

Safer Radiotherapy

Triannual RTE analysis and learning report

Issue 42: full radiotherapy error data analysis, August to November 2023

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Full radiotherapy error data analysis

The fundamental role of incident learning systems is to enhance patient safety by learning from failures of the healthcare system (<u>1</u>). It is imperative errors and near misses are learned from, and effective preventative measures are implemented (<u>2</u>).

The Safer Radiotherapy publication series facilitates comparison of locally identified trends against the national picture. The Patient Safety in Radiotherapy Steering Group (PSRT) 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 radiotherapy errors (RTE) reported voluntarily by UK radiotherapy (RT) providers. Anonymised reports were submitted through multiple routes, from England via the <u>National Reporting and Learning</u> <u>System (NRLS)</u> and the <u>Learn from Patient Safety Events Service (LFPSE)</u> at NHS England, from Wales via the <u>Once for Wales Concerns Management System (OfW)</u>, or directly to UKHSA from providers in Northern Ireland, Scotland and the independent sector. In England, the NRLS will be replaced by the LFPSE in 2024. RTE data submitted through both routes will be included within this analysis.

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

There is a requirement for RT providers to notify the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) (3, 4, 5) inspectorates of significant or clinically significant accidental or unintended exposures within designated timeframes in accordance with guidance (SAUE) (6). These events may be considered as 'reportable radiation incidents' (level 1) as defined in <u>Towards Safer Radiotherapy (TSRT)</u>. The UK inspectorates for IR(ME)R: Care Quality Commission, Healthcare Inspectorate Wales, Healthcare Improvement Scotland and the Regulation and Quality Improvement Authority, shared anonymised closed synopses of reported SAUE for analysis. It should be noted there may be a significant time lag between notification of an event to the inspectorates, completion of the detailed investigation and the subsequent sharing of information with UKHSA for inclusion in the analysis.

The classification level from <u>TSRT</u>, the pathway coding, failed safety barriers (FSB), methods of detection (MD) and causative factor taxonomies from the <u>Development of Learning (DoL) from</u> <u>Radiotherapy Errors</u> were employed for the analysis. FSB and MD are discussed further in the May 2021 issue of the <u>Safer Radiotherapy E-bulletin</u>. A series of <u>presentations</u> have been developed as free educational tools to support the RT community in engaging with this work. The analysis has been reviewed by the PSRT. If individual providers would like to comment on the analysis, share experience of learning from RTE or application of the coding please email the RT team at <u>radiotherapy@ukhsa.gov.uk</u>

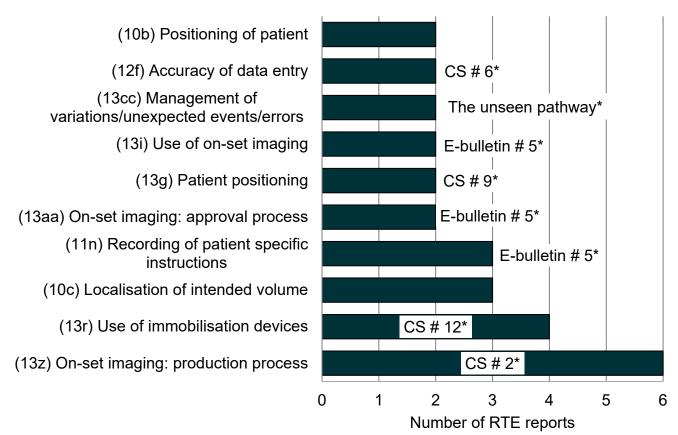
Inspectorate data

A breakdown of the inspectorate data for this reporting period can be seen in Figure 1. The inspectorates shared 42 anonymised closed synopses of reported SAUE for analysis. This is a marked decrease since the <u>previous analysis</u> (issue 41) when 94 reports were shared. This decrease in frequency may be partially attributed to the updated SAUE Guidance (<u>6</u>) which was issued in April 2023. The updated guidance included amendments to the notification criteria for radiotherapy.

The most frequently reported notifications were associated with 'on-set imaging: production process' (14.3%, n = 6). This also reflects a marked decrease since the <u>previous analysis</u> (issue 41) where 24 reports (25.5%) were associated with 'on-set imaging: production process'.

A number of case studies have been included in Safer Radiotherapy publications such as the <u>triannual analysis</u>, the <u>E-bulletin</u>, the <u>unseen pathway</u> and <u>good practice guidance</u>. Relevant published case studies are shown with an asterisk (*) in Figure 1.

Figure 1. Breakdown of most frequently reported inspectorate process subcodes from closed notifications (n = 28/42 subset of data) (CS = case study)



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Case study 12: Use of immobilisation devices (13r)

The treatment unit process pathway subcode (13r) 'use of immobilisation devices' was one of the most frequently reported inspectorate process subcodes for this reporting period (n = 4, 9.5%).

The pathway subcode is indicated in incidents when the immobilisation device is used incorrectly. This can include the omission of required immobilisation devices, the use of incorrect immobilisation devices and the setting of immobilisation devices incorrectly. This includes the use of gating devices for patient positioning.

These types of incidents can be detected during the 'end of process checks' (13hh), or the 'on-set imaging: approval process' (13aa). This type of incident is often linked to 'patient positioning' (13g).

Synopsis

Patient receiving 26Gy/5# breast treatment. Patient treated on incorrect breast board angle for first treatment, resulting in a geographical miss.

The patient was set up within the treatment room utilising the incorrect breast board angle. A verification image was then taken to confirm patient positioning as per local protocol. The verification image was matched incorrectly prior to treatment. The incorrect breast board angle was therefore not detected before treatment delivery. The error was subsequently identified during offline image review.

Dosimetry analysis completed by the medical physics expert (MPE) of the geographical miss. 5.2Gy dose deficit in the clinical target volume (CTV) affecting the superior 5mm of the volume. Approximately 1cm of the planning target volume (PTV) was missed. All subsequent fractions were treated correctly.

Contributory factors included: breast board was incorrectly set, and was not independently verified by the 2 operators, prior to leaving the treatment room. The on-line verification image was incorrectly reviewed and approved prior to treatment. Further investigation indicated that due to lack of staffing, the patient's first day discussion occurred in the treatment room. This led to operators' distraction, due to the patient having a lot of questions prior to proceeding with the treatment.

Outcomes of the investigation led to a review of the pause and check procedure and review of IGRT training.

