UK Health Security Agency

Safer Radiotherapy

E-bulletin #15
January 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.

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.

Anonymised RTE reports were 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, 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 learning from RTE and with any suggestions for the E-bulletin. Published three times a year, the next issue will be shared in May 2025. To subscribe to future editions please follow this link.

Thank you to all RTE reporters who facilitate this work.

PSRT membership update

The RCR representative for the PSRT has changed. Dr Petra Jankowska has been a member of the PSRT since October 2019. For the past five years Petra has helped develop the PSRT's work programme and been vital in the Safer Radiotherapy publications. Petra has taken on the role of Medical Director of Professional Practice and has now stepped down from the PSRT. We would like to extend our warmest wishes to Petra, she will be greatly missed.

Dr Peter Dickinson joins the group as the new RCR representative. Peter drives quality and safety in radiotherapy as part of the professional support and standards board at the RCR. Peter is a consultant clinical oncologist who specialises in the treatment of lung cancer and the use of SABR to treat metastatic cancer at Leeds Teaching Hospitals NHS Trust.

The PSRT look forward to Peter's contributions to this work.

Advancing Safer Radiotherapy update

The final document has now been peer reviewed and ready for publishing shortly. Alongside, Advancing Safer Radiotherapy, a new patient safety radiotherapy event (RTE) taxonomy guidance document will be published. This document will reflect the refined RTE taxonomy and consolidate all RTE taxonomies, definitions and guidance in one document.

This work could not have been completed without the support of the radiotherapy community, thank you.

Patient safety principles published

The patient safety commissioner has published patient safety principles. These aim to act as a guide for leaders at all levels on how to design and deliver safer care for patients and reduce avoidable harm, in a just and learning culture.

A list of the principles can be seen here alongside a toolkit on how to use the principles.

Darzi report

In July 2024, the Secretary of State for Health and Social Care commissioned Lord Darzi to conduct an immediate and independent investigation of the NHS.

The report contains findings of the current performance of the NHS across England and the challenges facing the healthcare system, this includes a section on the 'patient voice'. The full report can be found here.

Guidance on the management of patients with cardiac implantable electronic devices receiving radiotherapy published

The Radiotherapy Board's Guidance on the management of patients with cardiac implantable electronic devices receiving radiotherapy has been published. It is available on the Radiotherapy Board's Publications web page.

This new guidance replaces the earlier (2015) document titled Management of cancer patients receiving radiotherapy with a cardiac implanted electronic device: A clinical guideline which has now been withdrawn.

SoR publish Code of Conduct and Scope of Practice documents

Three new documents have been published by the SoR, to support the professional practice of members:

- Code of professional conduct
- Scope of practice
- Guidance on scope of practice for advanced practitioners and consultant practitioners

The 'scope of practice' document applies to radiography practice within clinical imaging and oncology, as carried out by the professional workforce. It describes the typical scope of practice across professional levels, covering practitioner, enhanced, advanced and consultant roles.

The 'guidance on scope of practice for advanced practitioners and consultant practitioners' is a new document that provides additional guidance on the scope of practice for members working in advanced and consultant practice roles.

Dates for the diary	
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
ESTRO 2025	2-6 May 2025, Vienna
IPEM Radiotherapy biennual meeting	2-3 July 2025, Midlands

Non RTE reporting

An RTE is a non-conformance where there is an unintended divergence between a radiotherapy treatment delivered or a radiotherapy process followed and that defined as correct by local protocol.

During the course of radiotherapy there may be occasions where repeat concomitant exposures are required, appropriately justified and authorised. If the repeat exposure is required due to procedural, human, systematic or equipment error, this may be considered an RTE. However, if the repeat exposure does not involve a non-conformance, for example due to random variation in patient anatomy, it does not meet the definition of an RTE. Examples of these technical repeats are listed below.

Non RTE examples

Patient requires full bladder for treatment. Just after CBCT patient is uncomfortable and needs to leave the treatment room without completing their treatment.
Upon completion of the bladder filling protocol the patient is ready to re-commence treatment. An additional verification CBCT is taken, in accordance with protocol, and the patient is treated correctly.

Patient requires head and neck mask for immobilisation. During set up of first fraction it is noted there is a gap between shell and the patient's skin. On review of the fit of the shell and the patient it is noted there has been significant weight loss. An additional patient CT planning scan is requested, fast track planning is completed and the patient is treated accurately on the new plan.

