

Safer Radiotherapy

Triannual RTE analysis and learning report

Issue 47: full radiotherapy event data analysis, April to July 2025

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Radiotherapy event data analysis

The Safer Radiotherapy publication series facilitates comparison of locally identified trends against the national picture. The <u>Patient Safety in Radiotherapy Steering Group (PSRT)</u> recommends implementing learning from this analysis locally. In doing so it is expected that these events might be mitigated in the future.

This analysis has been undertaken by the UK Health Security Agency (UKHSA) on anonymised radiotherapy events (RTE) reported voluntarily by UK radiotherapy (RT) providers.

As with any voluntary reporting system, the data will only reflect those events that are reported and may not necessarily be representative of the actual level of occurrence. As such, this data needs interpreting with care.

To facilitate timely analysis and learning both locally and nationally, all providers are asked to apply a trigger code (TSRT9), classification level, primary pathway subcode, additional pathway subcoding, method of detection (MD), contributory factors (CF) and modality code (D) to their RTE reports to facilitate both local and national analysis and submit data to UKHSA at the earliest opportunity, for example monthly.

Providers reporting through the LFPSE are encouraged to include the TSRT9 trigger codes for all RTE once the required investigation is complete and coding taxonomy has been applied. If a report does not contain the TSRT9 trigger code, it will not be shared by LFPSE with UKHSA.

More information, including the full taxonomy, case studies and recommendations for application, can be found in the <u>National patient safety radiotherapy event taxonomy publication.</u>

<u>Further information on the PSRT, patient safety initiative and RTE reporting</u> can be found online or accessed via the QR code located on this page. If individual providers would like to comment on the analysis or share experience of learning from RTE analysis, please email the RT team at radiotherapy@ukhsa.gov.uk

This is a newly designed, focused Triannual RTE analysis and learning report. Your feedback helps us improve our publications. Please share your thoughts with the radiotherapy team at radiotherapy@ukhsa.gov.uk



April to July 2025 national data analysis

Number of RTE reports

A total of 4,691 classified RTE reports were received between April and July 2025 reflecting an increase of 9.4% (n = 4,287) when compared to the <u>previous analysis</u> (issue 46) and an increase of 11.2% (n = 4,219) when compared to the same reporting period between April and July 2024 (<u>issue 44</u>). The volumes of classified reports received over the past 6 triannual analysis periods are shown in Figure 1.

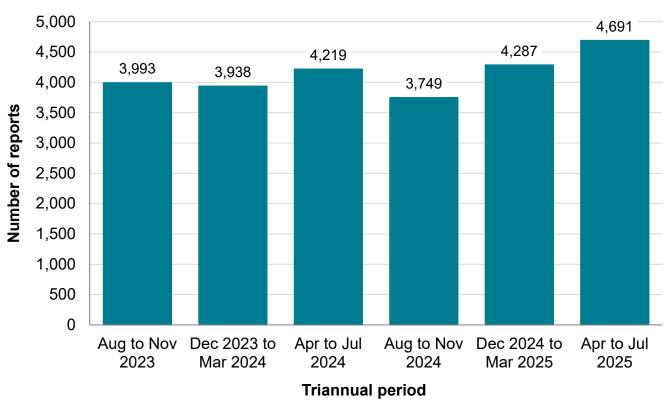


Figure 1. Number of voluntary RTE reports received by UKHSA over time

For this reporting period, data was received from 56 providers, including the NHS and independent sector. An average of 83 reports per provider were received, reflecting an increase of 15.2% (n = 72 reports) from the <u>previous reporting period</u> (issue 46). It should be noted that this increase does not mean every individual provider experienced an increase in reporting. Finally, those reporting higher numbers of RTE represent providers with mature reporting cultures and should be encouraged to continue reporting. The national analysis of reported RTE data is presented below.

Classification (level) of RTE

Each of the 4,691 RTE reports was classified either as Level 5 'other non-conformance' (29.7%, n = 1,395), Level 4 'good catch' (23.2%, n = 1,087), Level 3 'non-reportable (minor) radiation or

MRI incident' (43.9%, n = 2,059), Level 2 'non-reportable (moderate) radiation or MRI incident' (1.2%, n = 54), or Level 1 'reportable radiation incident or other notifiable event' (2.0%, n = 96).

