

# IR(ME)R annual report 2023/24

CQC is the competent authority in England for enforcement of the Ionising Radiation (Medical Exposure) Regulations 2017, known as IR(ME)R.

The regulations provide a regulatory framework to protect people against the dangers from exposure to ionising radiation as part of their diagnosis and treatment in healthcare settings. We receive and investigate notifications of radiation incidents where patients have received an accidental or unintended exposure, and we inspect IR(ME)R employers to ensure that they comply with the regulations.

Ionising radiation is fundamental to the diagnosis, surveillance, and treatment of a variety of health conditions and is an integral part of the majority of patient care pathways. It includes, for example, chest X-rays, CT scans and nuclear medicine examinations, to treatment of disease using nuclear medicine therapies and cancer treatments using external beam and brachytherapy.

The regulations state that every exposure needs to be justified and optimised to ensure that the benefit for the patient outweighs the risk.

In this report, we provide an update on what we have found from our inspections and the statutory notifications that we received of significant accidental and unintended exposures (SAUE). We share an overview of compliance with the regulations, and some examples of the actions that IR(ME)R employers have taken to improve the quality and safety of care, so that other employers, healthcare professionals and academic bodies can learn from them.

# Total activity in 2023/24

To provide context regarding the number of errors that happen compared with the total number of imaging tests carried out in England, we look at the [Diagnostic Imaging Dataset from NHS England](#). This collects information about tests carried out on NHS patients in England.

[Data for 2023/24](#) shows that between March 2023 and February 2024, NHS services in England carried out 45.5 million imaging tests across all modalities used (43.5 million in 2022/23).

In this report, we only focus on those examinations that use ionising radiation. This includes plain film X-rays, CT, fluoroscopy, nuclear medicine, PET-CT and SPECT, as opposed to other types of tests such as ultrasound, MRI scans or medical photography

In 2023/24, 30.6 million diagnostic examinations used ionising radiation (29.2 in 2022/23).

We can also compare the number of notifiable errors with the Radiotherapy Dataset (RTDS), which is managed by the [National Disease Registration Service \(NDRS\)](#) from NHS England. It collects, curates and analyses data on all radiotherapy activity delivered in NHS hospitals in England.

In 2023/24, there were over 116,000 episodes of radiotherapy treatment in England.

**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.

# Summary

## Key findings in 2023/24

Statutory reporting has seen an upward year-on-year trend in the annual number of accidental and unintended exposures that are notified to us. We believe this is a generally positive indicator of a good patient safety culture in medical exposure to ionising radiation.

But although we received a higher overall number of notifications, some medical radiological services with high levels of activity across a range of imaging modalities that provide complex medical exposures did not report a single event during 2023/24. Low rates of reporting and no reporting at all may indicate inadequate systems and processes to identify, manage and report incidents. We will therefore prioritise services with low and no reporting in our ongoing risk-based approach to inspections to determine compliance with the regulations.

## Effective procedures, protocols and guidance

Employers need to ensure that procedures, protocols and guidance for staff are up-to-date and effective, and to improve processes when investigating incidents.

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.

## Justification and authorisation

We also continue to find confusion around justifying and authorising medical exposures. As radiographic practice continues to expand and more advanced practice qualified radiographers are working in clinical areas, it is important to differentiate between:

- individuals who are adequately trained and entitled under an approved scope of practice to justify and authorise
- those who are authorising an exposure under guidelines.

## Workforce

A further concern from our work continues to relate to the shortages of medical physics experts (MPEs). We recognise the chronic shortages in the medical physics workforce and the need for a solution to increase numbers of MPEs across the country. We believe there is not enough emphasis on the importance of the medical physics expert and the physics workforce generally, and we also find that MPE workforce requirements are not factored into the procurement business cases for new equipment. Scientific staff need appropriate time and resources to quality assure equipment and fulfil all the duties under the regulations. But it is frequently noted that they have had to take on more work with limited or no increase in the workforce capacity.

## Statutory notifications of errors received in 2023/24

From 1 April 2023 to 31 March 2024, we received 819 statutory notifications of significant accidental and unintended exposures (SAUE notifications) that met the defined thresholds of notifiable events across all methods of treatment (modalities).

This compares with 727 received in 2022/23, an increase of 13%.

## Diagnostic imaging

- 447 notifications received (an 18% increase from 2022/23).
- Most notifications in diagnostic imaging were from CT (computed tomography) scans (65%), followed by plain film x-ray (25%). This is similar to the previous year.

- The most common type of error in diagnostic imaging (26%) noted this year is where a patient received an examination meant for another patient. Of the 447 notifications, 88 (20%) involved the wrong patient being referred for a diagnostic examination and a further 27 (6%) involved the wrong patient being exposed due to an identification (ID) error.
- Similarly to last year, operator errors accounted for the highest origin of incidents reported to us (41%), followed by referrer errors (33%).

## Radiotherapy

- 244 notifications (a 10% decrease from 2022/23)
- The decrease was almost entirely in planning and verification imaging (down from 146 to 108 notifications), due to amended thresholds for notifications to reflect changes in episode regimes.

## Nuclear medicine

- 128 notifications (a 66% increase from 2022/23).
- 88% of notifications related to diagnostic nuclear medicine and PET-CT/PET-MR studies.
- The number of notifications relating to preparation or administration of a radiopharmaceutical have increased with the introduction of a new notification category in this area.
- The number of notifications relating to hardware failure have increased during the last year.
- Although we received fewer notifications where referrers have failed to cancel requested examinations, we are still seeing incidents where an unintended dose has been administered.

## Inspections in 2023/24

In 2023/24 we carried out 40 inspections (compared with 35 in 2022/23). These were a mix of proactive inspections as part of the IR(ME)R annual inspection programme and reactive inspections in response to concerns and high-risk notifications. We inspected:

- 15 diagnostic imaging departments
- 15 radiotherapy departments
- 10 nuclear medicine services.

## Enforcement

Poor compliance with the regulations is often the result of an inadequate governance framework around radiation protection. We issued 14 Improvement Notices to IR(ME)R employers following inspections.

## Actions for employers to improve compliance

It's important for organisations to not only value and encourage learning from their own experiences, but to avoid complacency by looking beyond themselves for lessons from others. This, in turn, will help to improve patient safety and leadership, and embed a good safety culture.

Based on our findings during 2023/24, we recommend these general actions for IR(ME)R employers to improve compliance with the regulations, as well as the safety and quality of care for patients:

### Policy, procedure and protocol

- High numbers of errors are still resulting from inadequate checks. All IR(ME)R duty-holders must remain vigilant and follow procedures and safe practices, such as multi-point checks, at all stages of a patient's care pathway.

- In IR(ME)R documentation, it's important to differentiate the overall 'policy' aspects from the more practical 'clinical instructions'. It may be useful to separate these so that the working procedures only include the relevant information for the intended audiences, with separate high-level 'managerial' procedures.

## Justification and authorisation

- Carefully consider the role of the practitioner and the associated training needed for radiographers, who may be entitled within local procedures to act in this capacity.
- Provide adequate training, in line with Schedule 3 of IR(ME)R, for any radiographer seeking to be entitled to act as the practitioner. The Society of Radiographers have issued [guidance](#) to support entitlement of individuals other than radiologists to justify and authorise exposures.
- Ensure that all entitlement processes are thorough and effective, and clearly documented within the employer's procedures.

## Non-medical referrers

- Any person entitled to act as a referrer for an ionising radiation examination must be a registered healthcare professional.
- Radiology departments should not have sole responsibility for determining whether there is a service need for the entitlement of non-medical referrers. The relevant departments looking to refer should be engaged in the process and in creating an appropriate scope of practice. They should also be involved in the ongoing management and audit of non-medical referrers.

## Support from medical physics experts

- Ensure that appointed experts are fulfilling the duties required in the regulations. This is especially important when medical physics support is provided by a third party, as contracts must include sufficient resource for the MPE to undertake their responsibilities. Refer to [guidance](#) from the Institute of Physics and Engineering in Medicine for the recommended appropriate MPE support.

