UK Health Security Agency

Safer Radiotherapy

Triannual RTE analysis and learning report

Issue 44: full radiotherapy error data analysis, April to July 2024

Contents

Full radiotherapy error data analysis

Incident learning systems are a widely accepted safety tool internationally advocated by professional groups, bodies, agencies, and regulators in radiotherapy (1). Analysis of reported data facilitates the identification of areas for improvement and informs the direction of future refinements and improvements. It is imperative errors and near misses are learned from, and effective preventative measures are implemented (2).

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.

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 National Reporting and Learning System (NRLS) and the Learn from Patient Safety Events Service (LFPSE) at NHS England, from Wales via the Once for Wales Concerns Management System (OfW), or directly to UKHSA from providers in Northern Ireland, Scotland and the independent sector. In England, the NRLS has been replaced by the LFPSE in June 2024. Therefore, RTE data submitted through both routes has been included within the current analysis. MEG continues to work in collaboration with NHS England (NHSE) to ensure timely sharing of completed reports which include the radiotherapy trigger code (TSRT9) and corresponding coding taxonomy.

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 to 6) inspectorates of significant accidental or unintended exposures (SAUE) or ‘reportable radiation incidents’ (level 1) as defined in Towards Safer Radiotherapy (TSRT). 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.

The classification level from TSRT, the pathway coding, failed safety barriers (FSB), methods of detection (MD) and contributory factor taxonomies from the Development of Learning (DoL) from Radiotherapy Errors were employed for the analysis. FSB and MD are discussed further in the May 2021 issue of the Safer Radiotherapy E-bulletin. A series of presentations 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 radiotherapy@ukhsa.gov.uk

Inspectorate data

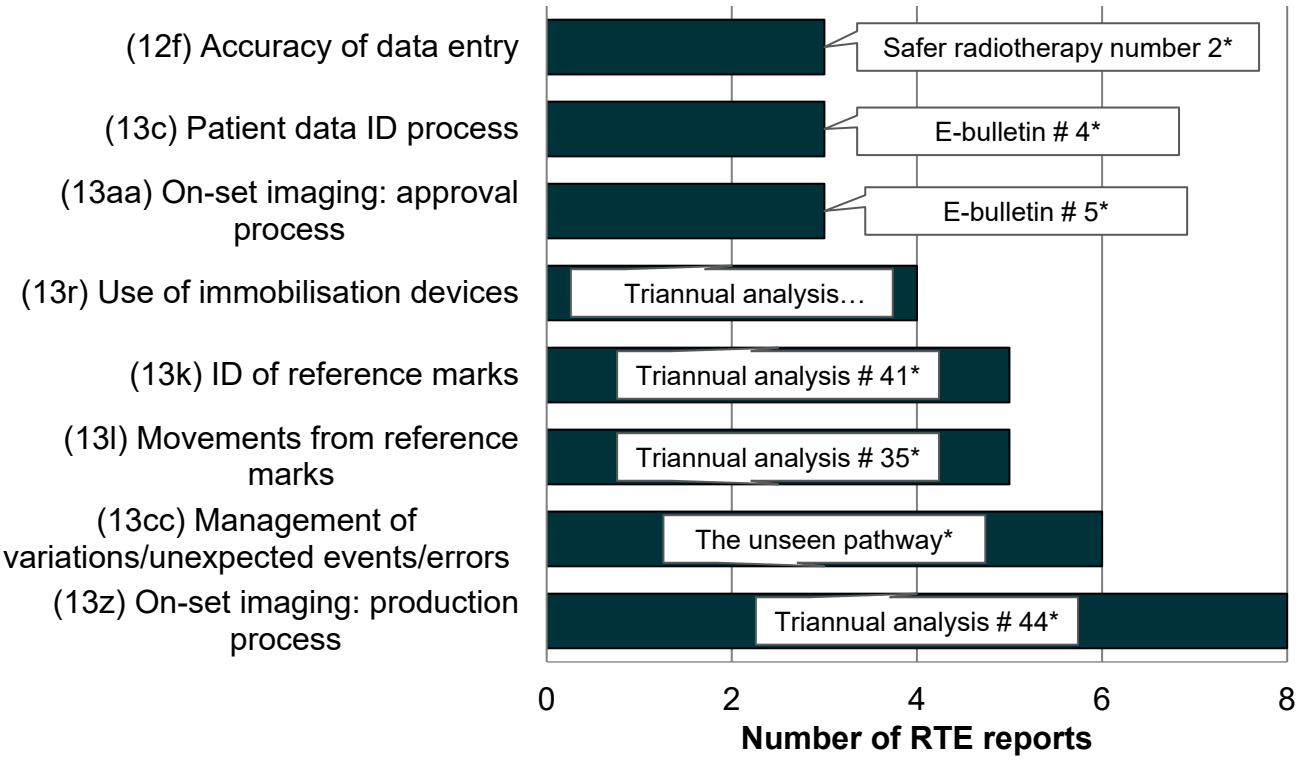
A breakdown of the inspectorate data for this reporting period can be seen in Figure 1. As IR(ME)R (3 to 6) applies to both NHS and independent RT providers, this data covers all RT providers. It should also be noted there may be a time lag between notification of an event to the inspectorates, completion of the detailed investigation and the subsequent sharing of information with UKHSA for inclusion in the analysis. Therefore, this data is analysed separately from the voluntary data.

The inspectorates shared 59 anonymised closed synopses of reported SAUE for analysis. This is a marked decrease since the previous analysis (issue 43) when 82 reports were shared. However, 42 reports were shared between August and November 2023 (issue 42).

The most frequently reported notifications were associated with 'on-set imaging: production process' (13.6%, n =8). This also reflects a marked decrease since the previous analysis (issue 43) where 14 reports (17.1%) were associated with 'on-set imaging: production process'.

A number of case studies have been included in Safer Radiotherapy publications such as the triannual analysis, the E-bulletin, the unseen pathway and good practice guidance. 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 = 37/59 subset of data)



Case study 14: On-set imaging: production process (13z)

The 8th biennial radiotherapy error data analysis and learning report, has demonstrated that treatment unit process pathway subcode (13z) 'on-set imaging: production process'. It continues to be the most frequently reported RTE, accounting for 13.0% (n = 2,875) of all RTE reported between January 2022 and December 2023 (n = 22,113).

Of the 2,875 'on-set imaging: production process' RTE reports received, 90.0% (n = 2,587) were classified as minor radiation incidents (level 3). Within this subset 55.9% (n = 1,446) of reports assigned 'equipment or IT network failure' during image acquisition as a contributory factor. An example of these types of RTE has been highlighted within the case study below.

The current analysis (April to July 2024) continues to reflect this trend with 'on-set imaging: production process' featuring as the most frequently reported RTE in the following subsets of data:

- 12.5% (n = 526) of all RTE process codes
- 13.6% (n = 8) of all RTE IR(ME)R inspectorate reports (level 1)
- 13.4% (n = 20) of all reportable radiation incidents (level1) voluntary reports

On-set imaging is an established cornerstone of modern radiotherapy delivery. It is essential in the delivery of image guided radiotherapy (IGRT) including adaptive radiotherapy (ART). Imaging is often acquired prior to each treatment delivery and may be coupled with the use of external surface tracking. The high incidence of on-set imaging associated RTE reflects not only the high volume of imaging taking place, but the complexity of modern radiotherapy technologies and techniques.

Synopsis

Patient undergoing radiotherapy with 45Gy in 25# for endometrial cancer. Departmental IGRT protocol requires a CBCT verification image to be taken prior to each treatment to confirm accuracy of set-up and target/organ-at-risk position.

On the 16th fraction, during image acquisition, the CBCT scan was interrupted with a fault message. The incident was reported to the engineers for investigation.

The engineer reviewed the equipment logs and saw that the reported cause of the problem was 'kV enable dropped-long position'. The fault was cleared by the engineer, and the operators were instructed to retract and reposition the image panel for the required imaging. A second CBCT was completed without problem. The patient was subsequently treated correctly.

The patient received one additional CBCT exposure, received dose: frames -261/660, dose-4.39mGy.

The error was logged on the local system for audit purposes and reported to the manufacturer. The manufacturer did not request any further action to be taken. Following an initial review of the log 2 similar incidents were noted in the previous week. A local multi-professional investigation including retrospective audit, was initiated. It was concluded the error was indicative of an on-going theme with the equipment, as 5 similar incidents had occurred within the last month. As multiple individuals were exposed within the same incident theme, the RTE was notified to the IR(ME)R regulator in accordance with SAUE guidance.

A trend analysis and subsequent study of risk of accidental or unintended exposures associated with on-set imaging was also undertaken. The system-based investigation confirmed that a programme of preventative maintenance and equipment QA had been completed correctly without issue, and the required images had been scheduled and undertaken correctly by the operators, in accordance with local protocol. Aging equipment was not found to be a contributing factor, and there were no external environmental factors reported which may affect the effectiveness of the equipment. The RTE was reported to MHRA and shared internally and nationally for learning.

Coding: TSRT9/ Level 1/ 13z/ MD13z/ CF3a

Contributory factors

Following investigation, the contributory factor (CF) for this synopsis was identified as ‘equipment or IT network failure’. Although the investigation reviewed external and internal environmental factors, as well as corresponding tasks and safeguards, such as the safe management of equipment, no other contributory factors were identified.

Safety barriers

The local management of equipment included multiple safety barriers:

- routine machine QA
- preventative maintenance and repair programme
- pre-exposure checks as part of the on-treatment end of process checks

On this occasion the safety barriers in place were unable to detect the intermittent equipment issue, prior to exposure.

Method of detection

The error was detected during on-set imaging production process, when the CBCT scan was interrupted with a message ‘kV enable dropped-long position’.

Corrective actions

Corrective actions for this type of RTE include:

- ensure fault reporting procedures are robust, clearly identifying tasks and action levels, indicating what escalation process to follow when things don't go to plan
- ensure contingency plans are in place and have been communicated to all appropriate staff, in case of equipment failure
- regular staff training should be provided on fault and RTE reporting
- report and investigate additional exposures, including retrospective review of records to identify thematic trends
- regular review or audit of fault reporting records to assist in the identification of thematic trends
- where thematic trends are identified consider appropriate action and escalation, for example review of procedures and corresponding risk management tools. Dependent on the severity of risk identified consideration may be given to removal of equipment or technique from practice. Ensure learning themes and corresponding corrective actions are shared with clinical and technical staff
- review and ensure imaging is included within QA process including proactive maintenance, preventative maintenance and repair programmes. Tasks, tolerance and action levels, as well as escalation routes should be clearly defined, and responsibilities allocated to appropriately trained and entitled staff
- ensure a positive safety culture is embedded within department, facilitating unambiguous multidisciplinary communication
- share the error with the wider department for learning

Learning from excellence and published guidance

Learning from excellence includes:

- guidance on reducing incidents associated with 'on-set imaging: production process' is included in case study 2 in issue 32 of 'Safer Radiotherapy: triannual error analysis and learning report', the 'good practice in radiotherapy error and near miss reporting' guidance series, and the 8th biennial radiotherapy error data analysis and learning report
- consider a review of affected patient plans with imaging dose summation to ensure OAR doses remain below tolerance

Further guidance and national tools to aid investigations are available (7 to 8). Following a simple risk matrix (9) a study of risk was produced for this case study and the process sub-code (13z) ‘on-set imaging: production process’.

