

# **Safer Radiotherapy**

# Triannual RTE analysis and learning report

Issue 36 - Full radiotherapy error data analysis August to November 2021

# **Contents**

Full radiotherapy error data analysis	3
Case study 6: Treatment data entry process	4
August to November 2021 data analysis	8
Number of RTE reports	8
Monitoring of RTE coding by radiotherapy providers	8
Number of reports per provider	11
Breakdown of process codes	12
Classification (level) of RTE	14
Reportable radiation incident (Level 1) RTE	15
Non-reportable radiation incident (Level 2) RTE	17
Minor radiation incident (Level 3) RTE	18
Near miss (Level 4) RTE	19
Other non-conformance (Level 5) RTE	20
Failed safety barriers	21
Method of detection	22
Causative factors	23
Brachytherapy RTE	25
References	28

# 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 ( $\underline{1}$ ). 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 minimised in the future.

This analysis has been undertaken by the UK Health Security Agency (UKHSA) (previously Public Health England (PHE)) on radiotherapy errors (RTE) including near misses, reported voluntarily by NHS radiotherapy (RT) providers. Anonymised reports are submitted from England and Wales to the National Reporting and Learning System (NRLS) at NHS England and Improvement using the TSRT9 trigger code (3), and directly to UKHSA from providers in Northern Ireland and Scotland. The NRLS will be replaced by the new Learn from Patient Safety Events Service (LFPSE) (4). Reports will be received from both sources until all providers have moved to LFPSE.

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) (5, 6, 7) inspectorates of significant accidental or unintended exposures (SAUE) (or 'reportable radiation incidents' (level 1) as defined in <u>Towards Safer Radiotherapy (TSRT)</u> (8). 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.

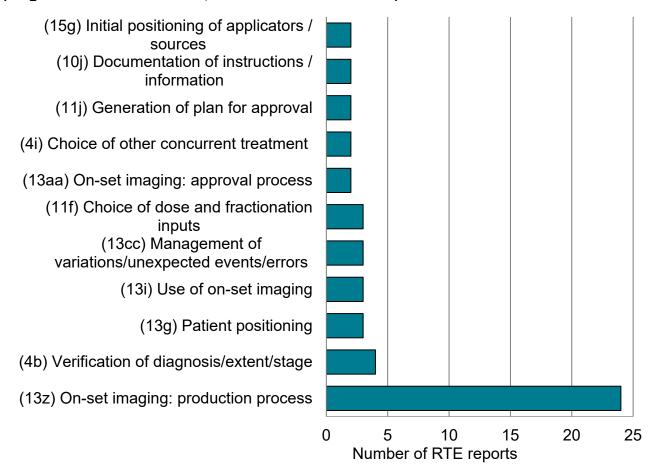
It should be noted there may be a significant time lag between notification of an event to the inspectorates, it being closed and then shared with UKHSA for inclusion in the analysis.

The classification from <u>TSRT</u> (<u>8</u>), the pathway coding, safety barrier, methods of detection and causative factor taxonomies from the <u>Development of Learning (DoL) from Radiotherapy</u> <u>Errors (9)</u> were employed for the analysis. Where appropriate, comparisons have been drawn with previous data analyses (<u>10</u>). The analysis has been reviewed and added to by the PSRT. If individual providers would like to comment on the analysis or share experience of learning from RTE please email the RT team at <u>radiotherapy@phe.gov.uk</u>

#### Case study 6: Treatment data entry process

A breakdown of the inspectorate data for this reporting period can be seen in <u>Figure 1</u>. The inspectorates shared 67 anonymised closed synopses of reported SAUE for analysis, this has increased by 81.1% from 37 in the <u>previous reporting period</u> (<u>10</u>). This increase is in part due to a greater lag time between the incident occurring and the summary of the closed investigation being shared with UKHSA for analysis. In addition there was a notable increase in the number of notifications shared associated with 'on-set imaging: production process', (35.8%, n = 24). This is a marked increase of 24.3% (n = 9) since the <u>previous reporting</u> <u>period</u> (<u>10</u>). A summary of this type of event is included in <u>issue 32</u> of the triannual analysis (<u>10</u>), further guidance on RTE associated with imaging is available (<u>11</u>). Further analysis of RTE by incident date will be included in the upcoming Safer Radiotherapy: Biennial Analysis.

Figure 1. Breakdown of inspectorate process subcodes from closed notifications (August to November 2021, n = 50/67 subset of data)



The following case study has been taken from the inspectorate data. Previous case studies can be seen in earlier editions of the <u>triannual analysis</u> (10).

#### **Synopsis**

Patient A was prescribed bi-lateral partial breast treatments (40Gy in 15 fractions) using a step and shoot IMRT technique. The patient's plan was transferred from the treatment planning system (TPS) to the oncology management system (OMS) correctly. During the second check of the treatment parameters in the OMS, the energy / fluence type was inadvertently changed from 6MV FFF (flattening filter free) to 6MV on the medial beam of the left breast plan. All other beams on both plans were entered and delivered as planned.

This was not picked up during the day one treatment checks. On investigation it was noted there was a time delay during completion of the second check of the parameter's indicative of a distraction. Also, there were difficulties with day one set-up and the final check before switch-on did not identify this difference in energy/fluence. It was later reported the beam energy on the pdf treatment planning summary included in the OMS was difficult to see. The patient received a dose 25% higher than intended to the target volume. The change in the organ at risk doses was minimal as this was a partial breast treatment.

This error was detected in response to a separate patient error, identified as part of routine planning checks. This was also an error related to a beam energy change from FFF to a flat beam. In follow-up to this, a computer script was produced to compare over 70,000 beam deliveries on the OMS with those planned on the TPS Use of the script identified this incident and further investigation highlighted some potential weaknesses in the pathway for this technique.

Firstly, when a prescription includes a specific energy / fluence type, for example 6MV FFF, and is imported to the OMS, there is a chance that the energy / fluence type will not match due to profile differences in the linacs (not all linacs have all energies / fluence types). In these situations, the OMS gives the operator the option to select a different energy / fluence. This requires manual data entry and can lead to an error.

Secondly, during the checking of parameters in the OMS, the mouse 'thumbwheel' is frequently used to scroll down the page. If the mouse pointer is located over a drop-down box, moving the 'thumbwheel' can inadvertently activate parameters and can lead to values being changed incorrectly.

Finally, the commercial software used to compare the plan from the TPS with the data in the OMS, did not detect this difference in energy/fluence.

