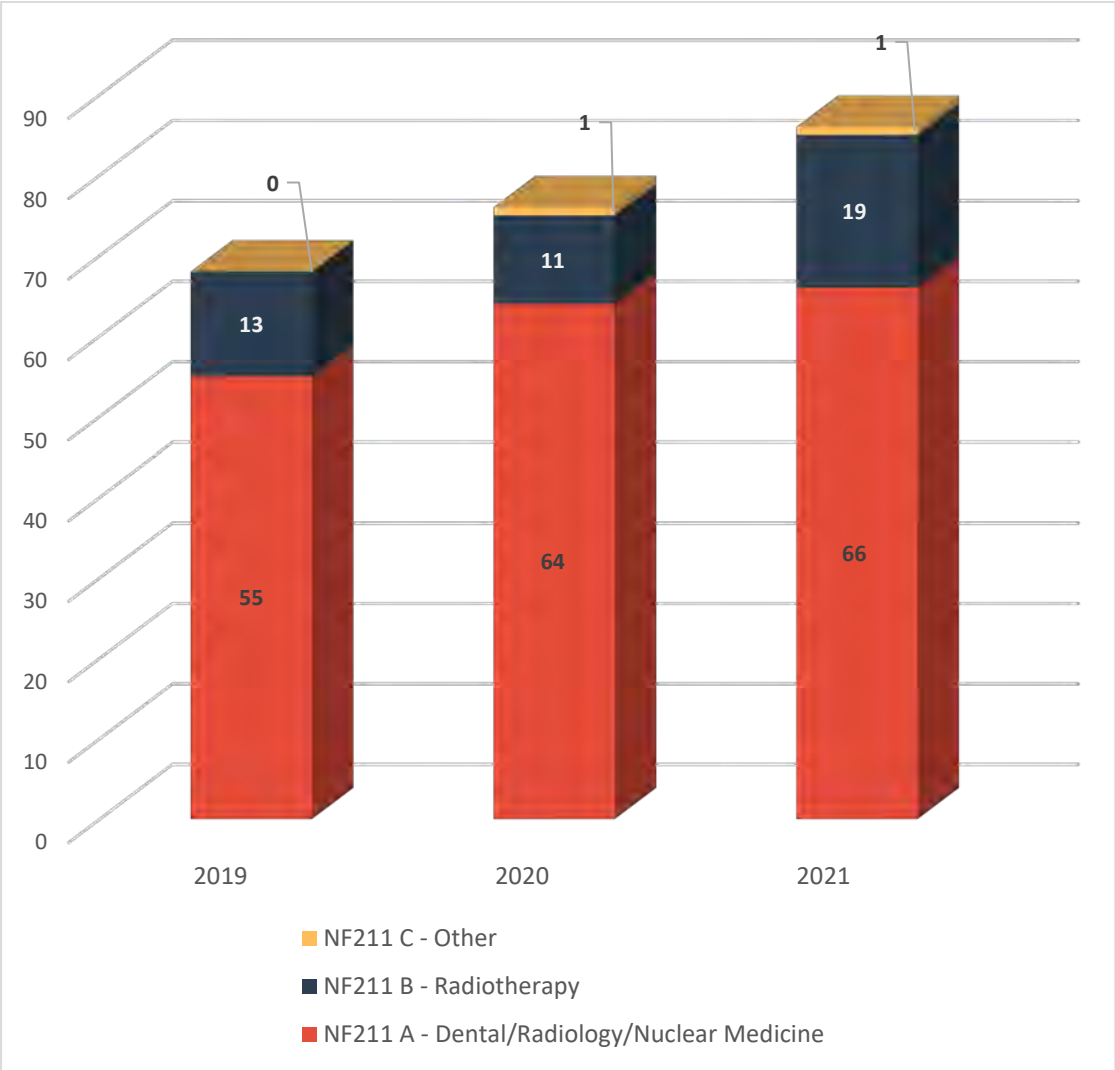
2.2 Notification type

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

- NF211 A Diagnostic Imaging (Dental/Radiology/Nuclear medicine)
- NF211 B Radiotherapy
- NF211 C Other

Diagnostic imaging and radiotherapeutic services are considered separately due to differences in operational service delivery, equipment and staff.
The inclusion of a third category of 'other' provides a reporting pathway for incidents that undertakings determine may not be easily categorised.
Figure 2 details the contribution of each notification type to the overall number of incidents reported to HIQA since 2019.