## Equipment

- Monitor and manage risk continually where equipment falls below normal standards of performance. This may be through a risk register. Consider how the equipment is used and limit its range where appropriate. Address faults with the equipment manufacturer first, but also report persistent issues to the [Medicines and Healthcare products Regulatory Agency](#) (MHRA).
- Make sure medical physics experts continue to get support from, and share experiences with, special interest groups and the Institute of Physics and Engineering in Medicine, particularly where issues may be widespread.
- Give more scrutiny, in terms of both quality control and routine maintenance, of systems with a history of unreliability and equipment still in clinical use – both towards and past its end of life. Medical physics experts should review the frequency and effectiveness of routine checks of these systems.
- Involve medical physics experts in decisions on purchasing any new piece of equipment to ensure the correct technical specification, and when making any changes to equipment that will affect image quality and patient dose. Include and consult them in any optimisation programme.

# Overall notifications in 2023/24

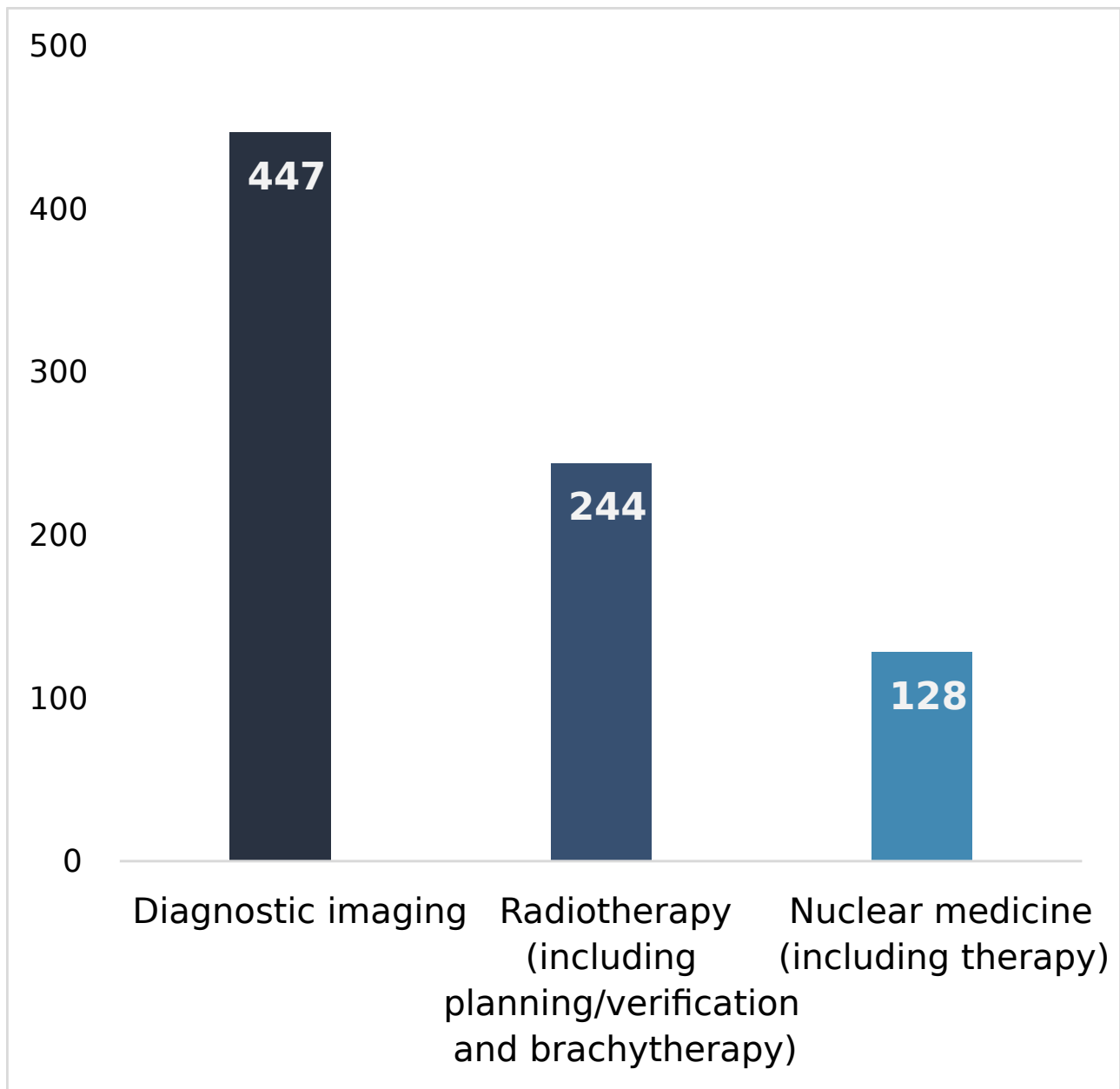


From 1 April 2023 to 31 March 2024, we received 819 statutory notifications of significant accidental and unintended exposures (SAUE notifications) that met the defined thresholds of notifiable events across all methods of treatment (modalities).

This compares with 727 received in 2022/23, an increase of 12%.

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**Figure 1: Total notifications received 1 April 2023 to 31 March 2024 by modality**



Source: CQC SAUE notifications data 2023/24

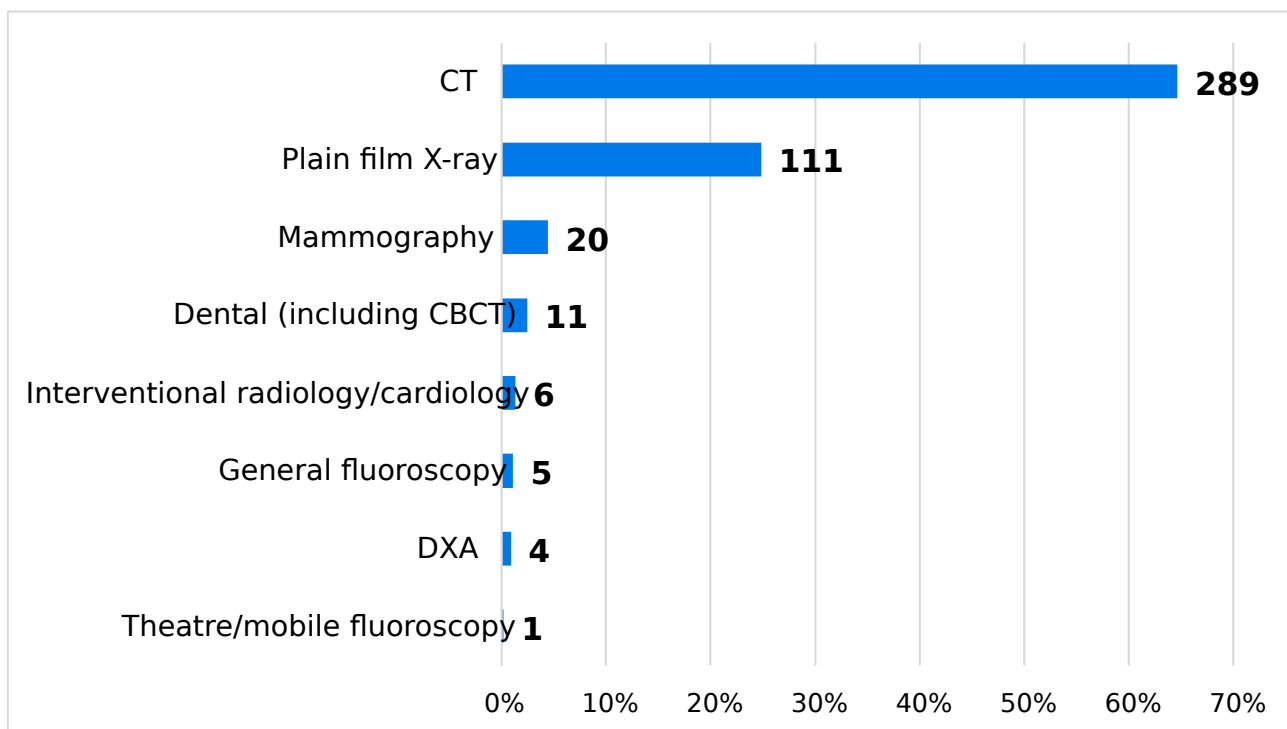
Note: Percentages may not add up to 100% as they have been rounded to the nearest whole number

# Diagnostic imaging activity

Notifications received in 2023/24

- 447 notifications (compared with 380 notifications in 2022/23)
- this represents 55% of all notifications received across all modalities
- 89% of notifications were from NHS acute trusts
- the highest proportion of notifications from diagnostic imaging (65%) was from CT (computed tomography)

**Figure 2: Notifications from diagnostic imaging received by sub-modality, 1 April 2023 to 31 March 2024**



Source: CQC SAUE notifications data 2023/24

Note: Percentages may not add up to 100% as they have been rounded to the nearest whole number

## Types of error

As in previous years, the most common error was where a patient received an examination meant for another patient. Of the 447 notifications, 88 (20%) involved the wrong patient being referred for a diagnostic examination and a further 27 (6%) involved the wrong patient being exposed due to an identification (ID) error.

