IR(ME)R annual report 2022/23

CQC's enforcement of the Ionising Radiation (Medical Exposure) Regulations 2017

Notifications received in 2022/23

From 1 April 2022 to 31 March 2023, we received 727 statutory notifications of significant accidental and unintended exposures (SAUE notifications) across all modalities. This compares with 611 received in 2021/22, an increase of 19%.

- 380 (52%) were from diagnostic imaging departments
- 77 (11%) were from nuclear medicine departments
- 270 (37%) were from radiotherapy departments

This is broadly comparable to 2021/22, where 60% of notifications received and investigated were from diagnostic imaging departments, 10% from nuclear medicine departments and 30% from Radiotherapy departments.

Diagnostic imaging notifications: Of the 380 notifications received, the most common type of error still involved carrying out an examination on the wrong patient (25% of all diagnostic imaging notifications). This reflects a similar trend to last year.

Of these notifications, 60 of the 380 (16%) received were where the wrong patient had been referred for a diagnostic examination. A further 35 (9%) notifications were where the wrong patient was exposed because of an operator identification (ID) error. Overall, 13% of the total number of notifications received (95/727) were for the wrong patient being imaged in diagnostic imaging.

As was the case last year, operator errors accounted for the highest origin of incidents reported to us (45%).

Within diagnostic imaging, the majority of notifications were from computed tomography (CT) (62%) followed by plain film x-ray (23%). This is similar to the previous year.

Nuclear medicine notifications: The majority of notifications related to PET-CT and PET-MR imaging (53%). Operator errors involving preparation and administration are still the primary source of notifications: the number of errors relating to incorrect administration of a radiopharmaceutical doubled from 5 to 10 in 2022/23. There has also been year-on-year increase in notifications relating to hardware failure and referrers failing to cancel requested examinations.

Radiotherapy notifications: There has been an increase in the number of notifications in radiotherapy from the previous year, which reflects that more treatment was being provided. Notifications were almost entirely in planning and verification imaging, which increased from 110 to 146 notifications. These related to a continued increase in the use of short course fractionation regimes, for example five fraction breast treatments, and incorrect patient set-up that resulted in the need for additional imaging, which triggers the notification threshold.

Inspections

In 2022/23, we inspected:

- 14 diagnostic imaging departments
- 6 nuclear medicine services

- 11 radiotherapy departments.

Key trends and concerns

- As in previous years, a key source of errors continued to be when the wrong patient received an examination that was meant for another patient. Inadequate checks about the patient's identity by both the referring clinician and the operator were common causes of errors.
- There was a need to ensure that procedures, protocols and guidance for staff are up-to-date and effective. Internal processes to audit and improve compliance and processes when investigating incidents also needed to improve.
- Many of our regulatory recommendations involved the need to improve the quality and availability of training records for staff.

Introduction

The Ionising Radiation (Medical Exposure) Regulations 2017 are known as IR(ME)R. They provide a regulatory framework to protect people against the dangers from being exposed to ionising radiation in a healthcare setting. The regulations state that each individual exposure should be justified and optimised to make it as effective as possible, and to ensure that the benefit for the patient outweighs the risk.

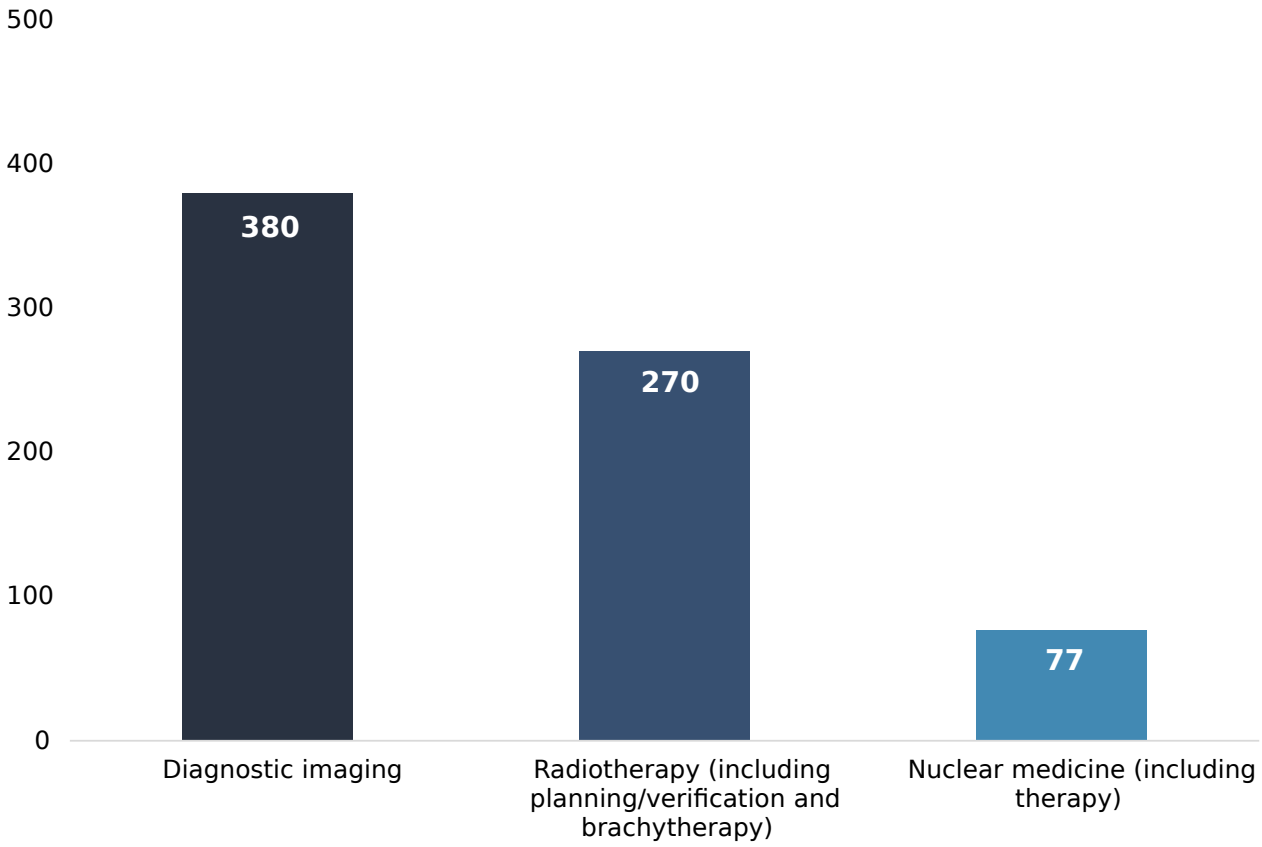
We enforce the regulations in England through on-site inspections and by reviewing statutory notifications from healthcare services about significant accidental or unintended exposures to patients. In this report, we provide an update on what we found from notifications received in the period 1 April 2022 to 31 March 2023, and from our inspection and enforcement activity over this period.

