Public Health England

Development of learning from radiotherapy errors

Supplementary guidance series

IPEM
Institute of Physics and Engineering in Medicine

Clinical Oncology
The Royal College of Radiologists

CoR
THE COLLEGE OF RADIOGRAPHERS

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health, and are a distinct delivery organisation with operational autonomy to advise and support government, local authorities and the NHS in a professionally independent manner.

Public Health England
133-155 Waterloo Road
Wellington House
London SE1 8UG
Tel: 020 7654 8000
www.gov.uk/phe
Twitter: @PHE_uk
Facebook: www.facebook.com/PublicHealthEngland

Prepared by: Medical Exposures Group, Public Health England
For queries relating to this document, please contact radiotherapy@phe.gov.uk.

This document has been reviewed and endorsed by The Institute of Physics and Engineering in Medicine, The Royal College of Radiologists (Faculty of Clinical Oncology) and the College of Radiographers.

Published December 2016
PHE publications gateway number: 2016522

This document is available in other formats on request. Please email radiotherapy@phe.gov.uk.

Contents

Introduction

The value of near miss and error reporting and learning processes is well appreciated in many sectors. National voluntary reporting of radiotherapy error and near miss events (RTE) is well established in the UK, with 100% of NHS Radiotherapy (RT) providers submitting RTE reports between 2010 and 2014.

Towards Safer Radiotherapy[1] (TSRT) provides definitions for the terminology to be used in discussing RTE and proposed two taxonomies for use in describing RTE. The 'classification of radiotherapy errors grid' describes the severity of the error and the 'radiotherapy pathway coding' describes where on the RT pathway the error occurred.

The proposed terminology and taxonomies have now been adopted for use by RT providers across the UK. These form the basis of the trend analysis of these events undertaken at a local and national level.

In 2008, the Patient Safety in Radiotherapy Steering Group (PSRT, Appendix A) was tasked with monitoring the implementation of the recommendations from TSRT, through a collaborative programme of work with the RT community. The group is made up of representatives of the Institute of Physics and Engineering in Medicine, Royal College of Radiologists, Society and College of Radiographers, a lay representative and Public Health England (PHE).

The Group is now seeking to enhance the learning from RTE and their analysis through several developments which include:

- proposal of a causative factor taxonomy
- refinement of the radiotherapy pathway coding
- introduction of safety barriers

These developments would augment the trend analysis of these events undertaken at a local and national level.

The Group proposes these developments would be implemented locally and shared for national analysis through existing mechanisms already used for the reporting and learning from RTE.

Background and objectives

The National Reporting and Learning System (NRLS) operate an anonymised voluntary reporting system to collect and learn from patient safety incidents for England and Wales. PHE entered a data sharing agreement with the NRLS in 2008 for the extraction of RTE data from the NRLS. PHE are tasked with the analysis of these events and sharing of learning to enable continual safety improvement.

This collaboration led to the introduction of a series of biennial reports[2] and quarterly newsletters[3] in 2010. These publications provide regular updates on the analysis of RTE reports for professionals working in the RT community. The second biennial report[2,] published in 2012, demonstrated a significant improvement in the quality of the reports submitted for analysis and a reduction in the proportion of higher level events.

Following the second biennial report, PHE developed a mechanism with RT departments in Northern Ireland and Scotland, so they too might submit reports under this voluntary scheme. In November 2013, PHE received the first of these data submissions. Work continues on streamlining this reporting mechanism for Northern Ireland and Scotland. The third in the series of biennial reports[2], marking the first complete dataset for the UK, was published in December 2014. This was emulated in the subsequent 2016 publication.

The PSRT are now seeking to enhance the learning from RTE and their analysis through:

- proposal of a causative factor taxonomy to enable the identification of system problems or root causes that could precipitate a range of different incidents
- refinement of the RT pathway coding to reflect contemporary RT practice
- introduction of safety barriers to enable the grouping of ineffective and identification of effective methods of error detection

The taxonomies should cover most events although there may be a requirement to revise and expand in the light of experience.

Objectives

The purpose of this document is to:

- present the causative factor taxonomy
- present the refinement to the RT pathway coding which includes the introduction of the safety barrier taxonomy
- provide guidance on the application of the taxonomy
- share submission procedures for coding with RT staff and risk managers for inclusion in national analysis
- encourage local application of the taxonomies to improve local learning from RTE

Description of causative factor taxonomy

The benefit of the use of causative factor taxonomy is that it enables identification of system problems or root causes that could precipitate a range of different incidents. If the root causes are addressed, it can be expected that overall system safety is enhanced and not just a particular weakness associated with a particular incident[4].

Dunscombe et al[5] stated, 'the balance to be struck in the design of taxonomy is that it is general enough to be usable in a wide range of circumstances and operational modes but not so general that essential information or guidance is lost'. A literature review was undertaken to inform this work which included a consideration of the recently developed AAPM[6] and IAEA[7] work. The taxonomy presented here includes 24 categories to be used for trend analysis.

However, in those cases where a full root cause investigation has been undertaken the NRLS recommend that the contributory factors list in full should be used. This is available from the NRLS, NHS England at:
http://www.england.nhs.uk/ourwork/patientsafety/root-cause/

The taxonomy is presented in Appendix B. Definitions and examples of the factors are presented below.

CF1 Individual

The field of human factors concerns the interaction between humans and the system in which they work[8]. It has been suggested that human error is a determining factor in 70 to 80% of incidents occurring in medicine[9]. Human error occurs when the actions and decisions of individuals result in failures that can immediately or directly impact patient safety. Human or individual factors may be divided into the following categories:

CF1a Failure to recognise the hazard is where the person simply did not know or understand the process or failed to recognise the hazard; the individual(s) involved did not know enough to recognise that the wrong thing was done; knowledge-based errors.

