Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Regulation of Health and Social Care Services

Statutory notifications for accidental or unintended medical exposures to ionising radiation

Guidance for undertakings carrying out medical exposures to ionising radiation on the statutory requirement to notify significant accidental or unintended exposure events to HIQA

Updated September 2019

Safer Better Care

About the Health Information and Quality Authority

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.

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Introduction

This document provides guidance on the statutory notifications for accidental or unintended medical exposures to ionising radiation an undertaking must make to the Health Information and Quality Authority (HIQA). These requirements are set out in the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019 (referred to in this document as "the regulations").

Under the regulations, HIQA is the competent authority for service user protection in relation to medical exposure to ionising radiation in Ireland. The Environmental Protection Agency (EPA) continues to be the competent authority for the protection of workers and members of the public. HIQA and the EPA will work together to carry out their separate but parallel functions under the legislation. A data sharing agreement has been put in place to support each body in their communication of relevant information for the purpose of fulfilling their respective legislative remits. This ability to share information is also provided for in legislation. The data sharing agreement is available to view at www.hiqa.ie.

This guide, which was developed in line with national legislation and standards,[1,2,3] provides:

- an outline of HIQA's regulatory role as the competent authority in receiving statutory notifications relating to medical exposures to ionising radiation (referred to in this document as significant events)
- an explanation for undertakings on the statutory requirement to notify HIQA of significant events
- information on who is responsible for notifying HIQA of significant events
- guidance on what significant events should be reported to HIQA
- guidance on completing and submitting the notification form for significant events (NF211) within the prescribed timescale
- information on submitting investigation results and corrective measures to HIQA following significant events

HIQA has also developed guidance on the definition of an undertaking, as outlined in the regulations, which identifies the specific roles and responsibilities of an undertaking regarding mandatory notifications. This guidance on undertakings can be found in the *Undertaking information handbook*, which is available at www.hiqa.ie.

Undertakings carrying out medical exposures to ionising radiation are responsible for ensuring they are familiar with their statutory obligation under Regulation 17(1) to ensure reporting of significant events within the timescales set out by HIQA. As an undertaking carrying out medical exposures to ionising radiation, you must ensure

that you have the appropriate arrangements in place to notify HIQA of the occurrence of a significant event and ensure submission of the relevant notification, as described in this document. Failure to do so is an offence under Regulation 29(1)(n).

This guidance document may be revised periodically in line with national and international requirements. For the most up-to-date version please refer to www.hiqa.ie.

1. Background

The fundamental role of an incident reporting framework is to enhance service user safety by learning from previous incidents and near-misses and putting systems and processes in place to minimise the risks.[4] Although the use of ionising radiation for diagnostic, interventional and therapeutic purposes is considered safe for the most part, unintended or accidental exposures can and do occur.[5] In the context of the considerable number of diagnostic procedures and radiotherapy treatments carried out in healthcare facilities each year, reported accidental and unintended exposures remain low. In Ireland, a high proportion of incidents that have historically been reported have related to incorrect service user identification, resulting in the wrong service user being exposed or individuals receiving a greater than intended radiation dose.[6] Similarly, medical exposures that are less than intended can also be a source of harm for service users, for example, in radiotherapy, less than intended dose could impact tumour control and service user outcome.

The majority of reported radiation incidents from medical exposures involve low radiation doses with minimal risk. However, some incidents of overexposure to ionising radiation have directly impacted on service user safety and welfare.[7,8,9] This was evident in a well-documented radiation incident that occurred in Cedars-Sinai Medical Centre in Los Angeles in 2009.[7] In this incident, multiple undetected radiation overexposures occurred as a result of a programming issue on a computed tomography (CT) scanner. Other notable radiation incidents include the overexposure and subsequent death of a service user at Beatson Oncology Unit in Glasgow in 2006 and the overexposure of an oncology service user in Edinburgh in 2015.[8,9] These incidents highlight the need for vigilance and structures that ensure service user safety when they are exposed to ionising radiation. Additionally, radiation incidents should be used as learning opportunities to improve radiation protection practices by preventing the reoccurrence of similar incidents.