We also highlight some key concerns around compliance with the regulations and provide actions for IR(ME)R employers to take to improve the quality and safety of care.

Notifications received in 2022/23

- From 1 April 2022 to 31 March 2023, we received 727 statutory notifications of significant accidental and unintended exposures (SAUE notifications) across all modalities. This compares with 611 received in 2021/22, an increase of 19%.
- The largest proportion of notifications came from diagnostic imaging (52%).

Figure 1: Notifications received by modality, 1 April 2022 to 31 March 2023



Source: CQC notifications data 2022/23

Activity data in England

NHS England collects information about tests carried out on NHS patients in England in the Diagnostic Imaging Dataset. Data for 2022/23 shows that between April 2022 and March 2023, NHS services in England carried out 43.5 million imaging tests across all modalities. Of these examinations, 29.2 million used ionising radiation (including plain film X-rays, CT, fluoroscopy, nuclear medicine, PET-CT and SPECT, as opposed to other types of test such as ultrasound, MRI scans or medical photography).

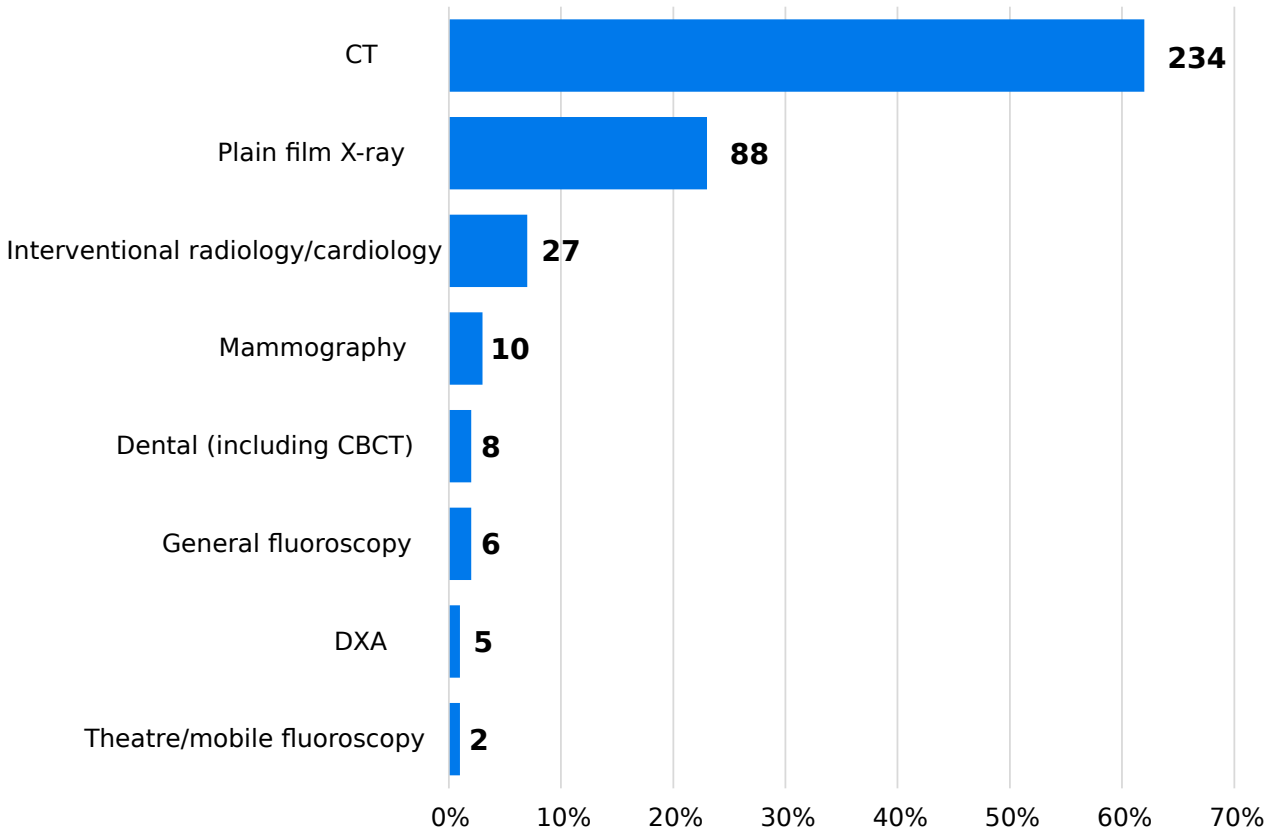
The Radiotherapy Dataset (RTDS) is managed by the National Disease Registration Service (NDRS). It collects, curates and analyses data on all radiotherapy activity delivered in NHS hospitals in England. In 2022/23, there were over 142,000 episodes of radiotherapy treatment in England, an increase of 10% on the previous year.