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 2023 to 31 March 2024**

- Tier 1: The duty holder from whom the error originated
- Tier 2: The point in the pathway where the error first occurred
- Tier 3: What went wrong

Tier 1: Employer (2 notifications)

Tier 2	Tier 3
Employer's responsibility (2)	<ul style="list-style-type: none"> <li>● Equipment not fit for purpose (1)</li> <li>● Inadequate training/supervision (1)</li> </ul>

Tier 1: Referrer (146 notifications)

Tier 2	Tier 3
Incorrect referral (100)	<ul style="list-style-type: none"> <li>● Wrong patient (88)</li> <li>● Wrong timing (10)</li> <li>● Wrong requested modality (2)</li> </ul>
Incorrect information (46)	<ul style="list-style-type: none"> <li>● Failure to cancel (17)</li> <li>● Duplicate/no check of previous imaging (14)</li> <li>● Inaccurate clinical information (15)</li> </ul>

Tier 1: Practitioner (10 notifications)

Tier 2	Tier 3
Justification (8)	<ul style="list-style-type: none"> <li>● Incorrect justification (8)</li> </ul>
Safety checks (1)	<ul style="list-style-type: none"> <li>● Imaging history check failure (1)</li> </ul>
Protocol (1)	<ul style="list-style-type: none"> <li>● Illegible/unclear protocol (1)</li> </ul>

Tier 1: Operator (183 notifications)

Tier 2	Tier 3
Pre-exposure checks (107)	<ul style="list-style-type: none"> <li>● Wrong patient position/setup/protocol (90)</li> <li>● Wrong use of equipment (17)</li> </ul>
Patient checks (29)	<ul style="list-style-type: none"> <li>● Patient ID error (27)</li> <li>● Failure to check pregnancy/breastfeeding (2)</li> </ul>
Clinical history (23)	<ul style="list-style-type: none"> <li>● Failure to check history/details (23)</li> </ul>
Post examination (18)	<ul style="list-style-type: none"> <li>● Failure to upload images (16)</li> <li>● Reporting failure (2)</li> </ul>
Authorisation (5)	<ul style="list-style-type: none"> <li>● Incorrect authorisation (5)</li> </ul>
Pharmaceutical contrast (1)	<ul style="list-style-type: none"> <li>● Preparation (1)</li> </ul>

Tier 1: Equipment (67 notifications)

Tier 2	Tier 3
Equipment related (67)	<ul style="list-style-type: none"> <li>● Hardware (40)</li> <li>● Equipment related (1)</li> <li>● Software (16)</li> <li>● IT failure (7)</li> <li>● Ancillary failure (3)</li> </ul>

Tier 1: Other (39 notifications)

Tier 2	Tier 3
Dose reference level (DRL)/Deterministic (2)	<ul style="list-style-type: none"> <li>● Deterministic effects (1)</li> <li>● 10x DRL (1)</li> </ul>
Patient related (15)	<ul style="list-style-type: none"> <li>● Unknown pregnancy (14)</li> <li>● Patient issue (1)</li> </ul>
Equipment related (1)	<ul style="list-style-type: none"> <li>● Software (1)</li> </ul>

Tier 2	Tier 3
Administrative staff error (10)	<ul style="list-style-type: none"> <li>● RIS input error (6)</li> <li>● Other admin error (4)</li> </ul>
Test results (1)	<ul style="list-style-type: none"> <li>● Request based on incorrect results (1)</li> </ul>
Other (10)	<ul style="list-style-type: none"> <li>● Not listed above (10)</li> </ul>

Total diagnostic imaging notifications: 447

Source: CQC SAUE notifications data 2023/24

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As in the previous year, operator errors accounted for the highest origin of incidents reported to us (183), rather than referrer errors (146). We have seen another notable increase in the number of incidents due to the operator either setting up the patient incorrectly or selecting an incorrect protocol (90 incidents, up from 79 in 2022/23 and 44 in 2021/22).

## Inspections and enforcement



Across our 15 inspections of diagnostic imaging centres, we found 8 cases of non-compliance with the regulations. We made 48 recommendations to help improve awareness and understanding of the regulatory requirements, improve compliance in specific areas and improve patient safety.

Our most common findings of non-compliance were similar to previous years and our recommendations related to:

- **Regulations 6(1), 6(2):** ensuring that all employer's procedures are in place to support staff, and that they reflect current clinical practice
- **Regulation 6(5)(b):** having an established assurance programme for written procedures and protocols
- **Regulations 6(5)(c)** regular review of diagnostic reference levels and enabling operators to access these
- **Regulation 15(2):** maintaining an equipment inventory that includes all information mandated by the regulations
- **Regulation 15(3):** undertaking adequate testing of equipment
- **Regulation 17:** having up-to-date training records available as evidence of adequate training

We also issued 4 Improvement Notices that require the duty holder to take remedial action within a specified timeframe. See further information on these in our [enforcement register](#).

## Key themes in diagnostic imaging

### Referrals outside scope of practice

In the NHS, workforce transformation is enabling changes in how health care is delivered to respond to the changing needs of local populations. This has resulted in an increasing number of staff groups making referrals for ionising radiation examinations. It is the employer's responsibility to entitle individual referrers and ensure that where group entitlement is made, there is a system to identify individuals within that group.

We were informed of unintended exposures from referrals made by members of staff who were not working within their scope of practice. This included both registered and unregistered health professionals.

## Example of error and actions taken

### **Referrals by unregistered healthcare professionals**

The issue was identified when a member of staff asked for additional training on requesting imaging procedures. These procedures were known to be outside of their scope of practice. A subsequent audit identified a significant number of referrals had been made by unregistered healthcare professionals.

### **Actions taken**

- Immediate communication from the Chief Medical Officer to relevant staff groups reiterated that only registered healthcare professionals can be authorised to make a referral for ionising radiation examinations.
- The radiology information system was amended to ensure that a professional registration number is displayed for referrers.
- A detailed scope of practice for the relevant staff group will be created and communicated to relevant members of staff.
- Future audits will include focus on specific staff groups.

## Learning from the incident

This example shows the significance of fully understanding the limitations of any existing measures to avoid errors. Although the incorrect referrals were driven by human factors, technical limitations to the referral system were not recognised, and the system did not prevent the possibility of inappropriate referrals as expected.

The initial corrective communication demonstrated the importance of having clear lines of escalation and a framework to quickly share key messages to a wide audience.

Organisational cohesion is central to managing referral processes consistently and effectively. There is a responsibility across an organisation to make staff aware of their scope of practice and work within it. Radiology staff are often seen as the gatekeepers of referrals, but they should not be working in isolation and the employer should support them by ensuring that all departments that make ionising radiation referrals are engaged in processes to maintain good practice.

## Paediatric over-exposures

We received multiple notifications regarding unintended doses to paediatric patients. These were often in relation to using adult exposure factors in general x-ray, and broadly fell into categories such as:

- lack of familiarity with x-ray systems
- operators feeling rushed or taking x-rays while distracted
- limited training on paediatric exposure factors
- equipment-related errors.

In some cases, it was not immediately identified that the patient had been over-exposed and subsequent images using incorrect factors continued to be taken.

### Actions for IR(ME)R employers

- Make sure staff have easy access to paediatric exposure factors, such as by programming the information into the mobile x-ray system. Attaching exposure charts is also useful as a cross-reference.
- Train staff on paediatric exposure factors so they can identify clear errors. All staff – including locum and agency radiographers – should have detailed induction training. Provide refresher training or updates at a sensible frequency, and review and update competency assessments as a matter of routine.
- Make sure that staff know they should keep accurate dose records, including those for rejected examinations due to using incorrect settings.
- Where a paediatric-specific room is out of action, make paediatric protocols available in alternative rooms.
- Staff should have enough time to perform a thorough pause and check. If using a mobile system, they may need extra time if the unit needs to be moved to another location.
- Set clear expectations around repeat exposures and communicate this to both permanent and temporary staff. Staff should be trained to ask for assistance or carry out quality control tests to rule out an equipment fault when an image is not adequate.