Table 1. Study of risk matrix

In this table, a G (green) in brackets indicates low risk, an A (amber) in brackets indicates a moderate risk.

Area of risk	Initial risk			Risk following mitigations (corrective action examples shown above)		
	Consequence	Likelihood	Risk score	Consequence	Likelihood	Risk score
Equipment failure	2	4	8 (A)	2	3	6 (G)
Incorrect management of equipment fault	2	3	6 (G)	2	2	4 (G)
Incorrect equipment testing, recording, communication or escalation of result	2	3	6 (G)	2	2	4 (G)
IT network failure or communication issue	2	4	8 (A)	2	3	6 (G)
Physical environmental factor such as power cut	2	4	8 (A)	2	3	6 (G)

April to July 2024 data analysis

Number of RTE reports

A total of 4,296 reports were received between April 2024 and July 2024, 57 were not RTE reports resulting in 4,239 RTE reports for analysis. This equates to a monthly average of 1,060 RTE reports, reflecting a slight increase from 988 (7.3%), when compared to the previous analysis (issue 43) and an increase from 864, (22.7%) when compared to the same reporting period in April 2023 and July 2023 (issue 41).

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 477 days, with a mean of 29 days and a mode of 0 days, reflecting that 1,165 were reported nationally on the same day as the incident. There were 11 reports which did not contain an incident date, and 34 outliers with a lag time greater than 365 days, reported from 8 providers. There was no reason annotated to explain this delay in reporting.

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

Monitoring of RTE coding by radiotherapy providers

All providers are asked to apply a trigger code (TSRT9), classification level, primary pathway subcode, additional pathway subcoding (including failed safety barriers (FSB)), method of detection (MD) and contributory factors (CF) to their RTE reports to facilitate both local and national analysis.

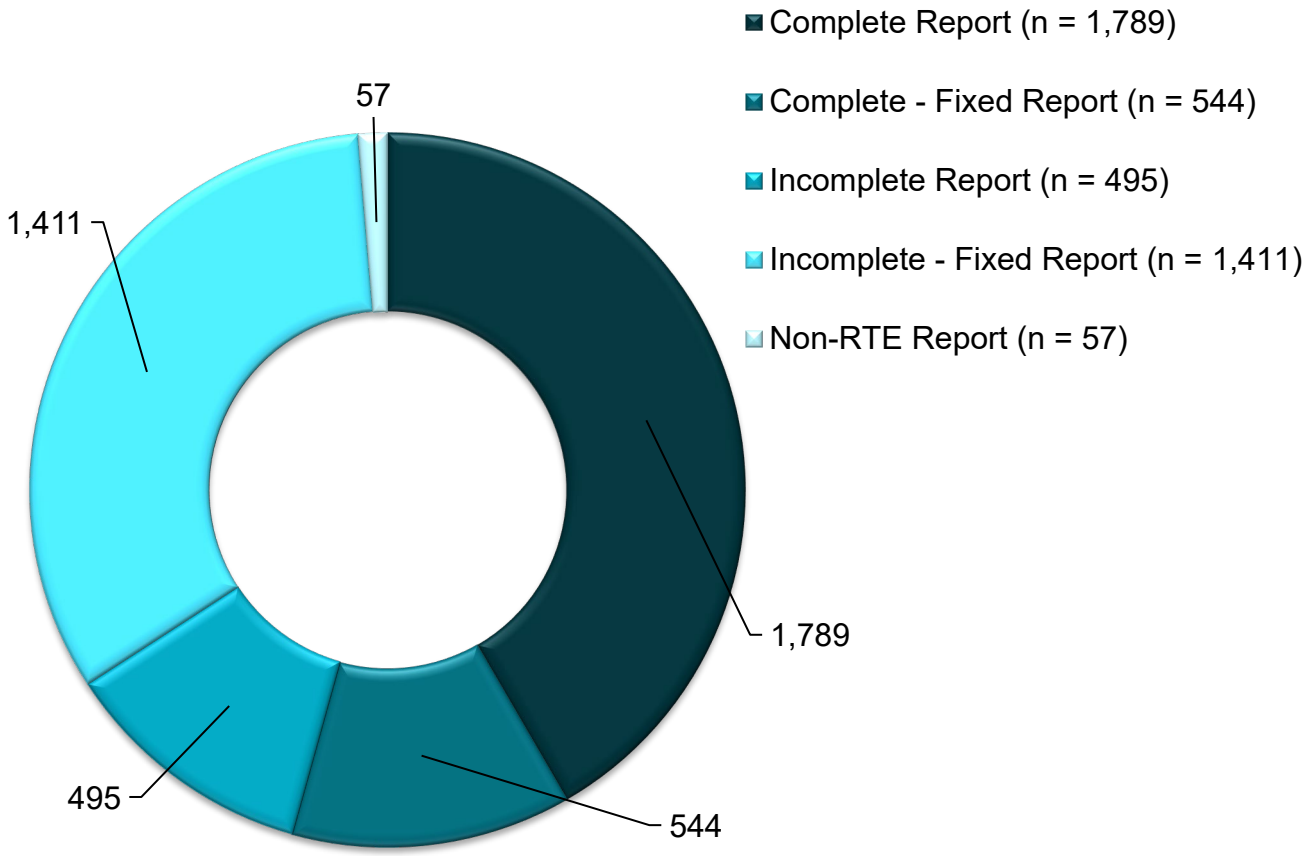
The format of coding for submission is TSRT9/ Level 4/ 13c/ 13l/ MD13hh/ CF1c/ CF2c. This should be included in the opening section of the first open text field of the local incident learning system where possible. English providers using LFPSE, can add this information to the “What is the radiotherapy error code?” 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 2,333 RTE reports classified and coded locally with all the taxonomies, 1,534 were classified as levels 1 to 4. A total of 446 levels 1 to 4 reports were amended (complete fixed in Figure 2 includes level 5 data (n = 544)). Thus, an 70.9% level of consistency was achieved for

levels 1 to 4 RTE. This reflects a decrease since the previous analysis (issue 43) when an 72.8% level of consistency was achieved.

Figure 2. Breakdown of report completeness (n = 4,296)



A total of 1,906 RTE reported did not contain one of the required taxonomies, including MD. A total of 1,411 were classified or coded by UKHSA staff using the supporting text supplied by the local providers (incomplete fixed report in Figure 2).

It is recommended that the entire pathway subcoding should be considered when allocating pathway subcodes. Further information on the consistent allocation of pathway codes can be seen in E-bulletin edition 3.

Non-RTE reports submitted formed 1.3% (n = 57) of all the reports for this reporting period. Data and accompanying text indicate that these were patient safety incidents (PSI) but not RTE. This reflects an increase (0.6%, n = 24) since the previous analysis (issue 43). A PSI 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’ (10). Further information on PSI can be found in issue 5 of Safer Radiotherapy. Non-RTE reports were excluded from the detailed analysis.

Of the incomplete reports, 20 RTE did not contain sufficient supporting text to assign any classification or coding taxonomy, therefore these have not been included in the detailed analysis. This is an increase from 15 in the previous analysis (issue 43).

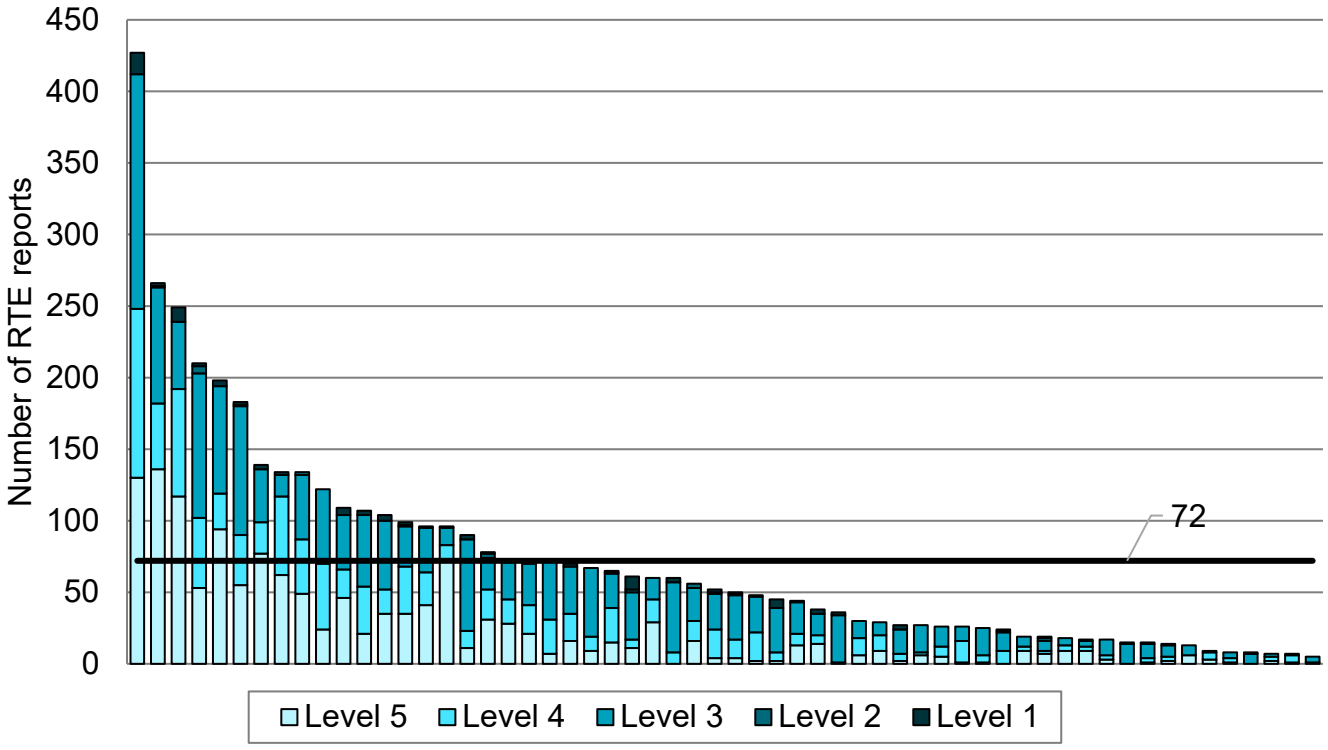
In total, 4,219 RTE for the reporting period from April 2024 to July 2024 were included for analysis. The analysis is presented here.

Number of reports per provider

Data was received from NHS providers and the independent sector. For this reporting period 58 RT providers have submitted reports. This is consistent with the previous analysis (issue 43) (n = 58). There were 431 anonymised reports received which did not indicate the RT provider, these have been included in Figure 3 as a single provider.

Figure 3 shows the number of RTE reports submitted by provider. This ranged from 4 to 431 reports, with a mean of 72. Of the 59 providers who reported, 64.4% (n = 38) reported less than the national mean. Figure 3 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.