Coding: Level 1/ 13r/ 13g/ 13aa/ 13hh/ MD13aa /CF1c/ CF2c/ CF5d/ CF4b

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Contributory factors

The contributory factors (CF) for this synopsis included 'slips and lapses' as the breast board position was set incorrectly and was not independently verified by the second operator as per local protocol ('adherence to procedures or protocols'). The on-set verification image was matched incorrectly prior to exposure. Upon investigation it was concluded that the operators were appropriately trained and entitled, but due to a 'slips and lapse', failed to match the verification image correctly on this occasion.

Finally, 'inadequate staffing' and 'communication with the patient' were cited as contributory factors as the operators were required to complete a first day discussion with the patient, within the treatment room, due to insufficient staffing levels. The staff members were distracted due to the patient having a lot of questions.

Failed safety barriers

The local protocol includes an independent verification process prior to leaving the treatment room as part of the 'end of process checks' to confirm patient positioning. Due to a 'slip or lapse' the operator did not correctly complete this step, in accordance with protocol. The onset verification image was not matched correctly prior to exposure ('on-set imaging approval process').

Method of detection

During the offline image review (on-set imaging: approval process) it was noted the patient was matched incorrectly during the on-line image review, resulting in a geographical miss. Upon investigation it was identified the patient was positioned incorrectly due to the incorrect setting of the breast board.

Corrective actions

Corrective actions include:

- consider comprehensive first day discussions outside of treatment room
- ensure time allocation for first day discussion
- liaise with booking team to ensure first day appointments are scheduled when appropriate staffing levels are available
- review end of process checks to ensure these include confirmation immobilisation devices are set appropriately and the patient is positioned correctly
- ensure staff are adequately trained, competent and appropriately entitled to undertake necessary tasks
- share the error with the wider department for learning

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Learning from excellence and published guidance

Learning from excellence includes:

- the use of appropriate tolerance tables for both couch and gantry have been effective in mitigating some set up errors (7)
- random errors should be minimised by careful attention to immobilisation and patient preparation techniques (<u>8</u>)
- appropriate optimisation of imaging selection and reference image production (9)
- consider the use of pause and check posters to support patient set up (<u>10</u>)
- checks and verification should be performed independently by entitled operators working to clear protocols (<u>11</u>)
- in accordance with IR(ME)R Regulation 8 (2) undertake a study of risk of accidental or unintended exposures (9)

Further guidance and national tools to aid investigations are available (<u>12</u>, <u>13</u>). Following a simple risk matrix (<u>9</u>) a study of risk was produced for this case study and process sub-codes (13r) 'use of immobilisation devices'.

Table 1. Study of risk matrix

In this table, a G in brackets indicates low or a green risk.

Area of risk	Initial risk			Risk following mitigations (corrective action examples shown above)		
	Consequence	Likelihood	Risk score	Consequence	Likelihood	Risk score
Incorrect use of immobilisation device resulting in the incorrect patient positioning, detected during end of process checks	1	4	4 (G)	1	1	1 (G)
Incorrect use of immobilisation device resulting in the incorrect patient positioning, detected during verification imaging	2	3	6 (G)	2	1	2 (G)
Incorrect use of immobilisation device resulting in the incorrect patient positioning, detected via use of appropriate set-up tolerances	1	4	4 (G)	1	1	1 (G)
Incorrect use of immobilisation device resulting in the incorrect patient positioning, not detected until completion of treatment	3	1	3 (G)	3	1	3 (G)
Incorrect placement of immobilisation device resulting in the incorrect patient position on treatment couch, leading to verification imaging through wrong section of bed	2	3	6 (G)	2	1	2 (G)
Incorrect placement of immobilisation device resulting in the incorrect patient position on treatment couch, leading to treatment through wrong section of bed	3	2	6(G)	3	1	3 (G)

August to November 2023 data analysis

Number of RTE reports

A total of 4,013 reports were received between August and November 2023, 16 were not RTE reports resulting in 3,997 RTE reports for analysis. This equates in a monthly average of 999 RTE reports, reflecting an increase from 864 (15.6%), when compared to the <u>previous analysis</u> (issue 41) and an increase from 943, (5.9%) when compared to the same reporting period in <u>2022</u> (issue 39).

There is some disparity in frequency of reporting across providers. A wide variation is seen when comparing the incident date with the date reported to the national voluntary reporting scheme. This time lag ranges from 0 days to 1,241 days, with a mean of 63 days and a mode of 0 days, reflecting that 424 were reported nationally on the same day as the incident. There were 78 outliers with a lag time greater than 365 days which were reported from 5 providers. There was no reason annotated to explain this delay in reporting. If the outliers are removed the mean average for the lag time is 49 days and mode of 0.

To ensure timely learning from RTE nationally, providers are asked to make RTE submissions at the earliest opportunity. <u>Issue 26 of Safer Radiotherapy</u> provides further information on reporting frequency.

Monitoring of RTE coding by radiotherapy providers

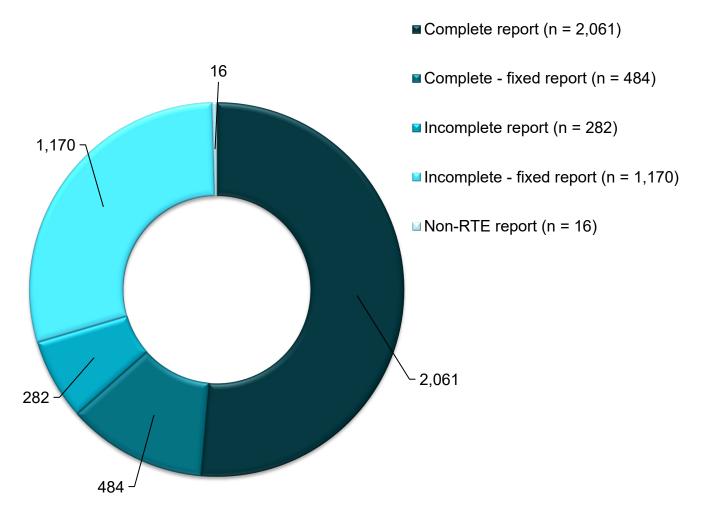
All providers are asked to apply a trigger code, classification level, pathway coding (including failed safety barriers (FSB)), method of detection (MD) and causative factors (CF) to their RTE reports to facilitate both local and national analysis.

The format of coding for submission is TSRT9/ Level 4/13c/13l/ MD13hh/CF1c/CF2c. This should be included in the opening section of the first open text field of the local incident learning system where possible.

Consistency checking was undertaken by UKHSA staff on the application of the RTE coding by RT providers. The coding was reviewed for all RTE classified as reportable through to near miss (levels 1 to 4) and 10% of non-conformances (level 5) RTE were audited. A complete report includes the trigger code, classification, pathway code, including FSB, MD, and CF taxonomies.