It is reassuring to note that 96.8% (n = 4,541) of RTE reports were Level 3 to 5 events with little or no impact on patient outcome. Of the remaining 3.2% (n = 150) of reports, 2.0% (n = 96) were reportable under IR(ME)R to the appropriate enforcing authority (Level 1). This represents a reduction from the previous reporting period when 3.2% (n = 138) of all RTE reports were classified as Level 1. The proportion of reports for each classification level across the 4 most recent triannual periods (April 2024 to July 2025) is shown in Figure 2. Of note, the proportion of Level 3 events has shown a statistically steady increase over time (p = 0.02).

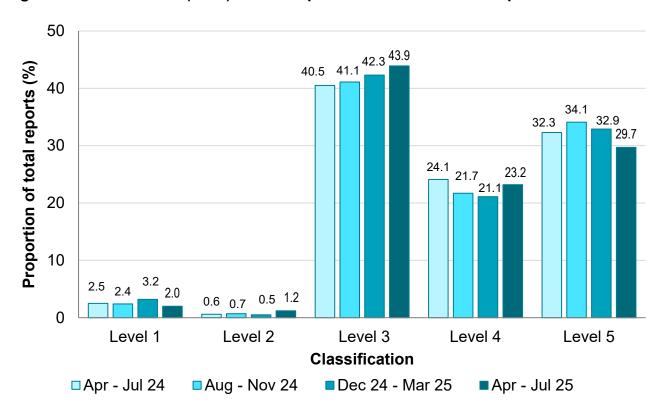
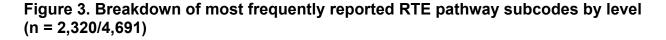
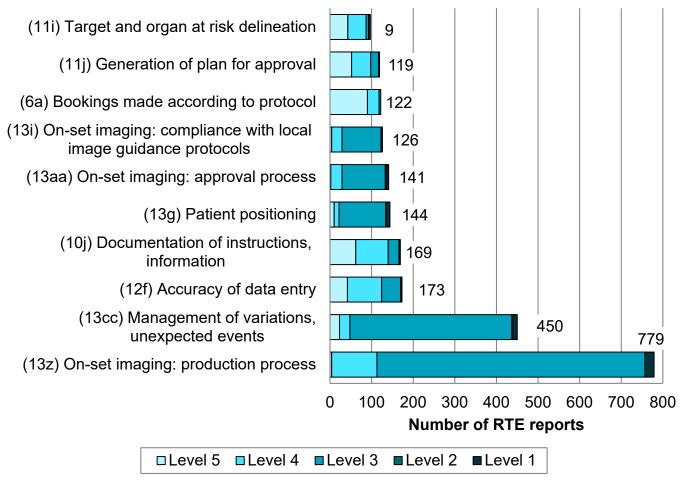


Figure 2. Classification (level) of RTE reports over last 4 triannual periods

Breakdown of pathway subcodes

The most frequently reported pathway subcodes are presented in <u>Figure 3</u>. This subset of data was also broken down by classification level so the main themes could be derived. The most frequently reported RTE was 'on-set imaging: production process' at 16.6% (n = 779) of all reports. This is an slight reduction from the <u>previous analysis</u>, (issue 46) at 17.2% (n = 738). Of this subset, 97.2% (n = 757) of the reports were minor radiation or MRI incident, good catch or other non-conformities with little or no impact on patient care. A large proportion of these reports were associated with contributory factor 'equipment or IT network failure' (62.3%, n = 485).





The second most frequently reported RTE was 'management of variations, unexpected events' at 9.6% (n = 450). Similarly, this pathway subcode is often associated with contributory factor 'equipment or IT network failure' (83.6%, n = 376) and with a large proportion comprising of minor radiation or MRI incident, good catch or other non-conformities with little or no impact on patient care (97.1%, n = 437).

<u>Figure 4</u> demonstrates a frequency trend analysis over time for the 5 most frequently occurring pathway subcodes for the current triannual period.

