UK Health Security Agency

Safer Radiotherapy

E-bulletin #16
May 2025

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

In this special edition we celebrate the publication of Advancing Safer Radiotherapy and the National Patient Safety Radiotherapy Event Taxonomy.

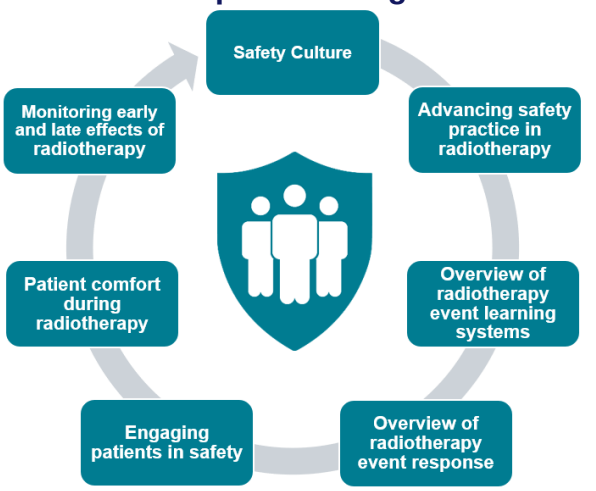
Advancing Safer Radiotherapy

Guidance for radiotherapy providers on improving patient safety.

UKHSA are delighted to announce the publication of Advancing Safer Radiotherapy (ASR): Guidance for radiotherapy providers on improving patient safety.

ASR will provide the radiotherapy community with guidance on how to place a greater focus on the patient as an active, valued participant in safety. Secondly, it will develop existing national recommendations, in place since the publication of Towards Safer Radiotherapy in 2008, to reflect contemporary approaches to patient safety.

Advancing Safer Radiotherapy chapter headings



Why do we need further guidance within radiotherapy to advance patient safety?

Since **Towards Safer Radiotherapy (TSRT)** was published in 2008, great strides have been taken by the radiotherapy community on improving and consolidating patient safety. Contemporary radiotherapy may be described as a safe treatment modality, with **current data** demonstrating that the likelihood of a notifiable event affecting delivery of radiotherapy is less than 0.03% per prescribed treatment course.

"Don't look where you fell, but where you slipped" African proverb

Despite the very small probability of radiotherapy events (RTEs) affecting the delivery of treatment to the patient, some patient safety RTEs do persist, and trends can remain stubbornly prevalent. **Data** demonstrates that contributing factors associated with RTE tend to focus on where we fall; on the actions of individuals involved in the last interaction prior to an event. However, events frequently originate where we slip; amongst the multiple interactions between myriad complex, dynamic environments, components and processes that constitute our radiotherapy systems.

To advance safety in radiotherapy we must progress from talking about human error towards talking about safer systems, adopting a philosophy of learning from what works, rather than only from what does not. Finally, we must consider the role of the crucial stakeholder in radiotherapy safety, the patient.

What was done?

Advancing Safer Radiotherapy (ASR) has been developed by the multi-disciplinary radiotherapy community not to replace TSRT, but to build on its foundational themes. Its purpose is also to reflect contemporary approaches to patient safety. This is achieved by seeking a deeper understanding of state-of-the-art safety tools and practices and to

offer guidance on their practical application, including system-based approaches to RTE analysis and proactive risk management.

Secondly, this document advocates for the positioning of the patient at the centre in radiotherapy safety. It underscores the merits of patient engagement in all areas of practice and encourages health professionals to consider how they can influence the future shape of radiotherapy services for the benefit of patients.

Where it is available?

The full published document “Advancing Safer Radiotherapy” can be accessed **here**.

National Patient Safety Radiotherapy Event Taxonomy

Why do we need updated taxonomy guidance within radiotherapy?

