

Safer Radiotherapy

Triannual RTE analysis and learning report

Issue 40 – Full radiotherapy error data analysis December 2022 to March 2023

Contents

Full radiotherapy error data analysis	
Inspectorate data	
Case study 10: brachytherapy patient data set identification	5
December 2022 to March 2023 data analysis	
Number of RTE reports	
Monitoring of RTE coding by radiotherapy providers	
Number of reports per provider	10
Breakdown of process codes	11
Breakdown of process subcodes	12
Classification (level) of RTE	13
Reportable radiation incident (level 1) RTE	
Non-reportable radiation incident (level 2) RTE	15
Minor radiation incident (level 3) RTE	
Near miss (level 4) RTE	
Other non-conformance (level 5) RTE	19
Failed safety barriers	
Method of detection	
Causative factors	
Brachytherapy RTE	
References	
About the UK Health Security Agency	

Full radiotherapy error data analysis

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

The Safer Radiotherapy publication series facilitates comparison of locally identified trends against the national picture. The Patient Safety in Radiotherapy Steering Group (PSRT) recommends implementing learning from this analysis locally. In doing so it is expected that these events might be mitigated in the future.

This analysis has been undertaken by the UK Health Security Agency (UKHSA) on radiotherapy errors and near misses (RTE), reported voluntarily by UK radiotherapy (RT) providers. Anonymised reports were submitted through multiple routes, from England via the <u>National Reporting and Learning System (NRLS)</u> or the <u>Learn from Patient Safety Events</u> <u>Service (LFPSE)</u> at NHS England and from Wales via the <u>Once for Wales Concerns</u> <u>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 by autumn 2023, RTE data submitted through both routes will be included within this analysis.

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

There is a requirement for RT providers to notify the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) (<u>3</u>, <u>4</u>, <u>5</u>) inspectorates of significant accidental or unintended exposures (SAUE) (or 'reportable radiation incidents' (level 1) as defined in <u>Towards Safer</u> <u>Radiotherapy (TSRT)</u>. 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. Please note the notification criteria for SAUE were updated in April 2023 (<u>6</u>). This data analysis has used the 2020 SAUE notification criteria. Future analysis will utilise the 2023 update.

The classification level from <u>TSRT</u>, the pathway coding, safety barrier (SB), methods of detection (MD) and causative factor taxonomies from the <u>Development of Learning (DoL)</u> <u>from Radiotherapy Errors</u> were employed for the analysis. SB 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.

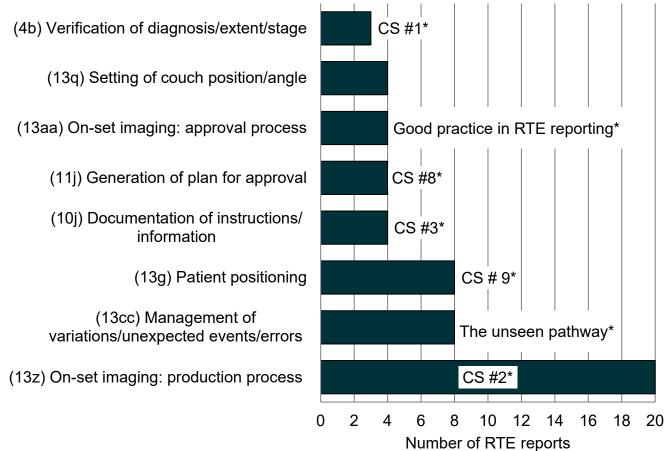
The analysis has been reviewed and added to by the PSRT. If individual providers would like to comment on the analysis, share experience of learning from RTE or application of the coding please email the RT team at radiotherapy@ukhsa.gov.uk.

Inspectorate data

A breakdown of the inspectorate data for this period can be seen in Figure 1. The inspectorates shared 81 anonymised closed synopses of reported SAUE for analysis.

The most frequently reported notifications were associated with 'on-set imaging: production process' (24.7%, n = 20). This is a slight change since the previous analysis (issue 39) when 51 reports were shared, and the most frequently reported process subcode was 'on-set imaging: approval process'. A number of the inspectorate process subcodes have had case studies included in Safer Radiotherapy publications such as the <u>triannual analysis</u>, the <u>unseen pathway</u> and <u>good practice guidance</u>, the specific case studies are shown with an asterisk (*) in Figure 1.

Figure 1. Breakdown of most frequently reported inspectorate process subcodes from closed notifications (n = 55 out of 81 subset of data) (CS = case study)



Case study 10: brachytherapy patient data set identification

There are 206 pathway subcodes (7); of these 19 are specific to brachytherapy (BRT). Within the BRT pathway subcodes there are none currently associated with patient identification, as it is included as treatment unit process (13b) 'patient ID process' or (13c) 'patient data ID process'. These types of RTE can include the incorrect identification of a patient or the incorrect identification of a data set, including patient plan, task lists or information within an electronic system.

Synopsis

Female patient (Patient A) completed a course of external beam radiation (54Gy/25#) for cancer of the cervix, this was then followed by brachytherapy (BRT) HDR 21Gy/3#. Error occurred during treatment of final BRT treatment for patient A. Patient B was due to have the same anatomical area treated after patient A.

A pre-treatment check was completed by operator 1 at the treatment communication console (TCC) which used the department oncology management system (OMS). During the pretreatment checks patient B was opened and the checking and importing of the plan for patient B was completed.

To complete the pre-treatment checks operator 1 confirmed the patient ID on the wristband against the electronic health record. This was not cross referenced against the TCC or OMS.

The second operator went into the room to check the machine attachments and set up. This did not flag any discrepancies as the set up for Patient A and B used the same applicator characteristics (6cm IU and 3cm ovoids with caps). Identification of the patient and data set was not confirmed during this second operator check. The pause and check between operator 1 and 2 should have been verbally completed at this point. This final check was missed.

The final treatment delivered for patient A was the planned treatment for patient B.