Figure 3. Number of RTE reported by provider (n = 4,239)



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 incident learning and local management of RTE survey is published in the September 2024 issue of Safer Radiotherapy E-bulletin. This survey demonstrated that only 89.1% (n = 41) of respondents reported all classification levels of RTE locally. Of those 41 respondents who

reported all levels of RTE locally only 29.3% (n = 12) shared all levels of RTE with their trust/board risk management team, however 48.8% (n = 20) shared nationally for inclusion in the national database. The time required for applying coding was given as an explanation for not reporting level 4 and 5 reports.

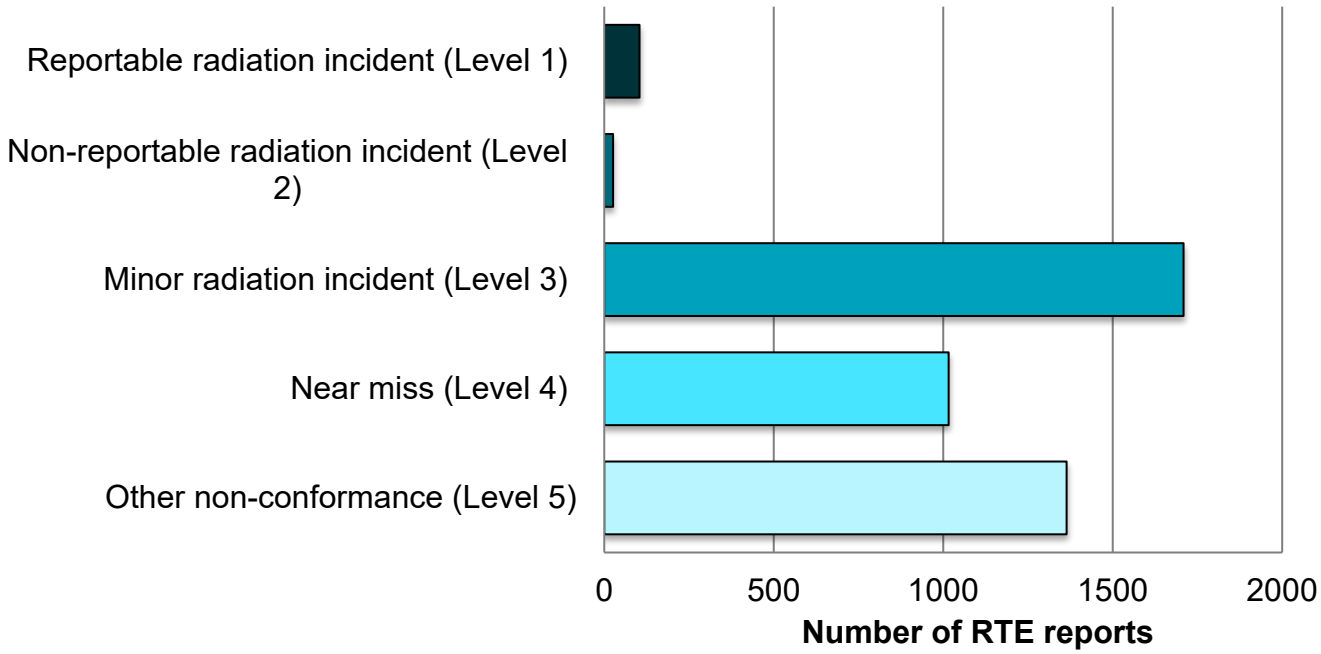
The number of reports per provider has not been normalised to account for the variation in provider capacity or service specification. It should be noted that those providers reporting higher numbers of RTE represent providers with mature reporting cultures and should be encouraged to continue reporting.

Classification (level) of RTE

Each of the 4,219 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 4).

Of the RTE reports, 96.9% (n = 4,089) were minor radiation incident, near miss or other non-conformities (levels 3 to 5) with little or no impact on patient outcome. Of the remaining 3.1% (n = 130) of reports, 2.5% (n = 104) were reportable under IR(ME)R to the appropriate enforcing authority (level 1).

Figure 4. Classification (level) of RTE reports (n = 4,219)

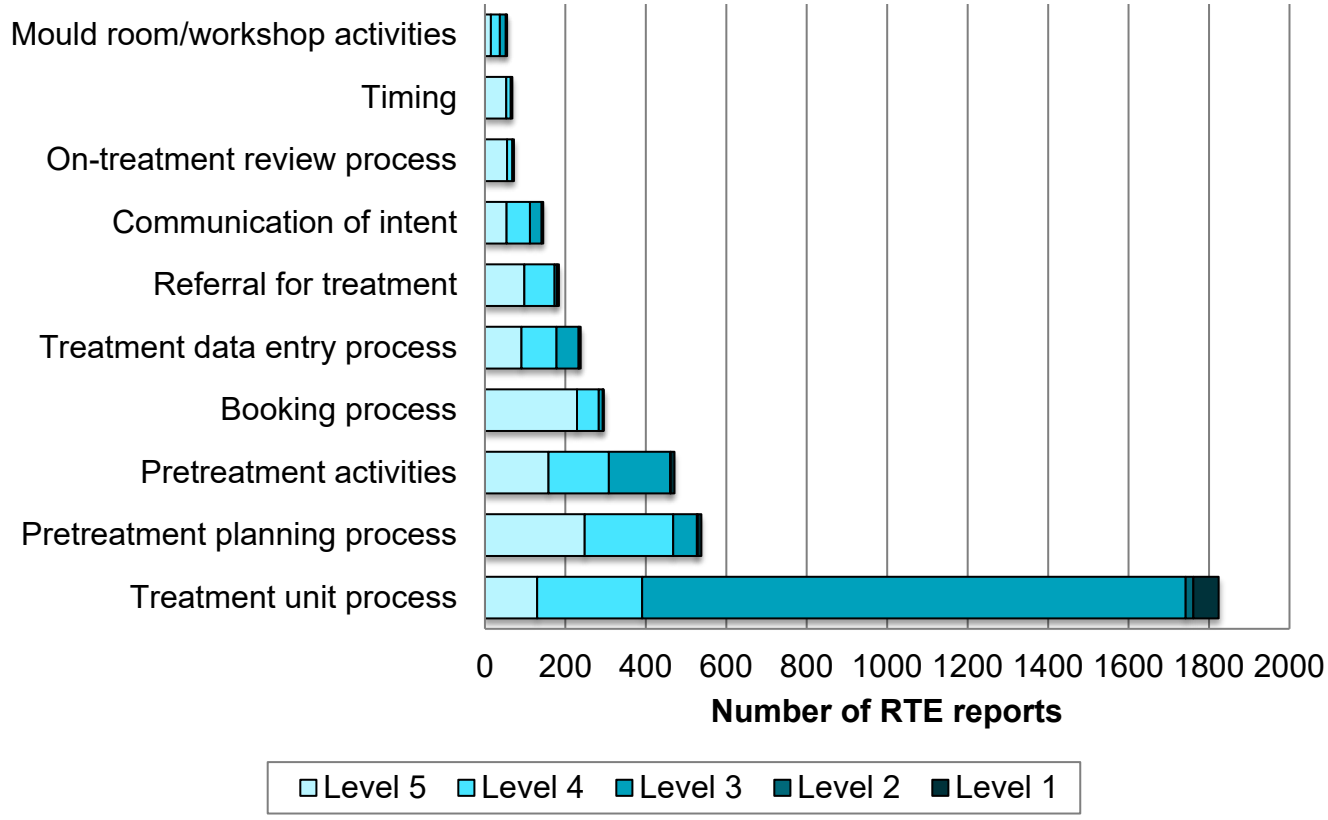


Breakdown of process codes

The 4,219 RTE reports were categorised by process code and classification level so the main themes could be derived. Figure 5 shows 43.2% (n = 1,824) of the RTE were reported to have occurred during treatment unit processes. The treatment set-up 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 the high prevalence of RTE within treatment unit processes. The most frequently reported process codes remain consistent with the previous analysis (issue 43), with the addition of 'mould room/workshop activities'.

Figure 5. Breakdown of RTE process code by level (n = 3,890/4,219 subset of RTE)



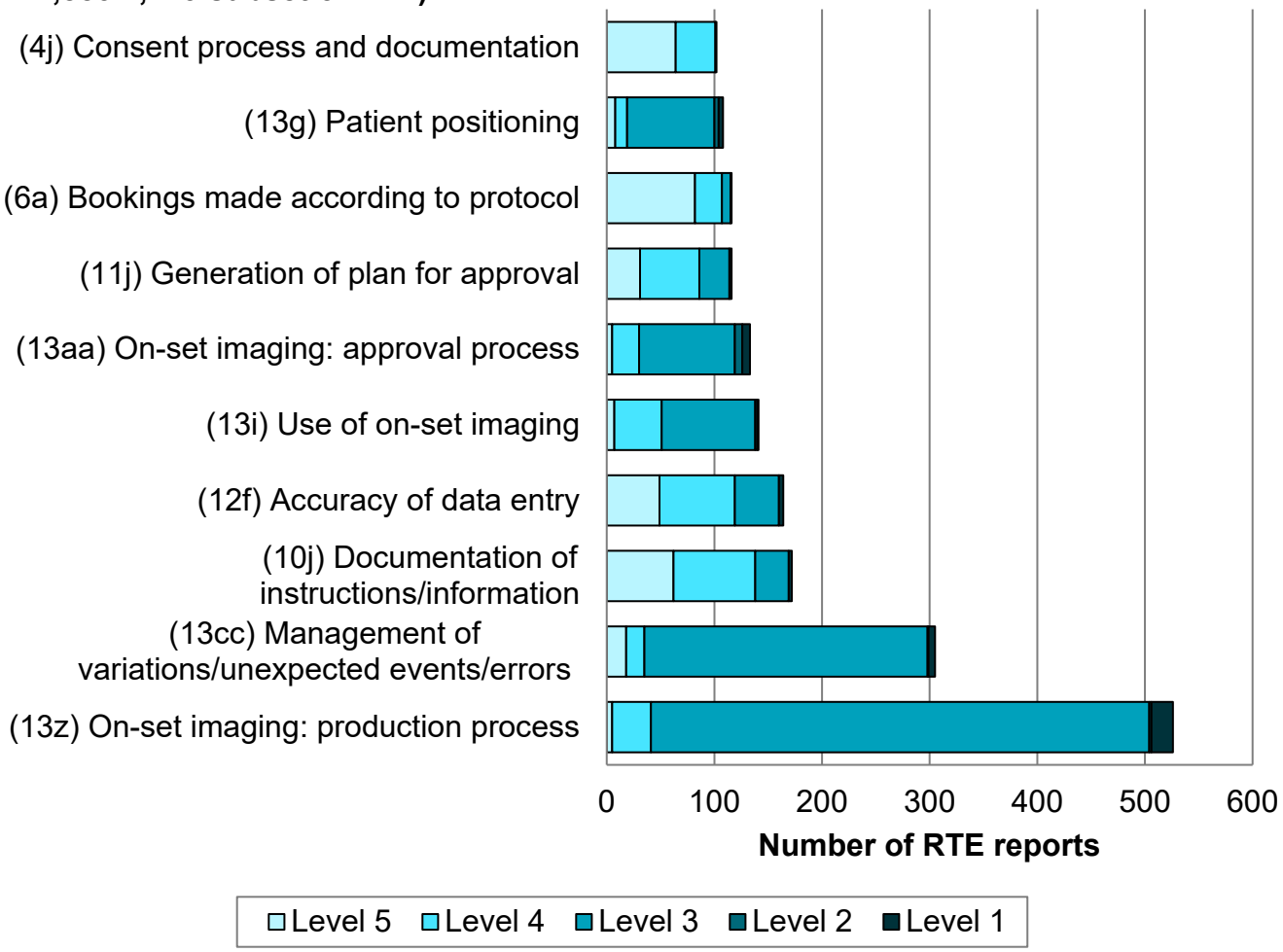
Breakdown of process subcodes

The most frequently reported process subcodes in the RT pathway are presented in Figure 6. This subset of data was also broken down by level.

