

Safer Radiotherapy

Triannual RTE analysis and learning report

Issue 39 – full radiotherapy error data analysis August to November 2022

Contents

Full radiotherapy error data analysis	3
Inspectorate data	4
Case study 9: patient positioning	
August to November 2022 data analysis	
Number of RTE reports	8
Monitoring of RTE coding by radiotherapy providers	8
Number of reports per provider	10
Breakdown of process codes	11
Breakdown of process subcodes	12
Classification (level) of RTE	13
Reportable radiation incident (level 1) RTE	14
Non-reportable radiation incident (level 2) RTE	16
Minor radiation incident (level 3) RTE	17
Near miss (level 4) RTE	18
Other non-conformance (level 5) RTE	
Failed safety barriers	
Method of detection	22
Causative factors	
Brachytherapy RTE	24
References	27
About the UK Health Security Agency	29

Full radiotherapy error data analysis

The fundamental role of reporting and 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 and near misses (RTE), reported voluntarily by UK NHS radiotherapy (RT) providers. Anonymised reports were submitted through multiple routes, from England via the National Reporting and Learning System (NRLS) at NHS England and from Wales via the Once for Wales Concerns Management System (OfW) (<u>3</u>), or directly to UKHSA from providers in Northern Ireland and Scotland. In England, the NRLS will be replaced by the Learn from Patient Safety Events Service (LFPSE) (<u>4</u>) by autumn 2023. UKHSA are working with NHS England to ensure the continuation of RTE data submissions. In the interim, UKHSA will continue to receive reports from the NRLS.

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) (<u>5</u>, <u>6</u>, <u>7</u>) inspectorates of significant accidental or unintended exposures (SAUE) (or 'reportable radiation incidents' (level 1) as defined in <u>Towards Safer</u> <u>Radiotherapy (TSRT)</u> (<u>8</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 significant accidental or unintended exposures (SAUE) for analysis. It should be noted there may be a significant time lag between notification of an event to the inspectorates, it being closed and then shared with UKHSA for inclusion in the analysis.

The classification level from <u>TSRT</u> (8), the pathway coding, safety barrier, methods of detection and causative factor taxonomies from the <u>Development of Learning (DoL) from</u> <u>Radiotherapy Errors (9)</u> were employed for the analysis. SB and MD are discussed further in the May 2021 issue of the <u>Safer Radiotherapy e-bulletin (10</u>). A series of <u>presentations</u> have been developed as free educational tools to support the RT community in engaging with this work. These include an introduction to learning from RTE, a description of the nationally agreed terminology and taxonomies used within this report, how the taxonomies should be

applied to RTE reports, the sharing of examples of the types of analysis that can be done on RTE to maximise learning opportunities and the requirements and methodologies for a study of risk of accidental or unintended exposures. additional learning resources will continue to be added to these pages ($\underline{11}$).

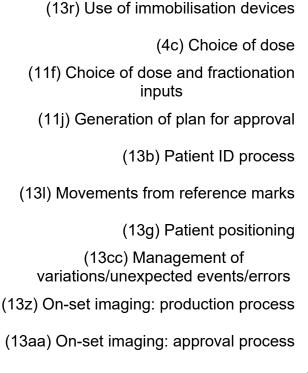
The analysis has been reviewed and added to by the PSRT. If individual providers would like to comment on the analysis, share experience of learning from RTE or application of the coding please email the RT team at radiotherapy@ukhsa.gov.uk.

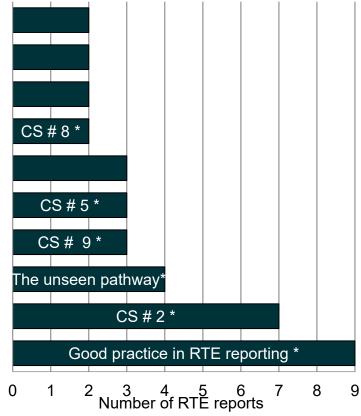
Inspectorate data

A breakdown of the inspectorate data for this period can be seen in <u>Figure 1</u>. The inspectorates shared 51 anonymised closed synopses of reported SAUE for analysis.

The most frequently reported notifications were associated with 'on-set imaging: approval process' (17.6%, n = 9). This is a slight change since the <u>previous analysis</u> (12) when 49 reports were shared, and the most frequently reported process subcode was 'on-set imaging: production process'. A number of the inspectorate process subcodes have had case studies included in Safer Radiotherapy publications such as the <u>triannual analysis</u> (13), the <u>unseen pathway</u> (14) and <u>good practice guidance</u> (15), the specific case studies are shown with an * in Figure 1.

Figure 1. Breakdown of most frequently reported inspectorate process subcodes from closed notifications (n = 37/51 subset of data) (CS = case study)





Case study 9: patient positioning

'Patient positioning' is one of the most frequently reported pathway subcodes. This type of RTE includes when a patient is positioned incorrectly, for either verification imaging or treatment. It may be detected by imaging, in-vivo dosimetry or end of process checks which can be either in-room, pre switch-on or at completion of treatment. Correct identification of reference marks, movements from reference marks, and use of immobilisation are critical aspects of patient immobilisation. This includes techniques using technology such as surface guided radiotherapy.

Synopsis

Palliative radiotherapy treatment of 8Gy in a single # was prescribed to the right-posterior chest wall. On completion of the treatment it was noted that an unintended exposure was given to the right arm.

Planning details included a setup note for a neutral shoulder position and a measurement of 5cm from medial elbow to lateral chest wall to abduct the right arm and remove it from the treatment field. The patient was set-up with their arm by their side for treatment. End of process checks were completed within the treatment room, which included the confirmation of the patient position. The use of EPID dosimetry detected that the arm was incorrectly positioned and received some of the treatment exposure.

