

Medical exposure to ionising radiation

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



Regulation of Health and Social care services



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

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 and Youth Affairs, 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 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

About the Health Information and Quality Authority (HIQA).....	3
Executive summary	6
1. Role of the Health Information and Quality Authority (HIQA) in respect of medical exposures.....	9
1.1 Process for notifications of significant events.....	10
2. Requirement for a positive culture for reporting	12
3. Key findings from 2019	14
3.1 Key findings in diagnostic imaging and interventional services.....	15
3.2 Key findings in radiotherapy	19
4. Findings for HIQA and learnings for undertakings based on notifications submitted in 2019	24
4.1 Local management of accidental and unintended exposures and potential incidents.....	24
4.2 Developing and sustaining a patient safety culture for medical exposures.....	25
4.3 Investigations of significant events	25
4.4 Efficacy of corrective measures taken	27
4.5 Submitting the results of an investigation.....	29
4.6 Utilisation of HIQA’s portal to submit notifications.....	30
5. Conclusion.....	32
Appendix A - How to report a significant event through HIQA’s Portal	34
Appendix B - Significant events of accidental or unintended exposures that are notifiable to HIQA	35
Glossary of terms.....	37
References	41

Executive summary

In January 2019, new regulations designated the Health Information and Quality Authority (HIQA) as the competent authority for regulating medical exposure to ionising radiation in Ireland.¹ As a result of this new role, HIQA began receiving incident notifications of significant events arising from accidental or unintended medical exposures on the commencement of the regulations in 2019. As part of its role, HIQA is responsible for sharing lessons learned from significant events. This report presents an overview of the findings from these notifications and aims to share learnings from these investigations.

The total number of medical radiological procedures carried out in Ireland from both public and private practice can be conservatively estimated at over three million per year.^{2,3} In 2019, HIQA received 68 notifications of significant events of medical exposures to patients, which is a small number of reported significant incidents relative to the total number of procedures taking place. While the occurrence of any significant incident is unwanted, incident reporting can be suggestive of a positive and transparent patient safety culture within a service.⁴ Low levels of reporting could be suggestive of a lack of reporting rather than a lack of errors.

The most common error reported in diagnostic imaging were failures in patient identification, resulting in an incorrect patient receiving an exposure. Failures in identifying the correct patient occurred at various points in the patient pathway, from the point of referral to initiating the exposure. While this finding is in line with previously reported nationally and international data, it certainly highlights an area for improvement for undertakings*.^{2,5}

Notifications were submitted from computed tomography (CT), nuclear medicine, general radiography and radiotherapy services. The majority of notifications were in relation to CT and radiotherapy, a finding which can be attributed to the threshold for reporting, service activity levels and a positive culture of reporting from these services. There was no reported significant events from the dental, dual-energy X-ray absorptiometry (DXA) and mammography sectors. However, in these areas, the dose of radiation involved would fall below threshold for a significant event and therefore, low levels of reporting would be expected given the current criteria.

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

In particular, it was noted that there was an absence of reporting from some areas associated with potential high radiation doses, such as interventional cardiology and interventional radiology. Acknowledging that relatively high radiation doses are utilised in a small number of these highly complex but clinically beneficial procedures, it is generally expected that there may be a small percentage of tissue reactions arising from these types of procedures.⁶ Undertakings should have appropriate mechanisms in place to identify, manage and subsequently report such instances to HIQA. The finding of low levels of reporting from these services is in line with other international statutory reporting systems, but nonetheless highlights a specific area for increased assessment and attention.²

The extent of investigations and quality of the reports submitted from radiotherapy was generally high. While no significant events were submitted in relation to brachytherapy, good levels of reporting were seen from external beam radiotherapy, with most services nationally submitting at least one notification. Overall, the approach in radiotherapy was aligned to positive risk management approaches, which is relative to the high radiological risk involved and potentially indicative of the patient safety culture in this sector.

A varied approach to patient safety was also evident on review of the corrective measures applied following the occurrence of a significant event. High efficacy corrective measures such as forcing functions[†], which can eliminate risk, were evident.⁷ However, in some cases, the corrective measures put in place to prevent recurrence were limited to low efficacy strategies such as re-education of staff. Undertakings should consider the risk management strategies applied to incident investigations and corrective measures to ensure they are robust and help prevent errors from reoccurring rather than punish.^{9,10,7}

Overall, many of the investigation reports received by HIQA were comprehensive and showed systems based approaches to reviewing incidents. Some however, focused on human error in isolation, without consideration of human error as a symptom of system weaknesses.^{8,9} Undertakings should ensure a just culture[‡] is in place where individuals feel free to report errors, assured that the response will focus on what happened,

[†] A forcing function is part of the design of a process that significantly reduces the likelihood of an error occurring.

[‡] A just culture is the reverse of a blame society where it is accepted that mistakes are generally a product of faulty organisational cultures, rather than brought about by the person or persons directly involved.

rather than who failed. This was not always evident in reports received by HIQA.¹⁰

Finally, it is noted that radiation incidents reported to HIQA in 2019 have involved relatively low radiation doses with limited risk to service users. The findings in this report indicate that overall the use of radiation in medicine in Ireland is generally quite safe for patients. However, radiation incidents have been reported internationally with severe detrimental effects to service users.^{11,12} The potential for such serious adverse events highlights the need for ongoing vigilance in relation to radiation protection and the necessity of reporting and learning frameworks. It is hoped that areas of improvement noted in this report would help reduce the likelihood of such events and drive quality improvements in safety mechanisms for medical exposures in Ireland.

1. Role of the Health Information and Quality Authority (HIQA) in respect of medical exposures

In January 2019, new regulations designated the Health Information and Quality Authority (HIQA) as the competent authority for regulating medical exposure to ionising radiation in Ireland.¹ The regulations defined new minimum safety requirements to protect patients and service users from any potential hazards associated with medical exposure to ionising radiation, such as a risk of developing cancer and tissue injuries.

The regulations extended HIQA's role and regulatory powers to include public and private radiological, radiotherapy, nuclear medicine and dental services. The regulations also include medical exposures to ionising radiation incurred by carers and comforters; and by volunteers in medical or biomedical research.

HIQA monitors compliance with the regulations by conducting inspections and assessing information which is received through notifications and unsolicited information received from staff and members of the public.

Following public information sessions held in June 2019, HIQA commenced a programme of inspection of ionising radiation services. The information sessions outlined HIQA's regulatory plan including details of how compliance is assessed on inspection.

In addition to these inspections, HIQA assesses compliance of ionising radiation services through information received from notifications. The statutory notification of a significant event arising from an accidental or unintended medical exposure is required under Regulation 17. HIQA began receiving such notifications on commencement of the regulations in 2019. Guidance for service providers on how to notify HIQA of a significant event was published in January 2019.¹³

As part of its role, HIQA is responsible for the sharing of lessons learned from significant events. This report presents an overview of the findings from these notifications and aims to share learning. The potential learnings we found are spread throughout this report in key findings, presentation of data trends and case studies from the incident notifications received from medical ionising radiation services. The report also provides information for those who submit notifications to HIQA on HIQA's portal system for processing notifications.