2. Who is required to record and analyse accidental or unintended medical exposures?

All undertakings are required under Regulation 17(1)(c) to implement an appropriate system for the record keeping and analyses of events involving, or potentially involving, accidental and unintended medical exposures to service users, commensurate to the radiological risk* posed by a type of practice.

* 'Radiological' and 'medical radiological' are terms used in the regulations which refer to both radiodiagnostic procedures, radiotherapeutic procedures, interventional radiology, interventional cardiology and or other medical uses of ionising radiation for planning, guiding and verification purposes.

3. Who defines what constitutes a significant event?

Under Regulation 17(1)(e), significant events are defined by the competent authority. To determine what constitutes a significant event, HIQA reviewed relevant literature, considered the approach taken by other regulators and consulted with an Expert Advisory Group (EAG). The role of the EAG is to advise HIQA on its regulatory approach. Decision-making related to such advice remains the responsibility of HIQA.

The membership of the EAG is listed in Appendix A. HIQA, in consultation with the EAG, has taken the decision to adopt (with some minor changes) the criteria for accidental or unintended exposure significant events recently developed by the Health Service Executive (HSE) National Radiation Safety Committee and the HSE Medical Exposure Radiation Unit (MERU) in their capacity as the previous competent authority.[10]

4. Who is required to notify HIQA of significant events?

All undertakings have a statutory obligation under Regulation 17(1)(e) to ensure that appropriate arrangements are in place to notify HIQA of significant events within **three working days** from discovery. An undertaking is a person or body, who in the course of a trade, business or other undertaking (other than as an employee), carries out, or engages others to carry out, a medical radiological or the practical aspects of a medical radiological procedure. This means that all undertakings with responsibility for medical exposures to ionising radiation in hospitals, dental practices and other premises, both public and privately funded, or expose volunteers as part of medical research are required by law to ensure significant events are reported to HIQA.

These appropriate arrangements should ensure that each undertaking makes or is always aware of submissions made to HIQA on its behalf. Please refer to the *Undertaking information handbook* for further information on appropriate delegation of roles in relation to an undertaking. Undertakings must familiarise themselves with the requirements of the regulations to ensure compliance with the notification process.

Following the occurrence of a significant event, appropriate immediate actions and corrective measures must be implemented to ensure the safety and wellbeing of all service users[†] and to avoid the reoccurrence of such events. Additionally, an undertaking must satisfy itself that they have appropriate systems in place to

[†] Service user is a service user, comforter or carer, or person involved in research which involves an exposure to ionising radiation.

effectively manage, analyse and record near-misses and actual accidental and unintended exposures.

5. What significant events are notifiable to HIQA?

Incidents involving medical exposures that are deemed to be above or below an acceptable threshold and have the potential to cause harm are called significant events. These incidents can occur from either diagnostic, interventional or therapeutic procedures when medical ionising radiation administered to the service user was greater or different to what was intended.

Notifiable significant events defined by HIQA are listed in Table 1**.** In addition, examples of notifiable and non-notifiable incidents in different settings are provided in Appendix B.

Table 1. Significant events of accidental or unintended exposures that are notifiable to HIQA

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

In some cases, local review, analysis and trending of all radiological safety incidents may lead to reclassification of incidents initially deemed non-notifiable to notifiable. For example, identification of multiple similar non-notifiable incidents may, on review, be identified as a potential safety concern for service users. Consequently, this may mean that such non-notifiable incidents are collectively reportable to HIQA as a notifiable significant event under notification 17 in Table 1.

6. Should significant events be reported to other competent authorities?

Some incidents may be notifiable to more than one competent authority. HIQA and the EPA have a dual and collaborative role in the regulation of ionising radiation in Ireland under their respective legislation. Indeed, under Regulation 3(4), there is a requirement for HIQA to co-operate with the EPA in the carrying out of the EPA's functions and HIQA may share data with the EPA for that purpose. In that regard HIQA and the EPA have signed a data sharing agreement which is available on our

website[‡]. It is the responsibility of an undertaking to ensure it is in compliance with the reporting requirements of all relevant legislation.

