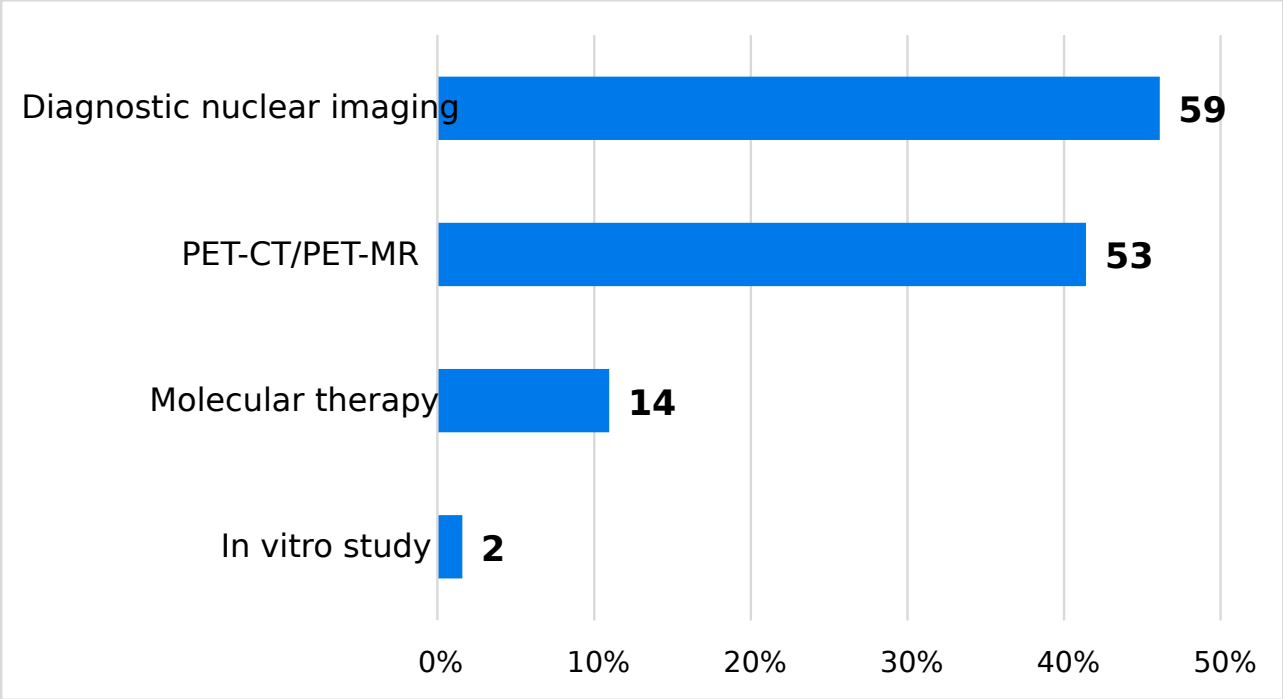
Nuclear medicine activity

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%

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.

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)	• Ancillary failure (5) • Hardware (24) • Software (7)

Tier 1: Operator (51 notifications)

Tier 2	Tier 3
Authorisation (1)	• Incorrect authorisation (1)
Clinical history (2)	• Failure to check history/details (2)
Patient checks (1)	• Failure to check pregnancy/breastfeeding (1)
Radiopharmaceutical (34)	• Administration (20) • Preparation (14)
Post examination (1)	• Reporting failure (1)
Pre-exposure checks (12)	• Wrong patient position/set-up/protocol (7) • Wrong use of equipment (5)

Tier 1: Other (10 notifications)

Tier 2	Tier 3
Administrative staff error (1)	• Other admin error (1)
Patient related (5)	• Patient (3) • Unknown pregnancy (2)
Other (4)	• Not listed above (4)

Tier 1: Practitioner (6 notifications)

Tier 2	Tier 3
Justification (3)	• Incorrect justification (3)
Protocol (3)	• Illegible/unclear protocol (3)

Tier 1: Referrer (25 notifications)

Tier 2	Tier 3
Incorrect information (11)	• Duplicate/no check of previous imaging (2) • Failure to cancel (6) • Inaccurate clinical information (3)
Incorrect referral (14)	• Failure to cancel a request made in error (1) • Wrong patient (12) • Wrong requested modality (1)

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.