1.1 Process for notifications of significant events

Undertakings are required to have an appropriate system in place to record and analyse potential and actual accidental and unintended exposures within their service. The criteria for a significant event which needs to be reported to HIQA was outlined in a previous guidance document.¹⁴ The criteria were adopted from the Health Service Executive (HSE) in their role under previous legislation, in consultation with HIQA's Expert Advisory Group.¹³ The process of how significant events are received and assessed by HIQA is summarised in Figure 1.

Figure 1. Process for submission and review of significant events



Notification

The undertaking must ensure that HIQA is notified of a significant event within three working days from discovery in the form of an NF211 notification via email or using HIQA's online portal system.



Assessment of the notification

HIQA assesses the notification dependant on the impact on the service user, likelihood of recurrence and considerate of the immediate actions taken thus far by the undertaking to mitigate recurrence.



Investigation results

The undertaking submits the results of the investigation and corrective actions taken within 120 working days from the discovery of the significant event.



HIQA review

The investigation report is reviewed and re-assessed based on the impact on the service user, likelihood of recurrence, including corrective measures taken to avoid the recurrence of such events. Regulatory action may be taken to provide additional assurances.



Retained for information

HIQA closes the notification but uses the information to inform future regulatory activity including contribution to the determination of compliance on inspection.

2. Requirement for a positive culture for reporting

Errors are an inevitable part of any human process.¹⁵ The reporting and investigating of errors is an important and logical step to improve patient safety and inform change. The transparent reporting of incidents is a key component of a positive patient safety culture.¹⁶ Studies have found a positive association between increased incident reporting rates and a patient safety culture.¹⁷ Therefore, high levels of incident reporting can be a good indicator of a positive patient safety culture and low numbers of reporting does not necessarily mean that low numbers of incidents or near misses are occurring. While reporting is an integral part of a safety culture, it is inherently reactive and should be coupled with prospective approaches to organisational safety.¹⁸

One of the key principles of patient safety is that harm is caused by bad systems, not bad people. However, healthcare systems can be prone to hierarchical structures and these structures can discourage transparency, commonly reacting with blame to errors. Such structures are most evident in areas of healthcare where multiple healthcare professionals are involved in delivering individual care but may not share information, inhibiting a transparent culture.¹⁶ Healthcare services should strive for a just culture where individuals feel free to report errors and are assured that the response will focus on what happened, rather than who failed.^{8,9}

The use of ionising radiation in medicine is considered safe, particularly relative to the high levels of service activity.^{19,20} Historically, in Ireland reported radiation incidents have involved relatively low radiation doses with minimal risk to service users. The most common error related to incorrect service user identification resulting in the wrong service user being exposed or individuals receiving a greater than intended radiation dose.⁵

Similarly, international data reports that most radiation incidents that occur are negligible in terms of clinical impact and on service users.²¹ However, radiation incidents impacting service user safety are possible and some reported serious adverse events highlight the potential risk of harm.^{11,12,22,23} The onset of potential harmful effects from radiation can be apparent immediately or take years to manifest. Tissue reactions as a result of radiation are a direct effect of the dose given and occur once a dose threshold has been reached. However, stochastic effects such as cancer induction occur by chance. Measuring risk of cancer from low doses of

radiation is difficult and while there is no threshold point, the risk increases proportionally with dose.^{24,25}

To prevent serious adverse events and minimise potential risks at a local level services should analyse previous events and near-misses.⁷ However, there is also a role for statutory reporting on a national level which encourages services to improve the safety of practice by increasing accountability. Statutory reporting provides assurance that significant events are reported, investigated and that appropriate action is taken to prevent recurrence. Furthermore, external reporting allows knowledge transfer and shared learned to improve safety and awareness on a national scale.^{26,27}

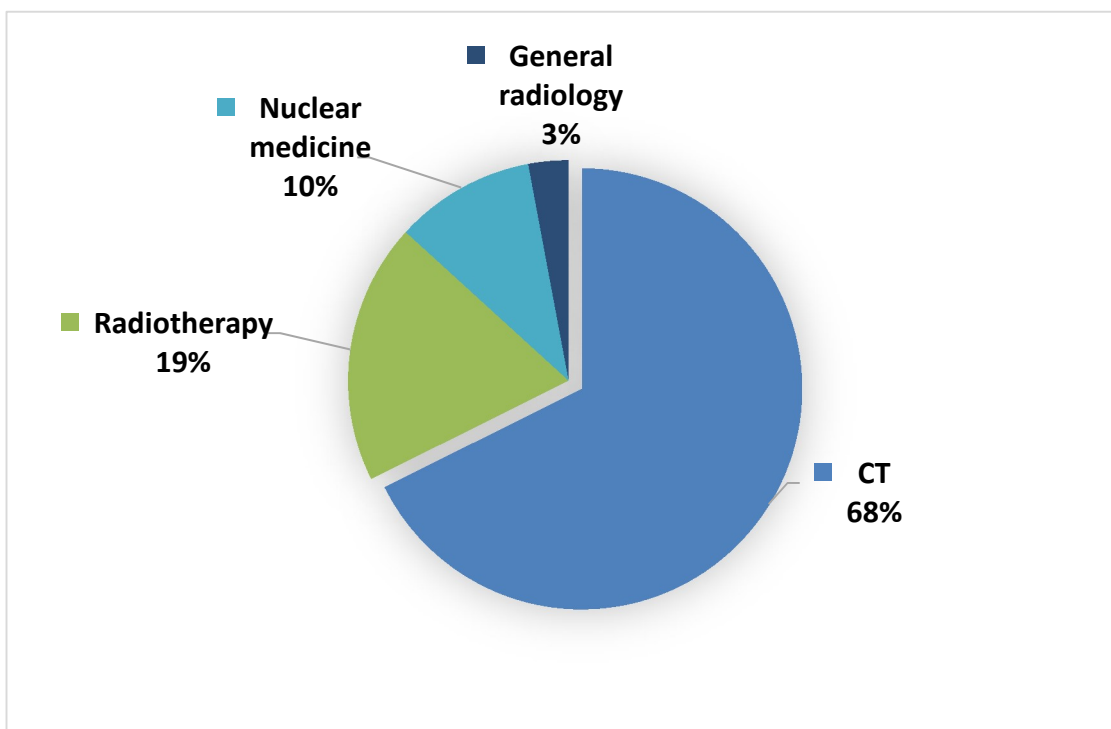
3. Key findings from 2019

There were 68 significant incidents reported to HIQA from 33 different public and private medical radiological facilities in 2019. Overall, the notifications received suggest a positive culture of incident reporting and learning in these services. The number received represents a slight increase from the significant events reported in previous years.⁵ While the level of reporting cannot be directly compared to international data, due to the unique significant event criteria applied, service activity levels would suggest that reporting levels in Ireland could be improved in certain sectors.^{2,5,28}

From a patient safety perspective, it is important to note that while the 68 notifications to HIQA in 2019 met the threshold as significant reportable events, the majority were rated as having a minor impact and did not cause direct harm to the patients involved. Currently, the determination of whether or not an incident is deemed clinically significant is at the discretion and judgment of the undertaking and clinical team submitting the notification. The regulations specify that for any clinically significant event, the service user or their representative must be informed. Of the notifications submitted to HIQA in 2019, 51% (35) were deemed clinically significant, yet in 87% of cases the service user was informed. This finding signifies good practice in terms of compliance with the requirement of this regulation however, open disclosure should be further improved in the future to align with contemporary best practice.