Note: the completeness of radiotherapy activity data varies by NHS trust and trusts may submit historical data at a later date. Therefore, it is possible that some data may still be missing and that there may be changes to overall figures as the RTDS is updated over time.

Notifications from diagnostic imaging

- 380 notifications received (366 notifications received in 2021/22)
- represents 52% of all notifications received
- 89% of notifications were from NHS acute trusts
- the highest proportion of notifications from diagnostic imaging (62%) was from CT (computed tomography)

Figure 2: Notifications from diagnostic imaging received by sub-modality, 1 April 2022 to 31 March 2023



Source: CQC SAUE notifications data 2022/23

Note: Figures may not add to 100% due to rounding

Types of error

As in the previous year, the most common error was where a patient received an examination meant for another patient (25% of all diagnostic imaging notifications).

We received 60 notifications where the wrong patient had been referred for diagnostic imaging examinations, and 35 where the operator failed to correctly identify a patient. Operator errors accounted for the highest origin of incidents (45%), followed by referrer errors (26%). Again, this is similar to the previous year.

We have seen a notable increase in the number of incidents due to the operator either setting up the patient incorrectly or selecting an incorrect protocol (79 incidents, up from 44 last year).

Figure 3 shows the number of detailed errors where tier 1 is the causative factor, with tiers 2 and 3 the contributory factors.

Figure 3: Notifications from diagnostic imaging by detailed error type, 1 April 2022 to 31 March 2023

Tier 1: Employer (3 notifications)

Tier 2	Tier 3
Employer's responsibility (3)	Equipment not fit for purpose (2) Inadequate training/supervision (1)

Tier 1: Referrer (99 notifications)

Tier 2	Tier 3
Incorrect referral (65)	Wrong patient (60) Wrong requested modality (3) Wrong timing (2)
Incorrect information (34)	Failure to cancel (16) Duplicate/no check of previous imaging (15) Inaccurate clinical information (3)

Tier 1: Practitioner (13 notifications)

Tier 2	Tier 3
Justification (9)	Incorrect justification (9)
Safety checks (2)	Imaging history check failure (2)
Protocol (2)	Illegible/unclear protocol (2)

Tier 1: Operator (170 notifications)

Tier 2	Tier 3
Pre-exposure checks (95)	Wrong patient position/setup/protocol (79) Wrong use of equipment (16)
Patient checks (38)	Patient ID error (35) Failure to check pregnancy/ breastfeeding (3)
Clinical history (18)	Failure to check history/details (18)
Post examination (14)	Failure to upload images (9) Reporting failure (5)
Authorisation (5)	Incorrect authorisation (5)

Tier 1: Equipment (52 notifications)

Tier 2	Tier 3
Equipment related (52)	Hardware (26) Software (14) IT failure (11) Ancillary failure (1)

Tier 1: Other (43 notifications)

Tier 2	Tier 3
DRL/Deterministic (20)	Deterministic effects (10) 10x DRL (10)
Patient related (8)	Unknown pregnancy (5) Patient issue (3)
Made in error or withdrawn (12)	Duplicate notification/other error (11) Below threshold (1)
Administrative staff error (1)	RIS input error (1)
Test results (1)	Request based on incorrect results (1)

Tier 2	Tier 3
Other (1)	Not listed (1)

