Significant accidental or unintended exposures

IR(ME)R notifications to Healthcare Inspectorate Wales
April 2023 to March 2024

ANONYMISED REPORT

Contents

Executive summary

Everyday, tens of thousands of patients undergo planned exposures to radiation as part of their medical care. Inevitably, in a small number of cases things can go wrong. It is imperative these events are monitored and learning shared to help mitigate their frequency and magnitude.

As part of its programme for assessing compliance with the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R), Healthcare Inspectorate Wales requested that the Medical Exposures Group within the UK Health Security Agency (UKHSA) undertake a review of IR(ME)R significant accidental or unintended exposures notifications submitted to them. This report covers the period between 1 April 2023 and 31 March 2024.

In total 82 notifications were subject to analysis during this period involving 110 patients across the modalities of diagnostic and interventional radiology, nuclear medicine, and radiotherapy. A number of employers provided one notification for incidents involving several individuals explaining the disparity in number between affected patients and notifications. Throughout the report each affected individual will be considered and referenced as a single patient notification.

Diagnostic radiology made up the largest proportion of the patient notifications with 80 in total (73%). This is likely due to the greater volume of diagnostic examinations performed compared to radiotherapy and nuclear medicine exposures. There were 17 radiotherapy patient notifications received representing 15% of the total, and 13 patient notifications in nuclear medicine, 12% of the total.

During the review period, the number of patient notifications varied by employer with numbers ranging across 11 employers from 1 to 21. It should be noted when reviewing notification numbers that they have not been normalised for activity levels or technique complexity.

Accidental exposures accounted for 30 % (n=33) of the patient notifications received. Accidental exposures occur when an individual receives an exposure in error, when no exposure of any kind was intended.

Unintended exposures made up 70% (n=77) of notifications. Unintended exposures occur when an individual is referred for radiation exposure, but the exposure delivered was significantly different to what was intended.

Additionally, of the submitted reports detailed above, voluntary notifications contributed 25% (n=27) of the notifications received. Voluntary notifications include incidents that may have not met the criteria or reporting threshold but are shared for learning so that similar events in the future might be mitigated.

As part of this analysis, it was not possible to determine the efficacy of actions put in place following any individual notification.

Eight recommendations have been included within this report.

Background

The Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R) provide a legislative safety framework to protect patients against hazards associated with ionising radiation. In the rare event when there is a significant accidental or unintended exposure to ionising radiation, the IR(ME)R employer must investigate the incident and notify the Healthcare Inspectorate Wales (HIW) under Regulation 8(4).

HIW is the independent inspectorate and regulator of all health care in Wales and therefore responsible for monitoring compliance with IR(ME)R in Wales. HIW encourages continuous improvement in the quality of services carrying out medical and non-medical exposures involving ionising radiation using medical radiological equipment, through a planned programme of inspections and reviews.

As part of its programme for assessing compliance with IR(ME)R, the HIW requested that the Medical Exposures Group (MEG) within the UKHSA undertake a review of submitted IR(ME)R significant accidental or unintended exposures notifications where the incident occurred between 1 April 2023 and 31 March 2024. The scope of this review was to identify themes and consider learning opportunities from shared notifications. It does not include assessment of the clinical outcome for the patient, or the efficacy of actions put in place following any individual incident.

Under IR(ME)R Regulation 9 HIW is required to put in place mechanisms to disseminate relevant information regarding significant events. To support this requirement, HIW may decide to publish key learning points from this report. This provides IR(ME)R employers and staff within Wales the opportunity to learn from the experience of others and implement effective preventative measures proactively. In turn, this may minimise the probability of similar events happening and thereby improve patient safety. HIW may also use this report to inform inspection themes and the overall inspection programme.

Detailed criteria are available to guide IR(ME)R employers on when to make a notification to HIW. and last updated 21st August 2024 (version 4). Version 3 of the guidance came into effect on the 19th April 2023, which therefore occurs part way through the period covered within this report. The notification codes, categories and criteria that were in use during this reporting period are included in Appendix 1.

The amendments to version 3 (April 2023) the reporting criteria included:

- Revised information on clinically significant accidental or unintended exposures (CSAUE)
- Amended notification criteria for interventional radiology and cardiology
- Changes to the thresholds for notifications relating to radiotherapy imaging exposures

- Foetal dose threshold was raised from 1 mGy to 10 mGy
- New reporting category to capture all administrations of an incorrect radiopharmaceutical, regardless of the dose to the patient.

Of the patient notifications included in this analysis, 11 occurred before 19th April 2023. The appropriate SAUE guidance was applied to the analysis, dependent on the incident date.

Accidental or unintended exposures (AUE) are defined in guidance as follows:

Accidental exposure: an individual has received an exposure in error when no exposure of any kind was intended.

Unintended exposure: although the exposure of an individual was intended, the exposure they received was significantly greater or different to what was intended. For example, in the dose received, there may have been an error in either the modality or technique carried out, anatomy, radiopharmaceutical or timing of exposure. These can happen for many reasons including procedural, systematic, human error or equipment malfunction. In addition, duplicate referrals that lead to repeat imaging are considered unintended exposures if occurring in the same episode and same condition.

AUE may be classified as significant or clinically significant.

SAUE: Significant accidental or unintended exposures (SAUE) include those that are significantly greater than intended or significantly lower than intended for radiotherapeutic exposures.

CSAUE: The concept of clinically significant accidental or unintended exposures (CSAUE) was introduced with IR(ME)R in 2017. Criteria to define clinically significant accidental or unintended exposures for diagnostic and therapeutic exposures were published for the clinical setting in June 2020.

Methodology

HIW shared relevant, anonymised notification data securely with MEG. The information included in each notification varied across the dataset. Most notifications included some, or all, of the following information:

- HIW notification of accidental or unintended exposure forms
- primary investigation reports
- Medical Physics Expert (MPE) dose assessment
- other supporting evidence

Key questions were generated by MEG to inform the analysis of the data. All data sources were reviewed by MEG and, where relevant information was available, entered in a Microsoft Excel® incident tracking spreadsheet to enable frequency trend analysis. A list of the fields used to analyse the data is included in Appendix 2.

All analysis was carried out per individual patient notification, rather than grouping notifications involving multiple individuals together.

Analysis

IR(ME)R patient notifications by modality

In total there were 85 notifications submitted for analysis. Three duplications were noted and removed. Therefore 82 notifications involving 110 patients reported to HIW under the SAUE notification criteria between 1 April 2023 and 31 March 2024 remained for analysis. A total of 14 notifications where multiple patients were involved, were received from 7 employers affecting 42 patients. A breakdown of the 110 patient notifications from 2023/24 is shown in figure 1.