The error was detected when the team started the treatment checks for patient B. Staff noted the plans were very similar, patient names were similar, and the plan had already been delivered on the TCC system. The TCC, OMS and electronic health record cannot be connected. This enabled different patient information to be opened and accessed across the different electronic systems.

The patient was spoken with by the consultant and theatre manager. The consultant advised that an error had occurred in that another patient's plan was used for third fraction of BRT

and an investigation was to be undertaken. They explained that the treatment received dose within an acceptable target range. The original plan was a total dose 94.8Gy to HRCTV (high risk clinical target volume) and dose delivered in error was 92.4Gy. Resulting in a 2.5% dose reduction overall. An apology was provided and contact number given for further questions

Coding: Level 1/ 13c/ 13b/ 15s/ MD15s/ CF2c/ CF2d

Causative factors

The causative factor (CF) for this synopsis was 'adherence to procedure' (CF2c) as the final pause and check procedure to confirm patient and data set ID was not completed. A review of the procedure indicated that the TCC, OMS and electronic health record could not be connected, allowing different patient data sets to be accessed across systems simultaneously (CF2d 'process design'). This should be formally risk assessed and considered as part of the pause and check procedure.

Safety barriers

The pause and check procedure included the requirement to verbally confirm correct patient ID and the correct patient data set across systems. The final pause and check was missed leading to the incorrect treatment of patient A using the treatment plan of patient B ((15s) 'end of process checks').

Method of detection

The BRT treatment checks ('end of process checks' (15s)) for patient B indicated that patient A had been treated on the incorrect plan for the final fraction of their BRT treatment.

Corrective actions

Corrective actions include:

- consider the timing of the patient ID process and the use of unlinked data systems
- review pause and check procedures for patient and data set ID
- consider the consistent use of nomenclature for ID across all unlinked systems
- ensure a 3 point ID is completed for all data sets

Learning from excellence and published guidance

Learning from excellence include:

- review and adapt pause and check for brachytherapy (8)
- use primary source data to accurately identify the patient and patient data set (9)
- review the <u>Society of Radiographers (SoR</u>) guidance on preventing patient identification incidents and the associated recommendations (<u>9</u>)

Further guidance and national tools to aid investigations are available (10, 11). Following a simple risk matrix (12) a study of risk was produced for this case study and other (13c) patient data ID processes.

Table 1. Study of risk matrix

In this table cells shaded green and containing a G in brackets indicate green risk.

Area of risk	Initial risk: Consequence	Initial risk: Likelihood	Initial risk: Risk score	Risk following mitigations: Consequence	Risk following mitigations: Likelihood	Risk following mitigations: Risk score
Patient plan incorrectly identified for wrong patient leading to incorrect treatment	3	2	6 (G)	3	1	3 (G)
Verification imaging data set incorrectly identified leading to incorrect imaging	2	2	4 (G)	2	1	2 (G)
Patient data set incorrectly identified leading to incorrect set up information and positioning of patient, corrected after verification imaging	2	2	4 (G)	2	1	2 (G)
Patient plan incorrectly identified leading to incorrect plan, treated on the correct patient	2	1	2 (G)	2	1	2 (G)

A special thank you to Louise Bagley, Christopher Lee, The Clatterbridge Cancer Centre NHS FT, Stuart McGrail, Deputy Head of Radiotherapy Services at The Beacon Centre, Musgrove Park Hospital, and Pauline Humphrey at Bristol Haematology and Oncology Centre for the review of this case study.

December 2022 to March 2023 data analysis

Number of RTE reports

A monthly average of 876 reports were received between December 2022 and March 2023. This was a decrease from 943 (7.1%), when compared to the <u>previous analysis (issue 39)</u> and an increase from 828, (5.8%) compared to the same reporting period published in <u>issue 37, 2022</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 791 days, with a mean of 40 days and a mode of 0 days, reflecting that 102 were reported nationally on the same day as the incident. There were 11 outliers with a lag time greater than 365 days which were reported from 6 providers. There was no reason annotated to explain this delay in reporting. This variation in timeliness of reporting is also reflected in the overall patient safety incident reports received by the <u>NRLS</u> who encourage organisations to report incidents monthly. To ensure timely learning from RTE nationally, providers are asked to make RTE submissions at the earliest opportunity. <u>Issue 26 of Safer Radiotherapy</u> provides further information on reporting frequency.

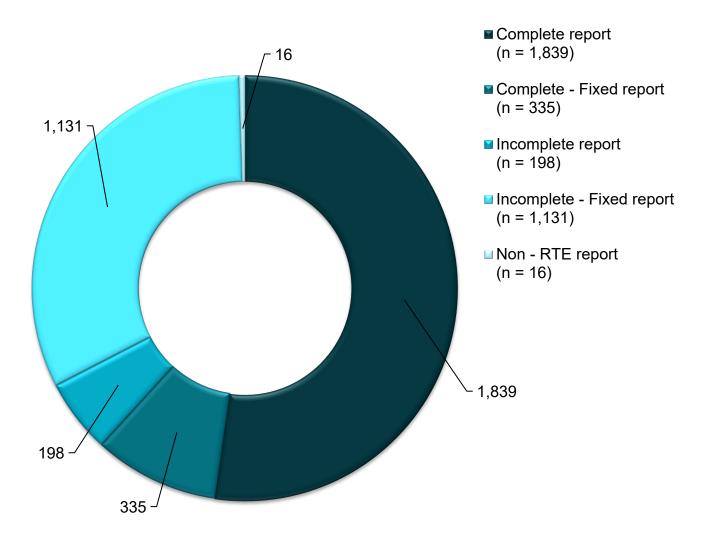
Monitoring of RTE coding by radiotherapy providers

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

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

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

From the 2,174 RTE reports classified and coded locally with all the taxonomies, 1,363 were classified as levels 1 to 4. A total of 227 of these were amended (complete fixed in Figure 2 includes level 5 data (n = 335)). Thus, an 83.3% level of consistency was achieved for levels 1 to 4 RTE. This is similar to the previous analysis (issue 39) when an 83.2% level of consistency was achieved.