CF1b Decision making process is where in non-routine events, the decided course of action is inappropriate, resulting in an error; flawed or inadequate decision making; poor judgement; actions that begin when faced with decisions about what skills to apply to a situation; individual encounters a relatively familiar problem, but applies the wrong pre-packaged solution; rule-based errors.

CF1c Slips and lapses are actions that are well learned and practiced, proceeding without much conscious involvement; may be associated with tasks of a

repetitive nature or preoccupation or distraction; includes a physical stressor or fatigue; involuntary automaticity; skill-based errors occurring in a pressurised work environment.

CF1d Communication includes those errors associated with human interaction failures within the team; poor or a lack of verbal and written communication leading to ineffective or inaccurate transfer of essential information; incomplete handovers; illegible hand-writing and unclear instructions.

CF1e Violation include deliberate actions by an individual; knowingly acting outside scope of practice.

CF2 Procedural

Procedural factors are associated with failure of procedure or process to prevent an error.

CF2a No procedures / protocols is where the appropriate supporting documentation is not in place or is unavailable for existing or new processes, techniques and technologies.

CF2b Inadequate procedures / protocols is where the supporting documentation is not sufficient or is out of date for existing or new processes, techniques and technologies.

CF2c Adherence to procedures / protocols is where the locally defined process was not adhered to.

CF2d Process design includes impractical and inefficient processes that cannot be performed properly in the allotted time; failure to execute the planned action.

CF3 Technical

Technical factors relate to the equipment used which directly contributes to the error.

CF3a Equipment or IT network failure factors include situations where a machine malfunction leads directly to an error; failure of an immobilisation device or accessory equipment; machinery that is unreliable and produces an excessive number of false alarms/alerts has potential to induce short cuts or block responses to a potentially hazardous situation. N.B: This should not be confused with the inappropriate handling of a machine malfunction that then leads to an error.

CF3b Commissioning / calibration / maintenance is defined as inappropriate or incomplete commissioning, calibration or maintenance of equipment (hardware and software) an immobilisation device or accessory equipment; includes situations where incorrect data was provided by the vendor or supplier.

CF3c Device / product design factors include flaws or inadequacies inherent in the design of equipment or ancillary kit used as part of the exposure or to inform the exposure.

CF4 Patient related

Patient factors relate to incidents where the actions or individual circumstances of the patient directly contribute to the error. These are sub-divided into the following categories:

CF4a Medical condition relates to where the patient general health condition is particularly complex or serious; inability to remain still.

CF4b Communication with the patient includes those errors associated with human interaction failures between the team and the patient; includes language issues, comprehension difficulties; through lack of or miscommunication the patient has misunderstood an instruction leading directly to an error.

CF4c Non-compliance is described as being when a patient does not comply with the procedure; this may be through their own volition or through an unknown inability to comply; where cultural, religious and social issues affect the ability of a patient to be consistent with pre-conceived expectations – i.e. tattoos / skin marking and compliance of paediatrics; where a patient has chosen to purposefully ignore advice which has directly led to an incident – i.e. deliberately withheld knowledge of a pregnancy.

CF5 Teamwork / management / organisational

Organisational / management factors are associated with poor organisational structures and culture. These factors transcend all levels of the organisation from senior management to individual teams working at an operational level. These are sub-divided into the following categories:

CF5a Inadequate leadership includes absence of a safety culture at a strategic or operational level; constructive challenging of policies is discouraged; outdated practice; inadequate supervision, congruence or consistency; where the emphasis might be to achieve imposed targets or waiting times without review of available resources; workload is not appropriately planned or managed.

CF5b Unclear responsibilities and lines of accountability at a strategic or operational level includes undefined roles, responsibilities and lines of accountability within the organisational structure; inconsistent approach to the management of all components of the RT pathway and associated processes; service level agreements or contracts are inadequate.

CF5c Inadequate capital resources includes equipment and finance and relates to situations where appropriate funding is not available to run the service as described in the quality management system; equipment is no longer fit for purpose; service level agreements or contracts are not supported.

CF5d Inadequate staffing relates to insufficient staffing levels or skill mix necessary to meet the demands of a service; inadequate staffing numbers or lack of availability of appropriately skilled staff.

CF5e Inadequate training includes inadequate or lack of training on local, new or changed processes, techniques and technologies.

CF5f Inadequate risk assessment includes the absence of, out of date and poorly maintained risk assessment and ineffective or poorly planned change management or introduction of new processes, techniques and technologies.

CF6 Environmental

Environmental factors are associated with the design of the work area and availability of equipment. It may be that flawed processes or violation-producing conditions lead to the occurrence of an error.

CF6a Physical includes poor design of equipment and poor workplace layout; power cuts; area excessively noisy etc

CF6b Natural factors include situations where a fire, flood etc have contributed to the error.

CF7a Other

If none of the codes above accurately describe the causative factor for the incident, please describe the causative factors in the free text to inform a future refinement of the taxonomy.

Description of refined radiotherapy pathway coding

Eight years' experience in the use of the 'radiotherapy pathway coding' has highlighted the need for some refinement to reflect contemporary RT practice. This marks the first review of the RT pathway coding. Consistency checking on the application of the pathway coding has highlighted areas where the coding might be further refined to reflect contemporary RT practice. PHE staff completed a database review which focused on the use of the 'other' coding and on changed coding of reports as part of consistency checking of data.