The erroneous dose distribution was simulated and discussed with the consultant who was satisfied with the clinical coverage to the tumour. Following local procedure, the patient was informed of the dose to the right arm by the consultant at an additional follow up appointment.

It was noted that the isocentre match was accurate but there was a missed opportunity to identify the difference in arm position which led to the over exposure. The use of a set-up field which included the field/jaw projection onto the patient contour may have provided an opportunity for radiographers on set to notice the field splash on the arm prior to the CBCT being acquired.

Learning identified that use of VacBags and set up photos for limb positioning should be considered for all relevant treatments and the reference images used should be appropriate to address the clinical question.

Coding: Level 1/ 13g/ 13hh/ 10b/ 13aa/ MD13h/ CF1c/ CF1a/ CF2d

Causative factors

A causative factor for this synopsis was 'slips and lapses' (CF1a) as the patient was incorrectly positioned during treatment set-up. 'Failure to recognise hazard' (CF1a) was also

included as the incorrect arm position was not recognised during the in room end of process check and the verification image review. Learning from this incident identified that a change in procedure such as the use of other immobilisation such as VacBags for limb positioning would strengthen set-up procedures (CF2d 'process design').

Safety barriers

The in-room end of process checks (13hh) included verifying that the patient was in the correct position. This check failed on this occasion. Verification imaging (13aa) is also used to ensure the correct patient position. However this process step only identified that the isocentre was correctly positioned and was not used to identify that the patient position was incorrect.

Method of detection

The completion of in-vivo dosimetry (13h) for this patient highlighted the unintended exposure given to the right arm.

Corrective actions

Corrective actions include:

- consider patient comfort and patient communication during immobilisation procedure and treatment to ensure compliance with set up instructions
- consider the use of immobilisation and the use of vacbags for limb positioning
- ensure availability of appropriate reference images (skin rendered and photos)
- review end of process checks to ensure these include confirmation of correct patient positioning and limb positioning
- review end of process checks to ensure they include a review of entry/exit beams
- consideration of incidental findings as part of image review should be included in local procedures
- utilise clear and accurate set up information with standard nomenclature
- ensure staff are adequately trained, competent and appropriately entitled in the use of the technology
- ensure availability of agreed up to date written procedures
- share the error with the wider department for learning

Learning from excellence and published guidance

Learning from excellence and published guidance include:

- the use of appropriate tolerance tables for both couch and gantry have been effective in mitigating some set up errors (<u>16</u>)
- random errors should be minimised by careful attention to immobilisation and patient preparation techniques (<u>17</u>)
- appropriate optimisation of imaging selection and reference image production (<u>18</u>)
- utilise light field visualisation to assess patient set up (<u>19</u>)

Further guidance and national tools to aid investigations are available ($\underline{20}$, $\underline{21}$). Following a simple risk matrix ($\underline{18}$) a study of risk was produced for this case study and other (13g) patient positioning related RTE.

Table 1. Study of risk matrix: R in brackets indicates red risk, A in brackets indicates
amber risk, G in brackets indicates green risk

	Initial risk			Risk following mitigations (corrective action examples shown above)		
Area of risk	Consequence	Likelihood	Risk score	Consequence	Likelihood	Risk score
Incorrect patient positioning, detected during end of process checks	1	4	4 (G)	1	1	1 (G)
Incorrect patient positioning detected during verification imaging	2	3	6 (G)	2	1	2 (G)
Incorrect patient positioning detected during in-vivo dosimetry	2	2	4 (G)	2	1	2 (G)
Incorrect patient positioning not detected until completion of treatment	3	1	3 (G)	3	1	3 (G)
Incorrect patient position on treatment couch, leading to verification imaging through wrong section of bed	2	4	8 (A)	2	1	2 (G)
Incorrect patient position on treatment couch, leading to treatment through wrong section of bed	3	2	6 (G)	3	1	(3) (G)

A special thank you to Stuart McGrail, Deputy Head of Radiotherapy Services at The Beacon Centre, Musgrove Park Hospital for the review of this case study.

August to November 2022 data analysis

Number of RTE reports

A monthly average of 943 reports were received between August and November 2022. This was an decrease from 1,052 (11.6%), when compared to the <u>previous analysis</u> (12) and an increase from 777, (21.4%) when compared to the same reporting period published in 2021 (22).

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 787 days, with a mean of 44 days and a mode of 0 days, reflecting that 172 were reported nationally on the same day as the incident. Two outliers of 787 and 560 days were detected whilst processing a new treatment course for patients who had received previous treatment. These were both non-conformances and had no effect on the patients treatment. The remaining 15 reports which had a lag time greater than 365 days were reported from 3 providers. This variation in timeliness of reporting is also reflected in the overall patient safety incident reports received by the NRLS who encourage organisations to report incidents monthly (23). To ensure timely learning from RTE nationally, providers are asked to make RTE submissions at the earliest opportunity. Issue 26 of Safer Radiotherapy (24) provides further information on reporting frequency.

Although the monthly average reports received for this 4-month period has decreased since the last reporting period, there was a spike of 1,315 reports received from 52 of the 59 providers during November. The average time lag for this data was 46 days meaning that this increase in data was not due to the reporting of back dated RTE, further detail on the monthly reporting of reports can be seen in this month's <u>Safer Radiotherapy e-bulletin (25)</u>.