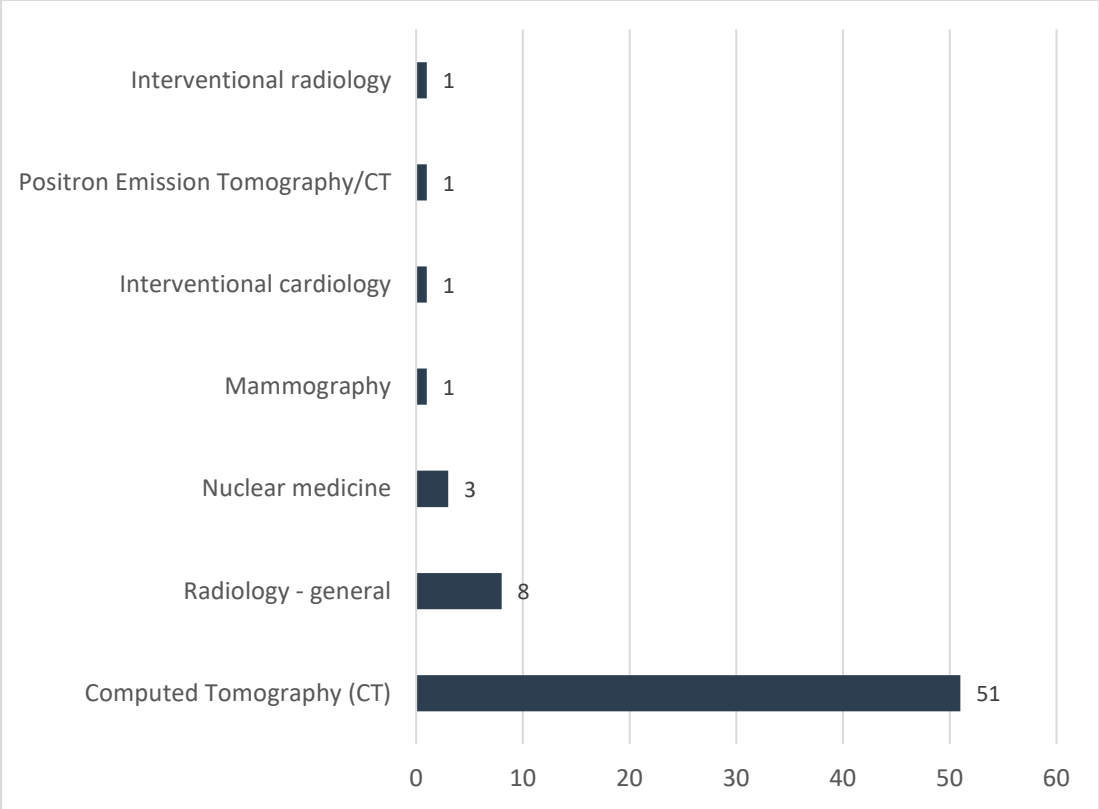
Figure 2: Notification type



Trends in the contribution of each notification type can be seen with those from diagnostic imaging outweighing those reported by radiotherapy consistently since 2019. This fact is largely due to the number of diagnostic imaging facilities far outnumbering the number of radiotherapy facilities.

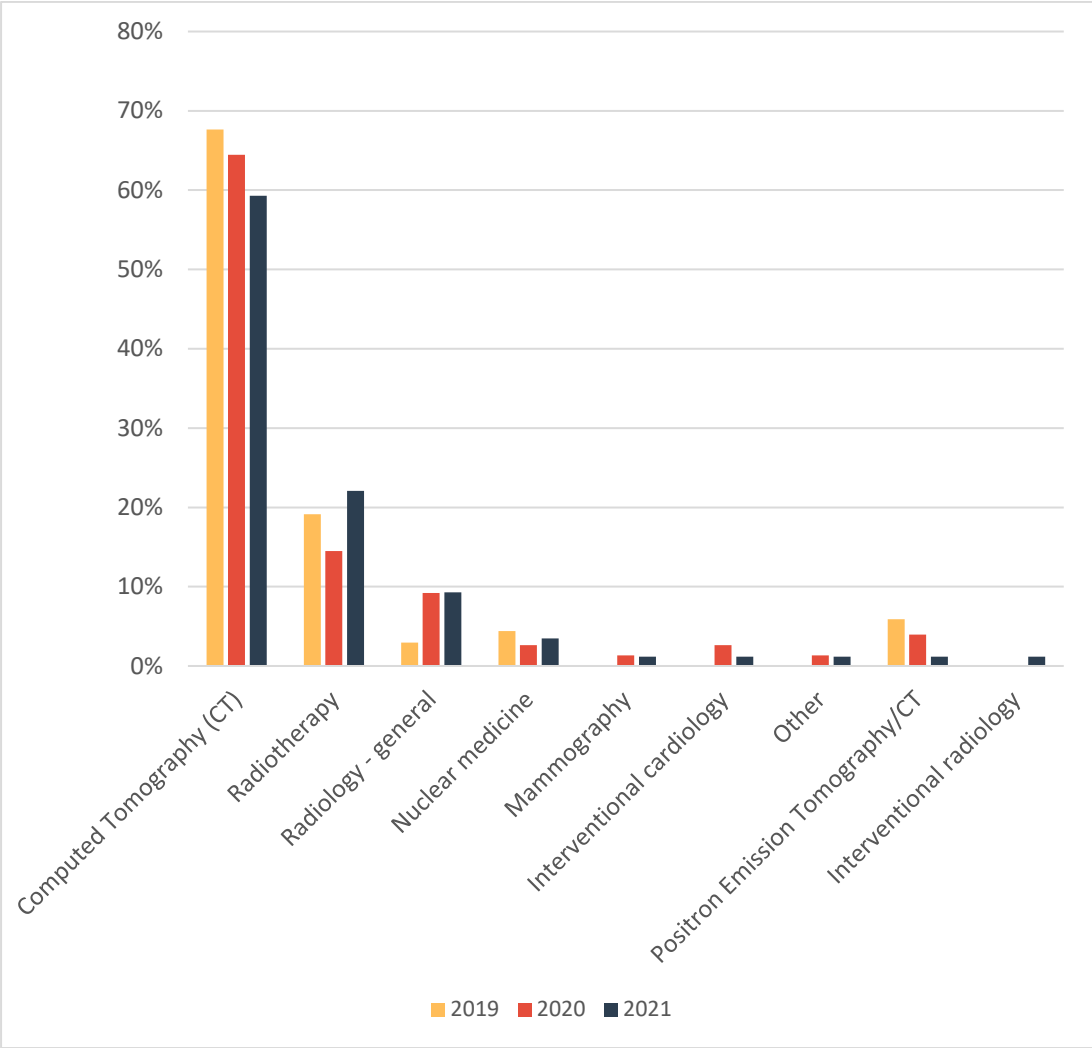
Incidents in diagnostic imaging are further sub-categorised to show which imaging modality the incident occurred in, and this is displayed in Figure 3.

Figure 3: Notifications received from diagnostic imaging facilities in 2021



Of the 66 diagnostic imaging incidents reported in 2021, 51 (77%) occurred in CT. Figure 4 displays multi-year data reflecting the areas where significant events are consistently occurring in Irish facilities. The year-on-year information supplied to HIQA demonstrates that the majority of incidents reportable to HIQA are consistently occurring in CT departments.