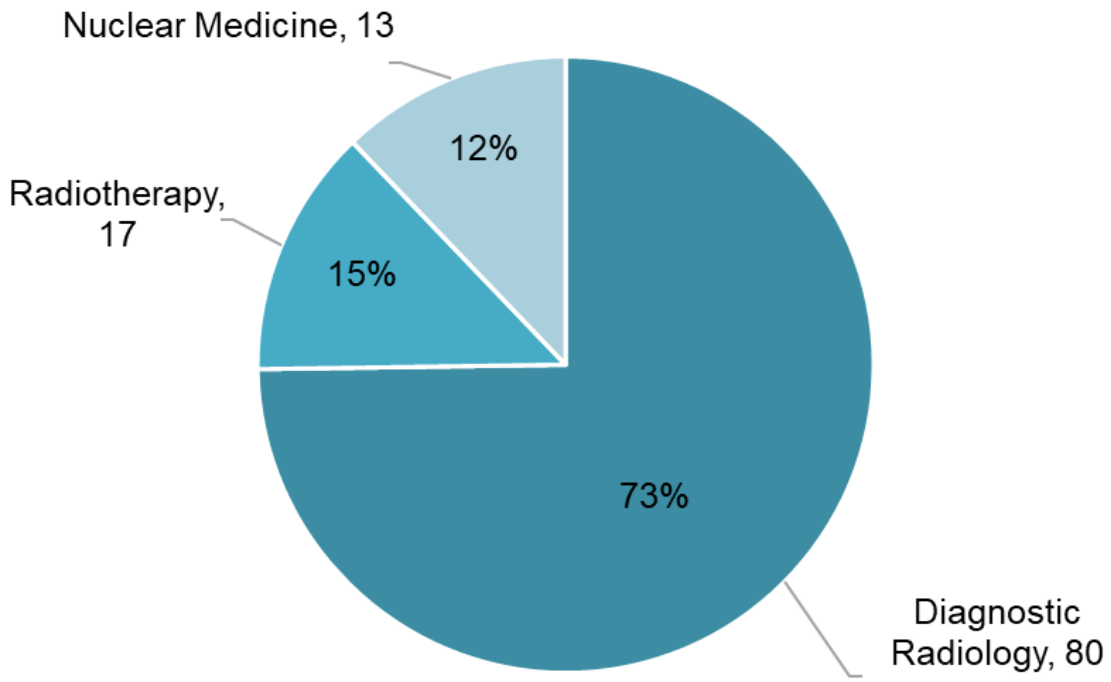

Figure 1. Number and percentage of individual patient notifications per modality (n = 110)

Diagnostic radiology contributed the largest proportion of patient notifications with 80 in total (73%). This is likely to be due to the greater volume of diagnostic examinations performed compared to radiotherapy and nuclear medicine exposures. Radiotherapy patient notifications received accounted for 17 patients representing 15% of the total notifications. There were 13 patient notifications in nuclear medicine, representing 12% of the total notifications.

IR(ME)R patient notifications per employer

Notifications of IR(ME)R SAUE were received by HIW from 6 Local Health Boards, 1 NHS Trust and 4 independent providers during the specified period. Figure 2 shows the breakdown of patient notifications per IR(ME)R employer.

It should be noted the number of notifications per employer is not normalised by activity, patient attendances and type or number of exposures undertaken at site. The population numbers and demographics (for example rural or city, age, deprivation, and healthy life expectancy), area covered, and number of hospitals should be taken into consideration when reviewing the number of notifications by each employer.

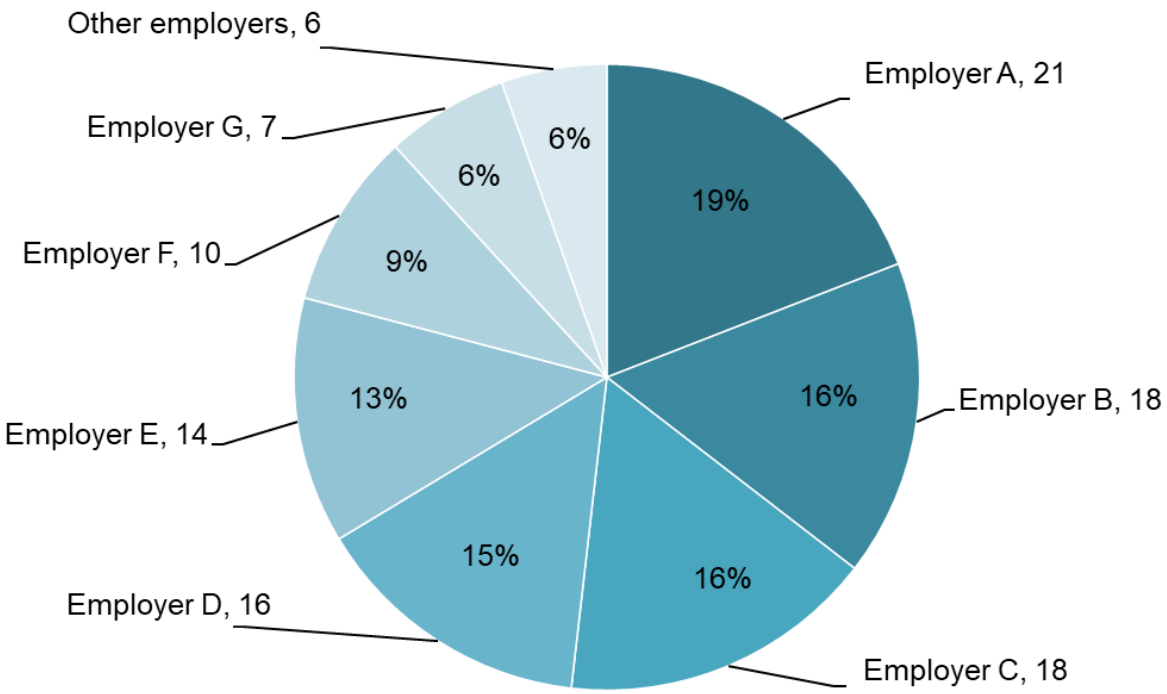

Figure 2. Number and percentage of patient notifications by employer (n = 110)

IR(ME)R patient notifications per employer by sub-modality

Figure 3 describes the number of patient notifications per employer by sub-modality for notifications submitted in 2023-2024.

The sub modalities included in notifications are:

- Radiotherapy (RT): imaging for planning, verification imaging and treatment exposures
- Diagnostic Imaging: General X-Ray, Computed Tomography (CT), dental, fluoroscopy, interventional radiology and mammography
- Nuclear medicine (NM): Positron Emission Tomography / Computed Tomography (PET/CT), Single-Photon Emission Computed Tomography (SPECT), Single-Photon Emission Computed Tomography / Computed Tomography (SPECT/CT), NM planar/dynamic imaging, non-imaging nuclear medicine.