These technical repeats should be logged for local learning, however if they do not constitute a divergence from the radiotherapy pathway, they should not be classified or coded as an RTE. If technical repeats persist, a review of local protocols should be considered, this may include local bladder filling guidelines or information shared with the patient prior to treatment.

National RTE aggregate data

The third full dataset for all RTE reported across the UK will be available from the end of February 2025. This will include data from January to December 2024.

This data is available to reporting RT providers upon request, and may assist providers in comparing local trends to the national picture.

If you would like to receive this dataset, please email **RTEdata@ukhsa.gov.uk** at the end of February with the following:

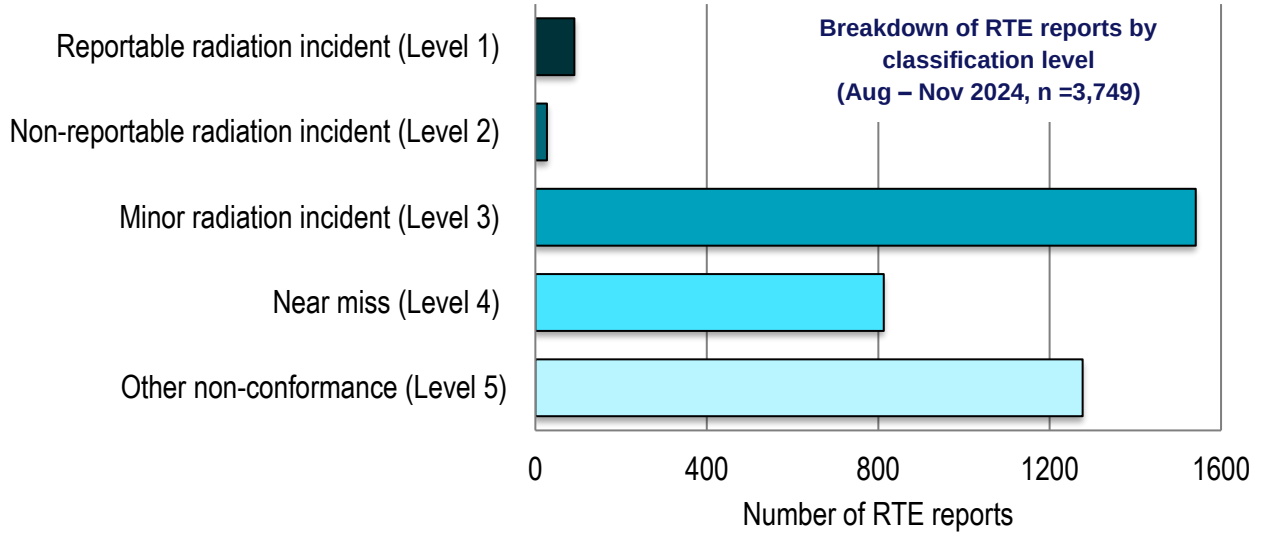
- Organisation name
- How you propose to use the national aggregate RTE data.

RTE data analysis – August to November 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.