For comprehensive information on reporting requirements to the EPA, please follow the appropriate guidelines issued by the agency. See Appendix C for the contact details and remit of organisations within Ireland with responsibility for receiving statutory notifications relating to ionising radiation.

Figure 1. Example of an unintended medical exposure which may meet the criteria for mandatory notification to HIQA and the EPA

Where a patient is incorrectly identified and receives an exposure that is not intended for them of over 1mSv of ionising radiation, this should be classified as both an unintended medical exposure under these regulations, and an exposure to ionising radiation of a member of the public under the parallel EPA legislation. Therefore, in this particular case, this incident is notifiable to both **HIQA** and the **EPA.**

7. How is a notification made to HIQA?

HIQA's online portal system (https://portal.hiqa.ie) facilitates undertakings to communicate with HIQA. Notifiable incidents can be submitted through this portal system. The notification forms are also available on the website in PDF format. If you require assistance completing the notification form, please email radiationprotection@hiqa.ie.

The portal system provides access to each undertaking and offers benefits such as:

- the ability to navigate to up to date forms
- immediate acknowledgment of receipt, including the reference notification number
- a record of previous significant events submitted to HIQA.

It is important that all fields in the notification form are completed before submitting to HIQA. The information provided should be factual, objective and accurate. A sample of the required information for a notification form is outlined in Table 2.

[‡] The HIQA and the Environmental Protection Agency Data Sharing Agreement is available for review on HIQA's website: https://www.hiqa.ie/sites/default/files/2017-12/HIQA-EPA-Data-Sharing-Agreement.pdf

From time to time, changes may be made to the notification form. The HIQA portal will always have the current version of the notification form; therefore, where possible, the forms should be accessed through portal rather than saved locally.

8. When should notifiable incidents be reported?

Under the regulations, undertakings must ensure that HIQA is notified, in writing, using the appropriate significant event notification (NF211) form **within three working days** of the discovery of any significant event listed in Table 1.

If the matter is especially urgent or serious, the undertaking may wish to inform HIQA of the significant event immediately by email to radiationprotection@hiqa.ie. In this instance, the communication of a significant event must still be confirmed in writing, within three working days, using the NF211 form.

Undertakings should select the relevant NF211 form from one of the three available options:

- **NF211A:** Dental, Radiology, or Nuclear Medicine – this form should be used to notify HIQA of a reportable accidental or unintended exposure to ionising radiation that occurred in relation to a Dental, Radiology, or Nuclear Medicine procedure.
- **NF211B:** Radiotherapy– this form should be used to notify HIQA of a reportable accidental or unintended exposure to ionising radiation that occurred in relation to a Radiotherapy procedure.
- **NF211C:** Other – this form should be used to notify HIQA of a reportable accidental or unintended exposure to ionising radiation which occurred in relation to a procedure which does not fit the areas described in either the NF211A or NF211B forms.

Table 2. Notification form and information requirements

Section 1. Undertaking details	
Incomplete or insufficient information will result in the form being returned for completion and potentially impact on timelines for processing the notification.	
Undertaking name	As per definition of undertaking outlined in the regulations and explained in the *Undertaking information handbook.*
Undertaking address (include Eircode)	You can access your Eircode at https://www.eircode.ie/
Undertaking email address	The undertaking email address must relate to the undertaking business type and be regularly monitored. The email supplied should not be an individual's email address. For more information please refer to the *Undertaking information handbook.*
Undertaking contact number	Please enter a contact telephone number for the undertaking that will be in operation during business hours (Monday to Friday, 09:00-17:00).
Medical radiological installation name where incident occurred	Please enter the name of the medical radiological installation where the incident occurred if it differs from the undertaking's name and address
Address incident occurred (include Eircode)	You can access your Eircode at https://www.eircode.ie/
Designated manager name	Please provide the name of the designated manager with responsibility for day-to-day management of the medical radiological installation where the incident occurred.
Designated manager email address	Please provide a valid business email address for the designated manager of the medical radiological installation where the incident occurred.
Designated manager contact number	Please enter a contact telephone number for the undertaking that will be in operation during business hours (Monday to Friday, 09:00-17:00).