From the 2,545 RTE reports classified and coded locally with all the taxonomies, 1,746 were classified as levels 1 to 4. A total of 384 levels 1 to 4 reports were amended (complete fixed in Figure 2 includes level 5 data (n = 484)). Thus, an 78.1% level of consistency was achieved for levels 1 to 4 RTE. This is a decrease since the previous analysis (issue 41) when an 84.9% level of consistency was achieved.





A total of 1,452 RTE reported did not contain one of the required taxonomies, including MD. A total of 1,170 were classified or coded by UKHSA staff using the supporting text supplied by the local providers (incomplete fixed report in Figure 2), 310 of these only required the MD to be included.

Some amendments were made to reports to ensure consistent allocation of the taxonomies. Table 2 indicates the amendments to the complete RTE reports.

It is recommended entire pathway sub coding should be considered when allocating primary pathway subcodes. Further information on the consistent allocation of pathway codes can be seen in <u>E-bulletin edition 3</u>.

Taxonomy amended (n = 484)	Initial coding	Most frequently amended to
Classification (19.0%, n = 92)	Level 5 'other non- conformances' (51.1%, n = 47)	Level 4 'near miss' (61.7%, n = 29)
Primary pathway subcode (58.5%, n = 283)	13i 'use of on-set imaging' (24.4%, n = 69)	13z 'on-set imaging: production process' (42.0%, n = 29)
MD (60.5%, n = 293)	13jj 'other' (31.4%, n = 92)	13cc 'management of variations/unexpected events/errors' (23.9%, n = 22)
CF (5.2%, n = 25)	CF7a 'other' (40.0%, n = 10)	CF1c 'slips and lapses' (40.0%, n = 4)

Table 2. Amendments to complete RTE report

Non-RTE reports submitted formed 0.4% (n = 16) of all the reports for this reporting period. Data and accompanying text indicate that these were patient safety incidents (PSI) but not RTE. This is consistent with the <u>previous analysis</u> (issue 41). A <u>PSI</u> is defined by NHS England as 'Something unexpected or unintended has happened, or failed to happen, that could have or did lead to patient harm' (14). Further information on PSI can be found in <u>issue 5 of Safer</u> <u>Radiotherapy</u>. Non-RTE reports were excluded from the detailed analysis.

Of the incomplete reports, 4 RTE did not contain sufficient supporting text to assign any the classification or the coding, these have not been included in the detailed analysis.

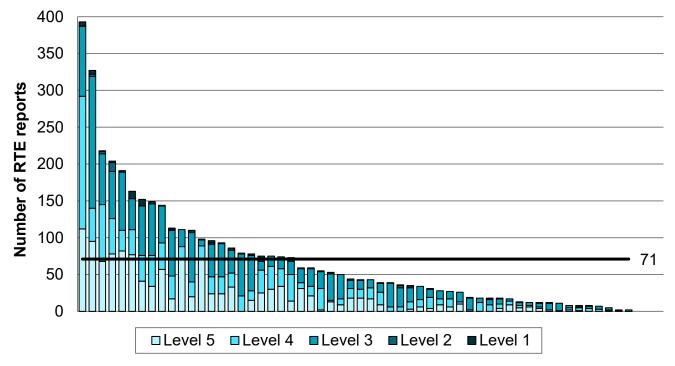
In total, 3,993 RTE for the reporting period from August to November 2023 were included for analysis. The analysis is presented here.

Number of reports per provider

Data was received from NHS providers and from the independent sector. For this reporting period 55 RT providers across both the independent and NHS providers have reported. This is a slight increase since the <u>previous analysis</u> (issue 41) (n=54). There were 43 anonymised reports received which did not indicate the RT provider, these have been included in <u>Figure 3</u> as a single provider.

<u>Figure 3</u> shows the number of RTE reports submitted by provider. This ranged from one to 393 reports, with a mean of 71. Of the 55 RT providers who reported, 60.0% (n = 33) reported less than the national mean. <u>Figure 3</u> also indicates the classification of reports received per provider. The providers that submitted higher numbers of RTE reports included all classification levels of reports. Seven providers did not report any level 5 RTE.

There may be several reasons for this disparity in reporting. Reporting culture varies across providers. Incident learning systems are not always easily accessible. Additional resource may be required to support a full incident learning system. Finally, a local requirement to use more than one system may disincentivise reporting. Findings of the most recent survey of UK RT providers on reporting culture is published in the January 2022 issue of <u>Safer Radiotherapy E-bulletin</u>. This survey demonstrated that those providers required to use more than one system were less likely to submit all classification of RTE. Furthermore, only 64.3% stated their local incident learning system.





The number of reports per provider has not been normalised to account for the variation in provider capacity or service specification. It should be noted that those providers reporting higher numbers of RTE represent providers with mature reporting cultures and should be encouraged to continue reporting.

Breakdown of process codes

The 3,993 RTE reports were categorised by process code and classification level so the main themes could be derived. Figure 4 shows 43.2% (n = 1,723) of the RTE were reported to have occurred during treatment unit processes. The treatment process represents the last opportunity to identify errors. Accurate treatment relies on the correct interpretation of the treatment plan and set up details which need to be replicated at each fraction of treatment. This might explain prevalence of RTE within treatment unit processes. The most frequently reported process codes remain consistent with the previous analysis (issue 41), with the addition of brachytherapy

during the current review period. A further breakdown of brachytherapy associated RTE can be seen at the end of this analysis.

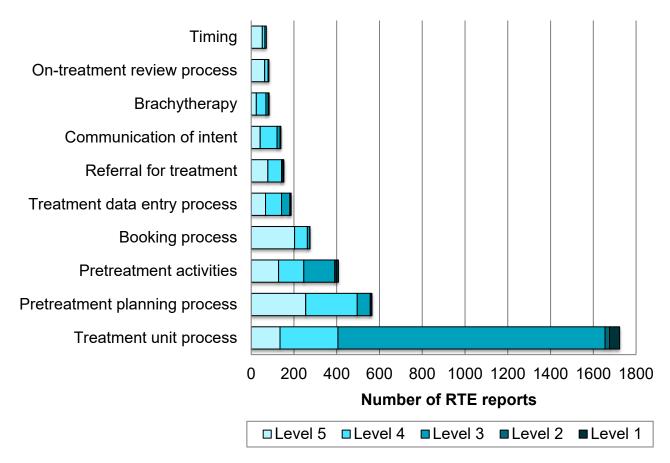


Figure 4. Breakdown of RTE process code by level (n = 3,688/3,993 subset of RTE)