Coding: TSRT9/ Level 1/ 12g/ 13hh/ CF6a/ CF2c/ CF3b / MD11v

#### Root causes or contributing factors

The root cause for this case study was identified as 'physical', due to the distraction during the checking process leading to the error occurring. There were also distractions due to the difficulties with patient set-up, which contributed to the change in fluence not being detected. Contributory factors included 'adherence to procedures'. This was indicated before switch on, when the final check did not detect the change in energy. Another contributory factor was related to the technical set-up of the commercial software used to compare the plan from the TPS with the data in the OMS. This did not detect the difference in energy/fluence.

#### Safety barriers

The 'end of process checks' did not identify this error. The pause and check at the treatment unit did not detect the difference in the TPS document and the data within the OMS. The weekly checks do not include a check of the TPS data with the OMS data.

#### Method of detection

An independent calculation check was completed for a different patient. During this process it was noted that an error observed with the energy fluence was not detected by the checking software. This instigated an audit of all other similar treatment plans using a bespoke computer script. During this audit the change in fluence was detected for this patient and a full investigation was carried out.

#### Corrective actions

Corrective actions include:

- work closely with manufacturer to review if any processes can be put in place to lock prescriptions and safety critical parameters such as energy, reducing the risk of inadvertently changing the field parameters
- consider removal of mouse thumbwheel to avoid possibility of inadvertent incorrect data selection in OMS
- review the inclusion of checking safety-critical items against original source data during pre-treatment checks
- consider use of computer scripts for routine audits to check for safety-critical items as it could identify errors before treatment and on-treatment

#### Learning from excellence and published guidance

Learning from excellence include:

 review working environment to ensure staff can work without inappropriate interruptions (8) Triannual RTE analysis and learning report: Issue 36: Full radiotherapy error data analysis August to November 2021

 review end of process checks to ensure safety-critical elements of the pathway are included (15)

Further guidance and national tools to aid investigations are available  $(\underline{12},\underline{13})$ . Following a simple risk matrix  $(\underline{14})$  a study of risk was produced for this case study.

Table 1. Study of risk matrix

In this table an A in brackets indicates amber risk, a G in brackets indicates green risk.

	Initial risk			Risk following mitigations		
Area of risk	Consequence	Likelihood	Risk score	Consequence	Likelihood	Risk score
Inadvertent change of beam parameters when data transferred from TPS to OMS	3	3	9 (A)	3	1	9 (G)
Change of beam parameters not detected during data entry checking	3	3	9 (A)	3	1	3 (G)
Change of beam parameters not detected during independent calculation check	3	3	9 (A)	3	1	3 (G)
Incorrect beam parameters not discovered during pause and check	3	3	9 (A)	3	1	3 (G)

# August to November 2021 data analysis

#### Number of RTE reports

For the reports received between August and November 2021 the average number of monthly reports was 777. When compared to the <u>previous reporting period</u> (10) the average number of reports per month has decreased from 890 (decrease of 12.7%). A decrease was also seen when comparing to the same reporting period in 2019 (897, 13.4% decrease) and 2020 (805, 3.5% decrease).

According to the <u>Radiotherapy Data Set (16)</u>, the estimated number of attendances in NHS providers across England and Wales for this reporting period was 490,902 (as of January 2022). There has been a decrease (6.6%) in activity since the <u>previous reporting period (10)</u>, when the estimated number of attendances was 525,561. The decrease in activity will account in some part for the decrease in reporting. Reporting levels will continue to be monitored.

Across England and Wales 2,975 RTE were detected and reported by NHS providers, equating to 7 per 1,000 attendances for this reporting period. This is the same as the <u>previous reporting period (10)</u>. Similar activity data is not yet available for the reported error rate to be calculated for Northern Ireland and Scotland.

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 462 days, with a mean of 47 days and a mode of 21 days. Only 4 reports had a greater lag time than 365 days. This is slightly lower than the previous reporting period (10) when 6 reports had a greater lag time than 365 days. 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 (17). To ensure timely learning from RTE nationally, providers are asked to make RTE submissions at the earliest opportunity. Issue 26 of Safer Radiotherapy (18) provides further information on reporting frequency.

# Monitoring of RTE coding by radiotherapy providers

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

The <u>DoL</u> guidance document ( $\underline{9}$ ) and <u>good practice in RTE reporting (11)</u> include examples of the application of the classification, pathway and causative factor coding. Safety barriers and

method of detection are discussed further in the May 2021 issue of <u>Safer Radiotherapy</u> (<u>18</u>). The format of coding for submission is TSRT9/ Level 4/ 13c/ 13l/ CF1c/ CF2c/ MD13hh. 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 failed safety barriers and causative factor taxonomies.

From the 2,559 RTE reports classified and coded locally, 1,616 were classified as levels 1 to 4. A total of 316 of these were amended (complete fixed in Figure 2 includes level 5 data (n = 83)). Thus, an 80.5% level of consistency was achieved for levels 1 to 4 RTE. This is a decrease from the previous reporting period (10) when an 83.4% level of consistency was achieved. Some amendments were made to reports to ensure consistent allocation of the taxonomies. Of the complete fixed reports 27.3% (n = 109) had the classification amended, 74.7% (n = 298) had the pathway code amended and 16.8% (n = 67) had the causative factor amended.

The classification was most frequently amended for RTE with primary pathway codes associated with on-set imaging (56.9%, n = 62). If a verification image is required to be repeated this should be classified as a radiation incident (level 1-3) and not a near miss (level 4) or non-conformance (level 5). The most frequently amended primary pathway code was 'use of on-set imaging', making up 20.8% (n = 62) of all the amended codes. This was most frequently amended to 'on-set imaging: production process'. For each part of the pathway there are 'other' pathway subcodes, 50.3% (n = 150) of all primary pathway codes were amended from a 'other' primary pathway code. It is recommended the entire pathway coding should be considered when allocating primary pathway codes. Further information on the consistent allocation of pathway codes can be seen in e-Bulletin edition 3 (18).

