

# **Safer Radiotherapy**

# Triannual RTE analysis and learning report

Issue 43: full radiotherapy error data analysis, December 2023 to March 2024

### Contents

Full radiotherapy error data analysis	3
Inspectorate data	4
Case study 13: Target and organ at risk delineation (11i)	5
December 2023 to March 2024 data analysis	9
Number of RTE reports	9
Monitoring of RTE coding by radiotherapy providers	9
Number of reports per provider	11
Classification (level) of RTE	12
Breakdown of process codes	13
Breakdown of process subcodes	14
Reportable radiation incident (level 1) RTE	15
Non-reportable radiation incident (level 2) RTE	17
Minor radiation incident (level 3) RTE	17
Near miss (level 4) RTE	19
Other non-conformance (level 5) RTE	20
Failed safety barriers	21
Method of detection	22
Contributory factors	23
Brachytherapy RTE	24
References	28
About the UK Health Security Agency	29

#### Full radiotherapy error data analysis

Incident learning systems are a widely accepted safety tool advocated internationally by professional groups, bodies, agencies, and regulators in radiotherapy (1). Analysis of reported data allows weaknesses in operational systems to be identified and inform the direction of future refinements and improvements. It is imperative errors and near misses are learned from, and effective preventative measures are implemented ( $\underline{2}$ ).

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 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 continues to 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) (<u>3 to 5</u>) inspectorates of significant accidental or unintended exposures (<u>SAUE</u>) or 'reportable radiation incidents' (Level 1) as defined in <u>Towards Safer Radiotherapy</u> (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 <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. As IR(ME)R (3 to 5) 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 82 anonymised closed synopses of reported SAUE for analysis. This is a marked increase since the <u>previous analysis</u> (issue 42) when 42 reports were shared. However, 81 reports were shared between December 2022 and March 2023 (issue 40).

The most frequently reported notifications were associated with 'on-set imaging: production process' (17.1%, n = 14). This also reflects a marked increase since the <u>previous analysis</u> (issue 42) where 6 reports (14.3%) 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 = 40/82 subset of data)



# Case study 13: Target and organ at risk delineation (11i)

The pretreatment planning process pathway subcode (11i) 'target and organ at risk delineation' has increased from 2.2% of all RTE reported in 2019 to 2.7% in 2023, there was a borderline statistically significant increasing trend with year (p = 0.05). This increase may, in part, be due to the increased use of peer review to detect inaccuracies in contouring or the increased complexities of structure set outlining.

The pathway subcode is indicated in incidents when target and organ at risk (OAR) delineation is incorrectly carried out. This can include the omission of an outline, the incorrect placement of an outline or the incorrect growing of volumes. This includes outlining during adaptive planning. The incorrect outlining of the target or OAR can affect the planning process and if undetected can lead to incorrect patient treatment.

These types of incidents can be detected before reaching the treatment unit, during the peer review process ('target and organ at risk delineation' (11i)), verification ('verification of plan' (11i)) or approval ('generation of plan for approval' (11j)) processes, as well as the 'end of process checks' during both the pretreatment planning process (11t) and the data entry process (12g). If these RTE are not detected during these checking processes, they can affect patient treatment.

#### Synopsis

Patient receiving 60Gy/8# lung stereotactic ablative radiotherapy (SABR) treatment. During the outlining process an extra 5mm added to internal target volume (ITV) in error resulting in a larger target with extra 5mm margin.

Clinician A marked up the ITV in the morning. A peer review check of the target volume was performed in the afternoon in the MDT meeting. Clinician B thought the ITV was large but did not query the mark up and approved the contours.

The individual who completed the planning check also noted the target contour seemed slightly generous but noted a 4DCT review comment about artefacts.

On day 1 of treatment, the treatment radiographers noted that ITV looked generous during onset verification imaging. The ITV was queried with the planning team in attendance, it was advised that this is sometimes the case when viewing the ITV contour on 4DCT image.

