IR(ME)R annual report 2024/25

CQC is the relevant enforcing authority of IR(ME)R in England.

We enforce the regulations through on-site inspections and by reviewing statutory notifications from healthcare services about significant accidental or unintended exposures to patients.

Every day, tens of thousands of patients undergo planned exposures to ionising radiation as part of their medical care. Inevitably in some cases, things can go wrong. It is imperative that these events are monitored and that learning is shared to help avoid the same mistakes happening again and to lessen the impact.

As part of our annual programme for assessing compliance with IR(ME)R, we review statutory notifications of significant accidental or unintended exposures (SAUE notifications) that providers have submitted to us. This report covers the period between 1 April 2024 and 31 March 2025.

Notifications received

In 2024/25, we received 842 SAUE notifications that met the defined thresholds of notifiable incidents across the modalities of:

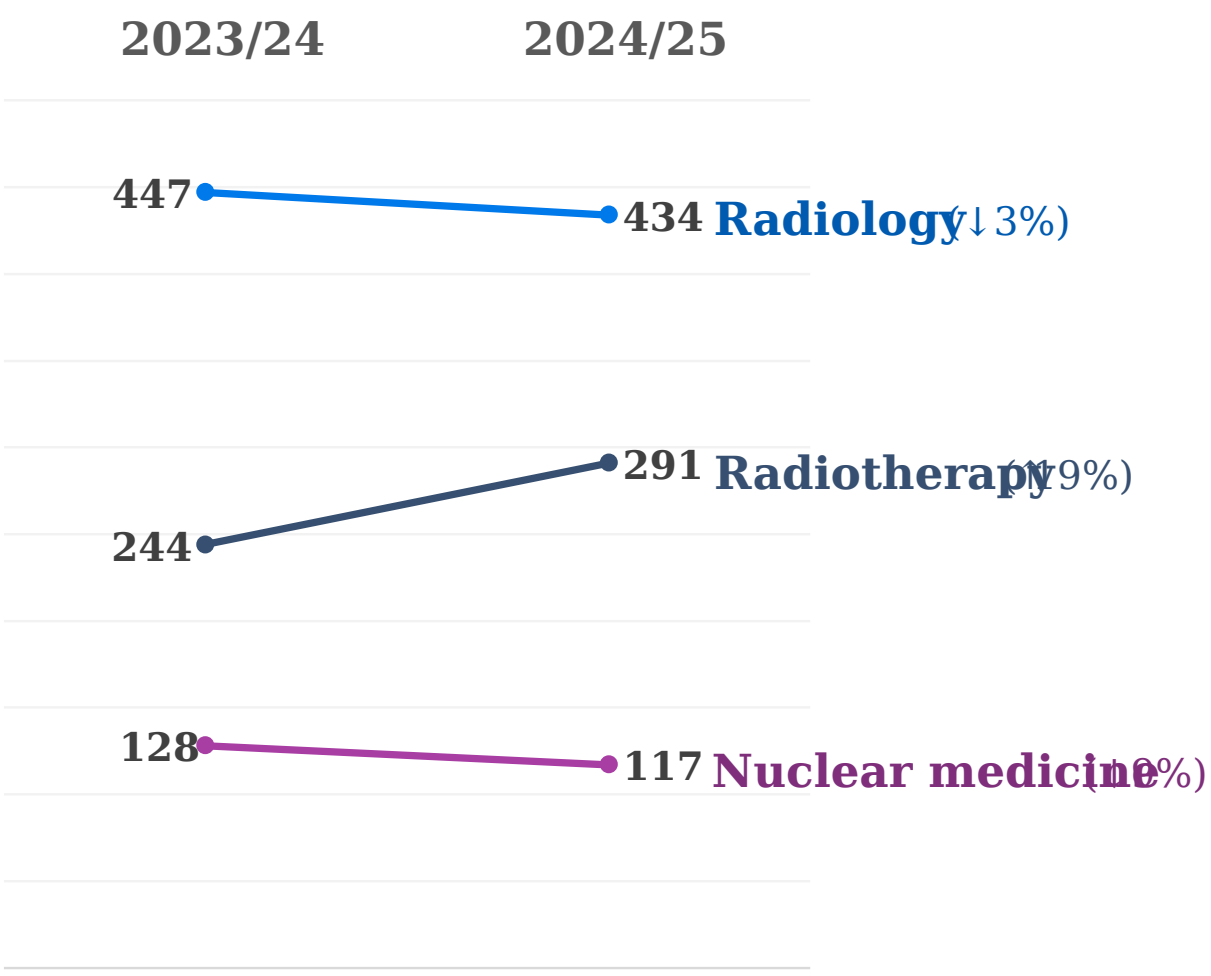
- Diagnostic and interventional radiology: 434 notifications (447 in 2023/24)
- Radiotherapy: 291 notifications (244 in 2023/24)

- Nuclear medicine: 117 notifications (128 in 2023/24).

This is broadly similar to 2023/24 (819 notifications), an increase of 3%.

Diagnostic radiology made up the largest proportion of total notifications (52%). This likely reflects the greater volume of diagnostic examinations performed compared with radiotherapy (35%) and nuclear medicine (14%).

Figure 1: Total number of SAUE notifications, 2023/24 and 2024/25, by modality



Key themes

We believe the numbers of notifications received is generally a positive indicator of a good patient safety culture in medical exposures. However, as in previous years, we have identified some persistent themes and patient safety incidents:

- Referral incidents continue to make up a significant proportion of notifiable incidents, most notably with incorrect patient referrals and failure to cancel referrals that are no longer required.

  Action for employers:
  There is now a legal requirement to have an IR(ME)R Schedule 2 Employer Procedure that details how to make, amend and cancel a referral. You also need to consider referral PAUSE and check guidance and other mechanisms that could minimise the risk.

- Errors in the practical aspects of an exposure remain prevalent, mostly in the pre-exposure checks.

  Action for employers:
  Ongoing training and education to support clinical staff should include IR(ME)R relevant training, so that staff understand their responsibilities as entitled IR(ME)R operators.

- Notifiable incidents directly related to equipment continued to increase during 2024/25.

  Action for employers:
  Although we accept there will always be a risk of equipment failures, you must have robust quality assurance programmes in place for equipment, and access to the right expert advice and support through your medical physics experts and manufacturer contracts.

As well as the persistent themes, we are aware that a number of medical radiological services carrying out high levels of activity have not reported a patient safety event for several years. These services operate across a range of imaging modalities and provide complex medical procedures. During 2024/25, we prioritised these services for inspection, and where we found breaches of regulations and gaps in compliance, we issued enforcement notices and quality improvement recommendations related to incident investigations, as required under IR(ME)R.

We will continue to prioritise these services in our inspection planning to determine compliance with the regulations, to promote radiation protection and improve the quality and safety of medical exposures for people.

Inspection activity

During this reporting period, we carried out 71 regulatory IR(ME)R inspections across all modalities. Of these:

- 68 were planned proactive inspections as part of our rolling risk-based graded inspection programme
- 3 were reactive inspections in response to information of concern shared with us.

We inspected:

- 22 diagnostic radiology services
- 28 nuclear medicine services
- 21 radiotherapy services.

Medical radiological practice continues to evolve, with technological advances, adoption of new techniques and changes to working practices. Clinical demand is also placing extensive pressure on services, stretching capacity to its limits, and we recognise that there are associated pressures within the clinical professional workforce. The community continues to work in an extremely fast-paced and challenging clinical environment and the opportunity for errors and mistakes is ever present.

We recognise that the risk of a notifiable significant accidental or unintended exposure remains relatively low in relation to the number of individual medical exposures to ionising radiation in a year. However, we know that in reality a high number of incidents, including near misses and 'good catches' across all types of service, do not meet the defined threshold for notification to the relevant enforcing authority.

The importance of having a strong safety culture, proactive risk management and systems-based approaches to analysing patient safety events must not be overlooked. A strong safety culture that encourages and supports staff to identify and report all patient safety events is how we can maximise learning and implement positive changes that continually improve patient safety.

Background

The Ionising Radiation (Medical Exposure) Regulations 2017 provide a legislative framework to protect patients against the hazards associated with ionising radiation.

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.

In the rare event when there is a significant accidental or unintended exposure to ionising radiation, the legislation requires that the IR(ME)R employer investigates the incident and notifies CQC under Regulation 8(4). Detailed criteria are available to IR(ME)R employers to explain when an incident needs to be notified to us.

As the relevant enforcing authority of IR(ME)R in England, we are responsible for monitoring compliance with IR(ME)R in England. We monitor compliance with the regulations through on-site inspections and by reviewing statutory notifications from healthcare services about significant accidental or unintended exposures to patients. The scope of our annual review of accidental and unintended exposures is to identify themes and consider learning opportunities. We do not include an assessment of clinical outcomes for patients.

The notifications we receive are a mix of accidental and unintended exposures:

- accidental exposures occur when a person receives an exposure in error, when no exposure of any kind was intended
- unintended exposures occur when a person is referred for a planned exposure, but the exposure delivered is significantly different to what was intended.

We also receive several voluntary notifications. These incidents do not meet the defined criteria or reporting threshold, but we share them for learning so that similar events can be mitigated.

This annual report

Under IR(ME)R Regulation 9, CQC is required to share relevant information regarding significant incidents, which we deliver in our annual IR(ME)R report.

During this reporting period (2024/25), amendments to the legislation were published and came into force on 1 October 2024. We granted a period of grace to all IR(ME)R employers allow time to incorporate the required changes to their procedures and processes before we started to inspect against the amended regulations on 1 April 2025. This means that in this year's report, we do not include an analysis of our findings against the amendments.

We report on what we have found from our annual inspection programme through an overview of compliance with the regulations. This enables other employers, healthcare professionals and academic bodies to learn from the examples of errors and good practice.

We provide a summary of our total IR(ME)R regulatory activity for 2024/25, and under each of the 3 modalities, the report further provides:

- a summary and analysis of the statutory notification data
- our inspection and enforcement actions in that area
- details of some of the most prevalent themes identified during the year, with some recommendations for IR(ME)R employers to consider.

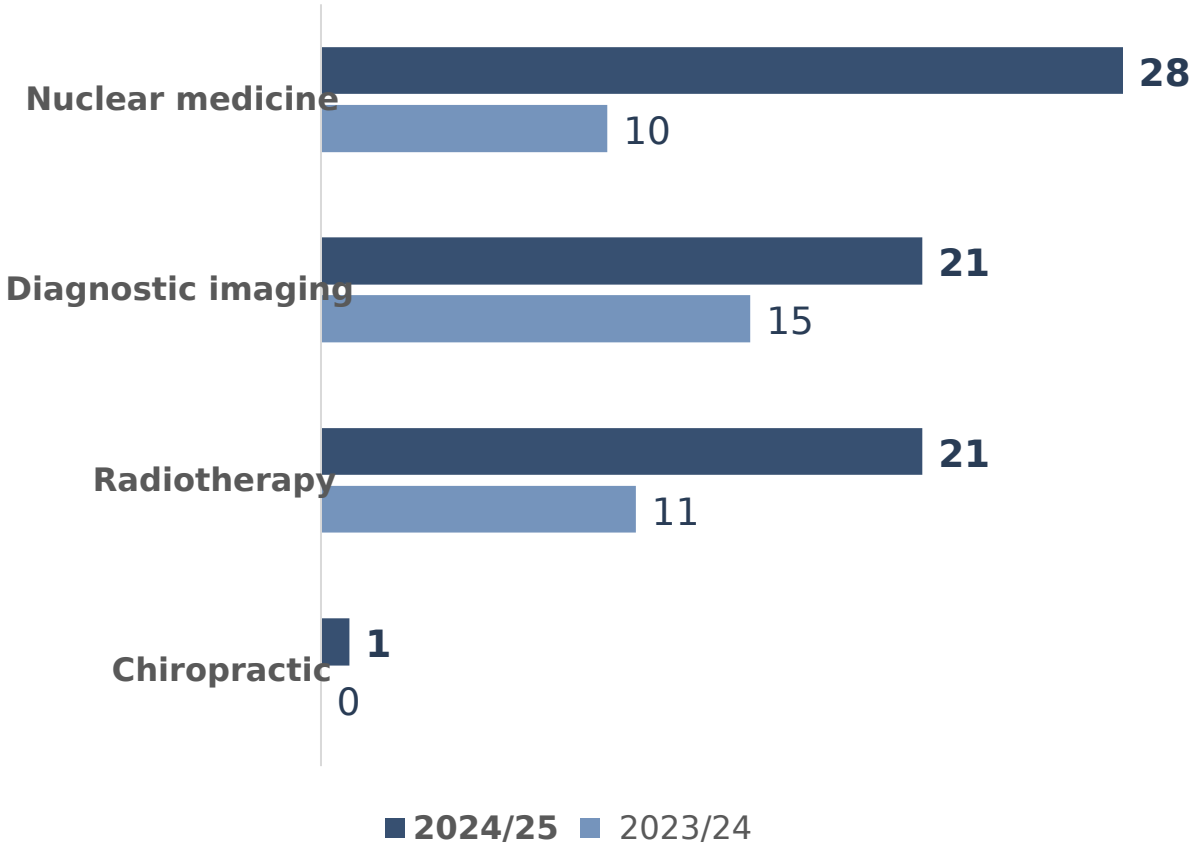
Inspection and enforcement activity in 2024/25

We continue to build capacity within our annual inspection programme and carried out 78% more inspections in 2024/25 (71 inspections) compared with the previous year (40 inspections).