Some amendments were made to reports to ensure consistent allocation of the taxonomies. Of the 335 complete fixed reports 19.7% (n = 66) had the classification amended, 58.5% (n = 196) had the pathway subcode amended, 55.2% (n = 185) had the method of detection amended and 3.0% (n = 10) had the causative factor amended.

The classification was most frequently amended for RTE with primary pathway subcodes associated with on-set imaging (71.2%, n = 47). 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 subcode was treatment unit process 'use of on-set imaging', making up 19.4% (n = 38) of all

the amended pathway subcodes. This was most frequently amended to 'on-set imaging: production process' 42.1% (n = 16). When an equipment fault occurs during image production this should be coded using 13z 'on-set imaging: production process'. The most frequently amended MD was treatment unit process 'other', making up 42.7% (n = 79) of all the amended MD. This was most frequently amended to 'end of process checks' 30.4% (n = 24), further detail on end of process checks can be seen in <u>e-bulletin edition 8</u>. It is recommended 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>.

A total of 1,329 RTE reported did not contain one of the required taxonomies, including MD. A total of 1,131 were classified or coded by UKHSA staff using the supporting text supplied by the local providers (incomplete fixed in <u>Figure 2</u>), 615 of these only required the MD to be included.

Non-RTE reports submitted formed 0.5% (n = 16) of all the reports for this reporting period. Data and accompanying text indicate that these were patient safety incidents (PSI) but not RTE. This is consistent with the <u>previous analysis (issue 39)</u>. A <u>PSI</u> is defined by the NRLS as 'any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving care' (<u>13</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.

In total, 3,503 RTE for the reporting period from December 2022 to March 2023 were included for analysis. The analysis is presented here.

Number of reports per provider

Data was received from NHS providers and from the independent sector for the first time. For this reporting period 58 RT providers across both the independent and NHS providers have reported.

<u>Figure 3</u> shows the number of RTE reports submitted by provider. This ranged from one to 201 reports, with a mean of 60. Of the 58 providers who reported, 60.3% (n = 35) 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 135 RTE did not report any level 5 RTE, a further 5 providers did not report any level 5 RTE.

There may be several reasons for this disparity in reporting. Reporting culture varies across providers. Incident learning systems are not always easily accessible. Additional resource may be required to support a full incident learning system. Finally, a local requirement to use more than one system may disincentivise reporting. Findings of the most recent survey of UK RT providers on reporting culture is published in the January 2022 issue of <u>Safer</u>

<u>Radiotherapy e-bulletin</u>. 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.

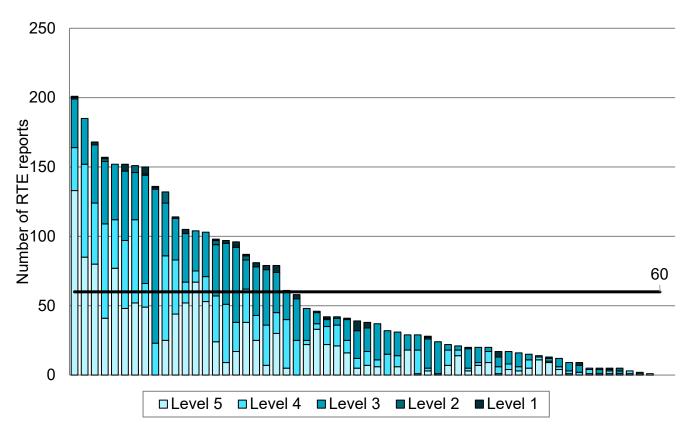


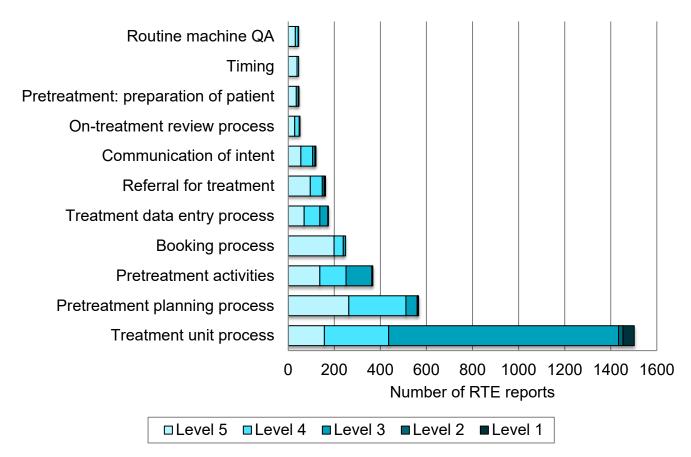
Figure 3. Number of RTE reported by provider (n = 3,503)

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

Breakdown of process codes

The 3,503 RTE reports were categorised by process code and classification level so the main themes could be derived. Figure 4 shows 42.9% (n = 1,502) of the RTE were reported to have occurred during treatment unit processes. The treatment process represents the last opportunity to identify errors. Accurate treatment relies on the correct interpretation of the treatment plan and set-up details which need to be replicated at each fraction of treatment. This might explain prevalence of RTE within treatment unit processes. All but 2 of the most frequently reported process codes are the same as the previous analysis (issue 39).