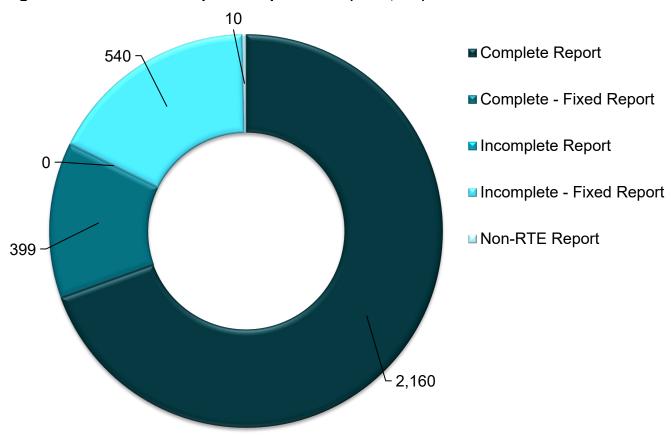


Figure 2. Breakdown of report completeness (n = 3,109)

A total of 540 (17.4%) RTE were classified or coded by UKHSA staff using the supporting text supplied by the local providers (incomplete fixed in <u>Figure 2</u>). This is similar to the <u>previous reporting period</u> (10) when 606 (17.4%) RTE were incomplete. Incomplete reports were submitted by 41 providers. However, 57.1% (n = 309) of the incomplete fixed RTE were reported from a single provider. If providers would like advice or support with coding RTE please email the RT team at <u>radiotherapy@phe.gov.uk</u>.

Non-RTE reports submitted formed 0.3% (n = 10) of all the reports for this reporting period. Data and accompanying text indicate that these were patient safety incidents (PSI). This is consistent with <u>previous analysis</u> (10). 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' (19). Further information on PSI can be found in <u>issue 5 of Safer Radiotherapy</u> (18). Non-RTE reports were excluded from the detailed analysis.

In total, 3,099 RTE for the reporting period from August to November 2021 were included for analysis. The analysis is presented here.

## Number of reports per provider

There are currently 59 NHS RT providers across the UK, this has reduced from 60 NHS providers due to trust mergers. For this reporting period, 86.4% (n = 51) of providers have submitted RTE reports using the TSRT9 trigger code, this is similar to the <u>previous reporting period</u> (86.7%, n = 52/60) (10).

<u>Figure 3</u> shows the number of RTE reports submitted by provider. This ranged from one to 376 reports, with a mean of 52.5. A total of 8 providers did not submit any reports for this reporting period. Of the 51 providers who reported, 62.7% (n = 32) reported less than the national mean. <u>Figure 3</u> 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 178 RTE did not report any level 5 RTE.

There may be several reasons for this disparity in reporting. Reporting culture varies across providers. Reporting and learning systems are not always easily accessible. Additional resource may be required to support a full reporting and learning system. Finally, a local requirement to use more than one reporting 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 <a href="Safer Radiotherapy">Safer Radiotherapy</a> (18). This survey demonstrated that those providers with requirements to use more than one reporting and learning solutions 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.

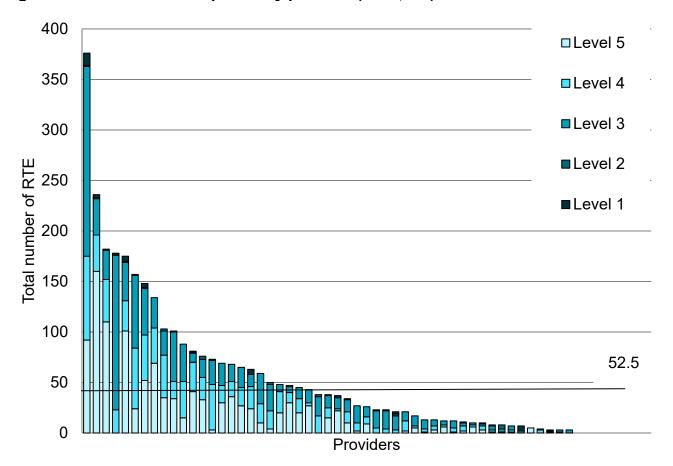


Figure 3. Number of RTE reported by provider (n = 3,099)

## Breakdown of process codes

The 3,099 RTE reports were categorised by process code according to  $\underline{DoL}$  ( $\underline{9}$ ) and level so the main themes could be derived.

<u>Figure 4</u> shows 43.1% (n = 1,336) 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.

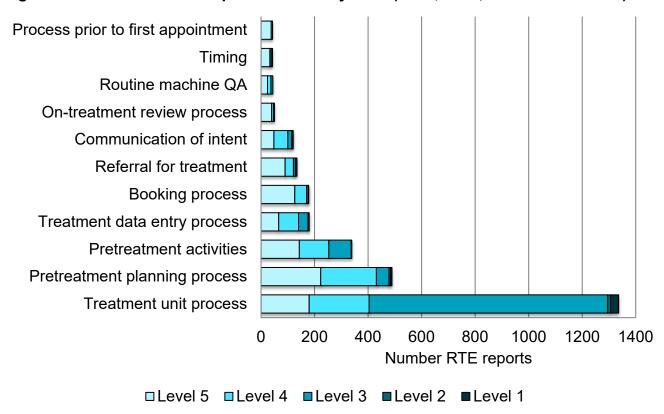
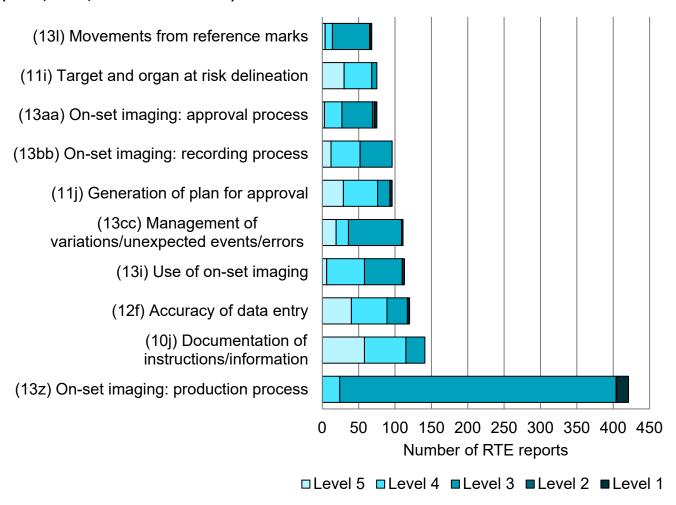


Figure 4. Breakdown of RTE process code by level (n = 2,956/3,099 subset of RTE)

The most frequently reported process subcodes in the RT pathway are presented in Figure 5. This subset of data was also broken down by level. The most frequently reported RTE reported was 'on-set imaging: production process' at 13.6% (n = 421) of all the reports. This is a slight increase since the previous reporting period (p = 0.28) (12.7%, n = 452) (10). Of this subset, 96.0% (n = 404) 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 'documentation of instructions or information' at 4.5% (n = 141), of these 81.6% (n = 115) were classified as level 4 or 5 indicating that the majority of this type of RTE were detected before treatment occurred. This was followed by 'accuracy of data entry' at 3.9% (n = 120). All but one ('movements from reference marks') of the most frequently reported process subcodes were seen in the previous reporting period (10).