The most frequently reported RTE was 'on-set imaging: production process' at 12.5% (n = 526) of all the reports. This is consistent with the previous analysis, issue 43 (13.0%, n = 512) (p = 0.50). Of this subset, 95.8% (n = 504) 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 or errors' at 7.2% (n = 305). The most frequently reported process subcodes during the current review period are similar to the previous analysis (issue 43), with the addition of 'consent process and documentation'. When compared to the previous analysis (issue 43) the prevalence of RTE associated with 'use of on-set imaging' has increased from 2.7% (n = 107) to 3.3% (n = 141) within the current reporting period.

Three of the most frequently reported RTE process subcodes shown in Figure 6 relate to on-set imaging; ‘on-set imaging: production process’, ‘on-set imaging: approval process’, and ‘use of on-set imaging’. These combined made up 19.0% (n = 800) 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.

Figure 6. Breakdown of most frequently reported RTE process subcodes by level (n = 1,883/4,219 subset of RTE)



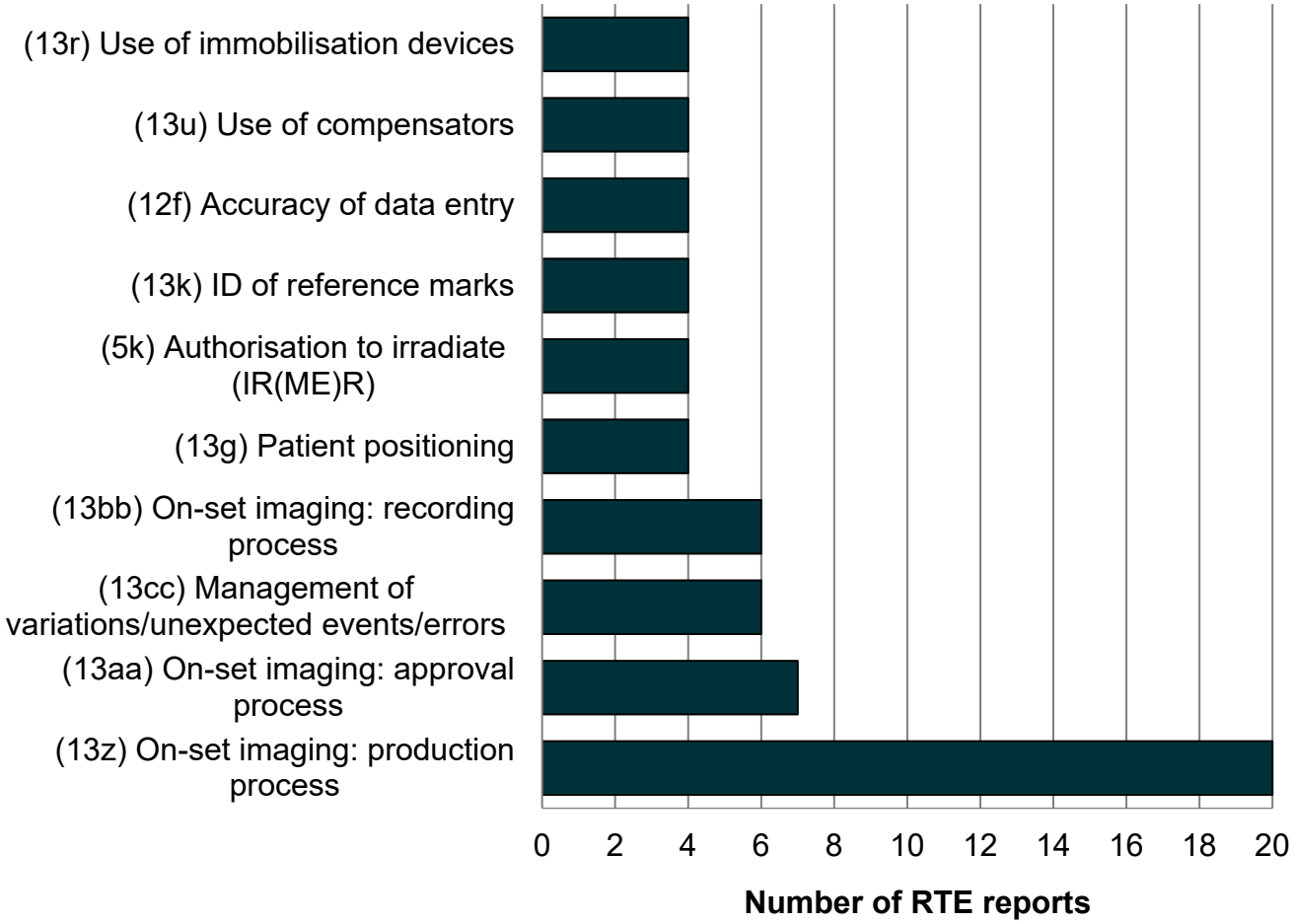
Reportable radiation incident (level 1) RTE

Reportable radiation incidents (level 1), as defined in TSRT fall into the category of reportable under IR(ME)R (3 to 6), in accordance with SAUE guidance. These incidents will generally be significant, although they may be correctable within the course of treatment. The majority of these incident reports relate to a single treatment exposure or multiple verification imaging exposures. As a result, corrective action may be applied to the remaining treatment fractions where required, so the incident does not have a significant impact on the patient or the outcome of their treatment.

There were 104 level 1 incidents submitted by 36 providers to the voluntary system for this reporting period, comprising 2.5% of all RTE (Figure 4). This reflects a statistically significant increase in proportion since the previous analysis, issue 43 (1.4%, n = 55) (p = <0.001). The

most frequently reported level 1 reports are shown in Figure 7. 'On-set imaging: production process' comprised of 13.4% (n = 20) of reports and was the most frequently reported level 1 event. 'On-set imaging: production process' was also the most frequently reported event within 6 of the last 7 previous analysis (issues 37 to 43), comprising 20.3% (n = 82 out of 403) of all level 1 incidents reported. An example of an 'on-set imaging: production process' reportable RTE is when verification images are repeated multiple times due to set-up error and/or hardware or software failure. Further information on radiotherapy verification imaging IR(ME)R notification criteria may be found within the SAUE guidance. Practical advice on reducing this type of event can be seen in case study 14, case study 2 in issue 32, the good practice guidance series and the biennial report.

Figure 7. Breakdown of most frequently reported level 1 RTE by process subcode (n = 63/104 subset of RTE)



'On-set imaging: approval process' comprised of 6.7% (n = 7) of all level 1 incidents. An example of 'on-set imaging: approval process' level 1 incident is when a mismatch of vertebral levels imaging leads to a geographical miss. Further guidance on reducing these types of events can be seen in the good practice guidance series.

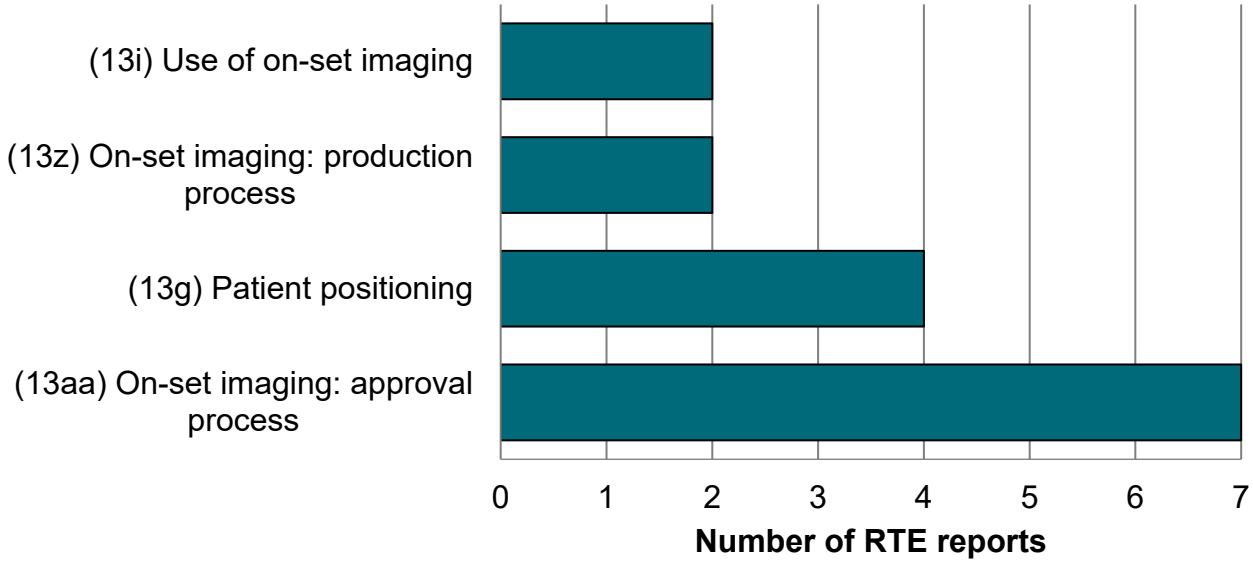
'Authorisation to irradiate (IR(ME)R)' comprised of 3.8% (n = 4) of all level 1 incidents. This may be an emerging theme, as it has not featured within the most frequently reported level 1 incidents within the previous analysis (issue 43) or the biennial report (report number 8). An

example of an ‘authorisation to irradiate (IR(ME)R)’ reportable RTE is when justification has not been evidenced prior to the planning or verification imaging exposure. This may be due to a change in the patient’s condition and subsequent treatment management or may occur in situations where the IR(ME)R operator cannot authorise the verification imaging exposure in accordance with authorisation guidelines and justification by the IR(ME)R practitioner has not been sought prior to exposure. A review of local processes to ensure they are achievable, effective, timely and reflective of current practice is recommended. This may mitigate the risk of similar events occurring.

Non-reportable radiation incident (level 2) RTE

A non-reportable radiation incident (level 2) is defined within TSRT as a radiation incident which is not reportable, but of potential clinical significance. Non-reportable radiation incidents comprised 0.6% (n = 26) of the RTE reported for this time period (Figure 4). This reflects a slight decrease since the previous analysis, issue 43 (0.7%, n = 28) (p = 0.57). Further analysis indicates the points in the pathway at which non-reportable radiation incidents initially occurred (Figure 8).