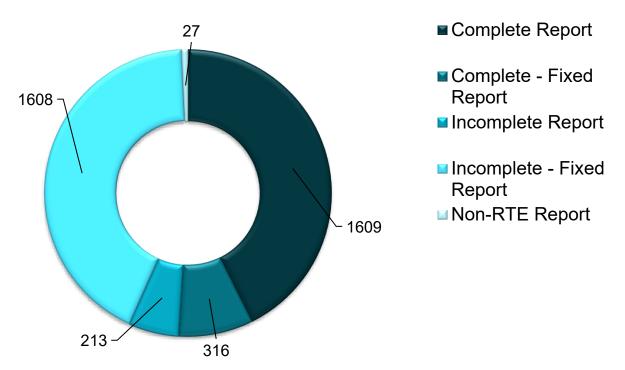
Monitoring of RTE coding by radiotherapy providers

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) (including root cause and contributory factors) 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 reporting and 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 1,925 RTE reports classified and coded locally with all the taxonomies, 1,244 were classified as levels 1 to 4. A total of 209 of these were amended (complete fixed in Figure 2 includes level 5 data (n = 316)). Thus, an 83.2% level of consistency was achieved for levels 1 to 4 RTE. This is similar to the previous analysis (12) when an 81.7% level of consistency was achieved.





Some amendments were made to reports to ensure consistent allocation of the taxonomies. Of the 316 complete fixed reports 15.5% (n = 49) had the classification amended, 56.0% (n = 177) had the pathway subcode amended, 65.2% (n = 206) had the method of detection amended and 7.3% (n = 23) had the causative factor amended.

The classification was most frequently amended for RTE with primary pathway subcodes associated with on-set imaging (55.1%, n = 27). If a verification image is required to be repeated this should be classified as a radiation incident (level 1 to 3) and not a near miss (level 4) or non-conformance (level 5). The most frequently amended primary pathway subcode was treatment unit process 'other', making up 16.4% (n = 29) of all the amended pathway subcodes. This was most frequently amended to 'management of variations/ unexpected events/ errors. 37.9% (n = 11). It is recommended the entire pathway subcoding

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> (26).

A total of 1,821 RTE reported did not contain one of the required taxonomies, including MD. A total of 1,608 were classified or coded by UKHSA staff using the supporting text supplied by the local providers (incomplete fixed in Figure 2), 927 of these only required the MD to be included.

Non-RTE reports submitted formed 0.7% (n = 27) 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 <u>previous analysis (12)</u>. A <u>PSI</u> is defined by the NRLS as 'any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving care' (<u>27</u>). Further information on PSI can be found in <u>issue 5 of Safer</u> <u>Radiotherapy (28)</u>. Non-RTE reports were excluded from the detailed analysis.

In total, 3,746 RTE for the reporting period from August to November 2022 were included for analysis. The analysis is presented here.

Number of reports per provider

There are currently 59 NHS RT providers across the UK. For this reporting period, 96.6% (n = 57) of providers have submitted RTE reports using the TSRT9 trigger code, this is an increase to the <u>previous analysis</u> (94.9%, n = 56) (<u>12</u>).

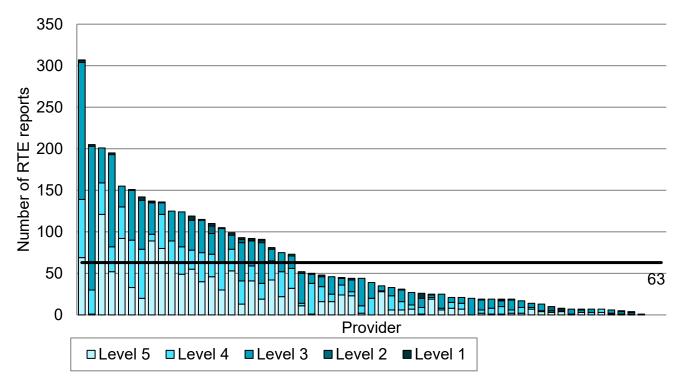


Figure 3. Number of RTE reported by provider (n = 3,746)

Figure 3 shows the number of RTE reports submitted by provider. This ranged from one to 307 reports, with a mean of 63. A total of 2 providers did not submit any reports for this reporting period. Of the 57 providers who reported, 63.2% (n = 36) reported less than the national mean. Figure 3 also indicates the classification of reports received per provider. The majority of providers that submitted higher numbers of RTE reports included all classification levels of reports. However, one provider who reported 205 RTE only reported 1 level 5 RTE and a further 6 providers did not report any level 5 RTE.

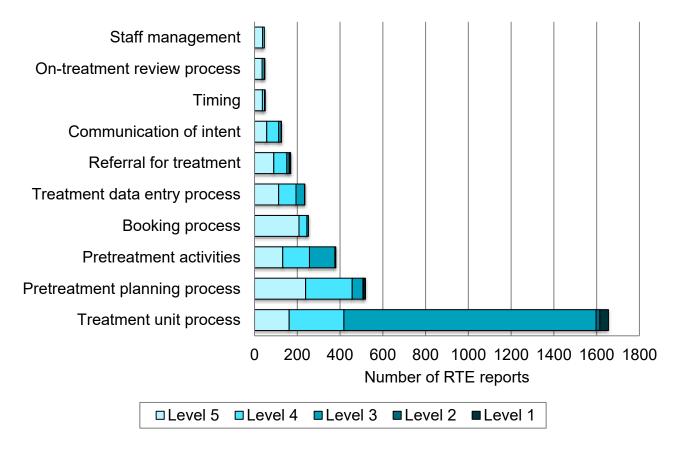
There may be several reasons for this disparity in reporting. Reporting culture varies across providers. Incident learning systems are not always easily accessible. Additional resource may be required to support a full incident learning system. Finally, a local requirement to use more than one system 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</u> <u>Radiotherapy e-bulletin</u> (29). 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 was linked for data transfer to the wider hospital/trust risk management 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 3,746 RTE reports were categorised by process code and classification level so the main themes could be derived. Figure 4 shows 44.2% (n = 1,654) 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. All but one of the most frequently reported process codes are the same as previous analysis (12). For the first time staff management processes are included in the most frequently reported process codes, (1.2% (n = 46)). Safe delivery of RT is reliant on an adequately resourced and skilled workforce, further information on workforce can be seen in the September 2022 issue of the Safer Radiotherapy e-bulletin (30).