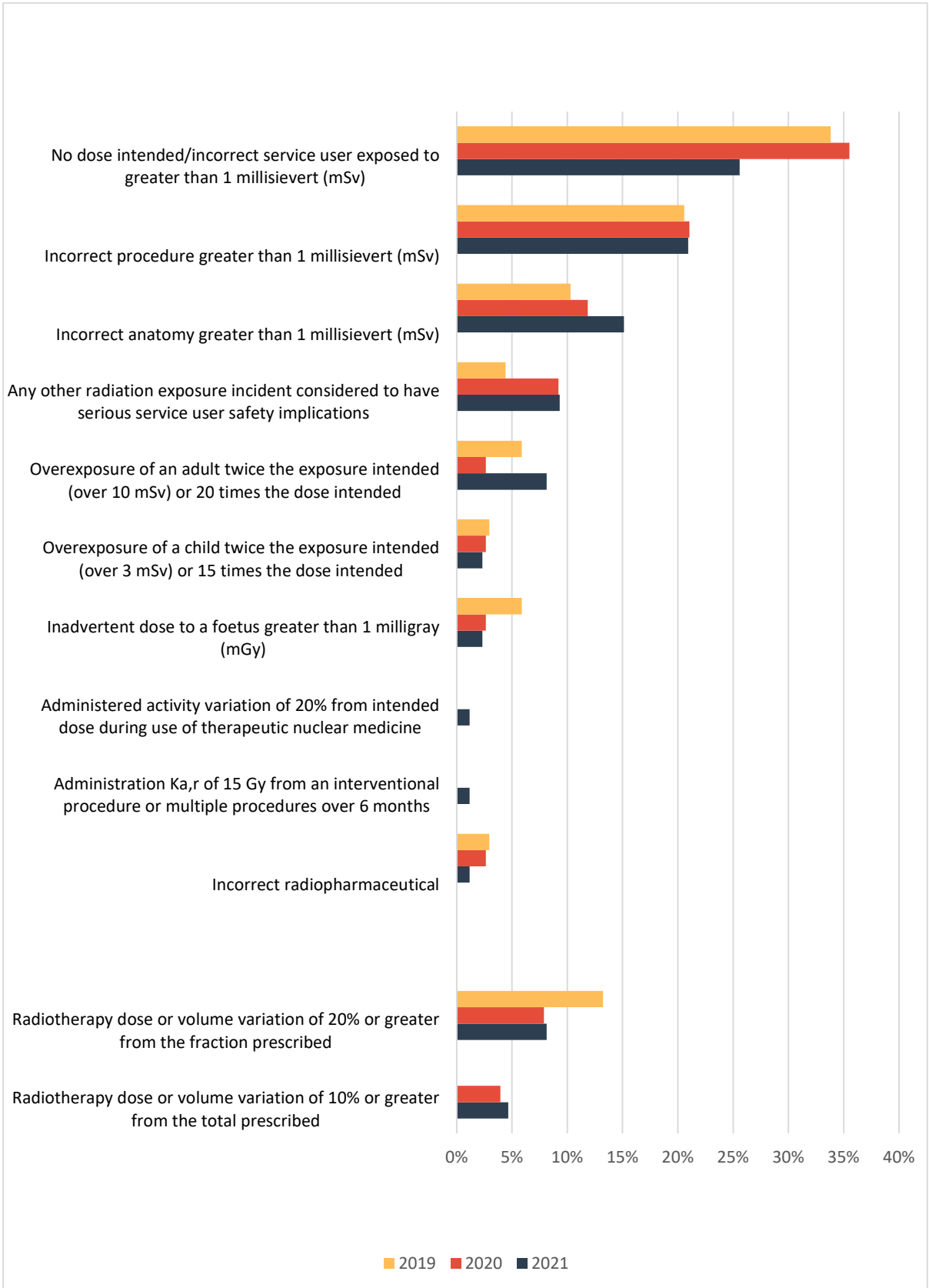
Figure 4: Notifications received per area (2019-2021)



2.3 Categories and associated circumstances of notifications

As part of the reporting of accidental and unintended exposures or significant events, undertakings are asked to categorise the nature of the incident. For the third consecutive year, the most common error reported to HIQA relates to circumstances in which radiation dose was not intended, or when an incorrect service user was exposed to a dose greater than 1 millisievert (mSv). In 2021, this accounted for 26% of the total number of reported significant events (Figure 5).

Figure 5: Notification categorisation



Again, trends in the nature of incidents are evident since 2019, the most common incidents reported to HIQA were:

- no dose intended/incorrect service user exposed to greater than 1 millisievert (mSv)
- incorrect procedure greater than 1 millisievert (mSv)
- incorrect anatomy greater than 1 millisievert (mSv)
- any other radiation exposure incident considered to have serious service user safety implications.

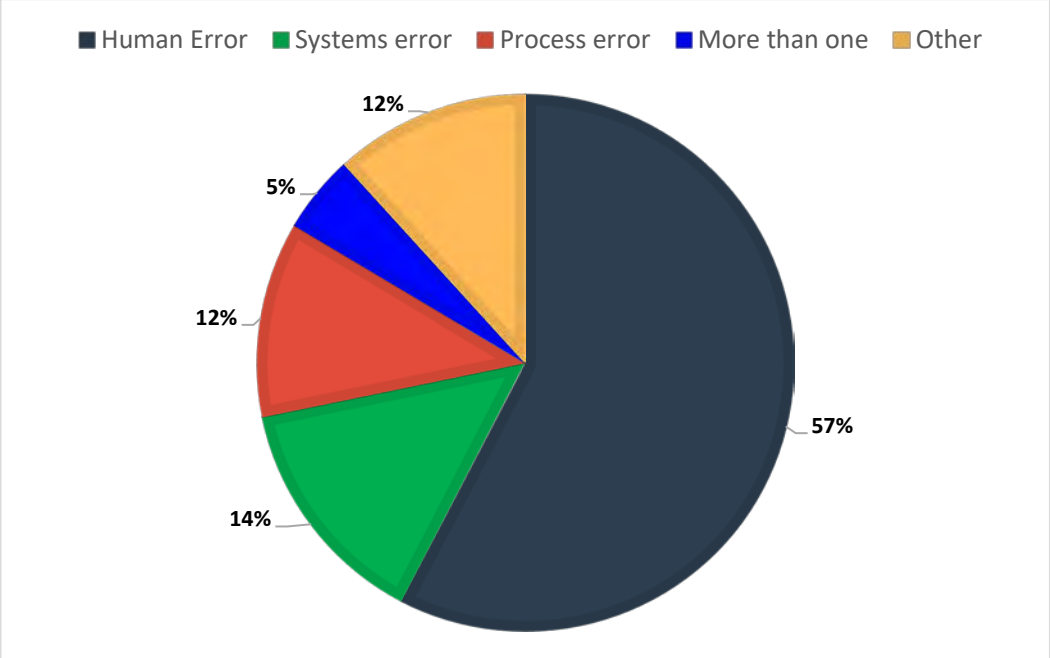
Similarly, radiotherapy incidents are further sub-categorised and the majority of incidents were either:

- radiotherapy dose or volume variation of 20% or greater from the fraction prescribed
- radiotherapy dose or volume variation of 10% or greater from the total prescribed.

2.4 Why the incident occurred

When undertakings were asked to assess the main cause of accidental and unintended exposures or significant events reported, human error was identified in 49 cases, representing 57% of all accidental and unintended exposures or significant events reported in 2021 (Figure 6), a trend mirrored in the 2020 report.