Our proactive annual inspection programme uses a risk-based graded approach, with the majority completed as planned proactive inspections.

We completed 3 reactive inspections in response to information of concern reported to us.

Figure 2: Total inspections carried out in 2024/25 and 2023/24, by modality



We issue an Improvement Notice when we have identified a significant compliance gap with the regulations on an inspection that could have serious consequences for patient safety. This involves:

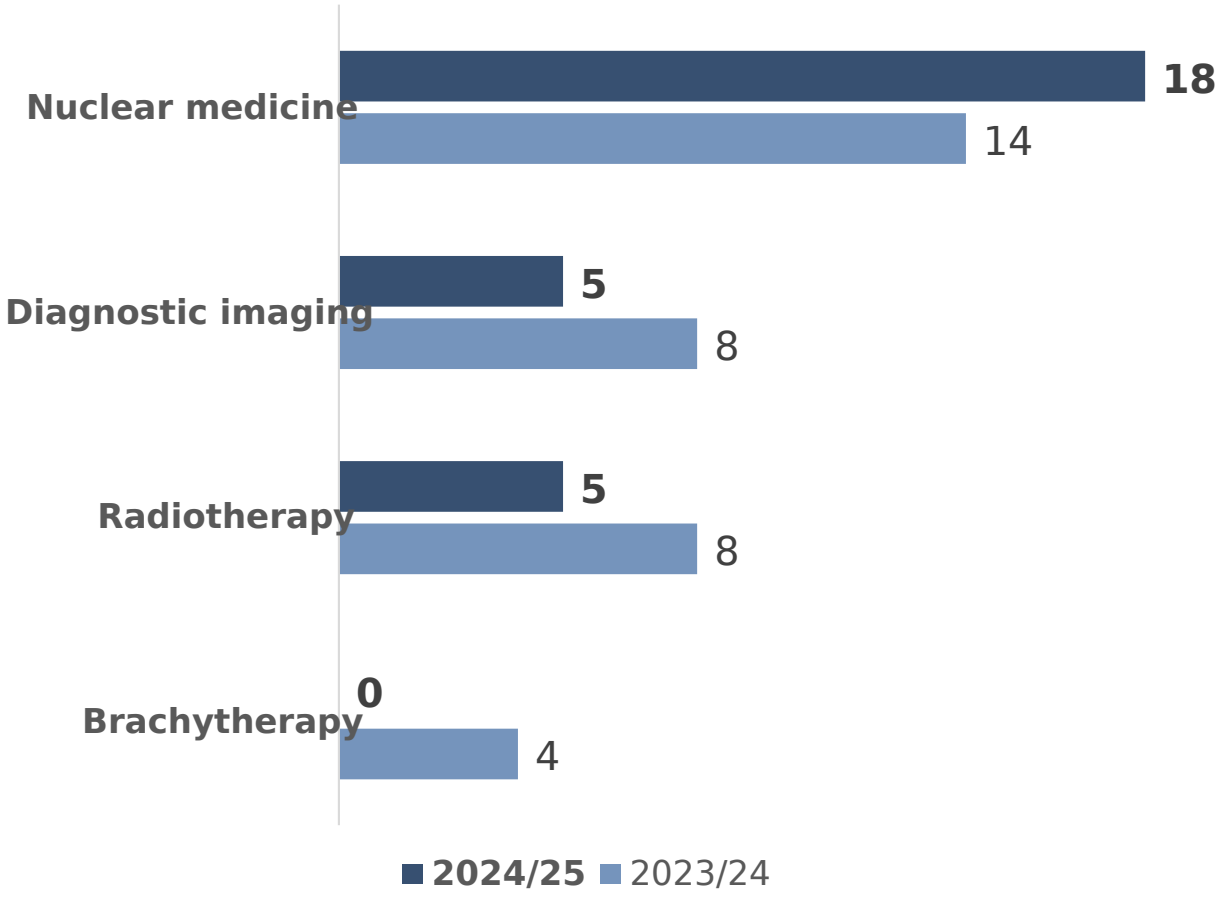
- considering the extent of the compliance gap, and the level of potential risk associated with the non-compliance in relation to patient safety at a formal decision-making meeting
- applying our enforcement decision making policy to decide if the gap reaches the threshold for an enforcement notice - the policy is derived directly from the Health and Safety at Work Act
- advising providers what they need to do to be compliant with the Notice and specifying a date for when this must be achieved.
- following up to seek assurances from the provider and confirm that they have completed the actions.

During 2024/25, we issued fewer formal enforcement Improvement Notices in both diagnostic imaging and radiotherapy, despite carrying out more inspections.

But in nuclear medicine, there was a notable increase in the number of Improvement Notices issued. This is a result of carrying out more inspections as opposed to more non-compliance within this clinical speciality.

We believe that enforcement notices are a positive function to support employers to meet the statutory requirements of IR(ME)R, and ultimately to drive patient safety improvements within a service.

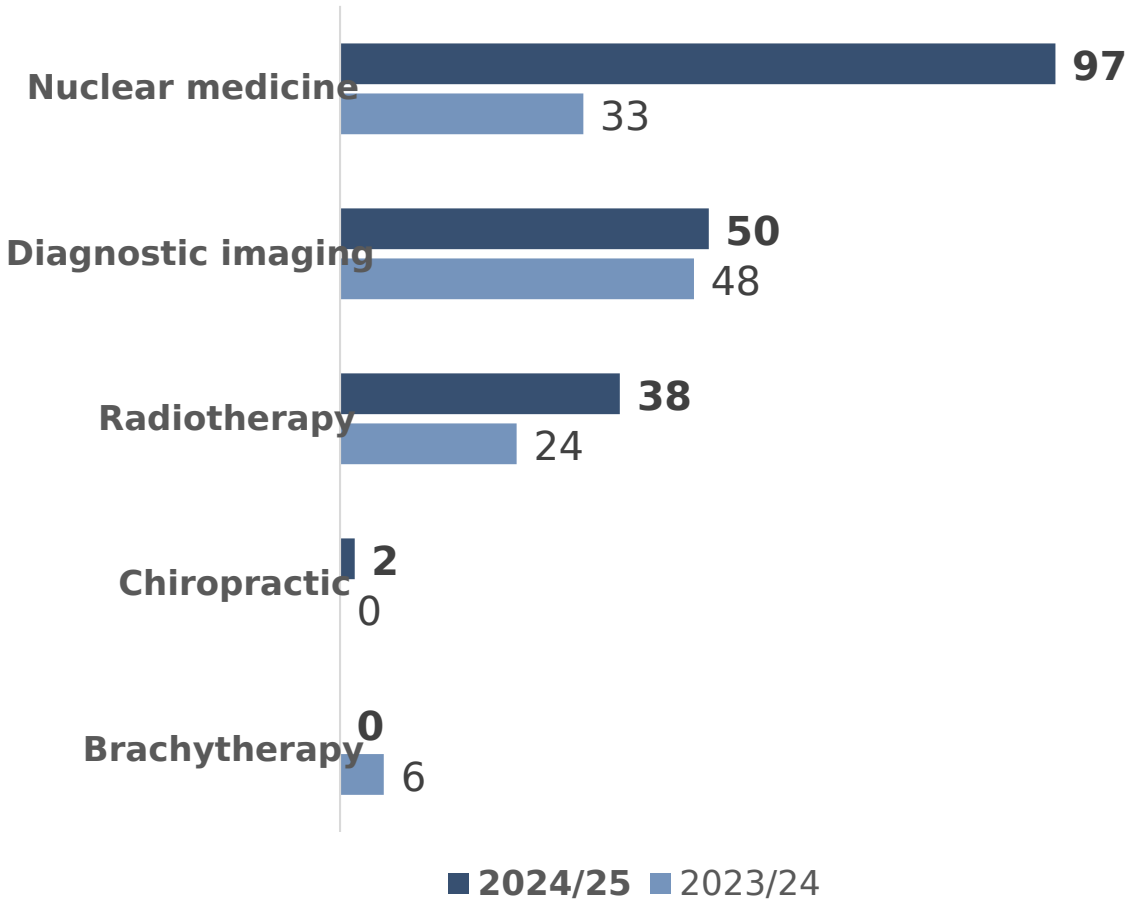
Figure 3: Total Improvement Notices issued for breach of regulations, 2024/25 and 2023/24 by modality



We continue to see areas of non-compliance with IR(ME)R in most of our inspections, which results in issuing quality improvement recommendations. Although they do not meet the threshold for an enforcement notice, they do require an employer to make changes to ensure compliance with IR(ME)R and other published standards that support current best practice and enhance quality of care for patients.

The number of recommendations in both diagnostic imaging and radiotherapy remained relatively similar to 2023/24, with another substantial increase noted in nuclear medicine. Again, we can attribute this to the increased number of inspections completed during this period. We noted persistent themes associated with gaps in compliance with the regulations and provide a detailed breakdown of inspection and enforcement activity under each modality.

Figure 4: Total recommendations issued in 2024/25 and 2023/24, by modality



Reminder for employers

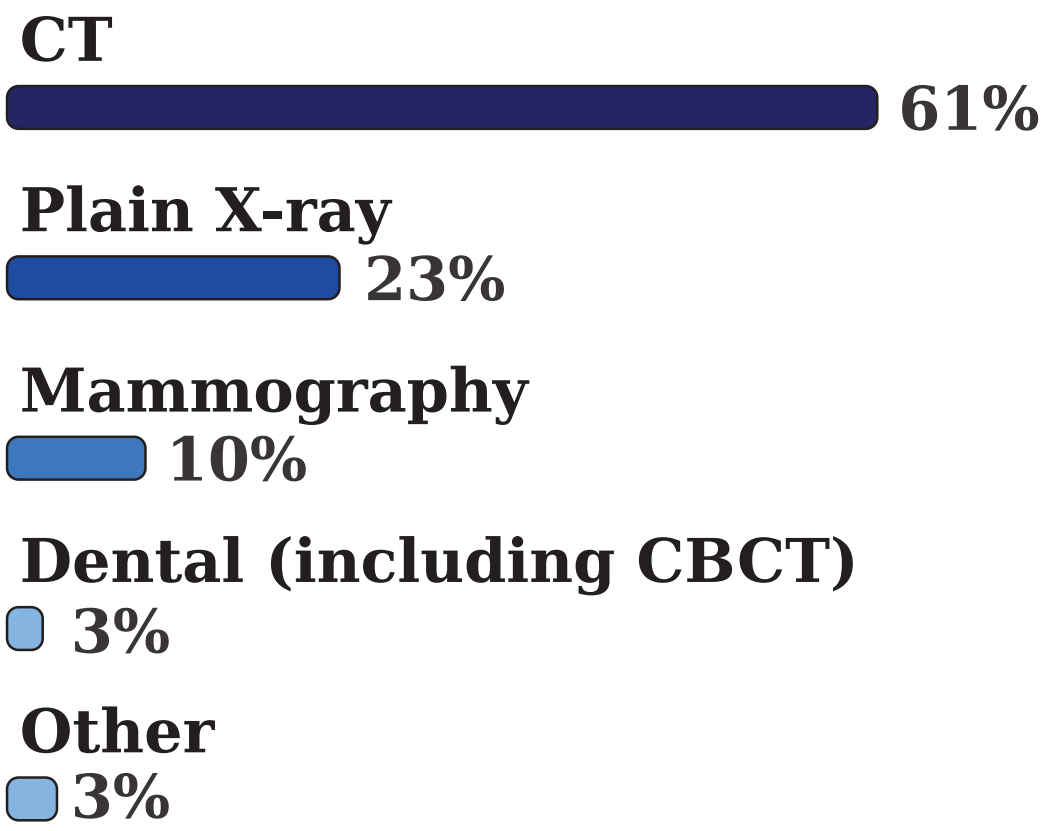
All IR(ME)R employers hold accountability for meeting legislative requirements, adhering to standards and best practices, and addressing any deficiencies identified during inspections.

Diagnostic imaging

Notifications

- There has been a small reduction in the number of notifications received this year, with 3% fewer than 2023/24 (434 compared with 447).
- Two-thirds of notifications (289) originate from within the patient pathway at either the referrer or operator points.
- Around a fifth of notifications related to equipment (76 notifications).
- Most notifications are from exposures in CT (computed tomography) (265 notifications, 61%), plain x-ray (101 notifications, 23%), and mammography (42 notifications,10%).
- We received very few notifications from within interventional or cardiology services.