### Support for internationally trained radiographers

We received notifications where it was identified that internationally trained radiographers needed additional training. Although registration with the Health and Care Professions Council (HCPC) requires equivalence checks, new international recruits may still need additional support. New international recruits may be less aware of requirements under relevant UK regulations and may not always have confidence in challenging more senior members of staff where there were concerns.

We identified some good practice with some sites delivering bespoke training sessions for new international recruits, providing them with relevant information about the regulations and their role, as well as a peer group for support.

Providers may want to consider [two e-learning sessions](#) from the Society of Radiographers, which are specifically for international recruits:

- Working in the NHS – a brief overview of the NHS and the principles and values within the constitution.
- The role of the radiographer in the UK – this outlines a radiographer's requirements under HCPC, the career structure, the other professional staff groups they may encounter and other professional differences.

## Mammography

We received 20 notifications related to mammography exposures. In many cases, we saw that the breast screening programme was using good governance, with incident reports shared appropriately with programme managers.

The main type of operator error was incorrect changes to protocol settings, either by the operator themselves or by equipment engineers. This was most commonly due to leaving the unit in manual mode rather than switching to clinical automatic exposure control settings. On several occasions, pause and check or QA tests did not pick errors up and they were picked up by clinical or dose audits.

## Example of error and actions taken

### Errors from protocol changes

Following a new tube installation, multiple patients received mammograms using incorrect factors, where clinical modes were set to expose using manual factors rather than automatic exposure control (AEC). This was eventually noticed by an operator, but was initially not picked up during QA or pause and check.

### Actions taken

- Access to console settings was restricted where possible to super users, including medical physics experts, applications specialists, and trained service personnel.
- Images were checked to determine whether they were clinically appropriate or if patients needed to be recalled.
- Equipment training and the competency sign-off process were reviewed, including awareness of doses.
- Staff received reminders of the importance of pause and check.
- The QA protocol was checked to determine whether it needed additional information.
- All relevant clinical staff received information and learning by email, team huddles, and shared learning meetings.

### Learning from the incident

It is important to have a robust handover process to ensure that staff know about any checks that are needed before using equipment clinically. However, this example highlights the benefit of pause and check where other safeguards may not be sufficient to highlight unexpected changes.

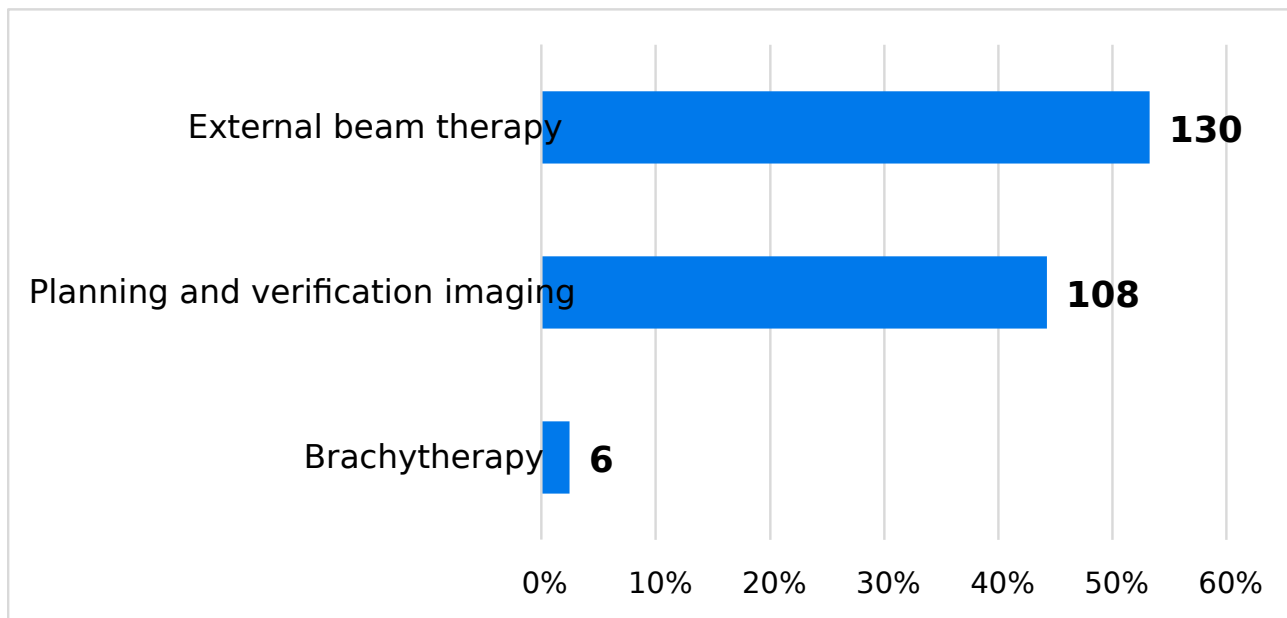
Operators should know not to assume that mitigations, such as QA or handover forms, will always catch errors.

# Radiotherapy activity

## Notifications received in 2023/24

- 244 notifications (compared with 270 notifications in 2022/23)
- this represents 30% of all notifications received across all modalities
- 97% of notifications were from NHS acute trusts
- planning and verification imaging accounted for 44% of all radiotherapy notifications received

**Figure 4: Notifications from radiotherapy by sub-modality, 1 April 2023 to 31 March 2024**



Source: CQC SAUE notifications data 2023/24

Note: Percentages have been rounded up to the nearest whole number to add up to 100%

In 2023/24, we received 244 notifications in radiotherapy, which was lower than the previous year (270 notifications). This was expected, as in April 2023, we amended the thresholds for notifications relating to planning and verification imaging to reflect changes in episode regimes. This resulted in an expected reduction in planning and verification notifications from 146 to 108, which affected the overall number received.

## Types of error

As in the previous year, the most common error related to treatment verification imaging (69 notifications). Although there were fewer than in 2022/23 because of the changes to the notification threshold, they still accounted for the highest proportion of the notifications reported from radiotherapy (figure 5).

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**Figure 5: Notifications from radiotherapy by detailed error type, 1 April 2023 to 31 March 2024**



- Tier 1: The duty holder from whom the error originated
- Tier 2: The point in the pathway where the error first occurred
- Tier 3: What went wrong

Tier 1: Referrer: (18 notifications)

Tier 2	Tier 3
Incorrect information (7)	<ul style="list-style-type: none"> <li>● Failure to cancel a request made in error (5)</li> <li>● Failure to check relevant patient RT history (2)</li> </ul>
Incorrect referral (11)	<ul style="list-style-type: none"> <li>● Not in accordance with guidelines (4)</li> <li>● Referral premature (6)</li> <li>● Wrong treatment protocol or dose/# requested (1)</li> </ul>

Tier 1: Practitioner (11 notifications)

Tier 2	Tier 3
Justification (11)	<ul style="list-style-type: none"> <li>● Failure to cancel radiotherapy (2)</li> <li>● Justify / authorise wrong plan or treatment protocol on prescription (2)</li> <li>● Target/volume error (7)</li> </ul>

Tier 1: Operator (168 notifications)

Tier 2	Tier 3
Clinical history (1)	<ul style="list-style-type: none"> <li>● Failure to check history/details (1)</li> </ul>
Pre-exposure checks (2)	<ul style="list-style-type: none"> <li>● Wrong patient position/set-up/protocol (2)</li> </ul>
Planning (32)	<ul style="list-style-type: none"> <li>● Inappropriate plan generated (8)</li> <li>● Inappropriate verification carried out (1)</li> <li>● Incorrect data transfer/input (22)</li> <li>● Wrong dataset used (1)</li> </ul>