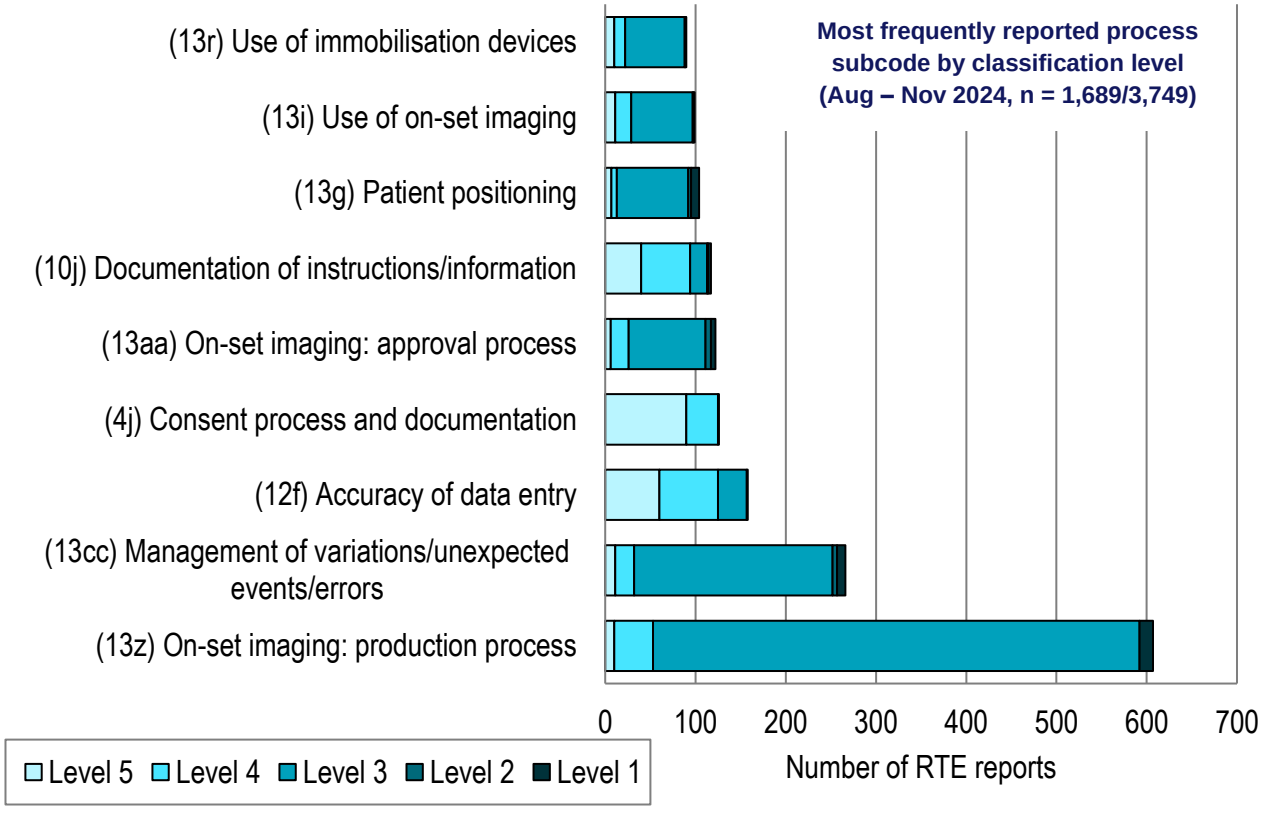
Classification (Level) of RTE

Of those 3,749 RTE reported, 3,631 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.