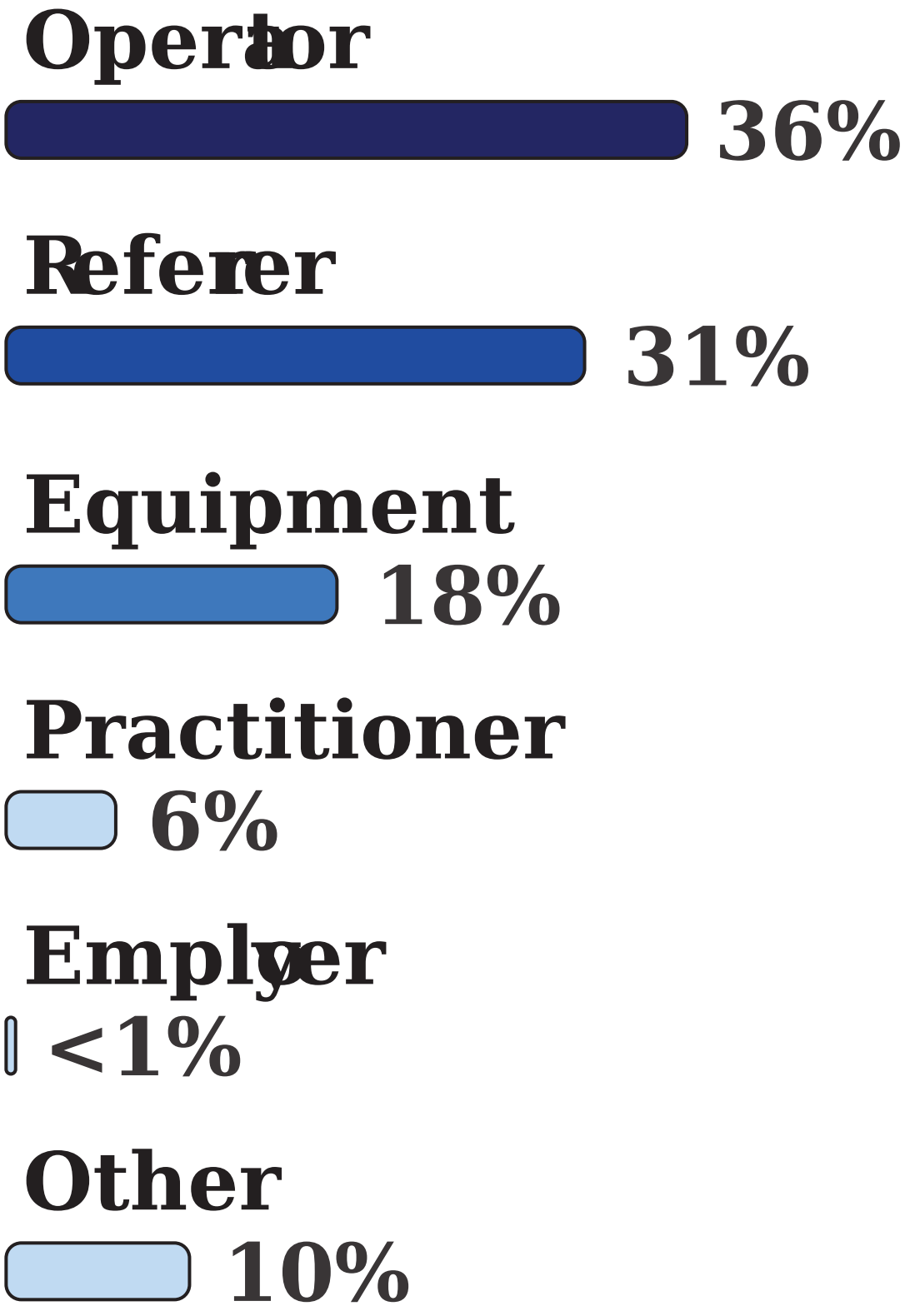
Figure 5: Diagnostic imaging notifications by modality, 2024/25



Note: there were 11 notifications for Dental (including CBCT) and 15 notifications for 'Other' modalities, which both round to 3%.

Two-thirds of notifications originated from within the patient pathway at either the referral or the entitled operator-led practical aspects of the exposure pathway (Figure 6).

Figure 6: Origin of notifications in diagnostic imaging in 2024/25


Operator
36%
Referrer
31%
Equipment
18%
Practitioner
6%
Employer
<1%
Other
10%

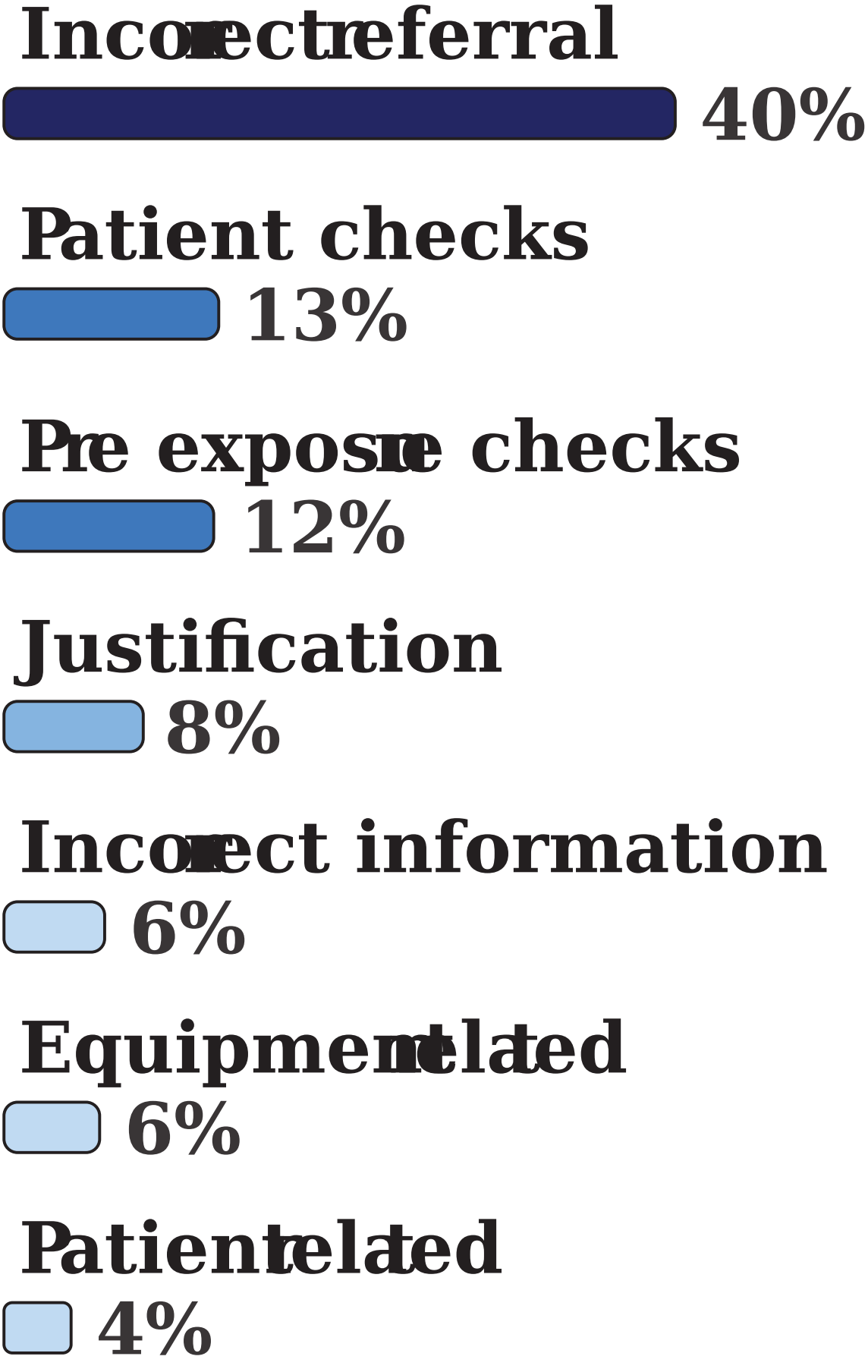
Of all the referral notifications, 123 (92%) originated within CT. We acknowledge that this is influenced by the notification criteria for accidental exposures and the dose threshold being more relevant to CT than other lower dose modalities.

In most cases, the error occurred at the point of referral – either with the wrong patient being referred or because of a failure to cancel a referral once it had been identified as inappropriate.

As an employer, you should consider:

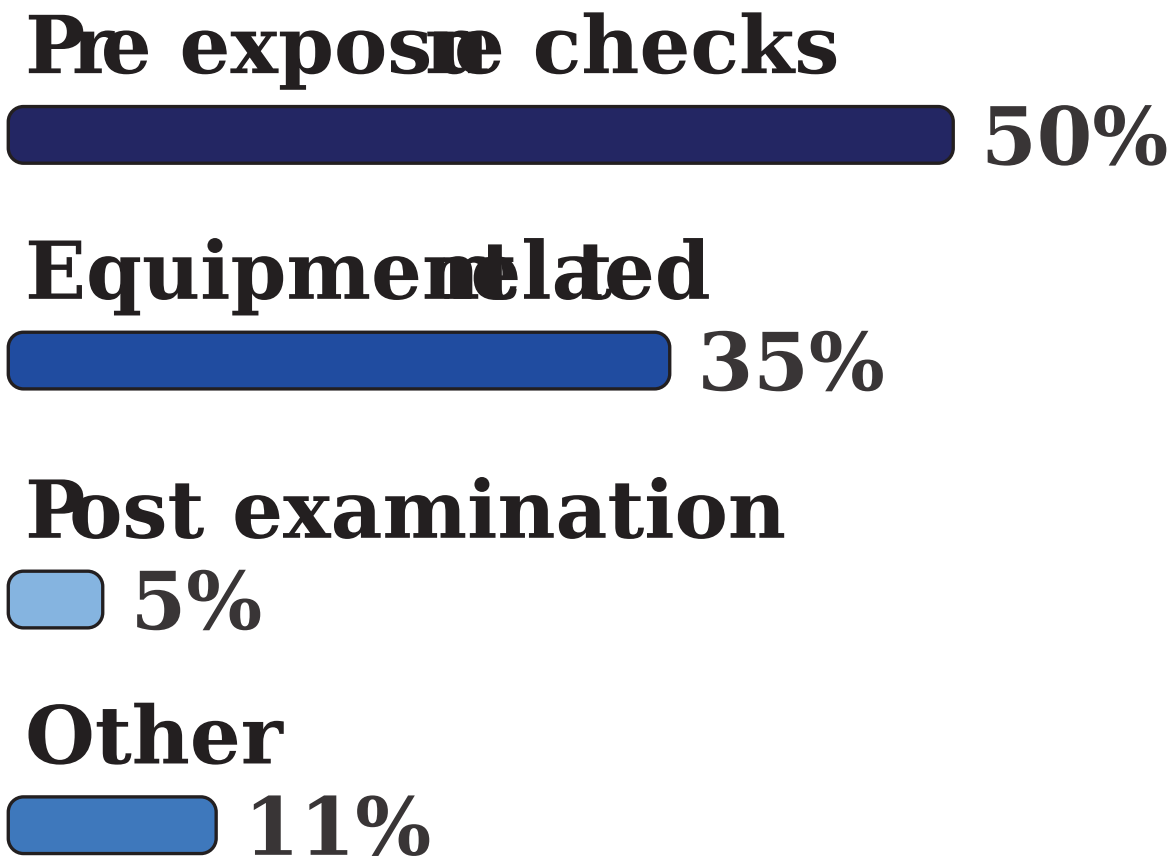
- how to reduce human errors among referrers, such as considering whether electronic platforms are sufficiently user friendly
- the effectiveness of the process to cancel a referral, and outline this in the relevant employer's procedure (EP), as this is now required following the recent amendments.

Figure 7: CT: Where incidents occurred in the patient exposure pathway


Incorrect referral
40%
Patient checks
13%
Pre exposure checks
12%
Justification
8%
Incorrect information
6%
Equipment related
6%
Patient related
4%

In planar X-ray, the most common type of incident happened during the pre-exposure checks. This includes incorrect use of equipment, incorrect patient set up, or incorrect protocol. We have identified a specific increase in the number of incidents because of detector errors (Figure 8).

Figure 8: Where incidents occurred in the X-ray patient exposure pathway



In mammography, most errors were a result of equipment faults covering both software and hardware. We highlighted this issue and shared learning about software in last year's report.

Inspection and enforcement activity

In 2024/25, we carried out 21 inspections in diagnostic imaging (15 in 2023/24).

We issued fewer Improvement Notices, which showed no specific theme. However, almost all inspections have resulted in at least one quality improvement recommendation to ensure compliance with the regulations. The total number of recommendations made has increased slightly, but this is largely due to carrying out more inspections.

Improvement recommendations from inspections

The following were the most common recommendations following an inspection:

Regulation 6(1) and 6(2): Recommendations under these regulations were the most common. They typically related to ensuring that there are suitable employer's procedures in place and that relevant duty holders follow them. We continue to see employer's procedures not being used as an effective guidance tool for operational staff, who often find them confusing.

We frequently find that the employer's procedures did not match clinical practice and that this has not been identified locally.

Actions for employers

As well as auditing practice, consider involving operational staff when reviewing employer's procedures to ensure they provide suitable and clear detail, and that you can communicate and rectify any divergence from current practice.

Regulation 6(5): In many cases, referral guidelines were not established and accessible to referrers, as required under Regulation 6(5). As demand for imaging continues to grow, the need for robust referral guidelines has become increasingly important to support external referrers in their decision making.