The breakdown of notifications per service type is highlighted in figure 2, with most incidents reported in relation to computed tomography (CT), followed by radiotherapy.

Figure 2. Breakdown of the 68 notifications received in 2019 per service type



3.1 Key findings in diagnostic imaging and interventional services

In total, 55 of the 68 notifications received were in relation to diagnostic imaging, including nuclear medicine. Table 1 below outlines the distribution of notifications from the various modalities used in diagnostic imaging.

Table 1. Notifications per modality in diagnostic imaging

Modality	Notifications in 2019
CT	46
PET/CT	4
Nuclear medicine	3
Radiology – general X-ray	2
Interventional radiology	0
Interventional cardiology	0
DXA (dual-energy x-ray absorptiometry)	0
Mammography	0
Total	55

Most notifications (84%) were from CT. In terms of the activity levels of diagnostic medical procedures, general X-ray accounts as the most frequently performed procedure type.³ However, the doses used in X-ray are generally below the 1mSv threshold for a significant event, which accounts for the low levels of reporting to HIQA.²⁹ Consequently, this may account for the relatively high proportion of significant events reported to HIQA in 2019 from CT. This finding is in line with international data and may also be indicative of a positive reporting culture in this modality.²



Figure 3. CT scanner

There was no reported significant events from DXA (used to measure bone mineral density), mammography and dental imaging which are relatively low dose procedures, generally falling below the threshold for reporting. Incidents and potential incidents from these modalities should be trended and analysed locally to support continuous learning and quality improvement. Where a pattern or trend is identified through local analysis, this may become reportable to HIQA.¹³

A key finding from diagnostic imaging was an absence of reporting from relatively high dose sectors such as interventional radiology and interventional cardiology. Interventional procedures provide significantly beneficial outcomes for patients but can utilise relatively high radiation doses to attain these outcomes. It is generally expected that tissue reactions may arise from a small percentage of these types of procedures.⁶ The absence of reporting may be seen to demonstrate safe delivery of interventional procedures. However, it may also indicate an absence of comprehensive assessment of doses delivered. Each undertaking must have an appropriate mechanism in place to identify and manage doses delivered. This could potentially be seen as an area of improvement for undertakings and will become a focus for HIQA in future inspections.

Types of error

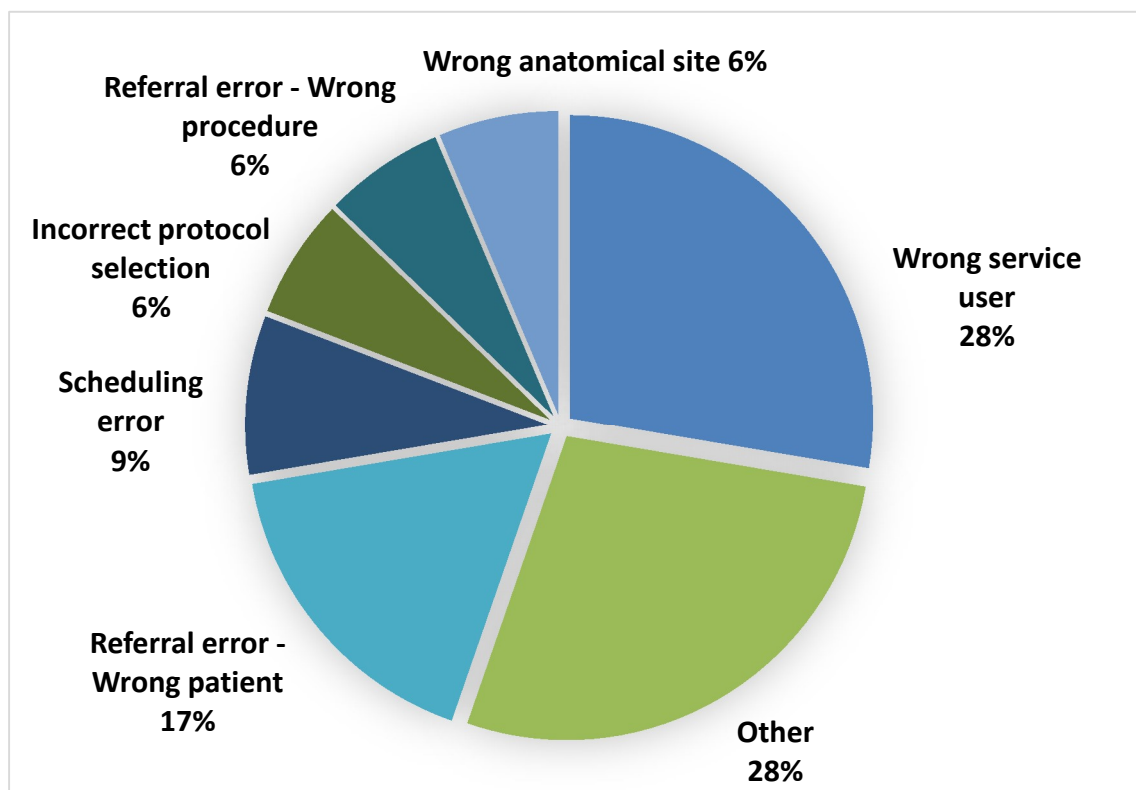
The types of error reported from CT are outlined in Figure 6. The most common type of notification received was in relation to the incorrect service user being exposed. Of all the CT notifications, 45% were related to either the incorrect patient being referred or errors in failing to correctly identify

patients at the point of exposure. The prevalence of identification errors in radiology is in line with international reporting systems.²

As a priority, undertakings should have systems in place to ensure that service users are correctly identified at all stages of their imaging pathway. To appraise their performance in relation to patient identification, services could look at trending and analysis of non-reportable events, such as policy non-conformances, near misses and errors in low dose procedures such as general X-ray. This may improve intelligence on the frequency of issues relating to identification to direct corrective measures to reduce the likelihood of a more severe incident taking place. Furthermore, the correct identification of patients is an important patient safety goal and is not an issue isolated to radiology services.³⁰ In the context of larger healthcare settings, the undertaking may take an organisational approach to improving patient identification which may in turn benefit diagnostic imaging services.

Only types of errors which were greater or equal to 6% were included in Figure 4. Examples of other errors included in Figure 4 include; inappropriate or incorrect justification, optimisation error and service user circumstance.

Figure 4. Types of error which occurred in CT



Case study 1

Example of incorrect service user exposed and actions taken

In a hospital, patient A received a CT brain scan which was intended for another service user. Patient identification was not carried out comprehensively prior to the transport of the patient to the radiology department, and immediately prior to the procedure. The incident was discovered by the radiologist at the time of reporting.

Immediately actions were taken. CT staff and relevant stakeholders were informed and the correct patient B was imaged. The local incident management process was instigated and the medical physics expert analysed the dose received incorrectly by patient A.

