

## Safer Radiotherapy

E-bulletin #14 September 2024

Welcome to the Safer Radiotherapy (RT) E-bulletin, which provides key messages and learning from radiotherapy error (RTE) reports and the national patient safety initiative.

Representatives from the UK Health Security Agency (UKHSA), the Royal College of Radiologists (RCR), the Society of Radiographers (SoR), Institute of Physics and Engineering in Medicine (IPEM), NHS England (NHSE) and a lay representative form the Patient Safety in Radiotherapy Steering Group (PSRT) which collaborates to support the coordination of efforts to improve patient safety in RT across the UK. This work includes the collation, analysis, and dissemination of learning from RTE reports.

Anonymised RTE reports were submitted on a voluntary basis through the National Reporting and Learning System (NRLS) and Learn from Patient Safety Events service (LFPSE) of NHSE, the Once for Wales (OfW) Concerns Management System and directly to UKHSA, to promote learning and to minimise recurrence of these events. Each Safer RT E-bulletin accompanies the Triannual RTE Analysis & Learning Report, which summarises learning from RTE reports submitted for the preceding 4-month period. The report is designed to disseminate learning from RTE to professionals in the RT community to positively influence local practice and improve patient safety.

Please email **radiotherapy@ukhsa.gov.uk** for advice on incident learning from RTE and with any suggestions for the E-bulletin. Published three times a year, the next issue will be shared in January 2025. To subscribe to future editions please follow this link.

Thank you to all RTE reporters who facilitate this work.

## LFPSE and English RTE reporting update

Every English NHS radiotherapy provider has contributed during the current review period (April-July 2024) via LFPSE or NRLS, a fantastic achievement which demonstrates a strong commitment to patient safety in the radiotherapy community. NRLS was decommissioned on 30<sup>th</sup> June 2024 and English NHS patient safety events, including RTE, are reported via LFPSE.

To ensure RTE reports may be identified within LFPSE, English radiotherapy providers are requested to ensure that the national radiotherapy trigger code "TSRT9" and full coding taxonomy is added to the "Describe what happened" field and / or the "What is the radiotherapy error code?" field.

If the radiotherapy trigger code (TSRT9) and coding taxonomy is not included within a report, the report will not be identified as an RTE, and subsequently will not be shared with UKHSA or included in the national analysis.

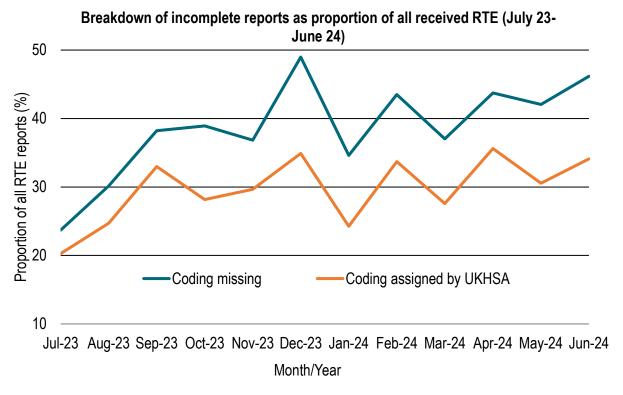
If you have any queries or questions about LFPSE reporting, please do not hesitate to email **radiotherapy@ukhsa.gov.uk** for advice.

# The Ionising Radiation (Medical Exposure) (Amendment) Regulations (IR(ME)AR) 2024

The IR(ME)AR 2024 were laid before Parliament on 3<sup>rd</sup> September 2024 and come into force in England, Scotland and Wales on 1<sup>st</sup> October 2024. An update on changes can be found within the first edition of the Medical Exposures Group E-bulletin.

## RTE data quality update

Between July 2023 and June 2024 12,729 RTE reports were received. Of these 7,915 were fully coded with RTE taxonomy, including classification, pathway, method of detection and contributory factors. The percentage of incomplete RTE reports with one or more of the required taxonomy coding missing can be seen as teal in the chart below. Over the one-year period 37.8% of RTE reports received were incomplete.



UKHSA completed coding for a proportion of the incomplete reports based on text contained within each RTE report (orange line on the chart). However, the percentage of incomplete reports which did not contain sufficient information to assign a full taxonomy increased from 7.7% between July to December 2023 to 10.2% for the first six months of 2024.