Figure 4. Breakdown of RTE process code by level (n = 3,480/3,746 subset of RTE)



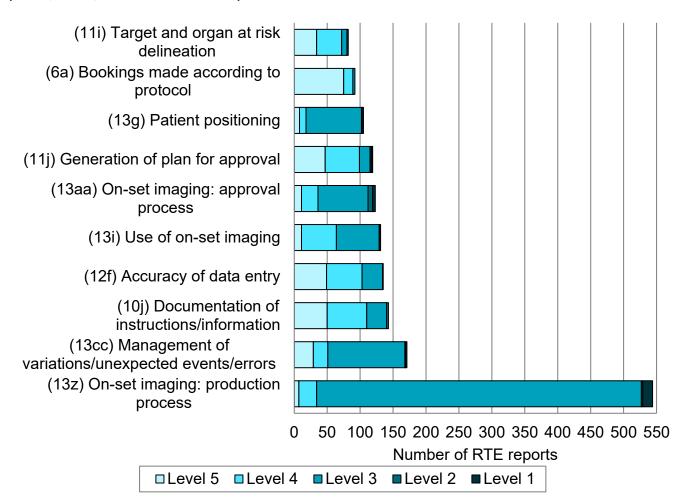
Breakdown of process subcodes

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 reported was 'on-set imaging: production process' at 14.5% (n = 544) of all the reports, which is a slight increase when comparted to the previous analysis (12.9%, n = 534) (12). Of this subset, 98.7% (n = 527) 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 4.6% (n = 171), further information including a case study of this type of event can be seen in Safer Radiotherapy: the <u>unseen pathway</u> (14). All but one ('bookings made according to protocol') of the most frequently reported process subcodes were seen in the <u>previous analysis (12</u>).

On-set imaging associated RTE include 'on-set imaging: production process', 'use of on-set imaging', 'on-set imaging: recording process' and 'on-set imaging: approval process'. These combined RTE made up 23.3% (n = 873) of all RTE reported for this period. Further guidance on mitigating and reporting these types of RTE can be seen in the Safer Radiotherapy good practice guidance series (15).

Figure 5. Breakdown of most frequently reported RTE process subcodes by level (n = 1,645/3,746 subset of RTE)



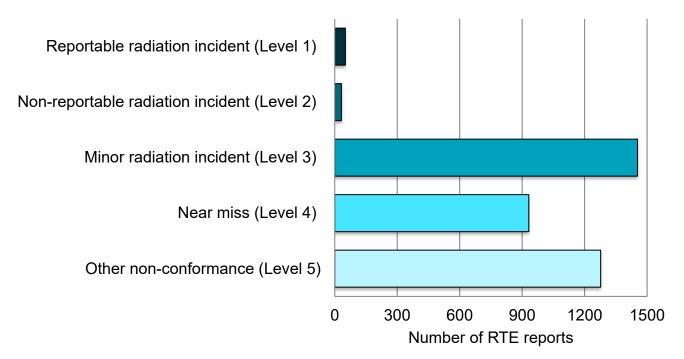
Classification (level) of RTE

Each of the 3,746 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)' (<u>Figure 6</u>).

Of the RTE reports, 97.8% (n = 3,663) were minor radiation incident, near miss or other nonconformities (levels 3 to 5) with little or no impact on patient outcome. Of the remaining 2.3% (n = 83) of reports, only 1.4% (n = 51) were reportable under IR(ME)R to the appropriate authority.

The national survey on reporting culture published in the January 2022 issue of <u>Safer</u> <u>Radiotherapy e-bulletin</u> (29) 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. 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.

Figure 6. Classification (level) of RTE reports (n = 3,746)



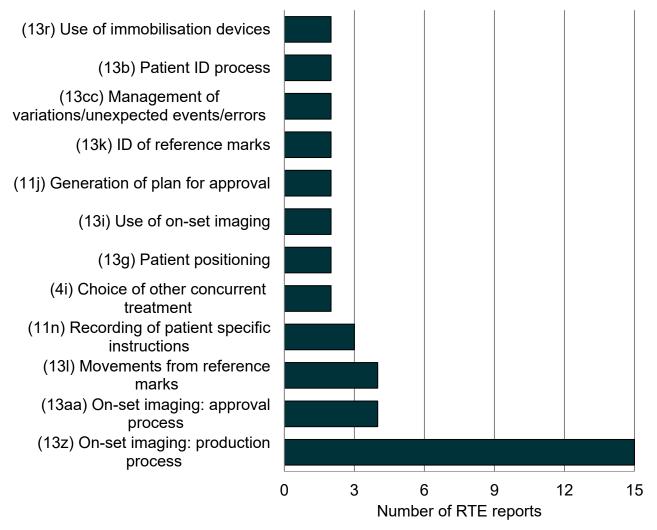
Reportable radiation incident (level 1) RTE

Reportable radiation incidents (level 1), as defined in <u>TSRT</u> (8) fall into the category of reportable under IR(ME)R (5, 6, 7). 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 51 level 1 incidents submitted by 26 providers to the voluntary system for this reporting period (Figure 6), comprising 1.4% of the RTE reviewed. This proportion is slightly higher than the previous analysis (12) (1.0%, n = 40) (p = 0.10). Further analysis of the reports indicates the points in the pathway at which the reportable incidents occurred (Figure 7).