Figure 4. Breakdown of RTE process code by level (n = 3,327 out of 3,503 subset of RTE)



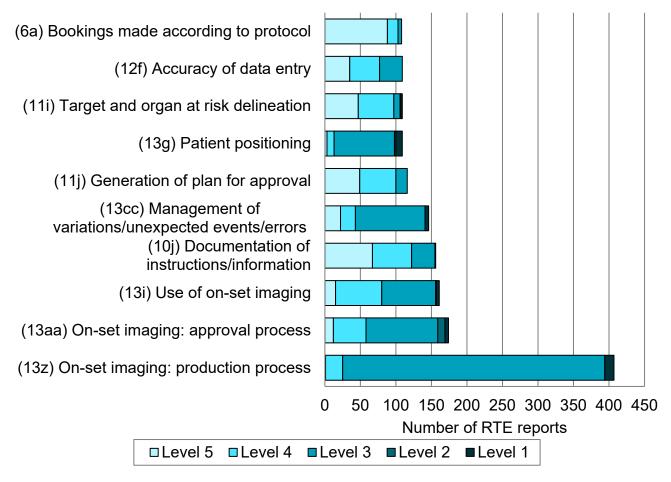
Breakdown of process subcodes

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

The most frequently reported RTE reported was 'on-set imaging: production process' at 11.6% (n = 407) of all the reports, which is a statistically significant (p = 0.001) decrease in percentage when comparted to the <u>previous analysis</u>, <u>issue 39</u> (14.5%, n = 544). Of this subset, 96.8% (n = 394) 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 'on-set imaging: approval process' at 5.0% (n = 174). All of the most frequently reported process subcodes were seen in the <u>previous analysis (issue 39</u>).

On-set imaging associated RTE include 'on-set imaging: production process', 'use of on-set imaging', 'on-set imaging: recording process' and 'on-set imaging: approval process', 3 of these were reported as the most frequently reported RTE process subcodes shown in Figure 5. These combined RTE made up 23.7% (n = 831) 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 5. Breakdown of most frequently reported RTE process subcodes by level (n = 1,595 out of 3,503 subset of RTE)



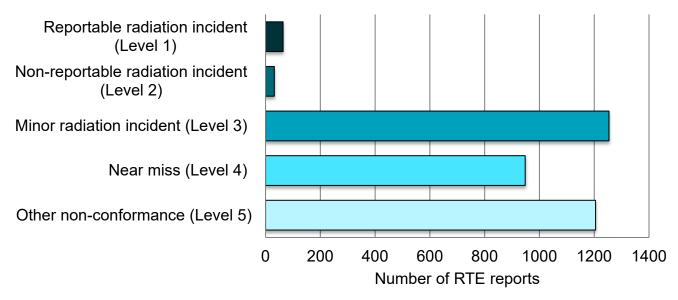
Classification (level) of RTE

Each of the 3,503 RTE reports was classified as 'other non-conformance (level 5)', 'near miss (level 4)', 'minor radiation incident (level 3)', 'non-reportable radiation incident (level 2)' or 'reportable radiation incident (level 1)' (Figure 6).

Of the RTE reports, 97.3% (n = 3,407) were minor radiation incident, near miss or other nonconformities (levels 3 to 5) with little or no impact on patient outcome. Of the remaining 2.7% (n = 96) of reports, only 1.8% (n = 64) were reportable under IR(ME)R to the appropriate authority.

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

Figure 6. Classification (level) of RTE reports (n = 3,503)



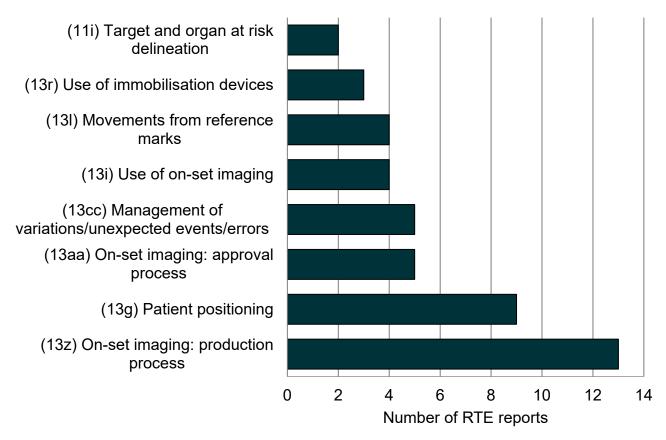
Reportable radiation incident (level 1) RTE

Reportable radiation incidents (level 1), as defined in <u>TSRT</u> fall into the category of reportable under $\underline{IR(ME)R}$ (3, 4, 5). 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 64 level 1 incidents submitted by 27 providers to the voluntary system for this reporting period (Figure 6), comprising 1.8% of the RTE reviewed. This proportion is slightly higher than the previous analysis, issue 39 (1.4%, n = 51) (p = 0.17). 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 20.3% (n = 13) and was the most frequently reported event within the reportable radiation incidents. This was also the most frequently reported event within the <u>previous analysis (issue 39)</u>, comprising 29.4% (n = 15) of all level 1 incidents for that time period. An example of an 'on-set imaging: production process' reportable RTE is when repeat verification image is taken multiple times due to either machine malfunction and or setting the incorrect position for the image panel. Taking 3 or more images in one fraction due to machine malfunction met the 2020 reportable threshold of the inspectorates. New guidance and notification criteria on reporting significant and accidental exposures has now been published (<u>6</u>). Further guidance on reducing this type of event can be seen in case study 2 in <u>issue 32</u>, the good practice guidance series and the <u>biennial report</u>.

Figure 7. Breakdown of most frequently reported level 1 RTE by process subcode (n = 45 out of 64 subset of RTE)



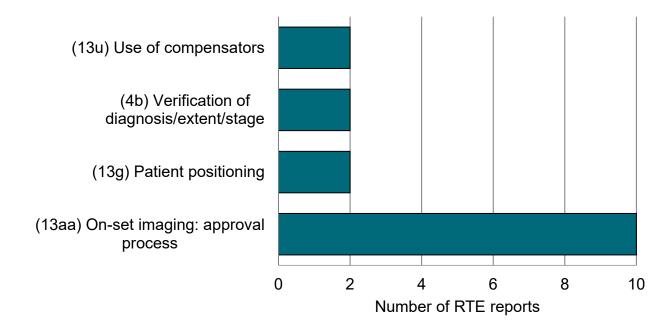
'Patient positioning' was the second most frequently reported level 1 RTE comprising of 14.0% (n = 9) of the reportable radiation incidents. An example of this type of RTE is when the patient is positioned incorrectly, including limb positioning, which leads to a geographical miss. Further guidance on reducing these types of events can be seen in the <u>previous</u> <u>analysis (issue 39)</u>.