All providers are asked to apply:

- Trigger code (TSRT9): for reporting via LFPSE
- Classification level: describes severity (5 levels)
- Primary pathway subcode: describes point in the pathway where error initially occurred
- Additional pathway subcodes: describes subsequent points in the pathway where errors may have occurred (including failed safety barriers (FSB))
- Method of detection: how the event was identified
- Contributory factor: describes a system failure or condition that precipitated the event. Multiple contributory factors may be assigned

The format of coding for submission is:

TSRT9/ Level 4/ 13c/ 13l/ MD13hh/ CF1c/ CF2c.

If you have any further queries in regard to the assignment of the taxonomies, please email **radiotherapy@ukhsa.gov.uk**.

## Advancing Safer Radiotherapy (ASR) - update

Work continues on ASR. All chapters have been drafted and peer reviewed. These chapters are currently being formatted for publication. Thank you to all those who are taking part in this work. It is hoped the document will be published by the end of 2024.

## Eighth Biennial RT error data analysis and learning report

The report published in July provides a broad and detailed overview of UK incident reporting between January 2022 and December 2023.

It compares data with the preceding 2-year period and additionally contains trend analysis of five years of UK reporting between 2019 to 2023. The following is a short synopsis of some of the findings whilst the full report is available here.

Over the last two years, all NHS providers submitted reports to the voluntary incident learning system, reflecting a strong community commitment to radiotherapy safety and shared learning from incidents. Across this two-year period 22,113 RTE reports were reviewed, an increase from 18,681 in the previous two-year period.

Most reports (97.5%) were categorised as lower-level (Level 3-5) events not affecting the outcome of patient care. However, the percentage of Level 1 incidents as a proportion of all RTE has increased from 0.9% to 1.6% compared to the previous 2-year reporting period.

In terms of data quality, 58.4% of reports were fully classified and coded by local RT providers. This represents a marked reduction from the previous 2-year period (79.6%). The ongoing transition to LFPSE for English providers may have contributed to this change in data report quality.

The most frequently reported subcode continues to be 'on-set imaging: production process' (13.0%). A large proportion of these were due to equipment malfunction. A case study concerning pathway subcode 13z; 'on-set imaging: production process' can be found in issue 44 of the triannual RTE analysis. Reports from all 4 on-set imaging pathway codes combined made up 22.6% of all RTE.

Over the past 5 years, the percentage of RTE associated "management of variations/unexpected events/errors" has doubled (2.4% to 4.8%). Most of these reports are triggered by equipment malfunction.

Level 3 delineation events coded under "target and organ at risk delineation" experienced a significant increase over the five-year period: 3.4% to 4.7%.

The report contains the following local recommendations:

- All NHS UK providers should continue to use the national taxonomies, including classification, pathway subcodes, failed safety barriers, method of detection and contributory factors, to code all levels of RTE for local analysis, learning and practice.
- Local employers should provide adequate resourcing to support the
  development and maintenance of effective patient safety systems and
  processes. Likewise, they should encourage national reporting of all
  classification Levels of RTE on a monthly basis to ensure timeliness of shared
  learning.
- Equipment-related incidents should be reported to the relevant regulator, manufacturer and UKHSA. If equipment faults persist a risk assessment should be undertaken for the ongoing use of the device.
- Local learning should be compared with national data and used to inform local and regional practice.

 Outputs from local RTE analysis should be used to inform prospective risk assessments as part of a study of the risk of accidental and unintended exposures.

Other national recommendations can be seen within the full report, of which a number have already been acted upon.

## Significant Accidental and Unintended Exposures (SAUE) under IR(ME)R guidance update, August 2024

The guidance for employers and duty-holders on notifying SAUE under IR(ME)R has been reviewed and updated, including:

- updated requirements for a detailed investigation and report when notifying a SAUE
- amended notification criteria, for example notification code 4.2a has been updated to include hardware or software failure.

Further detail including examples can be found here.

## Care Quality Commission (CQC) annual IR(ME)R report published

The CQC has published the IR(ME)R annual report 2023/2024. Between April 2023 to March 2024, CQC received 244 radiotherapy (RT) notifications. This is a decrease since 2022/2023 when 270 RT notifications were received. Planning and verification imaging accounted for 44% of all RT notifications received.