This provided the opportunity to:

- identify process sub-codes not used
- identify ambiguous terminology employed within the coding
- review RTEs coded as 'other'
- evaluate if/what new codes are needed to reflect new technologies and techniques

In addition, feedback from coding users and RTE reporters was amalgamated to inform the refinement of the coding. Descriptors were added to a total of 67 codes to reduce ambiguity of the terminology employed in the taxonomy and further improve consistency of application of the codes. A total of 14 additional sub-codes have been added to the pathway, bringing the total number up to 206. The refined RT pathway coding is presented in Appendix C.

Description of safety barriers

Recent consensus work on process mapping suggests that 40% of all workflow steps in RT are safety barriers (SB) focussed on detecting and preventing errors. Use of SB taxonomy would enable the grouping of ineffective methods of error detection. This in turn might support the identification of effective safety barriers and inform where resources are best placed in the development of rigorous safety barriers, target their use[4] and ultimately reduce RTE.

Safety barriers which are also known as critical control points, detection methods or defence in depth, are any process steps whose primary function is to prevent errors occurring or propagating through the RT workflow[6]. A safety barrier is the method used to detect RTE and also any process included in the RT pathway whose primary purpose is to identify potential errors, for example, use of *In vivo* Dosimetry (IVD), use of on-set imaging or end of process checks. The term safety barrier describes all measures that can limit the probability and severity of the event occurrence[10].

Several studies have illustrated the complexity of the chain of events that may lead to an adverse outcome[11]. Although a particular action or omission may be the immediate cause of an incident, closer analysis usually reveals a series of events and departures from safe practice which each influenced the event[12]. As such barriers or control measures are in place across the RT pathway to prevent incidents, when these barriers fail, incidents can occur.

Use of taxonomy enables tracking of safety barriers with the aim of identifying which safety barriers are most effective and at which stage in the patient's treatment the error was detected. This would provide an indication as to how effective existing barriers are. It may also add insight into where best to invest effort and resources to generate the most effective solutions. This might influence local departments' thinking about defence in depth, effectiveness of safety barriers and what safety barriers are in place for safety critical steps (NRLS & IAEA).

It is proposed that safety barriers are highlighted from within the pathway coding as part of the refinement process. These are denoted by the inclusion of 'SB' in the first column of the refined pathway coding (Appendix C). The taxonomy is designed to facilitate trend analysis on a local and national scale.

This approach optimises the use of this single taxonomy to undertake 4 functions: identification of where the initial and any subsequent errors have occurred and which safety barriers have failed and which have been effective. There are 86 identified possible safety barriers included within the RT pathway coding (out of a possible 206 codes). This approach has been adapted from the work of Ford et al 2012[6].

Application of taxonomies

It is intended that the taxonomies are applied by individuals with a firm understanding of RT processes and who will have received some training on the application of the taxonomies.

Causative factor taxonomy

Several studies have illustrated the complexity of the chain of events that may lead to an adverse outcome[13]. Although a particular action or omission may be the immediate cause of an incident, closer analysis usually reveals a series of events and departures from safe practice, each influenced by the working environment and the wider organisational context[10]. The taxonomy has been designed so that each of these events can be captured.

These events are described as root cause and contributory factors. Boadu et al[11] defined root cause as an identified event that leads to anticipated operational occurrences or accident conditions. A contributory factor is defined as the latent weakness that allows or causes the observed cause of an initiating event to happen, including the reasons for the latent weakness. The causative factor taxonomy may be used for coding both the root cause and contributory factors. Both should be considered when applying the taxonomy to each incident. The first code to be applied should be the root cause and subsequent causative factors would be considered to be contributory factors. Examples of the application of the taxonomy are provided in the section of this document entitled ‘examples of the application of taxonomies’.

Refined pathway coding (including safety barriers)

Most RTEs are multifactorial, but each will start with a primary initiating event. When reporting an RTE it is vital to tease out what happened first – the ‘what’ rather than the ‘why’. This will be the primary point on the RT pathway coding. Secondary points will be those that followed from this primary point; further errors which occurred in the pathway stemming from this primary point[14].

The application of the refined RT pathway coding for the purposes of identifying where in the pathway the error occurred is set out in the 2010 guidance document, ‘Implementing Towards Safer Radiotherapy: guidance on reporting radiotherapy errors and near misses effectively’[12].

Failed safety barriers are part of the chain of events leading to the incident and should be included as part of the coding process. Codes that act primarily as safety barriers have been identified within the refined pathway coding. This approach is designed to map the failed safety barriers associated with the RTE.

Inclusion of all process codes from the pathway coding associated with the error will enable the associated safety barriers to be identified at the time of analysis. Examples of the application of the taxonomy are provided in the section of this document entitled ‘examples of the application of taxonomies’.

Submission procedures of taxonomies for national analysis

Clinical RT departments are asked to apply the following for local analysis and include them in reports submitted to the NRLS and PHE to support national learning:

a. ‘TSRT9’ trigger code

b. classification of the RTE

c. refined RT pathway coding (including safety barriers)

d. causative factor taxonomy coding

This data will be included in the analyses currently undertaken by PHE and the results shared with the RT community on a triannual basis.

Consistent with current practice the codes should be added to the first open text field of the local reporting and learning system. Further guidance is available in ‘Implementing Towards Safer Radiotherapy: guidance on reporting radiotherapy errors and near misses effectively’[12] and in the ‘Good Practice in Radiotherapy Error Reporting’ series[14]. Examples of the format are included below. The trigger code, classification, refined pathway coding (including safety barriers) and causative factors for individual incidents should be entered when using a paper-based or electronic form.

Examples of the application of taxonomies

The placement of the following abbreviations in the example scenarios demonstrates how the coding is derived:

TSRT9 – trigger code

Level: classification level
PC: RT pathway coding
SB: safety barrier as identified in the refined RT pathway coding (therefore some codes are pathway points and safety barriers)
CF: root cause and contributory factors as defined in the causative factor taxonomy

Where a RT pathway code is also identified as a safety barrier only SB will be the abbreviation used in the examples below for the purposes of demonstration.