Planning team in attendance during fraction 2 reviewed the breathing trace following exposure. At this point the planning team investigated the size of the ITV, reviewing available primary source data. It was identified that an extra 5mm margin was added to the ITV resulting in the patient receiving unnecessary dose to 3 organs at risk (OAR) for 2 fractions of treatment.

Coding: Level 1/ 11i/ 11i/ 11t/ 13aa/ 13hh/ MD13aa /CF1c/ CF1a/ CF2c /CF1d

#### **Contributory factors**

The contributory factors (CF) for this synopsis included 'failure to recognise hazard' and 'communication' of the larger than usual ITV which had been noted at multiple steps including the peer review process and the end of process checks. The observation was not discussed further with the multidisciplinary team or appropriately investigated. When the treatment radiographers escalated the ITV, all imaging data were not reviewed by the planning team to fully investigate the issue. These events led to an additional exposure to the patient OARs (adherence to procedures or protocols).

#### Failed safety barriers

The local protocol included multiple safety barriers:

- independent checking process prior to leaving the pretreatment planning area
- peer review process
- pre-treatment checks
- on-set imaging: approval process
- on treatment end of process checks

Although the error could have been stopped by one of the safety barriers, appropriate action was not taken to fully investigate the error.

#### Method of detection

During the offline review of the on-set imaging following the second treatment, a review of the breathing trace led to an investigation which identified the ITV expansion error.

#### **Corrective actions**

Corrective actions include:

- consider local nomenclature and the use of standard protocols for target volumes
- consider the use of automated expansion of margins
- review end of process checks to ensure these include confirmation of target and OAR delineation, ensure protocol includes how to act upon findings
- ensure staff are adequately trained, competent and appropriately entitled to undertake necessary tasks
- ensure a positive safety culture is embedded within department, facilitating unambiguous multidisciplinary communication
- use appropriate primary source data to investigate queries as they arise
- share the error with the wider department for learning
- review all RCR peer review recommendations to reduce risk of error (<u>6</u>)

#### Learning from excellence and published guidance

Learning from excellence includes:

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- target volume contours should be subject to systematic review by appropriately trained and experienced peer professionals (<u>6</u>)
- review workflow and ensure adequate staffing in relevant teams to minimise unduly busy clinical and planning sessions (7)
- ensure job planning is appropriate for staff carrying out outlining and peer review (6)
- ensure appropriate work environment to complete the task (7, 8)
- in accordance with IR(ME)R Regulation 8 (<u>3 to 5</u>) undertake a study of risk of accidental or unintended exposures (<u>9</u>)

Further guidance and national tools to aid investigations are available (10, 11). Following a simple risk matrix (9) a study of risk was produced for this case study and process sub-codes (11i) 'target and organ at risk delineation'

#### 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
Wrong site of disease outlined for treatment	3	1	3 (G)	3	1	3 (G)
Incorrect outlining of planning target volume (PTV) or internal target volume (ITV)	3	2	6 (G)	3	1	3 (G)
Incorrect outlining of organs at risk (OAR)	3	2	6 (G)	3	1	3 (G)
Growing of volume completed incorrectly	3	2	6 (G)	3	1	3 (G)
Omission of outlining of OAR	2	2	4 (G)	2	1	2 (G)
Peer review of outlining not undertaken as per local procedures	2	2	4 (G)	2	1	2 (G)

A special thank you to Lisa Addis, Radiotherapy Operational Manager at Gloucestershire Hospitals NHS Foundation Trust, and Linnéa Freear, Principal Clinical Scientist (MR-Linac) - Radiotherapy at the Christie NHS Foundation Trust, for the review of this case study.

