



The PSRT Team

From L-R Tony Murphy (lay rep), Úna Findlay, Maddie Ottrey and Helen Best (PHE), Maria Murray (SCoR), Carl Rowbottom (IPEM), Martin Duxbury (SCoR Clinical rep). Tom Roque (RCR, not in picture).

Welcome to Safer Radiotherapy (RT). The aim of the newsletter is to provide a regular update on the analysis by PHE of radiotherapy error (RTE) reports. These anonymised reports are submitted on a voluntary basis through the National Reporting and Learning System (NRLS) of NHS Improvement or directly to PHE, to promote learning and minimise recurrence of these events. Safer RT is designed

to disseminate learning from RTE to professionals in the RT community to positively influence local practice and improve patient safety.

Published three times a year, Safer RT contains key messages and trends from the analysis of RTE reports. Any comments and suggestions for inclusion in the newsletter can be sent to radiotherapy@phe.gov.uk and would be gratefully received. Thanks to all contributors to this issue. The next issue of Safer Radiotherapy will be published in May 2018 and will be available at www.gov.uk/government/collections/medical-radiation-uses-dose-measurements-and-safety-advice

Helen Best, Editor

Editorial headline: Development of Learning Workshop

Public Health England and the Patient Safety in Radiotherapy Steering Group (PSRT) hosted a workshop on the implementation of learning from the *"Development of learning from radiotherapy errors"* guidance document found at

<https://www.gov.uk/government/publications/development-of-learning-from-radiotherapy-errors> on the 19th October 2017. The aim of the workshop was to support the radiotherapy community in maximising learning from radiotherapy errors (RTE) through:

- presentation of new and amended taxonomies and supporting delegates in their application and submission
- exploring opportunities to develop the national analysis of RTE to better inform local practice
- providing a platform for safety champions to network with each other and engage with the PSRT

A total of 83 delegates attended representing 58 UK radiotherapy providers. Feedback on the day indicated the high quality presentations and stimulating workshops were well received and will be used to inform future work.

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Independent Provider Submissions

Independent providers can report to the NRLS via the standard service eForm available on NHS Improvement at <https://improvement.nhs.uk/resources/report-patient-safety-incident/>

Large independent hospitals or provider groups are most likely to have a local risk management system in place and a reasonable volume of patient safety reports to submit, and should contact the NRLS directly for further information and initial assessment. The assessment will look at the size of the organisation and the compatibility of their local system, and from there the NRLS will be able to advise on best options for them. For further information please email patientsafetyhelpdesk@nrls.nhs.uk.

Identification of effective and failed safety barriers

Safety barriers (SB) are indicated within the refined pathway coding, denoted by 'SB' in the first column of the taxonomy included in the Development of Learning guidance document. SB are inherent across the radiotherapy pathway and are designed to reduce the risk of errors occurring. RTE reports which include SB specify where the SB failed. Feedback from the Development of Learning Workshop indicated that it would be beneficial to also recognise methods of detection of RTE, this would illustrate when a SB has been effective. The PSRT recommend reporting failed and effective SB as outlined in the guidance document. However,

To enhance and streamline how effective and failed SBs are analysed please place an 'MD' to denote method of detection after the effective SB pathway code e.g. TSRT9 / Level 4 / 13c / 13I / MD13hh / CF1c