'On-set imaging: production process' comprised 29.4% (n = 15) and was the most frequently reported event within the reportable radiation incidents. This was also the most frequently reported event within the <u>previous analysis</u> (12), comprising 17.5% (n = 7) of all level 1 incidents for that time period. An example of an 'on-set imaging: production process' reportable RTE is when repeat verification image is taken multiple times due to either machine malfunction and or setting the incorrect position for the image panel. Taking 3 or more images in one fraction due to machine malfunction meets the reportable threshold of the inspectorates (<u>31</u>). Further guidance on reducing this type of event can be seen in case study 2 in <u>issue 32 (32)</u>, the good practice guidance series (<u>15</u>) and the <u>biennial report (33</u>).

Figure 7. Breakdown of most frequently reported level 1 RTE by process subcode (n = 42/51 subset of RTE)



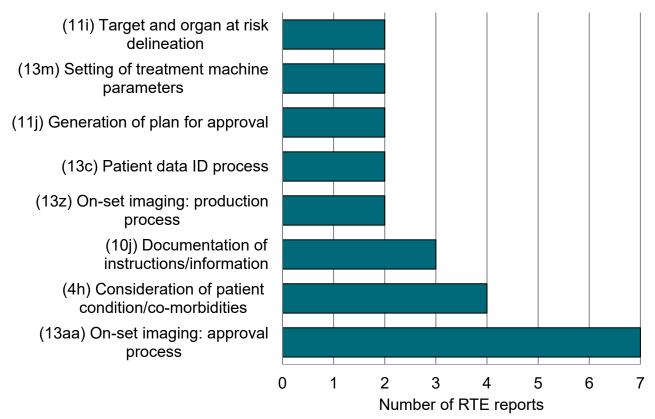
'On-set imaging: approval process' and 'movements from reference marks' each comprised of 7.8% (n = 4) of the reportable radiation incidents. An example of 'on-set imaging: approval process' level 1 RTE is when a mismatch of imaging leads to a geographical miss including vertebral mismatches. Further guidance on reducing these types of events can be seen in the <u>good practice guidance series</u> (15). An example of 'movements from reference marks' level 1 RTE is when a move from the reference mark is carried out in the incorrect magnitude and, or direction leading to a geographical miss during treatment. Further guidance on how to minimise this type of event can be seen in <u>previous analysis</u> (12).

Six of the process subcodes within the most frequently level 1 incidents were also featured in the most frequently reported level 1 RTE within the <u>previous analysis</u> (<u>12</u>). The level 1 RTE were spread across 21 different process subcodes. Of these, 7 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 pathway to the patient treatment process.

Non-reportable radiation incident (level 2) RTE

A non-reportable radiation incident (level 2) is defined as a radiation incident which is not reportable, but of potential clinical significance (8). Non-reportable radiation incidents comprised 0.9 % (n = 32) of the RTE reported for this time period (Figure 6). This is similar to the previous analysis (12) (1.0% (n = 42) but is not statistically significant (p = 0.64). Further analysis indicates the points in the pathway at which non-reportable radiation incidents occurred (Figure 8).

Figure 8. Breakdown of most frequently reported level 2 RTE by process subcode (n = 24/32 subset of RTE)



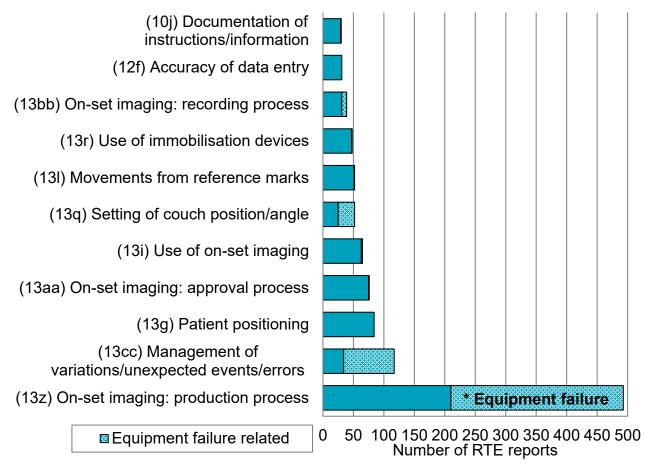
The reports were spread across just 16 different subcodes, 8 of which were singular and not shown within Figure 8. 'On-set imaging: approval process' comprised of 21.9% (n = 7) of all the non-reportable radiation incident reports. An example of this type of RTE is the incorrect approval of an on-set verification image which leads to a partial geographical miss which is non reportable.

Only the 3 process subcodes reported within the non-reportable radiation incidents reported during this period were also featured in the non-reportable RTE within the <u>previous analysis</u> (<u>12</u>).

Minor radiation incident (level 3) RTE

A minor radiation incident (level 3) is defined as a radiation incident in the technical sense, but of no potential or actual clinical significance (8). Minor radiation incidents comprised 38.8% (n = 1,454) of the RTE reported for this reporting period (Figure 6). This is an increase in proportion since the previous analysis (12) (37.2%, n = 1,536) and the differences are not statistically significant (p = 0.14). A breakdown of level 3 RTE by process subcode can be seen in Figure 9.

Figure 9. Breakdown of most frequently reported level 3 RTE by process subcode (n = 1,087/1,454 subset of RTE) *equipment failure related



'On-set imaging: production process' was the most frequently reported event (33.9%, n = 493) within this subset. This is a slight increase in proportion since the <u>previous analysis</u> (12) (31.8%, n = 488).

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 57.4% (n = 277) 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 issue 18 of Safer Radiotherapy (34).

'Management of variations/ unexpected events/ errors' made up (n = 117) of all minor radiation incidents, of these (n = 83) were due to equipment malfunction, examples of this type of event includes when treatment equipment malfunction leading to a patient requiring movement to a matched treatment machine, this 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 (14)</u>.