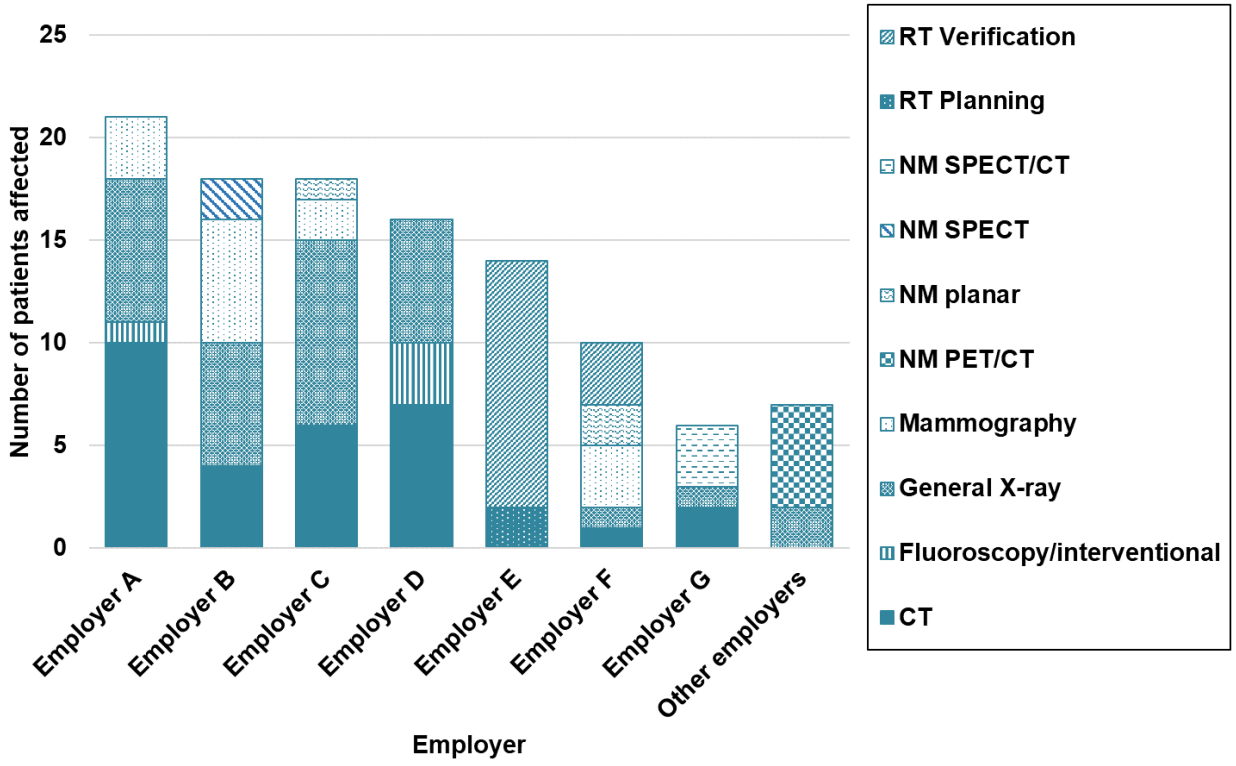

Figure 3. Patient notifications per employer by sub-modality (n = 110)

The largest proportion of reports submitted involved general X-ray (n = 32, 29%) and these were spread across all contributing Health Boards as well from some independent providers.

Patient notifications involving CT totalled 30 (27%) and were also spread across all Health Boards. Examples, in no particular order, include patients incorrectly scanned due to incorrect patient details on an addressograph or inputted erroneously into an electronic radiology request, or because a three-point identification check was not carried out. Duplicate referrals accounted for 5 of the CT referrals.

There were 14 (13%) mammography patient notifications submitted. The majority of these notifications (9) were caused by equipment malfunction. Of the remaining 5 mammograph notifications, 3 related to patients who had recently had mammograms, but operators failed to identify this on checking for previous imaging. An example is included in the case study below.

Case study – Unintended exposure to a patient within the breast imaging surveillance service.

Scenario: As part of the oncology follow-up pathway**,** a patient was referred for annual mammogram at the breast clinic.

In the interim period, the patient attended the symptomatic breast clinic with a suspicious lump in their breast tissue. During this attendance they had a mammogram examination. Two months after their symptomatic mammogram, an appointment was made for their routine surveillance mammogram. The patient had another mammogram as part of the surveillance programme 3 months after undergoing imaging at the symptomatic clinic.

Investigation: When performing the clinical evaluation, the reporting radiologists identified a patient who had received a routine screening mammogram within too short a time period after their symptomatic imaging. The incident was investigated and there was found to be failings in the referral process for this routine examination, which was found to be due to human error.

During pre-exposure checks, the patient indicated their last mammogram had been performed 12 months prior, referring to their previous surveillance imaging appointment. Previous imaging had not been reviewed prior to performing the exposure, which would have identified the additional symptomatic imaging three months prior. The investigation also found that the pre-imaging checks carried out by operators varied and lack consistency in both the questioning and recording of the answers.

Corrective actions included:

- Changes to the wording of the document and creating a more robust set of pre-imaging checks by ensuring that radiographers and admin staff check previous imaging prior to exposure.
- The learning and actions from the incident were shared with staff and the importance of checking patient's previous images

There were 15 patient notifications submitted as radiotherapy verification imaging. Equipment malfunction was ascribed as the cause for 13 of these.

One notification was received under interventional radiology where, three weeks after an embolisation procedure the patient reported open sores and hair loss. This event was not considered clinically significant. One fluoroscopy notification concerning three patients was submitted due to equipment malfunction.

One employer submitted 2 patient notifications for RT planning where 4D CT image sets failed to reconstruct. Of note there were no notifications received relating to radiotherapy treatment.

HIW were notified of 2 NM planar/dynamic imaging incidents due to licensing breaches. The majority of nuclear medicine notifications (8) involved equipment failure or malfunction. A report was submitted for a patient who received an incorrect radiopharmaceutical for a NM planar scan. A case study detailing the incident, corresponding investigation and corrective actions that followed are detailed below. There were no notifications relating to therapeutic nuclear medicine procedures.

Overall, 32% of all notifications referenced equipment and IT failure or malfunction as a contributory factor to the event.

Case study: Incorrect radiopharmaceutical dispensed and administered to a patient.

Scenario: Three patients were injected for a bone scan. At the imaging phase, one of the scans had no bone uptake. The other patients' scans demonstrated bone uptake. The patient affected was informed and another bone scan was scheduled on a different day which was completed successfully.

Investigation: The investigation involved staff from nuclear medicine and radiopharmacy. Images that were acquired following the first injection, suggested that the radiopharmaceutical administered was ^{99m}Tc-pertechnetate as uptake was seen in the thyroid and GI tract.

The investigation with radiopharmacy staff indicated that all processes were followed, operators did not report being distracted or any other factors that could have contributed to the incident. Other potential causes were investigated including equipment fault, incorrect radiopharmaceutical administered in nuclear medicine, problems with the bone kit, and patient factors.

The investigation found that the most likely scenario was that the eluate vial was used to draw up the bone injection instead of the bone kit.

A full root cause analysis was performed, and additional discussions were held with Wales national lead for radiopharmacy, another radiopharmacy, and at the Wales Regional Pharmacy Technical Services Meeting.

Corrective actions included:

- Training to ensure that vials are separated appropriately during drawing up
- Review and update procedure to ensure that segregation of vials is clear
- Assess whether alternative vials shields could be used to differentiate the eluate vial from kit vials
- Introduce annual assessment of competency as part of appraisal process.

IR(ME)R patient notifications per hospital site

Figure 4 shows a breakdown of the number of patient notifications at hospital sites where notifications were made. Reports were submitted from 17 hospitals, accounting for approximately 20% if all operating hospitals in the Welsh NHS region.