Pathway subcode 13z: 'On-set imaging: production process' has experienced a gradual rise over the 4 triannual periods, however, it is not statistically significant. Additionally, 'management of variations, unexpected events' has increased from 7.1% (n = 266) during Aug - Nov 2024 period to 9.6% (n = 450) for the current period but, again, is not considered statistically significant.

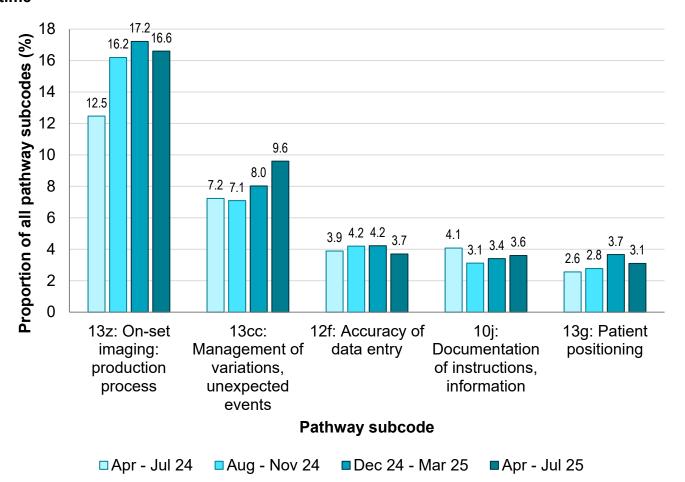


Figure 4. Breakdown of most frequently reported RTE pathway subcodes over time

Given the close association between the 2 most frequently cited pathway subcodes and contributory factor 'equipment or IT network failure' it may be beneficial to investigate whether this contributory factor has increased in proportion over time. Figure 5 illustrates proportionality of the 5 most commonly cited contributory factors over time. This analysis establishes that the only contributory factor demonstrating a statistically significant trend is 'equipment or IT network failure' which increased from 14.5% (n= 751) in April to July 2024 to 18.3% (n = 1,068) during the April to July 2025 triannual period (p = 0.002). Further analysis on contributory factors can be found below.

This trend analysis overview highlights notable changes over the 16-month review period. The increasing proportion of Level 3 minor radiation or MRI incidents illustrated in <u>Figure 2</u> may, in part, be attributable to increases in the 2 most frequently reported pathway subcodes demonstrated in Figure 4 – 'on-set imaging: production process' and 'management of variations, unexpected events'. As <u>Figure 5</u> suggests, the increase in volume and frequency of these of events may be associated with the increasing reporting frequency of the contributory factor 'equipment and IT network failure'.

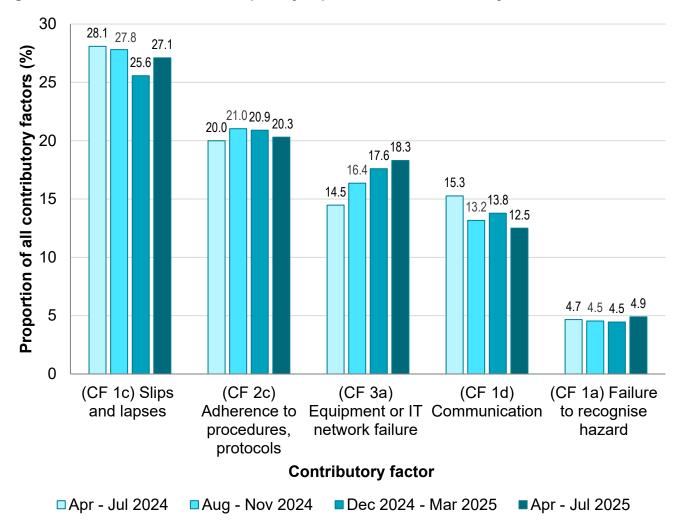


Figure 5. Breakdown of most frequently reported RTE contributory factors over time

It should be noted that the highlighted trend is not limited to this 16-month period. In the most recent <u>Safer Radiotherapy biennial report</u>, which interrogated data from January 2022 to December 2023, a statistically significant increase in the percentage of RTE associated with 'management of variations/unexpected events' across classification levels was identified. Most of these events were associated with 'equipment or IT network failure'.