Actions for employers

Make sure that referral guidelines are in place, are appropriate to their service and accurately reflect their patient pathways, and check whether they are accessible for both internal and external referrers.

Regulation 15(3): We made several recommendations against this regulation, often observing inadequate routine performance testing. This is typically for local routine performance testing within the department, where we see a lack of testing or escalation in line with local policy or expectations.

Actions for employers

Some departments have chosen to employ lead roles to support this testing, but, as the employer, you still need to ensure that the testing programme is robust and have suitable oversight that it is being undertaken as expected.

Regulation 17(4): We continue to highlight poor training records, which is often due to confused record keeping, with providers unable to provide evidence of documentation on request. We routinely see training records with one signature covering an operator's entirety of competency set at once, rather than incremental assessment.

Actions for employers

Consider your process for deciding whether staff demonstrate competence for an appropriate sign-off, and how you record this.

Key themes in diagnostic imaging

Clarifying pregnancy enquiries

During our inspections and analysis of notifications, we have identified various approaches to enquiring whether a person may be pregnant. The most common initial pregnancy queries we see for examinations in the relevant anatomical range are:

- a straightforward question of "could you be pregnant?"
- the additional use of a form that requires details of the person's last menstrual period, with no application of the 10-day rule
- querying the date of last menstrual period with the application of the 10-day rule.

In some cases, providers decide not to differentiate between low and high-dose procedures and use one of the above approaches to cover all relevant exposures.

We have received notifications where there has been a foetal over-exposure due to the patient stating that they could not be pregnant, but without prompting them to think about their last menstrual period. We acknowledge that there are different interpretations of professional guidance, and although it is up to providers to determine their approach to implementing pregnancy enquiries, we recommend that providers consider whether their current approach for pregnancy enquiries matches the intention and is suitably robust.

We have also observed clinical practice that does not match the approach outlined in the department's employers' procedure. For example, this may state that relevant high-dose procedures should be scheduled within the first 10 days of the menstrual period, but with no practical application of how to manage this.

Where the employer's procedure refers to the use of the 10-day rule, it should be clear how to apply this practically and the responsibilities for duty holders should be clearly set out. Where flow charts are used to support staff who undertake pregnancy enquiries, these should make the process clear for each situation.

Actions for employers

- Make sure your procedure matches its intended approach.
- Your employer's procedure should outline any differences or specifics across modalities or examinations and make clear to duty holders on how to document pregnancy enquiries.
- Check the purpose of any audits, and whether they intend to observe clinical practice or how pregnancy checks are recorded.

Use of employer's procedures across multiple modalities

We often come across examples of good employer's procedures that we believe have been well thought through and incorporate the point of view of those who are required to follow them. Many procedures have helpfully become more specific and relevant to the local clinical areas.

During inspection, we often look at things from the viewpoint of a member of staff joining a new area, for example a radiographer starting to work in a cardiac catheter lab for the first time. We often identify that all operators are aware of the requirements within the procedures, such as ID or pregnancy checks, but as they move from one hospital to another within a trust – or even to a different clinical area within the same hospital – they are not as aware of any new arrangements and how to document any responses.

We encourage organisations to consider adopting this approach when updating their own employer's procedures, promoting the idea that the procedures should support staff with specifics on 'this is how we do it here.'

In one inspection, we noted how the trust had written different sets of employer's procedures to reflect proper working practice within general radiography, cardiology, breast screening, and dental radiography. The service had taken the view that the arrangements in these clinical settings were sufficiently different to warrant multiple sets of procedures.

We recognise that such an approach will not work for all organisations. Others may prefer to have a set of procedures for specific modalities supported by an addendum for any nuances in specialised areas. We recognise that in some cases, due to workforce structure or rotations, it may be better to have a single set of employer's procedures.

Co-operation between employers within incidents

The 2024 amendments to the regulations included the requirement for co-operation between IR(ME)R employers to ensure that each can comply with the requirements of the regulations. This is required when 2 or more IR(ME)R employers are involved in the exposure to a person.

In these cases, it is important to have clear lines of responsibility, escalation and communication. We have identified good working practice where employers collaborate on joint investigations and share learning widely across organisations to improve safety. This collaborative approach has resulted in identifying any actions, mitigations and training that may be required by either or both employers.

We have also seen examples of delays to notifications as responsibility was not clearly defined or because of ineffective escalation mechanisms when an issue was identified. This has also resulted in delays in identifying training requirements, procedural errors and actions required.

Actions for employers

Ensure that co-operation regarding regulatory responsibilities is straightforward and unambiguous. There should be a clear process between the employers for the appropriate involvement in investigations of any accidental and unintended exposures.

Effective information technology systems to reduce errors and improve patient safety.

There are many advantages of electronic systems of work, from radiology information systems (RIS) to electronic patient referrals (EPR), including workflow efficiency and improved patient care.

However, we have identified areas of increased risk that can lead to errors where information technology (IT) systems are not integrated.

Examples from notifications where non-integrated IT systems were a primary or contributory factor include:

- referrers needing to have multiple screens open to make a referral and access patient records
- difficulty in cancelling referrals
- difficulty in identifying referrers and unretrievable images.

Actions for employers

Consider the compatibility of systems as part of the procurement process, and support radiology departments to manage and streamline the data requirements for an effective, safe, and efficient service within the constraints of current systems.

Detector incidents

We received an increase in notifications related to repeat exposures due to the incorrect detector being selected. The vast majority were extremity exposures that were reported as a theme under the 'M' category. None were attributable to design features from a specific manufacturer and were from both the NHS and independent sectors. Learning from detector errors was also previously highlighted in our 2019/20 annual report.

Through our inspection programme, we have identified that some services were identifying detector errors as a theme within their governance meetings but not reporting these to us as required under the criteria.

There were several possible reasons for an additional unintended exposure:

- The patient's own presentation being different to that in the standard protocol (for example, being unable to stand against an erect bucky). This would lead staff to use an alternative technique using a free wireless detector, often successfully for the initial projection but not for subsequent views where the system would default back to the erect bucky.

- The selectable displays of the equipment being unclear or misunderstood by operators. For example, staff believing that a green dot on the control panel suggested a specific detector was selected and enabled, when in fact it did not indicate which panel was selected.
- An unclear process when the detector battery runs flat, and whether the system automatically defaults to another detector, which can go unnoticed.
- The incorrect detector being set up in error within the protocol.

Here, we describe some of the learning identified and the actions taken to raise awareness and provide possible fixes:

Improving the equipment's user interface

Many providers identified areas for improvement within the equipment's user interface, which could help operators during set-up. For example:

- Some providers improved detector nomenclature and labelling
- One organisation re-arranged the order of the detector selection so that it was more logical for staff and removed detector selections that were not relevant
- Others have worked with manufacturers to add additional on-screen pop ups to remind operators to check that they have selected the correct detector

If your department has X-ray rooms from multiple manufacturers, it may help to assess differences between user interfaces and to ask operators to highlight positive attributes of certain user interfaces. This can help during discussions with manufacturers around potential changes and can help inform future procurement.

Refreshed checklists and reviewing protocols

Some providers found value in changing the tone of 'Pause and check' to 'Stop and check'. This introduced a firmer approach to ensuring that staff take the time to check their set-up – even when under pressure to take the exposure quickly. Others introduced additional checks for operators, for example a specific check of whether the bucky tray was open or closed.

Departments also found it useful to review their programmed equipment protocol settings to ensure that the preset detector choices matched the expected set-up of the clinical examination. Some departments provided additional bespoke free detector protocols for use with patients who were unable to undergo an exposure with the table or vertical bucky.

Staff training and competency assessments

All operators must undergo appropriate induction training. If certain equipment is more challenging for operators, departments can consider specific periodic refresher courses. We expect organisations to implement measures to ensure staff are adequately trained to use manufacturer-specific features. Some departments used bespoke sessions in a controlled environment to provide additional support. Some organisations provided training specifically focused on the need to take their time and not rush detector selection checks – even when under time pressure.

Review actions required following an incident

All incidents should be escalated locally and subject to appropriate trend analysis, which is often discussed during governance meetings. We have received notifications where operators have not always been able to identify when an incident has occurred, resulting in multiple unintended exposures within a short space of time.

Actions for employers

- You must train your operators to identify blank exposures, adopt a cautious approach and call for assistance where required.
- Any learning from incidents should be shared, discussed sensitively at team meetings or huddles, and emailed to staff who are unable to attend.

Human factors

We acknowledge that human errors will happen, and that detector errors may never be fully prevented. Detector errors have represented only a small portion of the total number of exposures in the notification received. We have seen that incidents still happen despite considering the learning available.

Actions for employers

Consider human factors – this may include the environment, time to carry out additional pre-exposure checks, as well as work patterns or culture.

Examples of notifiable accidental and unintended exposures and actions taken

Co-operation between employers

Several patients received low dose lung screening scans, despite having received relevant imaging examinations within the previous 12 months, which should have led to a deferred scan. The referring provider was expected to carry out previous imaging checks, with the provider undertaking the exposure being responsible for making an additional check with the patient.

Actions taken

- The investigation identified that the multi-organisational standard operating procedure was not detailed enough and did not appropriately outline responsibilities for checking previous imaging. The providers involved created a joint action plan that included adding additional information to the procedure.
- New staff had not been suitably trained to carry out prior imaging checks. The referring provider therefore created a training log to maintain a record, which was kept in an accessible location.
- Reminders were sent to the booking team to ensure all information, including details of previous scans, are recorded on the radiology information system and are therefore accessible to operators.
- The investigation identified additional opportunities for the provider undertaking the exposure to have discussions with the patient around possible previous imaging.
- The investigation also reviewed near misses and identified where scanning operators had made positive cancellations.

Learning from the incident

This example demonstrates the importance of a collaborative investigation, where both the IR(ME)R employers involved in the patient pathway identified improvements.

Providers have a responsibility to minimise the occurrence of accidental and unintended exposures and that even if there initially appears to be a failure from one employer, there should be an investigation that considers preventative opportunities across the whole patient pathway.

Where relevant near misses are identified, providers should consider whether their co-operation framework is suitable for sharing this learning.

This example also demonstrates the importance of having clear outlined responsibilities for their respective parts of the patient pathway under IR(ME)R.

X-ray detector errors

A thematic review identified several unintended exposures attributable to incorrect detector selection by the operators. Most of the unintended exposures had taken place on newly installed equipment.

Actions taken

- After installation, operators received cascaded training. Following initial incidents, staff received further training tailored to individual needs. Meetings were held with operators who had been involved in the incident as well as those who had not, to identify any differences in practice and possible learning.

- After previous similar incidents in other rooms, the provider had engaged with the manufacturer to adapt equipment. This successfully led to changes that prevented exposures based on tube direction, as well as if the free detector was docked. The department liaised with the manufacturer of the new x-ray room but in this case was unable to make any changes. However, the provider gave feedback to the manufacturer about possible improvements.
- The new x-ray room had a positioning camera that displayed on the console screen. This was shown to obscure warning messages when making certain detector selections. The department therefore added additional physical reminders to the consoles.
- The service reviewed its employer's procedure for minimising the probability and magnitude of accidental or unintended exposure to ensure received as much information as possible.
- Following a detailed human factors investigation, the department purchased multiple positioning aids to help with patient stability and reduce pressure on operators. Staff were reminded to document where any relevant patient information that affected planning exposures had been omitted.

Learning from the incident

We often see detector errors attributed to human error, but this notification was a good example of a provider doing a thorough assessment of contributory factors.

The department reflected on its procurement and commissioning process. It identified that, as the new equipment was from the same manufacturer as previously installed equipment, it was assumed that staff would be able to adapt more swiftly due to similarities.

Providers should be cautious of assuming that familiarity will carry over and should identify differences and provide corresponding training. They may also consider specific safety features and whether it is possible to make software adaptations as part of the procurement process.

This department acknowledges that there may still be ongoing incidents and that this is likely to be a continuous managed process. Where this is the case, it is important to consider human factors to reduce occurrence so far as reasonably practicable. Departments may consider including any relevant detail for operators in their employer's procedures.

Radiotherapy

Notifications

In 2024/25, we received 291 notifications – this is 19% more than last year (244 notifications). This was primarily due to an increase in the number of incidents involving equipment.

Notification coding was amended this year to reflect national patient safety taxonomy for adverse events and to help share lessons learned. Incidents often arise due to the complex and ever-changing nature of radiotherapy, rather than individual lapses or isolated system flaws. We have therefore moved away from reviewing the detail of incidents at the point of failure, for example practitioner failure or treatment operator error. Instead, we will review the notifications relating to where they occurred in the pathway. This will allow providers to use the information to review their existing systems and benchmark against our data.

We have separated events that have occurred in external beam therapy (EBT) from events in brachytherapy to further facilitate learning.