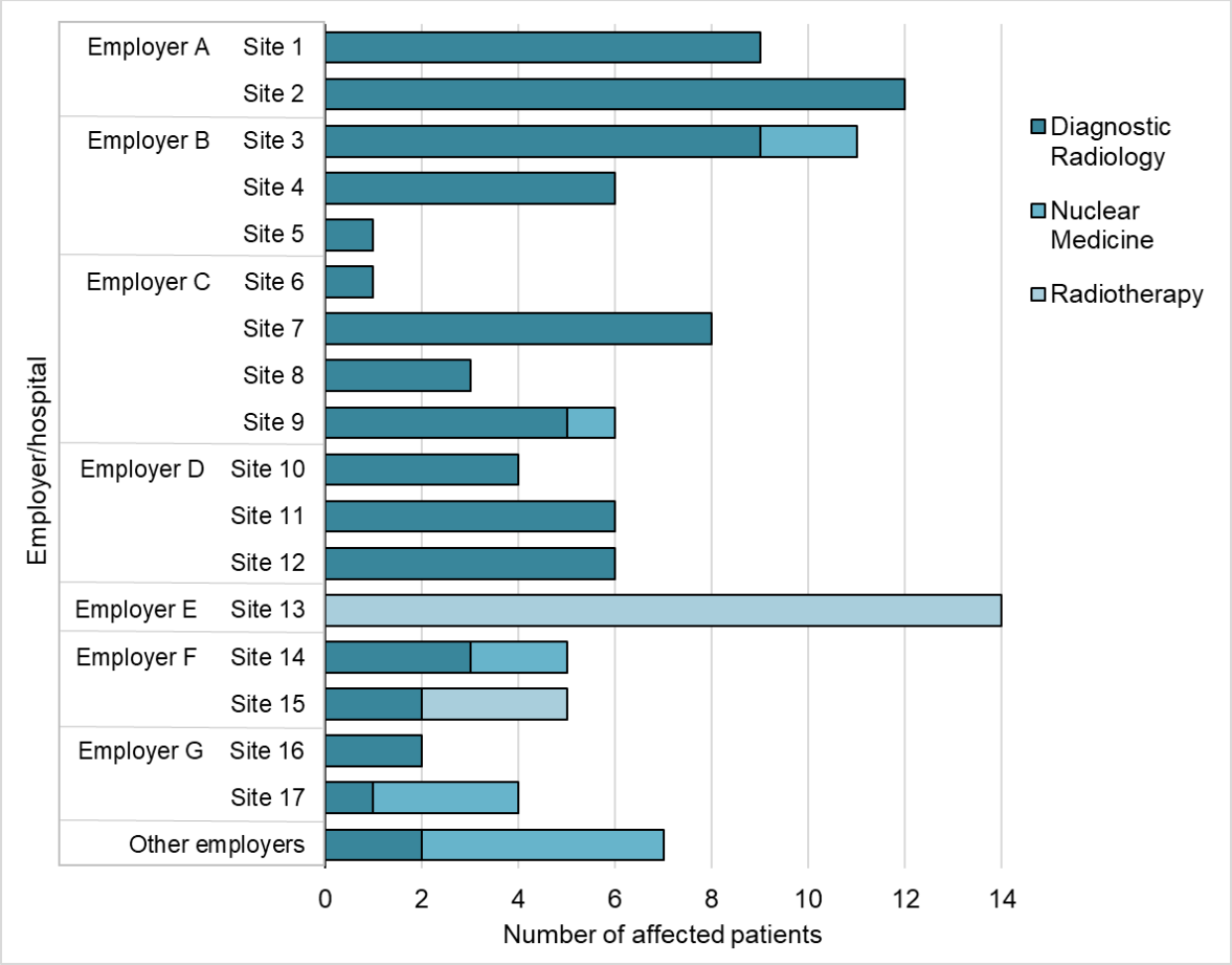

Figure 4. number of patient notifications per site and employer by modality for 2023-2024 (n = 110)

Nature of patient notification

Notification reports were analysed to group together themes relating to the nature of the incident. Where available, SAUE codes supplied were reviewed with the incident reports. MEG applied the SAUE coding criteria to those notifications based on the information shared by HIW where the coding was missing. Figure 5 shows the SAUE code applied to the patient notifications for 2023-2024.

There were 33 (30%) accidental exposures (shown as SAUE code 1 in Figure 5). Accidental exposures occur when an individual receives an exposure in error, when no exposure of any kind was intended. Examples of these types of errors include referral errors and failure to follow patient identification procedures.

Several notifications (n = 19) were classed as accidental by the reporting provider, however during UKHSA analysis were categorised as unintended for consistency across the dataset. Of these cases, 15 diagnostic imaging reports were duplicate referrals that occurred within the same episode and related to the same condition. Of the remaining four, two nuclear medicine patients required repeated exposure due to equipment fault, one patient required a post nasogastric tube placement check x-ray but was imaged without the tube in situ. The final case concerned a patient referred for an orthopantomograph but received a chest x-ray due to an identification check failure. Whilst all these cases were considered unintended exposures, none of them met the criteria for unintended exposure notification under SUAE. Therefore all 19 were classified within the analysis as voluntary.

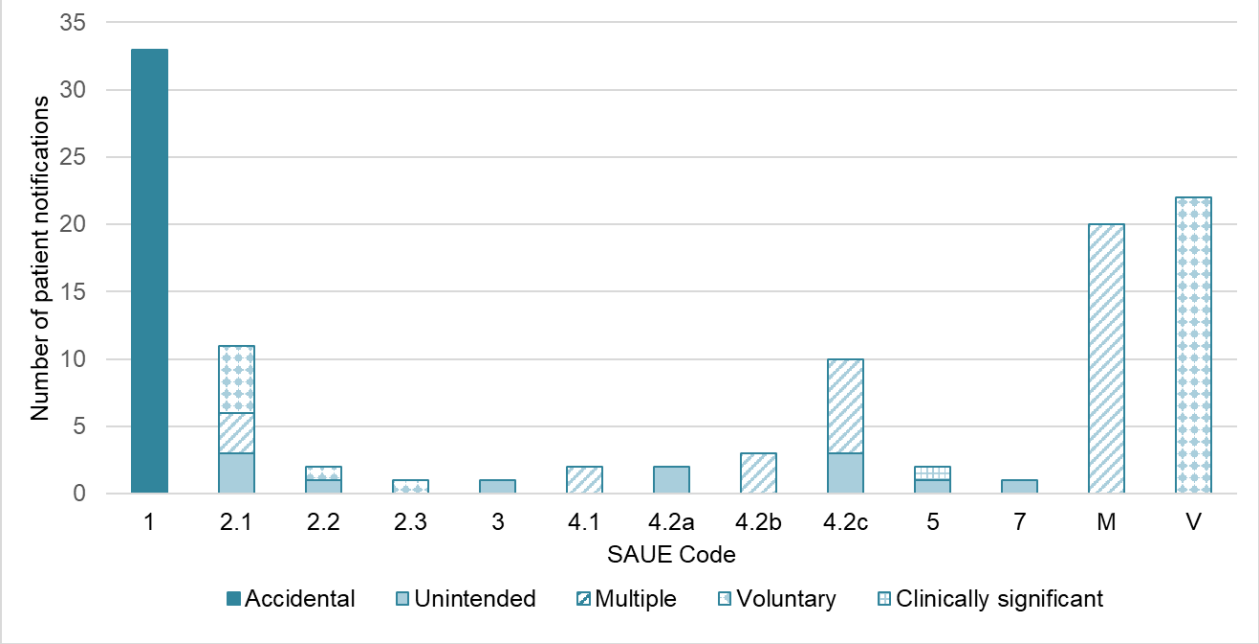

Figure 5. SAUE code of patient notification by theme (n = 110)

Notifications affecting multiple individuals (codes denoted with M in Figure 5) were predominantly caused by equipment malfunction or failure. One submission related to a nuclear medicine licensing breach involving two patients.

Notifications affecting multiple individuals

Examples of notifications that affected multiple individuals include a notification from an employer where four patients each received an unintended additional dose of radiation

following a fault during kilovoltage (kV) cone-beam CT (CBCT) treatment verification imaging on linear accelerators. Although each incident on their own did not constitute a significant unintended exposure, the criteria based on any theme affecting multiple patients was met and a case study detailing the incident, corresponding investigation and corrective actions that followed are detailed below.