Tier 2	Tier 3
Pre-treatment (17)	<ul style="list-style-type: none"> <li>● Incorrect scan protocol selected/procedure followed (7)</li> <li>● Marking of patient or immobilisation device (5)</li> <li>● Positioning of patient (5)</li> </ul>
Treatment (116)	<ul style="list-style-type: none"> <li>● Geographical miss - no verification image (3)</li> <li>● Geographical miss - shift error (10)</li> <li>● Geographical miss - verification image offline (1)</li> <li>● Geographical miss - verification image online (18)</li> <li>● Incorrect immobilisation applied (42)</li> <li>● Incorrect verification image type selected (37)</li> <li>● Patient ID/queuing error (1)</li> <li>● Skin app treatment (4)</li> </ul>

Tier 1: Equipment (40 notifications)

Tier 2	Tier 3
Equipment related (40)	<ul style="list-style-type: none"> <li>● Ancillary failure (3)</li> <li>● Hardware (25)</li> <li>● IT failure (1)</li> <li>● Software (11)</li> </ul>

Tier 1: Other (7 notifications)

Tier 2	Tier 3
Patient related (6)	<ul style="list-style-type: none"> <li>● Patient (1)</li> <li>● Unknown pregnancy (5)</li> </ul>
Other (1)	<ul style="list-style-type: none"> <li>● Not listed above (1)</li> </ul>

Total radiotherapy notifications: 244

Source: CQC SAUE notifications data 2023/24

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## Inspections and enforcement

We carried out 15 inspections, 4 of which were of brachytherapy services. From these inspections, we issued 6 Improvement Notices and made 26 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 (9 recommendations)
- **Regulation 7:** ensuring that employer's procedures include provision for carrying out clinical audit as appropriate, with particular focus on managing clinical audits within departments (6 recommendations)
- **Regulation 8(1):** ensuring a clear process relating to managing clinically significant unintended and accidental exposures and overall management of incidents (2 recommendations)
- **Regulation 8(4):** ensuring that all significant, accidental or unintended exposures that meet the threshold for notification are reported to the enforcing authority and that incidents are managed appropriately (2 recommendations)
- **Regulation 15(2) and 15(6)c:** ensuring that equipment QA processes are robust, and that the equipment inventories contain the correct information (3 recommendations)
- **Regulations 17(1) and 17(4):** training records for duty holders, with particular focus on practitioners (4 recommendations)

We issued Improvement Notices against:

- **Regulations 6(5)b:** where there was a failure to follow an established quality assurance programme for written procedures and written protocol
- **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
- **Regulation 15(2):** where the equipment inventory did not contain the correct information

## Key themes in radiotherapy

Through our work in radiotherapy over 2023/24, we have identified some concerns and themes in specific areas. We've taken the learning from these to provide some actions that employers can implement to help encourage improvement in these areas.

### Error management

The incident investigations we received as the enforcing authority showed that human factor errors form a large portion of the notifications. Human errors were often attributed to slip-ups or lapses in concentration as a direct result of staffing issues or working longer hours without an appropriate break.

We found that the management of human factor errors was inconsistent: some providers attributed the incident to the operators who were directly involved, whereas others would take a more systemic approach, assessing the whole process that led up to the incident to target the cause.

We found that where there was a systemic approach to reviewing the entire process that was affected by the error, there appeared to be more robust actions taken using the lessons learned.

Analysing trends of both reportable and non-reportable incidents is a vital part of applying lessons learned and reducing SAUE events. We noted during the year that this aspect of incident management was not happening as often as a direct result of lower staffing levels and fewer resources. This has a direct impact on the assessment of common errors, their causative factors and producing preventative procedures to enhance patient safety.

## Peer review of patient volumes

Peer review in radiotherapy is an essential step in clinical quality assurance to avoid planning-related errors that can affect patient safety and treatment outcomes. A lack of robust peer review across some providers of patient target volumes (the area to be treated) contributed to a large number of notifications received in 2023/24.

We found that routinely reviewing and discussing patient volumes in multi-disciplinary meetings of appropriately trained and experienced peer professionals was not happening in some services as there was no process for this. An under-resourced consultant workforce limited the ability to introduce systematic peer review of all target volumes and contributed to a rise in notifications. Where consultants were absent, there was inconsistent cover to effectively continue established peer review procedures.

As a result, documentation of peer review recorded on planning communication sheets was variable, and detailed changes were not always carried out effectively. However, we saw some effective use of established peer review processes that used the record and verify systems appropriately. Here, using specific activity codes for peer review tasks enabled clear oversight and management.

The investigation reports we received from radiotherapy departments that had established robust peer review procedures highlighted how anomalies in patient volumes were picked up and actioned successfully ahead of treatment.

## Staffing levels

Staffing levels and their effect on compliance with the regulations was a persistent theme, particularly their impact on notifiable errors. Several organisations had noted an increase in the number of notifications submitted to us, as well as events that did not meet the SAUE criteria. This related to all duty holders, clinicians, radiographers and medical physics experts, as well as radiotherapy engineering staff.

The risks associated with low staffing levels were managed inconsistently across organisations – some were well monitored and understood by senior leaders and others were poorly tracked. Providers that managed this well monitored their risk register regularly at both departmental and executive levels and assessed risks levels regularly. Departments that had benchmarked their staffing levels against national guidance were able to demonstrate where their shortfalls were and create business cases for additional staffing. In extreme circumstances, organisations had considered reducing their capacity to provide services or created waiting lists for certain treatment groups. We also saw that some had cut down on non-essential tasks to reduce the workload on treatment staff.

## Examples of errors and actions taken

### **Geographic miss of tumour position**

Following surgery, a patient was referred for radiotherapy to the right breast. Their initial consultation with the consultant clinical oncologist (CCO) took place over the phone. The intended treatment prescription was 26Gy/5# with 6MV photons, followed by a 13.35Gy/# electron boost if possible.

Typical practice is to wire any visible scars at the CT scan and identify the surgical clips in the tumour bed. This enables an assessment to see whether a patient is suitable for an electron boost. For this patient, no surgical clips were identified.



The CCO used the diagnostic CT key images but misidentified a nodule near the sternum as the site of the tumour. They used fused images to mark up the misidentified nodule as the boost volume to be treated, and adjusted the breast field margins accordingly.

On day 1 of the electron boost treatment, the patient raised a concern with the radiographers before being treated that the surgical scar, and therefore the tumour bed, was not being covered. Radiographers checked the plan and reassured the patient that the treatment was to the area marked up and approved by the CCO. The patient raised concerns again on day 2 of treatment as she was certain that the scar position was directly over the tumour bed. Although the radiographers raised this with the CCO by email, they did not get a response before the third treatment fraction was delivered.

When the CCO reviewed the treatment prescription following the email they identified the error and treatment was stopped.

### **Actions taken**

- The department implemented a change in the process, so that if patients do not have surgical clips in place, they must be seen by a CCO in a face-to-face appointment before treatment to confirm the tumour position.
- The surgical team was reminded of the importance of placing clips in the tumour bed wherever possible, with further education regarding the importance of this for radiotherapy.

### **Learning from the incident**

If clips are not placed at surgery, surgical diagrams should be provided to the radiotherapy department, indicating both the scar and tumour bed positions.

All teams were reminded that if the patient or member of staff has a concern about the planned treatment, these should be acknowledged and escalated as soon as possible so they can be addressed.

If a patient raises a concern regarding a geographic miss, treatment should be paused until a CCO has completed a review.

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### **Mismatch through poor image quality and over-worked staff**

A patient received a single fraction of palliative radiotherapy to the thoracic spine. A posterior kV verification image was acquired, and the operators online matched the image and applied the corrective moves. A second image was acquired to confirm the position, and the treatment was delivered.

During an offline review, it was discovered that the match was for the wrong vertebrae with a mismatch of 2.4cm longitudinally. Staff stated that the image quality was poor when matching online.

#### **Action taken**

- The department investigated the incident and assessed the dose to enable them to meet their duty of candour to the patient.
- The department tested and reviewed image quality on the treatment screens.

- A CBCT (cone beam computed tomography) pathway for palliative patients was developed; at the time of the report a small cohort of palliative patients had had received CBCT imaging with success.
- All staff received a presentation of the feedback to share the learning.
- The staffing policy has been changed to avoid a recurrence of this type of incident. The incident occurred during planned weekend working hours, and the staff involved were on-call as well as being on the rota to be treating the scheduled patients. But this meant they did not receive adequate breaks and were working long hours.