Section 2. Significant event details	
Exact location incident occurred (area or department or room or unit)	Please specify where in the medical radiological facility the incident occurred. This maybe within a radiology department or another area within the facility where the medical exposure resulting in a significant event occurred.
Date incident occurred	If the incident or similar incidents occurred on multiple dates the first date should be inserted here and further dates should be detailed in the brief details of incident section.
Time incident occurred (HH:MM)	If the incident or similar incidents occurred at multiple times the first time should be inserted here and further times should be detailed in the brief details of incident section.
Date incident discovered	This is the date the incident was first discovered and may be different to the date of incident occurrence. This date is significant as an undertaking must notify HIQA within three working days from date of discovery of a significant event and submit the results of the corrective action within **120 calendar days** of receipt of the initial notification by HIQA.
Multiple service users affected	Please indicate if one or more service users were involved in this incident giving the total number of service users involved. If multiple service users are affected, please contact HIQA at radiationprotection@HIQA.ie for further advice.
Service user Details	Please indicate gender and age of the service user. Age and gender are two factors that can affect the probability of developing stochastic effects. Identifiable service user or individual details must be redacted and should not be included in information submitted to HIQA.

Type of procedure or treatment involved in the incident	
This section lists the type of procedure or treatment that best describes the significant event to be notified to HIQA. This is done by ticking the tick box on right hand column beside the most relevant type of procedure or treatment on the notification form	
Significant event category	
This section lists the types of notifiable significant events. Please indicate the incident type that best describes the significant event to be notified to HIQA. This is done by ticking the tick box on right hand column beside the most relevant incident type on the notification form (listed in Table 1).	
Details of the incident	
Please provide brief details of the incident	Please provide a brief description of the incident for the purpose of the initial notification. The information submitted should be factual, objective and accurate. HIQA's assessment of the incident will be based on the information supplied. A more detailed and comprehensive report as required by Regulation 17(1)(f), should not be included as part of the initial notification (NF211) form. For further information on this please refer to Section 14.
Have appropriate actions been taken to mitigate against immediate recurrence of this incident?	Please answer yes or no to this question. It is the responsibility of the undertaking to ensure that all necessary actions are taken to prevent reoccurrence and ensure that any risk to service users is addressed.
Please provide brief details of the initial actions taken to mitigate against immediate recurrence of this incident.	Please give a list of immediate actions taken to prevent reoccurrence of the incident and to protect service users from potential harm. Actions outlined here are at the discretion of the undertaking but should provide assurance to HIQA that any immediate potential risks to service users have been fully addressed. The information submitted may reduce the requirement for HIQA to contact the undertaking about the significant event.

Section 3. Incident details Example applicable to NF211A (Dental, Radiology, or Nuclear Medicine)	
Radiology, diagnostic nuclear medicine and interventional procedures **Please provide an initial estimated effective dose in millisievert (mSv)**	Please indicate the most applicable range of the estimated effective dose in millisievert (mSv) relevant to the significant event being reported. The exact dose may not be available at the time of initial notification. The exact dose estimate or variation can be included in the final report submitted to HIQA after consultation with a Medical Physics Expert (MPE).
Therapeutic nuclear medicine procedures **Please provide an initial estimated radiation dose variation**	Please indicate the most applicable percentage dose variation relevant to the significant event being reported. The exact dose may not be available at the time of initial notification. The exact dose estimate or variation can be included in the final report submitted to HIQA after consultation with a Medical Physics Expert (MPE).
Type of incident	Please select the most appropriate incident type which best describes the significant event being reported by ticking the relevant tick box on the right hand column.
Section 3. Incident details Example applicable to NF211B (Radiotherapy)	
Process step where the incident occurred	Please indicate at what stage along the radiotherapy pathway the significant event occurred by ticking the relevant tick box on the right hand column.
Treatment intent	Please indicate if the treatment delivery is either palliative or radical category relevant to the significant event being reported.