All of the treatment process codes within the most frequently reported process subcodes within the minor radiation incidents (level 3) RTE also featured in the most frequently reported minor radiation incident RTE within the <u>previous analysis</u> (<u>12</u>).

Near miss (level 4) RTE

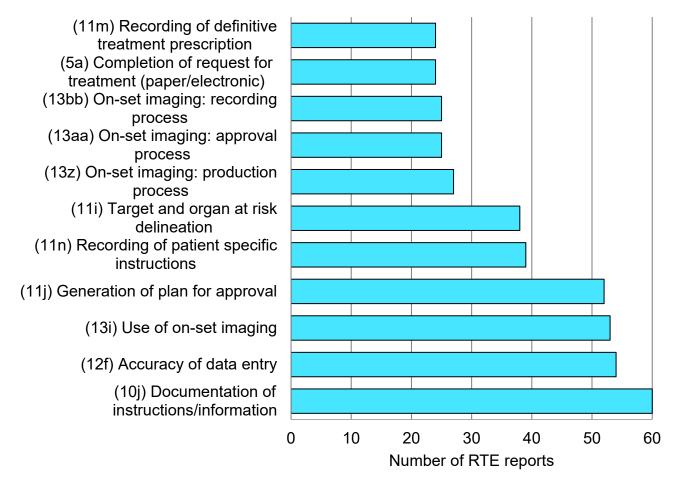
A near miss (level 4) is defined as a potential radiation incident that was detected and prevented before treatment delivery ($\underline{8}$).

Near misses comprised 24.9% (n = 932) of the RTE reported (Figure 6). The proportion of the current report is slightly lower (p = 0.54) than the <u>previous analysis</u> (12) (25.5%, n = 1,053). Figure 10 shows the most frequently reported process subcodes for level 4 RTE.

'Documentation of instructions/information' comprised 6.4% (n = 60) of level 4 RTE, followed by 'accuracy of data entry' at 5.8% (n = 54). An example of RTE associated with 'documentation of instructions/information' is the incorrect immobilisation information annotated at pre-treatment and detected during treatment unit patient positioning. An example of RTE associated with 'accuracy of data entry' is the error in transcription of vital information during the data entry process, this can include treatment set up information, movements from reference marks or bolus information. This type of event is then detected during patient set up at treatment. Further details on 'documentation of instructions/ information' and 'accuracy of data entry' related RTE can be found in <u>issue 8 and 7</u> of Safer Radiotherapy (<u>35, 36</u>).

All but 2 ('completion of request for treatment' and 'recording of definitive treatment prescription') of the most frequently reported process subcodes within the near misses (level 4) RTE also featured in the most frequently reported near miss RTE within the <u>previous</u> analysis (12).

Figure 10. Breakdown of most frequently reported level 4 RTE by process subcode (n = 421/932 subset of RTE)



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 (13.9%, n = 130). Examples of 'on-set imaging: production process' associated RTE include using a kV image for verification when a CBCT should have been acquired, the kV image is used for treatment verification and no additional exposure is given. An example of 'on-set imaging: approval process' RTE includes when the second review of a verification image has not been completed, this is then detected whilst performing end of process checks during the next fraction of treatment. An example of 'on-set imaging: recording process' RTE includes the actions following image review not being undertaken, where this does not lead to incorrect or additional exposure.

Other non-conformance (level 5) RTE

Other non-conformance (level 5) is defined as a non-compliance with some other aspect of a documented procedure, but not directly affecting RT delivery ($\underline{8}$).

Level 5 RTE comprised 34.1% (n = 1,277) of all RTE reported for this period (Figure 6). The number and proportion of other non-conformances is decreased in comparison with the previous analysis (12) (35.3%, n = 1,458), (p = 0.26).

The most frequently reported level 5 process subcodes were 'bookings made according to protocol' comprising of 5.9% (n = 75) 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 are detected during an end of process check before affecting patient treatment. The booking process includes 6 different process subcodes, which were reported in 16.3% (n = 208) of level 5 RTE.

'Availability of staff with competency appropriate to procedure' comprised of 3.0% (n = 38) of all level 5 RTE. Examples of this type of event includes when there are not appropriately trained staff available for tasks across the patient pathway.

There are no treatment process subcodes contained within the most frequently reported level 5 RTE as shown within <u>Figure 11</u>. Nine of the most frequently reported process subcodes in the other non-conformances RTE were also seen in the <u>previous analysis</u> (<u>12</u>).

Figure 11. Breakdown of most frequently reported level 5 RTE by process subcode (n = 542/1,277 subset of RTE)

(11i) Target and organ at risk delineation (6f) Communication of appointment between staff groups (20a) Availability of staff with competency appropriate to procedure (12g) End of process checks (11j) Generation of plan for approval (4j) Consent process and documentation (12f) Accuracy of data entry (10j) Documentation of instructions/information (11q) Timeliness of plan production or approval (6d) Communication of appointments to patient (6a) Bookings made according to protocol 0 10 20 30 40 50 60 70 80

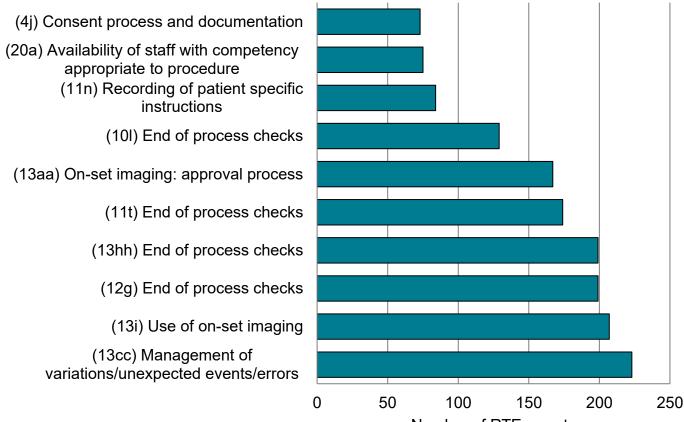
20

Number of RTE reports

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 (<u>37</u>). SB embedded in the pathway coding (<u>9</u>) can be allocated to each RTE report to identify all points in the pathway where the error was not detected (failed SB). Multiple SB codes can be attributed to each individual RTE. A total of 2,359 failed safety barriers (FSB) were identified across the RTE reported (<u>Figure 12</u>).