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 22.7% (n = 705) 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 (11).

Figure 5. Breakdown of most frequently reported RTE process subcodes by level (n = 1,316/3,099 subset of RTE)



## Classification (level) of RTE

Each of the 3,099 RTE reports was classified as 'other non-conformance', 'near miss', 'minor radiation incident', 'non-reportable radiation incident' or 'reportable radiation incident' (Figure 6).

Of the RTE reports, 97.6% (n = 3,026) were minor radiation, near miss or other non-conformities with little or no impact on patient outcome. Of the remaining 2.4% (n = 73) reports, only 1.5% (n = 47) were reportable under IR(ME)R to the appropriate authority. This is shown to be a slight increase from the <u>previous analysis</u> (10) when reportable radiation incidents made up 0.8% (n = 29) of all the RTE for that reporting period, this will be discussed further within the reportable radiation incident section of this report. The national survey on reporting culture published in the January 2022 issue of <u>Safer Radiotherapy</u> (18) indicates that providers are less likely to submit all levels of RTE reports to the national voluntary reporting system. It was found RTE reports of classification level 4 to 5 are less likely to be shared due to resource constraints and use of multiple reporting systems (18). This trend is also reflected in Figure 3 which shows providers who report a higher number of RTE report all levels of RTE.

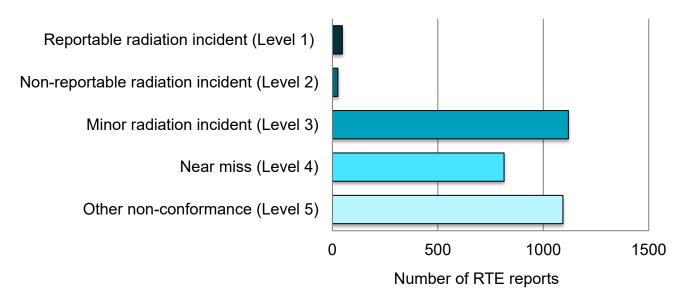


Figure 6. Classification (level) of RTE reports (n = 3,099)

## Reportable radiation incident (Level 1) RTE

Reportable radiation incidents, as defined in <u>TSRT</u> (8) fall into the category of reportable under <u>IR(ME)R</u> (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 47 reportable radiation incidents submitted to the voluntary system for this reporting period (Figure 6), comprising 1.5% of the RTE reviewed. This is an increase (p = 0.01) to the previous analysis (10) (0.8%, n = 29). 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 34.0% (n = 16) and was the most frequently reported event within the reportable radiation incidents. These 16 events were reported by just 5 different providers. This was also the most frequently reported Level 1 event within the inspectorate data (Figure 1) and within the previous analysis (10), comprising 27.6% (n = 8) of all reportable radiation incidents for that time period. An example of 'on-set imaging: production process' reportable RTE is when repeat verification cone beam computed tomography (CBCT) are taken multiple times due to machine malfunction, this then equates to the additional imaging exposures. Taking 3 or more images in one fraction due to machine malfunction meets the reportable threshold of the inspectorates (20). Further guidance on reducing this type of event can be seen in case study 2 in issue 32 and good practice guidance series (11, 18).

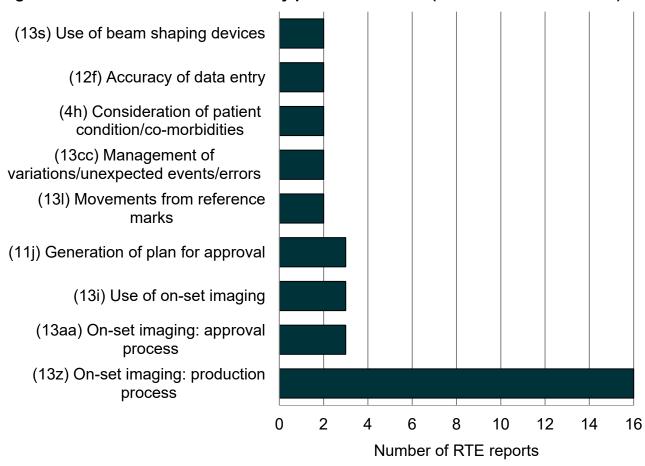


Figure 7. Breakdown of level 1 RTE by process subcode (n = 35/47 subset of RTE)

'On-set imaging: approval process', 'use of on-set imaging' and 'generation of plan for approval' each comprised of 6.4% (n = 3) of the reportable radiation incidents. An example of 'on-set imaging: approval process' level 1 RTE is when a mismatch in on-set verification leads to a geographical miss. An example of 'use of on-set imaging' is when a verification imaging exposure is carried out when there is no verification image required, if this occurs repeatedly it may meet the reportable threshold of the inspectorates (20). Further guidance on reducing these type of events can be seen in <u>Issue 28</u> and <u>good practice guidance series</u> (<u>11,18</u>). An example of 'generation of plan for approval' RTE is when a plan is produced with the incorrect gantry angle included and is used for one fraction of a patients treatment.

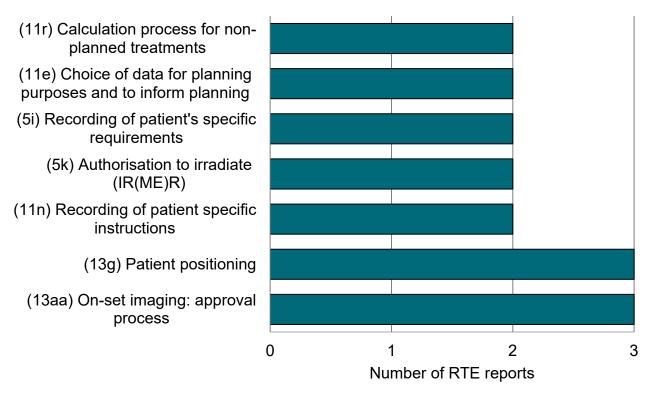
Only 6 of the process subcodes within the reportable radiation incidents shared during this reporting period were also featured in the reportable RTE within the <u>previous analysis</u> (10). The level 1 RTE were spread across 21 different process subcodes, of these, 12 did not generally occur during 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 is defined as a radiation incident which is not reportable, but of potential clinical significance ( $\underline{8}$ ).