### **December 2023 to March 2024 data analysis**

#### Number of RTE reports

A total of 3,977 reports were received between December 2023 and March 2024, 24 were not RTE reports resulting in 3,953 RTE reports for analysis. This equates in a monthly average of 988 RTE reports, reflecting a slight decrease from 999 (1.1%), when compared to the previous <u>analysis</u> (issue 42) and an increase from 876, (12.0%) when compared to the same reporting period in December 2022 to March 2023 (<u>issue 40</u>).

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 498 days, with a mean of 47 days and a mode of 0 days, reflecting that 715 were reported nationally on the same day as the incident. There were 6 which did not contain an incident date. There were 16 outliers with a lag time greater than 365 days which were reported from 9 providers. There was no reason annotated to explain this delay in reporting.

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 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.

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 2,321 RTE reports classified and coded locally with all the taxonomies, 1,524 were classified as levels 1 to 4. A total of 414 levels 1 to 4 reports were amended (complete fixed in Figure 2 includes level 5 data (n = 505)). Thus, an 72.8% level of consistency was achieved for levels 1 to 4 RTE. This reflects a decrease since the previous analysis (issue 42) when an 78.1% level of consistency was achieved.





A total of 1,632 RTE reported did not contain one of the required taxonomies, including MD. A total of 1,190 were classified or coded by UKHSA staff using the supporting text supplied by the local providers (incomplete fixed report in Figure 2), 452 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 that 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>.

Taxonomy amended (n = 505)	Initial coding	Most frequently amended to
Classification (n = 79)	Level 5 'other non- conformances' (40.5%, n = 32)	Level 4 'near miss' (78.1%, n = 25)
Primary pathway subcode (n = 290)	13i 'use of on-set imaging' (21.7%, n = 63)	13z 'on-set imaging: production process' (41.3%, n = 26)
MD (n = 291)	13i 'use of on-set imaging' (38.5%, n = 112)	13aa ʻon-set imaging: approval process' (50.0%, n = 56)
CF (n = 31)	CF7a 'other' (29.0%, n = 9)	CF1d 'communication' (44.4%, n = 4)

Table 2. Amendments to complete RTE report

Non-RTE reports submitted formed 0.6% (n = 24) 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 a slight increase (0.4%, n = 16) since the <u>previous analysis</u> (issue 42). 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" (<u>12</u>). Further information on PSI can be found in <u>issue 5 of Safer Radiotherapy</u>. Non-RTE reports were excluded from the detailed analysis.

Of the incomplete reports, 15 RTE did not contain sufficient supporting text to assign any the classification or the coding, these have not been included in the detailed analysis. This is a increase from 4 in the <u>previous analysis</u> (issue 42).

In total, 3,938 RTE for the reporting period from December 2023 to March 2024 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 58 RT providers across both the independent and NHS providers have reported. This is a slight increase since the <u>previous analysis</u> (issue 42) (n = 55). There were 205 anonymised reports received which did not indicate the RT provider, these have been included in <u>Figure 3</u> as a single provider.

Figure 3 shows the number of RTE reports submitted by provider. This ranged from one to 320 reports, with a mean of 67. Of the 58 RT providers who reported, 63.8% (n = 37) 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.

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 was linked for data transfer to the wider hospital or trust risk management incident learning system.



#### Figure 3. Number of RTE reported by provider (n = 3,938)

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 3,938 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, 97.9% (n = 3,855) were minor radiation incident, near miss or other nonconformities (levels 3 to 5) with little or no impact on patient outcome. Of the remaining 2.1% (n = 83) of reports, 1.4% (n = 55) 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.

#### Figure 4. Classification (level) of RTE reports (n = 3,938)



#### Breakdown of process codes

A single report classified by the reporting provider did not contain other required taxonomies nor enough detail to assign these taxonomies. Therefore could not be included in the following analysis. The remaining 3,937 RTE reports were categorised by process code and classification level so the main themes could be derived. Figure 5 shows 43.2% (n = 1,702) 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 42), with the addition of 'process prior to first appointment'.