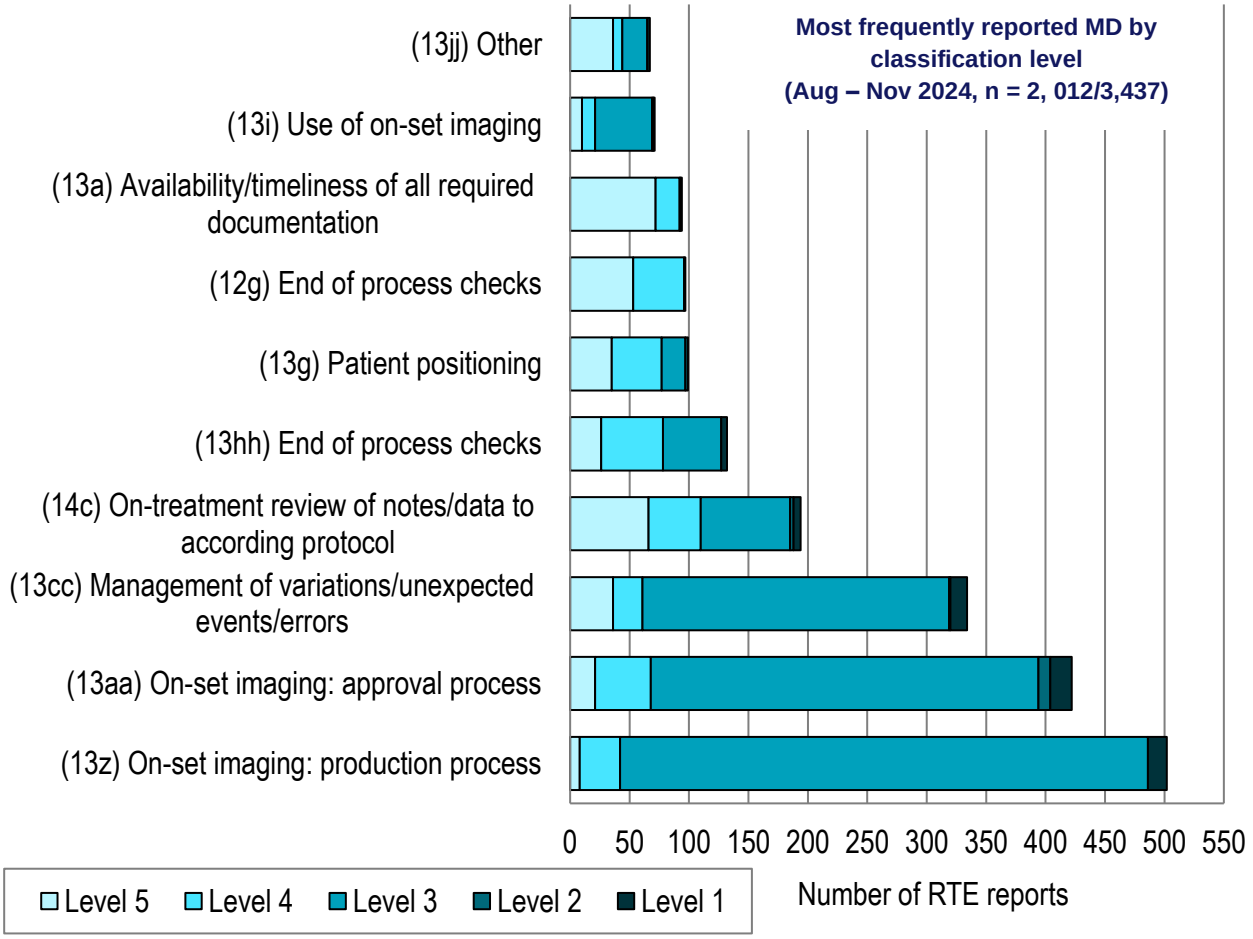
Primary process subcode

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 (16.2%, n = 607/3,749).



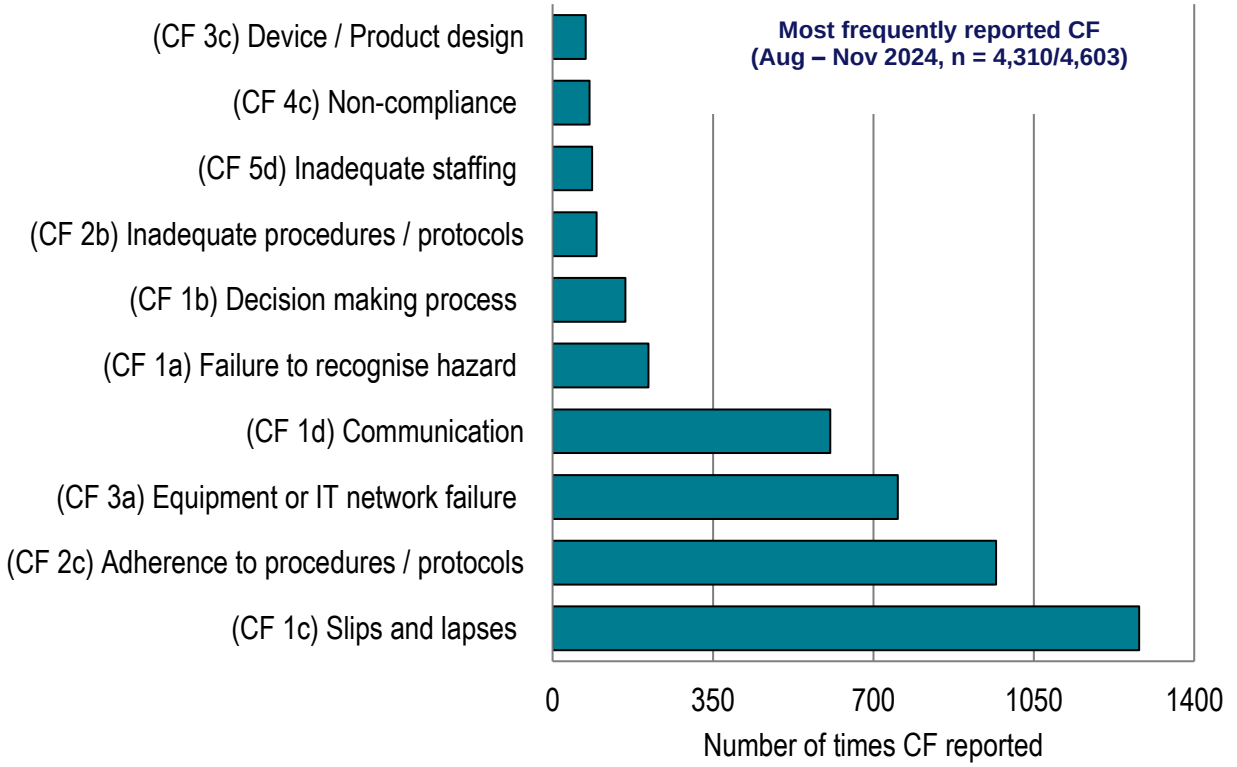
Method of detection (MD)