### **Learning from the incident**

In this example, incorporating an offline review for a single fraction treatment allowed the error to be discovered and any corrective action to be carried out, although this was not needed in this case. This led to a change in the palliative imaging pathway, providing assurances that similar incidents are less likely to occur. It also highlights that when staff work long hours with inadequate breaks, it has a direct impact on human factor errors with slips and lapses.

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### **Incorrect prescription delivered**

A patient saw the radiotherapy consultant in a clinic for treatment to their L4-S1 vertebra. The consultant made an electronic referral for a proposed dose of 20Gy/5# and referred on to the advanced clinical practitioner pathway.

However, the treatment was prescribed incorrectly as 8Gy/single # (instead of 20Gy/5# to L4-S1). The discrepancy in the referred dose/fractionation against the prescribed dose was not noticed during the virtual simulation checks or data preparation process. There was no annotated journal note to document an intended change in fractionation, and radiographers did not query the change in fractionation.

The patient themselves queried the change in dose/fractionation before having treatment, and the treatment radiographer queried this with the operational duty manager. However, they were reassured that the dose for that treatment was within protocol, so the patient received 8Gy single fraction.

The incident was identified during standard post treatment checks and discussed with the advanced clinical practitioner, referring consultant, clinical supervisor, and professional head of radiotherapy. The referring consultant confirmed that the incident was not of clinical significance, and therefore no additional treatment was required.

### **Actions taken**

- A copy of the radiotherapy consent procedure was re-distributed to all radiotherapy staff, who were reminded to follow the correct procedure.
- Because of the high number of patient referrals, the department reviewed capacity on linacs (linear accelerators). Consultants were advised to highlight any patient concerns, and not go ahead with treatment until the concerns are resolved.
- All palliative patients, including those on the ACP pathway, will be discussed during the consultants planning meeting facilitated by the pre-treatment team.

## Learning from the incident

- Historically, patients on the advanced clinical practitioner pathway were not routinely discussed at consultants planning meetings.

This meant that certain discussions around treatment could be missed. Following the incident, the department agreed that all patients on the ACP pathway should be discussed during the appropriate planning meeting.

## Actions for IR(ME)R employers

- Implement robust radiation protection governance structures and embed a clear incident management process within the organisation.
- Carry out thematic review of incidents that do not reach the reporting threshold to CQC routinely, with clear feedback mechanisms to all duty holders.
- Have a documented peer review process available when requested on inspection as evidence.
- Implement a process to address absence levels to ensure that the department follows peer review processes.
- If your department is operating with staff shortages that have a detrimental effect on the service, document this formally as a risk, and monitor it at senior management level.

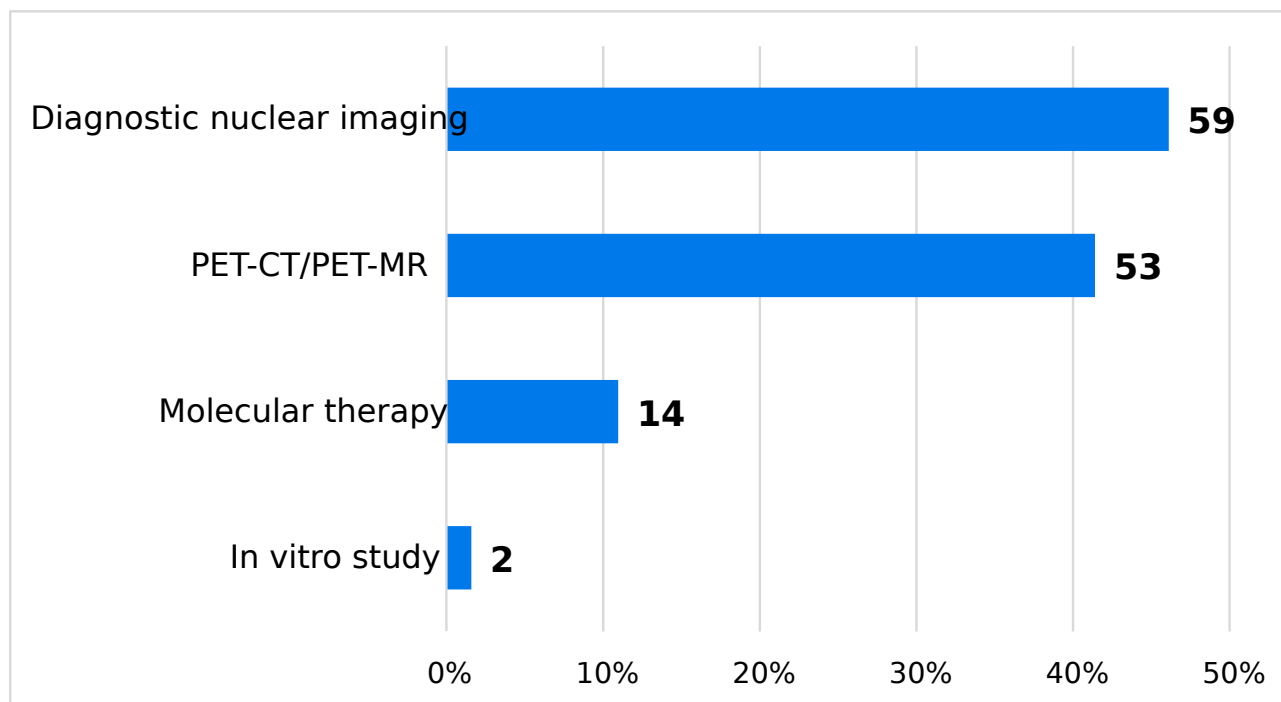
# Nuclear medicine activity

# Notifications received in 2023/24

- 128 notifications (compared with 77 notifications in 2022/23)
- this represents 16% of all notifications received
- 68% of notifications were from NHS acute trusts
- 32% of notifications were from independent healthcare providers
- 41% of notifications related to PET-CT/PET-MR studies

There has been a substantial increase in the number of nuclear medicine notifications compared with previous years (128 notifications, a 66% increase compared with 2022/23). The number of notifications relating to diagnostic nuclear medicine examinations has more than doubled compared with 2022/23 (up from 23 to 59 notifications), with a small increase in PET-CT/PET-MR incidents reported to us.

**Figure 6: Notifications from nuclear medicine by sub-modality, 1 April 2023 to 31 March 2024**



Source: CQC SAUE notifications data 2023/24

Note: Percentages have been rounded up to the nearest whole number to add up to 100%

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## Types of error

As in previous years, operator errors accounted for the highest proportion of notifications in nuclear medicine. The number of notifications relating to incidents when preparing or administering radiopharmaceuticals has more than doubled (43 in 2023/24, compared with 18 in 2022/23). This is likely due to increased reporting, as we introduced a new SAUE reporting category in April 2023, requiring employers to notify us if an incorrect radiopharmaceutical is administered to a patient. We discuss our findings relating to this new category in the key themes section.

There were also more operator errors relating to the incorrect use of equipment and incorrect patient set-up, positioning, or selection of protocol.

Notifications of incorrect referrals, usually for the wrong patient, also increased compared with last year, from 9 to 14. As in previous years, we reiterate the importance of having clear and effective processes for cancelling requests.

The impact of equipment failures continues to increase (36 notifications compared with 19 in 2022/23), as hardware faults have led to repeat studies, often for multiple patients. More than half of these related to PET-CT imaging, likely due to the high number of patients being imaged and the resulting workload on equipment, but we also saw the impact of hybrid CT breakdowns on diagnostic nuclear medicine and problems with ancillary equipment such as scales affecting glomerular filtration rate (GFR) tests.