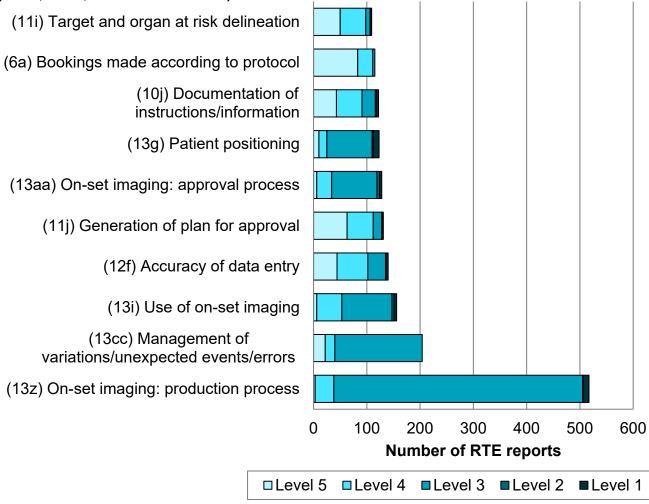
Breakdown of process subcodes

The most frequently reported process subcodes in the RT pathway are presented in <u>Figure 5</u>. This subset of data was also broken down by level.

The most frequently reported RTE was 'on-set imaging: production process' at 12.9% (n = 517) of all the reports. This reflects a decrease in percentage but increase in frequency when compared to the <u>previous analysis</u>, issue 41 (13.1%, n = 454). Of this subset, 97.7% (n = 505) of the reports were minor radiation, near miss or other non-conformities with little or no impact on patient care. The second most frequently reported RTE was 'management of variations/ unexpected events/errors' at 5.1% (n = 204). The most frequently reported process subcodes during the current review period are consistent with the <u>previous analysis</u> (issue 41).

Three of the most frequently reported RTE process subcodes shown in <u>Figure 5</u> relate to on-set imaging; 'on-set imaging: production process', 'use of on-set imaging', and 'on-set imaging: approval process'. On-set imaging associated RTE combined made up 22.5% (n = 898) of all RTE reported for this period. Further guidance on mitigating and reporting these types of RTE can be seen in the Safer Radiotherapy <u>good practice guidance series</u>.

Figure 5. Breakdown of most frequently reported RTE process subcodes by level (n = 1,745/3,993 subset of RTE)



Classification (level) of RTE

Each of the 3,993 RTE reports was classified as 'other non-conformance (level 5)', 'near miss (level 4)', 'minor radiation incident (level 3)', 'non-reportable radiation incident (level 2)' or 'reportable radiation incident (level 1)' (Figure 6).

Of the RTE reports, 97.0% (n = 3,875) were minor radiation incident, near miss or other nonconformities (levels 3 to 5) with little or no impact on patient outcome. Of the remaining 3.0% (n = 118) of reports, 2.0% (n = 79) were reportable under IR(ME)R to the appropriate enforcing authority (level 1).

The national survey on reporting culture published in the January 2022 issue of <u>Safer</u> <u>Radiotherapy E-bulletin</u> indicates that providers are less likely to submit all levels of RTE reports to the national voluntary reporting system. It was found that RTE reports of classification level 4 to 5 are less likely to be shared due to resource constraints and use of multiple reporting systems locally. This trend is also reflected in <u>Figure 3</u> which shows providers who report a higher number of RTE, report all levels of RTE. Triannual RTE analysis and learning report issue 42: Full radiotherapy error data analysis August to November 2023

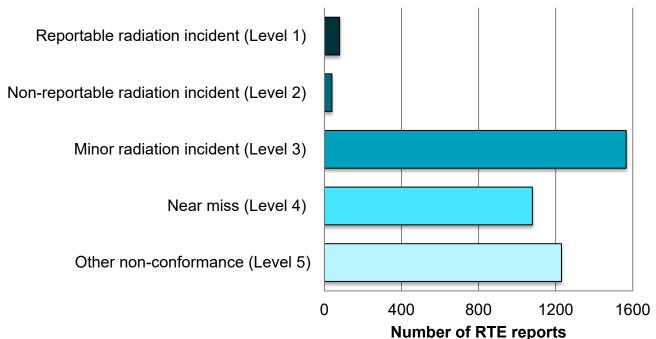


Figure 6. Classification (level) of RTE reports (n = 3,993)

Reportable radiation incident (level 1) RTE

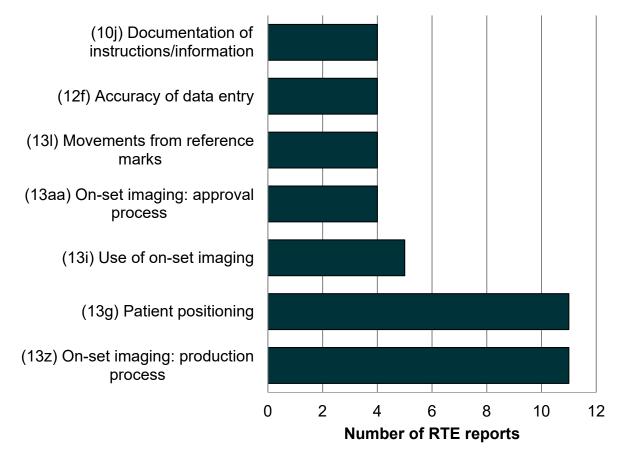
Reportable radiation incidents (level 1), as defined in <u>TSRT</u> fall into the category of reportable under $\underline{IR(ME)R}$ (2, 3, 5), in accordance with SAUE guidance (6). These incidents will generally be significant, although they may be correctable within the course of treatment. The majority of these incident reports related to a single exposure. This meant that corrective action could be applied to the remaining treatment fractions, so the incident did not have a significant impact on the patient or the outcome of their treatment.

There were 79 level 1 incidents submitted by 36 providers to the voluntary system for this reporting period (Figure 6), comprising 2.0% of the RTE reviewed. This proportion is similar to the <u>previous analysis</u>, issue 41 (2.1%, n = 71) (p = 0.76). Further analysis of the reports indicates the points in the pathway at which the reportable incidents occurred (Figure 7).

'On-set imaging: production process' and 'patient positioning' each comprised of 13.9% (n = 11) of reports and were the most frequently reported events within the reportable radiation incidents. 'On-set imaging: production process' was also the most frequently reported event within the <u>previous analysis</u> (issue 41), comprising 26.8% (n = 19) of all level 1 incidents. An example of an 'on-set imaging: production process' reportable RTE is when verification images are repeated multiple times due to either machine malfunction, set-up error or protocol failure. Further information on radiotherapy verification imaging IR(ME)R notification criteria may be found within the SAUE guidance (<u>6</u>). Practical advice on reducing this type of event can be seen in case study 2 in <u>issue 32</u>, the good practice guidance series and the <u>biennial report</u>.