For this reporting period 3,437 reports included MD coding or data. The most frequently reported MD was ‘on-set imaging: production process’ (14.6%, n = 502).



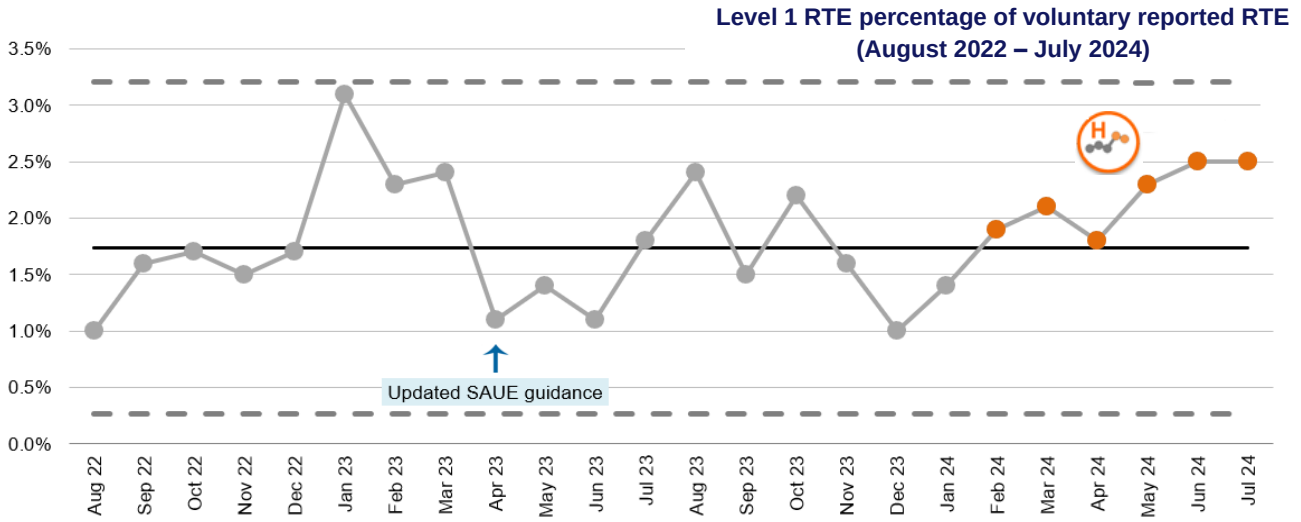
Contributory Factors (CF)

Each RTE can be assigned multiple CF codes. A total of 4,603 CF were reported in this period. The most frequently reported CF was ‘slips and lapses’ at 27.8% (n = 1,280).



Closer look – Level 1 voluntary RTE

A closer look at the RTE which were classified as reportable radiation incidents (Level 1) was completed. As seen in the SPC chart* below in August 2022 1.0% of all voluntary RTE reported were classified as Level 1 reports, with a steep increase to 3.1% in January 2023. The SPC chart* demonstrates a steady increase in the proportion of Level 1 RTE reports, from 1.0% in December 2023 to 2.5% of all voluntary RTE reported in June and July 2024. (*Further detail on SPC charts can be seen in issue 11 of the E-bulletin)



A special cause variation pattern is highlighted within the chart as orange points. This indicates a run of six points above the mean.

Due to the increase in proportion of Level 1 RTE between January 2024 and July 2024 as shown in the SPC chart above, a closer review of the primary pathway subcodes for this time period was undertaken. The table below indicates the proportion of Level 1 RTE associated with the most frequently reported primary pathway subcodes. Further details on these Level 1 RTE can be found in the different case studies within the Safer RT triannual analysis.