The report includes an overview of RT SAUE notifications, inspections and enforcement as well as key themes within RT.

## **Publication of IPEM Report 113: Medical and Dental Guidance Notes**

IPEM has published Medical and Dental Guidance Notes (Second Edition): A good practice guide on all aspects of ionising radiation protection in the clinical environment: IPEM Report 113. The guidance notes include general best practices of the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017. A hardcopy or eBook can be ordered from IOP Publishing bookstore.

## **Principles of Reirradiation**

The RCR has published the Principles of Reirradiation. The aim of the document is to provide general principles on clinical considerations for clinical oncologists contemplating reirradiation, including the likely benefit that reirradiation may achieve against the risk of toxicity that reirradiation may cause. The document provides links to tumour-site-specific guidance where available.

## National Guidance for volumetric-modulated arc therapy (VMAT) or intensity-modulated radiotherapy (IMRT) in anal cancer

The RCR has also published National Guidance for VMAT and IMRT in anal cancer. This document provides a practical and evidence-based consensus guideline for planning and treatment of patients receiving VMAT or IMRT to a full radiotherapy dose for anal cancer in the UK.

## **UK** incident learning and local management of RTE survey

A national survey was deployed in March 2024. The purpose of the survey was to investigate the current use of use of incident learning systems (ILS), application of the coding taxonomy and local management and analysis of RTE. The survey contained 15 questions and the response rate was 68.7% (46/67), although a small number of respondents did not complete all questions in the survey.

### Current use of local risk management systems

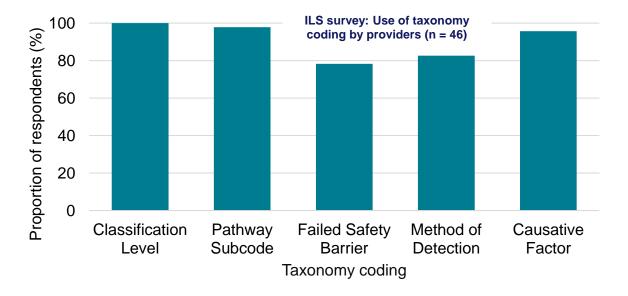
- 85% (n = 39) of respondents use electronic reporting systems, a minor increase from 81% during the 2021 survey. The remainder use a combination of paper and electronic, and 13 providers reported the use of multiple electronic systems.
- A dedicated member of staff for the management of departmental RTE was indicated by most respondents (83%, n = 38), with many respondents confirming they adopt a full MDT approach.
- Training for staff was given by 91% (n = 42) of respondents.

#### Reporting of classification levels

All classification levels were reported locally by 89% (n = 41) of providers; a
reduction from 100% respondents in the 2021 survey. Of those 41 respondents
reporting all levels of RTE locally only 12 (29%) shared all levels of RTE with
trust/board risk management teams, however 20 (49%) shared all RTE
nationally.

## Use of taxonomy coding

• All respondents utilised some of the RTE taxonomies. The breakdown in provider use is shown in the chart below. All reported use of the classification level, 98% (n = 45) utilised pathway subcodes, 96% (n = 44) used the causative factor taxonomy, 83% used the method of detection (n = 38), and 78% (n = 36) used the failed safety barrier taxonomies. This indicates that 83% of respondents include all required RTE taxonomies. However the 43<sup>rd</sup> issue of the Safer Radiotherapy: triannual analysis indicates that only 58% of reports shared nationally with UKHSA contain all required taxonomy codes. The recent transition between reporting platforms for English providers may account for some of this discrepancy.



#### Trend analysis and risk assessments

- All the 45 respondents who responded the relevant survey question stated they
  completed trend analysis of RTE and 73% (n = 33) completed this monthly. One
  respondent stated that levels 1 and 2 RTE reports were shared for regional
  learning.
- The Safer Radiotherapy publications were stated to be used to inform local analysis by 85% (n = 39) of respondents. The outputs of local RTE analysis were reported to be used to inform prospective risk assessments as part of the study of accidental or unintended exposures by 91% (n = 42) of respondents.