The investigation and corrective measures applied considered the environmental, task and human factors which caused the incident. The following corrective actions were applied:

- a change in workflow whereby the same staff member follows the patient throughout the CT pathway
- a 'Radiology Safety Pause' was put in place
- a review of staff rostering and staffing levels in CT
- identification protocol was changed and adapted to reflect all stages of patient identification in the patient pathway, and
- continued education.

Learning

The case study above highlighted a good example of appropriate review and follow up when an identification error is reported. The investigation was system focused and human error was considered as a system weakness rather than the sole cause of error. The investigation considered the way in which staff worked, which influenced the decisions made. Furthermore, the corrective actions were not reliant on education of staff alone, but also considered simplification and standardisation of work practices.

Opportunity for improvement

Undertakings must ensure that systems are in place to identify, record and analyse significant events. This includes tissue reactions and potential high skin doses as a result of interventional radiology and cardiology. Undertakings and practitioners should consider how potential tissue reactions can be identified to ensure that they are subsequently detected and managed. For example, the administration of a radiation dose (reference point air kerma) which measures 15 Gray (Gy) or more during a single procedure, is a reportable event to HIQA.

Each undertaking must ensure that there are systems in place to assess doses delivered to patients, manage instances of tissue reactions with each patient, and this learning should be used to optimise subsequent procedures, protocols and equipment.

3.2 Key findings in radiotherapy

HIQA received 13 of the 68 notifications from radiotherapy services in 2019. This comprised 19% of all notifications received.

While the number of significant events reported to HIQA from radiotherapy was not relatively high, most medical radiological facilities with radiotherapy services submitted at least one notification, indicating a positive culture of reporting across radiation oncology services.

All notifications received were related to external beam radiotherapy and none were received from brachytherapy. Lower rates of error reporting in brachytherapy may be accounted for by the relatively infrequent use of brachytherapy as a treatment option. This is in line with international literature.^{2,31,32,33}



Figure 5. Linear accelerator used in radiotherapy

Overall, a good culture of safety was suggested from the responses to errors seen in radiotherapy. Contemporary risk management approaches to investigating the causes of incidents was evident. Tools to aid determination

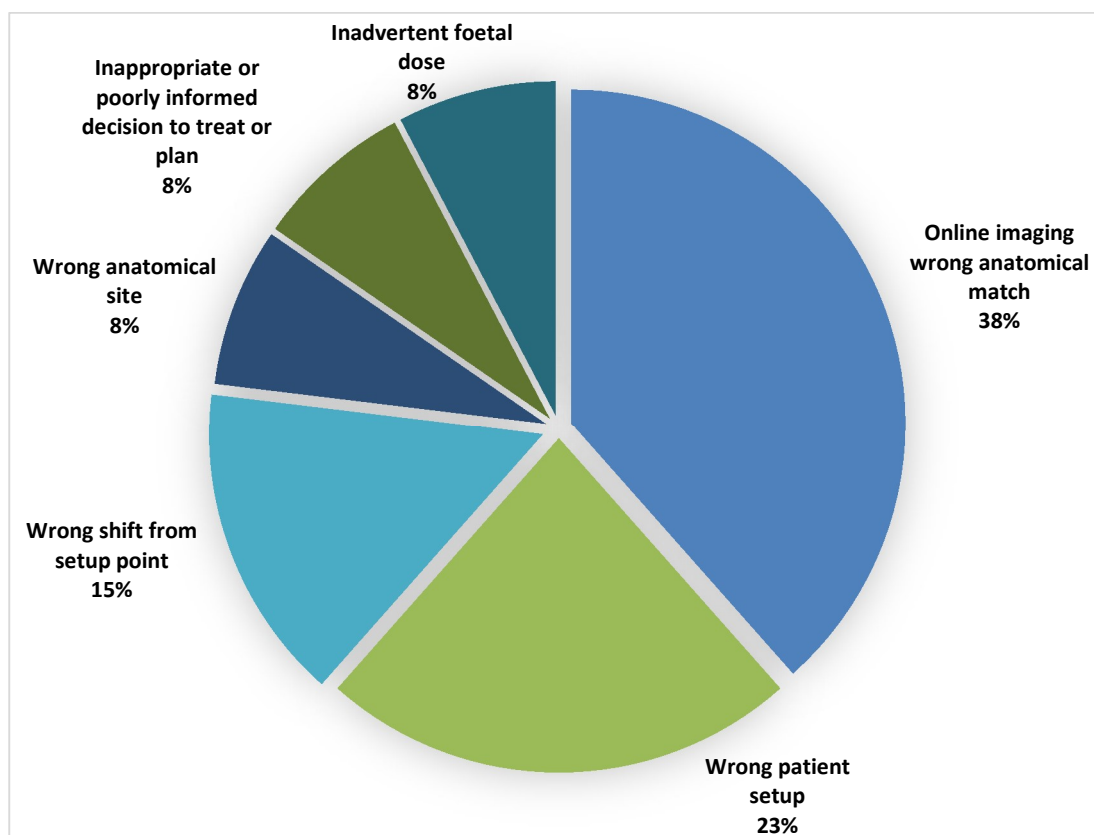
of causation, such as an Ishikawa diagram[§] and process maps were frequently used. In the majority of cases, the cause of the incident considered the various factors which influence the systems of work and which contribute to error. The resultant corrective measures were focused on correcting system weaknesses supported by, but not reliant on, a re-education of staff. Overall, in most cases in radiotherapy, it was suggestive of a strong just culture, which allows staff to report incidents and concerns without fear of punishment, and the reports received indicated investigations were relative to the severity of the events.

Types of error

Figure 6 outlines the types of error notifications received from radiotherapy services. Of the notifications received, 85% related to incidents which occurred during the delivery of external beam radiotherapy. All notifications were related to errors which occurred during one fraction of a course of fractionated treatment and most did not require any compensation of dose. The majority related to service users having radical courses of treatment and only two related to palliative cases. In 10 of the 13 incidents, the volume treated was partially different to that intended.

[§] Ishikawa diagram, otherwise known as a fishbone analysis, is a diagram used to show the cause-and-effect of an event.

Figure 6. Types of errors reported from radiotherapy



The most common type of error reported was a partial volume error^{**}. The majority (n=5) were caused by incorrect alignment of bony structures (bony matching) when using two dimensional imaging. The frequency of this type of error, resulting in a notifiable event, was comparable with recently published data from the United Kingdom.³³ A case study on the next page outlines one such significant event and how the hospital investigated it and the actions taken as a result to mitigate against reoccurrence.

^{**} A partial volume error occurs where some of the radiation intended for treatment falls outside the proposed area. This can be caused by an error in alignment when viewing the patient's anatomy on images.

Case study 2

Example of partial volume error and the actions taken

HIQA were notified that a treatment field was misaligned by approximately 2.5cm from what was planned for one fraction in a course of treatment for a patient receiving radiotherapy to their chest. Although 2-Dimensional imaging using kilovoltage (kV) energy was carried out during the treatment delivery session (online imaging), an incorrect anatomical match was performed. The incident was discovered after treatment delivery, during a quality control review. This allowed the appropriate corrections to be made for the next fraction.

A comprehensive investigation took place examining the cause and considering the system, process and human factors which contributed to the error. The findings included direct and indirect causes, which were presented in an Ishikawa diagram as part of the root cause analysis.