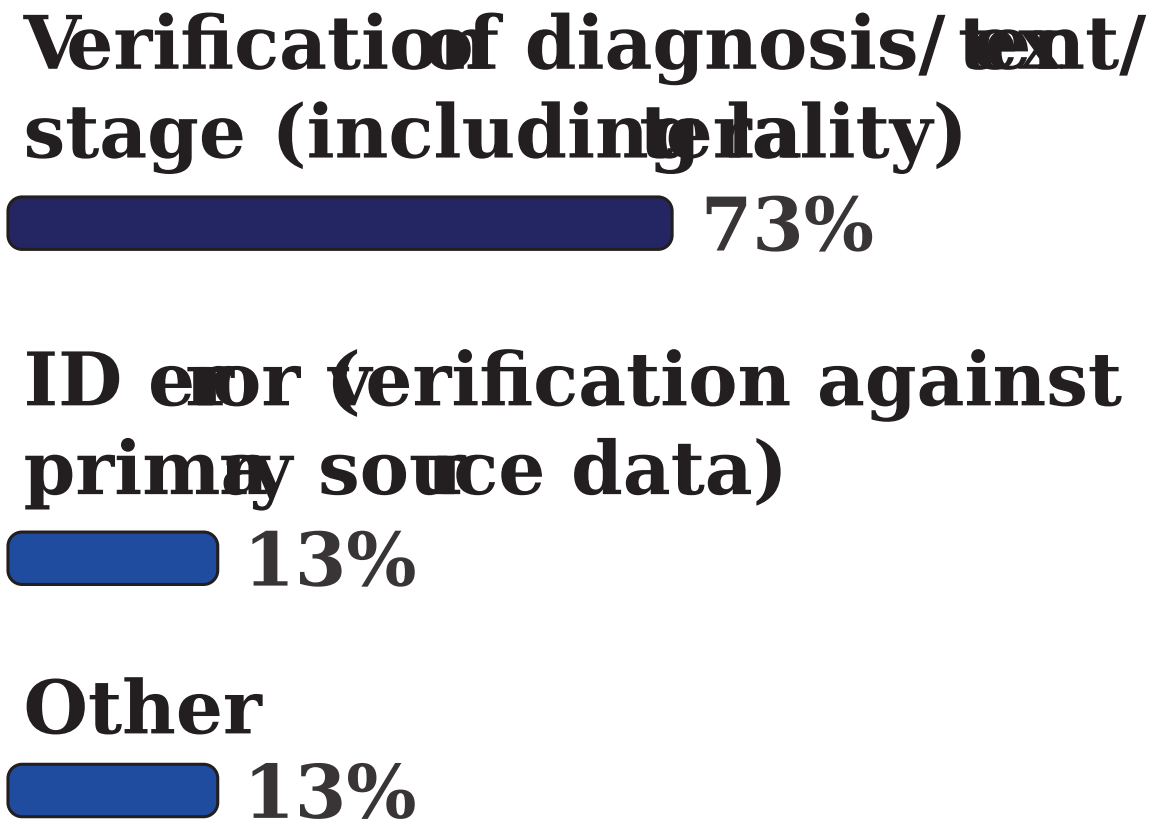
External beam therapy

Analysis of notifiable incidents in external beam therapy received during 2024/25 is broken down into relevant stages of the patient pathway where the incident occurred. Of the 291 notifiable radiotherapy incidents reported to us, 282 related to external beam therapy.

Incidents in referrals for external beam therapy

Incidents originating at referral stage (15) were predominantly the result of incorrect verification of the diagnosis, extent or stage (including laterality).

Figure 9: Referral incidents in external beam therapy, 2024/25



In these incidents, common points of failure included:

- no process to highlight patients who were waiting for results before being referred
- poor communication of additional information
- inadequate assessment of referrals before planning scans.

Mitigating actions taken in response included:

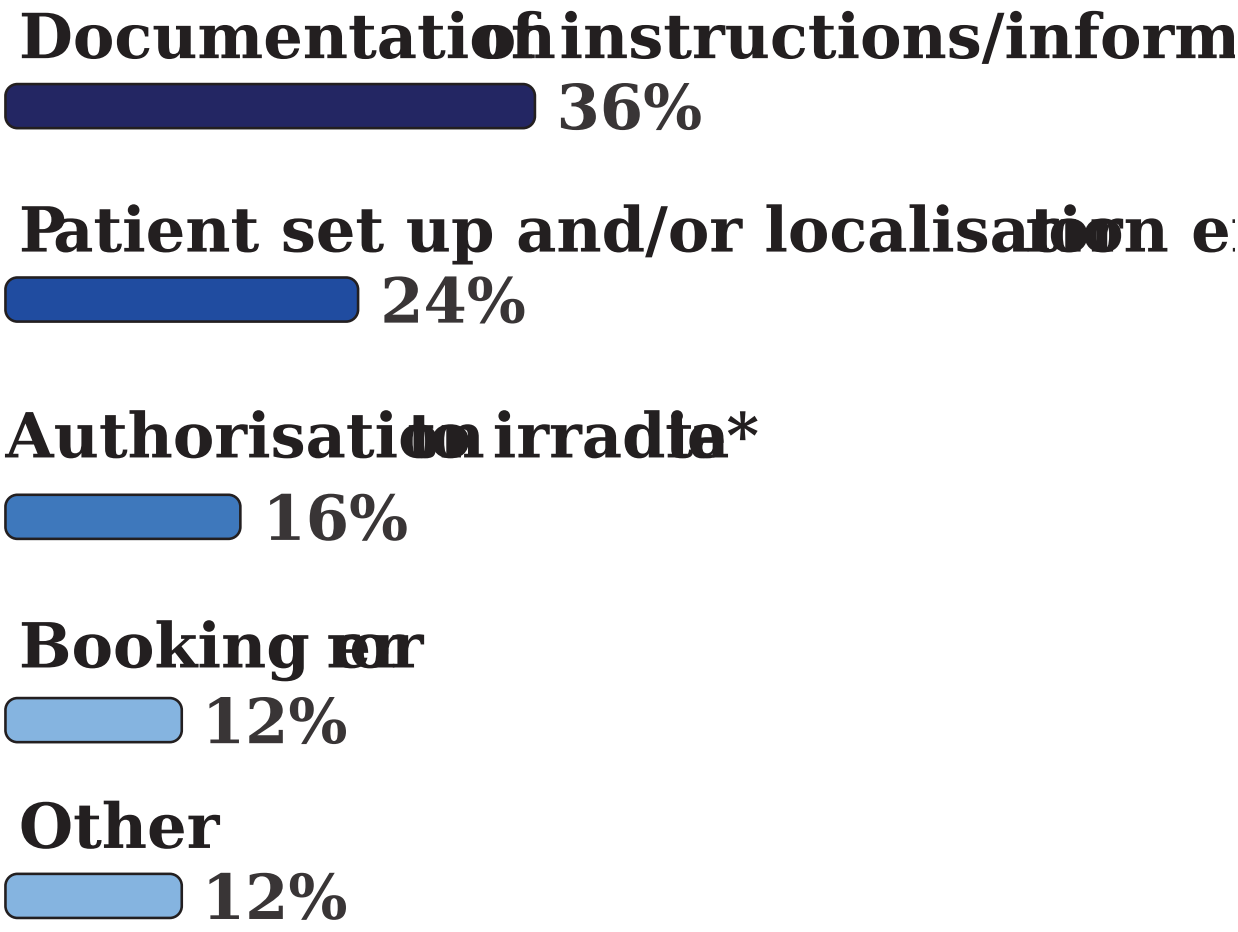
- amending referral processes and forms to be able to flag patients who were waiting for test results

- formalising communication pathways to include generic email addresses that are always monitored
- creating referral assessment processes and updated procedures to state that concerns relating to the referral must be discussed and documented before delivering the planning scan.

Incidents in pre-treatment external beam therapy

For notifications of incidents occurring at pre-treatment stage (25), 60% related to the documentation for instructions or information relating to treatment, for example immobilisation parameters or annotation of tattoo position. Other factors included authorisation to irradiate and booking events.

Figure 10: Notifications by type of error in external beam therapy pre-treatment stage, 2024/25



* Including requests not signed by appropriately entitled practitioner a authorisation of additional imaging

A persistent theme within this group of incidents was inaccurate data recording of patient immobilisation devices used to minimise patient movement during treatment. These were mostly attributed to lapses and human factor events. Mitigating actions therefore mainly focused on ensuring that documentation and training was adequate. Incident investigations highlighted the need for:

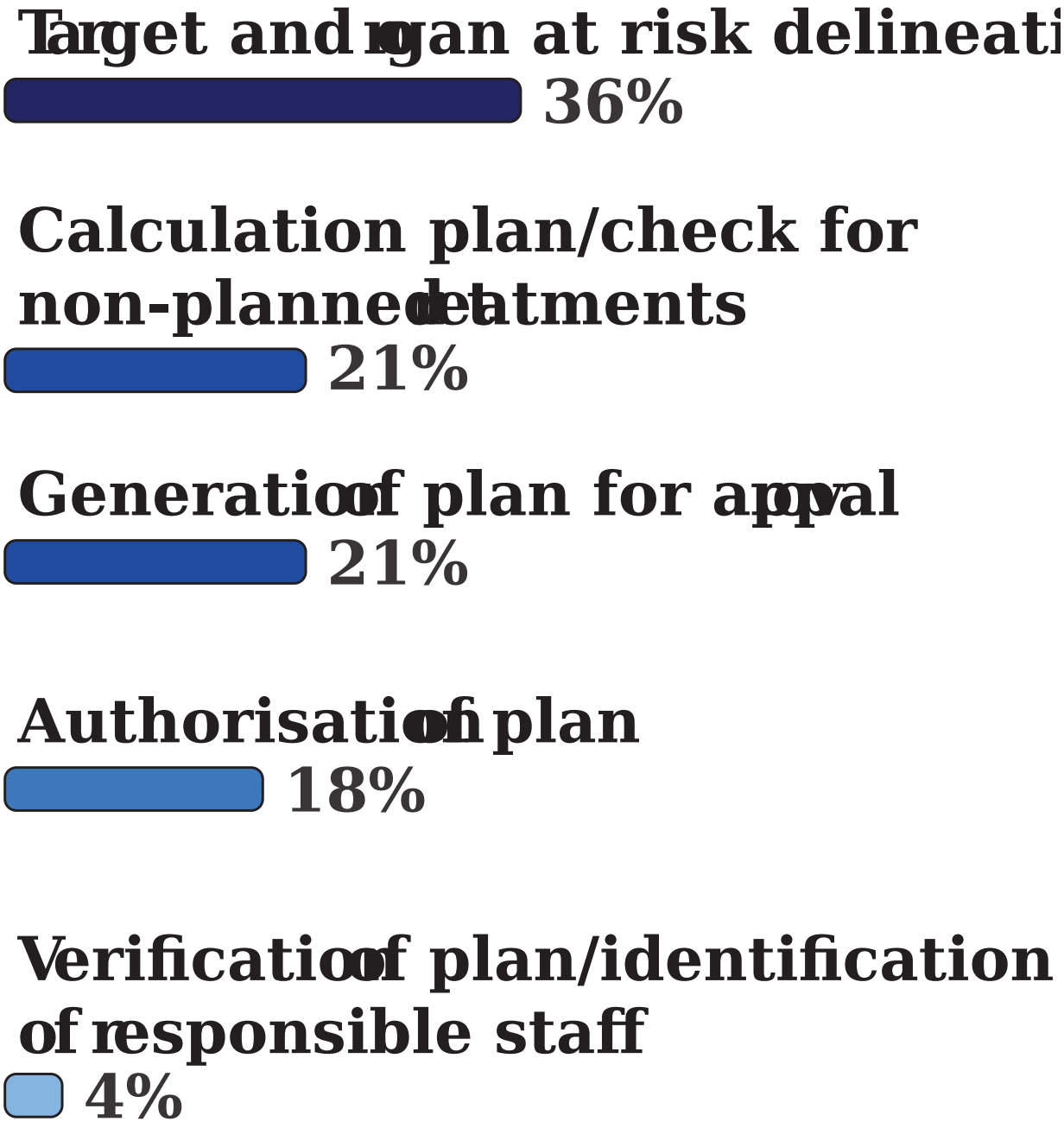
- a robust referral assessment ahead of scanning
- the importance of the pause and check process
- independent checking of data input.

Incidents in external beam therapy treatment planning

Over a third of planning stage incidents related to target and organ delineation. This could suggest that peer review of contours is still a risk factor.

We have seen on inspection that some centres are managing the peer review process well, using the recording and verification systems in innovative ways to record peer review. However, many centres still do not have systems in place for peer review, or, if they do, there is no formal method of recording the outcomes.

Figure 11: Notifications by type of error in external beam therapy treatment planning, 2024/25



We continue to receive notifications for errors occurring in the production of non-planned treatments, which rely on manual calculations and input. These techniques are often delivered out of hours or as emergency treatments, for example emergency cord compression. Our review of reports for incidents suggests that a common causative factor regarding these techniques is insufficient experience, training, and knowledge.