UK national voluntary reporting of RTE began in 2010 and has become well established with all NHS providers submitting reports. Independent providers began submitting from 2022. The use of standardised terminology, classification and coding allows providers to compare their local analysis to the regional and national picture. The terminology and taxonomies were originally defined in 2008 within **TSRT** and refined in 2016 with the publication of Development of Learning from Radiotherapy Errors.

In 2022, the PSRT agreed to update the taxonomy to better reflect contemporary practice and learning in the patient safety sphere. The objective of the work included:

- provision of amendments to definitions and taxonomies to be used when categorising RTE for analysis
- collating all terminology, definitions and taxonomies within a single document for ease of reference
- provision of guidance on the application of taxonomies and submission of RTE reports for inclusion in national analysis and learning

What was done?

The radiotherapy coding taxonomy includes all RTE along the radiotherapy pathway, including planning scans undertaken in the radiotherapy department, on-set verification imaging, and radiotherapy treatment exposures.

Terminology has been introduced, or updated, including examples detailed in Figure 1. Further refinements include:

- updates to the descriptions of 21 pathway subcodes to reduce ambiguity
- introduction of 11 new pathway subcodes
- merging of a number of pathway subcodes to reduce duplication
- end of process check codes expanded to allow for additional granularity

It is important that an RTE report contains sufficient information to confirm relevant codes and classification from the current taxonomy guidelines. The guidance contains further detail on the narrative of the event.

Updated terminology	Previous terminology	Acronym	Brief Description
Radiotherapy event	Radiotherapy error	RTE	Unintended divergence from local protocol of a radiotherapy treatment or process
Contributory factors	Causative factor	CF	Describes system failures or conditions that precipitated an RTE
Good Catch	Near Miss		Interception and prevention of a potential radiotherapy or MRI incident.
Modality		D	14 new codes that describe the radiotherapy type/technique.

Figure 1. Updated terminology for RTE reports.

Where it is available?

The published National Patient Safety Radiotherapy Event Taxonomy can be found **here**, along with a excel **spreadsheet** containing all the 2025 taxonomies.

For patient safety events which occur within diagnostic imaging, MRI outside the radiotherapy department, and nuclear medicine including molecular radiotherapy, providers should refer to the **national taxonomy for incident learning in clinical imaging user guidance.**

The PSRT would also like to thank the working party members and stakeholders who participated in the development of ASR and the RTE taxonomy refinement.

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).** The group collaborates to support the coordination of efforts to improve patient safety in radiotherapy across the UK. This work includes the collation, analysis, and dissemination of learning from RTE.

Anonymised RTE reports are submitted on a voluntary basis through the Learn from Patient Safety Events service (LFPSE) of NHSE, the Once for Wales (OfW) Concerns Management System, and directly to UKHSA. 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 learning from RTE and with any suggestions for the E-bulletin. Published three times a year, the next issue will be shared in September 2025. To subscribe to future editions please follow this link. Thank you to all RTE reporters who facilitate this work.

ARSAC Notes for Guidance Update

The latest version of the ARSAC Notes for Guidance (NfG) March 2025 is now published and can be found **here**. The following updates are of note:

- Updates on information to include in practitioner applications
- Additional guidance on the use of Diagnostic Reference Levels (DRLs)
- Updates to some of the national DRLs for Positron Emission Tomography (PET) procedures involving 18F-FDG
- Updates to guidance on conception and the avoidance of pregnancy following nuclear medicine administrations
- Update to guidance on the time to avoid pregnancy following therapeutic procedures
- Updates to guidance for individuals who are breastfeeding or lactating
- A change of the URL address for the ARSAC Online portal

The current URL address for the ARSAC online portal can be found **here**.

New Royal College of Radiologists radiotherapy consent forms

The RCR have published new consent forms for sarcoma, all of which can be found **here**.