Non-reportable radiation incidents comprised 0.8 % (n = 26) of the RTE reported for this time period (Figure 6). This is a slight increase (p = 0.32) since the <u>previous analysis</u> (10), when non-reportable radiation incidents comprised 0.6% (n = 21). Further analysis indicates the points in the pathway at which non-reportable radiation incidents occurred (Figure 8).

Figure 8. Breakdown of level 2 RTE by process subcode (n = 16/26 subset of RTE)



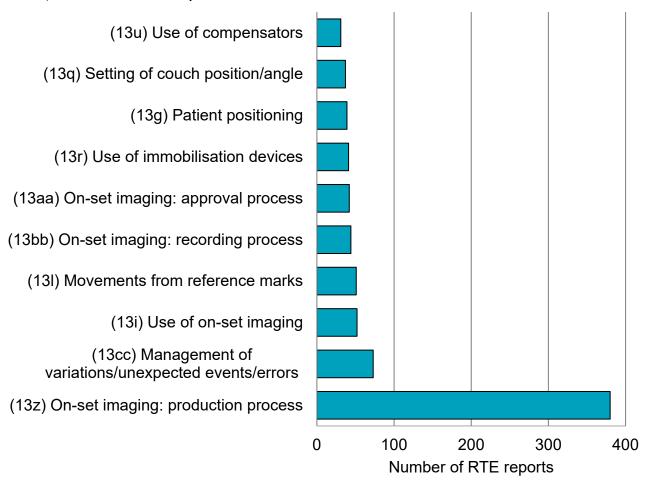
The reports were spread across 17 different subcodes. 'On-set imaging: approval process' and 'patient positioning', each comprised 11.5% (n = 3) and were the most frequently reported event within the non-reportable radiation incident reports. An example of RTE associated with 'on-set imaging: approval process' is the incorrect approval of an on-set verification image which leads to a partial geographical miss which is non reportable. An example of RTE associated with 'patient positioning' is the incorrect positioning of a patient. Only the top 2 process subcodes reported within the non-reportable radiation incidents reported during this period were also featured in the non-reportable RTE within the previous analysis (10).

## Minor radiation incident (Level 3) RTE

A minor radiation incident is defined as a radiation incident in the technical sense, but of no potential or actual clinical significance (8).

Minor radiation incidents comprised 36.1% (n = 1,119) of the RTE reported for this reporting period (Figure 6). This is a slight increase (p = 0.02) since the previous analysis (33.3%, n = 1,183) ( $\frac{10}{2}$ ). 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 = 790/1,119 subset of RTE)



'On-set imaging: production process' was the most frequently reported event (34.0%, n = 380) within this subset. This is similar to the previous analysis (10) (34.2%, n = 404).

Examples of this type of minor radiation incident include using the incorrect filter for CBCT imaging. A total of 51.3% (n = 195) level 3 RTE with the primary process subcode 'on-set imaging: production process' were attributed to equipment failure. 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> (18). All of the most frequently reported level 3 RTE occurred during treatment unit processes, this is reflective of the data shown in <u>Figure 4</u>.

All of the most frequently reported minor radiation incident RTE process subcodes also featured in the most frequently reported near miss RTE within the <u>previous analysis</u> (10). A large proportion of the level 3 reports were related to on-set imaging, (46.3%, n = 518), this is a slight decrease since the <u>previous analysis</u> (10) at 48.4% (n = 573). Further guidance on these types of RTE is <u>available</u> (11).

#### Near miss (Level 4) RTE

A near miss is defined as a potential radiation incident that was detected and prevented before treatment delivery (8).

Near misses comprised 26.3% (n = 814) of the RTE reported (Figure 6). This is similar (p = 0.93) to the <u>previous analysis</u> (10) (26.2%, n = 929). Figure 10 shows the most frequently reported process subcodes for level 4 RTE.

'Documentation of instructions/information' comprised 7.0% (n = 57) of level 4 RTE, followed by 'use of on-set imaging' at 6.4% (n = 52). An example of RTE associated with 'documentation of instructions/information' is the incorrect patient set-up information annotated at pre-treatment and detected during treatment unit patient positioning. An example of RTE associated with 'use of on-set imaging' is the omission of verification imaging on fractions required in the imaging protocol. Further details on 'use of on-set imaging' and 'documentation of instructions/ information' related RTE can be found in <u>issues 7 and 8</u> of Safer Radiotherapy (18).

All 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 analysis</u> (10). The most frequently reported level 4 RTE shown in <u>Figure 10</u>, includes the pathway subcodes associated with on-set imaging.

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.

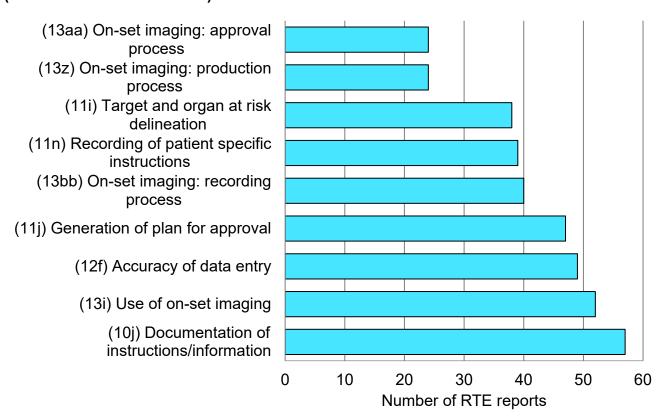


Figure 10. Breakdown of the most frequently reported level 4 RTE by process subcode (n = 370/814 subset of RTE)

## Other non-conformance (Level 5) RTE

Other non-conformance 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 35.3% (n = 1,093) of all RTE reported for this period (<u>Figure 6</u>). This is a slight decrease (p = 0.001) since the <u>previous analysis</u> (10) (39.1%, n = 1,386). The most frequently reported level 5 process subcodes were 'consent process and documentation' and 'documentation of instructions, information' each equally comprising of 5.3% (n = 58) of all level 5 RTE (<u>Figure 11</u>).