Figure 6: Main cause of accidental and unintended exposures or significant events



Similar trends were seen in diagnostic imaging and radiotherapy, with human error identified as the leading cause of the majority of accidental and unintended exposures or significant events, accounting for 61% in diagnostic imaging and 47% of incidents in radiotherapy.

2.5 Corrective measures used by undertakings

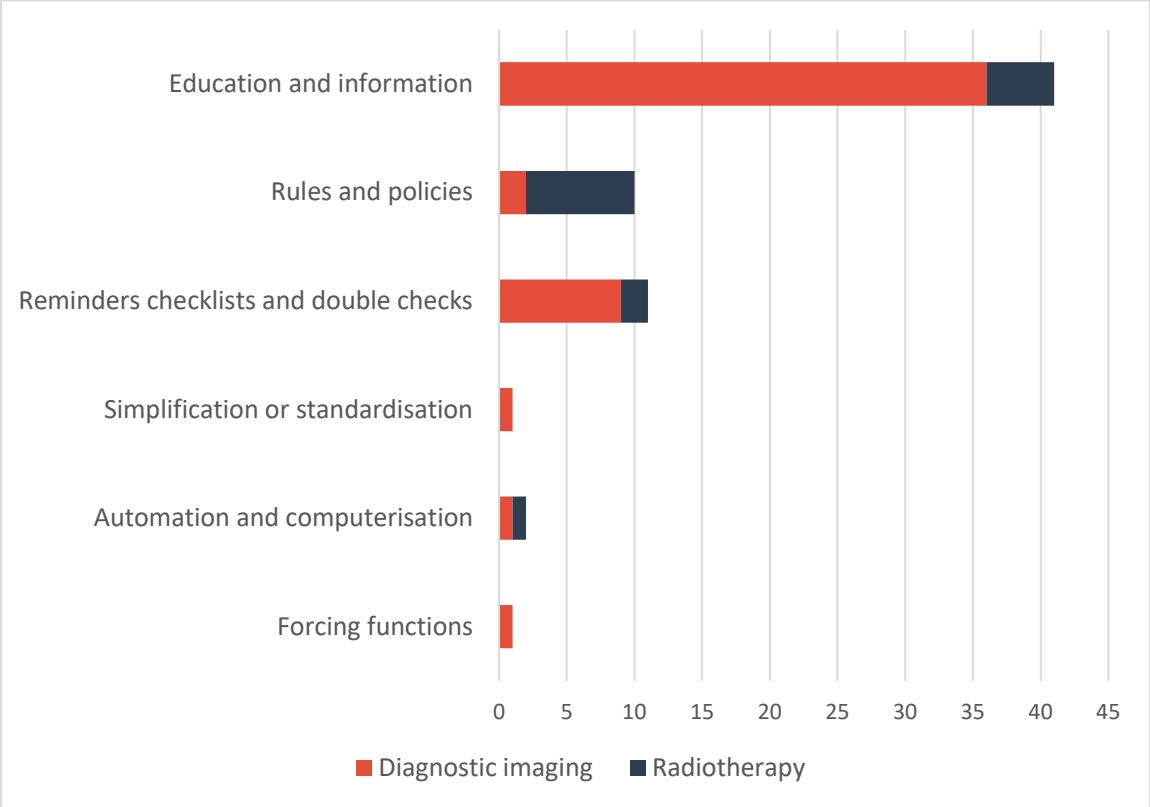
An analysis of the investigation reports looked at the type of corrective measures used by undertakings to minimise the probability and magnitude of re-occurrence. The analysis of investigation reports was based on a hierarchy of effectiveness framework[2] and categorised the corrective measures employed as outlined below in Table 1.

Table 1: Corrective measures used by facilities and rating of effectiveness

Risk reduction strategies/corrective measures	Effectiveness
Forcing functions	High
Automation and computerisation	High
Simplification or standardisation	Medium
Reminders, checklists and double checks	Medium
Rules and policies	Low
Education and information	Low

Differences were seen in the most common corrective actions taken between diagnostic imaging and radiotherapy. Diagnostic imaging facilities tended to focus on education and information for staff involved in accidental and unintended exposures or significant events, while radiotherapy facilities mainly implemented new rules and policies to reduce the possibility and magnitude of re-occurrence. Figure 7 details the most common corrective actions employed by undertakings for both notification types.

Figure 7: Common corrective actions taken by undertakings



As shown in Figure 7, forcing functions and simplification or standardisation were not commonly employed corrective actions identified in the investigation reports submitted for 2021.

2.6 Reporting time frames

Initial notifications must be reported to HIQA within three working days of discovery of the accidental and unintended exposure or significant event. The subsequent investigation results and corrective actions must be submitted by 120 days from the date of the initial notification.

During 2021, undertakings faced unique challenges due to the ongoing COVID-19 pandemic and a national public sector cyber-attack. The impact of these challenges affected some undertaking's ability to meet specified time frames

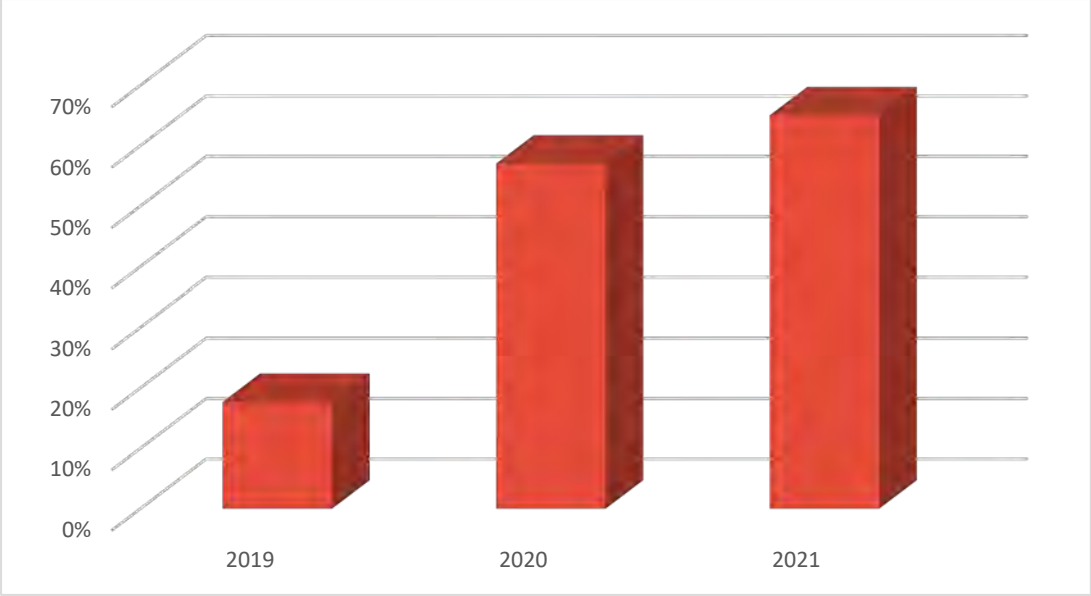
and was, in some cases, identified to HIQA as the main cause or a contributing factor for the late reporting of notifications. In 2021, over half (51%) of the initial notifications reported to HIQA were outside the specified time frame. The subsequent investigation reports associated with the initial notifications were mostly submitted within the specified 120 day time frame.