All but one of the process subcodes within the most frequently reported level 1 incidents were also featured in the most frequently reported level 1 RTE within the <u>previous analysis</u> (issue 39). The level 1 RTE were spread across 27 different process subcodes. Of these, 8 did not occur during a patient attendance. A review of checking processes to ensure they contain a minimum criteria for checking is recommended, this may mitigate RTE propagating through the pathway to the patient treatment process.

Non-reportable radiation incident (level 2) RTE

A non-reportable radiation incident (level 2) is defined as a radiation incident which is not reportable, but of potential clinical significance (14). Non-reportable radiation incidents comprised 0.9% (n = 32) of the RTE reported for this time period (Figure 6). This is the same as the previous analysis, issue 39 (0.9% (n = 32)) but is not statistically significant (p = 0.5). Further analysis indicates the points in the pathway at which non-reportable radiation incidents incidents occurred (Figure 8).

Figure 8. Breakdown of most frequently reported level 2 RTE by process subcode (n = 16 out of 32 subset of RTE)



The reports were spread across just 20 different subcodes, 16 of which were singular and not shown within Figure 8. 'On-set imaging: approval process' comprised of 31.3% (n = 10) of all the non-reportable radiation incident reports. An example of this type of RTE is the incorrect approval of an on-set verification image which leads to a partial geographical miss which is non reportable.

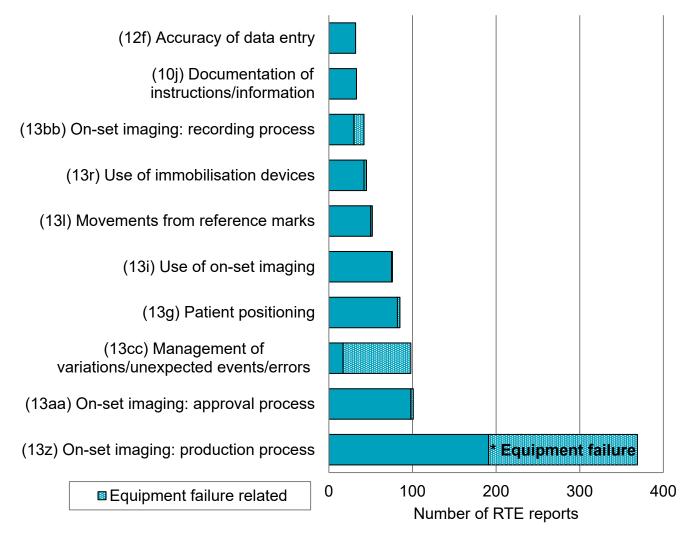
Minor radiation incident (level 3) RTE

A minor radiation incident (level 3) is defined as a radiation incident in the technical sense, but of no potential or actual clinical significance (14). Minor radiation incidents comprised 35.8% (n = 1,254) of the RTE reported for this reporting period (Figure 6). This is a decrease in proportion since the previous analysis, issue 39 (38.8%, n = 1,454) (p = 0.01). A breakdown of level 3 RTE by process subcode can be seen in Figure 9.

'On-set imaging: production process' was the most frequently reported event (29.4%, n = 369) within this subset. This is a slight decrease in proportion since the <u>previous analysis</u>, <u>issue 39</u> (33.9%, n = 493).

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 48.2% (n = 178) level 3 RTE with the primary process subcode 'on-set imaging: production process' were attributed to equipment failure, this is shown in Figure 9. Examples of this type of RTE include CBCT faults during acquisition. Equipment failure and on-set imaging: production process is discussed further in issue 18 of Safer Radiotherapy.

Figure 9. Breakdown of most frequently reported level 3 RTE by process subcode (n = 933 out of 1,254 subset of RTE) *equipment failure related



'On-set imaging: approval process' made up 8.1% (n = 101) of all minor radiation incidents, examples of this type of event includes the incorrect image approval which does not lead to a geographical miss. Further guidance on mitigating and reporting these types of RTE can be seen in the Safer Radiotherapy <u>good practice guidance series</u>. 'Management of variations, unexpected events or errors' made up 7.8% (n = 98) of all minor radiation incidents, of these 82.7% (n = 81) were due to equipment malfunction, examples of this type of event includes when treatment equipment malfunction leading to a patient requiring movement to a matched treatment machine, this re-set of the patient positioning then requires additional verification imaging. Further information on this type of event can be seen in Safer Radiotherapy the <u>unseen pathway</u>).

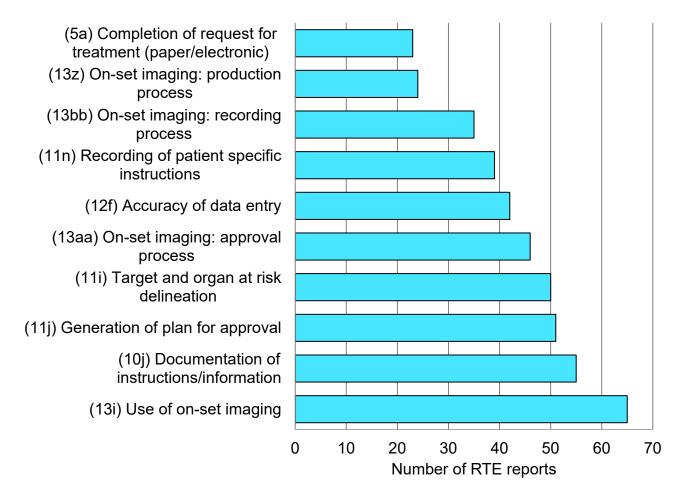
All of the most frequently reported process subcodes within the minor radiation incidents (level 3) RTE also featured in the most frequently reported minor radiation incident RTE within the <u>previous analysis (issue 39)</u>.