The direct causes included:

- not all tools available on the software system being used, and
- staff were under time pressure to complete the online matching task.

The indirect causes included:

- the correction applied to the incorrect vertebrae was smaller than to the correct vertebrae on this particular fraction
- 2-Dimensional imaging was used as per department policy, rather than 3-Dimensional, and
- an anatomical landmark was poorly visible on the acquired images
- manual image matching was used, which can be prone to inter-observer variability.

The corrective actions included a pilot of using automatic image registration, supported by improved training material and education for staff. A review was conducted to ensure that this error was isolated and not systematic.

Learning

The case study above provided a good example of how to determine the cause and contributing factors of an error. The causes included the equipment being used, policy decided at organisation level and a work environment influenced by staff workload. The corrective actions looked at piloting automation tools as a potential to enhance decision making. The investigation methodology provided assurance that the undertaking had a positive and systems based approach to patient safety.

Categorisation of reportable incidents in radiotherapy

Most notifications received were categorised as radiotherapy dose or volume variation of 20% or greater from the fraction prescribed. However, HIQA received a number of queries about potentially reportable events such as errors at CT planning acquisition, which did not strictly fit the categories specifically intended for radiotherapy. In addition, HIQA received a number of queries about the metrics to be used when comparing a deviation in dose to the threshold for reporting, particularly in the context of a complex radiotherapy procedures. It is intended that the categories and thresholds for reporting will be reconsidered in due course to ensure clarity and consistency in reporting from various medical radiological installations.

4. Findings for HIQA and learnings for undertakings based on notifications submitted in 2019

4.1 Local management of accidental and unintended exposures and potential incidents

Under the criteria for reporting to HIQA, low level incidents and potential events may be reportable if multiple types of the same error take place and are deemed to have a potentially serious safety implication for service users. Multiple similar errors should be identified from tracking and trending undertaken regularly. Learning from low level incidents is important as often the systemic causes of high and low severity incidents are similar. Hence, correcting the root causes of less severe incidents can directly impact the probability of high severity ones occurring.⁷

Undertakings need to assure themselves that there are appropriate systems in place to record and analyse all potential and actual incidents. On inspection, HIQA reviews the local system in place to record potential and actual incidents and how the learnings are effectively communicated to staff. Reports from individual inspections are published on HIQA's website and key preliminary findings in relation to local management of accidental and unintended exposures are summarised in these individual reports. The local systems in place should facilitate the incident learning feedback loop of reporting of events, analysis of the main themes and the development of interventions to prevent them from happening again.²⁷ The system should also allow the timely reporting of significant events and results of investigations to HIQA.

During the initial inspections in this new regulatory programme, HIQA identified potential improvements in harnessing intelligence from local incident management and learning systems. Incidences of accidental and unintended exposures should be recorded locally to inform quality improvements. The systems in place should be assessed within individual sites and across multiple facilities if governance systems are shared, to ensure the systems in place are adequate.

Furthermore, inspections conducted thus far identified the tracking, trending and identification of potential events as areas for improvement. The non-reporting and recording of near misses is not only a non-compliance with the regulations but also is a missed opportunity for learning and improved patient

safety. Addressing potential events has been shown to minimise the probability of a serious preventable adverse event occurring.⁷

Opportunity for improvement

Undertakings are required by the regulations to assure themselves that there are appropriate systems in place to record and analyse all potential and actual incidents. Regular trending should be used to identify key areas for safety and quality improvement. Incident learning should form part of a feedback loop of reporting, analysing and process improvements. Multiple similar errors discovered through trending which highlight a potentially serious safety implication can be reported to HIQA for dissemination of learning.

4.2 Developing and sustaining a patient safety culture for medical exposures

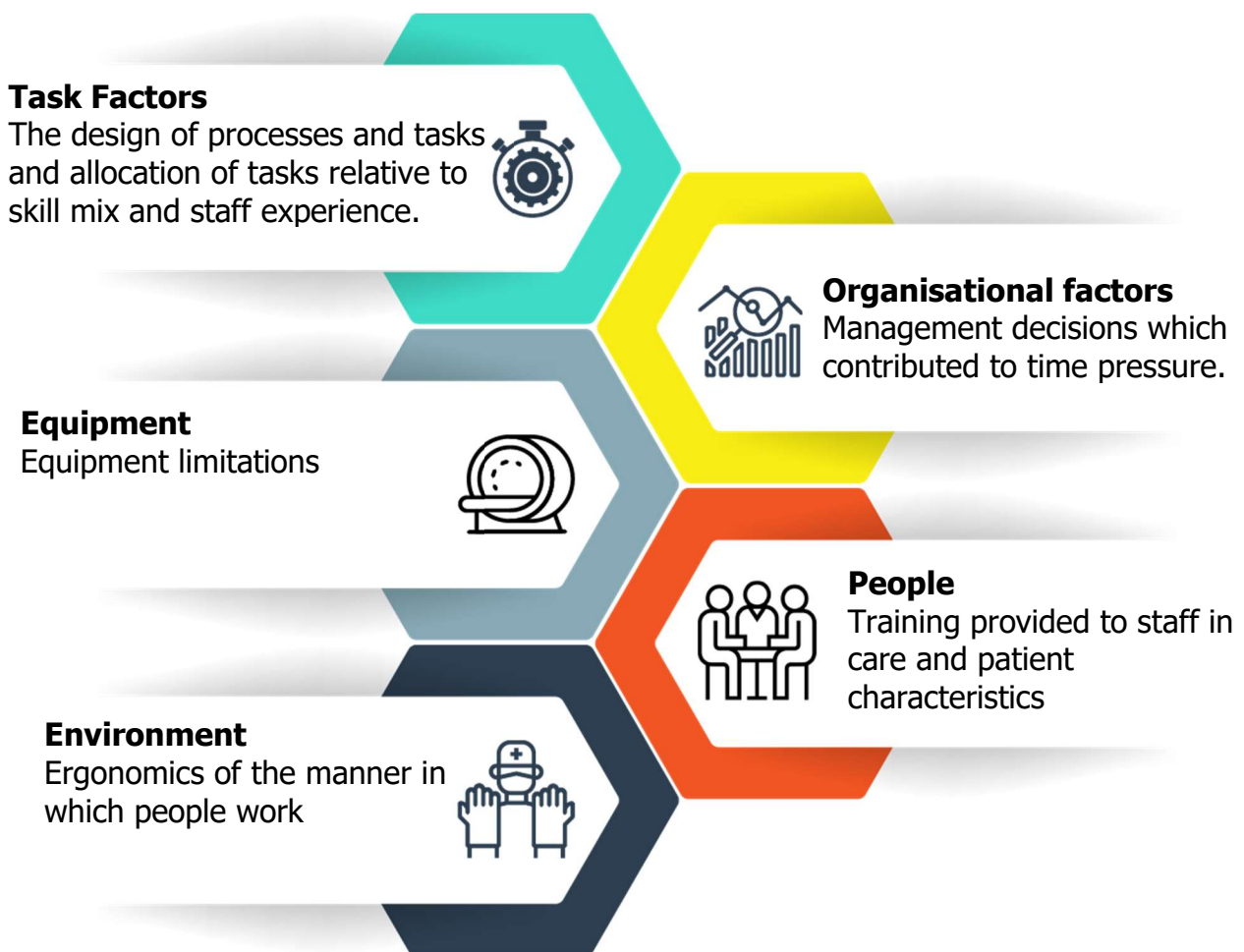
The regulations are relevant to dental services, diagnostic imaging, and interventional and therapeutic medical exposure practices. From the information received by HIQA in relation to significant events in 2019, variation was noted in some sectors both in terms of the reporting culture and the response when an error occurs. The results of the investigations submitted to HIQA demonstrated the varying approaches taken by different services when conducting an investigation into a significant event and the corrective actions applied to reduce or prevent the risk of reoccurrence. The case studies provided in this report under diagnostic imaging and radiotherapy findings highlight examples of good practice from which learning can be found. Potential learning in relation to investigating an incident and determining corrective actions are outlined below. These have relevance to all areas that utilise medical exposures and should be used to develop a stronger patient safety culture for medical exposures, particularly in areas that have not reported significant events to date.