BS EN IEC 60601-2-68:2025 - Medical electrical equipment

BS EN IEC 60601-2-68:2025 is a British and European standard that specifies the basic safety and essential performance requirements for X-ray-based image-guided radiotherapy equipment used with external beam equipment like electron accelerators or radionuclide beam therapy equipment. It covers safety aspects of both kilovoltage and megavoltage X-ray imaging devices integrated with external beam equipment for image-guided radiotherapy. The standard was published by BSI on 4 February 2025 and is available **here**.

The impact of staff fatigue on patient safety

A recent HSSIB report investigated the impact of staff fatigue on patient safety. While the investigation focused on staff working in acute hospitals, the findings will be relevant to providers and staff in other health and care settings. The report concluded that staff fatigue contributes directly and indirectly to patient harm. A positive safety culture is considered a key enabler to support organisations to recognise and manage fatigue risk. The report was published on 24 April 2025 and can be accessed **here**.

National RTE aggregate data

The third full dataset for all RTE reported across the UK including data from January to December 2024 is now available. This data is available to all reporting RT providers upon request.

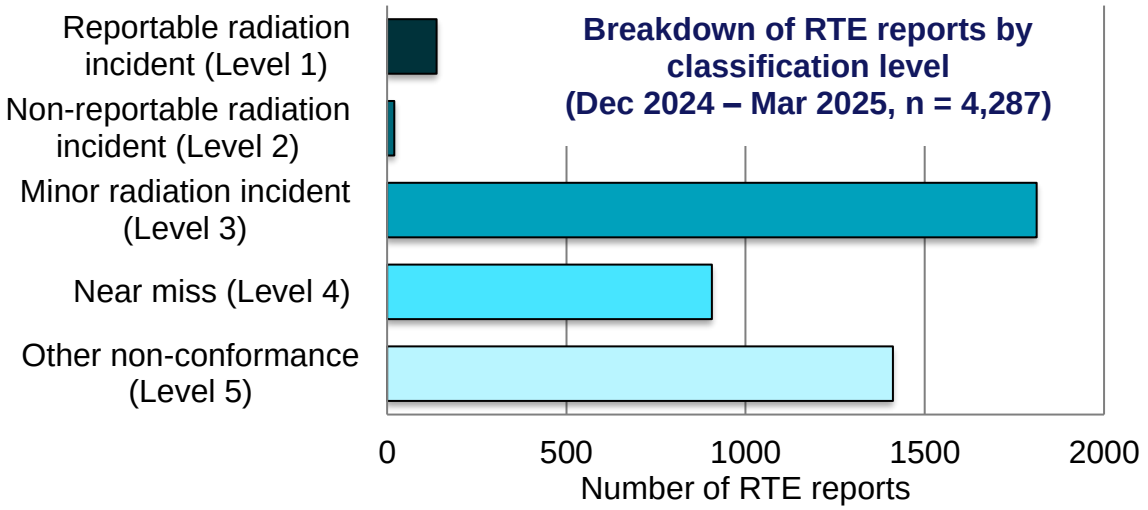
If you would like to receive this dataset, please email **RTEdata@ukhsa.gov.uk** with the organisation name and how you propose to use the national aggregate RTE data.

RTE data analysis – December 2024 to March 2025

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. A summary of findings is presented below.