Each notification and or investigation report that are not received within the specified time frames are routinely followed up by HIQA. However, undertakings should ensure that systems and processes are in place to consistently meet the specified time frames in all circumstances.

2.7 Methods used to submit notifications to HIQA

Of the 86 notifications received in 2021, 56 (65%) were submitted using HIQA's online portal system, with the remaining 30 notifications submitted by email (Figure 8).

Figure 8: Use of HIQA's portal system to submit notifications



The increased use of the HIQA's portal system by undertakings is considered a positive step as this system offers a more streamlined, secure and easy-to-use method to submit notifications. It also provides undertakings with an accessible record of the notification history and oversight of trending in notifications submitted to HIQA.

HIQA intends to move exclusively to receiving notifications of accidental and unintended exposures or significant events through the portal system.

2.8 Additional radiation dose received by service users

Similar to previous years, the vast majority of incidents reported to HIQA involved an additional dose delivered to service users in the range of 1-5mSv. This is comparable to the typical dose that each person receives annually from background radiation in Ireland,[3] which is approximately 4mSv a year, and is associated with minimal risk to the service user.[4]

3. Learning from national accidental and unintended exposures and significant events

This section takes a closer look at what HIQA found following the review of the incident notifications and the associated investigation reports for 2021. Data since 2019 is also considered to identify trends and potential learning at a national level from statutory reporting of accidental and unintended exposures and significant events.

3.1 Trends indicate an improving national radiation safety culture

Statutory reporting has seen an upward trend in the annual number of accidental and unintended exposures and significant events reported to HIQA since it began receiving notifications in January 2019. This consistent increase in reporting rates since 2019 is seen by HIQA as a positive finding and aligns with HIQA's previous findings in this area. The 2020 overview report noted that statutory reporting on a national level encourages undertakings to have comprehensive systems to identify, report and investigate accidental and unintended exposures and significant events.[5] The transparent reporting of incidents has been highlighted as a key component of a culture of patient safety[6] and higher incident reporting rates have been associated with a positive patient safety culture.[7]

3.2 Potential for improving the numbers of incidents reported to HIQA

While high levels of incident reporting can be a good indicator of a positive patient safety culture, it must also be noted that low rates of reporting do not necessarily mean that a low number of incidents or near misses are occurring. This, instead, may indicate that systems and processes are unable to, or inadequate in, identifying and subsequently reporting incidents.

Less than 20% of all facilities reported an event to HIQA in 2020. In 2021, this figure decreased slightly to 19%. Of the 202 public and private hospitals and imaging centres or facilities in Ireland, only 38[§] facilities reported incidents in 2021. This consisted of reports from 9 of the 16 (56%) facilities supplying a radiotherapy service, and 33 of the 186 (18%) facilities supplying a diagnostic imaging service. The lower percentage contribution from some facilities may be due to the relatively high number of facilities supplying lower dose services such as general radiography and DXA scanning, where accidental and unintended exposures are unlikely to reach thresholds for reporting to HIQA. Generally, radiotherapy services are associated with much larger patient doses and are therefore more likely to meet the threshold for reporting of incidents to HIQA.

Nearly half of all notifications reported to HIQA were received from six facilities. These six facilities, considered as having high levels of activity across a range of imaging modalities, and providing complex medical exposures, averaged nearly seven notifications per year. However, many comparable services did not report any or only reported a single event during 2021. The lack of reporting or low notification numbers in these facilities may be indicative of consistently good practice. Alternatively, it may suggest that not all errors or incidents that occur are identified or reported. This lack of reporting is considered by HIQA and is part of HIQA's ongoing monitoring of all facilities providing medical exposure to ionising radiation.

Facilities with high levels of activity, across a range of imaging modalities and providing complex medical exposures, particularly CT, who are not reporting accidental and unintended exposures and significant events should consider a review of their practice to assure themselves that the absent or low notification numbers do not represent an inability to detect such events.

[§] Note some facilities submitted notifications for both diagnostic imaging and radiotherapy services.

3.3 Potential for more effective measures to mitigate risk

Similar to the 2020 report, the analysis of investigation reports submitted noted that human error was the main cause for the majority of accidental and unintended exposures and significant events.

Again, the most common corrective action employed in 2021 mirrored the 2020 report, with undertakings relying heavily on education, information and implementation of new rules and policies.

The efficacy of the most common corrective measures employed by undertakings in 2021 has been previously highlighted as having a low impact and therefore is less effective at preventing a re-occurrence of similar incidents.[2,6] High-impact risk reduction strategies such as forcing functions[**] and automation and or computerisation were not routinely relied upon by undertakings to mitigate the risks associated with accidental and unintended exposures and significant events.

The reliance on low-impact, people-focused corrective actions may represent a minimally effective system for reducing the undertakings ability to effectively reduce the probability of re-occurrence and can also discourage individuals to report errors when they occur.[7,8,9]

Undertakings should aim to encourage and support individuals to report errors with the assurance that the response will be focussed on what happened, rather than who failed.[8,9] Therefore, undertakings should concentrate on more effective system-focused corrective actions rather than people-focused interventions such as education and information.

[**] Forcing functions are part of the design of a process that significantly reduces the likelihood of an error occurring.