Case study – Verification imaging fault causes repeat exposures for multiple patients

Scenario: The first two incidents occurred within two days of each other on the same treatment machine and had the same mode of failure. Midway through acquisition of the CBCT scan, delivery of radiation halted but the machine gantry continued to rotate until reaching the planned finishing position. An error then appeared on the treatment console. The reconstructed CBCT image was not suitable for clinical use due to artefacts caused by early termination of the image acquisition.

Investigation: During the first two occurrences local engineering support staff were called by the radiographers when the error message showed. The error was acknowledged, a repeat scan was successfully performed, and the patient was treated correctly. The issue was then escalated to the equipment manufacturer and regulator notified.

The treatment machine control software had been upgraded on the weekend before the incidents occurred and the manufacturer acknowledged that a bug relating to this software version can cause the issues experienced. The manufacturer proposed a workaround that was implemented locally. Since implementation the issue occurred four times on treatment machine Linac A over a 30-day period and on each occasion the workaround was successfully used without the requirement for additional imaging.

The issue was reported to other centres via the Medical Physics and Engineering JISCMail mailbase. A MHRA Yellow Card report was compiled and submitted.

Some weeks later the issue that affected the treatment unit occurred on a patient being treated on a second treatment machine. The workaround was not performed, and so led to unintended additional dose. This issue occurred again on the second treatment unit some days later, the workaround was again not performed leading to unintended additional dose. It is thought that radiographers working on the second treatment unit were less aware/knowledgeable about the issue and therefore not experienced in identifying the problem and applying the workaround (workaround is reliant on manual monitoring, and an intervention that must be executed within a short time window).

Corrective actions included:

- Implementation of manufacturers workaround
- Risk assessment undertaken for ongoing use of the affected equipment
- The learning and actions from the incident were shared locally and nationally

Notification risk data

Out of 110 patient notifications, data on effective dose was included in 91 reports (83%). 10 reports (9%) did not include effective dose, but provided an assessment of other dose parameters, for example mGy or DLP. Nine of the patient notification reports shared with MEG for review (8%) did not provide dose data.

Notifications with an estimate of the total effective dose were reviewed, expressed in millisieverts (mSv). Figure 6 shows a dose histogram from the relevant 91 patient notifications. The total effective dose (planned and unplanned exposures) ranged from 0.01mSv to 102mSv with an average of 6.53 mSv. The median dose received was 2.2mSv and mode of 0.88mSv.

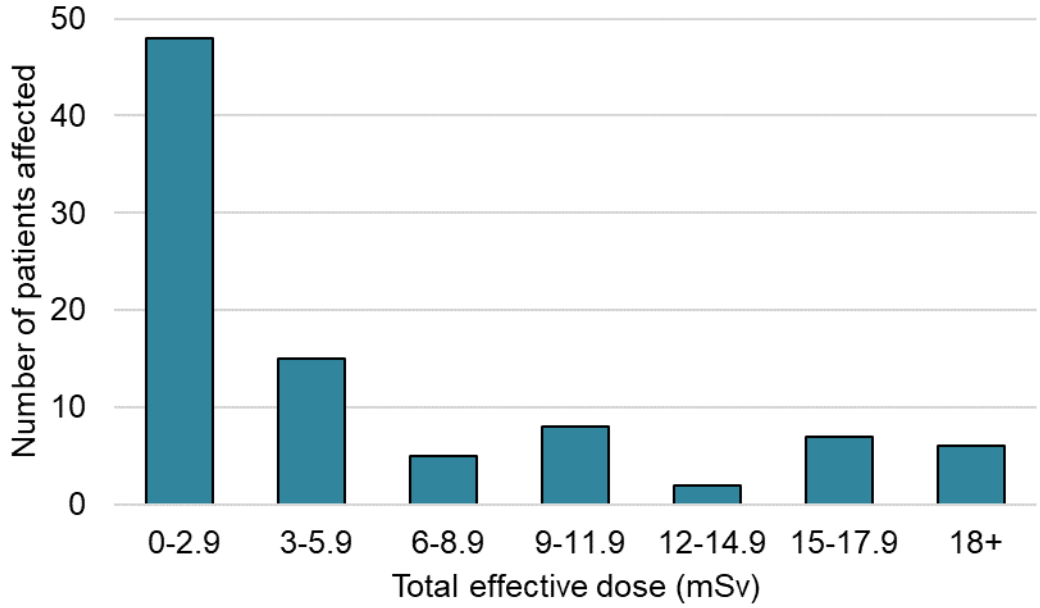

Figure 6. Histogram of total effective dose delivered (mSv) (n = 91)

There were 35 notifications with estimates of effective dose which resulted in a total dose of less than 1mSv. The maximum dose delivered (102mSv) resulted in a reported 1 in 1,000 risk of cancer induction. This incident occurred when the patient attended for a 4D radiotherapy planning CT scan. Equipment signal failure on the scanning terminal meant the scan had to be repeated. The procedure was completed as intended on the second occasion. Whilst this incident would not have met the criteria for notification one other patient also received a similar unintended dose due a repeat of the equipment malfunction. Therefore, the incident was considered reportable under SAUE code M as more than one individual was exposed within the same incident/theme.

Demographics

The age range of the patient cohort was from newborn to 96 years old with an average age of 62 years old. The median reported age was 68 years. The age distribution of the affected patients is summarised below in Figure 7.

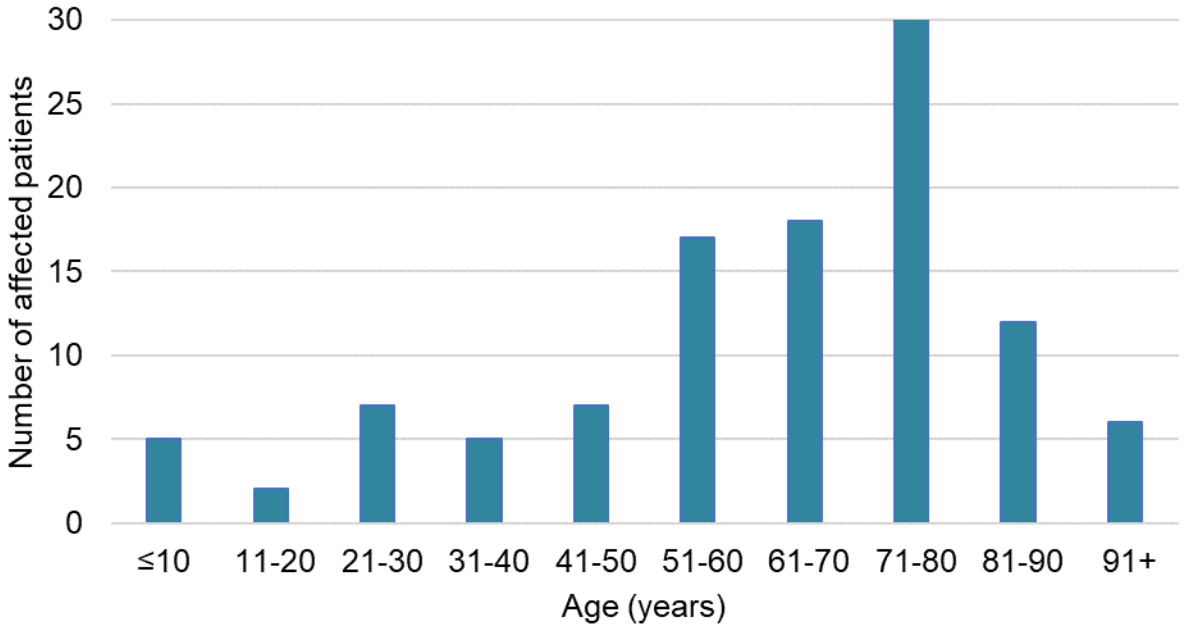

Figure 7. Age histogram of affected patients (n = 110)

Who was informed of the incident

There is a requirement under IR(ME)R to inform the referrer, practitioner, and the patient (or their representative) of clinically significant accidental or unintended exposures (CSAUE) and the outcome of the investigation of the event. One notification

of CSAUE was submitted during this reporting period. However, providers may inform the relevant duty holders and individuals concerned of significant accidental or unintended exposures as a matter of good practice. Information on whether the referrer or practitioner was informed or not was omitted in 53 notifications and for the individual/representative in 12 notifications. Occurrences for when referrer, practitioner or the individual/representative were indicated as being informed are summarised in table 2.

