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Safer radiotherapy

National patient safety radiotherapy event taxonomy

Contents

Introduction

Event learning systems are a widely accepted safety tool advocated internationally by professional groups, bodies, agencies, and regulators in radiotherapy (1). Analysis of reported data allows weaknesses in operational systems to be identified to inform the direction of system refinements and service improvements. It is imperative patient safety radiotherapy events (RTE) are learned from, and effective safety actions are implemented (2), so these events might be mitigated.

The national voluntary reporting of radiotherapy events (RTE) began in 2010 and has become well established. All NHS radiotherapy providers submit reports (3) with independent providers starting to share data in 2022. The terminology and taxonomies originally defined in 2008 within Towards Safer Radiotherapy (TSRT) have now been adopted across UK radiotherapy providers. The pathway coding was refined in 2016 within the Development of Learning from Radiotherapy Errors (DoL). The use of standardised terminology, classification and coding allows providers to compare their local analysis to the regional and national picture. In 2022, the Patient Safety in Radiotherapy steering group (PSRT) agreed to update these to better reflect contemporary practice and consolidate all RTE terminology and taxonomies in one document.

Objectives

This document marks the outcome of the work of the PSRT in the review of the terminology, definitions and taxonomies used in the description of RTE.

The objectives of this work include:

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

These definitions and taxonomies supersede the taxonomies included in TSRT and Development of Learning from Radiotherapy Errors. This document should be reviewed alongside Advancing Safer Radiotherapy (ASR) guidance (4).

Scope

The radiotherapy coding taxonomy includes all RTE along the radiotherapy pathway, including the following activities:

- planning scans undertaken in the radiotherapy department, for example computed tomography (CT) or magnetic resonance imaging (MRI)
- on-set verification imaging, for example megavoltage (MV), kilovoltage (kV), conebeam CT (CBCT) or MRI
- radiotherapy treatment exposures.

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

The national radiotherapy event taxonomy includes patient safety events which reflect a divergence from the radiotherapy pathway. Patient safety events that do not constitute a divergence from the radiotherapy pathway, or radiotherapy events that do not involve the patient, will not be classified or coded as an RTE but these should still be reported locally for learning purposes. Some examples of safety events that are not considered RTE include slips, trips and falls, or events involving staff or members of the public, for example accidental exposure of personal dosemeters.

Terminology

To reflect contemporary safety thinking outlined in ASR (4), some terminology has been revised. Table 1 includes previous terminology with updated terminology and acronyms.

Table 1. Updated terminology

Previous terminology	Updated terminology	Acronym
Radiotherapy error	Radiotherapy event	RTE
Near miss (a subset of radiotherapy error)	Good catch (a subset of radiotherapy events)	
Causative factor	Contributory factor	CF

Definitions of radiotherapy events and radiation incidents

Radiotherapy events (RTE)

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. Following an incorrect radiotherapy protocol is also a radiotherapy event and can lead to radiation incidents. Not all radiotherapy events lead to radiation incidents – for example, due to

a good catch the event is detected before the patient is treated or because the event happens not to affect the treatment delivery.

Radiation incident (RI)

A radiotherapy event where the delivery of radiation during a course of radiotherapy is other than that which was intended by the prescribing practitioner as defined in IR(ME)R (5 to 6) and which therefore could have resulted, or did result, in unnecessary harm to the patient.

A radiotherapy patient safety event (PSE) encompasses patient safety incidents and good care. The PSRT will investigate how learning from good care may be better reflected in future work.

Taxonomies

Classification taxonomy

The severity of a RTE is defined by the classification taxonomy. The classification taxonomy contains 5 severity classifications. Table 2 outlines the definition of each of the 5 classifications. A decision grid is available (Appendix 1) to enable coding of the RTE.