RTE associated with equipment or IT network failure continues to be a persistent and growing trend. As outlined in <u>Safer Radiotherapy E-bulletin #16</u>, every individual radiation incident involving a medical device, including those associated with aging equipment, or general wear and tear of equipment should be reported to the relevant equipment regulator.

The most recent <u>Safer Radiotherapy E-bulletin #17</u> features a good practice piece from the Scottish IR(ME)R regulator Healthcare Improvement Scotland (HIS). The good practice piece emphasises the importance of reporting and sharing learning from events involving hardware or software malfunctions, on a local and national level, to improve the safety and quality of care delivered to patients.

When these events persist, the most recent <u>Safer Radiotherapy biennial report</u> recommends that:

- logged events are documented and monitored to identify root cause and trends so that action, and escalation of these events, can be taken as appropriate
- the manufacturer, the relevant agency and, where appropriate, the IR(ME)R inspectorates are notified of the occurrence of these events
- providers are encouraged to investigate methods for predicting equipment failure and allow for proactive maintenance to limit the impact of unscheduled repairs on patient treatment (<u>1 to 3</u>)
- risk assessments are undertaken for ongoing use of the affected equipment. The
 provider must identify an appropriate threshold at which point there is consideration
 given to removing the device from clinical use

Whilst this trend analysis provides a broad overview of the national picture, further granularity within national data may be required to assist local learning and inform local and regional practice. Three full national annual aggregate data sets are available to reporting RT providers upon request. Please email RTEdata@ukhsa.gov.uk with the following:

- organisation name
- how you propose to use the national aggregate RTE data

Failed safety barriers

Safety barriers (SB) are additional tasks undertaken across the radiotherapy pathway with the primary purpose of identifying and mitigating an event. These process steps are over and beyond core tasks undertaken as part of the planning and delivery of radiotherapy treatment (4). Identifying those safety barriers that fail (FSB) most frequently is important in learning where vulnerabilities in radiotherapy safety systems reside.

Based on feedback from the radiotherapy community, the recent National patient safety radiotherapy event taxonomy guidance has refined many pathway subcodes, including the expansion of end of process check subcodes, for increased granularity. End of process checks are a subset of the pathway taxonomy that are often allocated as a failed safety barrier. Due to these changes the PSRT are currently reviewing FSB with the aim of refining those pathway subcodes that meet the criteria of an SB. Results from this ongoing work will be shared shortly.

In the interim period, <u>Figure 6</u> shows the breakdown of failed safety barriers based on the existing criteria. Multiple FSB codes can be attributed to each individual RTE. A total of 1,667 failed safety barriers (FSB) were identified from the RTE reported.

Treatment unit process 'management of variations, unexpected events' was the most frequently reported FSB (27.0%, n = 450). An example of an RTE with this FSB includes when a machine

failure occurs at the treatment unit, and the correct course of action is not taken in accordance with departmental protocol.

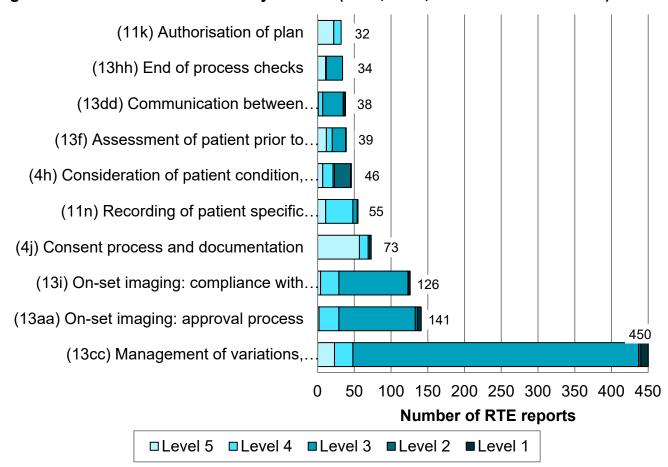


Figure 6. Breakdown of failed safety barriers (n = 1,034/1,667 subset of RTE data)

Method of detection

A method of detection (MD) is the process that identified the event and can be coded using the entire pathway taxonomy. The most frequently reported MD can be seen in Figure 7.