Informing others	Informed	Not informed	Not known
Referrer	54	3	53
Practitioner	57	0	53
Individual/representative	90	8	12

Table 2. Referrer, practitioner, individual or representative informed

Of note, the referrer was stated as being informed regarding 54 patient notifications included in notifications (49%), and the practitioner in 57 patient notifications (52%). There was insufficient detail in the reports submitted to determine if the referrer and practitioner were informed for 53 patients (48%). The patient or their representatives were informed on 90 occasions (82%). There may be some cases where the referrer, practitioner and individual or their representative were informed of the incident following notification to HIW, but this was not reflected in the data shared for analysis.

Discussion

As part of HIW's proactive IR(ME)R inspection programme, it is clear that there are employers with an excellent incident reporting culture, generating learning from analysis of incidents and near misses in order to improve patient safety. However, inevitably there are variations in notification levels across providers.

It should be noted the number of notifications from Local Health Boards, NHS Trusts and independent providers within this report are not normalised by activity or number of exposures undertaken at each site. Population numbers and demographics (for example, rural or city, age, depravation, healthy life expectancy), geographical area covered, and number of hospitals should also be considered when comparing the number of notifications to HIW by each employer.

Further confounders include differences in provision. Nuclear medicine and radiotherapy are only provided at certain sites, and this should also be appraised when reviewing the variation in levels of notifications.

The population numbers served by Local Health Boards range from approximately 692,000 to 134,000. One NHS Trust is the South and mid Wales specialist tertiary oncology centre and therefore serves a population of approximately 1.7 million delivering specialist cancer services such as radiotherapy.

From the data analysis, there appear to be variations in the numbers of notifications submitted by employers. For example, there were no reports submitted by one Health Board for this year. In terms of radiotherapy, whilst reports were received by two of the three radiotherapy centres in Wales, none were submitted by the third cancer treatment centre. Similarly, of those health boards who reported, only one failed to submit nuclear medicine SAUE over this period. HIW might consider if prioritising inspection of employers that do not report might help determine compliance with the regulations.

Analysis raised several associated themes; notifications raised due to erroneous referrals and requests, the failure to thoroughly check for previous imaging and insufficient identification checks being carried out. HIW may wish to consider encouragement of better practice for these tasks and procedures.

Notification information

In terms of consistency, all incident notifications assessed within this report were submitted to HIW using the recognised IR(ME)R notification form. However, the inclusion of supporting information, including MPE reports, was variable.

IR(ME)R requires the involvement of an MPE for radiation incident analysis (Regulation 14(3)(f)). An MPE dose assessment is key in providing an indicator of risk and potential degree of harm to the individual, whether it is a SAUE and notifiable to the regulator.

Of the reports shared for review, 34 (31%) included a MPE dose assessment report, 29 of which provided an effective dose estimate in mSv. An MPE dose report was not included in 76 (69%) notifications. Of these, 62 provided effective dose estimates in other documents, primarily in the IR(ME)R notification form (n = 36, 33%), whilst 26 (24%) provided effective dose estimates within either incident closure forms, serious incident review or incident investigation documents. The majority of these documents detailed membership of investigation teams including MPE participation.

Of the remaining 14 notifications, 9 contained dose information using alternative dose indicators such as centigray (cGy), dose length product (DLP) and dose-area product (DAP). There were 3 reports submitted where the patient did not receive any additional

exposure. This left 2 notifications which did not provide a dose assessment. This absence was acknowledged in both reports, one of which advised that a MPE dose & risk assessment would follow with the full investigation report, whilst the other advised that the MPE was still working on the dose calculations at the point of report submittal. HIW may wish to emphasise employers should include estimates of the doses involved when investigation reports are submitted, and no later than 12 weeks after the incident was discovered.

The variable level of information provided can lead to relevant details being omitted from some notifications such as dose delivered, or dose intended and SAUE criteria, as well as relevant learning and mitigations. Further consideration might be given to clarification of terminology used in the IR(ME)R notification, in addition to emphasising the required supporting information, to reduce ambiguity in notification submissions.

Some IR(ME)R employers evidenced more developed processes for incident reporting and management than others. Examples include the use of system analysis, assigning actions to individuals and providing a summary of actions, study of risk for mitigating actions, and monitoring and evidencing their successful completion.

Radiotherapy providers in Wales contribute radiotherapy error data voluntarily via the Once for Wales Concerns Management System to the UKHSA as part of the UK wide incident learning system for radiotherapy. This is consistent with national recommendations from Towards Safer Radiotherapy and the Development of Learning from Radiotherapy Errors. A series of reports summarising trends in radiotherapy errors are available for the UK.

National taxonomies for the coding and classification of Clinical Imaging and Nuclear Medicine patient safety events have since been introduced. These can be applied to future notification to aid analysis, and for submission via the Once for Wales Concerns Management System to the UKHSA as part of the UK wide incident learning system for diagnostic imaging and nuclear medicine.

Timing of notification

SAUE notification guidance states that the initial investigation report must be submitted to HIW within 2 weeks of identifying the incident. A total of 46 (42%) initial reports were submitted within 2 weeks of the incident date. The average time to notification was 34 days. Care needs to be taken when making comparisons based on lag time between incident date and report date. There are occasions where the date an incident is detected will be much later than the incident date. This can be due to a variety of reasons. Within this cohort, examples include scans erroneously performed that were identified later, during the reporting process. One report where multiple patients' images

were deleted from the system before they had been sent to PACS had a delay in being identified due to missing images not being reviewed within the standard two-week reporting turnaround timeframe. Others include when the reviewer realises the images being assessed do not match detail within the patients' clinical notes. In addition, there can be incidents discovered during retrospective audits following a previous incident investigation. These naturally have a longer lag time, although this process is indicative of a robust incident investigation approach taken by some IR(ME)R employers.

Effectiveness of actions and learning from notifications

Accidental exposures accounted for 30% (n=33) of the notifications received. Accidental exposures occur when an individual receives an exposure in error, when no exposure of any kind was intended. Examples of actions that were taken by employers to mitigate against accidental exposures included:

- opportunities for staff to reflect and refresher training for staff members involved
- staff reminded of responsibilities within employer's procedures and under IR(ME)R
- raising awareness and sharing learning with relevant staff groups

Unintended exposures compromised of 77 submitted reports (70%). Examples of action included:

- discussion of incidents with involved staff
- staff reminded of responsibilities within employer's procedures and under IR(ME)R
- IR(ME)R audits to confirm staff adherence to procedures
- incident details and learning outcomes shared via team meeting, emails, posters etc.