IPEM recommendations for the provision of a physics service to RT

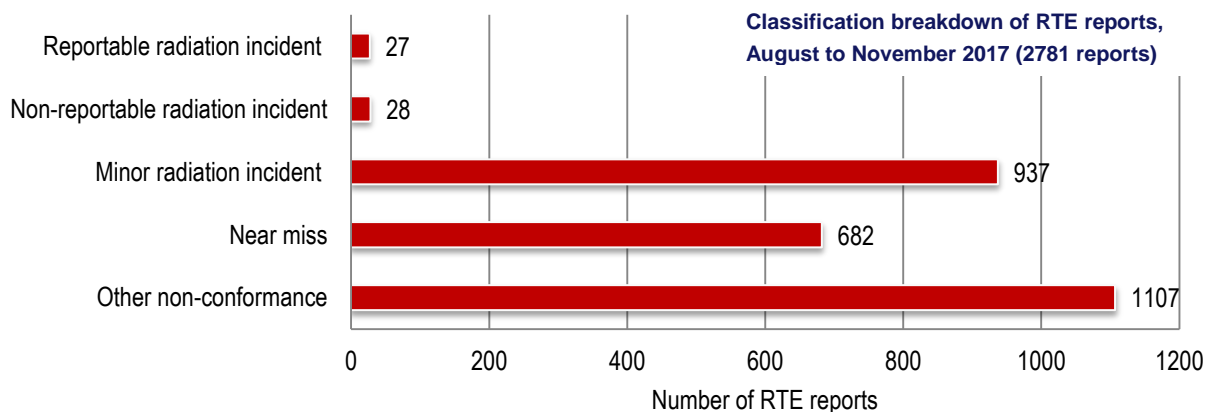
IPEM have published a policy statement on staffing levels with recommendations for the provision of a physics service to radiotherapy. The IPEM document seeks to address current issues and provide updated guidance on staffing. Minimum staffing requirements and skill mix are indicated in this document at www.ipem.ac.uk/ScientificJournalsPublications/IPEMStatementsandNotices.aspx.

RTE Data analysis: August to November 2017

Submissions from 55 NHS UK providers out of 62 contributed to this issue's full data analysis, covering August to November 2017. Seven departments have not reported or not used the TSRT9 trigger code to report RTE through the NRLS for this reporting period. If any departments require support in reporting please contact PHE staff at radiotherapy@phe.gov.uk.

The full data analysis is available at www.gov.uk/government/collections/medical-radiation-uses-dose-measurements-and-safety-advice and includes data on primary process coding, safety barriers, causative factors and the severity classification of the RTE.

Classification of RTE



Of those RTE reported for the period August to November 2017, 2726 out of 2781 reports (98.0%) were classified as minor radiation incidents, near misses or other non-conformances. These are lower-level incidents which would have no significant effect on the planning or delivery of individual patient treatments.

Reportable radiation incidents (level 1) made up 27 (1.0%) of all reports. 'Choice of other current treatment or interventions and their sequencing or timing' and 'on-set imaging: approval process' were equally the most frequently reported level 1 RTE (each 11.1%, n = 3). Non-reportable radiation incident reports (level 2) made up 28 of all reports (1.0%). 'Patient positioning' comprised 4 (14.3%) of all level 2 RTE. Level 1 and 2 reports made up 55 (2.0%) for this reporting period which is consistent with the previous analysis (1.9%, n = 49).

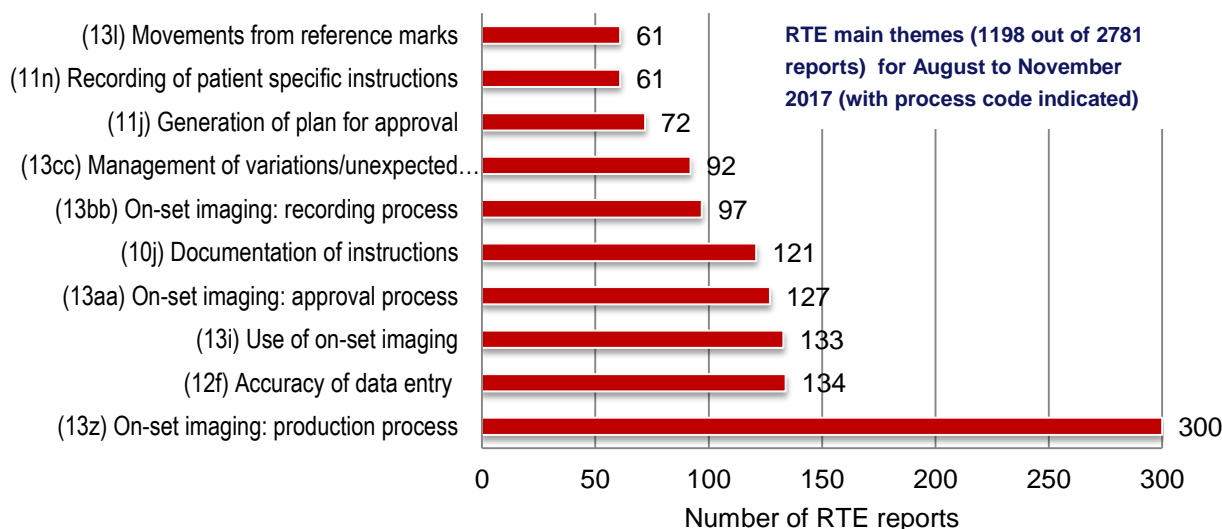
Of the 937 minor radiation incidents (level 3) reported, 266 (28.3%) of this subset were related to the 'on set imaging: production process', making it the most frequently reported code in this classification, consistent with previous analyses.