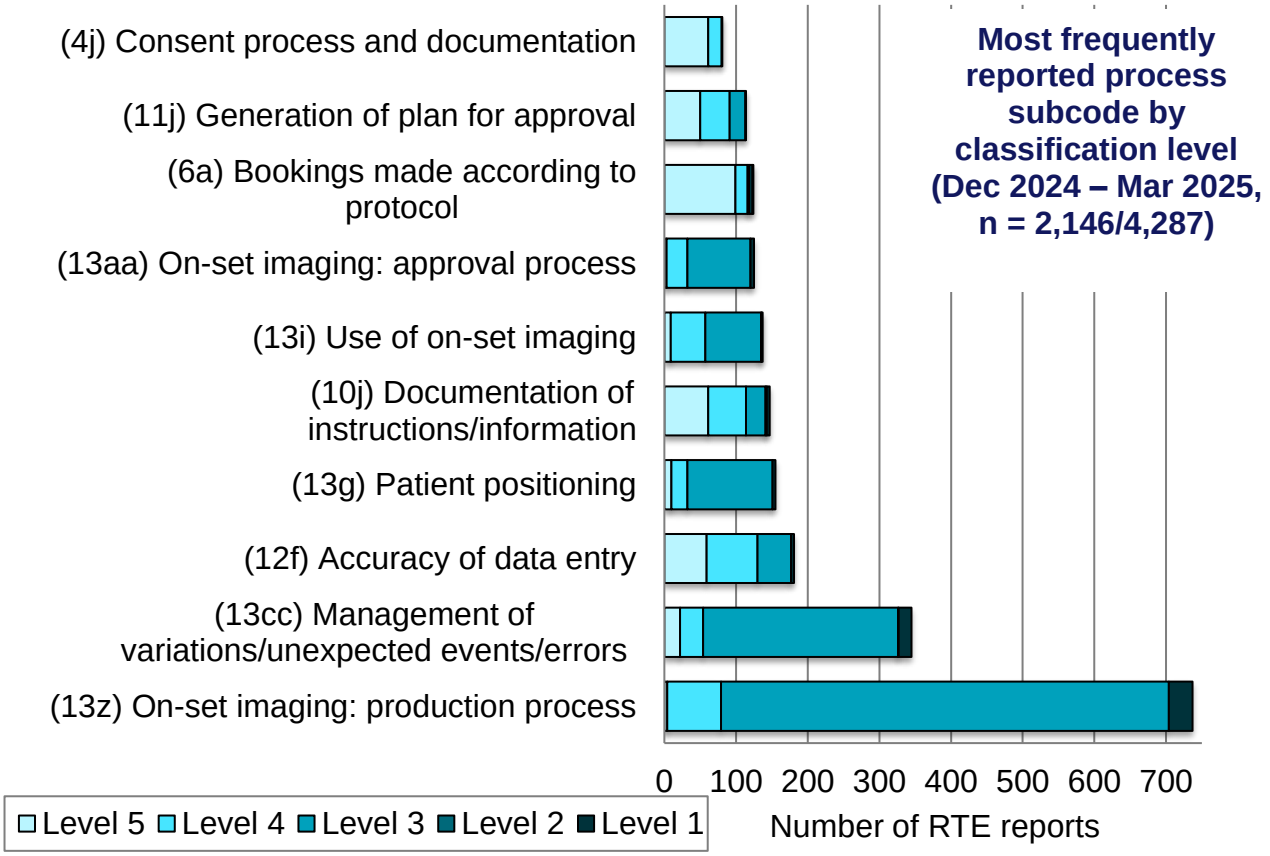
Classification (Level) of RTE

Of those 4,287 RTE reported, 4,129 reports (96.3%) were classified as minor radiation incidents, near misses or other non-conformances (Level 3 - 5). These had no significant effect on planning or delivery of individual patient treatments or outcomes.