4.3 Investigations of significant events

Undertakings should consider contemporary systems based approaches to incident investigations.^{34,35} However, the principles of a just culture and a systems analysis were not always prevalent in notifications received by HIQA in 2019. This was particularly notable in relation to patient identification

errors in diagnostic imaging. Some reports determined the causation of human error without consideration to other factors which contributed to the error. Conversely, there were many examples of good practice where various factors contributing to the cause of the error were considered. Figure 7 below is a summary of some of the factors which were considered by undertakings when determining the cause of error based on the reports received in 2019.

Figure 7. Factors considered by undertakings when determining the cause of error

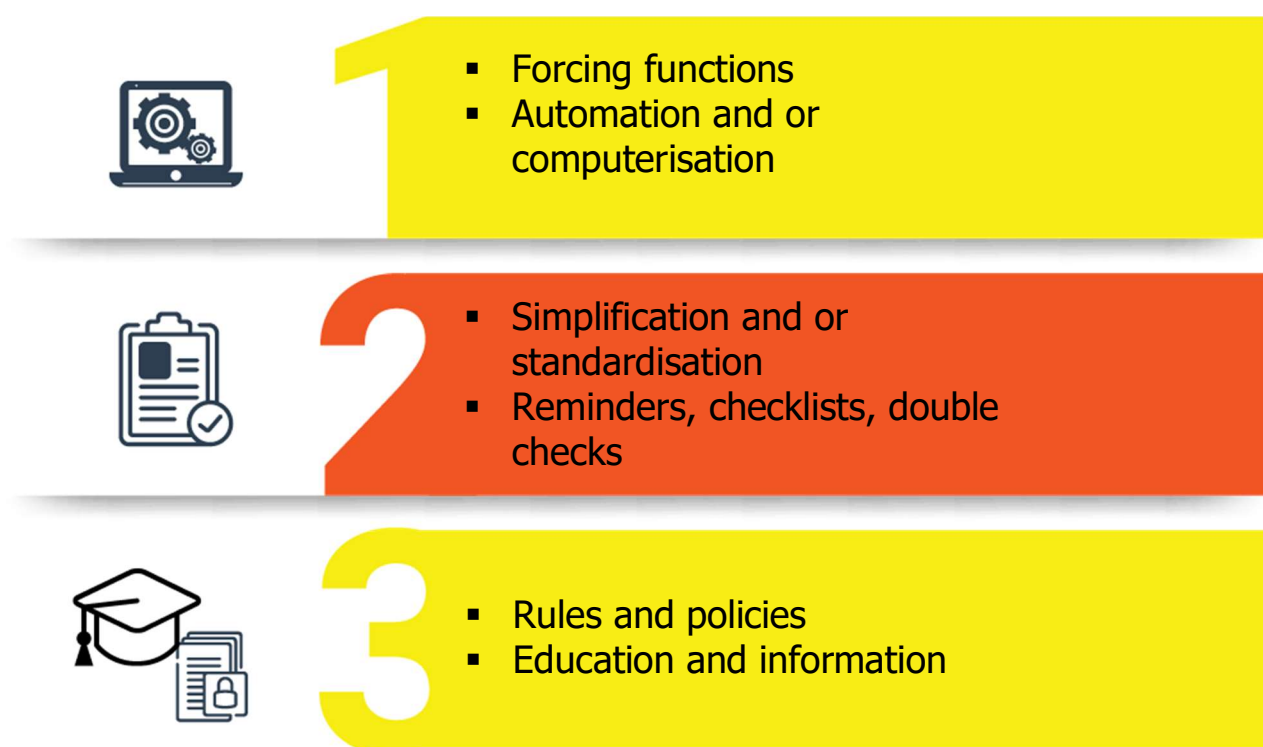


4.4 Efficacy of corrective measures taken

The regulations mandate that the corrective measures are put in place to prevent a significant event reoccurring and that these measures are reported to HIQA in the results of the investigation. The corrective measures provide assurance to HIQA that an undertaking has converted learning into risk-reducing actions.

The reports submitted to HIQA in 2019 showcased corrective measures of varying efficacy. Where human error alone was determined as a cause, some outcomes focused on reminding staff to be vigilant. However, reinforcement of information as a corrective measure is a low impact recommendation.⁸ The efficacy of risk-reduction strategies can be assessed using the hierarchy of effectiveness framework (see Figure 8 below). This framework rates strategies from most to least effective dependent on their reliance on person or system related change.³⁶