#### Figure 5. Breakdown of RTE process code by level (n = 3,663/3,937 subset of RTE)



#### Breakdown of process subcodes

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

The most frequently reported RTE was 'on-set imaging: production process' at 13.0% (n = 512) of all the reports. This reflects the previous analysis, issue 42 (12.9%, n = 517). Of this subset, 98.8% (n = 506) 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 5.5% (n = 216). The most frequently reported process subcodes during the current review period are similar to the previous analysis (issue 42). Differences include the addition of 'communication of appointments to patients' which will be discussed further in the level 5 data section. When compared to the previous analysis (issue 42) the prevalence of RTE associated with 'use of on-set imaging' has decreased from 3.9% (n = 156) to 2.7% (n = 107) within this reporting period, this may be in part due to the reallocation of the coding as shown in table 2 above.

Three of the most frequently reported RTE process subcodes shown in <u>Figure 6</u> 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 19.6% (n = 772) 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 6. Breakdown of most frequently reported RTE process subcodes by level (n = 1,752/3,937 subset of RTE)



#### Reportable radiation incident (level 1) RTE

Reportable radiation incidents (level 1), as defined in <u>TSRT</u> fall into the category of reportable under IR(ME)R (<u>3 to 5</u>), in accordance with <u>SAUE</u> guidance. 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 55 level 1 incidents submitted by 31 providers to the voluntary system for this reporting period (Figure 6), comprising 1.4% of the RTE reviewed. This reflects a statistically significant decrease in proportion since the <u>previous analysis</u>, issue 42 (2.0%, n = 79) (p = 0.04). A single report was classified as a level 1 report, this did not contain other required taxonomies nor enough detail to assign these taxonomies for inclusion in the following analysis. The most frequently reported remaining 54 level 1 reports are shown in Figure 7.

'Patient positioning' comprised of 20.4% (n = 11) of reports and were the most frequently reported events within the reportable radiation incidents. This was also one of the most frequently reported level 1 event within the <u>previous analysis</u> (issue 42), comprising 13.9% (n = 11). An example of 'Patient positioning' associated RTE is when the patient is positioned incorrectly, including limb positioning, which leads to a geographical miss or unintended irradiation. Further guidance on reducing these types of events can be seen in <u>previous analysis</u> (issue 39).

'On-set imaging: production process' made up 11.1% (n = 6) of all level 1 incidents. This was also one of the most frequently reported events within the <u>previous analysis</u> (issue 42), comprising 13.9% (n = 11) 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 <u>SAUE</u> guidance. Practical advice on reducing this type of event can be seen in case study 2 in <u>issue 32</u>, the <u>good practice guidance series</u> and the <u>biennial report</u>.

# Figure 7. Breakdown of most frequently reported level 1 RTE by process subcode (n = 37/54 subset of RTE)



All of the most frequently reported level 1 RTE process subcodes were also the most frequently reported level 1 RTE within the <u>previous analysis</u> (issue 42). The level 1 RTE were spread across 26 different process subcodes. Of these, 8 occur outside those activities involving patient attendance. A review of workflow processes to ensure they contain sufficient effective

checks and removal of task redundances is recommended. This will 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 0.7% (n = 28) of the RTE reported for this time period (<u>Figure 4</u>). This is a slight decrease since the <u>previous analysis</u>, issue 42 (1.0%, n = 39) (p = 0.15). 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 = 16/28 subset of RTE)



The reports were spread across 17 different subcodes, 12 of which were singular and not shown within Figure 8. 'On-set imaging: approval process' comprised of 25.0% (n = 7) 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. 'Assessment of patient prior to treatment' was the second most frequently reported level 2 RTE comprising 10.7% (n = 3) of all non-reportable radiation incidents. Examples of this includes when assessment of patient prior to treatment has not been completed leading to incorrect patient positioning and a partial geographical miss which is non reportable.