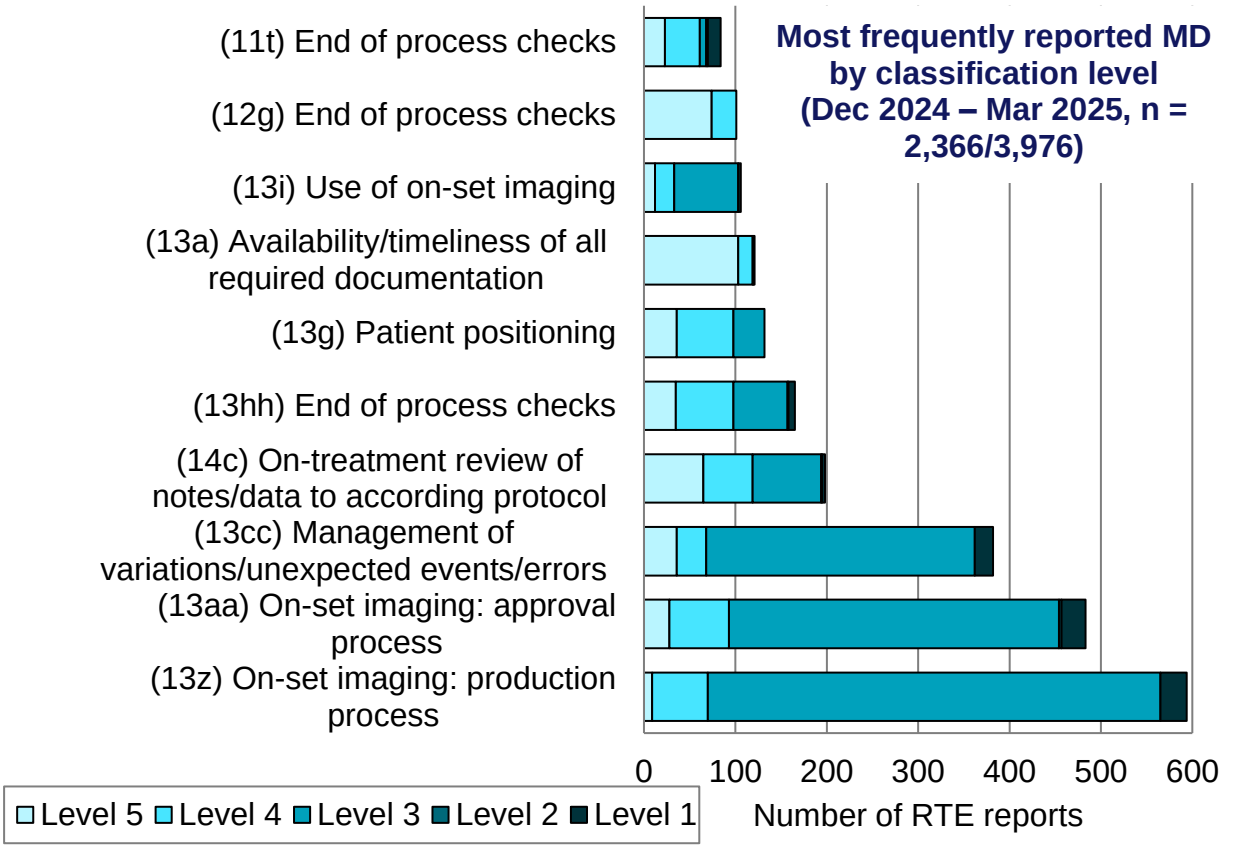
Primary process subcode

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 (17.2%, n = 738/4,287).