Figure 8. Breakdown of most frequently reported level 2 RTE by process subcode (n = 15/26 subset of RTE)

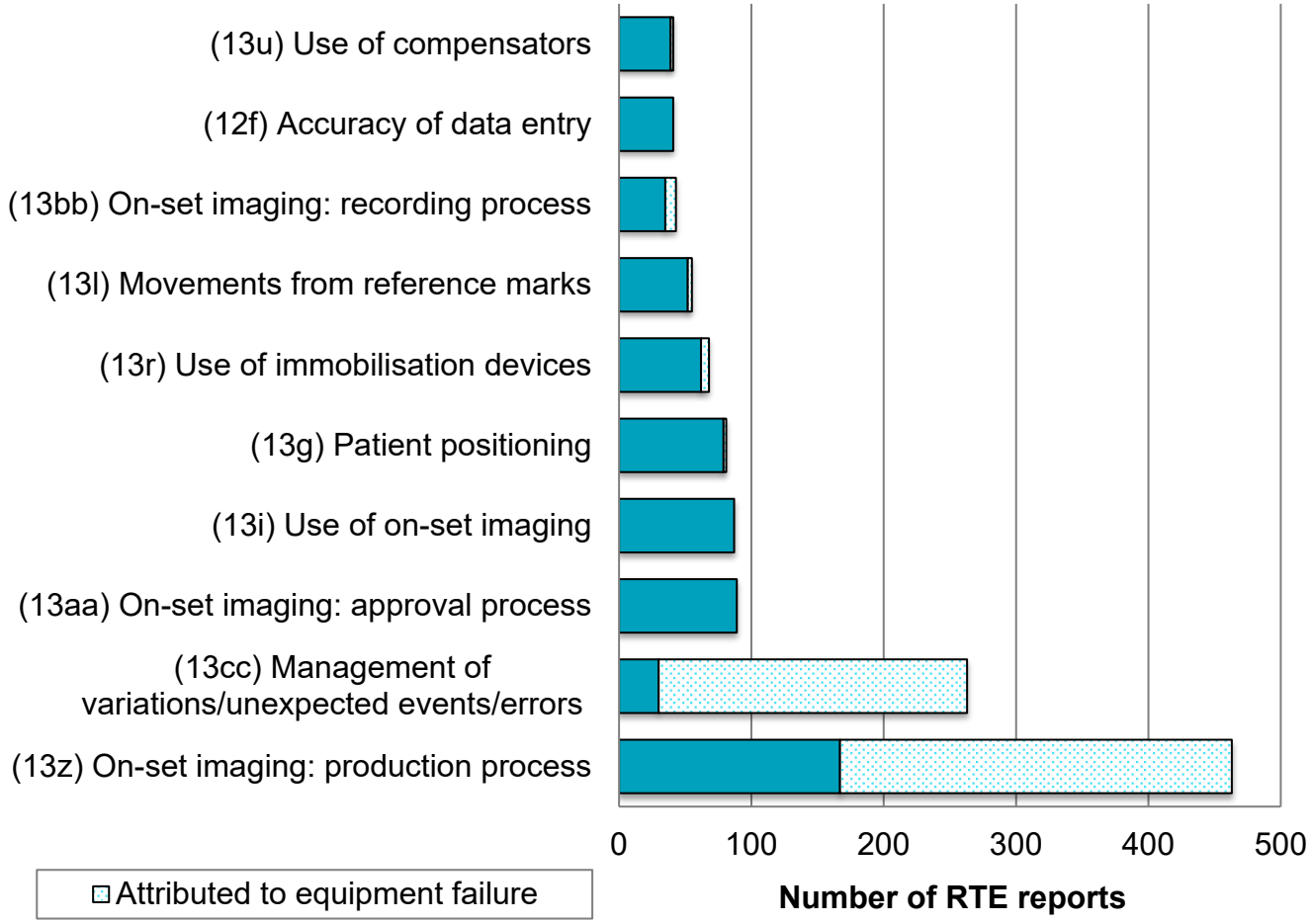


The 26 reports were spread across 15 different subcodes, 11 of which were singular and are not shown within Figure 8. ‘On-set imaging: approval process’ comprised of 26.9% (n = 7) of all non-reportable radiation incident reports. An example of ‘on-set imaging: approval process’ is the incorrect review of an on-set verification image which leads to a partial geographical miss which is non reportable. ‘Patient positioning’ was the second most frequently reported level 2 RTE comprising 15.4% (n = 4) of all non-reportable radiation incidents. Examples of this includes when the patient is positioned incorrectly leading to a partial geographical miss which is non reportable.

Minor radiation incident (level 3) RTE

A minor radiation incident (level 3) is defined within TSRT as a radiation incident in the technical sense, but of no potential or actual clinical significance. Minor radiation incidents comprised 40.5% (n = 1,709) of the RTE reported for this reporting period (Figure 4). This is similar to the previous analysis (issue 43) (39.0%, n = 1,535) (p = 0.17). 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 = 1231/1709 subset of RTE) includes equipment failure related



'On-set imaging: production process' was the most frequently reported event (27.1%, n = 463) within this subset. This is similar to the previous analysis (issue 43) (30.2%, n = 463). 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 63.9% (n = 296) 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 within case study 14.

'Management of variations, unexpected events or errors' made up 15.4% (n = 263) of all minor radiation incidents, of these 88.6% (n = 233) were attributed 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 unseen pathway.

There is 1 addition to the most frequently reported process subcodes within the minor radiation incidents (level 3) RTE when compared to the previous analysis (issue 43); 'use of compensators'. 'Use of compensators' is also a new addition within the reportable radiation incidents (level 1), as illustrated within Figure 7. Examples of this type of event includes the incorrect placement or omission of bolus during patient set-up, or the movement of bolus during treatment delivery.

Near miss (level 4) RTE

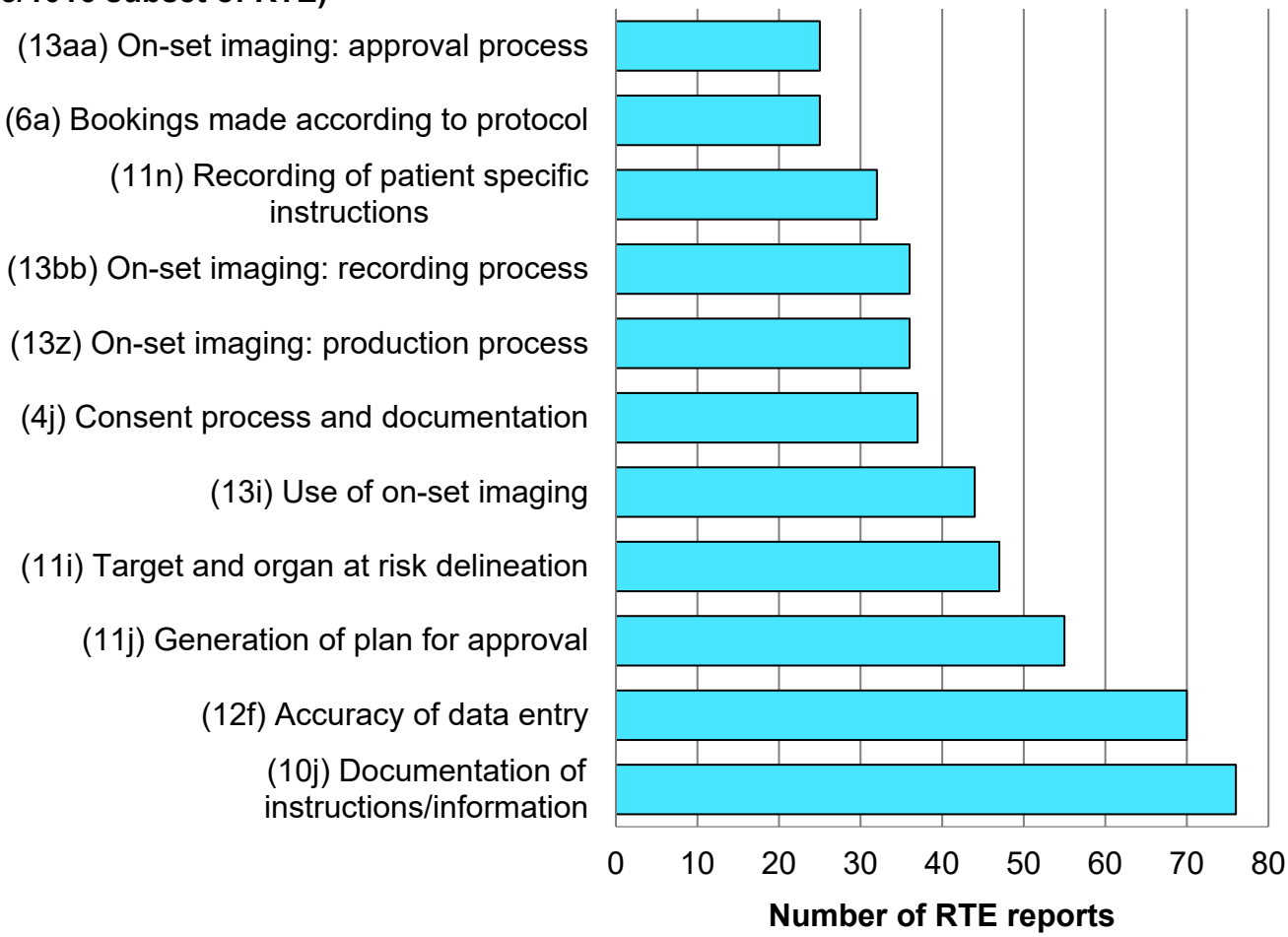
A near miss (level 4) is defined within TSRT as a potential radiation incident that was detected and prevented before treatment delivery.

Near misses comprised 24.1% (n = 1,016) of the RTE reported (Figure 4). This reflects a slight decrease in proportion in comparison to the previous analysis, issue 43 (25.8%, n = 1,016) (p = 0.08). Figure 10 shows the most frequently reported process subcodes for level 4 RTE.

'Documentation of instructions or information' comprised 7.5% (n = 76) of level 4 RTE. An example of this type of RTE would be incorrect documentation of patient positioning during CT planning which is detected and corrected at time of patient positioning at the treatment unit.

There is one addition to the most frequently reported process subcodes within the near miss (level 4) RTE when compared to the previous analysis (issue 43); 'consent process and documentation'. Examples of this type of event includes the omission of documented consent which is identified during the assessment of the patient prior to their first treatment.