An example of a RTE associated with 'consent process and documentation' includes the omission of information within a consent form. Examples of level 5 RTE associated with 'documentation of instructions, information' include the incorrect documentation of instructions and information from the pre-treatment area. This can include the incorrect patient set-up information or the incorrect patient preparation instructions. These are detected during an end of process check, before treatment occurs. The booking process includes 6 different process subcodes, which were reported in 11.5% (n = 126) of level 5 RTE. The most frequently reported level 5 RTE contained only one treatment process subcode. Seven of the most frequently reported process subcodes in the other non-conformances RTE were also seen in the previous analysis (10).

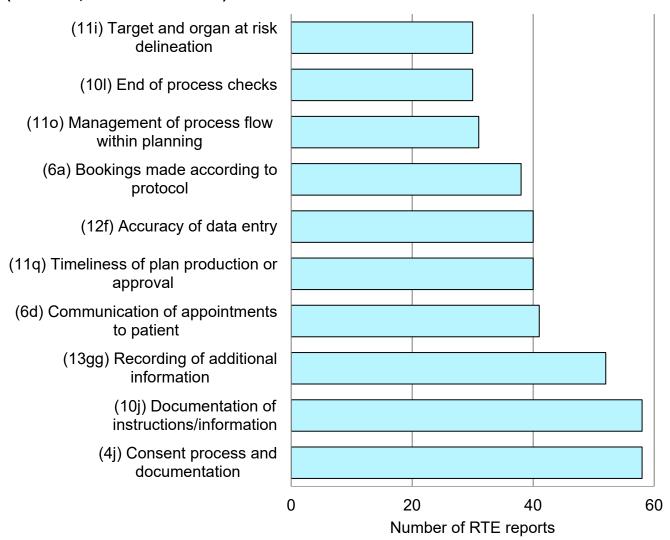


Figure 11. Breakdown of the most frequently reported level 5 RTE by process subcode (n = 418/1,093 subset of RTE)

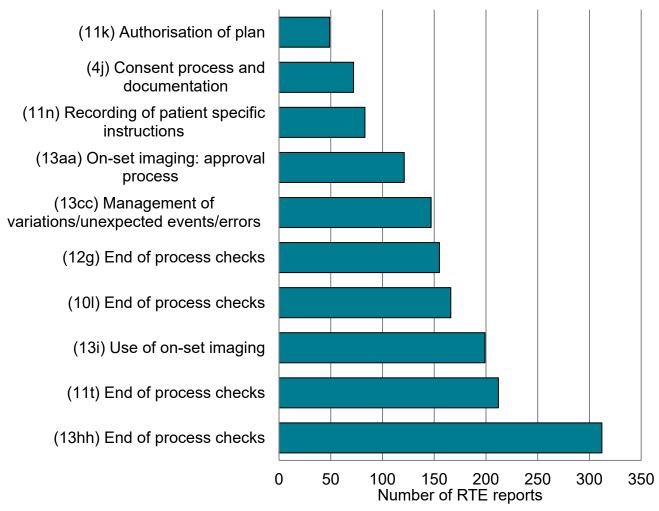
## Failed safety barriers

A safety barrier (SB) is a critical control point, defence in depth, or any process step whose primary function is to prevent errors occurring or propagating through the RT workflow (21). SB embedded in the pathway coding (9) 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 2,188 failed safety barriers (FSB) was identified across the RTE reported (Figure 12).

Treatment unit processes were attributed to 38.3% (n = 837) of all FSB. The most frequently reported FSB are represented in <u>Figure 12</u>. Treatment unit processes 'end of process checks' was the most frequently reported FSB (14.3%, n = 312). An example of an RTE with FSB 'end of process checks' is where an independent end of process check has either been omitted or carried out incorrectly at the end of the process. 'End of process checks' occur at the end of each discrete part of the pathway and include 6 different pathway codes, these comprised of 39.4% (n = 862) of all FSB. The PSRT are currently undertaking a piece of work to look at the

use of end of process checks which is highlighted in the January 2022 issue of <u>Safer</u> Radiotherapy (18).

Figure 12. Breakdown of failed safety barriers by level (n = 1,516/2,188 subset of RTE data)



#### Method of detection

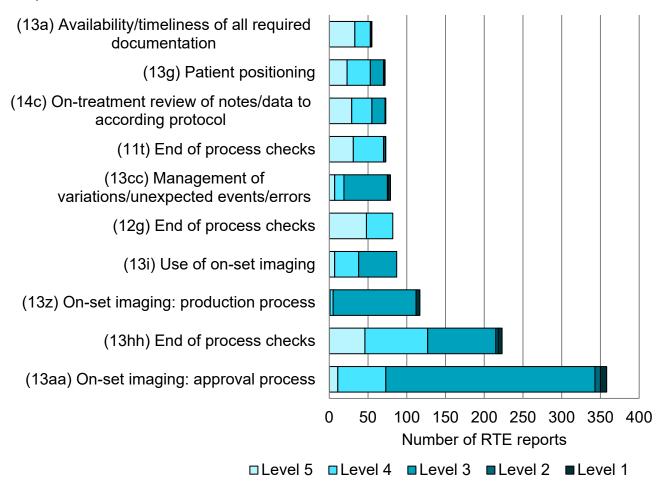
A method of detection (MD) is the process that identified the error and can be coded using the entire pathway taxonomy.

For this reporting period 30 providers indicated MD in 40.0% (n = 1,240) of reports. This is an increase in providers from the <u>previous analysis</u> (10), where 29 providers indicated MD in 34.2% (n = 1,210) of reports. Method of detection are discussed further in the May 2021 issue of <u>Safer Radiotherapy</u> (18). Following consistency checking, UKHSA coded a further 694 reports with SB taxonomy, resulting in 1,934 reports for analysis.

The most frequently reported MD can be seen in <u>Figure 13</u>. For this reporting period, the most frequently reported MD was 'on-set imaging: approval process' (18.5%, n = 358). This MD was most frequently reported with a primary process code 'on-set imaging: production process'

(30.2%, n = 108). It can also be seen RTE are most frequently detected during treatment unit processes.

Figure 13. Breakdown of method of detection by level (n = 1,219/1,934 subset of RTE data)



For each part of the pathway there are 'other' pathway subcodes. Before consistency checking 8.6% (n = 166) of RTE were assigned an 'other' pathway subcode. After consistency checking this was reduced to 4.2% (n = 82). It is recommended the entire pathway coding should be considered when assigning a MD. Further information on the allocation of the pathway coding for MD can be seen in the January 2022 issue of <u>Safer Radiotherapy</u> (18).