The most frequently reported MD was 'on-set imaging: production process' (13.9%, n = 605). This MD was most frequently reported with a primary process code 'on-set imaging: production process' (84.8%, n = 513) and a primary contributory factor of 'equipment or IT network failure' (68.8%, n = 416). Eight of the most frequently reported MD occurred at the treatment unit process.

'End of process checks' occur at the end of each discrete part of the patient pathway and include multiple different pathway subcodes. These comprised of 8.3% (n = 360) of all MD of which 39.4% (n = 142) were classified as Level 4: good catch, detecting and preventing a radiation or MRI incident from occurring.

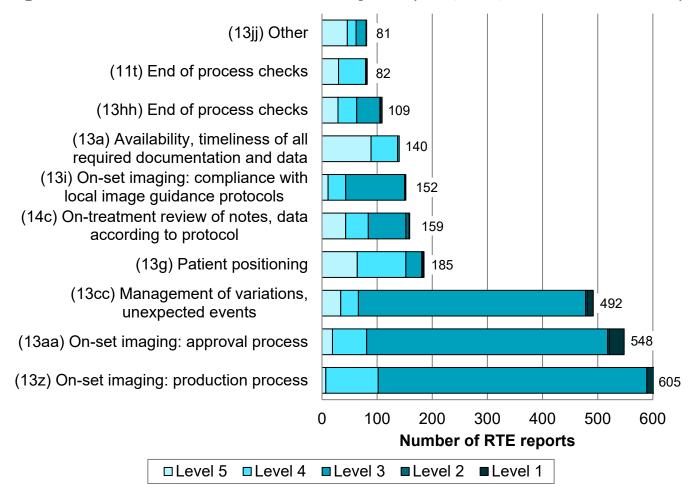


Figure 7. Breakdown of method of detection by level (n = 2,553/4,352 subset of RTE data)

Contributory factors

Including contributory factors (CF) within a RTE taxonomy enables identification of system problems that could precipitate a range of different events ($\underline{5}$).

A systems-based approach to RTE analysis may identify multiple CF for a single event. During the current review period, a total of 5,835 CF codes were assigned to 4,226 RTE, with 999 reports containing multiple CF.

The most frequently occurring CF codes are illustrated within <u>Figure 8</u>. The most frequently reported CF was 'slips and lapses' making up 27.1% (n = 1,581) of all CF. Although individuals are often involved in the last interaction prior to an event, actions and behaviour are the product of influences from the whole system, requiring a holistic approach to any response.

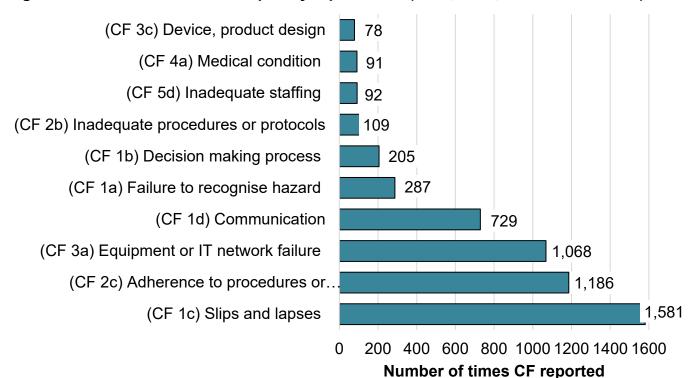


Figure 8. Breakdown of most frequently reported CF (n = 5,426/5,835 subset of data)

Advancing Safer Radiotherapy reflects and consolidates contemporary approaches to patient safety, including systems thinking, and recommends all contributory factors are identified and used to inform actions required to reduce risk and potential for harm. The range of CF is broadly similar to the <u>previous analysis</u> (issue 46). As illustrated in <u>Figure 5</u> above, 'equipment or IT network failure' increased in proportion from 17.6% (n = 972) in the <u>previous analysis</u> (issue 46) to 18.3% (n = 1,068) in the current analysis.