1. Prostate & Nodes IMRT 74Gy in 37# to PTV 1. Treatment #8. Set-up (PC) required a longitudinal shift of 5cm prior to imaging to get the image match volume in the CBCT FOV (SB). The shift was not applied despite a note in the oncology management system highlighting it as a requirement (CF – root cause). This was also missed by the second operator involved in the set-up (PC). Consequently the volume could not be matched effectively and a repeat CBCT was required (Level). Staff reported they were distracted by the patient (CF) who stated he was having difficulty holding his bladder during the set-up so missed the note in the additional set-up note in the oncology management system.
   Coding for submission: TSRT9 / Level 3 / 13l / 13i / 13hh / CF2c/ CF4a

2. Prostate VMAT 74Gy in 37#. Treatment #3. During routine CBCT the equipment developed a fault (CF- root cause) causing the scan to terminate prematurely and failure to capture an image fit for matching (PC). CBCT had to be repeated (SB), first incomplete scan contributed additional dose (Level). CBCT failure reported to local engineers, manufacturer and MHRA.
   Coding for submission: TSRT9 / Level 3 / 13z / 13cc / CF3a

3. Ca Rectum. Prescribed 45Gy in 25#. Conformal 3 field plan. FSD of beam 3 transcribed (PC) incorrectly (CF – root cause) onto treatment sheet. Data entry room very noisy and difficult for staff to concentrate (CF) and error not picked up during routine checking (SB). Calculation, patient set up and treatment delivery correct (Level). Diodes carried out and error detected when member of physics staff carried out routine check on diode readings (SB). Review of transcriptional errors in data entry room revealed error happened frequently. Room subsequently dedicated to data entry only and telephone removed.
   Coding for submission: TSRT9 / Level 5 / 12f / 12g / 13h / CF1d / CF1c/ CF6a

4. Radiotherapy to the Prostate with IMRT, 78Gy in 39 fractions. The longitudinal isocentre shift from reference marks was applied in the superior rather than inferior direction (PC). The treatment plan was delivered incorrectly for 1 fraction before the error was detected by weekly checks (SB) where the longitudinal override was queried. Error resulted in a partial geographical misplacement which was deemed clinically insignificant (Level). In room checks (SB) did not include the direction as well as the magnitude of shifts applied (CF – root cause) in accordance with local procedures.
   Coding for submission: TSRT9 / Level 3 / 13l / 13hh / 14c / CF2c/ CF1c

5. Ca Rectum. Input incorrect isocentre move into oncology management system (CF - root cause). The patient was to be treated prone with a posterior digital move. Patient orientation was not taken into account and iso height input into oncology management system (PC) resulting in a potential anterior move (CF). This was missed during checking processes (SB). Error picked up during patient set up (PC) when automated couch move, moved patient closer to gantry instead of further away when set-up was checked against primary source data (SB). Error was corrected before treatment (Level).
   Coding for submission: TSRT9 / Level 4 / 12f / 12g / 13l/ 13hh / CF1c / CF2c

6. Patient undergoing radiotherapy to the LT chest with parallel pair, 30Gy in 10 fractions. During fraction 4 machine malfunctions part way through treatment beam (CF- root cause), causing incomplete treatment (PC). Selects complete session instead of partial treatment (SB) against protocol (CF). Patient is then transferred to a matched treatment machine, staff override warnings (SB) entire beam is given to complete session, (CF) resulting in a non-reportable overdose to the patient (Level).
   Coding for submission: TSRT9 / Level 2 / 13ff / 13cc / 13dd / CF3a / CF2c / CF1c

7. Ca Lt Breast. Prescribed 40Gy in 15#. Tangential fields with dose compensation. Whilst confirming consent at CT (SB) the patient highlighted the intended treatment site was on the right and not the left as indicated on the referral form (SB). RTE detected prior to CT planning scan (Level). Investigation revealed an inconsistency of information within the patient's notes (CF – root cause). It was noted on review that this error occurs infrequently however the potential significance of error has led to the introduction of a new laterality check procedure (CF) that covers the entire patient pathway.
   Coding for submission: TSRT9 / Level 4 / 4b / 8b / CF1d / CF2b

8. Patient with metastatic prostate cancer, undergoing palliative treatment to the right hip, 8Gy in 1 fraction. Using CT data and virtual simulation software the doctor marked up (CF – root cause) the left hip using the posterior field projection instead of the right hip (PC). The incorrect treatment parameters were transferred to the OMS system (PC) by a staff member who was working under supervision (CF). The transferred parameters were checked independently (SB) but the staff member

undertaking the check was distracted by another problem due to lack of staff on a treatment unit (SB & CF). Monitor unit calculation (PC) and check (SB) was undertaken. The error was detected during routine pre-treatment imaging (SB) by the treating radiographer. Treatment was re-planned and the patient was treated correctly (Level).
Coding for submission:
TSRT9 / Level 3 / 10c / 10l / 11r / 11s / 11t / 20a / 13i / CF1b / CF1a / CF5a / CF5d