#### Causative factors

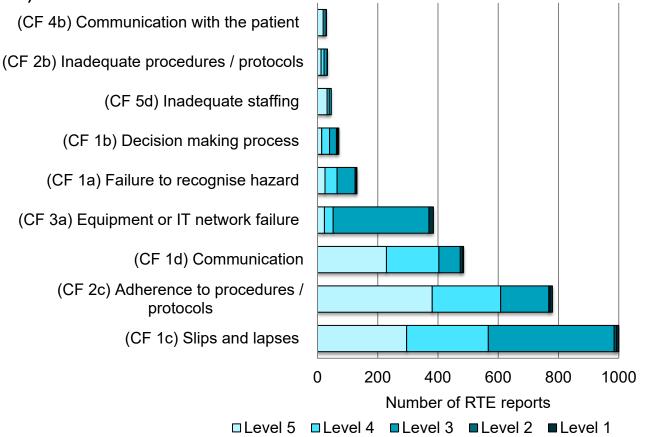
The use of a causative factor taxonomy enables identification of system problems or root causes that could precipitate a range of different incidents (22).

The causative factor taxonomy has been applied to 2,590 (83.6%) RTE reports by 46 providers for this reporting period. This is slightly lower than the <u>previous analysis</u> (10), when 46 providers applied the coding to 2,997 (84.5%) RTE. Following consistency checking, UKHSA coded a further 509 reports, resulting in all RTE reports containing coding for this

analysis. The PSRT recommend including the causative factor taxonomy for all RTE to identify system-problems or root causes.

Figure 14 shows the most frequently reported primary causative factors which are the root cause (RC) of an incident. The most frequently reported category of RC was 'individual' making up 54.6% (n = 1,692) of all RC. All of the most frequently reported RC also featured in the most frequently reported RC within the previous analysis (10). Also consistent with the previous analysis (10), the most frequently reported RC was individual 'slips and lapses' (32.3%, n = 1,000), followed by 'adherence to procedures or protocols' (25.2%, n = 780). 'Slips and lapses' was most frequently attributed to 'on-set imaging: production process' (14.1%, n = 141), and 'adherence to procedures or protocols' was most frequently attributed to 'use of on-set images' (6.5%, n = 51). Issue 22 of Safer Radiotherapy (18) includes guidance on minimising the occurrence of RTE caused by a slip or lapse of an individual

Figure 14. Breakdown of most frequently reported RC by level (n = 2,961/3,099 subset of data)



Several causative codes can be attributed to each individual RTE. A review of the second to fifth codes indicates the contributory factors associated with an incident. Contributory factors were indicated across 782 (25.2%) reports. Of these, 105 (13.4%) contained multiple codes leading to 902 CF. Figure 15 shows the most frequently reported contributory factor, with 'adherence to procedures or protocols' at 36.9%, (n = 333).

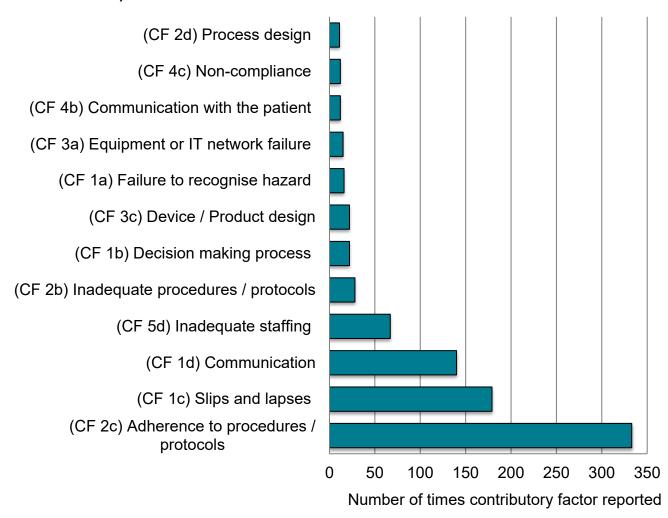


Figure 15. Breakdown of most frequently reported contributory factor (n = 857/902 subset of data)

## **Brachytherapy RTE**

Brachytherapy (BRT) is a RT sub-speciality which involves the placement of a sealed source inside or close to the treatment area (23). BRT makes up less than 3% of all RT episodes (16). Therefore, the number of BRT associated RTE would be expected to be low. RTE coded with BRT process subcodes as the primary code account for 0.5% (n = 17) of reports, a slight decrease to the <u>previous analysis</u> (10) (0.7%, n = 25). A breakdown of the brachytherapy RTE can be seen in <u>Figure 16</u>.

The most frequently reported BRT process subcodes were 'initial positioning of applicators, sources', 'management of variations/ unexpected events/ errors' and 'end of process checks' each comprised 17.6% (n = 3) of all BRT RTE. An example BRT RTE associated with 'initial positioning of applicators, sources' is when the applicator is not positioned correctly. An example of BRT RTE associated with 'management of variations/ unexpected events/ errors' is when the seeds from a treatment cartridge cannot be expelled due to machine malfunction. An example of 'end of process checks' includes the omission of the documentation confirming

the end of process checks have been completed. <u>Issue 20 of Safer Radiotherapy</u> (<u>18</u>) includes further guidance on BRT RTE.

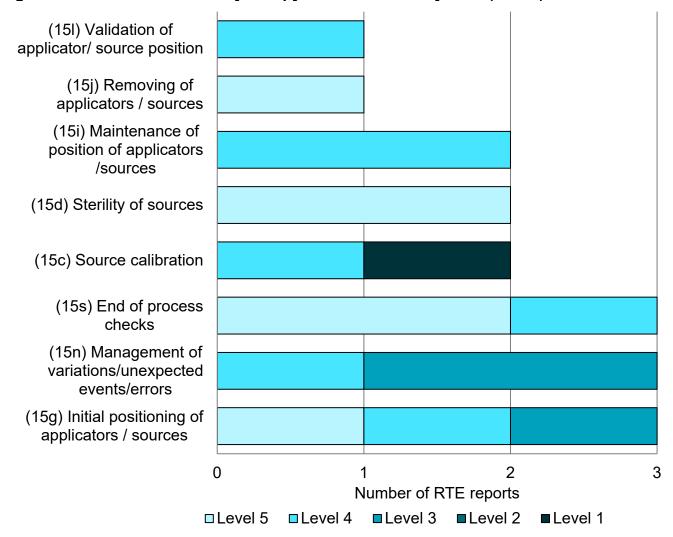


Figure 16. Breakdown of brachytherapy RTE coded '15' by level (n = 17)

Multiple pathway subcodes can be assigned to each RTE. A total of 25 subcodes were identified across the 17 BRT RTE reports. Only 15 subcodes were identified as FSB. The most frequently reported FSB was 'management of variations/ unexpected events/ errors' and 'end of process checks' each at 33.3% (n = 5) as seen in <u>Figure 17</u>. The FSB seen across the entire pathway shown in <u>Figure 12</u> indicate imaging associated FSB. This difference is due to the uptake of IGRT in external beam RT and less so in BRT.