Radiotherapy treatment delivery **Please provide an initial estimated radiation dose variation**	Please indicate the initial estimated dose variation relevant to the significant event being reported, indicating whether the dose difference occurred for one or multiple fractions. If the exact dose variation is not available at the time of initial notification it can be included in the final report submitted to HIQA after consultation with a Medical Physics Expert (MPE).
Other radiotherapy incidents	Please provide initial estimated dose error for any significant events in radiotherapy falling outside the categories above.
Type of incident	Please select the incident type which best describes the significant event being reported by ticking the relevant tick box on the right hand column.
Section 4. Open Disclosure	
Was the incident that occurred considered to be a clinically significant unintended or accidental exposure?	Please tick yes or no as relevant.
Did you inform the following individuals of this incident?	Regulations require undertakings to inform the referrer, the practitioner, and the service user or their representative about clinically significant events. This should be done as soon as possible and in line with the regulations and applicable national standards.

Section 5. Notification of stakeholders	
Have appropriate stakeholders been notified of the incident?	In addition to informing persons listed in Section 5, undertakings should ensure that information relating to significant events is appropriately communicated within the organisation to relevant stakeholders. Dissemination of information of a significant event is integral to quality assurance programmes to minimise the potential harm and likelihood of the occurrence of accidental or unintended exposures of individuals undergoing medical exposure procedures. Please tick the box beside each one to confirm who has been informed of the significant event. Some stakeholders may not be applicable to all medical radiological installations.
Section 6. Follow-up documentation	
What follow up documentation needs to be submitted to HIQA following the notification of a significant event?	Follow-up documentation relating to notification of significant events refers to the internal investigation results and corrective measures to avoid such events which must be completed and returned within **120 calendar days** of receipt of the initial notification by HIQA. Additional information or documentation may also be requested by HIQA from time to time. Personal identifiable information must be removed on documentation submitted to HIQA in line with General Data Protection Regulation. Follow-up information should be submitted by email to HIQA to radiationprotection@hiqa.ie. Your email should quote the notification reference number to which it relates.

Section 7. Declaration	
How do I complete the declaration section?	The declaration section of each form must be completed when submitting a notification to HIQA. The person completing the declaration section must be a suitable individual with appropriate seniority within the governance structure of the undertaking. This may be the undertaking representative or the designated manager depending on the arrangements in place within an undertaking. For more information please refer to the *Undertaking information handbook*. The person completing the declaration section must be sufficiently knowledgeable about the incident in order to declare that the information provided in the form is correct to the best of their knowledge and belief

9. What immediate actions should be taken by an undertaking following the discovery of an incident?

All incidents relating to medical exposures should be managed locally in line with internal risk management and incident management systems. Initial management of the incident should reduce or eliminate the likelihood of a similar medical exposure to ionising radiation incident occurring. Under Regulation 17(1)(a), there is an obligation on each undertaking to ensure that all reasonable measures are taken to minimise the probability and magnitude of accidental or unintended exposures to individuals subject to medical exposure.

In cases where a serious incident is identified, immediate actions should be taken to mitigate this risk in line with local policy and the national standards.[3] HIQA should be notified immediately when a serious risk to service user safety is identified.

10. What are the data protection and confidentiality requirements?

Undertakings have a duty to comply with current data protection legislation.[11,12,13] HIQA only request the age and gender of the individual involved in a significant event. Age and gender are two factors that can affect the probability of developing stochastic effects.[11] Names or personal details that can identify service users, service

users, staff members or any individual **MUST NOT** be included in notifications or information submitted to HIQA.