It is recommended that all levels of RTE are reported locally and nationally, and where possible, the national RTE taxonomies should be used to complete trend analysis. The PSRT are currently refining the national RTE taxonomies as part of the ASR work and hope this will reflect current techniques and technologies.

Sincere thanks to all radiotherapy services who were able to participate in the survey.

## New Royal College of Radiologists radiotherapy consent forms

The RCR have published three new consent forms relating to Central Nervous System (CNS), bladder radiotherapy and prostate brachytherapy, all of which can be found here

## **Ro-ILS** publication update

RO-ILS are celebrating the 10-year anniversary of their launch. They aim to facilitate safer and higher quality care in radiation oncology by providing a mechanism for shared learning and have recently produced four educational publications, all of which are recommended reading.

Case Study 18: Pictures Worth a Thousand Words

Physician Great Catch

Case Study 19: Wrong Vertebral Body Alignment Using Auto-Registration for SBRT

Rushing Themed Report

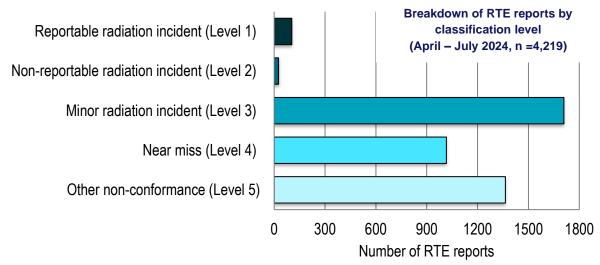
Dates for the diary	
MPEP, Al in imaging and treatment planning	12 November 2024, online
RTQ SIG meeting	6 December 2024, London
RCR, Shaping the future of AI in healthcare	3-4 February 2025, London
BIR Annual Radiotherapy and Oncology Meeting 2025	6-7 March 2025, London
UKHSA Conference 2025	25-26 March 2025, Manchester

## RTE data analysis - April 2024 to July 2024

The full detailed data analysis is available here and includes data on primary process subcoding, failed safety barriers, methods of detection, contributory factors, and the severity classification of the RTE. These taxonomies are described in the Development of Learning from RTE. A summary of findings is presented below.

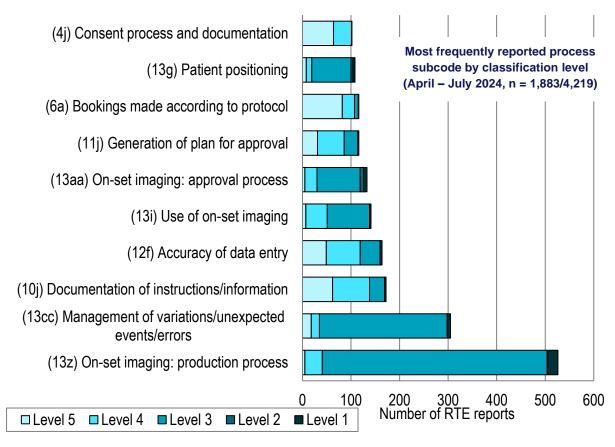
### Classification (Level) of RTE

Of those 4,219 RTE reported, 4,089 reports (96.9%) were classified as minor radiation incidents, near misses or other non-conformances (Level 3 - 5). These had no significant effect on the planning or delivery of individual patient treatments or their outcome.



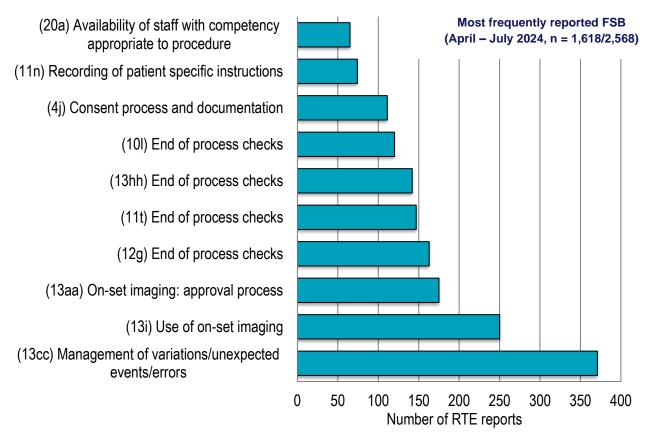
## Primary process subcode

The most frequently reported points in the patient pathway where the RTE occurred are shown below. This is broken down by classification level. Consistent with the previous analysis 'on-set imaging: production process' was the most frequently reported process code (12.5%, n = 526/4,219).