Only 11 MD subcodes were assigned to the BRT RTE. These were 'management of variation/ unexpected events/ errors' (n = 3), 'end of process checks' (n = 2), 'validation of applicators or sources position' (n = 2), 'delivery of sources' (n = 1), 'removing of applicators or sources' (n = 1), 'initial positioning of applicators/ sources' (n = 1) and 'authorisation of plan' (n = 1).

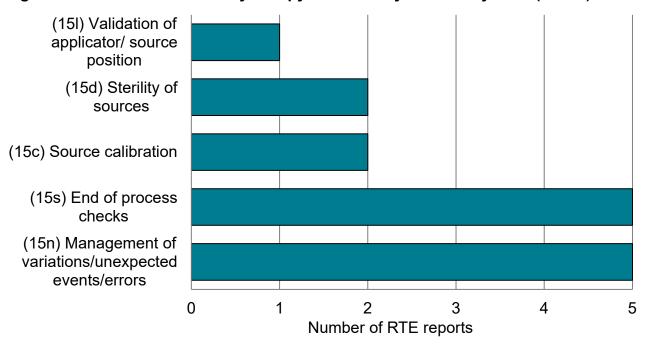


Figure 17. Breakdown of brachytherapy failed safety barriers by level (n = 15)

The causative factors were reviewed within this subset of the data set. All 17 BRT RTE were attributed to 7 different RC as shown in <u>Figure 18</u>. The most frequently reported RC associated with BRT RTE was 'adherence to procedure/ protocols' comprising of 23.5% (n = 4) of all the BRT RTE. The trends of these BRT RC are slightly different when compared to the entire data as in <u>Figure 14</u>.

There were just 8 providers who reported BRT RTE for this reporting period. As this number is very small, this may skew the data presented in <u>Figure 18</u>, leading to the differences in CF when compared to the entire data set for this reporting period.

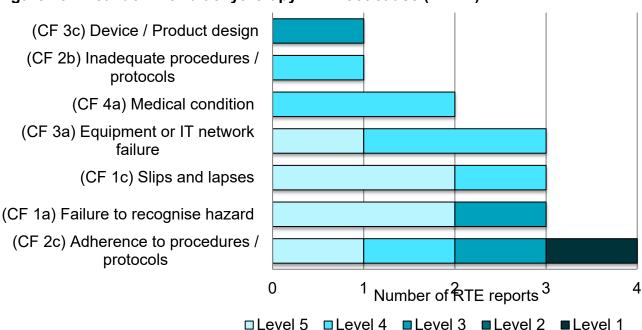


Figure 18. Breakdown of brachytherapy RTE root cause (n = 17)

#### References

- 1. World Health Organization. 'Reporting and learning for patient safety.'
- 2. European Commission. 'Radiation Protection No. 181, General guidelines on risk management in external beam radiotherapy.' 2015
- 3. National Patient Safety Agency. 'Implementing Towards Safer Radiotherapy: guidance on reporting radiotherapy errors and near misses effectively'
- 4. NHS England. 'Learn from patient safety events (LFPSE) service'
- 5. '<u>The Ionising Radiation (Medical Exposure) Regulations 2017</u>.' The Stationery Office, London, SI 2017/1322
- 6. '<u>The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018</u>.' The Stationery Office, London, SR 2018/17
- 7. '<u>The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2018</u>.' The Stationery Office, London, SI 2018/121
- 8. Royal College of Radiologists, Society and College of Radiographers, Institute of Physics and Engineering in Medicine, National Patient Safety Agency, British Institute of Radiology. '<u>Towards Safer Radiotherapy</u>'. London: Royal College of Radiologists, 2008
- 9. Public Health England. 'Radiotherapy: learning from errors'
- 10. Public Health England. 'Safer Radiotherapy: Triannual analysis'
- 11. Public Health England. 'Radiotherapy: good practice'
- 12. NHS England and Improvement. 'Patient Safety incident investigation (PSII)'
- 13. Imperial College London. 'Systems analysis of clinical incidents: The London protocol'
- 14. The Radiotherapy Board made up of the Society and College of Radiographers; Institute of Physics and Engineering in Medicine and the Royal College of Radiologists. 'Ionising Radiation (Medical Exposure) Regulations: Implications for clinical practice in radiotherapy.' London: The Royal College of Radiologists 2020 Ref RTBoard20202
- 15. Public Health England. '<u>Learning from the past 10 years of the radiotherapy clinical site</u> visit'
- 16. Cancer statistics
- 17. NHS Improvement. 'NRLS organisation patient safety incidents reports: commentary'
- 18. Public Health England. 'Safer Radiotherapy'
- 19. National Reporting and Learning Service (NRLS).
- 20. Care Quality Commission 'SAUE: Criteria for making a notification'
- 21. Ford E and others. 'Consensus recommendation for incident learning database structures in radiation oncology.' Medical Physics December 2012: volume 39, issue 12, pages 7,272-7,290
- 22. Clark B and others. 'The management of radiation treatment error through incident learning.' Radiotherapy and Oncology 2010: volume 95, pages 344-349
- 23. Felder S, Morley L, Ng E, Chan K, Ballantyne H, Di Tomasso A and others. 'Brachytherapy patient safety events in an academic radiation medicine program.' Brachytherapy 2018: volume 17, issue 1, pages 16-23

# About the UK Health Security Agency

The <u>UK Health Security Agency</u> is an executive agency, sponsored by the <u>Department of Health and Social Care</u>.

© Crown copyright 2022

For queries relating to this document, please contact: radiotherapy@phe.gov.uk

Published: January 2022

Publishing reference: GOV-11118



You may re-use this information (excluding logos) free of charge in any format or medium, under the terms of the Open Government Licence v3.0. To view this licence, visit <u>OGL</u>. Where we have identified any third party copyright information you will need to obtain permission from the copyright holders concerned.



UKHSA supports the Sustainable Development Goals