9. Ca Lung. Prescribed 40Gy in 15 #'s. Patient was receiving treatment on a linear accelerator with micro 2.5mm MLC's. Consultant had requested spinal shielding from treatment number 13. The MLC's were brought in accordingly, however 1 micro MLC was inadvertently omitted (CF – root cause) by the radiographer carrying out the first treatment input (PC) and was not noticed by the second radiographer carrying out the second treatment check (SB). This may have occurred due to the micro MLC's smaller size as they are harder to visualise in the OMS. Before treatment the MLC shielding was verified on-set (SB), however the kV planar imaging modality was selected by the treatment radiographers rather than MV planar imaging (CF). Although the kV image demonstrated the treatment was within tolerance it did not verify the MLC positions (as kV imaging does not capture MLC's positioning) and so the treatment radiographers did not realise that 1 MLC leaf had not been brought in (Level). An MV image should have been used to verify MLC positions prior to treatment, but this had not previously been considered and so was not stipulated within the relevant imaging protocols or procedures (CF). A kV planar imaging risk assessment had not yet been carried out (CF). The patient therefore received one fraction of treatment with one micro MLC leaf not pulled into the treatment field (Level). A dose assessment was carried out and the remaining fractions were altered accordingly. Upon investigation it was discovered an OMS application tool could have been utilised when carrying out treatment checks, which would have enhanced the micro MLC's visibility. The use of this tool had not been incorporated into the radiographers training (CF).
   Coding for submission:
   TSRT9 / Level 3 / 12f / 12g / 13z / CF1c / CF1b / CF2b / CF5f / CF5e

10. Gastric Adenocarcinoma. Prescribed 20Gy in 5#'s. Patient was receiving first fraction of their palliative radiotherapy for an inoperable gastric adenocarcinoma. Patient was correctly set-up and a kV planar image was taken as per protocol. The kV blades, however, had not been positioned (PC) by the treatment radiographers as per protocol (CF – root cause), prior to image acquisition resulting in an image of insufficient quality for image matching purposes (SB). As a result a second image was required before the patient was correctly treated (Level). Although setting the blades to the imaging field size is an established part of the radiographers training, the use of kV imaging within palliative treatments was relatively uncommon and so had not been incorporated into the appropriate training competencies (CF). This

incident led to the incorporation of palliative kV imaging competencies into the relevant training procedures.
Coding for submission: TSRT9 / Level 3 / 13z / 13aa / CF1c / CF5e

11. Ca Breast. Prescribed 40Gy in 15#'s.On the third day of treatment patient was set up correctly and imaged according to protocol. Image was matched and a shift was required of 0.8cm to the right. Shift was correctly taken and treatment site was re-imaged to verify. When the images were checked (SB) the next day for approval it was discovered the images were matched incorrectly (SB & CF – root cause) and a further lateral shift of 0.7cm to the right was required. An assessment was carried out by treatment planning and no further action was deemed necessary (Level). During the patient's treatment the patient was very upset, and found it difficult to remain still and comply with the radiographer's requests (CF).
Coding for submission: TSRT9 / Level 3 / 13aa / 13hh / CF1c / CF4a

References

1. Towards Safer Radiotherapy. 2008. Royal College of Radiologists, Society and College of Radiographers, Institute of Physics and Engineering in Medicine, National Patient Safety Agency, British Institute of Radiology. Royal College of Radiologists, London. Available at: www.rcr.ac.uk/index.asp?PageID=149&PublicationID=281
2. Radiotherapy errors and near misses: biennial reports. Available at: https://www.gov.uk/government/publications/radiotherapy-errors-and-near-misses-data-report
3. Safer Radiotherapy newsletters & supplementary data analysis. Available at: www.gov.uk/government/publications/safer-radiotherapy-error-data-analysis-report
4. Clark B et al. The management of radiation treatment error through incident learning. Radiotherapy and Oncology. 2010; Vol.95, pp344-349.
5. Dunscombe P. et al. Taxonometric applications in radiotherapy incident analysis. International Journal Radiation Oncology, Biology & Physics. 2008; 71(1) Suppl S200-203.
6. Ford E. et al. Consensus recommendations for incident learning database structures in radiation oncology. Medical Physics. 2012; December 39 (12); 7272-7290.
7. IAEA, SAFRON. Available at: https://rpop.iaea.org/RPOP/RPoP/Modules/login/safron-register.htm
8. World Health Organisation. 2008. Learning from Error: Patient safety Workshop. Geneva: WHO.
9. Ed Vincent & de Mol. 2000. Safety in Medicine. Oxford: Elsevier
10. Scalliet P. Risk, society and system failure. Radiotherapy and Oncology. 2006; (80) 275-281.
11. Boadu M & Mohan Rehani M. Unintended exposure in radiotherapy: Identification of prominent causes. Radiotherapy and Oncology. 2009; Vol. 93, pp609-617.
12. Implementing Towards Safer Radiotherapy: guidance on reporting radiotherapy errors and near misses effectively. Available at http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/radiology-and-radiotherapy/
13. Vincent C et al. How to investigate and analyse clinical incidents: Clinical Risk Unit and Association of Litigation and Risk Management Protocol. British Medical Journal. 2000. Vol 320. Pp 777-781.
14. Good Practice in Radiotherapy Error Reporting. Available at www.gov.uk/government/publications/radiotherapy-good-practice-in-error-reporting

Appendix A: Patient Safety in Radiotherapy Steering Group membership

Helen Best, Public Health England.

Martin Duxbury, Society and College of Radiographer's clinical representative, Deputy Head of Radiotherapy, St James Institute of Oncology, Leeds.

Úna Findlay, Public Health England and Group Chair.

Leslie Frew, Institute of Physics and Engineering in Medicine, Head of Radiotherapy Physics Service, Belfast City Hospital.

Maria Murray, Society and College of Radiographers, Professional Officer for Scotland and UK Radiation Protection lead.

Tony Murphy, lay representative

Madeleine Ottrey, Public Health England

Tom Roques, Royal College of Radiologists, Consultant Clinical Oncologist and Clinical Director for Oncology and Haematology, Norfolk and Norwich University Hospital NHS Foundation Trust.