Near miss (level 4) RTE

A near miss (level 4) is defined as a potential radiation incident that was detected and prevented before treatment delivery (14).

Near misses comprised 27.1% (n = 948) of the RTE reported (Figure 6). The proportion of in the current reporting period has increased since (p = 0.03) the previous analysis, issue 39 (24.9%, n = 932). 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 = 430 out of 948 subset of RTE)



'Use of on-set imaging' comprised 6.9% (n = 65) of level 4 RTE. An example of this type of RTE would be the omission of a verification image before the start of a treatment fraction, this is then detected during treatment, a verification image is then acquired and treatment continues. Further guidance on mitigating and reporting these types of RTE can be seen in the Safer Radiotherapy good practice guidance series.

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>

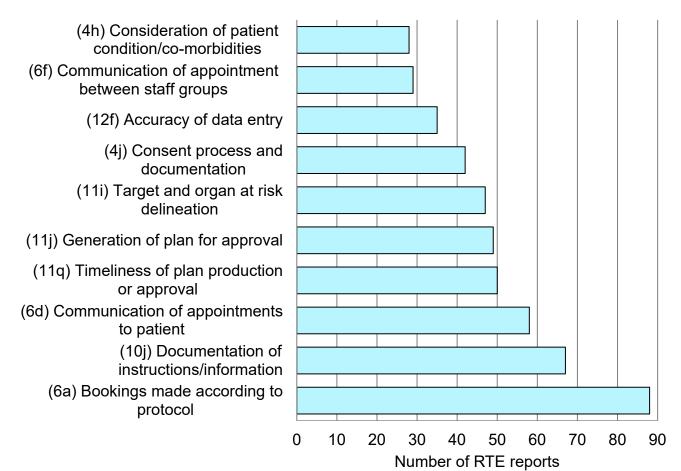
(issue 39). Similar to the minor radiation incidents (level 3), the most frequently reported level 4 RTE shown in Figure 10, includes the pathway subcodes associated with on-set imaging (17.9%, n = 170). Examples of 'on-set imaging: production process' associated RTE include using a kV image for verification when a CBCT should have been acquired, the kV image is used for treatment verification and no additional exposure is given. An example of 'on-set imaging: approval process' RTE includes when the second review of a verification image has not been completed, this is then detected whilst performing end of process checks during the next fraction of treatment. An example of 'on-set imaging: recording process' RTE includes the actions following image review not being undertaken, where this does not lead to incorrect or additional exposure.

Other non-conformance (level 5) RTE

Other non-conformance (level 5) is defined as a non-compliance with some other aspect of a documented procedure, but not directly affecting RT delivery (14).

Level 5 RTE comprised 34.4% (n = 1,205) of all RTE reported for this period (<u>Figure 6</u>). This is similar to the <u>previous analysis</u>, issue 39 (34.1%, n = 1,277), (p = 0.79).

Figure 11. Breakdown of most frequently reported level 5 RTE by process subcode (n = 493 out of 1,205 subset of RTE)



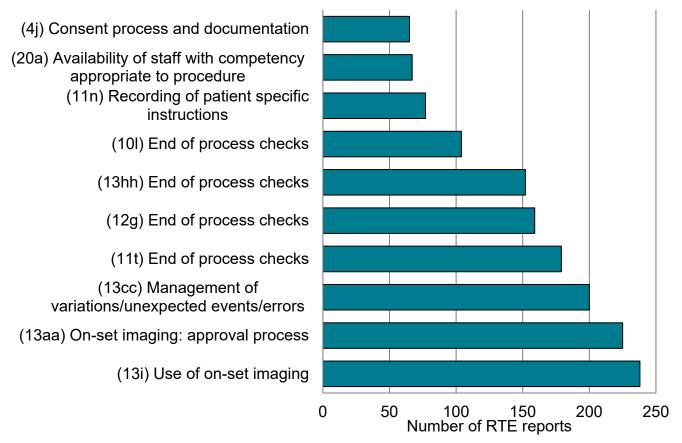
The most frequently reported level 5 process subcodes were 'bookings made according to protocol' comprising of 7.3% (n = 88) of all level 5 RTE (Figure 11). An example of this type of RTE is the incorrect booking of patient appointments, this includes booking appointments on the incorrect day and/or treatment machine. These are detected during an end of process check before affecting patient treatment. The booking process includes 6 different process subcodes, which were reported in 16.5% (n = 199) of level 5 RTE.

There are no treatment process subcodes contained within the most frequently reported level 5 RTE as shown within <u>Figure 11</u>. Nine of the most frequently reported process subcodes in the other non-conformances RTE were also seen in the <u>previous analysis (issue 39)</u>.

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>15</u>). SB embedded in the pathway coding (<u>7</u>) can be allocated to each RTE report to identify all points in the pathway where the error was not detected (failed SB). Multiple SB codes can be attributed to each individual RTE. A total of 2,241 failed safety barriers (FSB) were identified across the RTE reported (<u>Figure 12</u>).

Figure 12. Breakdown of failed safety barriers (n = 1,466 out of 2,241 subset of RTE data)



Treatment unit processes were attributed to 41.1% (n = 921) of all FSB. The most frequently reported FSB are represented in Figure 12. Treatment unit processes 'use of on-set imaging' was the most frequently reported FSB (10.6%, n = 238). An example of an RTE with this FSB includes when a verification image is not taken when required, this then has the potential for corrections to be missed. All of the FSB were also seen in the previous analysis (issue 39).

'End of process checks' occur at the end of each discrete part of the pathway and include 6 different pathway subcodes, these comprised of 27.0% (n = 604) of all FSB. The PSRT have undertaken a piece of work to look at the use of end of process checks which is highlighted in the January (number 6) and September (number 7) 2022 issues of <u>Safer Radiotherapy e-bulletin</u>.