Total notifications 380

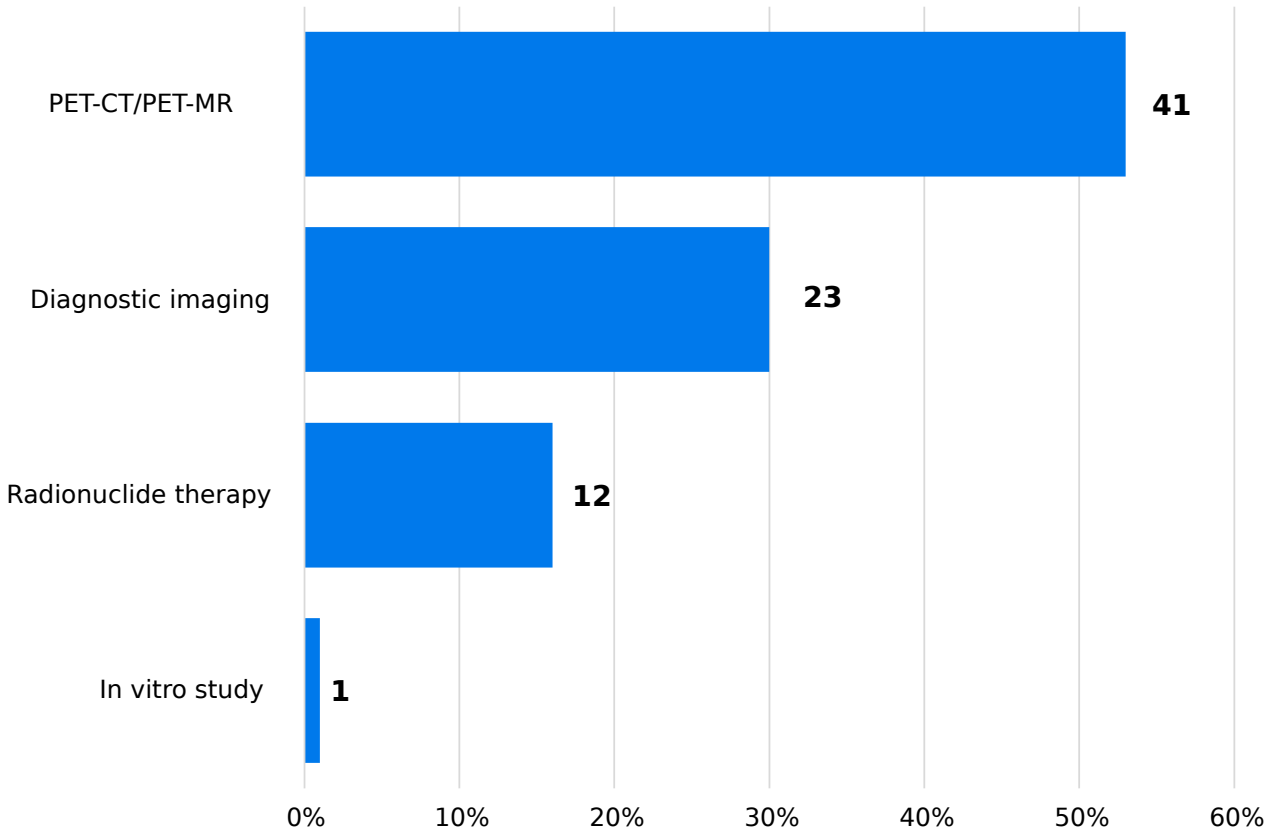
Notifications from nuclear medicine

- 77 notifications received (63 notifications in 2021/22)
- Represents 11% of all notifications received
- 71% of notifications were from NHS acute trusts
- 27% of notifications were from independent healthcare providers
- 53% of notifications related to PET-CT and PET-MR studies

There continues to be an increase in the number of nuclear medicine notifications compared with previous years. Notifications from PET imaging now make up more than half of those received in this modality (up from 38% last year), and account for the increase in total notifications received from 2021/22 to 2022/23.

These figures do not include any notifications relating to licensing breaches, where a SAUE did not occur. We manage these voluntary notifications through a separate process and webform.

Figure 4: Notifications from nuclear medicine by sub-modality, 1 April 2022 to 31 March 2023



Source: CQC SAUE notifications data 2022/23

Note: Figures may not add to 100% due to rounding

Types of error

As in previous years, most notifications related to operator errors, but they represent a smaller proportion (27% this year compared with 38% in 2021/22). The number of mistakes by operators in the administration of radiopharmaceuticals has increased (from 5 to 10).

In 2022/23, we received more nuclear medicine notifications related to referrer and equipment errors. This has increased the total number of nuclear medicine notifications. Hardware related incidents have nearly doubled since last year, suggesting that ageing equipment continues to affect service delivery in nuclear medicine. Ancillary system failures also continue to be a common contributing factor to equipment breakdowns.

There has also been a large increase in the number of notifications from referrers failing to cancel requests. This re-iterates the importance of effective cancellation processes. Employers must provide clear instructions for referrers on how they should cancel requests, particularly when requesting electronically. Many errors happened because referrers should have contacted departments directly to cancel, but instead they cancelled using e-requesting, which was not then communicated to the radiology information system (RIS) or department ahead of the appointment.

We also received one notification caused by inadequate employer's procedures relating to pregnancy checks. It is imperative that employers implement appropriately detailed procedures and protocols for duty holders to follow.

Figure 5 shows the number of detailed errors where tier 1 is the causative factor, with tiers 2 and 3 the contributory factors.

Figure 5: Notifications from nuclear medicine by detailed error type, 1 April 2022 to 31 March 2023

Tier 1: Employer (1 notification)

Tier 2	Tier 3
Employer's responsibility (1)	Inadequate procedures (1)

Tier 1: Referrer (19 notifications)

Tier 2	Tier 3
Incorrect information (10)	Failure to cancel (10)
Incorrect referral (9)	Wrong patient (7) Wrong requested modality (2)

Tier 1: Practitioner (1 notification)

Tier 2	Tier 3
Justification (1)	Incorrect justification (1)

Tier 1: Operator (21 notifications)

Tier 2	Tier 3
Pharmaceutical/Contrast (18)	Administration (10) Preparation (8)
Clinical history (1)	Failure to check history/details (1)
Patient checks (1)	Patient ID error (1)

Tier 2	Tier 3
Pre-exposure checks (1)	Wrong use of equipment (1)

Tier 1: Equipment (19 notifications)

Tier 2	Tier 3
Equipment related (19)	Hardware (13) Ancillary failure (4) IT failure (1) Software (1)

Tier 1: Other (16 notifications)

Tier 2	Tier 3
Administrative staff error (5)	RIS input error (3) Other admin error (2)
Patient related (3)	Patient (2) Unknown pregnancy (1)

Tier 2	Tier 3
Made in error or withdrawn (1)	Duplicate/other (1)
Test results (1)	Request based on incorrect results (1)
Other (6)	Not listed (6)

Total notifications 77

Source: CQC SAUE notifications

Licensing notifications

Employers can notify us voluntarily about licensing breaches using a separate webform, as this is outside of the process for statutory notification of SAUEs. We have received only a small number of notifications in this area, but key themes included:

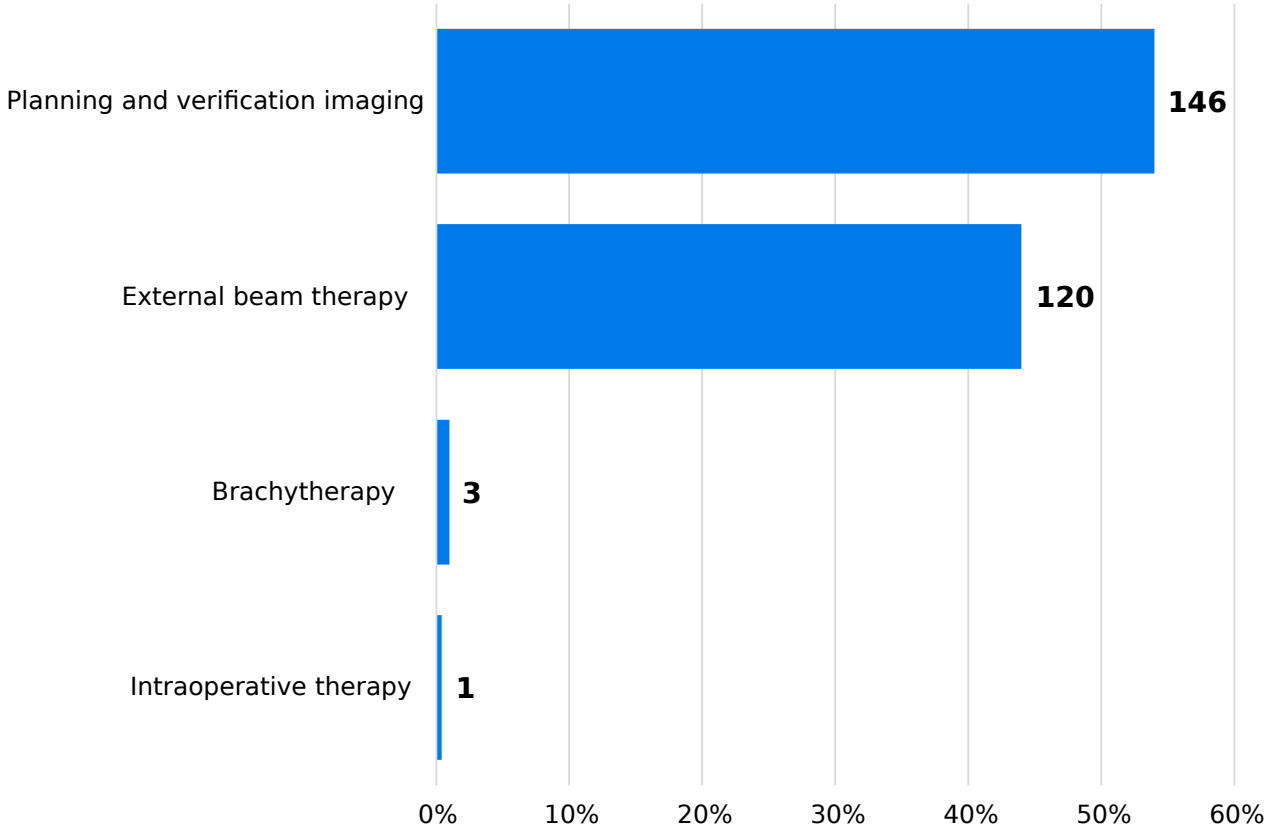
- omitting certain procedures from the application form when applying for a new or renewed licence
- carrying out procedures under a research licence that has expired after the trial had ended, without applying for a new licence for routine use
- using an incorrect radiopharmaceutical that was appropriate for the type of study, but different from that specified on the employer licence.

Employers must review licences regularly, so they are aware when all licences are due to expire – not just employer licences. When renewing or applying, individuals should take care to include all relevant procedure codes.

Notifications from radiotherapy

- 270 notifications received (182 notifications received in 2020/21)
- represents 37% of all notifications received
- 94% of notifications were from NHS acute trusts
- planning and verification imaging accounted for 54% of all radiotherapy notifications received

Figure 6: Notifications from radiotherapy by sub-modality, 1 April 2022 to 31 March 2023



Source: CQC SAUE notifications data 2022/23

Note: Figures may not add to 100% due to rounding

Types of error

In 2022/23, we received more notifications in radiotherapy than the previous year. This was almost entirely in planning and verification imaging, which increased from 110 to 146 notifications. This was due to a continued increase in the use of short course fractionation regimes, for example five fraction breast treatments. Furthermore, if any additional image needs to be taken because of equipment or procedural failure when carrying out these regimes, it triggers the notification threshold.

Figure 7 shows the number of detailed errors where tier 1 is the causative factor, with tiers 2 and 3 the contributory factors.

Figure 7: Notifications from radiotherapy by detailed error type, 1 April 2022 to 31 March 2023

Tier 1: Referrer (19 notifications)

Tier 2	Tier 3
Incorrect information (8)	Failure to check relevant patient RT history (8)
Incorrect referral (11)	Not in accordance with guidelines (6) Wrong treatment protocol or dose requested (5)

Tier 1: Practitioner (5 notifications)

Tier 2	Tier 3
Justification (5)	Failure to cancel radiotherapy (2) Incorrect justification (1) Justify/authorise wrong plan or treatment protocol on prescription (2)

Tier 1: Operator (178 notifications)

Tier 2	Tier 3
Patient checks (2)	Patient ID error (2)
Pre-exposure checks (10)	Wrong patient position/set-up/protocol (9) Wrong use of equipment (1)
Planning (37)	Inappropriate plan generated (17) Inappropriate verification carried out (7) Incorrect data transfer/input (10) Wrong dataset used (3)
Pre-treatment (11)	Incorrect scan protocol selected/procedure followed (2) Marking of patient or immobilisation device (8) Positioning of patient (1)