An example of 'Patient positioning' associated RTE is when the patient is positioned incorrectly, including limb positioning, which leads to a geographical miss. Further guidance on reducing these types of events can be seen in <u>previous analysis</u> (issue 39).

Figure 7. Breakdown of most frequently reported level 1 RTE by process subcode (n = 43/79 subset of RTE)

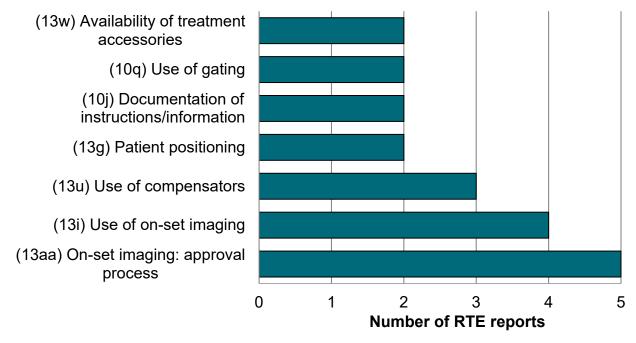


Two of the process subcodes within the most frequently reported level 1 incidents were not featured in the most frequently reported level 1 RTE within the <u>previous analysis</u> (issue 41). This included 'movements from reference marks' and 'accuracy of data entry'. The level 1 RTE were spread across 36 different process subcodes. Of these, 13 did not occur during a patient attendance. A review of checking processes to ensure they contain a minimum criteria for checking is recommended, this may mitigate RTE propagating through the patient pathway to the treatment process.

Non-reportable radiation incident (level 2) RTE

A non-reportable radiation incident (level 2) is defined within <u>TSRT</u> as a radiation incident which is not reportable, but of potential clinical significance. Non-reportable radiation incidents comprised 1.0% (n = 39) of the RTE reported for this time period (<u>Figure 6</u>). This is a slight increase since the <u>previous analysis</u>, issue 41 (0.7%, n = 24) (p = 0.16). Further analysis indicates the points in the pathway at which non-reportable radiation incidents occurred (<u>Figure 8</u>).

Figure 8. Breakdown of most frequently reported level 2 RTE by process subcode (n = 20/39 subset of RTE)



The reports were spread across 26 different subcodes, 19 of which were singular and not shown within Figure 8. 'On-set imaging: approval process' comprised of 12.8% (n = 5) of all the non-reportable radiation incident reports. An example of 'on-set imaging: approval process' is the incorrect approval of an on-set verification image which leads to a partial geographical miss which is non reportable. 'Use of on-set imaging' was the second most frequently reported level 2 RTE comprising 10.3% (n = 4) of all non-reportable radiation incidents. The pathway code 'use of on-set imaging' should be used when imaging has not been conducted according to protocol, for example kV imaging is undertaken when the imaging protocol stipulates CBCT imaging on a specific day.

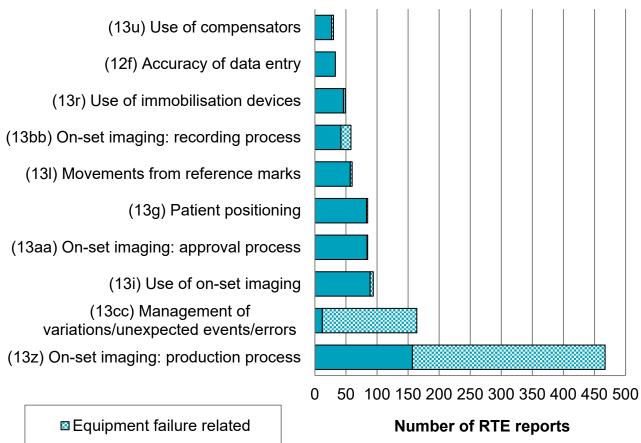
Minor radiation incident (level 3) RTE

A minor radiation incident (level 3) is defined within <u>TSRT</u> as a radiation incident in the technical sense, but of no potential or actual clinical significance. Minor radiation incidents comprised 39.2% (n = 1,566) of the RTE reported for this reporting period (Figure 6). Although the proportion of level 3 RTE has remained consistent (p = 0.48) with the previous analysis, issue 41 (40.0%), the number of level 3 reports has significantly increased, from 1,382 in the previous analysis, to 1,566 during the current reporting period. A breakdown of level 3 RTE by process subcode can be seen in Figure 9.

'On-set imaging: production process' was the most frequently reported event (29.8%, n = 467) within this subset. Although the proportion of reports has remained similar to the <u>previous</u> <u>analysis</u>, issue 41 (29.2%) the frequency of reports has increased (n = 404).

Examples of this type of minor radiation incident can include setting the jaws incorrectly for a single image, leading to an additional image. A total of 66.4% (n = 310) level 3 RTE with the primary process subcode 'on-set imaging: production process' were attributed to equipment failure, this is shown in Figure 9. Examples of this type of RTE include CBCT faults during acquisition. Equipment failure and on-set imaging: production process is discussed further in <u>issue 18 of Safer Radiotherapy</u>.

Figure 9. Breakdown of most frequently reported level 3 RTE by process subcode (n = 1,125/1,566 subset of RTE) includes equipment failure related



'Management of variations, unexpected events or errors' made up 10.5% (n = 164) of all minor radiation incidents, of these 92.7% (n = 152) were due to equipment failure, examples of this type of event includes when treatment equipment failure leads to a patient requiring transfer to a matched treatment machine. The re-set of the patient positioning then requires additional verification imaging. Further information on this type of event can be seen in Safer Radiotherapy the <u>unseen pathway</u>.

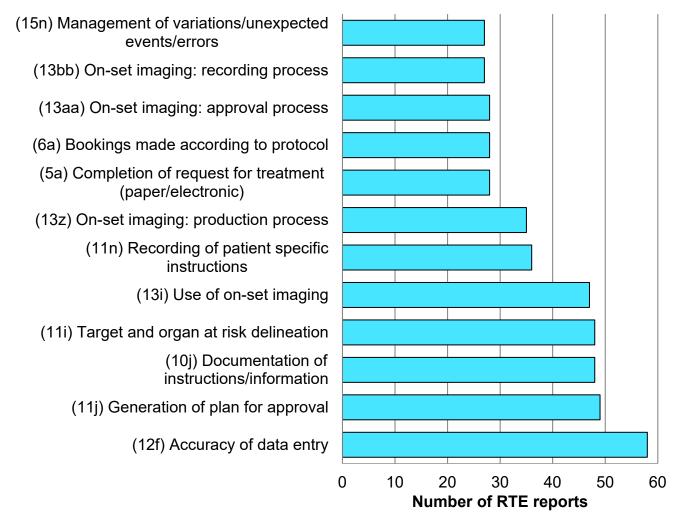
There has only been 1 addition to the most frequently reported process subcodes within the minor radiation incidents (level 3) RTE when compared to the <u>previous analysis</u> (issue 41); 'use of compensators (including bolus)'.