Corrective measures such as refresher-training, individual reflection on what went wrong, and re-reading policies and procedures can be less effective if used in isolation. Incident investigations should include a system level review to identify appropriate corrective actions. Consideration should also be given to actions linked to system improvements such as refinement of processes or automation of a manual process. Simplifying processes, including the removal of redundant or duplicate tasks, and adding in additional safety measures can also support reducing incidents. The most effective preventative strategies to mitigate incidents are linked to addressing all contributory factors of an incident.

It is recommended that providers take a blended approach so that both staff and system focused actions targeting the failed processes identified within the system are included.

Auditing the effect of measures put in place following an incident helps ascertain if applied actions are, indeed, effective in leading to improvements in patient safety.

Learning culture

From the analysis of notifications provided it is clear there are variations in the number and quality of notifications submitted across the region and measures taken to mitigate these events.

Different organisations develop distinctly individual cultures, where employees share similar values and attitudes. Within those cultures what is fundamental is the importance of a positive learning culture. This requires the appreciation of a robust, accessible event learning system, transparent encouragement of safety reporting, and that appropriate responses are seen to be actioned. Subsequent learning is actively employed to inform improvements and mitigate the risk of recurrence.

A systems-based approach to incident learning appreciates the complexity of health care systems and can identify both safety gaps and areas of high risk and help formulate strategies to strengthen relevant systems. Systems orientated safety actions; those forcing functions whose design eliminates the possibility of events occurring, are considered more effective than human orientated actions, examples of which include updating and adding to protocols, policies, checklists, and training.

These systems processes are more difficult to adopt and implement, therefore a blended approach, using both systems and human orientated methods, is recommended.

It is important that employers are proactive, learning from ‘better practice’ where things have gone right, not simply reacting when things have gone wrong. Organisations should be alert to the many factors that influence and contribute to events. This extends from how staff interact within multidisciplinary teams, the environment (for example, poor workspace layout, noisy areas, interruptions), the equipment, the workload through to the organisational culture that is fostered by the employer.

Conclusion

This is the first analysis carried out by the UKHSA on behalf of HIW for significant accidental or unintended exposure notifications to ionising radiation submitted under IR(ME)R Regulation 8(4). Assessment of data from a 12-month period has shown that all notifications are from the hospital setting and include diagnostic imaging, nuclear medicine, and radiotherapy modalities. It is not clear why there were no notifications received from other settings such as chiropractors and dental practices, although this may be influenced by the dose thresholds used in the SAUE criteria (listed in Appendix 1).

The notification data in this report is not normalised by activity or complexity of work at different sites. From the data analysis, however, it is evident there are variations in the levels and quality of reporting incidents between Health Boards/Trusts. It is notable that one Health Board has not submitted any notifications for this reporting period.

It is encouraging to see many voluntarily reported notifications, which do not reach the SAUE notification criteria, demonstrating a positive reporting culture within these organisations.

Incident investigations should include a system level review to identify appropriate corrective actions. The most effective preventative strategies to mitigate incidents are linked to the contributory factors of the incident. From the data analysis, further improvements could be made to identify more effective strategies.

Within this analysis, it was not possible to determine how often providers audited the efficacy of actions put in place following any individual incident and identify whether any had any measurable impact. HIW may consider this as an inspection theme in the future.

Notifications provide intelligence that can be used to inform proactive IR(ME)R inspection programmes. It is encouraging to see employers with a positive reporting culture, and this is not taken as a sign that patient care or safety is compromised, more that there is a willingness to share learning from patient safety events. Employers that do submit notifications to HIW might benefit from a proactive inspection to ensure they have a full understanding of notification requirements as part of Regulation 8(4) and to understand whether there are underlying challenges or barriers to reporting.

Recommendations

Recommendations for HIW:

1. HIW should consider standardising additional reporting information to simplify the process for employers. This will improve future notification analysis and allow coding and classification using the updated national taxonomies for Clinical Imaging, Nuclear Medicine and Radiotherapy.
2. HIW should encourage timely reporting of notifications, including following up with employers after an initial notification is submitted to ensure the detailed report is received on time. It may be beneficial for HIW to remind employers to submit IR(ME)R notifications within the 2-week timeframe. In addition, establishing an agreed timeframe for the return of MPE dose assessments to allow the notification to be fully investigated locally and closed by HIW in a timely fashion is recommended.
3. HIW should use learning from this analysis to inform inspection themes, in addition to a risk-based approach, when developing their pro-active inspection programme.
4. HIW should publish lessons learned from significant events reported to them.

Recommendations for employers:

5. Employers should continue to develop their local reporting and learning culture and encourage openness, voluntary reporting and routine analysis and learning from these events.
6. Employers should ensure current criteria for SAUE notifications are readily available and understood by staff locally.
7. Employers should ensure that local reporting systems are accessible, efficient and where notifications are required to be submitted to HIW, that this is done in a timely fashion.
8. Employers should ensure that corrective actions implemented after incidents or near misses are effective. These should target contributory factors and include a system review. Corrective actions should be audited to monitor their effectiveness in mitigating against incidents and addressing improvements in patient safety.

Appendix 1

SAUE notification codes, categories and criteria published in August 2020

Notification code	Exposure category	Criteria for notification [a], [b]
Accidental exposure		
1 (England only)	All modalities including therapy	3 mSv effective dose or above (adult) 1 mSv effective dose or above (child) [c]
1 (Northern Ireland, Scotland & Wales)	All modalities including therapy	All, regardless of dose
Unintended exposure		
All modalities including nuclear medicine and radiotherapy pre-treatment imaging		
2.1	Intended dose less than 0.3mSv	3mSv or above (adult) 1mSv or above (child)
2.2	Intended dose between 0.3mSv and 2.5mSv	10 or more times than intended
2.3	Intended dose between 2.5mSv and 10mSv	25mSv or above
2.4	Intended dose more than 10mSv	2.5 or more times than intended
3	Interventional/cardiology	Where there has been **NO** procedural failure **AND** either: the dose is 10 or more times the Local Diagnostic Reference Level **OR** there are observable deterministic effects excluding transient erythema
4.1	Radiotherapy pre-treatment planning scans	If CT planning scan needs to be repeated twice to obtain an appropriate data set (3 scans in total, including the intended scan)
4.2	Radiotherapy treatment verification images	Set-up error leads to 3 or more imaging exposures in a single fraction (including the intended image, i.e. 3 images in total) **OR** when the number of additional imaging exposures is 20% greater than intended over the course of treatment or than was described in the protocol [d]
5	Foetal All modalities	Where there has been a failure in the procedure for making pregnancy enquiries **AND** the resultant foetal dose is 1mGy or more

6	Breast feeding infant Nuclear medicine only	Where there has been a failure in procedure **AND** the resultant infant effective dose is 1 mSv or more
	Radiotherapy delivered dose (including brachytherapy)	
7.1	Therapy over-exposure	Delivered dose to the planned treatment volume and/or organs at risk is 1.1 or more times (whole course) or 1.2 or more times (any fraction) the intended dose
7.2	Therapy under-exposure	Delivered dose to the planned treatment volume is 0.9 or less times the intended dose (whole course) [(e)]
	Radiotherapy geographical miss (including brachytherapy)	
8.1	Total	All total geographical misses, even for a single fraction or significant part thereof
8.2	Partial	Where the miss exceeds 2.5 times the locally defined error margin [(f)] **AND** the guideline dose factors above (as 7.1 & 7.2) for the PTV or OAR are exceeded
	Nuclear medicine therapy	
9.1	Selective Internal Radiation Therapy	Delivered activity is outside +/- 20% of the prescribed activity.
9.2	All other nuclear medicine therapies	Delivered activity is outside +/- 10% of the prescribed activity.
Complementary notification codes		
M	More than one individual exposed within the same incident/theme. (plus suffix with relevant 1 to 9 code)	All cases regardless of dose
E	Equipment fault exposure (suffix as above)	
V	Voluntary notification (suffix as above)	
C	Clinically significant event (suffix as above)	

Notes to the table

(a) Criteria apply to the total exposure from the incident, including any intended component plus over-exposure and/or necessary repeat exposures. Where a multiplication factor is specified this is defined as **the total dose from the incident divided by the intended dose**.