Figure 10. Breakdown of most frequently reported level 4 RTE by process subcode (n = 483/1016 subset of RTE)



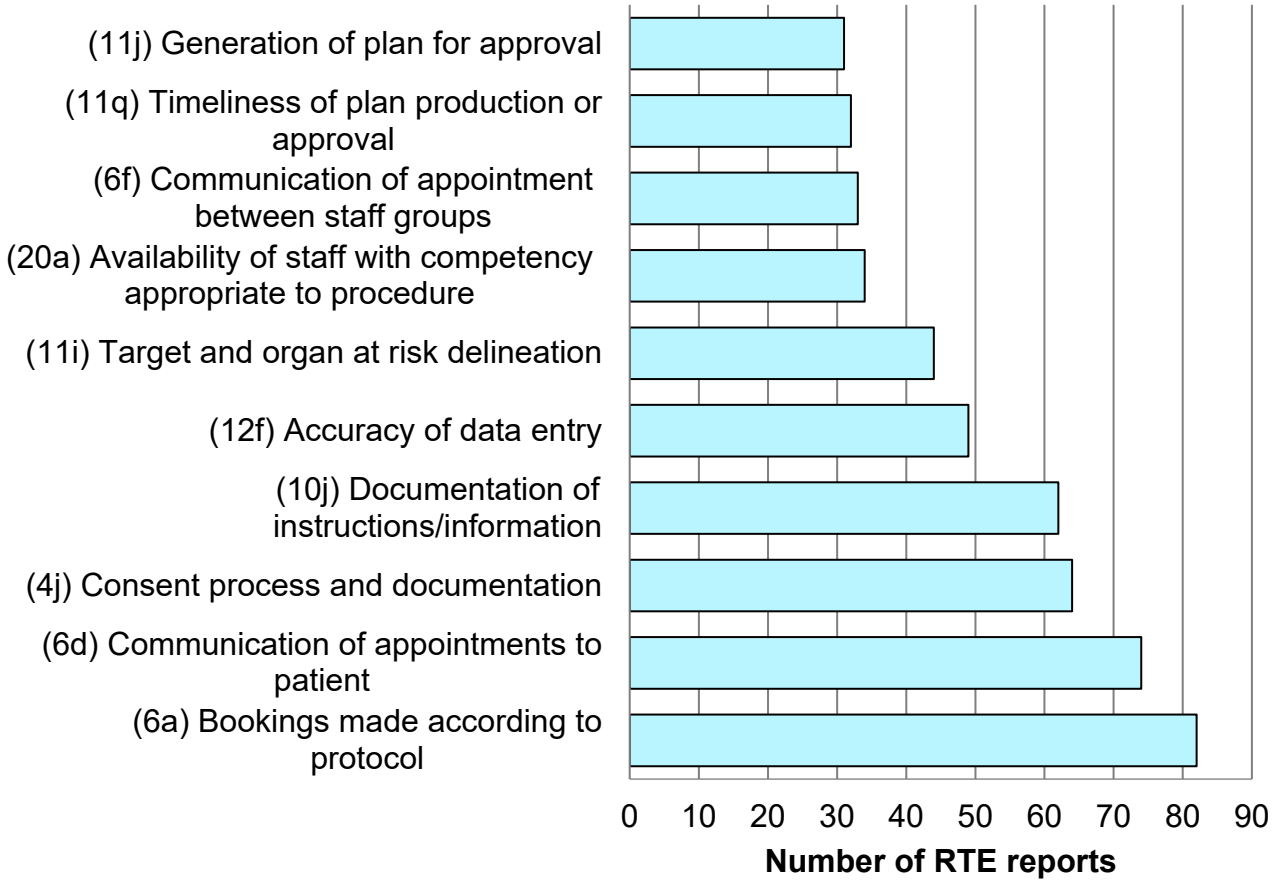
Similar to the minor radiation incidents (level 3), the most frequently reported level 4 RTE shown in Figure 10, includes the pathway subcodes associated with on-set imaging (13.9%, n = 141). Example of ‘on-set imaging: production process’ associated near miss may include a verification image not reconstructed 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.

Other non-conformance (level 5) RTE

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

Level 5 RTE comprised 32.3% (n = 1,364) of all RTE reported for this period (Figure 4). This reflects a statistically insignificant increase in the proportion of non-conformance reports in comparison to the previous analysis, issue 43 (33.1%, n = 1,304), (p = 0.44).

Figure 11. Breakdown of most frequently reported level 5 RTE by process subcode (n = 505/1,364 subset of RTE)



The most frequently reported level 5 process subcodes were ‘bookings made according to protocol’ comprising 6.0% (n = 82) of all level 5 RTE (Figure 11). This has decreased slightly since the previous analysis (issue 43) when bookings made according to protocol made up 7.1% (n = 92) of all level 5 RTE. 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 and do not affect patient treatment. ‘Communication of appointments to patient’ is the second most frequently reported pathway subcode within the other non-conformances (5.4%, n = 74). This has decreased since the previous analysis (issue 43) when ‘communication of appointments to patient’ made up 6.7% (n = 87) of all other non-conformances. An example of this type of RTE includes when appointments are amended during treatment, however the patient is not informed. The booking process includes 6 different process subcodes, which were reported in 16.8% (n = 229) of level 5 RTE.

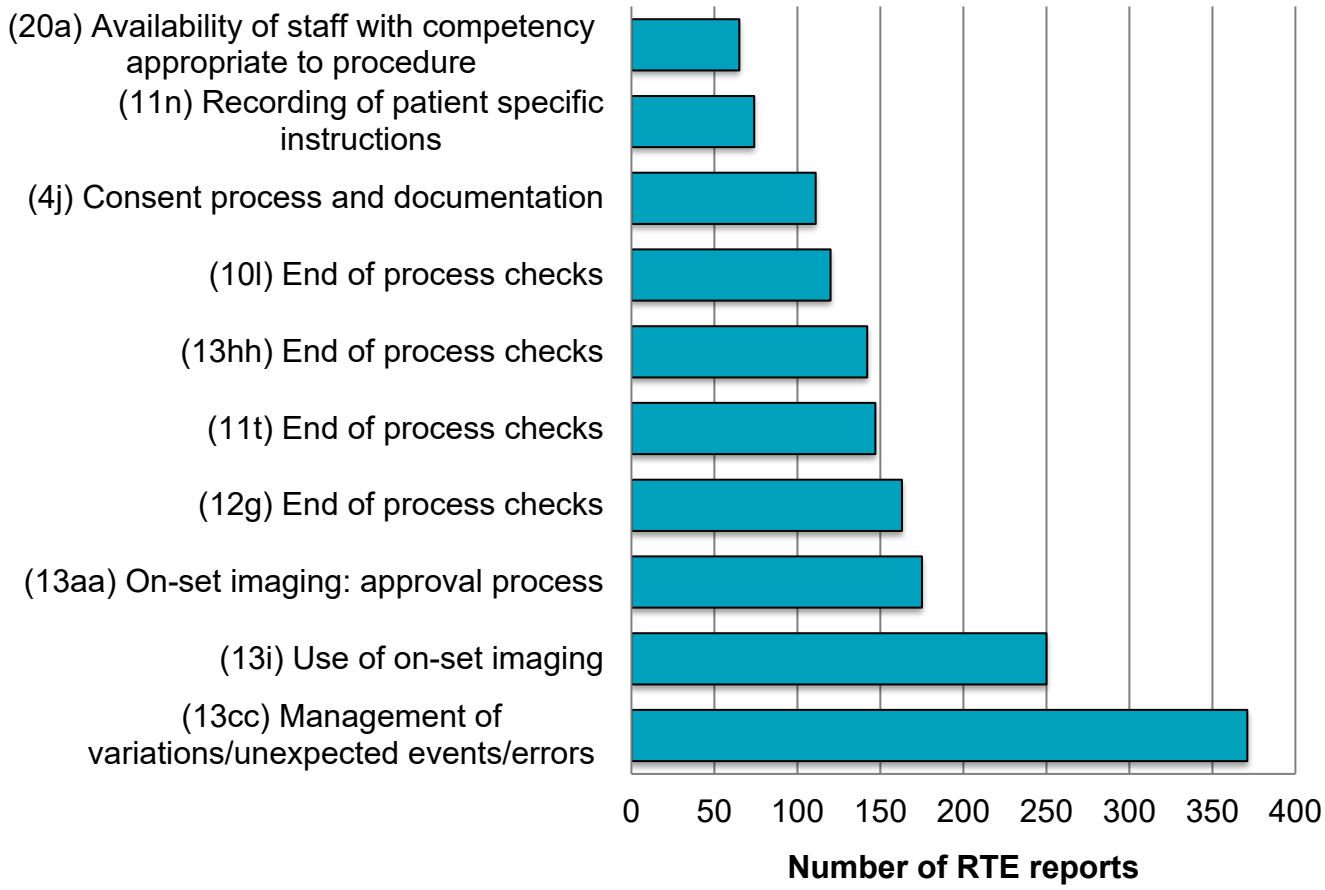
Treatment process subcodes were not included in the most frequently reported level 5 RTE (Figure 11). There has been 2 new additions to the most frequently reported process subcodes within the other non-conformance (level 5) RTE when compared to the previous analysis (issue 43); ‘availability of staff with competency appropriate to procedure’ and ‘communication of appointment between staff groups’.

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 (11). SB embedded in the pathway coding (12) 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 2,568 failed safety barriers (FSB) were identified from the RTE reported (Figure 12).

Treatment unit processes were attributed to 42.7% (n = 1096) of all FSB. The most frequently reported FSB are represented in Figure 12. Treatment unit processes 'management of variations, unexpected events or errors' was the most frequently reported FSB (14.4%, n = 371). 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 12. Breakdown of failed safety barriers (n = 1,618/2,568 subset of RTE data)



All but one of the FSB were also seen in the previous analysis (issue 43), 'availability of staff with competency appropriate to procedure' was the addition to the most frequent FSB for this reporting period.

'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 22.5% (n = 579) of all FSB. The PSRT provided further information on the use of end of process checks in the January (issue 6) and September (issue 7) 2022 issues of Safer Radiotherapy E-bulletin.