Should a significant event involve a staff member, the staff member's role may be referred to instead of the staff member's name. Personal data must be redacted.

Any individual identifiable information submitted by an undertaking cannot be processed by HIQA and may affect submission timelines. Where there has been a breach of the personal data identified, it will be the responsibility of the undertaking to address this breach in line with best practice guidance.[14,15]

11. What information should be disclosed to service users?

Open disclosure is an approach to communicating with service users following a service user safety incident and should be carried out in line with the regulations, applicable national standards and local policies.[2,3,16] Regulation 17(1)(d) requires undertakings to inform the referrer, the practitioner and the service user or their representative about **clinically significant** events. This includes ensuring the service user is informed about the occurrence of the event, possible effects, requirements for follow-up or aftercare and the results of the analysis of the event.

12. Why do investigation results and corrective measures need to be submitted to HIQA?

Under Regulations 17(1)(f), there is a legal requirement on undertakings to report to HIQA the results of an investigation conducted following the notification of a significant event to HIQA. The results of the investigation must also include the corrective measures implemented to avoid the reoccurrence of such events. Any personal identifiable information must be redacted in line with the General Data Protection Regulation (GDPR).

13. When should the final investigation results and corrective measures be submitted to HIQA?

An investigation results and corrective measures must be submitted to HIQA for **all** significant events in relation to medical exposures to ionising radiation notified to HIQA. This should be submitted within **120 calendar days** of receipt of the initial notification by HIQA.

14. What information should be included in the investigation results and corrective measures?

HIQA does not require the full investigation report. The undertaking must submit the results of the internal investigation and corrective measure to avoid such significant

events. The internal investigation should be completed in line with the undertaking's internal policies and procedures. These policies and procedures should reflect the *National Standards for the Conduct of Reviews of Service user Safety Incident*[3] in addition to other national standards.

At a minimum, the following should be included in the outcome of the investigation report submitted to HIQA:

- the findings of the investigation including causation and contributing factors if known
- corrective actions taken immediately following identification of the significant event and those due to be taken
- any recommendations (which should be specific and time bound) made or implemented as a result of the investigation conducted
- confirmation that those affected by the significant event and relevant stakeholders were informed.

This list is not exhaustive. HIQA may require additional information to be submitted for clarification and monitoring purposes in order to be assured that the risk of reoccurrence has been mitigated.

15. What happens after information is submitted to HIQA?

Following submission of the initial notification form, the notification will be reviewed and assessed. If the information provided is incomplete or contains errors HIQA will contact the undertaking. Once any issues identified are fully addressed, an acknowledgement email with a notification reference number will be issued by HIQA to the undertaking. This individual notification reference number should be included on all future correspondence relating to the specific significant event.

When the completed notification (NF211) form is received, the information will be risk-assessed. The notification will remain open until such time as the investigation results and corrective measures on the results of the investigation is received and reviewed by HIQA. However, there may be instances where HIQA may escalate its regulatory response in the interim if a significant risk to service users is identified. The investigation results and corrective measures must be submitted to HIQA within **120 calendar days** of receipt of the initial notification by HIQA.

Following submission of the investigation results and corrective measures, HIQA will review and risk rate the information again. If the information gives HIQA the necessary assurances that reasonable efforts have been taken to mitigate the occurrence of future similar incidents, the notification will be closed and retained for information. However, if the information provided is incomplete, contains errors or does not provide the required assurances, the undertaking will be contacted.

Once the information provided has been risk-assessed, HIQA will decide on an appropriate response. Possible responses include:

- closure and retention of the notification
- requesting further or follow-up information
- seeking further assurance from the undertaking that further occurrences of a similar incident has been mitigated
- referring the information to an appropriate agency or competent authority
- carrying out other regulatory activity such as an inspection of the service.

16. When will further information be requested by HIQA?

Further or follow-up information is not always required by HIQA. However, it must be submitted if it is requested. Please ensure the following details are included with all further information submitted to HIQA:

- notification reference number assigned by HIQA
- undertaking name
- type of the original notification, and
- date that the initial notification of a significant event was submitted.