The most commonly reported RTE process code in the near miss (level 4) classification were both 'accuracy of data entry' and 'documentation of instructions' with 54 reports each (7.9%). Within the non-conformance (level 5) classification 'accuracy of data entry' comprised 55 reports (5.0%) making this the most frequently reported RTE in this classification.

Primary process code

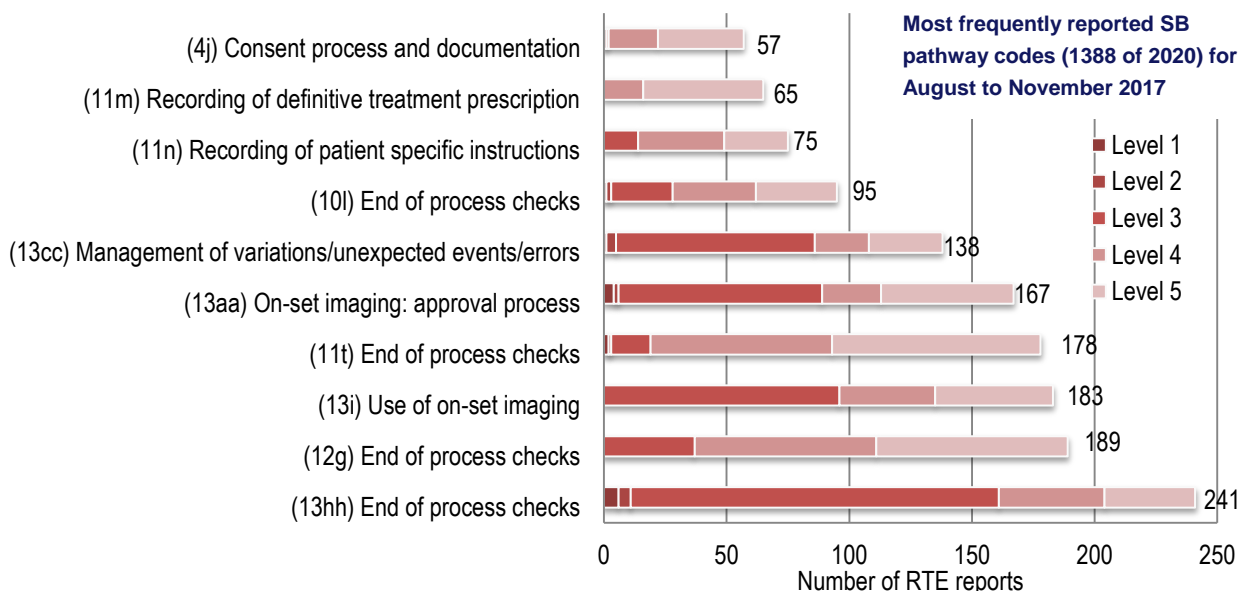
The main themes (points in the patient pathway where the majority of reported RTE occurred) for this dataset are shown below. On-set imaging process codes contributed 657 of the reports in main themes (54.8%), making up 23.6% of all

reports for this reporting period. Consistent with the previous 11 analyses ‘on-set imaging: production process’ is the most commonly occurring process code, examples of this include selecting the incorrect pre-set for an exposure. Guidance on this error can be found in issues 7 and 18 of Safer RT.