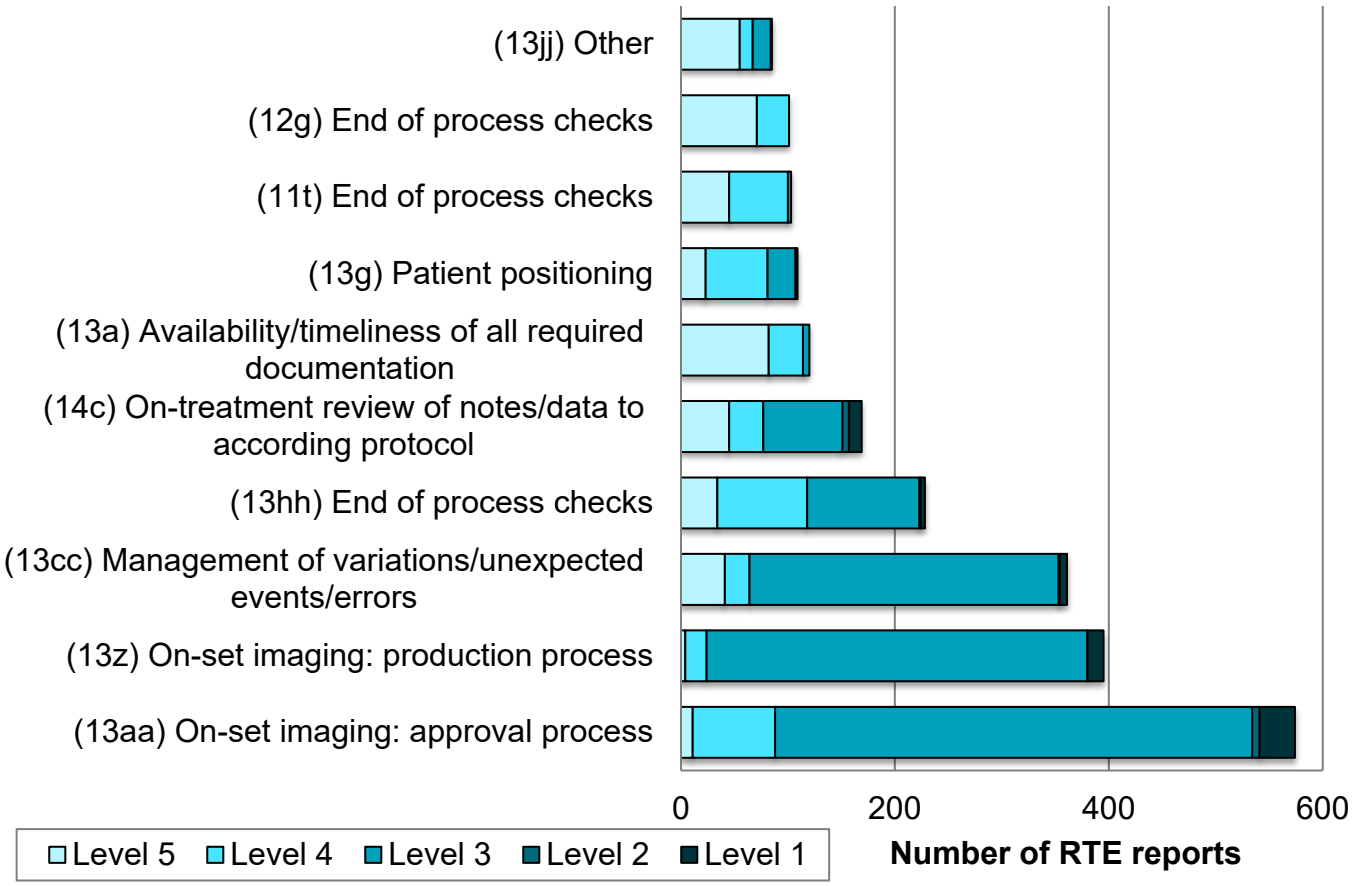
Method of detection

A method of detection (MD) is the process that identified the error and can be coded using the entire pathway taxonomy. A total of 3,829 MD were identified from the RTE reported. The most frequently reported MD can be seen in Figure 13.

There has been a decrease in the number of providers including the MD taxonomy within reports, from 50 providers during the previous analysis (issue 43), to 47 providers during the current review period.

The most frequently reported MD was 'on-set imaging: approval process' (15.0%, n = 574). This MD was most frequently reported with a primary process code 'on-set imaging: production process' (20.7%, n = 119). Seven of the most frequently reported MD occurred at the treatment unit process.

Figure 13. Breakdown of method of detection by level (n = 2,245/3,829 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 12.6% (n = 484) of all MD, of which 69.0% (n = 334) 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. 'Other' pathway subcodes attribute 5% (n = 216) of assigned MD. It is recommended the entire pathway coding should be considered when assigning a MD as described in the January 2022 issue of Safer Radiotherapy E-bulletin.

Contributory factors

Including contributory factors (CF) within a RTE taxonomy enables identification of system problems that could precipitate a range of different incidents (13).

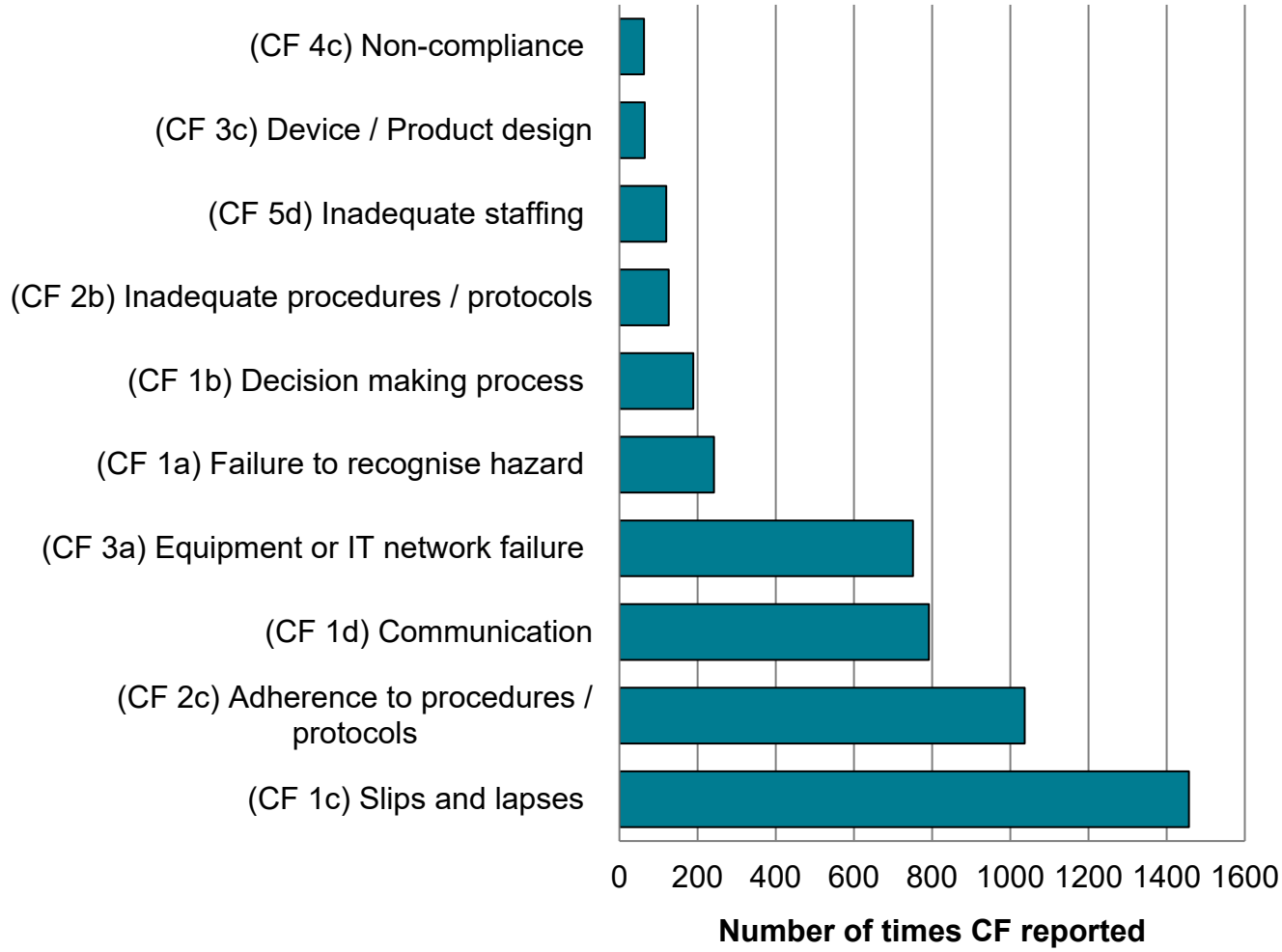
From the 4,219 RTE reported, 76.5% (n = 3,229) included CF coding. These were reported from 53 providers. This reflects a slight decrease in the total frequency of CF coding reported since the previous analysis (issue 43), when 53 providers included CF coding in 3,273 of RTE reports (83.1%).

Multiple CF codes can be assigned to a single RTE. Following UKHSA analysis a total of 5,187 CF codes were assigned to the 4,219 RTE. A total of 4,116 reports contained at least one CF code with 21.9% (n = 901) of these reports containing multiple CF codes.

The most frequently occurring CF codes are illustrated within Figure 14. The most frequently reported CF was 'slips and lapses' making up 30.1% (n = 1,457) of all CF reported (Figure 14). Issue 22 of Safer Radiotherapy includes guidance on minimising the occurrence of RTE which may be attributed to a slip or lapse of an individual.

There are 2 differences to the most frequently reported CF when compared to the previous analysis (issue 43); 'device / product design' and 'non-compliance'. The increasing application of 'device / product design' may in part be due to the implementation of system-based approaches to incident investigations, such as the Systems Engineering Initiative for Patient Safety (SEIPS) framework. SEIPS is a framework for understanding how interactions between work systems, environments and people can influence processes and shape outcomes (14 to 15). An enhanced awareness of tools and technologies as an element within a system, may attribute to the increased application of 'device / product design' as a contributory factor.

Figure 14. Breakdown of most frequently reported CF (n = 4,842/5,187 subset of data)

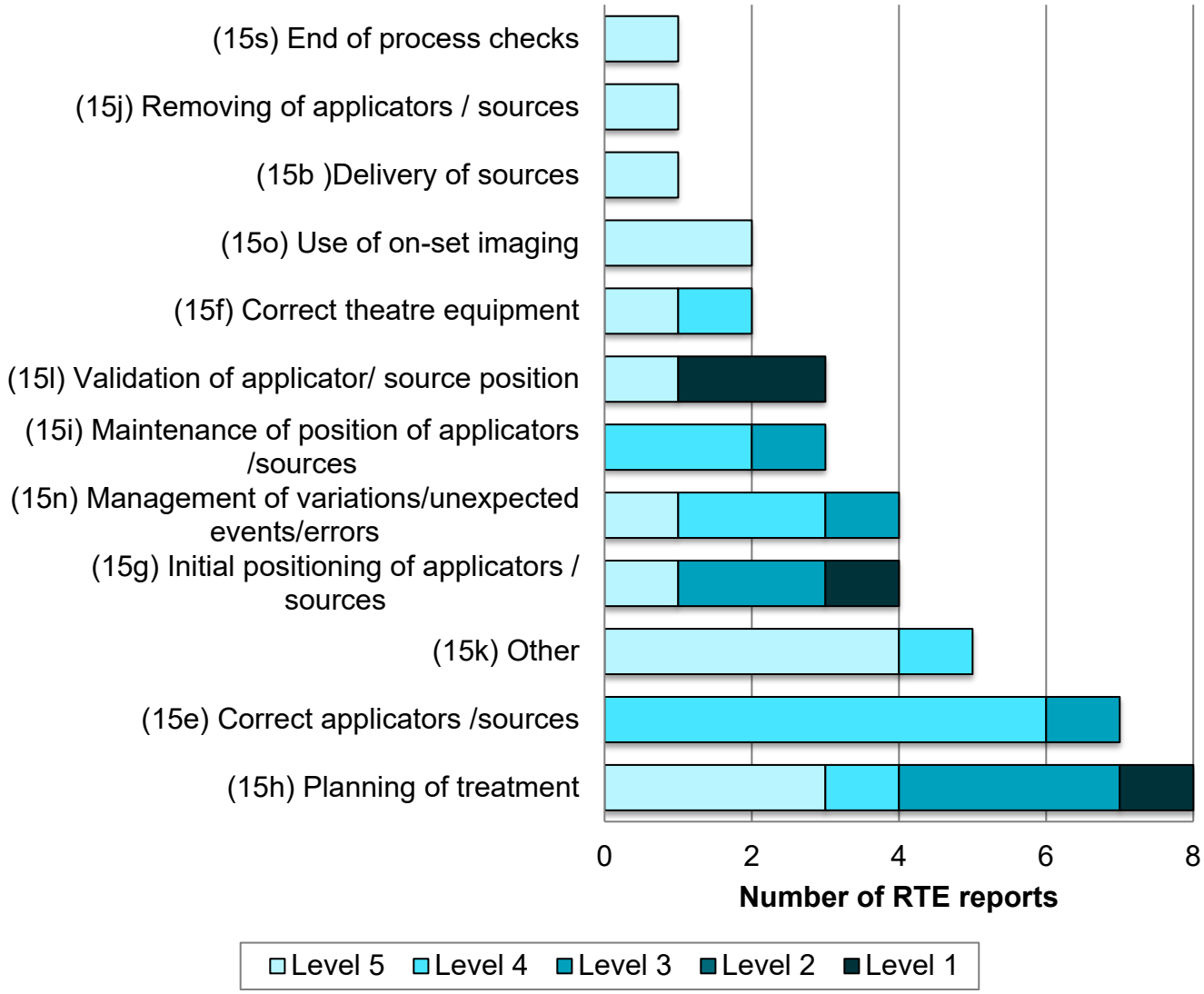


Brachytherapy RTE

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 (16). 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 learning resource.