#### 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 39.0% (n = 1,535) of the RTE reported for this reporting period (<u>Figure 4</u>). This is similar to the

previous analysis (issue 42) (39.2%, n = 1,566) (p = 0.86). 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 (30.2%, n = 463) within this subset. This is similar to the <u>previous analysis</u> (issue 42) (29.8%, n = 467). 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 63.5% (n = 294) 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 = 1,172/1,535 subset of RTE) includes equipment failure related



Attributed to equipment failure

) 50 100 150 200 250 300 350 400 450 500 Number of RTE reports

'Management of variations, unexpected events or errors' made up 11.9% (n = 183) of all minor radiation incidents, of these 90.7% (n = 166) 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 <u>unseen pathway</u>.

There are 2 additions to the most frequently reported process subcodes within the minor radiation incidents (level 3) RTE when compared to the <u>previous analysis</u> (issue 42); 'positioning of patients' and 'localisation of intended volumes'.

### 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 25.8% (n = 1,016) of the RTE reported (Figure 4). This reflects a slight decrease in comparison to the <u>previous analysis</u>, issue 42 (27.0%, n = 1,079) (p = 0.23). 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 = 427/1,016 subset of RTE)



'Documentation of instructions or information' comprised 7.4% (n = 75) of level 4 RTE. An example of this type of RTE would be incorrect documentation of patient positioning during CT planning is not detected until patient positioning at the treatment unit.

All of the most frequently reported process subcodes within the near misses (level 4) also featured in the most frequently reported near miss RTE within the <u>previous analysis</u> (issue 42).

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 (13.6%, n = 138). 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 <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 33.1% (n = 1,304) of all RTE reported for this period (Figure 4). This reflects a statistically significant increase in the proportion of non-conformance reports in comparison to the <u>previous analysis</u>, issue 42 (30.8%, n = 1,230), (p = 0.03).

# Figure 11. Breakdown of most frequently reported level 5 RTE by process subcode (n = 545/1,304 subset of RTE)



The most frequently reported level 5 process subcodes were 'bookings made according to protocol' comprising 7.1% (n = 92) of all level 5 RTE (Figure 11). This has increased slightly since the previous analysis (issue 42) when bookings made according to protocol made up 6.7% (n = 83) 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 (6.7%, n = 87). This has increased since the previous analysis (issue 42) when 'communication of appointments to patient' made up 4.7% (n = 58) 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 19.0% (n = 248) of level 5 RTE.

No treatment process subcodes were included in the most frequently reported level 5 RTE (Figure 11). There has only been one addition to the most frequently reported process subcodes within the other non-conformance (level 5) RTE when compared to the previous analysis (issue 42), 'timing of chemo or irradiation'.

#### 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>13</u>). SB embedded in the pathway coding (<u>14</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 2,297 failed safety barriers (FSB) were identified from the RTE reported (<u>Figure 12</u>).

Treatment unit processes were attributed to 40.7% (n = 936) of all FSB. The most frequently reported FSB are represented in <u>Figure 12</u>. Treatment unit processes 'management of variations, unexpected events or errors' was the most frequently reported FSB (11.1%, n = 256). 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.

All but one of the FSB were also seen in the <u>previous analysis</u> (issue 42), 'timing of chemo or irradiation' 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 25.4% (n = 584) of all FSB. The PSRT provided further information on the use of end of process checks in the January (number 6) and September (#7) 2022 issues of <u>Safer Radiotherapy E-bulletin</u>.

#### Figure 12. Breakdown of failed safety barriers (n = 1,433/2,297 subset of RTE data)



Number of RTE reports

#### 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 50 providers indicated MD in 68.3% (n = 2,481) of reports. This is a decrease in numbers, but increase in proportion since the <u>previous analysis</u> (issue 42), where 46 providers indicated MD in 65.4% (n = 2,611) of reports. Following consistency checking, UKHSA coded a further 1,150 reports with MD taxonomy, resulting in 3,631 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' (14.0%, n = 510). This MD was most frequently reported with a primary process code 'on-set imaging: production process' (19.4%, n = 99). Eight of the most frequently reported MD occurred at the treatment unit process.