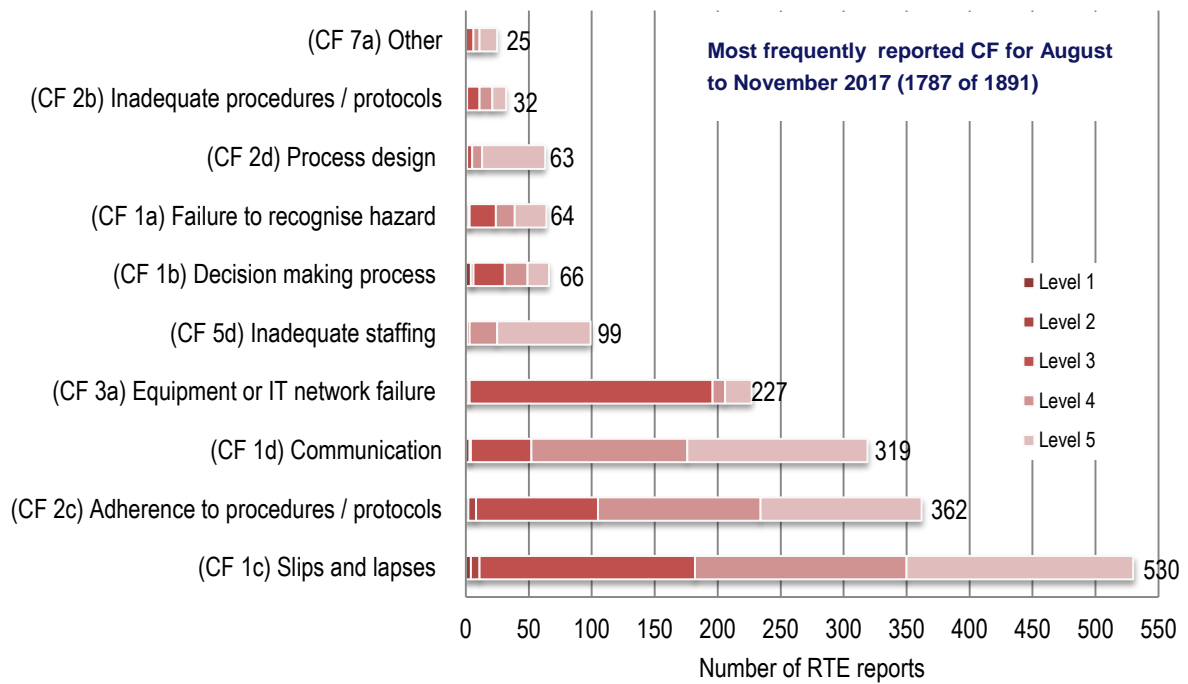
Safety Barriers (SB)

All pathway subcodes from primary to quarterly were analysed across the 2781 RTE for the reporting period and 2020 SB were identified. Only 29 of these RTE were Level 1 or 2 errors where the SB had failed. The most common SB reported are represented below and are broken down by classification. Treatment unit process ‘end of process checks’ is the most commonly reported failed SB (11.9%, n=241). ‘End of process checks’ across the entire pathway account for 35.4% (n = 716) of all reported failed SB.



Causative Factors (CF)

CF have been applied to 1462 RTE during the reporting period August to November 2017 by 47 RT departments. Multiple CF can be associated with each RTE, across the 1462 RTE there were a total of 1891 CF identified. The most common CF are shown below. The most commonly reported CF was individual ‘slips and lapses’ (28.0%, n=530), closely followed by ‘adherence to protocols/procedures’ (19.1%, n=362). Guidance on ‘slips and lapses’ can be found in issue 22 of Safer RT.



International Spotlight

IAEA Technical Meeting on Strengthening Safety Culture, 10-13 Oct 2017

A technical meeting on strengthening of safety culture in radiotherapy through the use of incident learning systems was held at the IAEA, in Vienna. The meeting was attended by 50 professionals from 41 countries. Una Findlay, PHE was invited to give an overview of reporting and learning systems and to share the UK experience of a voluntary reporting and learning system from radiotherapy errors.