Carl Rowbottom, Institute of Physics and Engineering in Medicine, Head of Physics, The Clatterbridge Cancer Centre NHS Foundation Trust.

Appendix B: Causative factor taxonomy

Category	Code	Description
Category	**CF 1**	**Individual**
Sub-category	CF 1a	Failure to recognise hazard (knowledge-based etc)
	CF 1b	Decision making process (rule-based or old or invalid rule used etc)
	CF 1c	Slips and lapses (skill-based, involuntary automaticity etc)
	CF 1d	Communication (inaccuracy or omission of verbal, written etc)
	CF 1e	Violation (deliberate action, acting outside scope etc)
Category	**CF 2**	**Procedural**
Sub-category	CF 2a	No procedures / protocols (not in place or unavailable etc)
	CF 2b	Inadequate procedures / protocols
	CF 2c	Adherence to procedures / protocols
	CF 2d	Process design (impractical and inefficient processes etc)
Category	**CF 3**	**Technical**
Sub-category	CF 3a	Equipment or IT network failure (including immobilisation & accessories)
	CF 3b	Commissioning/ calibration/ maintenance (including immobilisation & accessories)
	CF 3c	Device / Product design
Category	**CF 4**	**Patient Related**
Sub-category	CF 4a	Medical condition (inability to remain still etc)
	CF 4b	Communication with the patient (language issues, comprehension etc)
	CF 4c	Non-compliance
Category	**CF 5**	**Teamwork / Management / Organisational**
Sub-category	CF 5a	Inadequate leadership (inadequate supervision, congruence or consistency etc)
	CF 5b	Unclear responsibilities and lines of accountability (across the radiotherapy pathway)
	CF 5c	Inadequate capital resources (equipment in use no longer fit for purpose etc)

Category	Code	Description
	CF 5d	Inadequate staffing (insufficient staffing levels or skill mix necessary to meet the demands of a service etc)
	CF 5e	Inadequate training (inadequate or lack of training etc)
	CF 5f	Inadequate risk assessment (poor change management etc)
Category	**CF 6**	**Environmental**
Sub-category	CF 6a	Physical (power cut, control area excessively noisy, distractions etc)
	CF 6b	Natural factors (fire, flood etc)
Category	**CF 7**	**Other**
	CF 7a	Other

Appendix C: Refined radiotherapy pathway coding (including safety barrier taxonomy)

Text in red denotes additions to the pathway coding in terms of descriptors and new codes. SB denotes pathway codes that are also safety barriers.

Safety barrier	Process code	Activity code
	0	**Infrastructure**
SB	0a	Implementation of national and international codes of practice for radiation dosimetry
	0b	Development of dosimetry algorithms for local application (includes locally developed software/ programs/ tools for clinical use)
	0c	Development of treatment planning algorithms for local application
	0d	Other
	0e	IT infrastructure (includes change in hardware/ software/ upgrades/ network changes/ archive process/ system compatibility/ data transfer)
		Equipment-specific activities
	1	**Room design**
SB	1a	Patient safety (includes alteration of room design or use)

SB	1b	Staff and public safety (includes alteration of room design or use)
SB	1c	Environmental controls
SB	1d	Access control
	1e	Other
	2	**New equipment**
	2a	Installation
SB	2b	Manufacturer's tests
SB	2c	Acceptance tests
SB	2d	Critical examination under IRR99
	2e	Customisation and configuration of equipment
SB	2f	Commissioning
	2g	Data recording
	2h	Preparation of data files for planning systems (to include treatment planning systems, virtual simulation, independent dosimetry checking software etc)
	2i	Other
	3	**Routine machine QA**
SB	3a	Daily consistency checks – geometric parameters (including CT, Linac, gated equipment, in vivo dosimetry devices etc and discrepancies between reporting and action level)

SB	3b	Daily consistency checks – dosimetric calibration (including CT, Linac, gated equipment, in vivo dosimetry devices etc and discrepancies between reporting and action level)
SB	3c	Daily consistency checks – safety (IRR compliance)
SB	3d	Daily verification of accuracy of data transfer between TPS, R&V system and treatment equipment
SB	3e	Planned QA programme checks – geometric parameters (including CT, Linac, gated equipment, in vivo dosimetry devices etc and discrepancies between reporting and action level)
SB	3f	Planned QA programme checks – dosimetric calibration (including CT, Linac, gated equipment, in vivo dosimetry devices etc and discrepancies between reporting and action level)
SB	3g	Planned QA programme checks – safety (IRR compliance)
SB	3h	Planned QA programme checks – image quality parameters (including CT, MR, portal, cone-beam, film processor)
SB	3i	Regular preventative maintenance and repair programme
	3j	Handover of radiotherapy equipment after planned QA and maintenance (including handover to other department such as diagnostic colleagues)
SB	3k	Routine radiation safety checks
	3l	Other
		Patient-specific activities
	4	**Referral for treatment**
SB	4a	Identification of patient (verification against primary source data)
SB	4b	Verification of diagnosis/extent/stage (including laterality)

	4c	Choice of dose
	4d	Choice of modality
	4e	Choice of energy
	4f	Choice of fractionation
	4g	Choice of start date
SB	4h	Consideration of patient condition/co-morbidities (including ICED or pacemaker status, prosthesis, patient unsuitable for IV contrast and changing performance status)
SB	4i	Choice of other concurrent treatment or interventions and their sequencing or timing (including patient selection criteria not met)
SB	4j	Consent process and documentation
	4k	Other (previously 4i)
	5	**Communication of intent**
	5a	Completion of request for treatment (paper/electronic) (including incomplete requests or insufficient data and failure to handover referral)
	5b	Recording of patient ID
	5c	Completion of required demographics
	5d	Completion of tumour-specific information (including laterality)
	5e	Completion of radiation-specific information
	5f	Completion of details of other professionals