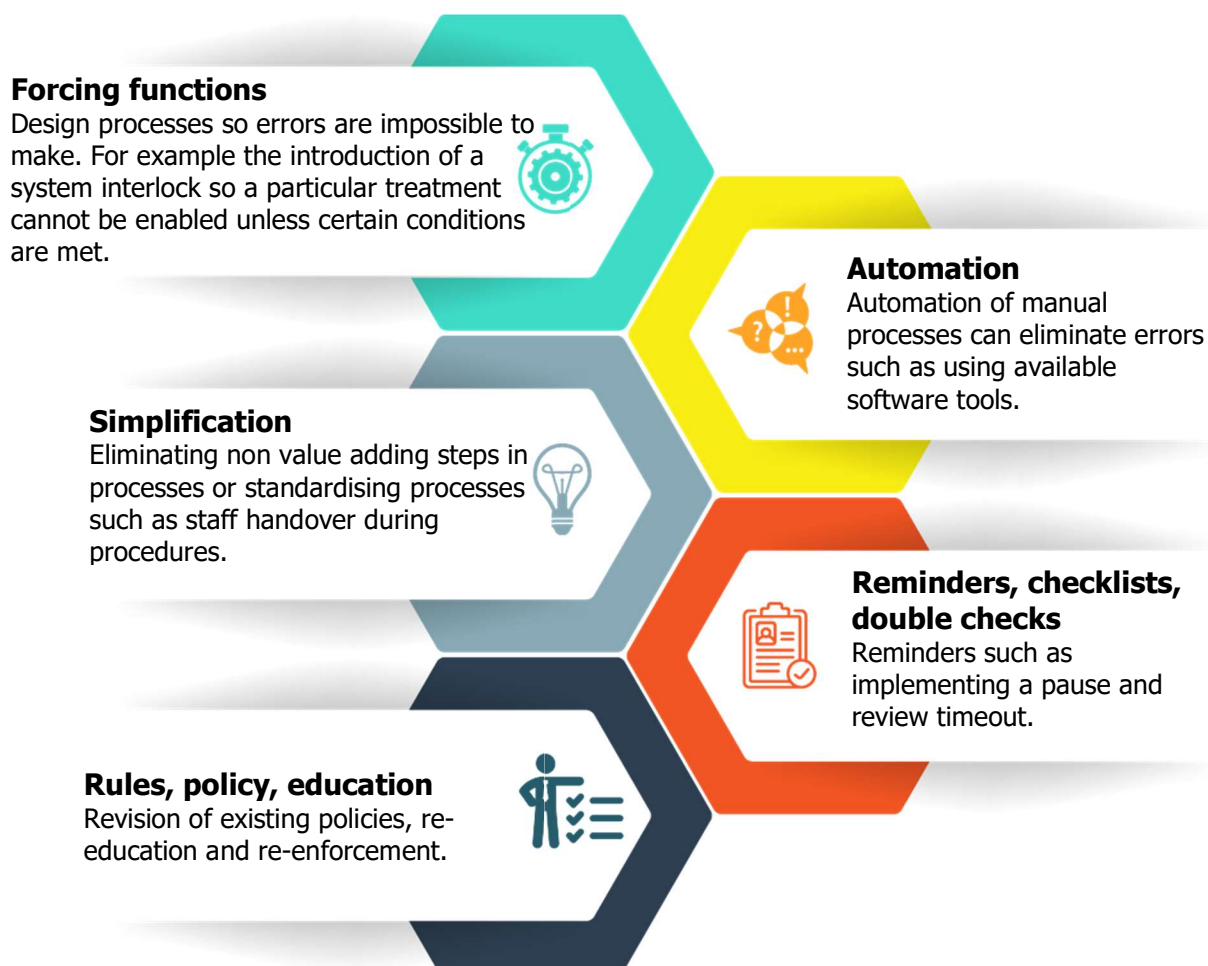
Figure 8. Efficacy of types of corrective actions ³⁶



High impact risk-reduction strategies such as automation and forcing functions can prevent errors occurring and reaching patients. Conversely, low impact risk-reduction strategies such as revision of existing policies and re-education can be less effective. For example, if a service understands why a policy was not followed, this may produce a more effective outcome as opposed to just re-educating staff in the use of the same policy.

Figure 9 below outlines examples from the 2019 reports of the types of corrective measures which were applied. Undertakings should consider the efficacy of corrective measures when conducting an investigation.

Figure 9. Examples of the corrective measures implemented following investigations of incidents



Opportunity for improvement

Most incidents are not as a result of malevolence, and should be approached as system level failures. Factors such as environment, equipment and people factors should be considered to determine contributing factors causing error.

Corrective actions put in place after a significant event, should minimise the likelihood of event occurrence by looking at how to improve the system in which people work. As corrective actions, re-education and reinforcement have low efficacy and can be demoralising which in turn can promote a blame culture. While there may also be a place for other types of corrective actions, more effective risk-reduction strategies, such as forcing functions, are preferable where possible.

4.5 Submitting the results of an investigation

Undertakings carrying out medical exposures to ionising radiation are responsible for ensuring they fulfil their statutory obligation under Regulation 17(1) to report significant events within the timescales set out by HIQA. The results of an investigation into a significant accidental or unintended exposure to ionising radiation must be submitted within 120 calendar days of receipt of the initial notification by HIQA. In 2019, the majority of undertakings submitted reports within this timeframe, with a small number exceeding 120 days. There will be a renewed focus by HIQA on breaches of this specific regulatory obligation.

HIQA previously published [guidance](#) outlining the process and content of an investigation of a significant event. A comprehensive investigation report provides assurance to the regulator that the corrective actions outlined reduced or eliminated any risk identified. Most reports received in 2019 were comprehensive and provided sufficient information, whereas some reports lacked the required detail and further information was sought. Based on the reports received in 2019, HIQA have compiled the following recommendations for undertakings when conducting an investigation into a radiation incident.

Opportunity for improvement

Investigation reports should include:

- an investigation team that demonstrates multidisciplinary team involvement
- the identification of the individual(s) within an undertaking with authority to implement any changes required
- findings of the investigation, including causation and contributing factors
- evidence of medical physics expert involvement in the analysis of the event
- specific and time bound corrective measures applied or implemented
- confirmation that open disclosure has been applied in line with regulatory requirements and contemporary best practice, and
- assurance that the undertaking is aware of the occurrence of a significant event and can oversee any changes required.

4.6 Utilisation of HIQA's portal to submit notifications

HIQA's provider portal is a website that allows online submission of regulatory notification information to HIQA.

Access to the Portal

The designated manager of each facility has access to the HIQA portal system. The designated manager can provide access to authorised users to complete and submit information in respect of the facility through their portal access. An authorised user must be a suitable individual with appropriate seniority within the facility and have sufficient knowledge and technical expertise in the area of radiation protection to submit solicited information, such as incident notifications and questionnaires as required by HIQA. It should be noted that HIQA portal access can only be granted if authorised by the designated manager. The process for submitting NF211 notifications via the portal is outlined in Appendix A. HIQA does not currently accept individual email requests or individual registrations through the portal. If you need help with HIQA's portal, you can email portalsupport@hiqa.ie.

Future changes

Currently, notifications of significant accidental or unintended exposures can be notified to HIQA either via email or the Provider Portal. The availability for an online system to receive and record notifications has improved pathways for communicating to HIQA. In an effort to streamline communications in the future, the use of email for submitting notifications will be phased out and the portal will become the sole mechanism for submitting notifications. Undertakings will be informed of this change in advance.

Why use HIQA's Portal

Time-saving:	Less fields to complete
Reliable:	All mandatory fields completed before you can submit
Correct forms:	Portal versions are always up-to-date
Security:	Information is securely transmitted
Record-keeping:	Notification history has details of previous notifications submitted

5. Conclusion

Significant events which were reported to HIQA in 2019, involved relatively low radiation doses which posed a limited risk to service users. Furthermore, the number of significant events compared to the total numbers of medical exposures conducted, demonstrates that the use of radiation in medicine in Ireland is generally quite safe for patients.

While the occurrence of significant events is an unwanted outcome, HIQA encourages open and honest reporting where accidental or unintended exposures occur. Active participation in reporting at a national level has the benefit of improved oversight by HIQA of issues occurring and meaningful learning opportunities shared to centres and services. It is an integral step to improving patient safety and informing change. The transparent reporting of incidents is a key component of a positive patient safety culture and studies have found a positive association between increased incident reporting rates and a patient safety culture.

This report has provided a detailed overview of key lessons learned from the statutory notifications of significant events received. In 2019, 68 notifications were submitted to HIQA. This represents a modest increase in those reported to the previous competent authority.¹¹ However, there is potential to further develop reporting, by encouraging reporting from services where under reporting may be an issue and in supporting undertakings to develop local incident learning.