Figure 12. Breakdown of failed safety barriers (n = 1,530/2,359 subset of RTE data)



Number of RTE reports

Treatment unit processes were attributed to 39.3% (n = 926) 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 (9.4%, n = 223). An example of an RTE with this FSB includes when a linac fault leads to patient requiring reset up or movement to another matched treatment machine. All of the FSB were also seen in the <u>previous analysis</u> (<u>12</u>).

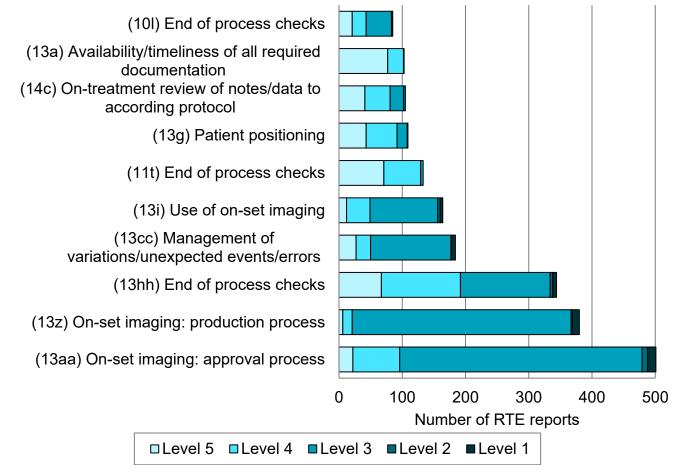
'End of process checks' occur at the end of each discrete part of the pathway and include 6 different pathway subcodes, these comprised of 30.2% (n = 712) of all FSB. The PSRT have undertaking a piece of work to look at the use of end of process checks which is highlighted in the <u>January</u> and <u>September</u> 2022 issue of Safer Radiotherapy e-bulletin (29,30).

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 43 providers indicated MD in 50.0% (n = 1,875) of reports. This is a vast increase since the <u>previous analysis</u> (<u>12</u>), where 36 providers indicated MD in 34.4% (n = 1,420) of reports. Following consistency checking, UKHSA coded a further 1,664 reports with MD taxonomy, resulting in 3,539 reports for analysis. The most frequently reported MD can be seen in <u>Figure 13</u>.

Figure 13. Breakdown of method of detection by level (n = 2,108/3,539 subset of RTE data)



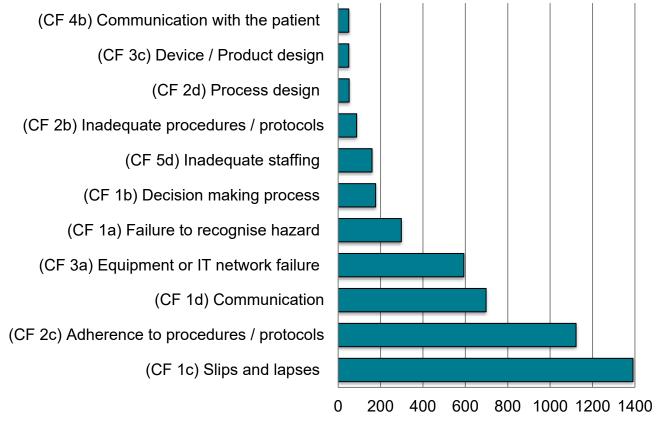
For this reporting period, the most frequently reported MD was 'on-set imaging: approval process' (14.2%, n = 501). This MD was most frequently reported with a primary process code 'on-set imaging: production process' (26.3%, n = 132). Seven of the most frequently reported MD occurred at the treatment unit process.

'End of process checks' occur at the end of each discrete part of the pathway and include 6 different pathway subcodes. These comprised of 18.1% (n = 639) of all MD, of which 68.1% (n = 435) detected the error, stopping the RTE from propagating across the pathway. For each part of the pathway there are 'other' pathway subcodes. Before consistency checking 8.5% (n = 160/1,875) of MD were assigned an 'other' pathway subcode. After consistency checking this was reduced to 5.4% (n = 101). 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> (29).

Causative 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 (<u>38</u>).

Figure 14. Breakdown of most frequently reported CF (n = 4,678/4,920 subset of data)



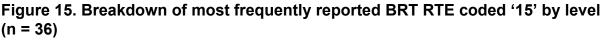
Number of times contributory factor reported