	5g	Completion of administrative data (including documentation of MDT outcomes)
SB	5h	Recording of previous radiotherapy treatment details
SB	5i	Recording of patient's specific requirements (includes communication/ handover/ documentation of patient specific information etc)
SB	5j	Recording of non-standard information/protocol variations
SB	5k	Authorisation to irradiate (IR(ME)R) (including requests not signed by appropriately entitled practitioner and authorisation of additional imaging)
	5l	Other
	6	**Booking process (pretreatment, planning, treatment and follow up)**
	6a	Bookings made according to protocol
	6b	Bookings made according to request details (including requested changes following initial booking)
	6c	Recording of booked appointments (including requested changes following initial booking)
	6d	Communication of appointments to patient (including requested changes following initial booking)
	6e	Other
	6f	Communication of appointment between staff groups (including requested changes following initial booking)
	7	**Processes prior to first appointment**
	7a	New patient: registration with healthcare organisation's PAS
	7b	New patient: registration with department PAS

	7c	New patient: generation of notes (including their availability as required across the patient pathway)
	7d	Old patient: location of healthcare organisation's notes
SB	7e	Old patient: location of department notes/previous treatment details (including availability of archived materials)
SB	7f	Availability of reports/imaging required by protocol for treatment (including requirements for these at all points on the pathway)
SB	7g	Availability of consent documentation
	7h	Other
	8	**Pretreatment: preparation of patient**
SB	8a	Confirmation of ID
SB	8b	Confirmation of consent
SB	8c	Confirmation of fertility/pregnancy status
SB	8d	Advice on procedure (including training on breath hold, bladder or bowel preparation, ICED or pacemaker status, information on pre-medication, fiducial insertion etc)
	8e	Other
	9	**Mould room/workshop activities**
SB	9a	Confirmation of ID
	9b	Pre mould room diagnostics/interventions
	9c	Production of immobilisation devices

SB	9d	Checking/fitting of immobilisation devices
	9e	Production of other accessories/personalised beam shaping device
SB	9f	Checking of other accessories/personalised beam shaping device
	9g	Labelling of mould room/workshop outputs
	9h	Recording of information in patient record (includes communication/ handover/ documentation of patient specific information etc)
	9i	Instructions to patient
SB	9k	End of process checks
	9l	Other
	10	**Pretreatment activities / imaging (to include CT, simulation, clinical mark-up, reference image production)**
SB	10a	Confirmation of ID
	10b	Positioning of patient
	10c	Localisation of intended volume (including insufficient scan length, incorrect scanning protocol, incorrect laterality)
	10d	Production of images using correct imaging factors (including production of reference images)
	10e	Production of images using appropriate field sizes (including production of reference images)
	10f	Production of images demonstrating correct detail (including incorrect scanning protocol and production of reference images)
	10g	Labelling of images (including pre-scan data entry eg ID format, orientation etc and production of reference images)

	10h	Saving of planning geometry data
SB	10i	Recording of radiation data
	10j	Documentation of instructions/information
	10k	Marking of patient or immobilisation device
SB	10l	End of process checks (including timeliness of sending scans to treatment planning)
	10m	Identification of staff
	10n	Other
SB	10o	Assessment of patient prior to exposure
	10p	Use of contrast (including unplanned event such as leaking out, extravasation, timing of contrast etc)
	10q	Use of gating (including discrepancy between intended treatment technique and pretreatment scan, scan acquisition, construction of image sequence or application of gating equipment etc)
	11	**Pretreatment planning process (including virtual simulation and replans)**
SB	11a	Verification of patient ID, orientation and data entry format to include all patient data, imaging etc
	11b	Recording of patient ID on plan
	11c	Importing of data from external and internal administrative sources
	11d	Importing of data from external and internal imaging sources
	11e	Choice of data for planning purposes and to inform planning eg MRI, PET, angio, contrast , pre-op/post op data etc

	11f	Choice of dose and fractionation inputs
SB	11g	Availability of source data
	11h	Choice of technique/modality (including IMRT/ volumetric/ ART/ superficial or protons etc)
	11i	Target and organ at risk delineation (including incorrect growing of volume)
	11j	Generation of plan for approval (to include DVH, incorrect labelling, inappropriate beam arrangement, replans or missing plan information etc)
SB	11k	Authorisation of plan
SB	11l	Verification of plan/identification of responsible staff
SB	11m	Recording of definitive treatment prescription
SB	11n	Recording of patient specific instructions
	11o	Management of process flow within planning (including plan export)
	11p	Management of authorisation process
	11q	Timeliness of plan production or approval
	11r	Calculation process for non-planned treatments
SB	11s	Calculation checking process for non-planned treatments
SB	11t	End of process checks
SB	11u	Identification of responsible staff

	11v	Other
	12	**Treatment data entry process**
SB	12a	Pre-data entry verification (including OMS data import)
	12b	Choice of data entry method (input vs. transcription)
SB	12c	Use of correct data
SB	12d	Correct ID of patient/all patient input data
SB	12e	Correct ID of patient output data
	12f	Accuracy of data entry (including field sequencing and image scheduling and any required amendments)
SB	12g	End of process checks (including OMS data import)
SB	12h	Identification of responsible staff
	12i	Other
	13	**Treatment unit process (including EXBRT, Protons and Superficial)**
	13a	Availability/timeliness of all required documentation
SB	13b	Patient ID process
SB	13c	Patient data ID process
	13d	Explanation/instructions to patient
SB	13e	Confirmation of pregnancy/fertility status