Brachytherapy RTE

Brachytherapy (BRT) is a RT sub-speciality which involves radiotherapy treatment inside or close to the treatment area. BRT makes up less than 3% of all RT episodes (6). Therefore, the number of BRT associated RTE would be expected to be low and should be interpreted with caution.

RTE coded with BRT process subcodes as the primary code accounted for 0.7% (n = 33) of reports, a decrease from the <u>previous analysis</u> issue 46 (1.0%, n = 42). Conversely, providers reporting BRT RTE increased to 15 compared to 11 within the <u>previous analysis</u>. A breakdown of the BRT RTE can be seen in <u>Figure 9</u>.

The most frequently reported BRT process subcode was '15k' comprising 27.3% (n = 9) of all BRT RTE. This reflects an increase from the <u>previous analysis</u>, issue 46, where this type of event made up 23.8% (n = 10) of all BRT RTE. Whilst there are likely to be occurrences where the use of this code is appropriate, it is non-specific and generic in nature and reporters should

consider the full range of pathway subcodes available for the relevant activity in question before selecting an 'other' pathway subcode.

Descriptions of 13 BRT pathway subcodes have been updated to reduce ambiguity, and an additional 4 subcodes have been added to the BRT pathway taxonomy to reflect contemporary practice in the recently published National patient safety radiotherapy event taxonomy document.

During this review period, no BRT RTE were classified as reportable radiation incidents (Level 1). This represents a decrease since the <u>previous analysis</u>, issue 46 (2.3%, n = 1).

(150) Imaging: compliance with local 2 image guidance protocols (15n) Management of variations, 2 unexpected events (15m) Authorisation of plan 2 2 (15j) Removing of applicators, sources (15f) Correct and functioning medical 2 equipment (15e) Correct applicators, sources 2 (15a) Ordering of sources (15h) Planning of treatment 6 (15k) Other 9 0 1 2 3 5 6 7 8 9 10 **Number of RTE reports** □ Level 5 □ Level 4 ■Level 3 ■Level 2 ■Level 1

Figure 9. Breakdown of most frequently reported BRT RTE coded '15' by level (n = 29/33)

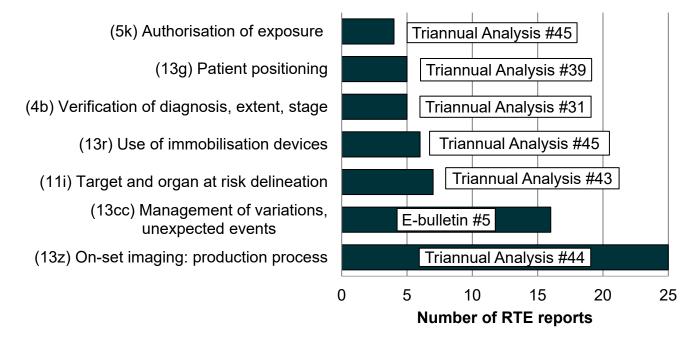
Inspectorate data

A breakdown of the inspectorate data for this reporting period can be seen in <u>Figure 10</u>. The inspectorates shared 110 anonymised closed synopses of reported SAUE. This is an increase since the <u>previous analysis</u> (issue 46) when 79 reports were shared.

The most frequently reported notifications were associated with 'on-set imaging: production process' (22.7% n = 25). This represents a decrease since the <u>previous analysis</u> (issue 46) where 23 reports (29.1%) were associated with 'on-set imaging: production process'.

Publications with relevant case studies considering each pathway subcode are indicated in Figure 10.

Figure 10. Breakdown of most frequently reported inspectorate Level 1 pathway subcodes from closed notifications (n = 68/110 subset of data)



Case study 17: Setting of couch position, angle (13q)

Setting of couch position, angle is cited as a primary pathway subcode in a higher proportion of Level 1 events (6.2%) compared to the average of all submitted reports (2.3%) over the past two-year period (reports received August 2023 to July 2025). Events that specify 'setting of couch position, angle' include scenarios where the treatment couch has been set to a height other than that intended prior to imaging or treatment delivery. These types of events are often associated with techniques such as direct fields and parallel pairs. One area where this pathway code has been referenced in Level 1 reports involve extended SSD palliative techniques.