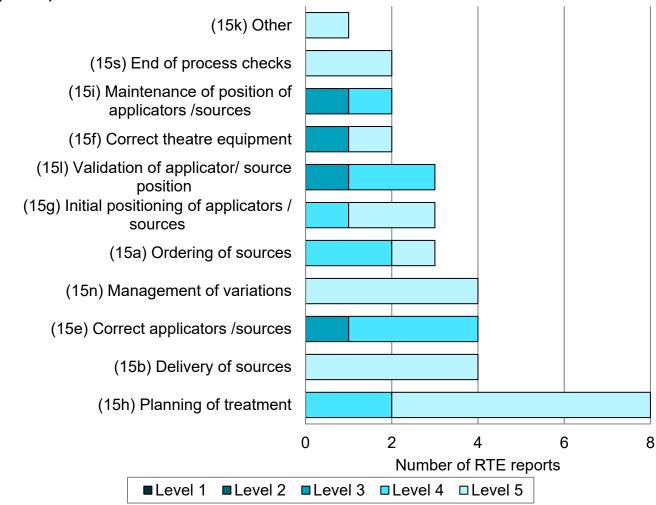
From the 3,746 RTE reported 83.1% (n = 3,114) contained CF coding. These were reported from 54 providers. This is a slight decrease in providers since the <u>previous analysis</u> (<u>12</u>),when 56 providers reported and 83.2 (n = 3,436) of RTE contained CF. Multiple CF can be assigned to a single RTE, across the 3,746 RTE reported 922 contained multiple CF totalling 4,920 CF codes. <u>Figure 14</u> shows the most frequently reported CF codes.

The most frequently reported CF was 'slips and lapses' making up 28.3% (n = 1,391) of all CF reported (<u>Figure 14</u>). <u>Issue 22 of Safer Radiotherapy</u> (<u>39</u>) includes guidance on minimising the occurrence of RTE caused by a slip or lapse of an individual.

Brachytherapy RTE

Brachytherapy (BRT) is a RT sub-speciality which involves the placement of a sealed source inside or close to the treatment area (<u>40</u>). BRT makes up less than 3% of all RT episodes (<u>41</u>). 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 1.0% (n = 36) of reports, a slight decrease to the <u>previous analysis</u> (<u>12</u>) (1.3%, n = 55). BRT RTE were submitted from just 17 providers for this reporting period. A breakdown of the brachytherapy RTE can be seen in <u>Figure 15</u>.





The most frequently reported BRT process subcodes was 'planning of treatment' comprising 22.2% (n = 8) of all BRT RTE, these were all level 5 non-conformances. An example this type of BRT RTE includes when the organs at risk are incorrectly outlined during planning process.

From the 36 BRT RTE, 20 subcodes were identified as FSB, these are shown <u>Figure 16</u>. The most frequently reported was 'management of variations' comprising 30.0% (n = 6) The FSB seen across the entire pathway shown in <u>Figure 12</u> indicate imaging associated FSB. This difference is due to a perceived greater uptake of IGRT in external beam RT than in BRT

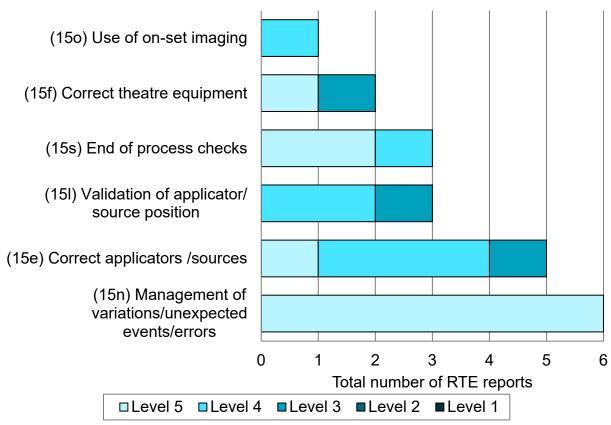
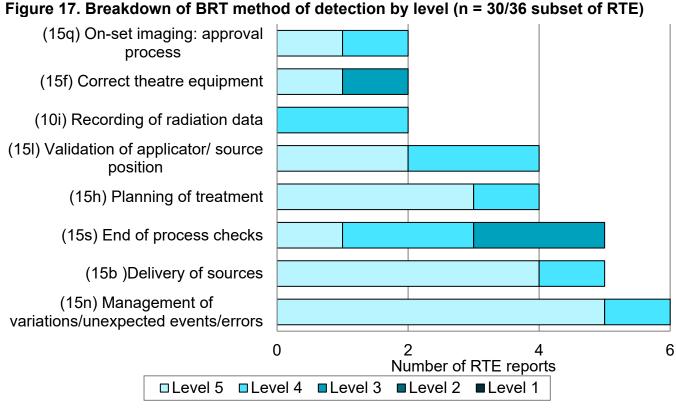


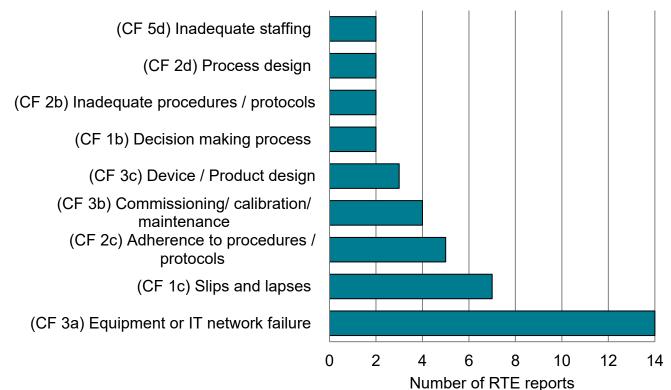
Figure 16. Breakdown of BRT failed safety barriers (n = 20)

Of the 36 BRT RTE, 38.9%, (n = 14) were assigned a MD subcode, during consistency checking the remaining 22 were also assigned a MD using the text within the report. These are shown in <u>Figure 17</u>.



All CF codes were reviewed within this subset of the data and 45 CF identified (Figure 18). The most frequently reported CF associated with BRT RTE was 'equipment or IT network failure' comprising of 31.1% (n = 14) of all the CF for BRT RTE. The trends of these BRT CF are slightly different when compared to the entire data as in Figure 14.

Figure 18. Breakdown of BRT RTE CF (n = 41/45 subset of RTE)



26

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Published: January 2023 Publishing reference: GOV-14055



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