Near miss (level 4) RTE

A near miss (level 4) is defined within <u>TSRT</u> as a potential radiation incident that was detected and prevented before treatment delivery.

Near misses comprised 27.0% (n = 1,079) of the RTE reported (Figure 6). This reflects an increase in comparison to the previous analysis, issue 41 (24.8%, n = 858) (p = 0.03). Figure 10 shows the most frequently reported process subcodes for level 4 RTE.

Figure 10. Breakdown of most frequently reported level 4 RTE by process subcode (n = 459/1,079 subset of RTE)



'Accuracy of data entry' comprised 5.4% (n = 58) of level 4 RTE. An example of this type of RTE would be a transcription error or the omission of information during a data entry task.

Three of the most frequently reported process subcodes within the near misses (level 4) RTE did not feature in the most frequently reported near miss RTE within the <u>previous analysis</u> (issue 41); (6a) 'bookings made according to protocol', (13aa) 'on-set imaging: approval process' and (15n) management of variations/unexpected events/errors'.

Similar to the minor radiation incidents (level 3), the most frequently reported level 4 RTE shown in Figure 10, includes the pathway subcodes associated with on-set imaging (12.7%, n = 137). Example of 'on-set imaging: production process' associated near miss may include a verification image not reconstructed due to a software failure. However, in some cases the image may be retrieved negating the need for further imaging. An example of 'use of on-set imaging' includes the incorrect scheduling of verification imaging not in accordance with protocol. However, the error was detected prior to exposure. An example of 'on-set imaging: recording process' near miss includes the actions required following image review were not recorded, but the error was identified and action was correctly taken prior to exposure.

Brachytherapy associated RTE are included in the most frequently reported near miss reports. Further detail on brachytherapy RTE can be seen at the end of this analysis.

Other non-conformance (level 5) RTE

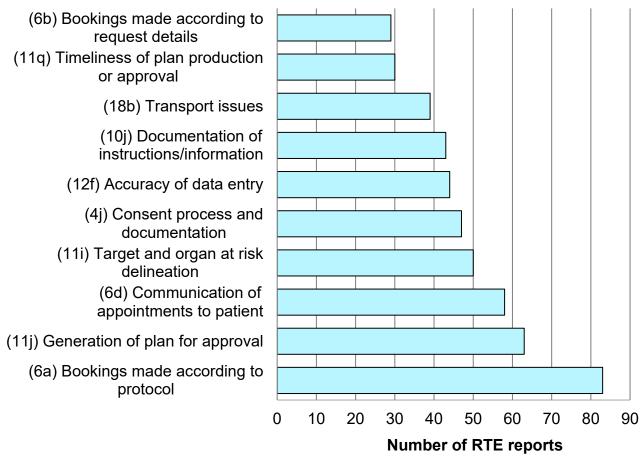
Other non-conformance (level 5) is defined within <u>TSRT</u> as a non-compliance with some other aspect of a documented procedure, but not directly affecting RT delivery.

Level 5 RTE comprised 30.8% (n = 1,230) of all RTE reported for this period (Figure 6). This reflects a slight decrease in the proportion of non-conformance reports in comparison to the previous analysis, issue 41 (32.4%), but a slight increase in frequency (n = 1,121), (p = 0.14).

The most frequently reported level 5 process subcodes were 'bookings made according to protocol' comprising 6.7% (n = 83) of all level 5 RTE (Figure 11). An example of this type of RTE is the incorrect booking of patient appointments, this includes booking appointments on the incorrect day and/or treatment machine. These errors are often detected during an end of process check before affecting patient treatment. The booking process includes 6 different process subcodes, which were reported in 16.5% (n = 203) of level 5 RTE.

No treatment process subcodes were included in the most frequently reported level 5 RTE (Figure 11). All of the most frequently reported process subcodes were also seen in the previous analysis (issue 41).

Figure 11. Breakdown of most frequently reported level 5 RTE by process subcode (n = 486/1,230 subset of RTE)



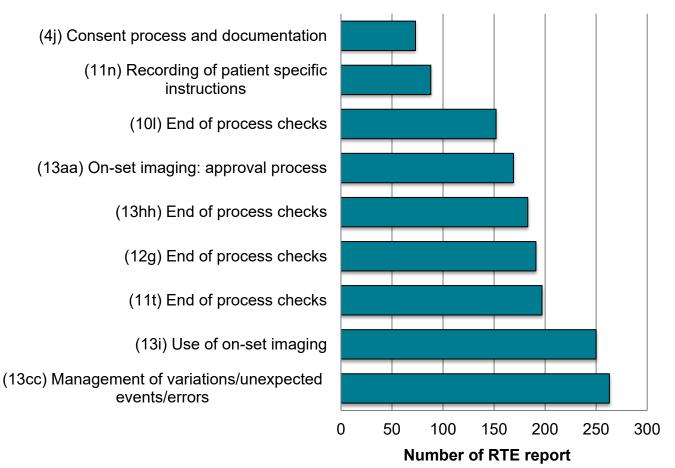
Failed safety barriers

A safety barrier (SB) is a critical control point, defence in depth, or any process step whose primary function is to prevent errors occurring or propagating through the RT workflow (15). SB embedded in the pathway coding (<u>16</u>) can be allocated to each RTE report to identify all points in the pathway where the error was not detected (failed SB). Multiple FSB codes can be attributed to each individual RTE. A total of 2,513 failed safety barriers (FSB) were identified from the RTE reported (<u>Figure 12</u>).

Treatment unit processes were attributed to 40.1% (n = 1,007) of all FSB. The most frequently reported FSB are represented in <u>Figure 12</u>. Treatment unit processes 'management of variations/unexpected events/errors' was the most frequently reported FSB (10.5%, n = 263). 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. Each of the FSB were also seen in the <u>previous analysis</u> (issue 41).