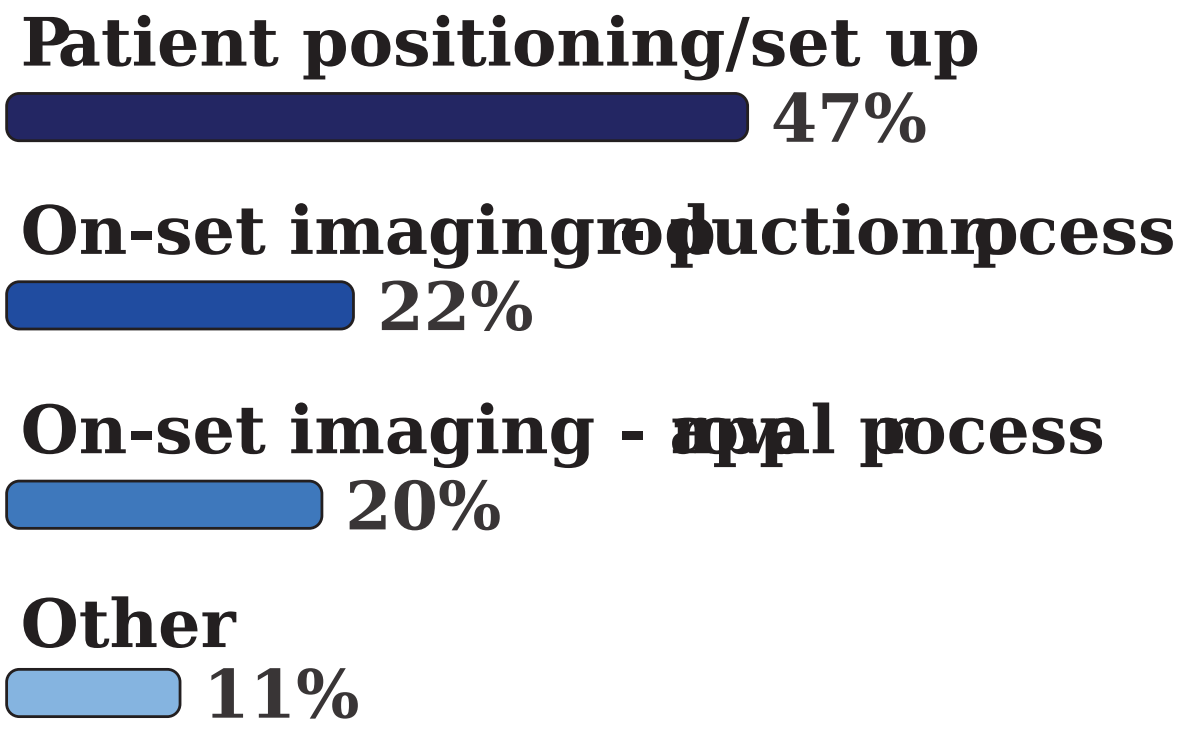
Departments should aim to assess staff competency for rarer techniques regularly. Some effective interventions included developing processes that would remove the manual element of dose calculation. Moving forward, many departments are considering planning all treatments using the treatment planning system and no longer using manual calculations.

Incidents in external beam therapy treatment

This continues to be the area where most incidents happen in external beam treatment, accounting for nearly half of all external beam notifications (128). Of these:

- 47% were due to incorrect set up or positioning of the patient
- 42% were due to incorrect verification imaging – either the production of the image, or inappropriate approval of the image.

Figure 12: Notifications by type of error in external beam therapy treatment delivery, 2024/25



Accurate patient positioning continues to remain an important area of practice, with many incidents originating from the selection of immobilisation equipment or use of documented patient set up information.

Effective actions to address these challenges included:

- having one single source of information for treatment set up that is not transcribed from the pre-treatment records
- consistent selection of immobilisation equipment and use of indexing on treatment couches, even for non-planned treatments
- using skin-render or photographs for treatments where required
- using surface guided monitoring systems to mitigate patient positioning errors.

The number of notifications relating to image production and approval process are consistent with previous years and reflect the full integration of image guided radiotherapy (IGRT) into the treatment pathway. IGRT is a key element of delivering and developing advanced radiotherapy techniques. It depends on skilled interpretation and decision making while interacting with complex equipment. Therefore, the high level of incidents in this area is the predictable result of human and technological interactions within a complex system.

Incident reports advised that effective changes to practice included:

- protocols that are site-specific with defined imaging frequency and escalation processes
- site-specific imaging pre-sets
- regular departmental imaging audits to monitor compliance and concomitant doses for patients.

Brachytherapy

There were a small number of incidents in Brachytherapy, 44% of which related to the positioning of the applicators or sources.

The nature of brachytherapy treatment means that this remains an area of concern, and common failure points included inadequate work instructions, faulty equipment, and human factor errors.

Mitigating actions included:

- reviewing protocols to ensure they are accurate and reflect practice
- robust pre-treatment checklist with role-specific steps
- ensuring adequate staffing levels
- using retrospective audit.

Inspection and enforcement activity

We carried out 21 inspections of radiotherapy services in 2024/25, which is more than the previous year (15). We have now inspected all providers and have started the second round of inspections using a new inspection methodology.

We have used the new methodology in the most recent inspections, using an IR(ME)R inspection self-assessment questionnaire. This asks the provider to complete a questionnaire and provide evidence that we request as part of the inspection. The inspector reviews all information ahead of the site visit, which allows more time for inspectors to observe clinical practice in all aspects of the patient pathway while they are on site.

Providers report that the process is effective, as it allows them to review their compliance in a systematic way. As part of the process, the questionnaire asks providers to declare any areas of non-compliance, along with any ongoing actions to address them. This gives providers an opportunity to detail how they are mitigating against any areas of non-compliance with the regulations.

We continue to recommend that providers share their experience of inspection to share the learning.

In 2024/25, we issued an Improvement Notice against one provider, compared with 4 in the previous year. We also completed 3 inspections where we did not identify any compliance gaps, compared with our inspection programme in 2023/24 where we made recommendations against every provider inspected. This shows an overall improvement in the application and adoption of the requirements of the legislation for the benefit of patient safety.

Superficial radiotherapy inspection programme

We carried out a targeted inspection programme of services that deliver superficial radiotherapy (SXR), primarily for skin or non-malignant conditions. The programme of 5 inspections used a combination of our standard method and the self-assessment questionnaire inspection method.

We did not issue any Improvement Notices for SXR services during the inspection programme, but we made 4 improvement recommendations for:

- Regulation 6(1)(a): unclear guidance for the exposure of carers and comforters
- Regulation 6(4): clinical protocols were missing for benign/non-malignant treatments
- Regulation 17(1): inadequate training records
- Regulation 17(4): unable to provide evidence of relevant training record(s).

We found examples of good practice, including:

- an SXR-specific study of risk
- cross-site peer reviews
- additional checks for high-dose treatments.

We also noted some limitations across the service, including:

- operator competence acquisition (and maintenance)
- staffing issues
- a lack of clinical audit and non-specific competencies.

There are also concerns regarding the potential fragility of the service nationally. This is due to:

- ageing treatment equipment (the average age of treatment units was 11 years)

- the availability of adequately trained operators and practitioners
- minimal superficial consultants within services.

Improvement Notices

We issued one Improvement Notice this year to a service providing radiotherapy, although the Notice detailed compliance gaps against 5 separate regulations. The following summarises the regulations cited within the Improvement Notice and the actions that the trust took to become compliant:

- Regulation 6(5)(b): The employer must establish quality assurance programmes for written procedures and written protocols. Actions taken include:
- giving consultants more capacity to review clinical protocols
- staggering document review dates over a longer period
- updating the trust's policy relating to QA.
- Regulation 8(1): Providers must understand the requirements of the legislation in relation to accidental or unintended exposures that are deemed to be clinically significant, and their employer's procedure must detail the responsibilities of individual IR(ME)R duty holders if a clinically significant incident occurs. Actions taken include:
- updating the incident management policies
- regularly auditing new processes would be regularly audited
- Regulation 14(2): A medical physics expert must be closely involved in every radiotherapeutic practice. Actions taken include:
- implementing a workforce plan with support from the trust, which included a formal rota for medical physics expert cover
- arranging with a neighbouring service to provide support when required

- Regulation 15(1)(b): The employer must draw up, keep up-to-date and preserve an inventory of radiobiological equipment. Actions taken include:
- updating the inventory document
- Regulation 17(4): The employer must keep and have available for inspection by the relevant enforcing authority an up-to-date record of all relevant training undertaken by all practitioners and operators. Actions taken include:
- the trust producing a specific training and competency policy for physics staff and streamlined competency levels
- updating the training records and associated processes for maintaining training records for staff employed at the trust before IR(ME)R 17 was updated, and including those who had been granted entitlement under 'grandparenting' rights in the training matrix
- implementing electronic training records in the trust.

Improvement recommendations from inspections

In 2024/25, we issued 38 recommendations following 18 inspections. Of these, 37 related to only 4 regulations.

Inspection recommendations for Regulation 6

Regulation 6 relates to the duties of the employer, which includes the management of procedures and protocols, particularly those relating to Schedule 2. We issued 14 recommendations that covered the following:

- procedures and protocols were missing, unclear or did not reflect practice
- controlled documents were printed off at point of use and not updated as required
- procedures and protocols were not reviewed within the timescale specified by the organisation

Complex systems such as radiotherapy services need documented procedures to guide practice. It is imperative that access to the quality management system (QMS) is available at the point of use and includes procedures that reflect practice and are audited regularly. The QMS should be appropriately monitored through governance meetings and resources made available to manage it.

Staffing issues were often cited as a reason for the breach, for example the unavailability of clinicians means they are unable to approve clinical protocols.

We saw examples where the QMS status was either not monitored, where it was monitored and not actioned, and, in good departments, where it was actioned and escalated appropriately.

Providers that demonstrated good practice had common processes to manage the QMS, including:

- a dedicated quality manager
- clinicians' job allocations included time for tasks such as clinical protocol approval
- a clear process to review documents, with escalation processes and actions for non-adherence.

Inspection recommendations for Regulation 7

Regulation 7 relates to the management of clinical audit in a service, which includes taking appropriate actions following an audit. We issued 5 recommendations against a breach of Regulation 7 as we had identified areas including:

- a poor definition of clinical audit, with multiple references to regulatory audit
- receiving examples of regulatory audit only, rather than examples of clinical audit as requested
- poor or missing procedures relating to managing clinical audits
- inconsistent or missing processes for disseminating audit findings.

Clinical audit relates to improving patient outcomes, whereas regulatory audits assess whether practice reflects the documented process. It is vital that providers clearly define clinical audit, including how to manage it and how to take appropriate actions following completion. This also requires there to be a process to re-audit at a suitable time gap once appropriate actions have been implemented to measure the efficacy of the changes.

Inspections where we made no recommendations all had similarities in how they managed clinical audit, including:

- a clear process showing how clinical is managed within departments, with regular tracking in meetings as standing agenda items – some centres used the QMS for this with good results
- a defined process to disseminate outcomes, to ensure appropriate actions are taken.

Inspection recommendations for Regulation 8

Regulation 8 relates to the management of significant accidental or unintended exposures (SAUE).

We issued 13 recommendations relating to this regulation due to:

- missing or unclear procedures relating to clinically significant accidental or unintended exposures (CSAUE)
- providers not reporting incidents in line with reporting requirements
- poor documentation management relating to incident investigation
- poor management of non-notifiable events

Providers that were compliant with this regulation had clearly identified the process to manage CSAUE events, which included escalation processes. They were also able to demonstrate that this process was followed in practice.

Providers must ensure that all duty holders are aware of the thresholds for reporting to the enforcing authority. Some centres relied on a single individual to code an incident, or decide whether it was notifiable, which had significant points of failure. Effective management included:

- a multi-disciplinary team approach to reviewing and coding events
- keeping investigation reports and related documents in an easily accessible location, for example in incident management systems, QMS or patient notes
- including decision making relating to incidents and their classification in the investigation, for example dose assessments or email chains relating to CSAUE events
- sharing lessons learned from incidents with the whole department or across the organisation as standard practice.

Inspection recommendations for Regulation 17

Regulation 17 relates to the training of duty holders and the associated training records.

We identified 14 instances where training arrangements and records were inadequate. Although we noted an overall improvement in the training records for practitioners. This may be directly attributable to the professional guidance published in 2023 which provides specific advice on the management of training records for clinical oncologists.

We found that multiple employers were transitioning between using paper and electronic records, which sometimes made it difficult to locate records. We also noted that training requirements for entitled operators who were authorised to carry out additional imaging, pre-treatment, or verification imaging is still unclear.