17. What are the consequences of failure to notify/submit an investigation results and corrective measures?

Failure of an undertaking to comply with the requirement of Regulation 17(1) to notify HIQA of the occurrence of a significant event or to submit the results of investigations or corrective measures to avoid such events, following a significant event, is an offence under Regulation 29(1)(n).

18. What information will be requested as part of an annual return of incidents relating to medical exposures?

All incidents relating to medical exposures should be managed locally in line with internal risk management and incident management systems. Incidents that do not need to be notified to HIQA within three working days include near misses, potential errors and other events involving medical exposures which are deemed to be outside the thresholds outlined in Table 1.

Under Regulation 28 on the provision of information to HIQA, annual incident returns of all medical ionising radiation incidents must be returned to HIQA each year. All medical ionising radiation incidents include all non-notifiable and potential accidental and unintended exposures in addition to any significant events already notified to HIQA.

Further information will be provided to undertakings at a future date regarding the process for submitting annual incident returns to HIQA.

The information provided through annual returns will enable HIQA to monitor and trend incidents at both undertaking and national level. In addition, the submission of annual returns from undertakings will allow HIQA to determine compliance with mandatory notification of significant events and record keeping and analysis of all events involving or potentially involving accidental and unintended medical exposures.

19. How will radiation protection in medical exposure information be dissemination by HIQA?

Regulation 17(2) requires HIQA to ensure that mechanisms are in place for the timely dissemination of information relevant to radiation protection in medical exposure regarding lessons learned from significant events.[1] Additionally, information sourced from annual returns will provide valuable feedback and learning to stakeholders with the aim of enhancing the safety of service users undergoing medical exposures to ionising radiation. This data will also be included in an overview report of radiation incidents to be published periodically by HIQA.

A culture of incident reporting will provide the opportunity for shared learning on a local and national platform. Learning from radiation incidents is essential to drive improvements for service users and to prevent the reoccurrence of similar radiation incidents. The dissemination of information by HIQA will place a strong emphasis on incident learning. Undertakings should use this information as an opportunity to promote a culture of radiation safety for medical exposures to ionising radiation.

Glossary

Absorbed dose: the energy absorbed per unit mass. The unit of measurement for absorbed dose is the Gray (Gy).

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

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.

Dose constraint: a prospective upper threshold of individual dose given during a medical exposure. This is not a dose limit but should be used to define the range of options considered consistent with best practice for planned medical exposures.

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).

Environmental Protection Agency: an independent public body established under the Environmental Protection Agency Act 1992. It has a broad range of functions relating to environmental protection in Ireland, including environmental licensing; enforcement of environmental law; environmental planning, education and guidance; monitoring, analysing and reporting on the environment; regulating

Ireland's greenhouse gas emissions; environmental research development; strategic environmental assessment; waste management; and radiological protection.

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.

MERU: the HSE Medical Exposure Radiation Unit, which acts on behalf of the Department of Health (as the former competent authority) to audit service user radiation practice in medical radiological installations in Ireland.

National Radiation Safety Committee: a statutory committee established under Statutory Instrument 478 in 2002 to advise the Directory General of the HSE on matters relating to service user radiation protection in both public and private medical radiological installations.

Near miss: an 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.

No harm incident: an incident where ionising radiation reaches the service user but results in no injury to the service user. Harm is avoided by chance or because of mitigating circumstances.

Non-notifiable incident: an event relating to medical exposures to ionising radiation which is managed at a local level and does 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 designed to go to a target organ and 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.

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.

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

Radiation protection advisor (RPA): an individual or body with the knowledge, training and experience needed to give radiation protection advice in order to ensure the effective protection of individuals and whose competence in this respect is recognised by a competent authority.

Radiographs: often referred to as X-rays, these are two-dimensional images obtained to identify disease or injury.