'End of process checks' occur at the end of each discrete part of the patient pathway and include 6 different pathway subcodes. These comprised of 29.4% (n = 739) of all FSB. The PSRT provided further information on the use of end of process checks in the January (#6) and September (#7) 2022 issues of <u>Safer Radiotherapy E-bulletin</u>.

Figure 12. Breakdown of failed safety barriers (n = 1,729/2,513 subset of RTE data)



Method of detection

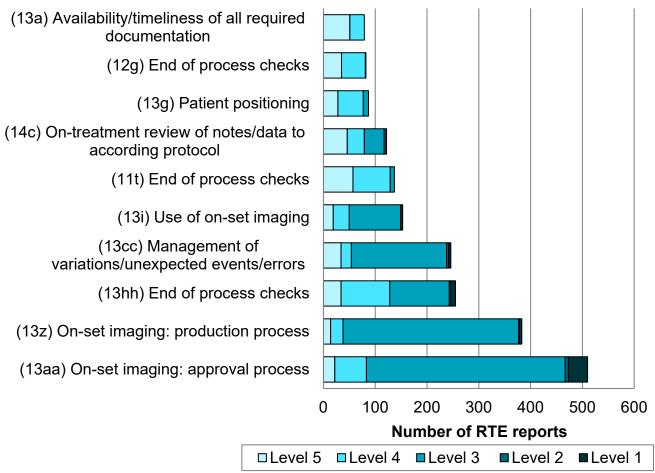
A method of detection (MD) is the process that identified the error and can be coded using the entire pathway taxonomy.

For this reporting period 46 providers indicated MD in 65.4% (n = 2,611) of reports. This is an increase in numbers since the <u>previous analysis</u> (issue 41), where 42 providers indicated MD in 64.0% (n = 2,243) of reports. Following consistency checking, UKHSA coded a further 1,113 reports with MD taxonomy, resulting in 3,724 reports for analysis. The most frequently reported MD can be seen in <u>Figure 13</u>.

The most frequently reported MD was 'on-set imaging: approval process' (13.7%, n = 510). This MD was most frequently reported with a primary process code 'on-set imaging: production process' (21.2%, n = 108). Seven of the most frequently reported MD occurred at the treatment unit process.

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Figure 13. Breakdown of method of detection by level (n = 2,054/3,724 subset of RTE data)



'End of process checks' occur at the end of each discrete part of the patient pathway and include 6 different pathway subcodes. These comprised of 14.6% (n = 542) of all MD, of which 68.1% (n = 369) were classified as either near miss or other non-conformances, stopping the RTE from propagating across the patient pathway.

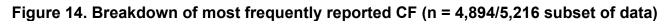
For each part of the patient pathway there are 'other' pathway subcodes. Before consistency checking 12.4% (n = 323/2,611) of MD were assigned 'other' pathway subcode. After consistency checking this was reduced to 6.0% (n = 156). It is recommended the entire pathway coding should be considered when assigning a MD as described in the January 2022 issue of <u>Safer Radiotherapy E-bulletin</u>.

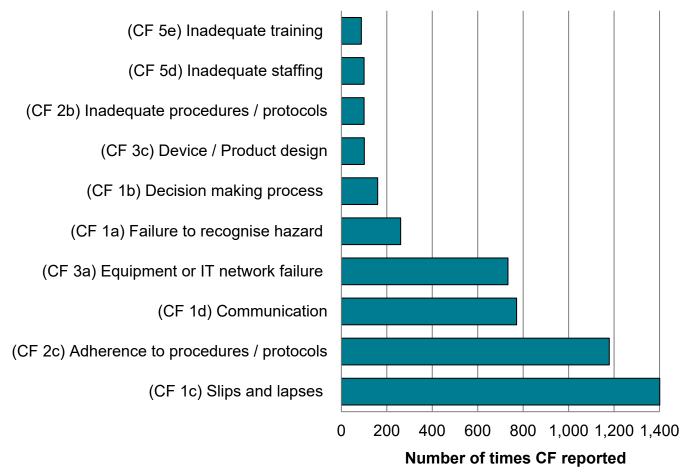
Contributory factors

The use of a causative factor (CF) taxonomy enables identification of system problems or contributory factors that could precipitate a range of different incidents (17).

From the 3,993 RTE reported, 85.9% (n = 3,428) included CF coding. These were reported from 53 providers. This reflects a slight increase in providers, but decrease in the total frequency of

CF coding reported since the <u>previous analysis</u> (issue 41), when 48 providers reported 3,0899 of RTE reports included CF (89.4%). UKHSA were able to assign a further 551 primary CF, resulting in 3,979 primary CF for analysis.





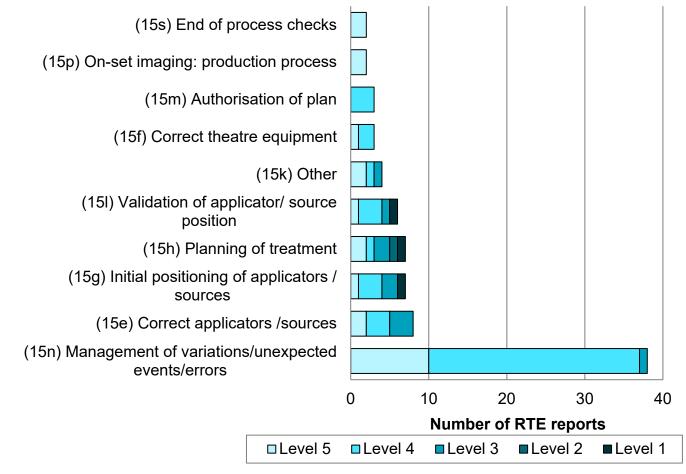
Multiple CF can be assigned to a single RTE, across the 3,979 RTE, 1,055 contained multiple CF totalling 5,216 CF codes. Figure 14 shows the most frequently reported CF codes. The most frequently reported CF was 'slips and lapses' making up 26.9% (n = 1,401) of all CF reported (Figure 14). <u>Issue 22 of Safer Radiotherapy</u> includes guidance on minimising the occurrence of RTE caused by a slip or lapse of an individual. There are 2 additions to the most frequently reported CF when compared to the <u>previous analysis</u> (issue 41); 'inadequate training' and 'device or product design'.

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 (<u>18</u>). Therefore, the number of BRT associated RTE would be expected to be low and should be interpreted with caution. Further learning from BRT RTE can be seen in a separate <u>learning resource</u>.

RTE coded with BRT process subcodes as the primary code accounted for 2.1% (n = 84) of reports, a notable increase from the <u>previous analysis</u>, issue 41 (0.6%, n = 21). Providers reporting BRT RTE has also increased from 10 within the <u>previous analysis to 18</u> for this reporting period. A breakdown of the brachytherapy RTE can be seen in Figure 15.