Tier 2	Tier 3
Treatment (118)	Geographical miss - no verification image (5) Geographical miss - shift error (8) Geographical miss - verification image offline (14) Geographical miss - verification image online (11) Incorrect immobilisation applied (47) Incorrect verification image type selected (25) p-ID/queuing error (7) Skin app treatment (1)

Tier 1: Equipment (52 notifications)

Tier 2	Tier 3
Equipment related (52)	Ancillary failure (2) Hardware (24) IT failure (1) Software (25)

Tier 1: Other (16 notifications)

Tier 2	Tier 3
Administrative staff error (1)	Other admin error (1)
Clinically significant (1)	Not related to other (1)
Made in error or withdrawn (8)	Below threshold (1) Duplicate notification/other error (7)
Patient related (4)	Patient (2) Unknown pregnancy (2)
Other (2)	Not listed (2)

Total notifications 270

Inspections and enforcement activity in 2022/23

Using a graded approach to regulatory activity

We reviewed our approach to scheduling inspections in response to findings from the International Atomic Energy Agency's peer review in 2019. Along with the IR(ME)R enforcement authorities in Wales, Northern Ireland and Scotland, we take a graded approach to our work.

Our approach to the levels of analysis, frequency of inspection and actions we are required to take are proportionate to the extent of the radiological hazards posed by the modality or practice. In practice, we therefore focus more resources on those areas that pose a greater potential radiological risk to patients, such as radiotherapy and nuclear medicine therapies, and less on those such as dental and plain film X-ray.

Diagnostic imaging

Inspections during the year included:

- 7 diagnostic imaging centres
- 6 chiropractic inspections
- 2 dental inspections

Across the 7 inspections of diagnostic imaging centres, we found 12 cases of non-compliance with the regulations and we made 24 recommendations following inspection activity. Some more detailed examples are in the key themes section.

Regulations 6(1), 6(2) and 6(5)(b): As in previous years, the most common recommendations related to the employer's procedures. We made 12 recommendations to ensure that employers have a full set of procedures that clearly support staff when delivering care, and that reflect clinical practice.

Other recommendations related to regularly testing equipment performance and ensuring that training records for practitioners and operators are available and up-to-date.

We also issued 6 Improvement Notices, 2 of which were from chiropractic inspections. See further information on these in our enforcement register.

Nuclear medicine

We carried out 3 inspections and made 10 recommendations relating to:

- **Regulation 6, 6(1)(a), 6(2):** reviewing the employer's procedures to ensure they are reflective of current practice and contain sufficient detail to exclude pregnancy, and that duty holders can access them (3 recommendations)
- **Regulation 6(5)(a):** making referral guidelines available to both internal and external referrers (1 recommendation)
- **Regulation 6(5)(c):** ensuring diagnostic reference levels for the CT component of hybrid imaging studies are available to operators (1 recommendation)
- **Regulation 7:** planning and undertaking routine clinical audit (1 recommendation)
- **Regulation 12(1):** ensuring that patient doses are kept as low as reasonably practicable through an ongoing programme of optimisation (2 recommendations)
- **Regulation 15(2):** including all required fields in the equipment inventory (1 recommendation)
- **Regulation 17(4):** having clear and up-to-date training records for all practitioners and operators (1 recommendation)

We also issued one Improvement Notice relating to providing referral guidelines, quality-assuring written procedures and protocols, and establishing authorisation guidelines for practitioners without a licence.

Radiotherapy

We carried out 11 inspections, one of which was of a brachytherapy service. From these inspections, we issued 3 Improvement Notices and made 30 recommendations, which included:

- **Regulations 6(1) and 6(5)b:** reviewing the employer's procedures to ensure they reflect clinical practice, with an appropriate quality assurance process (11 recommendations)
- **Regulation 8(2):** ensuring that the study of risk relating to accidental and unintended exposures for all aspects of radiotherapy was present and reflective of practice (3 recommendations)
- **Regulation 8(4):** ensuring that there was a clear process relating to the management of clinically significant unintended and accidental exposures and overall management of incidents (7 recommendations)
- **Regulation 15(2) and 15(6)a:** ensuring that equipment QA processes are robust, and that the equipment inventory contains the correct information (2 recommendations)
- **Regulations 17, 17(2) and 17(4):** training records for duty holders, with particular focus on practitioners (7 recommendations)

We issued Improvement Notices against:

- **Regulations 6(1)b & 15(1)a**: where there was no documented process for commissioning new equipment and a subsequent failure to calibrate the machine effectively
- **Regulation 8(4):** where the service did not have an adequate process for incident management and therefore multiple incidents were not reported to the regulating authority in line with the regulations
- **Regulation 11(5):** where there were no authorisation guidelines to enable operators to authorise exposures in the practitioner's absence

Key themes and concerns in 2022/23

When we identify significant concerns and recurring themes in our work, we share the learning to provide actions that can help employers to improve in these areas.

Key themes in diagnostic imaging

Referral errors

We received 99 notifications relating to errors by referrers. Of these, 60 related to the wrong patient, 16 were due to the scan not being cancelled in time, and a further 15 were due to not checking previous imaging.

In many cases, the error could have been prevented by having more robust systems or making additional checks. For example, in many cases opportunities were missed by not checking the clinical indications against the person having the procedure.

Some providers have considered additional steps and equipment to try to reduce manual errors, such as using barcode scanners instead of having to type in the patient's ID number.

Actions for employers

- Think about how the referral pathway works in practice, such as when cancellations are needed.
- Think of different methods to cut down on potential input errors, such as using barcode scanners.

- Make sure staff are trained and understand the importance of following additional steps beyond the patient ID check.