Actions for employers

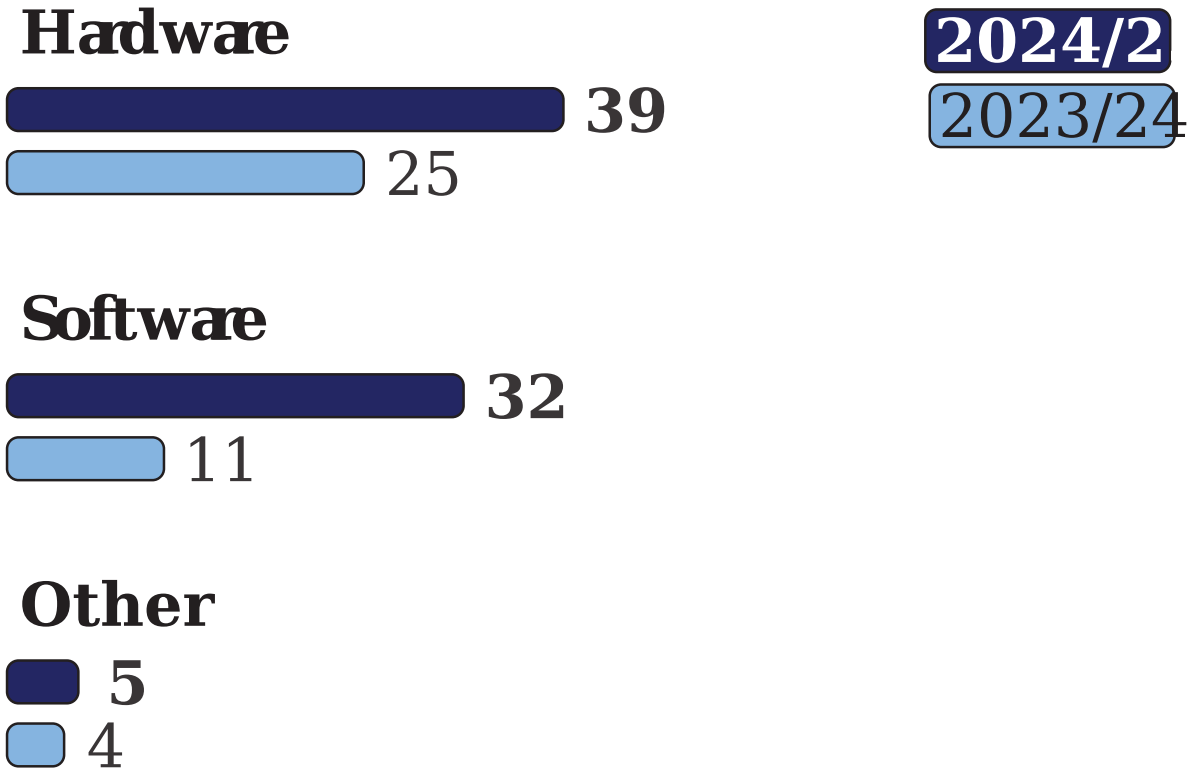
You must ensure that operators are adequately trained and competent to perform the tasks assigned to them.

Key themes in radiotherapy

Equipment faults

There has been a marked increase in the number of notifications as a result of equipment faults, with a 90% increase from 2023/24.

Figure 13: Total radiotherapy equipment fault incidents, 2024/25 and 2023/24



The equipment faults in 2024/25 all related to the delivery of external beam treatment using linacs (linear accelerators). Several incidents have affected multiple providers nationally. These included:

- a frame rate error that delivered an increased dose to patients during treatment verification
- CBCT (cone beam computed tomography) that stopped emitting X-rays mid-acquisition, which results in the image being unusable
- communication failures when acquiring kV images.

In all these cases, although the actual dose delivered to the patient was minimal compared with the intended dose, the fault affected multiple patients, in some cases over 1,000 patients were affected, therefore action is needed to minimise the risks associated with these faults.

Actions for providers

- Monitor equipment proactively by using fault logs and provide more education for operators on what to look out for, as these incidents are often not apparent when they occur.
- Make sure departments have clear strategies to deal with equipment faults and specific escalation processes for operators to follow to ensure they manage incidents appropriately.

We also received multiple notifications relating to treatment delivery through a specific section of the treatment couch. Sections of the metallic couch support structure significantly increased attenuation of the treatment beam, resulting in a relative underdose of intended treatment areas under certain geometric conditions. These notifications demonstrated unclear guidance from the manufacturer, and providers were not made aware to prevent treatment through this section of the couch.

Actions that providers took to address the error included:

- using radio-opaque markers applied to the CT couch to identify any patients that could be affected
- improving checking procedures for this subset of patients
- updating treatment planning systems to avoid this structure if possible, and if not, taking the additional attenuation into account.

This type of incident was happening in providers across England, and it is vital that providers report all equipment incidents – including software incidents – to the Medicines and Healthcare products Regulatory Agency (MHRA), which regulates equipment manufacturers. Reporting these incidents ensures that they can be managed at a national level and helps to develop a cohesive programme for monitoring manufacturers' actions, for example releasing software code adjustments. The MHRA can also issue field safety notices, ensuring all providers are aware of the potential for error so they can take action to prevent incidents.

Staffing levels

Staffing levels and their effect on compliance with the regulations was a persistent theme, particularly their impact on notifiable errors. 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. However, we saw that risks were well-monitored and understood by senior leaders, with concerns included on risk registers that were regularly monitored.

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. Some departments considered reduced service capacity or created waiting lists for certain treatment groups.

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. Across some providers, a lack of robust peer review of patient target volumes (the area to be treated) contributed to a large number of notifications received in 2024/25, which is consistent with previous years.

We found that employers did not review treatment volumes of organs at risk consistently. An under-resourced consultant workforce continued to limit 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.

However, we did see some departments that had developed robust procedures to document how anomalies in patient volumes were picked up and actioned successfully ahead of treatment. These centres were using the QMS or record and verify system to track peer review, with comments from practitioners easily accessible to the treatment planners and operators. Some centres used a RAG rating to code these amendments, which allowed them to be audited and identified where practice needed to be changed or identified training needs.

Examples of notifiable accidental and unintended exposures and actions taken

Multiple verification errors due to set up error

A patient was referred for a single fraction of treatment. At the planning scan, the pre-treatment operators used a previous tattoo as the origin point but had incorrectly annotated its position in relation to the xiphisternum in the longitudinal direction.

This position coincided with another, not previously identified tattoo. The pre-treatment operators had asked the patient if they had a tattoo from previous treatment, to which they indicated they had only one.

Treatment staff incorrectly set up treatment that was relative to the wrong origin point twice, imaging both times. This resulted in gross errors requiring re-imaging, before the incident was appropriately investigated. This investigation identified the mistake, and the patient was treated correctly.

The incident was attributed to multiple factors including:

- failure to check the patient for previous tattoos and failure to review the previous treatment set-up sheet to ensure all information was available
- human factor error in transcribing the longitudinal position of the tattoo on the set-up sheet
- failure to independently check the set-up sheet

- treatment operator staff not checking with pre-treatment staff on the position of the tattoo after the first image had identified a gross error.

Actions taken in response included:

- a review of documentation to include the need to review previous treatment set up for patients who have had treatment previously
- including this process in the referral check process carried out by pre-treatment operators ahead of the planning scan
- discussion with operators about the importance of independent checking of data input.

Couch density resulting in relative underdose to patients

There is a generic issue affecting all models of a particular generation of linear accelerator. The issue was related to the potential to treat through a high density, metallic substructure, which is used to support the carbon fibre couch top. It was possible for this to be placed in the path of the treatment beam. This only affected treatments where the couch was positioned extremely longitudinally towards the gantry and with large treatment fields. This resulted in beam attenuation that affected the planned dosimetry of the treatment and resulted in an underdose that was not compensated for.

The department was unaware of the issue, either through machine quality control or treatment verification images. Additionally, with the use of arc therapy, posterior fields are not routinely visually checked, which may have highlighted the issue. They were made aware by a national professional network.

Following the investigation, the department carried out a large retrospective review of all potential patients using the record and verify system, which ranged back over a decade and included thousands of patients. For all the patients identified who were affected, a thorough dosimetric assessment was carried out to ascertain the dose difference from that planned. For all instances discovered, a multi-disciplinary team assessed the clinical effect and significance of the dose difference. Duty of candour was completed as necessary.

Of all the cases identified, none reached the reportable threshold for a therapy under-exposure. However, it was notified to CQC, as a theme had been identified.

Actions taken in response included:

- placing markers on the CT couch that would highlight the possibility of an overlap of the treatment field and the substructure at the planning stage
- highlighting the area on the treatment couches where the overlap could occur as a visual aid
- making procedural updates, with additional checks and couch limits, for treatments identified as being at risk of an overlap
- informing the MHRA
- running the script used in the initial retrospective audit at regular intervals to assess if there have been any further instances.

A key finding from this incident was the importance of having a national platform, and cross-trust communication, to highlight and discuss incidents across radiotherapy.

Brachytherapy

A patient receiving treatment in the vaginal vault was treated for 2 of 3 fractions using a test plan rather than the clinically approved plan. The test plan had been left in the planning system from commissioning and was not meant to still be visible in the system. This incident was identified as part of the checking process before the third fraction in the treatment plan was delivered. This check had not been completed for the previous 2 treatments.

Investigation identified that:

- planning protocols were not accurate or reflective of practice
- allocation of tasks in the planning process was unclear
- There was human factor error in failing to follow process.

Actions taken in response included:

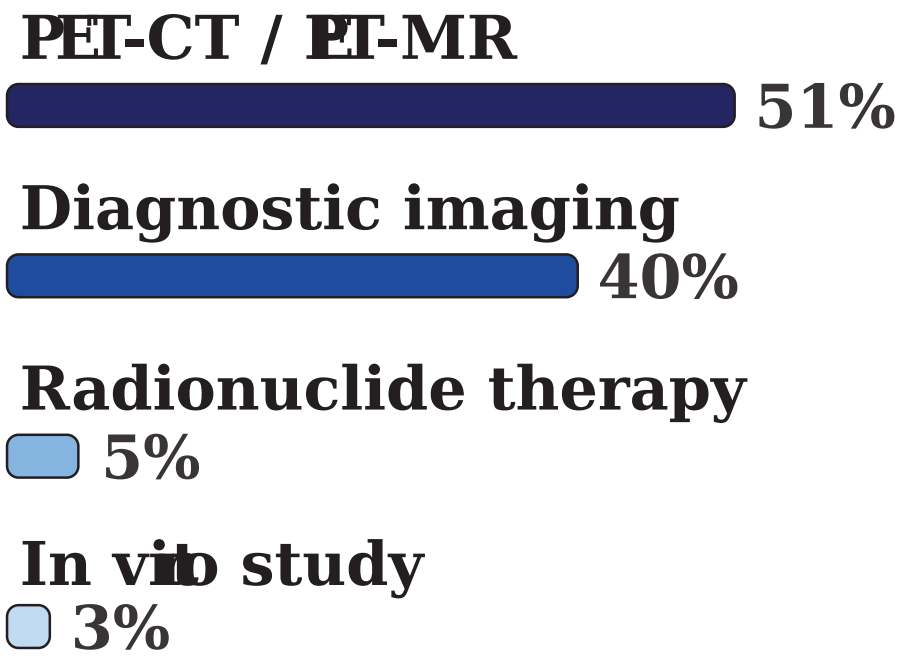
- reviewing protocols to ensure they were accurate and reflective of practice
- creating a pre-treatment checklist with role specific steps
- reviewing staffing levels to ensure adequate support
- removing all plans from the treatment system that are not clinical.

Nuclear medicine

Notifications

This year we saw a 9% decrease in the number of SAUE notifications received in nuclear medicine (117 in 2024/25 compared with 128 in 2023/24).

Figure 14: Nuclear medicine notifications by sub-modality



Despite this overall trend, we have seen an increase in notifications relating to PET-CT and PET-MR imaging of 13%. As a result, we have completed a separate analysis of notifications in this sub-modality to identify key themes specific to this field.

PET-CT/PET-MR notifications

In England, approximately 43% of PET-CT imaging is delivered by independent healthcare providers, resulting from the national contract. These services usually deliver only PET-CT imaging and are not part of a conventional nuclear medicine department. Many scans are performed using mobile facilities, which move between different host sites, and staff involved in delivering these exposures may be peripatetic.

Equipment-related incidents

The patient exposure pathway for PET imaging is broadly similar to conventional nuclear medicine. However, the shorter tracer uptake and image acquisition times means that when equipment breaks down, more patients are likely to have been already injected and therefore receive an unintended exposure if their examination cannot go ahead. As a result, equipment-related notifications are more likely to be reported due to the application of the 'multiple' complementary SAUE notification code. This is reflected by the proportion of equipment-related incidents in PET.

Equipment-related incidents are more prevalent in PET (35%) than in the other 3 sub-modalities (21% in diagnostic imaging, in vitro studies and radionuclide therapy combined).

Of these equipment-related SAUEs in PET, 62% result from hardware faults, (malfunction of the imaging system itself), with the remainder split between software problems and failure of ancillary equipment, such as power supply or air conditioning systems. The high proportion of these types of notification, as well as the number of patients affected when these systems fail, illustrates the need for regular preventative maintenance, robust quality control testing and risk management for scanners reaching the end of life or with impaired performance.

Actions for employers

Ensure that you have procedures in place to verify the correct functioning of imaging equipment and supporting systems before administering radiopharmaceuticals to patients.

Radiopharmaceutical errors

The next most common source of notifications in PET-CT was misadministration of radiopharmaceuticals. These included:

- incorrect radiopharmaceuticals

- extravasation
- incorrect administered activity.

Administrations of the wrong radiopharmaceutical are always reportable under SAUE code 7, which was introduced in April 2023.

Since the introduction of a broader range of tracers into routine practice, more patients in PET-CT are receiving the wrong radiopharmaceutical, such as fluorine-18 FDG instead of fluorine-18 PSMA. In some cases, incidents originate when administrative staff incorrectly add referrals to the radiology information system (RIS). Patients may be booked to attend sites where FDG is the only tracer in use, and so it may be less likely for operators to detect this mistake.