Accidental and unintended exposures which do not meet the threshold for a significant event are to be recorded and analysed locally. This includes potential events or near misses and the local system will be assessed during inspection to ensure regulations are met. So far, inspection findings in this area have indicated room for improvement. The local systems should offer sufficient intelligence to prompt quality improvement initiatives and provide assurances in radiation protection practices. The local incident learning or management system in place is assessed during inspection to ensure the basic requirements of the regulations are met.^{1,37}

Despite a positive patient safety culture shown in some undertakings and sectors, areas for further improvement have also been identified through this report. These areas include the level of investigation taken in respect of significant events and the prevalence of a just culture which supports incident reporting and efficacy of corrective measures applied.

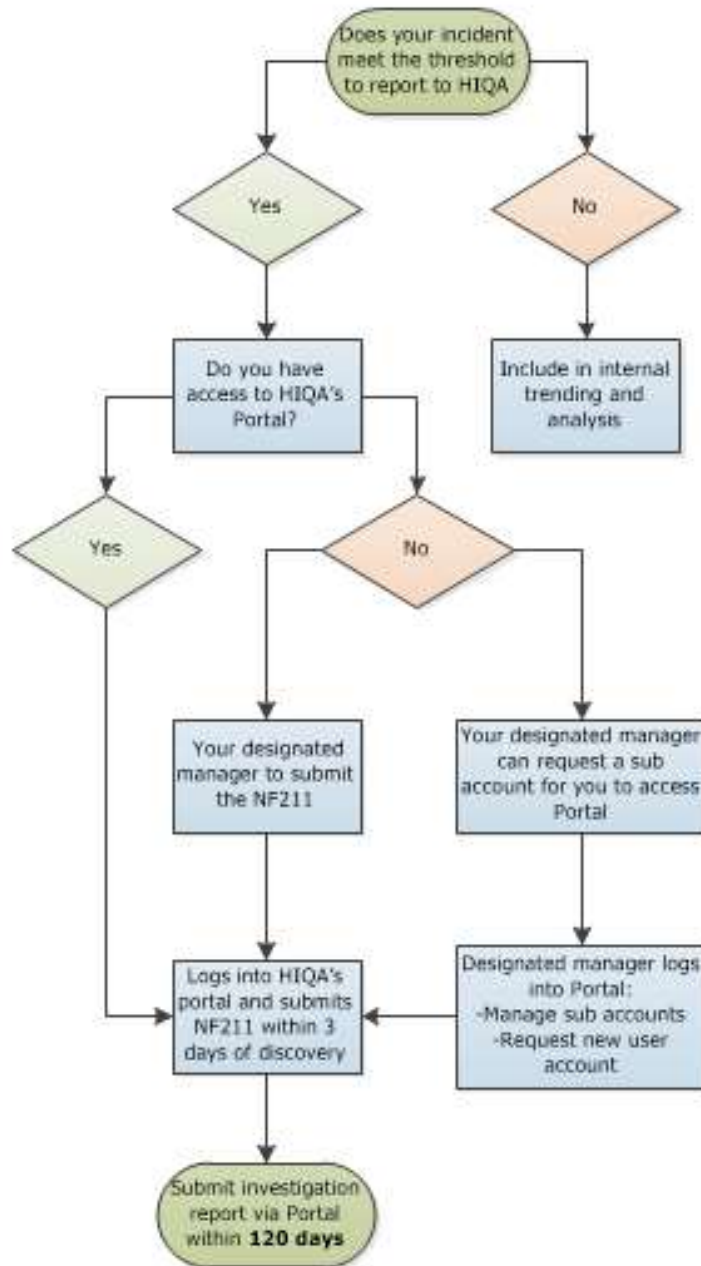
The thresholds of significant events were, following a review by HIQA to ensure continued appropriateness, adopted from the previous competent authority. This was done in part, to ensure a seamless transition for undertakings in 2019. It was noted that of the significant events submitted in 2019, the vast majority were submitted under only three category types. This resulted in a noticeable absence of reporting in other categories such as in the interventional radiology and cardiology sector. Each undertaking should have an appropriate mechanism in place to identify and manage doses delivered. This can be seen as an area of improvement for undertakings and will become a focus for HIQA in future inspections.

Feedback from service providers has indicated that revision and updating of the categories and thresholds may be warranted which may also benefit future reporting levels by improving clarity and scope for reporting from certain sectors.

HIQA's role as the competent authority regulating medical exposure to ionising radiation in Ireland is relatively recent. It is hoped that the knowledge gained from the collation and publication of these composite findings will help drive quality improvements in incident reporting and risk management strategies.

In 2020 and beyond, the programme of monitoring and inspecting services will continue in order to ensure that radiation protection practices for service users in public and private radiological facilities in Ireland are compliant with the regulations. HIQA will continue to build upon its programme to date to promote patient safety in relation to radiation protection and to improve the quality and safety of services for all.

Appendix A - How to report a significant event through HIQA's Portal



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

1	Administration of a Reference Point Air Kerma ($K_{a,r}$) of 15 Gray (Gy) or greater as a result of a single interventional radiological procedure (including interventional cardiology) or a cumulative $K_{a,r}$ 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.

Bony matching: a technique used to compare images to check the correct alignment of bony structures to ensure accurate field placement during radiotherapy.

Brachytherapy: a radiotherapy procedure used to treat cancer by inserting radioactive material directly into the affected area.

Comforters and carers: persons who care for service users who are undergoing a diagnostic or therapeutic medical exposure and may be exposed to ionising radiation in this capacity.

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.

Designated manager: a person engaged in and responsible for the day-to-day management of the medical radiological installation. The designated manager must have the full support of the undertaking to ensure a safe and quality service is being delivered in the medical radiological installation. Please refer to the Undertaking information handbook for more information.

Diagnostic medical exposures: 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 or osteoporosis is suspected.

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).

External beam radiotherapy: is a treatment that uses high-energy beams to destroy cancer cells. The beams are given using equipment similar to a large x-ray machine called a linear accelerator.

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.

Individuals participating in research: any persons who participate in medical or biomedical research involving a medical exposure of ionising radiation.

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

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.

Mammography: the specialised area of radiology involved in the imaging of breast tissue.

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.

Medical radiological installation: means a facility where medical exposures are carried out.

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.

Offline review check: a quality control review which is carried out after treatment to check the accuracy of the delivered radiotherapy.

Online imaging: additional imaging obtained during a radiotherapy delivery session.

Palliative radiotherapy: is radiotherapy that is delivered to shrink tumors and relieve patients' pain or other symptoms. It is intended to help make patients comfortable and improve their quality of life.

Positron emission tomography (PET): a specialist, functional type of nuclear medicine which uses a radiopharmaceutical to assess the metabolic processes within the body. PET scanners are often combined with CT scanners which allow highly detailed images to be obtained. This procedure is often referred to as PET/CT imaging.

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

Radical radiotherapy: is radiotherapy that is intended to destroy cancer cells and give long term benefits.

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 ($K_{a,r}$): 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 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.

Stochastic effect: the random or probable occurrence of a hereditary change or the possibility of an induced cancer due to a medical exposure to ionising radiation.

Therapeutic medical exposures: medical exposures to ionising radiation that are used to treat a disease.

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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