Recommendations from the meeting included strengthening the role of radiotherapy leaders in supporting a strong safety culture in radiotherapy, the continued collaboration between of the various incident learning systems by sharing newsletters and reports, to evaluate the need for an alert system where significant transboundary events that have a negative impact on patients can be shared between incident learning systems and radiotherapy facilities and a commitment to continue to work together to strengthen safety culture in radiotherapy. Further information can be found at www.iaea.org/newscenter/news/technical-meeting-on-strengthening-safety-culture-through-the-use-of-incident-learning-systems-10-11-october-2017-vienna-austria

International Conference on Radiation Protection in Medicine, 11-15 Dec 2017

The IAEA held an international conference on radiation protection in medicine: achieving change in practice. The objective of this conference was to review the actions taken and developments following the 2012 Bonn conference (www-pub.iaea.org/IAEAmeetings/41578/radprom2012). The conference focused on strengthening the position of and improving radiation protection in medicine globally, taking into account the diverse challenges in radiation protection in medicine regionally, responding to radiation protection challenges from imaging and therapy modalities, and setting out new findings and priorities relating to radiation safety. Una Findlay, PHE was asked to share the UK experience of using a national incident learning system in radiotherapy to prevent medical radiation incidents and accidents. Further information can be found at www-pub.iaea.org/iaeameetings/50820/International-Conference-on-Radiation-Protection-in-Medicine

Links to international patient safety resources

ASTRO and AAPM RO-ILS [Quarterly report Q2 2017](#)

Autorité De Sûreté Nucléaire (French Nuclear Safety Authority) [Publications for Professionals](#)

IAEA, SAFRON [Updates](#)

Case note of an unintended overexposure of a patient during radiotherapy treatment, in August 2014

On the 21 June 2017 the New Zealand Health and Disability Commissioner published a case note on an incident where a radiation dose significantly higher than prescribed was delivered to a patient. The following is a brief synopsis of the event as described in the case note, coded and classified using the taxonomies from *Towards Safer Radiotherapy* and *Development of Learning* for shared learning.

The full report is available at www.hdc.org.nz/media/384972/16hdc00650.pdf.

Patient A was diagnosed with metastatic prostate cancer to the bone and prescribed radiotherapy. Patient A was prescribed 30Gy in 10 fractions treating once daily to T11–L2. Treatment was a 3D conformal technique composed of 4 beams, 1 direct anterior, 1 direct posterior and 2 posterior oblique beams with 60 degree wedges for 100% of the treatment field delivery. Diodes were used to verify dose on the anterior beam only.

Between 21 August 2014 and 3 September 2014, Mr A incorrectly received 71.4Gy at the isocentre instead of the prescribed 30Gy (**Level 1**). This overdose occurred due to the absence of the 60 degree wedge on the two posterior oblique fields. It was not clear if this error occurred at the plan transfer to the treatment delivery system (**11l / 11t**) or if there was an accidental deletion of wedges in the beam parameters (**12a / 12g**). The error was not detected prior to or during treatment (**13hh**), but came to light after a review of his case several months later due to the ongoing severity of his radiation reaction.

The team attributed the root cause of the incident as a combination of human error and stressful working environment (**CF1a**). It was reported the department did not have an appropriate policy for the pre-treatment check of beam parameters (**CF2a**).

In summary the incident might be coded as follows:

Level 1/ 11l/ 11t/ 12a/ 12g/ 13hh/ CF2a/ CF1a

Processes put in place to reduce the risk of recurrence included the extension of the pretreatment check to all parameters on day 1 of patients' treatments. Diode measurements were extended to all treatment fields where appropriate or the use of EPID verification introduced. All planned fields are now tracked from import from the planning system to export into the delivery system. A review of staffing during busy periods was undertaken. An electronic programme for the 2nd plan check to eliminate the risk of human error was established. A review of procedures and protocols was completed to ensure they were adequate in view of the incident.