'End of process checks' occur at the end of each discrete part of the patient pathway and include 6 different pathway subcodes. These comprised of 12.0% (n = 435) of all MD, of which 67.8% (n = 295) 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 = 308/2,481) of MD were assigned 'other' pathway subcode. After consistency checking this was reduced to 7.5% (n = 186). 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>.

# Figure 13. Breakdown of method of detection by level (n = 2,006/3,631 subset of RTE data)



#### **Contributory factors**

Including contributory factors (CF) within a RTE taxonomy enables identification of system problems that could precipitate a range of different incidents (15).

From the 3,937 RTE reported, 83.1% (n = 3,273) included CF coding. These were reported from 53 providers. This reflects a slight decrease in the total frequency of CF coding reported since the <u>previous analysis</u> (issue 42), when 53 providers reported 3,428 of RTE reports included CF (85.9%). UKHSA were able to assign a further 504 primary CF, resulting in 3,777 primary CF for analysis.

Multiple CF can be assigned to a single RTE, across the 3,777 RTE with a primary CF, 804 contained multiple CF, and a total of 4,723 CF codes were assigned to the 3,777 RTE. Figure

14 shows the most frequently reported CF codes. The most frequently reported CF was 'slips and lapses' making up 24.4% (n = 1,152) of all CF reported (Figure 14). <u>Issue 22 of Safer</u> <u>Radiotherapy</u> includes guidance on minimising the occurrence of RTE caused by a slip or lapse of an individual. There is one difference to the most frequently reported CF when compared to the <u>previous analysis</u> (issue 42), 'communication with the patient'. This in part may be due to the inclusion of 'communication of appointments to patients' within the most frequently reported pathway subcodes as seen in Figure 6.

#### Figure 14. Breakdown of most frequently reported CF (n = 4,361/4,723 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 (<u>16</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 0.6% (n = 22) of reports, a notable decrease from the <u>previous analysis</u>, issue 42 (2.1%, n = 84). Providers reporting BRT RTE has also decreased from 18 within the <u>previous analysis</u> to 14 for this reporting period. A breakdown of the brachytherapy RTE can be seen in <u>Figure 15</u>.

#### Figure 15. Breakdown of most frequently reported BRT RTE coded '15' by level (n = 22)



The most frequently reported BRT process subcodes were equally 'correct applicators or sources', 'maintenance of position of applicators or sources', 'management of variations, unexpected events or errors' and 'other' each comprising 13.6% (n = 3) of all BRT RTE. The one BRT RTE which was classified as a reportable radiation incident (level 1) was 'correct applicators or sources'. An example of this type of BRT RTE is when the incorrect size of applicator is utilised for treatment.

From the 22 BRT RTE, there were 27 subcodes reported. Of these, 15 were FSB, the most frequently reported was 'management of variations, unexpected events or errors' and 'correct applicators or sources' each comprising 26.7% (n = 4).

Of the 22 BRT RTE, 50.0%, (n = 11) were assigned a MD subcode. During consistency checking 8 further BRT RTE were assigned a MD using the text within the report. These are shown in <u>Figure 16</u>. The most frequently reported MD was 'management of variations, unexpected events or errors' (26.3%, n = 5).

#### Figure 16. Breakdown of BRT method of detection by level (n = 19 subset of RTE)



All CF codes were reviewed within this subset of the data and 25 CF identified (Figure 17). The most frequently reported CF associated with BRT RTE was 'equipment or IT network failure' comprising of 40.0% (n = 10) 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 14</u>, which may be indicative of differences in the equipment, skill mix and workflow between areas.

Triannual RTE analysis and learning report issue 43: Full radiotherapy error data analysis December 2023 to March 2024

#### Figure 17. Breakdown of BRT RTE CF (n = 25)



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Published: May 2024 Publishing reference: GOV-16730



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