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**Figure 7: Notifications from nuclear medicine by detailed error type, 1 April 2023 to 31 March 2024**

- Tier 1: the duty holder the error originated from
- Tier 2: the point in the pathway where the error first occurred
- Tier 3: what went wrong

Tier 1: Equipment (36 notifications)

Tier 2	Tier 3
Equipment-related (36)	<ul style="list-style-type: none"> <li>● Ancillary failure (5)</li> <li>● Hardware (24)</li> <li>● Software (7)</li> </ul>

Tier 1: Operator (51 notifications)

Tier 2	Tier 3
Authorisation (1)	<ul style="list-style-type: none"> <li>● Incorrect authorisation (1)</li> </ul>
Clinical history (2)	<ul style="list-style-type: none"> <li>● Failure to check history/details (2)</li> </ul>
Patient checks (1)	<ul style="list-style-type: none"> <li>● Failure to check pregnancy/breastfeeding (1)</li> </ul>



Tier 2	Tier 3
Radiopharmaceutical (34)	<ul style="list-style-type: none"> <li>● Administration (20)</li> <li>● Preparation (14)</li> </ul>
Post examination (1)	<ul style="list-style-type: none"> <li>● Reporting failure (1)</li> </ul>
Pre-exposure checks (12)	<ul style="list-style-type: none"> <li>● Wrong patient position/set-up/protocol (7)</li> <li>● Wrong use of equipment (5)</li> </ul>

Tier 1: Other (10 notifications)

Tier 2	Tier 3
Administrative staff error (1)	<ul style="list-style-type: none"> <li>● Other admin error (1)</li> </ul>
Patient related (5)	<ul style="list-style-type: none"> <li>● Patient (3)</li> <li>● Unknown pregnancy (2)</li> </ul>
Other (4)	<ul style="list-style-type: none"> <li>● Not listed above (4)</li> </ul>

Tier 1: Practitioner (6 notifications)

Tier 2	Tier 3
Justification (3)	<ul style="list-style-type: none"> <li>● Incorrect justification (3)</li> </ul>
Protocol (3)	<ul style="list-style-type: none"> <li>● Illegible/unclear protocol (3)</li> </ul>

Tier 1: Referrer (25 notifications)

Tier 2	Tier 3
Incorrect information (11)	<ul style="list-style-type: none"> <li>● Duplicate/no check of previous imaging (2)</li> <li>● Failure to cancel (6)</li> <li>● Inaccurate clinical information (3)</li> </ul>
Incorrect referral (14)	<ul style="list-style-type: none"> <li>● Failure to cancel a request made in error (1)</li> <li>● Wrong patient (12)</li> <li>● Wrong requested modality (1)</li> </ul>

Total nuclear medicine notifications 128

Source: CQC SAUE notifications data 2023/24

## 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 were similar to previous years, including:

- omitting certain procedures from the application form when applying for a new or renewed licence
- carrying out procedures at a different location that did not have the specific procedure on its employer licence
- using an incorrect radiopharmaceutical that was appropriate for the type of study, but different from that specified on the employer licence.

We found a need for employers to cross-check their active procedure against both practitioner and employer licences, particularly when renewing or applying, to ensure that all procedure types are included.

## Inspection and enforcement

We carried out 10 inspections, one of which was focused in response to information of concern. We issued 4 Improvement Notices and made 33 recommendations relating to the following regulations:

- **Regulations 17 and 17(4):** training records must be available for all operators, detailing when and how they were deemed to be competent at each practical aspect they perform, and a training procedure should detail how this competency is assessed and maintained (8 recommendations)

- **Regulations 6, 6(1) and 6(5)(b):** ensuring all required procedures are in place, making sure they reflect clinical practice and contain enough information for duty holders to follow (9 recommendations)
- **Regulation 15(2):** ensuring that the equipment inventory contains all required fields (4 recommendations)
- **Regulations 11 and 11(5):** having a clear procedure for justification and authorisation of exposures, and using authorisation guidelines issued by the practitioner (3 recommendations)
- **Regulation 8:** implementing a study of risk for radiotherapeutic exposures, arrangements for clinically significant accidental or unintended exposures and notifying the enforcing authority of any reportable SAUEs (3 recommendations)
- **Regulation 7:** regularly undertaking clinical audit (2 recommendations)
- **Regulation 12:** having an ongoing programme of optimisation to ensure patient doses remain as low as reasonably practicable (2 recommendations)
- **Regulations 6(2) and 6(4):** ensuring written procedures are accessible to duty holders and that they comply with them, and that written clinical protocols contain enough information (2 recommendations)

We issued 4 Improvement Notices during this inspection period, against the following areas:

- **Regulation 17:** where training records were incomplete, and operators could not demonstrate their competence to undertake practical aspects they performed (1 notice)
- **Regulation 15:** where performance testing of gamma probes used in theatre was not being undertaken often enough, and records did not include acceptable performance criteria (1 notice)
- **Regulation 14:** where the medical physics expert did not offer sufficient support to the service and was not involved in all matters requiring their input (1 notice)

- **Regulation 8(2):** where there was no study of the risk of accidental or unintended exposures for therapeutic nuclear medicine procedures (1 notice)
- **Regulation 6(5)(a):** where referral guidelines were not available to referrers (2 notices)
- **Regulations 6(1) and 6(2):** where some procedures required by schedule 2 were not available and other procedures did not reflect clinical practice (2 notices)
- **Regulation 6(5)(b):** where many procedures, protocols and policies were held on the department's quality management system and most were overdue for review, did not reflect clinical practice or referred to out-of-date regulatory terms (1 notice)

## Key themes in nuclear medicine

Through our work in nuclear medicine over 2023/24, 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.

### Pregnancy and molecular radiotherapy

An investigation was triggered in 2022 following an administration of a therapeutic dose of iodine-131 to treat benign thyroid disease to a patient in their third trimester of pregnancy. We issued a Prohibition Notice against the service (detailed in our [enforcement registry](#)).

Although the investigation was closed in 2023, it has enabled us to identify and highlight several significant concerns with the safety of the service:

- The employer's procedure for making pregnancy enquiries did not include any arrangements for molecular radiotherapy.
- There was no written clinical protocol for iodine-131 treatments.

- The exposure was authorised by an endocrinologist who did not hold a practitioner licence, and there were no authorisation guidelines available.
- Support from a medical physics expert was provided by a third party with no nuclear medicine training. On-site physics staff also had limited training working in nuclear medicine.
- There were no training records to show how the operator had been deemed competent to complete any of the practical aspects associated with the treatment.

It is imperative that procedures for making pregnancy enquiries include enough detail for patients undergoing molecular radiotherapy. This is especially important for treatments such as iodine-131 for benign thyroid disease where pregnancy is absolutely contraindicated, and the patients are often young women. Employers must consider the increased risk to patients with child-bearing potential. Pregnancy testing can yield false negative results, therefore the employer's procedure should set out the appropriate test. We strongly advise the use of pregnancy testing as close as possible to the administration of the treatment to mitigate these risks as far as possible.

There were notifications of 3 similar incidents involving administrations to pregnant patients. In those cases, a urine pregnancy test gave a negative result. However, all 3 patients were in very early pregnancy, when urine tests are less accurate. This highlights the importance of using the right type of test, at the right time, appropriate to the type of patient, as some medical conditions can affect the efficacy of pregnancy tests.

### Actions for IR(ME)R employers

- Make specific arrangements for pregnancy testing of patients receiving molecular radiotherapy in employer's procedures, ensuring that the methods and timing used are appropriate. This should include where to record the pregnancy status or test result, who will conduct tests, and ensuring appropriate training.

- Do not use pregnancy testing to exclude pregnancy in isolation. It is essential to include thorough counselling of the patient, as part of the consent process.
- Ensure that patient information leaflets and pre-exposure counselling gives patients enough information about the risks associated with pregnancy and molecular radiotherapy. Make sure patients have sufficient time to consider this information, so that they can give informed consent.
- Include information about the use of effective contraception in the lead-up to treatment as part of advice about avoiding pregnancy following treatment.
- Ensure operators involved in the administration are trained, competent and entitled to counsel patients about risk, understand the risks involved and administer the radiopharmaceutical safely.
- Refer to professional literature, such as the ARSAC Notes for Guidance (<https://www.gov.uk/government/publications/arsac-notes-for-guidance>) for advice on best practice.

## Arrangements for carers and comforters

We see a wide variation between different departments in their practice and approach to managing exposures to carers and comforters. These are people who knowingly and willingly expose themselves to ionising radiation to enable them to care for or support someone having a procedure involving radiation. To comply with the regulations, we look for the following to be in place when we inspect:

- The employer's procedure required by Schedule 2(n).
- A protocol or procedure setting out the responsibilities of duty holders, and the information they need to comply with the employer's procedures, including:

- who can be designated as a carer and comforter
- dose constraints for carers and comforters
- estimated dose or risk to the carer and comforter
- benefit and risk information and what advice should be given to the carer and comforter
- the process for justification and authorisation, who undertakes this and where it is recorded
- where the exposure is recorded
- A leaflet or guidance for the carer and comforter, providing information on benefit and risk.
- A physical or electronic form or record, where the details of the exposure are recorded.