Radioactive Substances Advisory Committee (ARSAC) Approvals Update

New regulations coming into force on the 6th February 2018 will greatly change how the Administration of Radioactive Substances Advisory Committee (ARSAC) issues approvals for the administration of radioactive substances. Further information is available on the ARSAC website www.gov.uk/ARSAC and by subscribing to the email bulletin

https://public.govdelivery.com/accounts/UKHPA/subscriber/new?topic_id=UKHPA_43

Virtual Workspace for Radiation Protection

Officers at the Society & College of Radiographers (SCoR) have designed a virtual workspace for radiation protection (RP) matters. It provides a safe forum for members to share and learn about the governance, compliance and assurance of RP matters. It is aimed at members working in or managing ionising radiation environments and not just for Radiation Protection Supervisors. Discussion is encouraged to stimulate and generate safe and high quality patient services that meet current legislative requirements. If you are a SCoR member and are interested in joining the group please contact Maria Murray, SCoR Professional Officer for RP matters at MariaM@sor.org

Medicines & Healthcare Products Regulatory Agency Update

The Medicines & Healthcare Products Regulatory Agency (MHRA) is the UK regulator of medical device manufacturers. Manufacturers are legally obliged to report medical device safety issues to the MHRA. Healthcare professionals can also report any unanticipated or unwanted medical device issues to the MHRA. What may appear to be a minor issue may have greater significance if the MHRA receives similar reports from other healthcare establishments.

There is a specialist radiotherapy, nuclear medicine & imaging team at the MHRA, who investigate incidents. For questions, you can contact the team through the central enquiry point - AIC@MHRA.gov.uk. You can find more information on what to report and how at www.gov.uk/report-problem-medicine-medical-device

Dates for the diary

26 Feb	BIR webinar, IR(ME)R 2017, An evolution of UK Medical Exposure Regulation
6 Mar	RTQSIG meeting, London, Health Foundation
8 Mar	CoR study day, London, The New UK Radiation Regulations (2017)
21 Mar	BIR, Manchester, Palliative Radiotherapy
20-24 Apr	ESTRO, Barcelona, ESTRO 37
May 2018	Safer Radiotherapy Issue 25

Guest Editorial

IR(ME)R 2017, Implications for Radiotherapy Services

Steve Ebdon-Jackson, Public Health England

The Ionising Radiation (Medical Exposure) Regulations 2017 will come into force on 6 February 2018, meeting the requirements for medical exposures included in the EU Basic Safety Standards Directive 2013/59/Euratom (BSSD).

For those familiar with the Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R 2000), the obvious change is that IR(ME)R 2017 is double the length. This meets the additional requirements of the BSSD for licensing for the administration of radioactive substances, including therapeutic administrations, and far more extensive provisions for equipment. The latter reflects the decision to move requirements around equipment quality assurance, performance testing and maintenance into IR(ME)R 2017. The offset to this is that the opportunity has been taken to include, previous provisions addressed under the Medicines (Administration of Radioactive Substances) Regulations 1978, the Medicines (Radioactive Substances) Order 1978 and those sections of the Ionising Radiations Regulations 2017 which addressed directly medical exposures. This has made the legislative framework simpler and easier to understand and has consolidated all of the Directive's requirements for medical exposures into one set of regulations.

Much of the content and the general format of IR(ME)R 2017 is similar to IR(ME)R 2000. IR(ME)R 2017 perpetuates the approach of IR(ME)R 2000 by placing responsibilities on four key duty holders – the employer, referrer, practitioner and operator. The employer is required to provide a framework under which professionals can undertake the key activities of justification and optimisation of medical exposures.

Nevertheless, there are additional requirements which have specific impact for the radiotherapy community. For mega voltage therapy equipment, record and verify systems will be required – hardly new but now a legislative requirement. The most significant new requirements relate to the provisions for accidental or unintended exposures. Previously it was a requirement to report incidents to the enforcing authorities where doses were much greater than intended. This is essentially retained, with a change of terminology. Additional requirements include recording of analyses of incidents involving or potentially involving accidental and unintended exposures and provision of information concerning clinically significant exposures. A major addition specific to radiotherapy is the requirement to include a study of the risk of accidental or unintended exposures and the inclusion of exposures that are less than intended that are considered to be significant. This represents a key development and it is expected to be widely supported by the radiotherapy community. In practice however, most of these requirements have been addressed for many years, in response to administrative requirements and professional activities.

In summary, IR(ME)R 2017 represents evolution rather than revolution with consolidation of requirements into a single set of Regulations and reporting of incidents, whether procedural or equipment based, to one relevant enforcing authority for each of the Home Countries. Revision will be intended in 2023.