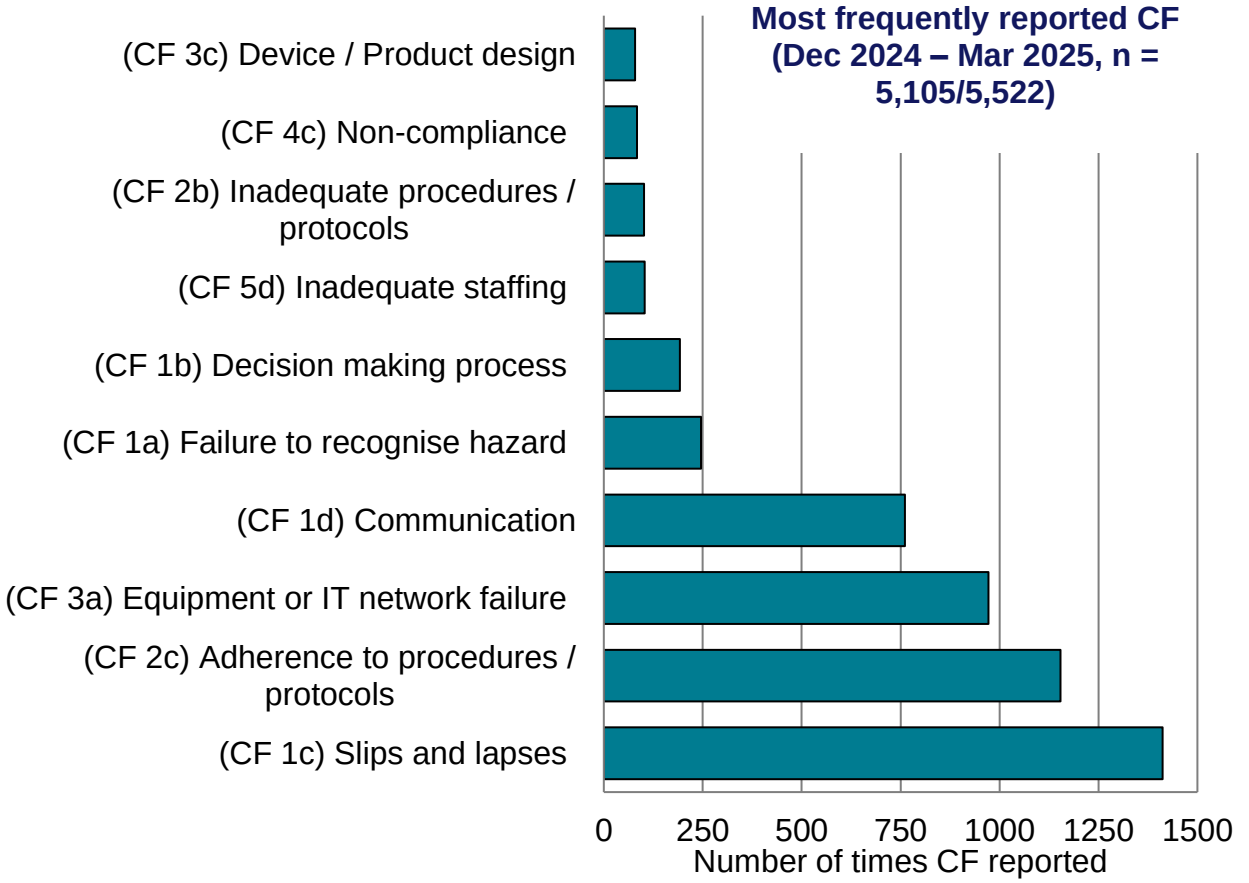
Method of detection (MD)

For this reporting period 3,976 reports included MD coding or data. The most frequently reported MD was ‘on-set imaging: production process’ (14.9%, n = 594).



Contributory Factors (CF)

Each RTE can be assigned multiple CF codes. A total of 5,522 CF were reported in this period. The most frequently reported CF was ‘slips and lapses’ at 25.6% (n = 1,412).



Learning from good practice - The Medicines & Healthcare products Regulatory Agency (MHRA) Adverse Incident Reporting

Paul Sandhu, The Medicines & Healthcare products Regulatory Agency

Who is the MHRA?

The Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicines, medical devices, and blood components for transfusion in the UK and its responsibilities include ensuring that these products meet applicable standards of safety, quality and efficacy.

Why report to the MHRA?

As the designated authority that administers and enforces the law on medical devices in the UK, the MHRA has a range of investigatory and enforcement powers to ensure their safety and quality. Through the **Yellow Card scheme**, the MHRA collects and monitors information on suspected safety concerns involving healthcare products, such as adverse incidents involving medical devices. The information from adverse incident reports can identify faults with medical devices, help provide early warning signals, identify products requiring further investigation and may prevent similar incidents happening again.

The Yellow Card scheme relies on voluntary reporting of any problems with a healthcare product by the public (including patients, parents, and carers), as well as by healthcare professionals.