Actions for employers

Consider whether tasks performed by administrative staff constitute practical aspects due to the impact on the potential exposure and therefore whether these staff should be considered operators. IR(ME)R requires operators to be adequately trained and to comply with written employer's procedures.

Referral information and PAUSED checks

In line with persistent trends, we continue to see notifications caused by poor quality referrals. This includes incidents where:

- the wrong patient had a scan (accidental exposure)
- requests made for the wrong modality (for example, instead of CT or cardiopulmonary exercise test (CPET))
- incorrect timing
- using outdated forms.

It is difficult to eliminate referral errors completely, which is why we expect the exposure pathway to include checks that may detect these mistakes, such as PAUSED. These checks should be used by practitioners and operators and are most effective when duty holders have the resources to check each patient's previous imaging and clinical history. But we have found that this is not always possible in PET-CT services, due to a lack of connectivity between RIS and other electronic patient records. Operators rely on the information provided in the initial referral, which may be incorrect or incomplete.

Similarly, there have been incidents involving incorrect justification, authorisation, or protocolling of exposures, which could have been detected if previous imaging or patient history were checked.

The regulations were amended in October 2024 to introduce a new requirement under Regulation 6A, which sets out the duty of co-operation between IR(ME)R employers. This regulation requires employers to work together to ensure that information about patient exposures or potential exposures is shared appropriately, enabling each employer to comply with their obligations under IR(ME)R. Employers should also consider how clinical and imaging history is accessed, and where such access is not available, clarify who is responsible for providing the necessary information to support safe and appropriate use of radiation.

Diagnostic nuclear medicine (including in vitro studies)

The highest proportion of notifications in this sub-modality were due to errors during the preparation of radiopharmaceuticals. Most were linked to failures in the PAUSED check process, for example where operators did not identify that the radionuclide calibrator was set to the wrong isotope, or where there was incorrect labelling of vials or syringes. This further highlights the importance of embedding PAUSED checks within the exposure pathway. This process is significantly strengthened when another operator carries out a second, independent check.

Only a small number (4 notifications) related to in vitro studies, with no clear trends. All reported SAUEs involved glomerular filtration rate (GFR) assessments and were notifiable due to multiple patients being affected. These incidents typically involved equipment failures, incorrect use of equipment, or errors in sample preparation.

Therapeutic nuclear medicine

There were 6 SAUEs reported to us involving radionuclide therapies. Of these, 3 resulted from issues during the administration of the radiopharmaceutical, particularly where high vial residues were identified but the underlying cause was not understood or investigated.

In addition, there were incidents caused by:

- faulty administration lines
- incorrect calculation of prescribed activity
- use of contrast during CT imaging 2 weeks before iodine-131 ablation.

Inspection and enforcement activity

We carried out 28 comprehensive inspections of nuclear medicine services. We issued 9 Improvement Notices, comprising 18 significant compliance gaps in total, and we made 97 quality improvement recommendations in our inspection reports.

Analysis of the regulations involved in this activity demonstrates the key areas of non-compliance identified during our inspections of nuclear medicine services.

Procedures and protocols

A total of 25 breaches were identified in relation to procedures, protocols, and other key documents. In most cases, this was due to missing or inadequate employer's procedures, or because procedures were not accessible to staff or not being followed in practice. Employers must ensure that procedures are fit for purpose and that they provide effective support for staff to enable them to carry out their duties in line with IR(ME)R.

Training and records

We identified 14 instances where training arrangements and records were inadequate. Of particular concern were cases where operators undertook tasks beyond their normal professional scope and training, such as clinical scientists evaluating imaging studies, without documented evidence of assessed competence.

Actions for employers

Make sure practitioners and operators are adequately trained and competent to perform the tasks assigned to them. Individual entitlement and scope of practice should be clearly linked to up-to-date training and competency records.

Referral guidelines

We identified 12 breaches relating to the provision of referral guidelines. Regulation 6(5)(a) requires employers to establish referral criteria and make them available to all referrers, but guidelines are often missing or not easily accessible, particularly for external referrers. Referral guidelines are essential to support appropriate referrals and ensure exposures are justified. They should clearly state:

- who can refer
- how to refer (including the system or process)
- what information is needed (for example, patient ID and clinical history)

- the clinical criteria for referral, including indications, contraindications, and dose information.

Commercially available tools can provide a helpful starting point, but local adaptation is essential. In many services, referral guidelines align closely with authorisation guidance, and linking the two can improve consistency and support compliance.

Carers and comforters

We identified 11 breaches relating to the arrangements for carers and comforters, highlighting ongoing gaps in understanding and implementation across many nuclear medicine services. Some departments mistakenly believed that designation depends on a dose threshold or constraint. However, under IR(ME)R, designation is based on the nature of the exposure, not the dose. In last year's report, we outlined what compliant procedures could look like to support services in meeting this requirement, and further detail is available in professional guidance.

- IR(ME)R: Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine (Royal College of Radiologists)

We also took multiple actions relating to:

- authorisation arrangements
- quality assurance of procedures
- study of risk
- clinical audit
- equipment performance and inventory
- incident management.

We encourage employers to review the relevant IR(ME)R requirements, consult guidance from professional bodies, and collaborate with other services to strengthen their compliance and share good practice.

Key themes in nuclear medicine

Employer's procedures

We continue to see, and in some cases take regulatory action, where these are not fit for purpose. Often, they are too generic, do not reflect actual practice, or fail to meet the requirements of IR(ME)R Schedule 2. Recommendations and enforcement commonly relate to procedures that do not support staff in complying with the regulations or ensuring safe, consistent practice.

Under IR(ME)R, the employer's written procedures are a legal requirement. Their primary purpose is to guide staff in performing their roles in compliance with the regulations and in line with the employer's own processes. This means procedures must be tailored to reflect the unique workflows, risks, and responsibilities involved in individual nuclear medicine services.

A good procedure in nuclear medicine should be:

Clear and specific: Avoid vague or generic instructions. Procedures must be easy to follow and describe clearly what is required, for example, how to make pregnancy enquiries and what to do in response, or how to measure activity and where to record it.

Relevant: Tailored to the service model, staff roles, and local equipment. Procedures must address nuclear medicine-specific requirements, including arrangements for breastfeeding and the provision of written instructions to patients. They should cover both diagnostic and therapeutic studies, with appropriate measures in place for each, for example, pregnancy enquiries.

Aligned with IR(ME)R: Procedures must address all the requirements of Schedule 2.

Accessible: They should be available where and when needed (for example, injection rooms, scanner control rooms, dispensing areas) and in usable formats.

Up to date: Reviewed regularly and updated when practice, equipment, or legislation changes.

Implemented: Actively followed in practice – not just held in a policy folder. Audits, incident reviews, and staff feedback should be used to ensure they are fit for purpose and being applied correctly.

Supported by training: Staff must understand not only what the procedures require, but also why they matter and how to apply them safely in the nuclear medicine context.

Ultimately, ensuring procedures are service-specific, reflect Schedule 2, and embedded into practice is fundamental to both regulatory compliance and patient safety.

Multiple notification code

Regulation 8 of IR(ME)R explains the employer's duties around statutory notifications about accidental or unintended exposures. When these are judged to be 'significant', they need to be notified to the enforcing authority under Regulation 8(4).

The multiple notification category is a complementary notification code, where a single incident or theme involves multiple patients and is particularly relevant to nuclear medicine and PET/CT.

During inspections, we have noticed a misunderstanding around reporting multiple code incidents. Some departments were not reporting incidents as they thought the patient dose received by each individual person needed to hit the dose threshold detailed in the SAUE guidance for providers, and some departments were not reporting theme incidents if only one patient had been affected in each incident.

Examples of incidents under multiple codes

- **A single incident that involved multiple patients:** This incident reported to us involved multiple patients attending for a Glomerular Filtration Rate (GFR) test. An error with the standard was identified during the processing stage, which meant all the GFR tests were non-diagnostic, and the patients were re-booked.
- **Recurring incident:** This notification of an incident involving Sentinel Lymph Node (SLN) injections. was identified during an audit, where 5 patients over a 7-month period received a SLN injection, but the surgery did not go ahead.
- **Similar, separate incidents:** An error occurred on the PET/CT scanner during PET reconstruction, which led to data being lost. Similar incidents occurred over a 3-month period resulting in 3 patients being recalled for a repeat PET/CT appointment and was reported as a theme.

- **Radiopharmacy-related incident:** A multiple incident reported involved 5 renal patients who were injected with MAG3, but the images were undiagnostic due to a mis-labelling error possibly due to an error using a heat block. All 5 patients were re-booked.

The multiple complementary code does not depend on patient dose. It should be used when:

- a single error or failure affects multiple patients, or
- similar incidents recur over time affecting more than one patient.

Study of risk for therapeutic nuclear medicine

Regulation 8(2) requires employers to include a study of the risk of accidental or unintended exposures within their quality assurance (QA) programme. This applies to all exposures for radiotherapeutic purposes, including therapeutic nuclear medicine. However, this requirement is often poorly understood, and many departments do not yet have an appropriate, documented study of risk in place.

The study of risk must be clearly directed at identifying failures that could lead to accidental or unintended exposures, distinct from general safety or radiation protection risk assessments. It should span the full therapeutic pathway, from referral and justification through to treatment delivery, follow-up, and incident management. Proactive risk assessment helps organisations understand the likelihood and impact of possible failures and supports a preventive safety culture.

A range of methods can be used to meet this requirement, and these are outlined in guidance.

- IR(ME)R: Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine (Royal College of Radiologists)

A recent project presented at the British Nuclear Medicine Society demonstrated how failure mode and effects analysis (FMEA) can be effectively applied to therapeutic nuclear medicine. Four NHS centres collaborated to assess common therapies (for example, iodine-131 for thyroid cancer, radium-223, lutetium-177 DOTATATE). Using detailed process maps, they identified up to 60 points of failure for each treatment pathway. Common high-risk failures included:

- missed pregnancy checks
- failure to identify carers/comforters
- incomplete incident learning.

Comparison with local incident records and CQC IR(ME)R reports helped identify additional gaps, demonstrating the value of this structured approach.

To be effective, the study of risk should:

- be multidisciplinary (for example, involving MPEs, clinicians, technologists)
- be repeated periodically, and especially when introducing new techniques or after incidents
- be specific to the service and well-documented
- feed into quality improvement and learning processes.

Employers should ensure staff are trained in risk assessment techniques and supported with time and resources to complete this work. Failing to implement a robust study of risk not only breaches IR(ME)R but may leave departments exposed to avoidable harm and regulatory action.

Examples of notifiable accidental and unintended exposures and actions taken

PAUSED check failure in PET-CT

A patient was referred for a fluorine-18 FDG scan using a handwritten referral form. The referral was legible and included all necessary clinical information. The IR(ME)R practitioner justified and protocolled the request in line with the intended FDG scan after it was transcribed onto the electronic booking system.

However, administrative staff incorrectly booked the patient for a fluorine-18 PSMA scan on the radiology information system (RIS). According to local procedures, the electronic record of authorisation should have been printed and attached to the referral, with RIS updated if any changes were required.

On the day of the scan, the authorisation record was not attached. The patient attended, received a fluorine-18 PSMA injection, and was scanned accordingly. The error was identified only after the scan, when the operator reviewed the images against the original authorisation record.

Lessons identified

- PAUSED checks must be embedded throughout the entire patient pathway, including administrative stages such as data entry and appointment booking.
- Printed authorisation records must be attached to the referral.
- Operators must review the day's referrals in the morning huddle and make a final check of referral and authorisation details before administration of radiopharmaceuticals.

Making, amending and cancelling referrals

A patient was referred for both ultrasound parathyroid and nuclear medicine (NM) parathyroid imaging during a clinic consultation. The plan was explained to the patient, who expected both scans before their next appointment with a consultant.

Following the parathyroid ultrasound, the findings indicated that the NM scan was not necessary. The referrer cancelled the NM request on the electronic patient record (EPR). However, this cancellation did not propagate to the radiology information system (RIS), which is the system NM staff use to track referrals, and the NM team was unaware as they were not contacted directly to inform them of the cancellation.

The patient subsequently attended for their NM scan. The radiographer, seeing a valid referral on RIS and receiving confirmation from the patient that they were expecting the scan, proceeded with the examination. As a result, the patient received an unnecessary radiation exposure.

The investigation found the following points:

- The radiographer acted appropriately based on available information – a live referral on RIS and patient confirmation.
- The root cause was the referrer not following the correct process for cancelling referrals, which requires direct communication with the NM team.

Lessons identified

- The case illustrates a recurring issue where referrers fail to cancel unnecessary referrals appropriately, resulting in avoidable exposures.

- Referrals must be cancelled according to the correct local procedure, ensuring that all relevant systems are updated and that the imaging department is informed directly.
- This reinforces the importance of complying with the new procedure mandated in the 2024 amendment to IR(ME)R for making, amending, and cancelling referrals.
- Clear communication and system integration are critical to prevent similar incidents and uphold patient safety.

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