4. Case studies from national accidental and unintended exposures and significant events

This section of the report details a number of case studies that represent the types of accidental and unintended exposures, and significant events reported to HIQA in 2021. These case studies were chosen to highlight learnings for service users and undertakings. The term service user is a regulatory term which includes patients, comforters and carers and volunteers participating in research. However, for these case studies, the term patient is used as each case relates to a patient.

Information provided by undertakings about the corrective actions which were taken are categorised by HIQA according to a hierarchy of effectiveness framework.[2] HIQA have detailed some learnings to assist undertakings in considering and choosing the most effective corrective actions available to them in future cases.

4.1 Interventional radiology – significant dose to the skin

Scenario

A fluoroscopically guided intervention was carried out on a patient by a multi-disciplinary healthcare team. Due to the complex nature of the case, the patient received a significant dose to the skin, which was greater than 15 Gray (Gy).

Clinical follow-up of this patient was discussed after the procedure, to identify radiation induced skin reactions after administration of a significant dose. On follow-up, hair loss was observed. A second follow-up appointment identified that no further radiation induced skin reactions were present.

Corrective actions taken by undertakings

- Policies outlining the safe delivery of medical exposure were revised, trialled, finalised and brought to the Radiation Safety Committee for approval.
- An information session was held for staff to ensure compliance with revised policies and standardisation of practice.
- Discharge instructions were revised and updated to ensure adequate patient follow-up in the event of the administration of a significant dose.
- All interventional radiology procedure protocols were reviewed and further optimised.

Learnings for undertakings

Although radiation induced skin reactions are now widely accepted as a possible but rare side effect of fluoroscopically guided interventions,[10] all undertakings should ensure that systems and processes are in place to identify, report, follow up and investigate all potential radiation induced skin reactions following fluoroscopically guided interventions.
All patients should be informed of, consented for and appropriately monitored for possible radiation induced skin reactions associated with a small number of fluoroscopically guided interventions.

Risk reduction strategies used	Effectiveness
➢ simplification and or standardisation	**Medium**
➢ rules and policies	**Low**
➢ education and information	**Low**

4.2 Nuclear medicine – incorrect injection

Scenario

A patient was injected with a nuclear medicine kidney scan injection instead of a thyroid scan injection. The contents of the injection box were not checked prior to administration. Advice was sought from the medical practitioner and Medical Physics Expert upon discovery of this error. Subsequently the patient received the correct injection.

Corrective actions taken by undertakings

- It was acknowledged that greater attention should be given by staff to patient specific details.
- It was recommended that two staff members should be present for all injections with each verifying the injection type for the intended patient.

Learnings for undertakings

Undertakings should have systems and processes in place to ensure that the correct patient receives the correct nuclear medicine injection in all scenarios. In this case, increased staffing levels and added procedural steps were utilised to reduce the possibility of re-occurrence of similar events in the nuclear medicine department.

However, learnings from this event could have been shared beyond the nuclear medicine department and this may subsequently enhance the undertaking's ability to prevent similar occurrences throughout the facility.

Risk reduction strategies	Effectiveness
➢ reminders, checklists, double checks	**Medium**
➢ education and information	**Low**

4.3 CT – failure to complete triple identification check

Scenario

Many patients were waiting for CT scans outside the CT scan room. A patient was called by staff into the CT room. However, the wrong patient entered. Staff failed to carry out a triple identification check, resulting in the patient receiving the incorrect examination. Staff noticed that the image acquired did not relate to the patient's medical history.

Corrective actions taken by undertakings

- The error was identified immediately and the patient had the correct procedure.
- The senior staff member in the area reminded the staff member involved of the importance to follow the patient identification procedures.
- A staff meeting was held where details of the incident and the importance of the triple identification check were discussed.
- An audit of compliance levels with the triple identification policy was carried out and the results were discussed at a staff meeting.

Learnings for undertakings

While the use of audits to establish the frequency and associated risk of similar events is considered a positive measure, this case study also shows an opportunity for improvement when dealing with human errors and failures to follow well-established and understood policies.

Forcing functions, computerisation or automation of the patient identification process was not considered by the undertaking and may have had a significant positive effect preventing a similar event occurring. Also in this case, the working environment was not considered as a contributing factor by the undertaking. Work reviews may have enabled the implementation of a more effective strategy to mitigate the risk of re-occurrence.

Risk reduction strategies	Effectiveness
➢ rules and policies	Low
➢ education and information	Low

4.4 CT – unintended exam

Scenario

A patient had a CT exam in mid-2021. The referral for this exam specified that it was to be performed in December 2021 as a twelve month assessment. The patient received the CT exam in July and also in December 2021. The CT exam carried out in July 2021 was not necessary. An investigation into this incident determined that the staff member performing the exam did not notice the date specified on the referral. This resulted in the exam being booked for the nearest available date instead of the date specified on the referral.

Corrective actions taken by undertakings

- Radiography staff will check referrals to confirm the correct required scan date.
- The Radiation Safety Committee approved an amendment of the referral form to include a date for the exam.
- A communication was issued to referrers to include the date for exams on referrals.
- A booking procedure was written to include detail about the exam date.
- Audits were performed and continue in relation to routine checks for outpatient CT, appropriateness of CT justification and general justification in CT.

Learnings for undertakings

In this case, the undertaking used a range of corrective actions to reduce the possibility of re-occurrence. These actions, when considered collectively and used in conjunction with multi-disciplinary communication and corporate oversight, are likely to reduce the possibility of re-occurrence and mitigate associated risks. The addition of an audit function is seen as beneficial, providing a quality assessment element allowing ongoing monitoring of service delivery.

Risk reduction strategies	Effectiveness
➢ simplification and or standardisation	**Medium**
➢ reminders, checklists, double checks	**Medium**
➢ rules and policies	**Low**
➢ education and information	**Low**

4.5 CT – duplicate referral during cyber attack

Scenario

An outpatient arrived for a CT scan. Once the scan was completed, the patient questioned why they needed the same scan twice. It was then discovered that the patient had already had the scan the previous month. A duplicate referral had been made following the cyber attack. This duplication was not identified at the time of booking or when the second scan was justified.

Corrective actions taken by undertakings

- The booking system was checked for any duplicate bookings.
- Staff were reminded to check for duplicate bookings and of the importance of checking previous imaging and future bookings.
- Relevant policies were reviewed and signed by all staff.
- An education session was carried out by the Radiation Protection Officer.

Learnings for undertakings

In this case, the undertaking used a range of corrective actions to reduce the possibility of re-occurrence. The cyber attack produced new and unseen causes for accidental and unintended exposures and significant events. The undertaking developed and used a range of corrective actions to address these novel scenarios.