RTE coded with BRT process subcodes as the primary code accounted for 1.0% (n = 41) of reports, reflecting an increase from the previous analysis, issue 43 (0.6%, n = 22). Providers reporting BRT RTE has also decreased from 14 within the previous analysis to 12 for this reporting period. A breakdown of the BRT RTE can be seen in Figure 15.

Figure 15. Breakdown of most frequently reported BRT RTE coded '15' by level (n = 41)



The most frequently reported BRT process subcode was 'planning of treatment' comprising 19.5% (n = 8) of all BRT RTE. This reflects an increase from the previous analysis, issue 43, where 9.1% (n = 2) of all BRT RTE were attributed to 'planning of treatment'.

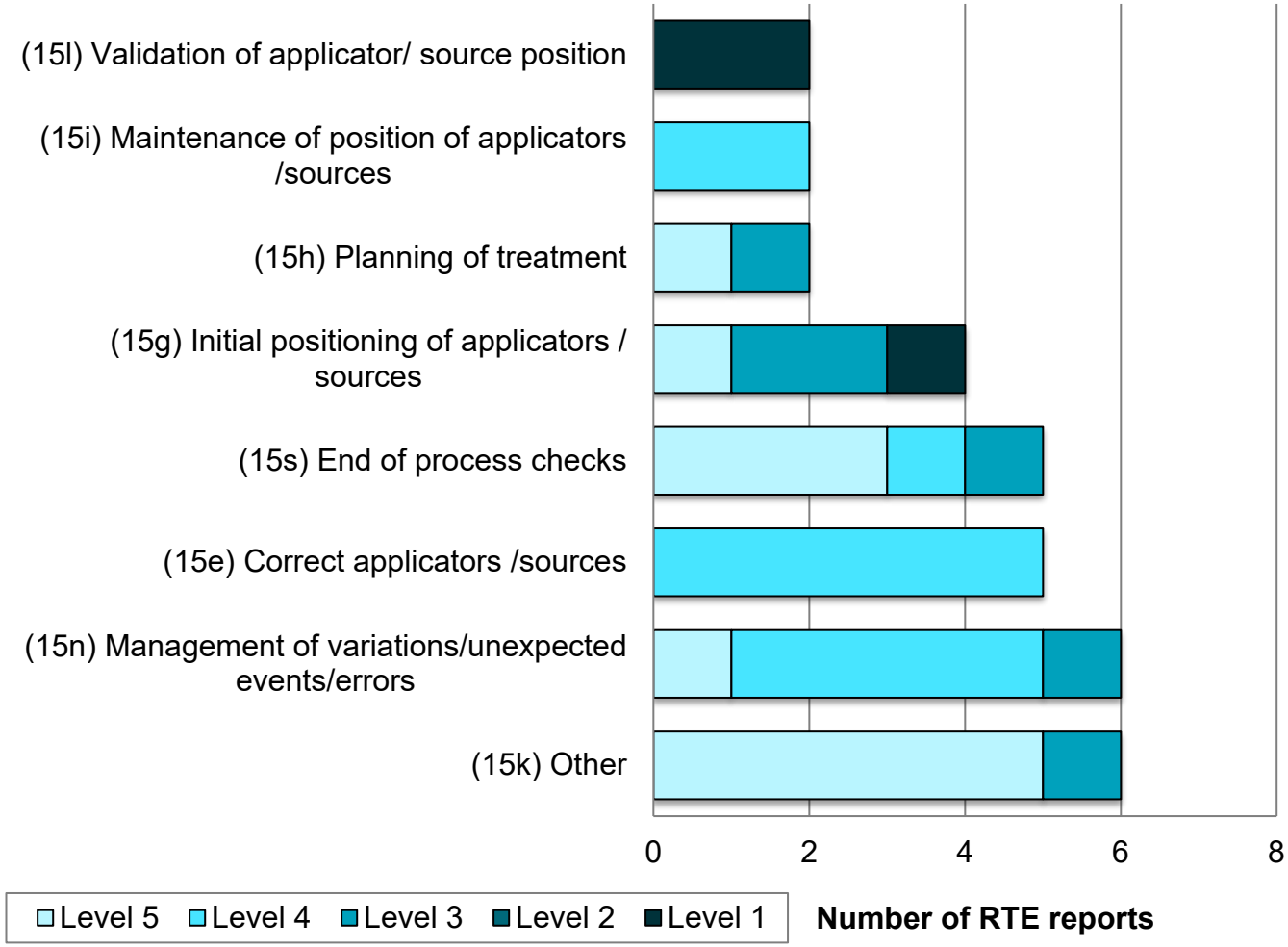
During the current review period 9.8% (n = 4) BRT RTE were classified as reportable radiation incidents (level 1), reflecting an increase from the previous analysis, issue 43 (4.5%, n = 1). The most frequently reported level 1 BRT RTE may be attributed to 'validation of applicator / source position' (4.9%, n = 2). An example of this type of BRT level 1 RTE may include the identification of the incorrect applicator or source position and subsequent utilisation for treatment delivery.

From the 41 BRT RTE, there were 46 subcodes reported. Of these, 21 were FSB, the most frequently reported was 'correct applicators / sources' comprising 33.3% (n = 7).

Seven of the 12 providers who submitted BRT RTE reports provided a MD subcode. Following UKHSA consistency checking a MD subcode was assigned to each of the 41 BRT RTE reported. The most frequently reported BRT MD are illustrated in Figure 16. The 2 most

frequently reported MD included ‘management of variations, unexpected events or errors’ and ‘other’, with both accounting for 14.6% (n = 6) of MD subcodes reported.

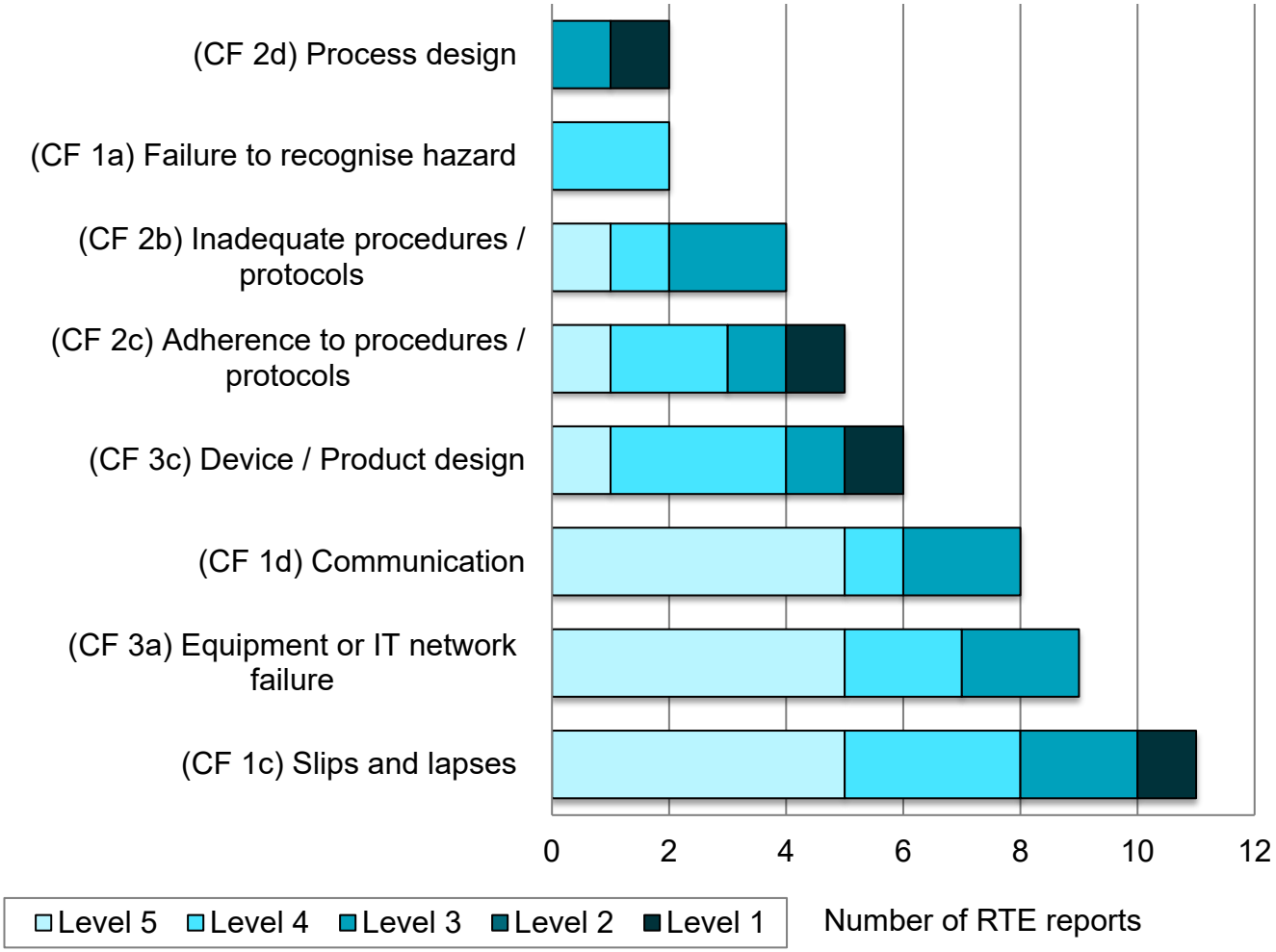
Figure 16. Breakdown of BRT method of detection by level (n = 32/41 subset of RTE)



All CF codes were reviewed within this subset of the data and 52 CF identified (Figure 17). The most frequently reported CF associated with BRT RTE was ‘slips and lapses’ comprising of 21.2% (n = 11) 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, which may be indicative of differences in the equipment, skill mix and workflow between areas.

Figure 17. Breakdown of BRT RTE CF by level (n = 47/52 subset of data)



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