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 dose used to estimate the peak skin dose for interventional radiological procedures. It is the dose calculated at a point along the beam axis, 15cm from the isocentre, in the direction of the X-ray tube. It is measured in Gray (Gy).

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.

Undertaking representative: a person who has the knowledge and ability to answer for, and on behalf of the undertaking in relation to medical exposures to ionising radiation and any associated matters. The undertaking representative must hold a senior position within the undertaking, and should demonstrate an appropriate level of knowledge in relation to the executive governance arrangements in place to assure compliance with the regulations. Please refer to the *Undertaking information handbook* for more information.

Unintended exposure: medical exposure that is significantly different from the medical exposure intended for a given purpose.

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http://www.hse.ie/eng/about/Who/QID/Other-Quality-Improvement-Programmes/opendisclosure/opendiscFiles/opendiscpolicyoct13.pdf

Appendix A: Membership of Expert Advisory Group

Member	Nominated on behalf of
Dr. David Fitzpatrick	Faculty of Radiologists (Radiation Oncology)
David Pollard	Environmental Protection Agency
Elaine Brown	Health Service Executive Acute Hospitals Division
Gavin Maguire	Quality Assurance and Verification Division Health Service Executive
Dr. Jane Renehan	Irish Dental Association
Dr. John Feeney	Faculty of Radiologists (Radiology)
Dr. Niall MacAleenan	Health Products Regulatory Authority
Paddy Gilligan	Irish Association of Physicists in Medicine
Paul Lynam	Private Hospitals Association
Dr. Robert O'Connor	Irish Cancer Society
Dr. Shane Foley	Irish Institute of Radiographers and Radiation Therapists

International expert	Organisation
Dr. Steve Ebdon-Jackson	Public Health England

Appendix B: Examples of notifiable, non-notifiable and near miss incidents

Type of event	Radiotherapy	Radiology	Nuclear Medicine	Dental
Significant event (Notifiable)	A service user receives a total dose or volume variation of greater than 20% from the fraction prescribed.	A service user who had a chest X-ray ordered receives a computed tomography thoracic examination instead of the requested chest X-ray.	A service user presented for a technetium bone scan; however, the wrong radiopharmaceutical was administered and a diagnostic scan was not captured. This resulted in an effective dose of greater than 1mSv.	An incorrect service user receives a cone beam computed tomography examination. This resulted in an unintended dose greater than 1mSv.
Non-notifiable	A service user receives a minor tissue reaction which would be reasonably expected to occur in service users undergoing this treatment when national and international evidence-based best practice has been adhered to.	A service user request states that the service user is for an X-ray of the left hand for following a fall. The radiograph of the left hand is completed; however, after the exam, the service user queries why the right hand had been X-rayed instead of the left.	A service user presented for a diagnostic thyroid scan. During administration the injection activity differs by greater than 20% from the intended activity.	A radiograph was performed and it was noted that the incorrect body region had been imaged.
Near Miss	During identification check, service user A's date of birth differs from the request form, despite the name being correct. This is queried with the referrer, who notes that they have two service users of the same name and service user A was not meant to have the procedure. No inadvertent dose was received by the service user.			

Appendix C: Competent authorities in Ireland with legal remit for receiving statutory notifications on ionising radiation

Competent Authority	Contact details	Remit
HIQA	**Website:** https://www.hiqa.ie/ **Email:** radiationprotection@hiqa.ie **Phone:** 01 828 6750	All medical ionising radiation incidents involving service users and/or carers and comforters.
EPA	**Website:** https://www.epa.ie/ **Email:** RadRegulatory@epa.ie **Phone:** 01 268 0211	Environmental, public and occupational incidents involving ionising radiation

Revision history

Revision History	Publication date / revision date	Title / version	Summary of changes
Version 1	January 2019	Statutory notifications for accidental or unintended medical exposures to ionising radiation	
Version 1.1	September 2019	Statutory notifications for accidental or unintended medical exposures to ionising radiation	This guidance was revised to reflect the amendments to the primary regulations and availability of HIQA's online portal system.

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