What should be reported?

Any adverse incident involving a medical device should be reported to the MHRA, through the **Yellow Card scheme**. An adverse incident is an event that caused, or could have caused, an injury to a patient or other person, or a wrong or delayed diagnosis and treatment of a patient. This includes adverse incidents associated with aging equipment, or general wear and tear of equipment. Every individual incident should be reported rather than waiting until you observe an emerging trend. This is because MHRA systems rely on pattern recognition to identify early warning signals and trends in reports where in-depth investigation is required. Some apparently minor incidents may have greater significance when aggregated with other similar reports. The MHRA advises that if a provider is in any doubt about reporting, they should report the event.

How to report

Adverse incidents involving medical devices in England and Wales should be reporting using the **Yellow Card scheme** or via the Yellow Card app (see QR codes).

MHRA reporting QR

Please note that such incidents should be reported to the **Northern Ireland Adverse Incident Centre** in Northern Ireland and to the Incident Reporting and Investigation Centre (IRIC) **online incident reporting system** or **adverse incident reporting web form** in Scotland. If a report is submitted in Northern Ireland or Scotland, there is no need to provide a duplicate report to the MHRA. The Northern Ireland Adverse Incident Centre and National Services Scotland would carry out the investigation and inform MHRA of concerning trends or signals.

Submitting a report only takes 5-10 minutes.

Examples of adverse incidents involving medical devices within radiotherapy include, but are not limited to:

- Hardware or software malfunction that affects the ability of the equipment to acquire planning or verification images and data.
- Hardware or software malfunction that leads to incorrect dose calculations, contouring or other relevant planning requirements.
- Hardware or software malfunction that affects the ability of equipment to deliver the radiotherapy treatment as intended.
- Hardware or software malfunction that affects the ability of the equipment to deliver the planned exposure within brachytherapy, for example where the integrity of the applicator is compromised.

Due to the volume of reports the MHRA receive, not every incident can be investigated. However, reports concerning fatalities or serious public health threats are routinely assessed. Every report is also shared with the device manufacturer for their own investigation, and they may contact you for additional information. You should keep devices involved in adverse incidents in case the manufacturer needs to examine them as part of their root cause investigation.
The manufacturer must investigate and submit a formal response to MHRA for every incident which meets the reporting criteria. Please note that MHRA do not currently provide updates or notification of investigation outcomes directly to the reporter. The manufacturer will share their response with the reporter on request.
You will only be contacted if the MHRA are requesting further information about an incident. Therefore, after submitting a Yellow Card report, please do not wait for a response, but instead follow local procedures within your organisation to best manage the risk in a proportionate way.
The MHRA also encourage reporting for repeat incidents as the frequency of the issue and the number of devices affected is factored in when determining whether an investigation will be triggered.
Radiotherapy events involving medical devices should also be reported locally and where appropriate, notified to the corresponding regulator in accordance with IR(ME)R and IRR.

Safer Radiotherapy resources
Safer RT: **triannual analysis and learning** reports contain analysis and learning from RTE reported by UK RT providers and relevant reporting authorities.
Safer RT: **E-bulletins** provide key messages from the national patient safety initiative
Safer RT: **biennial analysis and learning** reports contain 2 years analysis and learning from RTE reported by UK RT providers and 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**
Advancing Safer Radiotherapy provides contemporary guidance for radiotherapy providers on improving patient safety
National Patient Safety Radiotherapy Event Taxonomy contains the RTE classification taxonomy
National RTE aggregate data provides a dataset for all RTE reported across the UK including data from January to December 2024

Links to key publications

- Medical Exposures Group update E-bulletin
- 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

Dates for the diary

UKIO 2025	2-4 June 2025, Liverpool
IPEM Radiotherapy biennial meeting	2-3 July 2025, Birmingham
BIR, IRMER update 2025	30 September 2025, London