However, staff responsible for the booking systems were not involved in the investigation nor were higher efficacy corrective actions considered by the undertaking. Consideration and investigation into the possibility of such corrective actions may have provided a more effective method for reducing the possibility of re-occurrence.

Risk reduction strategies	Effectiveness
➢ reminders, checklists, double checks	**Medium**
➢ rules and policies	**Low**
➢ education and information	**Low**

4.6 Radiotherapy – incorrect prescription highlighted during cyber attack

Scenario

A patient was to receive an atypical radiotherapy prescription. The patient's treatment was interrupted due to the May 2021 cyber attack and the patient was transferred to another centre for treatment. The consultant made a new prescription to complete the patient's treatment at the new centre. However, at this stage, it was discovered that the original non-standard prescription was incorrect. A review of this incident determined that while the daily number of treatments needed to be increased slightly, there was no clinical impact on the patient.

Corrective actions taken by undertakings

- Whenever an atypical radiotherapy treatment is prescribed, the reasons for such prescriptions should be clearly stated on the oncology information system.
- Staff working in the treatment planning department will confirm any non-standard prescriptions with the consultant before starting the planning process.

Learnings for undertakings

The corrective actions implemented in this case were developed to address the issue caused by needing to use an atypical prescription. The undertaking developed and implemented bespoke corrective actions, providing assurances that similar incidents are less likely to occur. However, the review and investigation did not involve staff outside the radiotherapy department. Other departments and patients may benefit if learnings are shared across the entire facility as the use of quality, risk and safety resources, when available, is always beneficial.

Risk reduction strategies	**Effectiveness**
➢ **reminders, checklists, double checks**	**Medium**
➢ **rules and policies.**	**Low**

4.7 Radiotherapy – image mismatch

Scenario

On a patient's second day of radiotherapy, it was discovered that a slight variation from the intended position had occurred when delivering the first day's treatment. A dosimetric analysis was conducted and this confirmed that there was no clinical impact for this patient as a result of this incident. The patient continued their course of treatment as planned. The direct cause of this incident was identified as a mismatch when using kV imaging to confirm the intended position for treatment. Indirect causes of the incident included insufficient anatomical information available on the images and the absence of highlighted structures on the reference imaging which are typically used to help guide the treatment. In addition, marks usually put on the sides of the patient to help guide treatment were not possible in this case as there were no stable points available.

Corrective actions taken by undertakings

- This type of incident has occurred previously and measures implemented included changes to the length of the CT scan used as a reference image and staff to be vigilant to this issue when dealing with treatment in particular regions of the body.
- Using specialised techniques to position and align patients could reduce these types of errors and such devices will be installed.
- A new training manual is to be introduced for staff detailing specific imaging and positioning and staff are to be reminded of the importance of checking anatomical levels.

Learnings for undertakings

In this case, the undertaking used a multidisciplinary approach with a root cause analysis, including the undertaking's quality, safety and risk department. A wide range of corrective actions, including those considered to have high efficacy were considered and used by the undertaking. The investigation and oversight of this event was seen as a comprehensive and effective approach to mitigate similar events.

Risk reduction strategies	Effectiveness
➢ automation and or computerisation	**High**
➢ reminders, checklists and double checks	**Medium**
➢ simplification and or standardisation	**Medium**
➢ education and information.	**Low**

4.8 Summary of case studies

Generally, corrective measures employed by undertakings tend to be risk reduction strategies with low levels of efficacy. Human error is attributed as the main cause of the majority of accidental and unintended medical exposures and significant events. However, a person-focused approach may not be as effective as a systems-focused solution. Preferably a systems-focused solution associated with a higher effectiveness should be used where possible. Undertakings should consider corrective actions across the entire effectiveness range to minimise the probability and magnitude of accidental and unintended medical exposures and significant events.

Input from quality, risk and safety resources would allow undertakings to enhance their oversight and mitigate risks associated with accidental and unintended medical exposures and significant events. Quality, risk and safety resources should always be used by undertakings where available.

5. Conclusion

This report presents the analysis of national trends in the notifications of significant events arising from accidental or unintended medical exposures to ionising radiation. Since 2019, there has been a year-on-year increase in the number of notifications received by HIQA, representing a 26% increase in notifications submitted in 2021 when compared with that of 2019, and this is a positive finding.

While overall numbers are increasing, the overall contribution by service type, incident categorisation and area or modality in which the incidents occurred has remained relatively unchanged. Findings from 2021 reflect previous years, with the majority of incidents occurring in computed tomography (CT) departments and involving the exposure of the wrong service user.

In 2021, six facilities submitted nearly half of all notifications reported to HIQA. The number of incidents reported to HIQA across comparable facilities varied significantly. Lower numbers of incidents in busy multi-imaging modality facilities may indicate good practice. However, undertakings should also consider if this suggests that incidents are not being identified or reported. Undertakings should aim to encourage and support individuals to report incidents with the assurance that the response will be focused on what happened, rather than who failed.

Human error was identified as the main cause in over half of the reported incidents and the implemented corrective actions largely relied on people-focused interventions such as education and information. This combination of human error as a main cause and education and information as a corrective action may represent a minimally effective system for reducing the undertakings ability to effectively reduce the probability of re-occurrence. System-focused changes should be the preferred method for undertakings in effectively reducing the possibility of reoccurrence of incidents.

In 2022 and beyond, HIQA's programme of monitoring and inspecting services will continue in order to ensure that radiation protection practices in public and private radiological facilities in Ireland are compliant with the regulations. HIQA will continue to build upon this programme to promote patient safety in relation to radiation protection and to improve the quality and safety of medical exposures for service users.