Method of detection

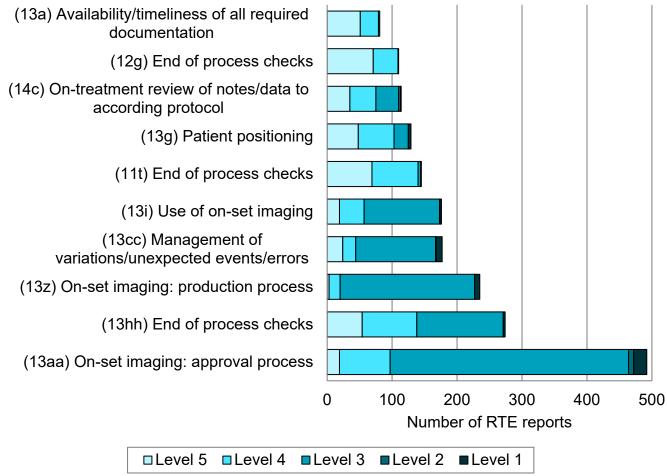
A method of detection (MD) is the process that identified the error and can be coded using the entire pathway taxonomy.

For this reporting period 45 providers indicated MD in 64.0% (n = 2,243) of reports. This is an increase since the <u>previous analysis (issue 39)</u>, where 43 providers indicated MD in 50.0% (n = 1,875) of reports. Following consistency checking, UKHSA coded a further 1,062 reports with MD taxonomy, resulting in 3,305 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' (14.9%, n = 492). This MD was most frequently reported with a primary process code 'on-set imaging: production process' (28.7%, n = 141). Seven of the most frequently reported MD occurred at the treatment unit process.

'End of process checks' occur at the end of each discrete part of the pathway and include 6 different pathway subcodes. These comprised of 17.5% (n = 580) of all MD, of which 71.0% (n = 412) detected the error, stopping the RTE from propagating across the pathway. For each part of the pathway there are 'other' pathway subcodes. Before consistency checking 13% (n = 291 out of 2,243) of MD were assigned an 'other' pathway subcode. After consistency checking this was reduced to 6.6% (n = 149). 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 = 1,933 out of 3,305 subset of RTE data)



Causative factors

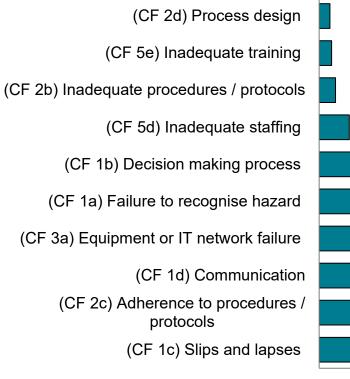
The use of a causative factor (CF) taxonomy enables identification of system problems or contributory factors that could precipitate a range of different incidents ($\underline{16}$).

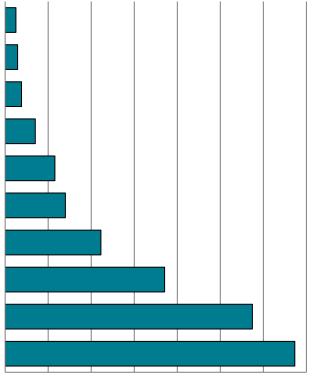
From the 3,503 RTE reported, 87.3% (n = 3,059) contained CF coding. These were reported from 54 providers. This is a slight increase in RTE allocated with CF since the <u>previous</u> <u>analysis (issue 39)</u>, when 54 providers reported and 83.1% (n = 3,114) of RTE contained CF. UKHSA were able to assign primary CF to all but one of the remaining RTE reports.

Multiple CF can be assigned to a single RTE, across the 3,502 RTE, 976 contained multiple CF totalling 4,783 CF codes. <u>Figure 14</u> shows the most frequently reported CF codes.

The most frequently reported CF was 'slips and lapses' making up 28.1% (n = 1,346) of all CF reported (<u>Figure 14</u>). <u>Issue 22 of Safer Radiotherapy</u> includes guidance on minimising the occurrence of RTE caused by a slip or lapse of an individual.

Figure 14. Breakdown of most frequently reported CF (n = 4,516 out of 4,783 subset of data)





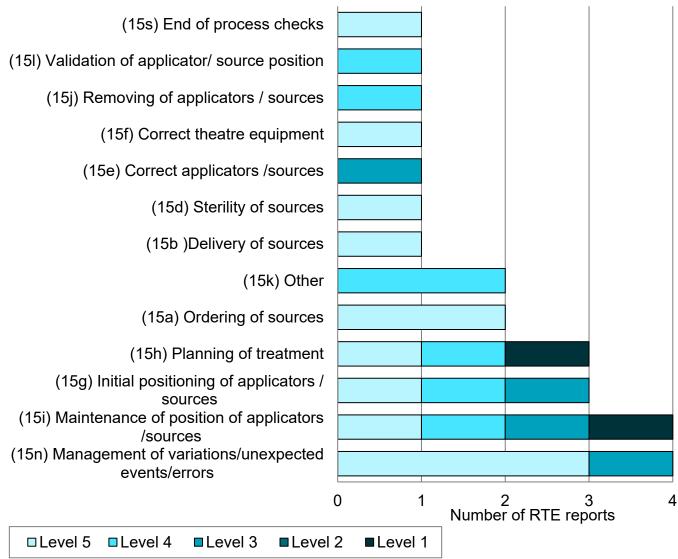
0 200 400 600 800 1000 1200 1400 Number of times contributory factor reported

Brachytherapy RTE

Brachytherapy (BRT) is a RT sub-speciality which involves the placement of a sealed source inside or close to the treatment area (<u>17</u>). BRT makes up less than 3% of all RT episodes (<u>18</u>). Therefore, the number of BRT associated RTE would be expected to be low and should be interpreted with caution. RTE coded with BRT process subcodes as the primary code accounted for 0.7% (n = 25) of reports, a slight decrease from the <u>previous analysis</u>, <u>issue</u> <u>39</u> (1.0%, n = 36). BRT RTE were submitted from just 13 providers for this reporting period. A breakdown of the brachytherapy RTE can be seen in <u>Figure 15</u>.