(b) This column of the table defines the various notification criteria. Where the exposure is not easily estimated in mSv or the dose unit specified, an alternative recognised unit may be applied and specified in the notification.

(c) In England, Wales and Northern Ireland, a child is someone who has not yet reached their 18th birthday. In Scotland, this is someone who has not yet reached their 16th birthday.

(d) Excluding where there has been no breakdown in protocol and repeat verification imaging has facilitated correction of a 'setup' error so preventing a geographical miss in treatment.

(e) Excluding where the under-exposure to the target volume is a result of a geographical miss, which is reportable under 8.1 or 8.2.

(f) A surrogate for the locally defined error margin might be a displacement of 2.5 times the local imaging action level for specific anatomical site and treatment intent.

SAUE notification codes, categories and criteria published in April 2023

Accidental exposure

Notification code	Exposure category	Criteria for notification
1 (England only)	All modalities including therapy	3 mSv effective dose or above (adult) 1 mSv effective dose or above (child) *In England, Wales and Northern Ireland, a child is someone who has not yet reached their 18th birthday. In Scotland, this is someone who has not yet reached their 16th birthday.*
1 (Northern Ireland, Scotland & Wales)	All modalities including therapy	All, regardless of dose

These notification criteria apply to the total exposure from the incident, including any intended component plus over-exposure and/or necessary repeat exposures. Where a multiplication factor is specified, this is defined as **the total dose from the incident divided by the intended dose**.

Where the exposure is not easily estimated in mSv or the dose unit is not specified, you may apply an alternative recognised unit and specify this in the notification.

Unintended exposure

All modalities including nuclear medicine and radiotherapy imaging

Notification code	Exposure category	Criteria for notification
2.1	Intended dose less than 0.3mSv	3mSv or above (adult) 1mSv or above (child)
2.2	Intended dose between 0.3mSv and 2.5mSv	10 or more times than intended
2.3	Intended dose between 2.5mSv and 10mSv	25mSv or above

2.4	Intended dose more than 10mSv	2.5 or more times than intended.
3	Interventional/cardiology	Where there has been a procedural failure resulting in observable deterministic effects. Procedures that do not have a procedural error but result in unintended or unpredicted observable deterministic effects.
4.1	Radiotherapy planning scans	If a planning scan needs to be repeated twice to obtain an appropriate dataset (3 scans in total, including the intended scan).
4.2a	Radiotherapy treatment verification images	Set-up error leads to 3 or more imaging exposures in a single fraction (including the intended image, 3 images in total). *This applies to all radiotherapy treatment regimes, including radical short course fractionation (defined as 10 fractions or less).*
4.2b	Radiotherapy treatment verification images	When the number of additional imaging exposures is 50% greater than intended over the course of treatment as a result of **protocol failure**. *This applies to all radiotherapy treatment regimes, including radical short course fractionation (defined as 10 fractions or less).*
4.2c	Radiotherapy treatment verification images	When the number of additional imaging exposures is 50% greater than intended over the course of treatment as a result of **thematic hardware or software failure**. *This applies to all radiotherapy treatment regimes, including radical short course fractionation (defined as 10 fractions or less).*
5	Foetal All modalities	Where there is an unintended foetal exposure **AND** the resultant foetal dose is **10mGy** or more.
6	Breast feeding infant Nuclear medicine only	Where there has been a failure in procedure **AND** the resultant infant effective dose is 1 mSv or more.
7	Incorrect radiopharmaceutical	Any administration of the incorrect radiopharmaceutical to a patient, regardless of dose.

Radiotherapy delivered dose (including brachytherapy)

Notification code	Exposure category	Criteria for notification
8.1	Therapy over-exposure	Delivered dose to the planned treatment volume or organs at risk is 1.1 or more times (whole course) or 1.2 or more times (any fraction) the intended dose.
8.2	Therapy under-exposure	Delivered dose to the planned treatment volume is 0.9 or less times the intended dose (whole course). *This excludes where the under-exposure to the target volume is a result of a geographical miss, which is reportable under either 8.1 or 8.2.*

Radiotherapy geographical miss (including brachytherapy)

Notification code	Exposure category	Criteria for notification
9.1	Total	All total geographical misses, even for a single fraction or significant part thereof.
9.2	Partial	Where the miss exceeds 2.5 times the locally defined error margin AND the guideline dose factors (codes 8.1 and 8.2) for the planning target volume or organs at risk are exceeded. *A surrogate for the locally defined error margin might be a displacement of 2.5 times the local imaging action level for specific anatomical site and treatment intent.*

Nuclear medicine therapy

Notification code	Exposure category	Criteria for notification
10.1	Selective internal radiation therapy	Delivered activity is outside +/- 20% of the prescribed activity.
10.2	All other nuclear medicine therapies	Delivered activity is outside +/- 10% of the prescribed activity.

Complementary notification codes

For these codes, you need to add the relevant suffix code 1 to 9. For example:

- M1 (accidental exposure of more than one individual within the same incident or theme)
- M2.1 (unintended exposure of more than one individual within the same incident or theme)

Notification code	Exposure category	Criteria for notification
M	More than one individual exposed within the same incident or theme. (plus relevant suffix code 1 to 9)	All cases regardless of dose.

Notification code	Exposure category
E	Equipment fault exposure (plus relevant suffix code 1 to 9)
V	Voluntary notification (plus relevant suffix code 1 to 9)
C	Clinically significant event (plus relevant suffix code 1 to 9)

Appendix 2

List of fields used to analyse data

The data input spreadsheet contained the following fields:

- incident reference number
- date of incident
- notification date
- health board, trust, or independent employer
- hospital site
- type of exposure (diagnosis or treatment, health screening)
- modality (diagnostic imaging, nuclear medicine or radiotherapy)
- sub-modality
    - diagnostic imaging general X-ray
    - diagnostic imaging CT
    - diagnostic imaging dental
    - diagnostic imaging DXA
    - diagnostic imaging fluoroscopy/interventional
    - diagnostic imaging mammography
    - diagnostic cardiology
    - nuclear medicine PET/CT
    - nuclear medicine SPECT
    - nuclear medicine SPECT/CT
    - nuclear medicine planar
    - nuclear medicine non-imaging
    - radiotherapy planning imaging
    - radiotherapy treatment
    - radiotherapy verification imaging
- number of individuals affected
- reported age and gender of the individual(s) affected
- reported as clinically significant
- referrer informed
- practitioner informed
- individual or representative informed
- intended dose
- total dose delivered (planned and unplanned)
- actions preventing reoccurrence
- reported SAUE code

About the UK Health Security Agency

The UK Health Security Agency is an executive agency, sponsored by the Department of Health and Social Care.

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Version 1.0

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