Synopsis

Patient attended for single 8Gy palliative radiotherapy treatment to left hip and femur for bone metastases from metastatic breast cancer. Due to length of field the treatment was planned as an extended SSD parallel pair prescribed to 120cm.

Patient set up, imaged and anterior field delivered at 120cm FSD without any issues. Gantry taken to 180°, couch raised, SSD set, and treatment delivered to posterior field.

During the treatment summary task the operator noted a discrepancy in the expected and recorded couch heights. Immediate investigation confirmed that the posterior field had been delivered at 100cm rather than 120cm. Subsequent MPE dose assessment established that the delivered dose had met the criteria for reporting under SAUE guidelines for 8.1 therapy overexposure. A full explanation and apology were provided to the patient over the telephone and then again in person when they attended for a subsequent appointment.

Retrospective audit identified a similar error made by different radiographers at an earlier date. Both events require reporting under IR(ME)R.

Coding: TSRT9/ Level 1/ 13q/ MD14c/ CF1a/ CF5d/ CF5e/ CF2b

RTE response

A robust RTE response will maximise potential learning from this event. Table 1 contains the key stages to an RTE response and further considerations for this case study $(\underline{7})$.

Table 1. Key response stages to RTE described above (13q)

| RTE response stage | Considerations |
|---|--|
| Identification and local reporting of RTE | Staff are appropriately trained and supported to identify and report RTE locally. This event was detected during the |

| RTE response stage | Considerations |
|---|--|
| | treatment summary task and reported on the local reporting system. |
| Decision to investigate | Preliminary investigation identified the posterior field had been delivered at an SSD different than planned. The delivered dose had met the criteria for reporting under SAUE guidelines for 8.1 therapy overexposure. In accordance with SAUE guidance, this event is therefore a reportable radiation event (Level 1) which requires a detailed investigation in accordance with local procedures. |
| Planning and selection of investigation team | An interdisciplinary team, including staff from pre-treatment, treatment, clinical oncology and an MPE, was formed to investigate the event. |
| Recording of investigation | The local investigation report template was utilised to guide the investigation and capture the relevant information. |
| Information gathering | Operators involved in the event contributed to the investigation. A review of relevant documentation and a walkthrough of the treatment technique were carried out. During the investigation a retrospective audit of RTE was completed to determine if this type of event was thematic. |
| Analysis and identification of contributory factors | Analysis was completed using a SEIPS (8-9) framework. Investigation established that the operators should have considered their unfamiliarity with the technique and have contacted a more experienced colleague to assist (CF1a). The investigation established that extended FSD treatments are not normal daily practice within the department, and whilst operators may be deemed competent, the lack of familiarity with the technique may create vulnerabilities in achieving safe delivery (CF5d). Lack of refresher training which might ensure operators are well practiced in the technique was highlighted (CF5e). Technique protocols were reviewed and considered lacking in sufficient clarity and may have contributed to the event (CF2b). |
| Identification of areas for improvement and agree action plan | The following were agreed within a local action plan: immediate establishment of alert system to notify duty manager when patients for this technique are identified. Manager responsible for ensuring the treating team have competent, confident and suitably experienced staff available to participate all treatment staff to attend practical run through training for the technique |

| RTE response stage | Considerations |
|-----------------------------|--|
| | technique protocol to be reviewed and rewritten for clarity |
| | urgent reviews and risk assessments of other less commonly used 'non-standard' techniques |
| | interprofessional review of palliative extended field methodology to investigate if it can be standardised with other techniques, or if it can be replaced by alternative method |
| Dissemination of learning | A summary of the investigation was shared with staff at different staff meetings and through an email alert. Feedback was sought from staff for areas for improvement ideas. Training provided as per action plan. |
| Assessment of effectiveness | An audit of improvement actions to be completed 3 months after implementation. |

Further guidance and national tools to aid investigations are available (7 to 9).

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About the UK Health Security Agency

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