Fluoroscopy training for radiologists

We received multiple notifications regarding unintended doses in fluoroscopic procedures where the radiologist was operating the equipment. The primary cause of the notifications was a lack of training in using the equipment, leading to errors such as:

- using acquisition instead of fluoroscopy
- switching to inappropriate clinical protocols
- performing incorrect acquisition runs when fluoroscopy was more suitable because of a misunderstanding in terminology.

Actions for employers

- Make sure radiologists are trained on equipment specific features and have adequate in-person supervision where appropriate.
- Clarify any terminology that staff may misunderstand, especially for new members of staff or those who work at multiple sites.

Dental over-exposures

We received notifications where multiple patients had received over-exposures as part of a dental examination. The cause of the errors was a result of altering either protocol settings or equipment features (such as collimation attachments) and not subsequently correcting them.

For these notifications, there were several notable contributing factors:

- Some members of staff were not always adequately trained on the site-specific equipment features, and therefore did not recognise the implications of making changes.
- In some cases, staff were not aware that settings had been changed and subsequently did not notice.
- Spot checks or audits were not carried out following maintenance visits, which may have picked up the alterations.

Actions for employers

- Train staff sufficiently on equipment features and their potential dose implications.
- Make sure staff know when to escalate queries or concerns around changing equipment settings.
- Carry out spot audits following visits from external contractors to ensure that the equipment settings and set-up remain optimised.

Key themes in nuclear medicine

Through our work in nuclear medicine over 2022/23, we have identified some concerns and themes in specific areas. We've taken the learning from these to provide some actions that employers can take to help encourage improvement in these areas.

Incorrect radiopharmaceuticals and operator errors

In April 2023, we published the latest version of the guidance on significant accidental and unintended exposures (SAUEs), which added a new category. This addition makes all instances reportable where a patient received the incorrect radiopharmaceutical – regardless of activity or dose. We added this to address the upwards trend of operator errors in preparation or administration of radiopharmaceuticals.

Unsafe staffing levels are often contributing factors for these incidents, with operators being forced to rush due to high workloads and therefore missing key checks. Often, another operator had not carried out a second check, or this second operator did not check all elements, for example, vial label, calibrator setting, or syringe volume.

Actions for employers

- Review the staffing levels to ensure that operators can carry out critical safety checks.
- Review and adapt patient lists when staffing levels are reduced.
- Have a clear procedure to make second checks of radiopharmaceuticals at both preparation and administration stages, detailing the factors that should be checked.
- Make sure the process involves confirming in writing that the first and second checks have taken place and by whom.
- Ensure that both operators are adequately trained to detect any errors.

Coordinating sentinel lymph node biopsy procedures

We received 4 notifications relating to sentinel lymph node biopsy (SLNB) procedures in 2022/23. In all 4 incidents, inadequate communication between surgical and nuclear medicine departments was the root cause. In 3 instances, failure to notify the nuclear medicine department of cancelled surgeries meant patients received an unnecessary administration of a radiopharmaceutical. In the other case, not enough injections were requested for the list, which meant the patient could not receive the full number.

Although the radiation exposure from these administrations is very low, it indicates a theme of poor communication between hospital departments, which has a negative effect on patients.

Actions for employers

- Review the co-ordination and communication processes between departments and improve where necessary.
- Establish clear processes to communicate when there are changes and cancellations of surgical lists.

Pregnancy procedures for nuclear medicine

Regulation 6 and Schedule 2 of IR(ME)R 17 require the employer to have procedures that include establishing whether a person is or may be pregnant or breastfeeding. The risk to patients who are pregnant or breastfeeding, and their children, is different in nuclear medicine, due to the systemic administration of radiopharmaceuticals. As such, pregnancy procedures must set out specific arrangements for nuclear medicine examinations and include information on when to test for pregnancy. For some therapeutic administrations, confirmation of menstrual history is not sufficient to exclude pregnancy, due to the risk to the foetus.

Actions for employers

- Ensure procedures to check for pregnancy include specific arrangements for procedures involving the administration of radiopharmaceuticals.
- Consider relevant publications, including the ARSAC Notes for Guidance, when writing and reviewing procedures.
- Review the current measures for excluding the possibility of pregnancy before carrying out therapeutic exposures, and include the process for pregnancy testing, where appropriate.

Key themes in radiotherapy

Through our work in radiotherapy over 2022/23, we have identified some concerns and themes in specific areas. We've taken the learning from these to provide some actions that employers can take to help encourage improvement in these areas.

Brachytherapy authorisation guidelines

IR(ME)R states that a medical exposure to ionising radiation cannot take place unless the referral has been justified and authorised (Regulation 11(1)(c)).

- **Justification** is the responsibility of the practitioner – in the case of brachytherapy treatments, the practitioner must hold a practitioner licence from the Administration of Radioactive Substances Advisory Committee (ARSAC) (IR(ME)R Reg 5).
- **Authorisation** is a separate process to justification and is the documentation confirming that justification has taken place.

Where it is not possible for the practitioner to authorise every exposure, they may issue written authorisation guidelines to allow appropriately trained and entitled operators to authorise these exposures (IR(ME)R Regulation 11(5)). Authorisation may be carried out by either a practitioner or an operator in accordance with the authorisation guidelines. Practitioners and operators should be entitled to authorise referrals following the employer's procedures. A letter from the practitioner permitting an operator to authorise under their practitioner licence is not sufficient to meet the requirements of IR(ME)R.

An ARSAC practitioner licence is not required for individuals who authorise exposures according to authorisation guidelines or who perform other practical aspects of the exposure such as treatment planning, insertion, and clinical evaluation. Authorisation guidelines should be written within the local protocols and available to the operator following the authorisation guidelines.