We have seen different ways of approaching this and we highlight the following examples of good practice.

## Examples of good practice

### **Standard operating procedure**

An NHS employer had a standard operating procedure in nuclear medicine specifically for carers and comforters, which underpinned the trust-level employer's procedures. This included all the information that we would expect to see to guide duty holders in managing and recording exposures to carers and comforters.



A particular highlight was the use of a radiation dose risk classification table. This showed estimated doses for each type of diagnostic study that were colour-coded according to additional lifetime cancer risk and based on the level of support needed, for example escorting patients or providing close care. The table also highlighted where the medical physics expert needed to carry out individual risk assessments, including for therapy procedures.

## **Guidance leaflet**

We also inspected an independent nuclear medicine department, where staff had developed a detailed guidance leaflet for carers and comforters. This included information to explain common questions to put people at ease, including:

- What is a carer and comforter?
- What are the hazards and risks?
- How much radiation dose will I receive?
- Who decides if the radiation dose to me is acceptable?
- How can I reduce the radiation dose to myself?
- What happens if I get radioactivity on my skin?
- What do I do during the procedure?
- How do I consent? What happens if I say no?
- Where can I get more information?

## **Record of exposure**

We have seen a variety of ways to record exposures to carers and comforters, including through the radiology information system (RIS) and hard copy paper files. Some employers record these exposures on their RIS to enable them to run a query to extract all exposures of this type. Managers review these records every month to identify any individuals who exceeded the dose constraint and investigate appropriately. The form does not need to be lengthy, but should capture the following information:

- identifying information for carer and comforter
- type of examination
- exposure parameters
- estimated dose
- signature of authorising operator
- evidence that they have “knowingly and willingly” consented.

## Incorrect radiopharmaceutical administrations

We introduced a new reporting category for incorrect radiopharmaceutical administrations in the April 2023 revision to our SAUE guidance. Since its introduction, we received 20 notifications in this category.

On reviewing these notifications, we found that, despite a second check of the patient dose before release, in many cases this failed to prevent the error. This was due to various factors, such as:

- time pressures
- not correctly following the standard operating procedure

- interruptions during the dispensing and checking processes.

This suggests a need to ensure that staff have enough time and support to carry out a thorough second check of all doses. This includes checking the vial of origin to ensure the correct radiopharmaceutical as well as checking the activity of the dispensed dose.

As well as errors when dispensing and administering radiopharmaceuticals, we have also seen notifications caused by incomplete referrals and incorrect justification and authorisation.

In one incident, a patient's fluorine-18 FDG PET-CT examination was wrongly protocolled for rubidium-82-chloride cardiac PET-CT. This was due to significant cardiac history on the request card, despite it being unrelated to the reason for the scan. The practitioner misread the information as they were working under severe time pressure, which highlights the need for adequate time and focus for justification and protocolling – even for experienced clinicians.

This notification also shows the importance of clear, concise radiology requesting by referrers to ensure they provide the correct, relevant information and reduce errors.

## Under-dosing incidents

We received 12 notifications related to under-dosing in nuclear medicine. These happened across diagnostic nuclear medicine, PET and in molecular radiotherapy.

The primary cause (10 notifications) was operator error. Of these:

- 3 were attributed to incorrect use of a calibrator during preparation
- 4 were due to incorrect set up of lines, not flushing as per protocol or incorrect weight-based calculations
- 2 reported incidents were due to ordering errors
- 1 was due to a reduced activity being released by the radiopharmacy.

## Examples of errors and actions taken

### Residual dose in infusion set

A patient attended for a Lu-177 Dotatate treatment. During the infusion, the patient needed to use the toilet. The infusion rate was increased before being disconnected to allow the patient to go. However, the line was not flushed a second time as per protocol, which resulted in a higher residual activity in the infusion set and a reduction in the activity administered to the patient.

### Actions taken

- The infusion rate was increased to complete administration before being disconnected in order to reduce environmental contamination through accidental voiding of the bladder. If the patient had not been able to reach the toilet, there was potential for significant radioactive contamination of the chair, skin and exposure to staff.
- The administration protocol was amended to include a formal request for patients to empty their bladder before the radiopharmaceutical infusion.

### Learning from the incident

- Following the incident, staff have been made aware of the risk of residual activity if they do not follow the protocol, and the service has introduced a verbal check before infusion.
- Staff are now reminded not to dismantle the set before a clinical decision is made as this affects the sterility, removing the option for a second line flush.

### Incorrect calibrator setting

Following the calibrator quality control (QC) checks, 2 radiopharmaceutical doses were measured using the incorrect calibrator setting. The dose calibrator was set to Iodine-131 instead of Technetium-99m. This resulted in 2 patients receiving a dose lower than intended. The operators carried out a double check and, although they noted something was not right, they did not escalate further. Although a procedure was in place, it was not followed correctly and subsequently resulted in the incident.

### **Actions taken**

- The practitioner was informed and no repeat imaging was required.
- Documentation was reviewed and the procedure amended to include the pathway for corrective action when results are out of tolerance.

### **Learning from the incident**

After a review of this incident, there were staff discussions and refresher training for operators on both the dispensing procedure and the importance of checking the calibrator settings when checking patient doses as an active process – independent of dispensing. The employer also carried out an audit to monitor compliance with the procedures.

# Other IR(ME)R related activity

## Statutory instrument review

The Department of Health and Social Care (DHSC) must review the regulations every 5 years. The first post-implementation review was undertaken in 2023 and the recommendations from the review have been published. DHSC is currently working to implement these recommendations.

## IAEA Integrated Regulatory Review Service mission to the UK

In 2019, the Minister for Business, Energy and Industrial Strategy invited the International Atomic Energy Agency (IAEA), on behalf of the UK government, to carry out a peer review of the UK's regulatory infrastructure for nuclear, radiation, radioactive waste, and transport safety. This mission was to evaluate the UK's regulatory framework for nuclear and radiation safety against the IAEA safety standards.

This involved government bodies, such as the Department of Health and Social Care, advisory bodies, such as UK Health and Security Agency (UKHSA), as well as 15 regulatory bodies including CQC, and took place over 2 weeks in October 2019. The report was published in July 2020, detailing the findings in relation to each standard and giving recommendations and suggestions for improving regulatory oversight.

The IAEA returned in January 2024 to complete a peer review of the UK's progress against the 2019 Mission. This involved a self-assessment and interviews with representatives from CQC. The report of the review is due to be published in 2024.

## Committees and liaison

Our IR(ME)R team continues to provide support and involvement in several committees and groups across both imaging and radiotherapy. This includes liaison with other agencies and regulatory bodies, including:

- Medical Radiation Liaison Group (MRLG), which includes regulatory and government bodies involved in medical exposures across the UK and is chaired by UKHSA Medical Exposures Group
- Clinical Imaging and Radiotherapy Boards that involve the professional bodies in England such as the Society of Radiographers (SoR), the Royal College of Radiologists and the Institute of Physics and Engineering in Medicine (IPEM).
- Special interest groups led by the British Institute of Radiology and IPEM, which include radiotherapy, nuclear medicine, diagnostic radiology and radiation protection
- regular meetings with SoR, IPEM and UK Health Security Agency to discuss topical issues and contribute to working parties.

## Heads of European Radiological Competent Authorities

CQC maintains a role within working parties at Heads of European Radiological Competent Authorities (HERCA) meetings.

HERCA is a voluntary association in which the Heads of Radiation Protection Authorities work together to identify common issues and propose practical solutions. HERCA is working on topics generally covered by provisions of the EURATOM Treaty. The programme of work of HERCA is based on common interest in significant regulatory issues.

## Updating our guidance

Together with our IR(ME)R colleagues of the devolved administrations of Northern Ireland, Scotland and Wales, we published updated guidance on what constitutes a notifiable incident under IR(ME)R in April 2023. However, we have found some inconsistencies with the interpretation of the guidance and a need for more clarification.

We have supported services where needed and have reviewed the current guidance, which will be updated where needed and published on our website.

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