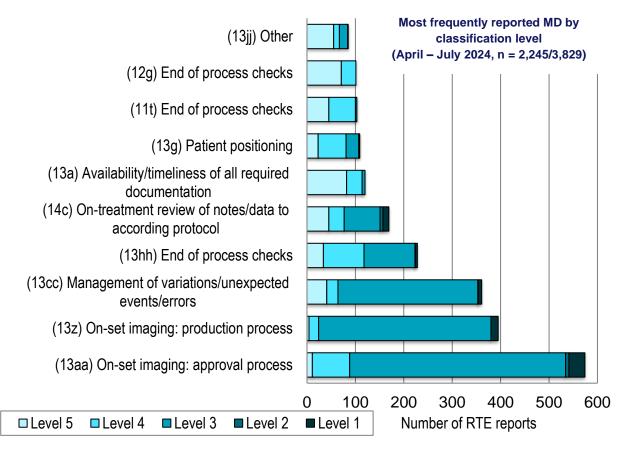
## Failed safety barriers (FSB)

Multiple FSB can be attributed to each individual RTE. A total of 2,568 FSB were identified across all reported RTE. Treatment unit process 'management of variations/ unexpected events/ errors' was the most frequently reported FSB (14.4%, n = 371).



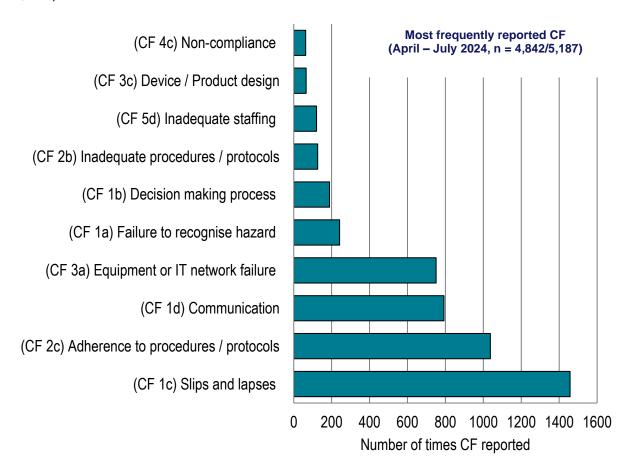
## Method of detection (MD)

For this reporting period 3,829 reports included MD coding or data. The most frequently reported MD was 'on-set imaging: approval process' (15.0%, n = 574).



## **Contributory Factors (CF)**

Each RTE can be assigned multiple CF codes. A total of 5,187 CF were reported in this period. The most frequently reported CF was 'slips and lapses' at 30.1% (n = 1,457).



#### Safer Radiotherapy resources

Safer RT: **triannual error analysis and learning** reports contain analysis and learning from RTE reported voluntarily by UK RT providers and the relevant reporting authorities.

Safer RT: E-bulletins provide key messages from the national patient safety initiative

Safer RT: biennial error analysis and learning reports contain 2 years analysis and learning from RTE reported voluntarily by UK RT providers and the relevant reporting authorities.

A series of 15 minute RT learning resources developed to support RT healthcare professionals in learning from RTE are included on the **Medical Exposures Group webpages** 

**Towards Safer Radiotherapy** contains the classification taxonomy for use when assigning a RTE severity level

**Development of Learning from Radiotherapy Errors** provides the pathway coding safety barrier, method of detection and causative factor taxonomies

#### Links to key publications

IR(ME)R: implications for clinical practice in radiotherapy

Guidance for compiling training records for clinical oncologists

IR(ME)R notification codes, categories and criteria

#### **Guest editorial:**

Trending error and incident reports to influence workforce changes
Damian Parr
Head of Therapeutic Radiography Services
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Within radiotherapy it is vital that risks are managed to minimise the potential for adverse events (1). Our local practice encourages reporting of all levels of radiotherapy errors (RTE) and supports a no blame culture. The radiotherapy management team wanted to explore whether utilising trend analysis of reported RTE data would allow us to:

- Identify areas for improvement
- Compare local trends to national RTE data
- Identify anomalies of potential concern
- Consider appropriate actions to rectify identified issues
- Improve future practice

#### Methods

RTE reports were collated monthly from May 2020. Trend analysis was performed, considering the following factors: number of reports, RTE classification level, process subcode, failed safety barrier, method of detection, and causative factor. Data was compared monthly, quarterly, yearly and against national data to identify trends and patterns. The analysis provided information on outliers, local patterns, and reporting peaks within certain operational areas. This permitted investigation into possible contributing factors, particularly in terms of correlation with workforce fluctuations.

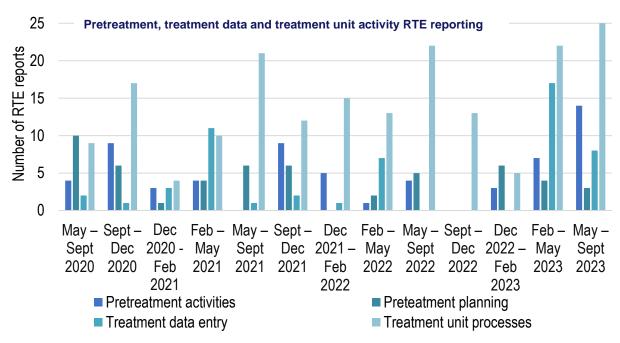
#### Results

Comparisons with national data confirmed similarities with local RTE reporting, for example the highest number of RTE occurred during treatment unit processes (47.0% compared with national figure of 44.7%) (1).

The data analysis proved useful in highlighting areas of concern. Analysis over time allowed identification of increased error activity as seen in the chart. Of note, increased error activity was seen in the pretreatment area during three quarters (Sept - Dec 2020, Sept - Dec 2021, May - Sept 2023), treatment data entry during a further three quarters (Feb - May 2021, Feb - May 2022, Feb - May 2023) and pre-treatment planning during one quarter (May - Sept 2020). Please see figure 1.

Staffing levels and experience were correlated within the study timeframe. In-depth analysis highlighted some commonalities, primarily peaks in pre-treatment and treatment data entry error reporting activity occurred during periods of insufficient staffing, increased staffing changes, or when new or inexperienced staff were operating in these areas.

In the data entry area, errors increased when the staff allocated to that area had to be moved to work clinically on a machine due lack of staffing, resulting in data entry being completed by staff with conflicting clinical priorities rather than data entry as their sole focus.



Other correlations included increased number of new staff members, and the introduction of changes of practice or new developments, examples being the introduction of new image scheduling and DIBH implementation.

Peaks in pre-treatment activities, mainly CT, proved similar, but were attributed mainly to staff being pulled into the area in an ad hoc fashion due to staffing pressures. High levels of staff rotation created areas of uncertainty and unfamiliarity and appears to have led to increased levels of errors reported.

This analysis, alongside staff group engagement, permitted opportunities to identify areas of improvement. These include changes to staffing and workforce allocation considering a safe staffing level in all areas of the department, and to investigate ways to minimise inconsistent rotation of staff. Monthly information posters aims to increase engagement with staff by creating a forum for conversation and improvement. Evaluation of the impact of implemented changes is key and carried out within a reasonable timeframe by analysing further trends in error reporting.

#### Conclusion

Locally analysing RTE has proved a useful tool in understanding the types of infrastructure changes that may influence when and why errors occur. It has allowed us to not only retrospectively look at why RTE occur but also prospectively highlight situations where errors are more likely to happen and take actions to alleviate this. This information can feed into workforce planning to establish a minimum safe staffing level and rotational pattern.

#### **Future**

Our next step is to map the level of RTE occurrence and consider staff absence and sickness levels, annual leave, and headcount. We would like to see if any of these variables influence reporting volumes in various departmental areas. Alongside this we feel it would be enlightening to achieve better mapping of national data onto our local data to determine if there are common areas contributing to errors in radiotherapy across the UK.

#### Reference

1. UK Health Security Agency (2023). Safer Radiotherapy: Triannual RTE analysis and learning report. Issue 41