SB	13f	Assessment of patient prior to treatment (including pre-medication prior to treatment eg analgesia, antiemetics etc, pace-maker or ICED status)
	13g	Patient positioning
SB	13h	Use of IVD according to local protocol
SB	13i	Use of on-set imaging (including imaging according to local protocol)
	13j	Transfer of marks
	13k	ID of reference marks
	13l	Movements from reference marks
	13m	Setting of treatment machine parameters
	13n	Setting of collimator angle
	13o	Setting of jaw position
	13p	Setting of asymmetry
	13q	Setting of couch position/angle (incorrect setting of couch following movement to allow gantry clearance)
	13r	Use of immobilisation devices (including gating equipment)
	13s	Use of beam shaping devices
	13t	Use of beam direction aids/applicators
	13u	Use of compensators (including bolus)

	13v	Use of wedges
	13w	Availability of treatment accessories
	13x	Setting of energy
	13y	Setting of monitor units
	13z	On-set imaging: production process (including inappropriate exposure used, image not captured, incorrect CBCT filter used or left in for kV image, incorrect field localisation of exposure, unsuitable positioning of imaging panel)
SB	13aa	On-set imaging: approval process (including image review not completed, image review inaccurate, image matched to wrong reference image, incorrect prioritisation of structures for matching)
	13bb	On-set imaging: recording process (recording of result of image review not undertaken, resultant actions from image review not undertaken, documentation and application of systematic correction)
SB	13cc	Management of variations/unexpected events/errors (including management of replans, migration of fiducials, transfer between treatment machines)
SB	13dd	Communication between treatment unit and V&R
	13ee	Recording of patient attendance
	13ff	Recording of delivered treatment data
	13gg	Recording of additional information
SB	13hh	End of process checks (including checking of clearance for automated set-ups)
SB	13ii	Identification of responsible staff
	13jj	Other

	14	**On-treatment review process**
SB	14a	On-treatment review of patient according to protocol by RT staff
SB	14b	On-treatment review of patient according to protocol by other professional
SB	14c	On-treatment review of notes/data to according protocol (including omission of weekly chart checks)
	14d	Actions following on-treatment review
	14e	Other
	15	**Brachytherapy (including Molecular RT and sealed source IORT)**
	15a	Ordering of sources
	15b	Delivery of sources
SB	15c	Source calibration
SB	15d	Sterility of sources
SB	15e	Correct applicators /sources
SB	15f	Correct theatre equipment
	15g	Initial positioning of applicators / sources
	15h	Planning of treatment (including replans)
	15i	Maintenance of position of applicators /sources
	15j	Removing of applicators / sources

	15k	Other
SB	15l	Validation of applicator/ source position
SB	15m	Authorisation of plan
SB	15n	Management of variations/unexpected events/errors (including management of replans, seed migration or fiducial migration etc)
SB	15o	Use of on-set imaging (including imaging according to local protocol)
	15p	On-set imaging: production process (including inappropriate exposure used, image not captured, incorrect field localisation of exposure, unsuitable positioning of imaging panel)
SB	15q	On-set imaging: approval process (including image review not completed, image review inaccurate, image matched to wrong reference image, incorrect prioritisation of structures for matching)
	15r	On-set imaging: recording process (recording of result of image review not undertaken, resultant actions form image review not undertaken, documentation and application of systematic correction)
SB	15s	End of process checks
	16	**End of treatment process**
	16a	Communication of appropriate end of treatment information to patient
SB	16b	Recording of treatment summary information in notes
	16d	Communication of information to referring clinician/GP/CNS etc
	16e	Organisation of follow-up appointment to protocol
	16f	Communication of follow-up to patient
	16g	Other

	17	**Follow-up process**
	17a	Follow-up consultation and documentation
	17b	Management of non-attendance
	17c	Archiving of details of treatment
		Other activities contributing to protocol violations
	18	**Timing**
SB	18a	Timing of chemo/irradiation
	18b	Transport issues
	18c	Portering issues
	19	**Document management**
SB	19a	Availability of current protocol, procedures, work instructions forms, training and competency documentation
	20	**Staff management**
SB	20a	Availability of staff with competency appropriate to procedure (including engineers, IT, medical, nursing, physics, radiographer etc)

Acknowledgements

This document has been reviewed and endorsed by The Institute of Physics and Engineering in Medicine, The Royal College of Radiologists (Faculty of Clinical Oncology) and the Society and College of Radiographers.

The PSRT would like to acknowledge the help of all those involved in the development of this taxonomy and guidance document. This work would not have been possible without the contribution of a number of individuals and the support of their organisations.

Donna Forsyth & Frances Healey, NHS England; Andrea Hirst, Weston Park Hospital, Sheffield; Andrew Morgan, Taunton & Somerset NHS Foundation Trust, Taunton; Clare Hutton, Castle Hill Hospital, Hull; Cristiona Logan, Belfast City Hospital, Belfast; Deborah Bennet, Freeman Hospital, Newcastle; Julie Johnston, North Wales Cancer Treatment Centre, Ysbyty Glan Clwyd; Karen Postlewaite, Clatterbridge Cancer Centre Foundation Trust, Clatterbridge; Linda Harvey, UCLH, London; Mark Rose, Norfolk and Norwich University Hospitals NHS Foundation Trust, Norwich; Michael Graveling, Northampton General Hospital NHS Trust, Northampton; Nicola Redgwell, Aberdeen Royal Infirmary, Aberdeen, Steve Williams, University Hospital Birmingham NHS Foundation Trust, Birmingham, LASER (London and South East Radiotherapy Quality Managers Group: 'LASER QMG') and MOSQuITO (Midlands Organisation of Specialists in Quality Improvement for Therapeutic Oncology)