Actions for employers

- When using authorisation guidelines, make sure they are written and ratified by one named IR(ME)R practitioner. When medical staff are acting under the supervision of a licensed practitioner, this should be as part of their training and the practitioner should be involved in oversight and mentorship, with appropriate authorisation guidelines in place.
- Once appropriately qualified and trained, medical staff should obtain their own licence and be entitled as a practitioner. The practitioner should have oversight of the procedure for which they are responsible.

Employers' procedures

Regulation 6(1) requires the employer to have written procedures, as specified in Schedule 2, as a minimum – they may provide additional Schedule 2 procedures than the minimum required by IR(ME)R.

We have made recommendations against Regulation 6 where employers' procedures read more as a 'policy statement'. These described **why** a procedure was being carried out, rather than providing duty holders with specific procedural steps to follow.

Actions for employers

Make sure your employer's procedures are documented and that they define the responsibilities of the duty holders involved in the process. They should include clear instructions on how and when a process should be carried out and who is responsible.

SAUE threshold awareness

Regulation 8 requires the employer to have systems and procedures to reduce the likelihood of a SAUE occurring and to appropriately manage incidents that do happen.

Most centres use commercially available incident management systems that all duty holders can use to report incidents when they happen. In these systems, all incidents are logged on the system – ideally by the individual who was either involved with or discovered the occurrence, regardless of its severity. Incidents are then triaged and reviewed by either a dedicated individual or group, who grades them and escalates appropriately. Following an investigation or closure of the incident, the reporting individual is then informed of the outcome.

This approach means centres are confident that all exposures that meet the threshold for notification to the regulating authority are reported, as all incidents – regardless of severity – are captured.

However, during our inspections we have found that, because of this, duty holders and operators appear to have poor awareness of what constitutes a notifiable incident and there is significant confusion, especially in relation to verification imaging thresholds. The system also relies heavily on the triage process in identifying events that are notifiable.

We have issued multiple enforcement notices and recommendations against Regulation 8 relating to incidents not being reported to the regulating authority in line with the regulations. These resulted from an inadequate triage process that was exacerbated by lack of awareness by the reporting individual.

Actions for employers

- Make sure all duty holders are aware of the notification thresholds for reporting to the regulating authority.
- Check that the triage process for assessing incidents involves more than one person to ensure that the process is robust.

Other IR(ME)R related activity

Guidance on significant accidental and unintended exposures

In January 2023, we completed a complete review of the SAUE guidance and statutory notification criteria in consultation with the devolved administrations of Scotland, Northern Ireland and Wales, and with advice from the Medical Exposures Group at the UK Health Security Agency. This was to ensure that the notification criteria keep pace with developments and changes in clinical practice and that the requirement for notifying the relevant enforcing authorities remains accurate.

Summary of the changes

Clinically significant accidental and unintended exposures

Regulation 8(1) refers to the employer's responsibilities when an incident is considered as 'clinically significant' (CSAUE), which must also be notified to the appropriate enforcing authority under Regulation 8(4). The regulations do not define CSAUE, but the Royal College of Radiologists and other professional bodies provide guidance to help employers in establishing what constitutes a clinically significant accidental or unintended exposure:

- IR(ME)R: Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine
- Radiotherapy Board guidance

We remind employers of their responsibility to apply the duty of candour for CSAUE events.

Incorrect radiopharmaceutical administration

A new reporting category now captures all administrations of an incorrect radiopharmaceutical, regardless of the dose to the patient. This applies even when the correct isotope was given but with the wrong tracer, for example technetium-99m MAA instead of technetium-99m HDP.

Interventional radiology and cardiology: summary of change

Determining the extent of any 'unintended' dose across the range of examinations and treatments in interventional radiology and cardiology is complex.

The UK enforcing authorities have determined that the following must be reported:

- all procedural failures resulting in observable deterministic effects (excluding transient erythema)
- procedures that do not have a procedural error but result in unintended or unpredicted observable deterministic effects.

Radiotherapy treatment verification imaging

There is no change to the threshold relating to images in a single fraction (category 4.2a). However, the thresholds for notifications relating to imaging exposures over the course of treatment have changed (4.2b and 4.2c).

In this previous threshold:

"When the number of additional imaging exposures is 20% greater than intended over the course of treatment due to protocol failure or equipment error".

The threshold has increased to 50%. This is to reflect the increase in short course fractionation treatments and the relatively low dose of verification images.

You now only need to make notifications in the following situations:

- Set-up error leads to 3 or more imaging exposures in a single fraction (including the intended image, which is 3 images in total).
- When the number of additional imaging exposures is 50% greater than intended over the course of treatment as a result of protocol failure.
- 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.

These thresholds apply to all radiotherapy treatment regimes, including radical short course fractionation (classed as 10 fractions or less). Examples of thematic failure could be a persistent equipment fault or repeated human factor error. However, we rely on employers to use professional judgement to identify themes.

Foetal dose

The reporting threshold for foetal exposures has changed. Previously a procedural failure was needed to instigate reporting, but this is no longer the case. However, the dose threshold has been raised from 1 mGy to 10 mGy, in line with guidance from the Royal College of Radiologists Protection of Pregnant Patients during Diagnostic Medical Exposures to Ionising Radiation.

Therefore, you must report if a foetus has an exposure over 10 mGy – even when procedures were followed.

Statutory instrument review

The Department of Health and Social Care must review the regulations every 5 years. The review process began in 2022, comprising a post-implementation review and is being followed with a full review of the IR(ME)R in consultation with relevant stakeholders and enforcing authorities.

The review process has been ongoing through 2022/23 and the conclusion is expected to be published in April 2024.