The most frequently reported BRT process subcodes was 'management of variations, unexpected events or errors' and 'maintenance of position of applicators or sources' comprising 16.0% (n = 4) of all BRT RTE. An example of BRT RTE associated with 'management of variations/unexpected events or errors' includes equipment malfunction leading to delays in treatment, this can include a breakdown in the loader for LDR, or cracks in central tube for HDR vault kit. An example of 'maintenance of position of applicators or sources' includes a change in the position of applicators, this may be detected prior to treatment using on-set verification imaging.

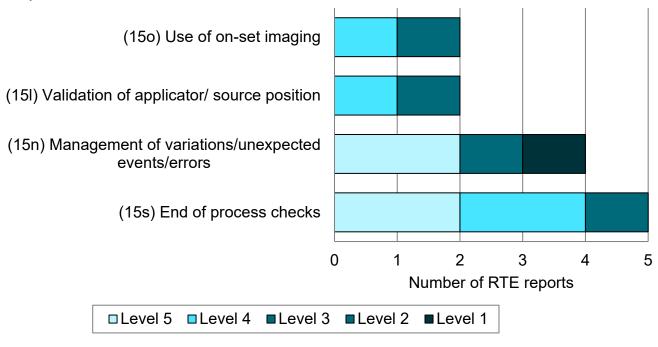
Figure 15. Breakdown of most frequently reported BRT RTE coded '15' by level (n = 25)



From the 25 BRT RTE, there were only 32 subcodes reported. Of these, 12 were FSB, the most frequently reported was 'management of variations' comprising 33.3% (n = 4). The FSB shown in <u>Figure 12</u> indicate imaging associated FSB as the most frequently reported FSB associated with external beam deliveries. This difference is due to a greater uptake of IGRT in external beam RT than in BRT

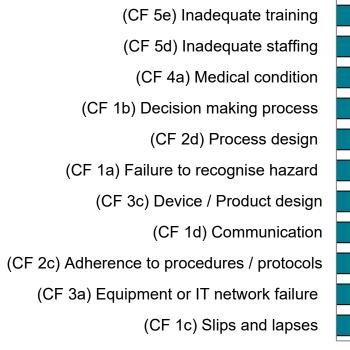
Of the 25 BRT RTE, 38.9%, (n = 12) were assigned a MD subcode. During consistency checking 12 further BRT RTE were assigned a MD using the text within the report. These are shown in <u>Figure 16</u>, 12 of which of which were singular and not shown within the chart.

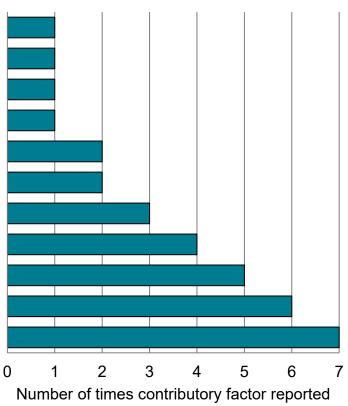
Figure 16. Breakdown of BRT method of detection by level (n = 13 out of 24 subset of RTE)



All CF codes were reviewed within this subset of the data and 33 CF identified (Figure 17). The most frequently reported CF associated with BRT RTE was 'slips and lapses' comprising of 21.2% (n = 7) of all the CF for BRT RTE. The trends of these BRT CF are slightly different when compared to the entire data as in Figure 14.

Figure 17. Breakdown of BRT RTE CF (n = 33)





References

- 1. World Health Organization. <u>Reporting and learning for patient safety</u>
- 2. European Commission 2015. <u>Radiation Protection No. 181, General guidelines on risk</u> management in external beam radiotherapy
- 3. The Stationery Office, London, SI 2017/1322. <u>The Ionising Radiation (Medical Exposure) Regulations 2017</u>
- 4. The Stationery Office, London, SR 2018/17. <u>The Ionising Radiation (Medical Exposure)</u> <u>Regulations (Northern Ireland) 2018</u>
- 5. The Stationery Office, London, SI 2018/121 <u>The Ionising Radiation (Medical Exposure)</u> (Amendment) Regulations 2018
- 6. Care Quality Commission. <u>IR(ME)R notification guidance</u>
- 7. Public Health England (PHE). <u>Development of learning from radiotherapy errors</u>
- 8. Society of Radiographers. <u>Pause and check</u>
- 9. Society of Radiographers. <u>Preventing patient ID errors</u>
- 10. NHS England. Patient safety learning response toolkit
- 11. Imperial College London. Systems analysis of clinical incidents: The London protocol
- 12. The Radiotherapy Board made up of the Society and College of Radiographers; Institute of Physics and Engineering in Medicine and the Royal College of Radiologists. <u>Ionising Radiation (Medical Exposure) Regulations: Implications for clinical practice in</u> <u>radiotherapy</u>. London: The Royal College of Radiologists 2020 Ref RTBoard
- 13. National Reporting and Learning Service (NRLS)
- 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
- Ford E and others. 'Consensus recommendation for incident learning database structures in radiation oncology.' Medical Physics December 2012: volume 39, issue 12, pages 7,272 to 7,290
- 16. Clark B and others. 'The management of radiation treatment error through incident learning.' Radiotherapy and Oncology 2010: volume 95, pages 344 to 349
- 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 to 23
- 18. <u>Cancer statistics</u>

About the UK Health Security Agency

UKHSA is responsible for protecting every member of every community from the impact of infectious diseases, chemical, biological, radiological and nuclear incidents and other health threats. We provide intellectual, scientific and operational leadership at national and local level, as well as on the global stage, to make the nation health secure.

UKHSA is an executive agency, sponsored by the Department of Health and Social Care.

© Crown copyright 2023

For queries relating to this document, please contact: <u>radiotherapy@ukhsa.gov.uk</u>

Published: May 2023 Publishing reference: GOV-14750



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