The table identifies an emerging trend of RTE associated with 5k 'authorisation to irradiate'. An example of this includes when a patient receives an exposure such as a CT scan or verification image without prior justification and authorisation by an appropriately trained and entitled individual, this may be due to inadequate adherence to, or failure to follow local protocols. Further detail on this type of Level 1 RTE is included in case study #15 within this month's publication of the Safer RT triannual analysis.

	13z 'on-set imaging: production process' Case study #14	13g 'patient positioning' Case study #9	13aa on-set imaging: approval process Case study #5	5k 'authorisation to irradiate' Case study #15
Jan-24	7.7%	30.8%	0	0
Feb-24	6.7%	33.3%	6.7%	0
Mar-24	26.3%	10.5%	10.5%	0
Apr-24	18.8%	0	12.5%	0
May-24	9.1%	4.5%	9.1%	9.1%
Jun-24	13.6%	0	4.5%	18.2%
Jul-24	24.0%	0	8.0%	16.0%

Guest editorial:

The rise of the machines? Opportunities and challenges from automation and artificial intelligence

Carl Rowbottom
Head of Physics
The Clatterbridge Cancer Centre NHS Foundation Trust

There is increasing interest in the use of automation and artificial intelligence (AI) in radiotherapy (1, 2) with AI-based auto-contouring and automated treatment planning active areas for research and commercialisation. The main drivers for this interest are to address:

- workforce shortages
- workload increases
- quality improvements from standardisation
- financial and operational efficiency

In general, automation and AI can be implemented either as assistive or generative technologies. For example, AI-based auto-contouring tools create initial contours that must be reviewed by trained healthcare professionals and potentially edited prior to use (2). The application is therefore assistive, with the healthcare professional approving auto-contours being '*ultimately responsible for their clinical use*' (3). Healthcare professionals should be adequately trained and understand the potential software biases as well as user risks of automation and anchoring biases (3).

By contrast, automated treatment planning software can be used in a variety of ways, from performing parts of the process to full automation. When performing only parts of the process under human supervision the technology is assistive. If used to complete the whole process with little or no human interaction the technology would more likely be considered generative.

Generative technology raises questions regarding responsibility if the technology fails and is not corrected prior to exposure. What responsibility is vested with:

- the software developer,
- the individual that approved the commissioning of the software prior to local use,
- the individuals that completed commissioning or QA tasks
- the healthcare professional that initiated the automation?

Responsibility for safety resides ultimately with the organisation exposing the patient to ionising radiation. Therefore, local understanding of the intended use of the software and warnings contained within manuals is essential prior to clinical use. Completion of a comprehensive pro-active risk assessment remains a fundamental requirement. Automated treatment planning is increasingly being developed 'in-house' using commercially available scripting interfaces. Development of software as a medical device presents unique challenges due to potential mutability and ease of code sharing. Best practice for in-house software development of medical devices is available (4) and

should be followed to minimise patient risk. Automation is an enabler of lean processes providing opportunities for operational efficiency but must be appropriately balanced against the need for multiple layers of defence as described by Reason's Swiss cheese model (5).

Treatment planning clearly meets the definition of a practical aspect as defined by IR(ME)R. However, the regulations state that an operator is 'responsible for each practical aspect which the operator carries out' leaving fully automated treatment planning (generative) as a new area that will require further guidance prior to implementation, to ensure compliance with regulations.

There are clear opportunities from the adoption of automation and AI technologies. Identifying and addressing the challenges will ensure patient benefit from adoption of the technology outweighs the potential harms.

References

1. Callens et al. Is full-automation in radiotherapy treatment planning ready for take off?. Radiotherapy and oncology. Vol. 201 (2024): 110546 .j.radonc.2024.
2. Artificial intelligence technologies to aid contouring for radiotherapy treatment planning: early value assessment. National Institute for Health and Care Excellence. September 2023.
3. RCR Clinical Oncology Guidance on auto-contouring in radiotherapy. London. November 2024.
4. IPEM. Best-practice guidance for the in-house manufacture of medical devices and non-medical devices, including software in both cases, for use within the same health institution. (2024).
5. Reason J. *Human error*. Boston: Cambridge University Press; 1990.

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

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