Figure 15. Breakdown of most frequently reported BRT RTE coded '15' by level (n = 80/84 subset of RTE)



The most frequently reported BRT process subcode was 'management of variations, unexpected events or errors' comprising 45.2% (n = 38) of all BRT RTE, 86.8% (n = 33) of which were reported from one provider. An example of BRT RTE associated with 'management of variations, unexpected events or errors' includes equipment failures. A large proportion of these types of events were classified as either near miss or other non-conformances (97.4%, n = 37) meaning there was little or no impact on patient care.

From the 84 BRT RTE, there were 97 subcodes reported. Of these, 73 were FSB, the most frequently reported was 'management of variations/unexpected events/errors' comprising 54.8% (n = 40). The FSB shown in Figure 12 indicate imaging associated FSB as the most frequently reported FSB associated with external beam deliveries. This difference is due to a greater uptake and availability of IGRT in external beam RT than in BRT and the high frequency of equipment failure associated RTE in BRT (Figure 17).

Of the 84 BRT RTE, 64.3%, (n = 54) were assigned a MD subcode. During consistency checking 25 further BRT RTE were assigned a MD using the text within the report. These are shown in Figure 16, the most frequently reported MD was 'management of variations, unexpected events or errors' (50.0%, n = 42).

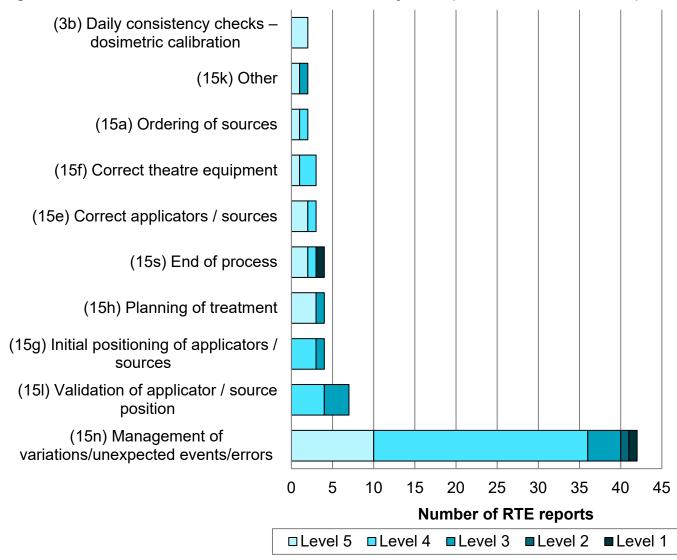
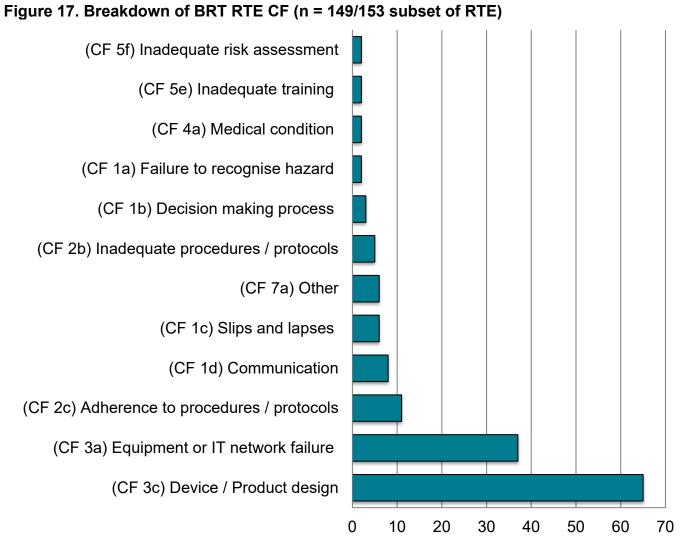


Figure 16. Breakdown of BRT method of detection by level (n = 73/79 subset of RTE)

All CF codes were reviewed within this subset of the data and 153 CF identified (Figure 17). The most frequently reported CF associated with BRT RTE was 'equipment or IT network failure' comprising of 42.5% (n = 65) of all the CF for BRT RTE.

The trends of these BRT CF are slightly different when compared to the entire data as in <u>Figure</u> <u>14</u>, which may be indicative of differences in the equipment, skill mix and workflow between areas.



Number of times contributory factor reported

References

- 1. World Health Organization. 'Reporting and learning for patient safety'
- 2. European Commission (2015). '<u>Radiation Protection No. 181, General guidelines on risk</u> management in external beam radiotherapy'
- 3. <u>'The Ionising Radiation (Medical Exposure) Regulations 2017'</u> The Stationery Office, London, SI 2017/1322
- 4. <u>'The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018</u>.' The Stationery Office, London, SR 2018/17
- 5. <u>'The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2018</u>.' The Stationery Office, London, SI 2018/121
- 6. Care Quality Commission. 'IR(ME)R notification guidance'
- 7. International Atomic Energy Agency 'Safety in Radiation Oncology (SAFRON)'
- 8. RCR, Institute of Physics and Engineering in Medicine, Society and College of Radiographers. <u>'On target 2: updated guidance for image guided radiotherapy'</u>
- 9. The Radiotherapy Board made up of the Society and College of Radiographers; Institute of Physics and Engineering in Medicine and the Royal College of Radiologists. <u>'Ionising</u> <u>radiation (medical exposure) regulations: implications for clinical practice in radiotherapy</u>' London: The Royal College of Radiologists 2020 Ref RTBoard
- 10. Society of Radiographer. 'Pause and Check'
- 11. Royal College of Radiologists, Society and College of Radiographers, Institute of Physics and Engineering in Medicine, National Patient Safety Agency, British Institute of Radiology. <u>'Towards Safer Radiotherapy</u>' London: Royal College of Radiologists, 2008
- 12. NHS England. 'Patient safety learning response toolkit'
- 13. Imperial College London. 'Systems analysis of clinical incidents: the London protocol'
- 14. NHS England. 'Policy guidance on recording patient safety events and levels of harm'
- 15. Ford E and others. 'Consensus recommendation for incident learning database structures in radiation oncology.' Medical Physics December 2012: volume 39, issue 12, pages 7,272 to 7,290
- 16. Public Health England. 'Development of learning from radiotherapy errors'
- 17. Clark B and others. 'The management of radiation treatment error through incident learning.' Radiotherapy and Oncology 2010: volume 95, pages 344 to 349
- 18. <u>CancerData statistics</u>

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