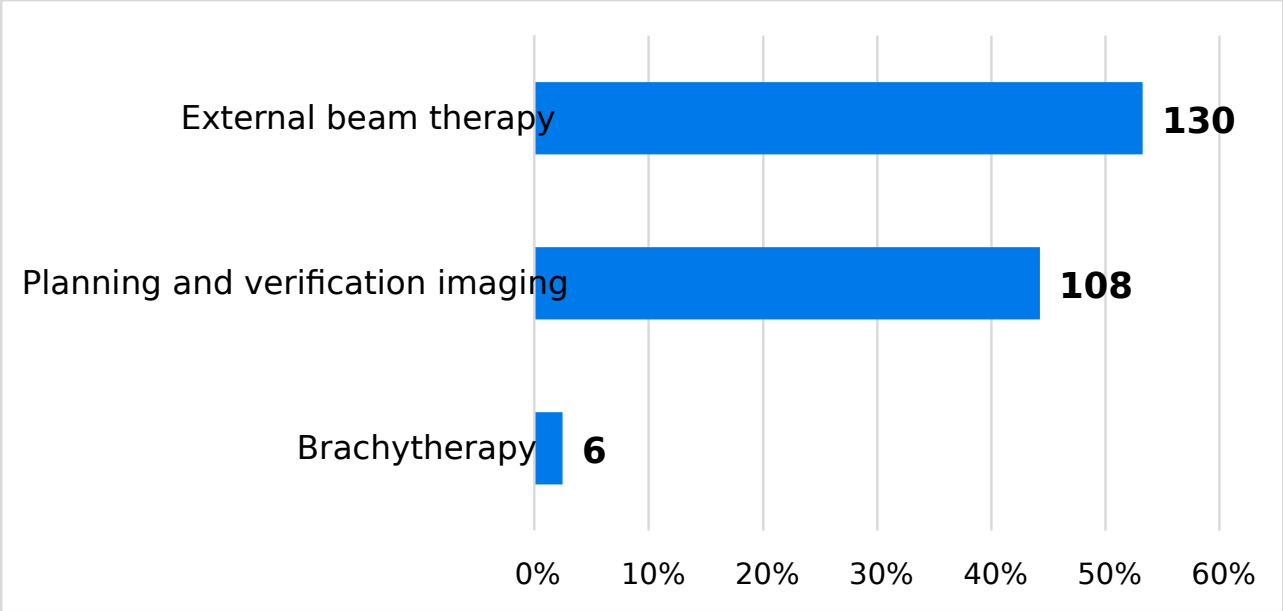
Radiotherapy activity

Notifications received in 2023/24

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

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



Source: CQC SAUE notifications data 2023/24
Note: Percentages have been rounded up to the nearest whole number to add up to 100%

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

Types of error

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

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

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

Tier 1: Referrer: (18 notifications)

Tier 2	Tier 3
Incorrect information (7)	• Failure to cancel a request made in error (5) • Failure to check relevant patient RT history (2)
Incorrect referral (11)	• Not in accordance with guidelines (4) • Referral premature (6) • Wrong treatment protocol or dose/# requested (1)

Tier 1: Practitioner (11 notifications)

Tier 2	Tier 3
Justification (11)	• Failure to cancel radiotherapy (2) • Justify / authorise wrong plan or treatment protocol on pres cription (2) • Target/volume error (7)

Tier 1: Operator (168 notifications)

Tier 2	Tier 3
Clinical history (1)	• Failure to check history/details (1)
Pre-exposure checks (2)	• Wrong patient position/set-up/protocol (2)
Planning (32)	• Inappropriate plan generated (8) • Inappropriate verification carried out (1) • Incorrect data transfer/input (22) • Wrong dataset used (1)
Pre-treatment (17)	• Incorrect scan protocol selected/procedure followed (7) • Marking of patient or immobilisation device (5) • Positioning of patient (5)

Tier 2	Tier 3
Treatment (116)	• Geographical miss - no verification image (3) • Geographical miss - shift error (10) • Geographical miss - verification image offline (1) • Geographical miss - verification image online (18) • Incorrect immobilisation applied (42) • Incorrect verification image type selected (37) • Patient ID/queuing error (1) • Skin app treatment (4)

Tier 1: Equipment (40 notifications)

Tier 2	Tier 3
Equipment related (40)	• Ancillary failure (3) • Hardware (25) • IT failure (1) • Software (11)

Tier 1: Other (7 notifications)

Tier 2	Tier 3
Patient related (6)	• Patient (1) • Unknown pregnancy (5)
Other (1)	• Not listed above (1)

Total radiotherapy notifications: 244

Source: CQC SAUE notifications data 2023/24

Inspections and enforcement

We carried out 15 inspections, 4 of which were of brachytherapy services. From these inspections, we issued 6 Improvement Notices and made 26 recommendations, which included:

- **Regulations 6(1) and 6(5)b:** reviewing the employer's procedures to ensure they reflect clinical practice, with an appropriate quality assurance process (9 recommendations)
- **Regulation 7:** ensuring that employer's procedures include provision for carrying out clinical audit as appropriate, with particular focus on managing clinical audits within departments (6 recommendations)

- **Regulation 8(1):** ensuring a clear process relating to managing clinically significant unintended and accidental exposures and overall management of incidents (2 recommendations)
- **Regulation 8(4**): ensuring that all significant, accidental or unintended exposures that meet the threshold for notification are reported to the enforcing authority and that incidents are managed appropriately (2 recommendations)
- **Regulation 15(2) and 15(6)c:** ensuring that equipment QA processes are robust, and that the equipment inventories contain the correct information (3 recommendations)
- **Regulations 17(1) and 17(4):** training records for duty holders, with particular focus on practitioners (4 recommendations)

We issued Improvement Notices against:

- **Regulations 6(5)b**: where there was a failure to follow an established quality assurance programme for written procedures and written protocol
- **Regulation 8(4):** where the service did not have an adequate process for incident management and therefore multiple incidents were not reported to the regulating authority in line with the regulations
- **Regulation 11(5):** where there were no authorisation guidelines to enable operators to authorise exposures in the practitioner's absence
- **Regulation 15(2):** where the equipment inventory did not contain the correct information

Key themes in radiotherapy

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

Error management

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

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

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

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

Peer review of patient volumes

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

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

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

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

Staffing levels

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

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

Examples of errors and actions taken

Geographic miss of tumour position

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

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

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

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

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

Actions taken

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

Learning from the incident

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

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

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

Mismatch through poor image quality and over-worked staff

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

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

Action taken

- The department investigated the incident and assessed the dose to enable them to meet their duty of candour to the patient.
- The department tested and reviewed image quality on the treatment screens.
- A CBCT (cone beam computed tomography) pathway for palliative patients was developed; at the time of the report a small cohort of palliative patients had had received CBCT imaging with success.
- All staff received a presentation of the feedback to share the learning.

- The staffing policy has been changed to avoid a recurrence of this type of incident. The incident occurred during planned weekend working hours, and the staff involved were on-call as well as being on the rota to be treating the scheduled patients. But this meant they did not receive adequate breaks and were working long hours.

Learning from the incident

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

Incorrect prescription delivered

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

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

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

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

Actions taken

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

Learning from the incident

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

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

Actions for IR(ME)R employers

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