Appendix A - Significant events of accidental or unintended exposures that are notifiable to HIQA

Category Number	Category details
1	Administration of a Reference Point Air Kerma (Ka,r) of 15 Gray (Gy) or greater as a result of a single interventional radiological procedure (including interventional cardiology) or a cumulative Ka,r dose of 15 Gy arising from a series of interventional radiological procedures carried out over a six month period
2	Tissue reactions (deterministic effects) as a result of interventional radiology/cardiology
3	Diagnostic overexposure of an adult of more than twice the exposure intended that leads to a dose that is greater than 10 millisievert (mSv) or 20 times the dose intended
4	Diagnostic overexposure of a child of more than twice the exposure intended that leads to a dose that is greater than 3 millisievert (mSv) or 15 times the dose intended
5	Dose given to comforters and carers greater than 3 millisievert (mSv) for adults under 60 years of age and 15 millisievert (mSv) for those over 60 years of age
6	Dose to a breastfed child greater than 1 millisievert (mSv)
7	Inadvertent dose to a foetus greater than 1 milligray (mGy)
8	Incorrect anatomy greater than 1 millisievert (mSv)
9	Incorrect procedure greater than 1 millisievert (mSv)
10	Incorrect radiopharmaceutical
11	Therapeutic dose given instead of diagnostic dose, for example, in the use of radioiodine
12	Administered activity variation of 20% from intended dose during use of therapeutic nuclear medicine

13	No dose intended/incorrect service user exposed to greater than 1 millisievert (mSv)
14	Radiotherapy dose or volume variation of 10% or greater from the total prescribed
15	Radiotherapy dose or volume variation of 20% or greater from the fraction prescribed
16	Unexpected tissue reactions (deterministic effects) as a result of radiotherapy treatment
17	Any other radiation exposure incident considered to have serious service user safety implications, for example, multiple non-notifiable incidents of a similar nature

Glossary of terms

Accidental exposure: an exposure of individuals, other than emergency worker, as a result of an accident.

Computed tomography (CT): a technique for imaging the body in sections or slices using specialised computers and imaging equipment. An alternative name for CT is computer-aided tomography or CAT scan.

Diagnostic imaging: medical exposures to ionising radiation undertaken to identify a disease or injury.

Dual-energy X-ray absorptiometry (DXA or DEXA): is a type of medical exposure used to assess bone density in service users where low bone density.

Effective dose: Effective dose is an indicator of dose received from an exposure to ionising radiation. This is calculated considering the absorbed dose and the potential effect the exposure is likely to have on the tissues and organs in the body. Effective dose of typical diagnostic examinations are usually recorded in millisieverts (mSv).

Fluoroscopy: a type of medical exposure that uses a continuous beam of ionising radiation to create an image on a monitor. During a fluoroscopy procedure, the image that is transmitted to the monitor displays the movement of a body part, instrument or contrast agent through the body in real-time.

Fractions: the smaller doses that a series of treatment sessions are divided into to make up a full radiotherapy course. This allows healthy cells to recover between treatments.

Gray (Gy): a unit of measurement for absorbed dose. It is equivalent to one joule of energy absorbed per kilogram of material.

Interventional cardiology: procedures that use fluoroscopy equipment to obtain real-time imaging to help introduce and guide devices and equipment used for diagnostic or treatment purposes in cardiology.

Ionising radiation: radiation with enough energy so that during an interaction with an atom, it can remove tightly bound electrons from the orbit of an atom, causing the atom to become charged or ionised. It has a higher energy than light and therefore can pass through the body. Ionising radiation is not without risks, as the body can absorb some of the energy. However, ionising radiation is a valuable medical tool for the diagnosis and treatment of

diseases and injuries. Types of ionising radiation commonly used in medical exposures are alpha, beta, gamma radiation and X-rays.

Justification: is one of the core principles of radiation protection and means that for each individual exposure the benefits of the exposure should be considered to outweigh the risk associated with the exposure. This means that a justified procedure should do more good than harm.

Medical exposure (ionising radiation): an exposure of ionising radiation delivered to service users or asymptomatic individuals as part of their own medical or dental diagnosis or treatment. Medical exposures are intended to benefit an individual's own health. Additionally, comforters or carers and volunteers in medical or biomedical research can receive medical exposures.

Medical ionising radiation incident: accidental, unintended or other incidents occurring or potentially occurring within an undertaking which could impact on the safety and welfare of service users, comforters and carers or research volunteers.

Medical physics expert (MPE): an individual having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure and whose competence is recognised by the Minister for Health.

Near miss: a potential incident that was prevented from occurring due to timely intervention or chance and which there are reasonable grounds for believing could have resulted in unintended or unanticipated injury or harm to a service user during the provision of a health service.

Non-notifiable incident: an event relating to medical exposures to ionising radiation which is managed at a local level and does not need to be reported to HIQA as a significant event.

Notifiable incident: a significant event relating to medical exposures to ionising radiation which is reportable to HIQA. A list of reportable incidents is included in this document.

Nuclear medicine: a type of medical exposure where a radiopharmaceutical or radioactive dye is used which is designed to go to a target organ. It is administered to a service user by injection, inhalation or ingestion. Areas of disease and injury can then be diagnosed by imaging the service user under a detector called a gamma camera.

Practitioner: a person who is entitled to take clinical responsibility for a medical exposure under the regulations.

Radiation dose variation: is the difference in delivered dose of radiation from that which was intended or planned to be delivered.

Radiopharmaceutical: pharmaceuticals (drugs) that are labelled (attached) with a radioactive tracer designed to go to a target organ such as the thyroid or bones. Radiopharmaceuticals can have diagnostic or therapeutic uses.

Reference point air kerma (Ka, r): a quantity of radiation dose used to estimate the peak skin dose (the highest dose to a single area of the skin) for interventional radiological and cardiology procedures.

Referrer: a person who is entitled to refer individuals for medical radiological procedures to a practitioner in line with the regulations.

Service Provider: a person or body who provides a medical imaging service as an undertaking or as part of a larger undertaking's service.

Service user: a person or persons who attends an undertaking for the purpose of undergoing a medical exposure. This includes a patient, comforters and carers and volunteers participating in research.

Sievert (Sv): the measurement unit of both equivalent and effective dose to a service user. Equivalent and effective dose consider the absorbed dose and the effect this is likely to have on the tissues and organs in the body. Effective dose of typical diagnostic examinations are usually recorded in millisieverts (mSv).

Significant event: an event which should be notified to HIQA (and other competent authorities, if required) according to legislation.

Tissue reaction: (previously known as deterministic effects) a harmful tissue reaction due to tissue death or malfunction following a medical exposure to ionising radiation which delivers a dose above a specific threshold level. Examples of tissue reactions include skin reddening or hair loss.

Undertaking: a person or body who has a legal responsibility for carrying out, or engaging others to carry out, a medical radiological procedure, or the practical aspects of a medical radiological procedure, as defined by the regulations. For the purpose of this guidance, this means the person or body legally responsible for medical exposures of ionising radiation. Please refer to the Undertaking information handbook for more information.

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