Table 2. Definition of classification taxonomy

Classification	Definition
Reportable RI Or: Other Notifiable Event (Level 1)	Incidents that require notification to the relevant regulatory authorities; such as an RI that falls into the category of notifiable under IR(ME)R (5 to 6) Further definition for a reportable RI can be seen in the significant accidental or unintended exposures (SAUE) guidance (7 to 10). An example includes a total geographical miss. Other such authorities include the Medicines and Healthcare products Regulatory Agency (MHRA) for MRI incidents. MRI incident examples include (11) : • patient burn • projectile incident resulting in patient injury • ferromagnetic item brought into the MRI environment resulting in patient injury • scanning of undeclared MRI unsafe implants

Classification	Definition
Non-reportable (moderate) radiation or MRI incident (Level 2)	An RI or MRI safety event that does not reach the threshold for notification in accordance with guidance, but may be of potential significance. These may affect tumour control, normal body toxicity or quality of life. An example includes a mismatch of verification imaging leading to treatment outside of locally defined tolerances but not a geographical miss notifiable under IR(ME)R (7 to 10)
Non-reportable (Minor) Radiation or MRI incident (Level 3)	An RI in the technical sense, or an MRI safety event, but one of no potential or actual significance. Examples include equipment malfunction during treatment leading to additional verification imaging, omission of required verification imaging or a patient scanned incorrectly in MRI resulting in an additional examination being required at a later date.
Good catch (Level 4)	Involves the interception and prevention of a potential RI or MRI incident. An example includes the incorrect recording of patient set up instruction at pre-treatment CT, which traverses undetected local standard pre-treatment checks. The omission of the set-up information was then detected during patient set-up within the treatment room, preventing the requirement for additional verification exposures.
Other non-conformance (Level 5)	None of the above; that is, a non-compliance with some other aspect of a documented procedure but not directly affecting radiotherapy delivery. Examples include the incorrect booking of patient appointments detected during local checking processes, or a hazard identified before a patient entered the MRI environment.

Pathway taxonomy

The radiotherapy pathway coding describes the points in the radiotherapy pathway where an RTE may have occurred. To reflect contemporary radiotherapy practice the 2016 pathway taxonomy was reviewed and the following actions were taken:

- national RTE reports voluntarily submitted to UKHSA were analysed to assess the use of ‘other’ coding taxonomy – this process highlighted areas of coding which may benefit from further clarification
- upon receipt of national RTE reports consistency checking on the application of the RTE taxonomies is completed by UKHSA staff – this process identified areas of coding which may benefit from further refinement

- feedback from RTE reporters, the ASR working party and the PSRT have been amalgamated to inform this review and further refine the pathway taxonomy

Pathway taxonomy refinement

Descriptions of 21 pathway subcodes have been updated to reduce ambiguity, 13 of which were related to brachytherapy associated subcodes. An additional 11 subcodes have been added to the pathway taxonomy as presented in Appendix 2, these include coding to reflect contemporary practice across the radiotherapy pathway. Table 3 includes the new pathway subcodes and further descriptors or examples.

Table 3. New pathway subcodes and examples (text in teal denotes additions in terms of descriptors and new codes)

New pathway subcodes	Descriptors or examples
(6g) Use of electronic task lists (quality check list, care pathway)	Electronic task incomplete, which may lead to assignment of next step not occurring correctly
(10r) Monitoring of patient during pretreatment activity exposure	Patient not appropriately observed during imaging exposure
(10s) Assessment of patient after exposure (including RF burns for MRI)	Assessment of patient directly after scan, for example to ensure all markers removed
(10t) Management of variations, unexpected events (including pretreatment equipment failure)	Equipment malfunction during pretreatment which can include CT, MRI, simulator, ultrasound and any other pretreatment equipment
(13kk) Monitoring of patient during treatment exposure	Patient not appropriately observed during treatment exposure
(15t) Patient ID process	Patient identification not completed correctly
(15u) Patient data ID process	Import of incorrect data set for example, fraction 1 MRI scans for fraction 2. Cross checking of unlinked databases
(15v) Assessment of patient prior to treatment (including pre-medication, anaesthetic, for example, anticoagulation, analgesia, antiemetics and so on, cardiac implanted electronic device (CIED) status)	Failure to check previous radiotherapy details, staging imaging demonstrated contraindication to brachytherapy. Suboptimal Hb levels for HDR, missing or incomplete pre op information
(15w) Monitoring and assessment of patient during treatment	Patient not appropriately monitored during brachytherapy procedure

New pathway subcodes	Descriptors or examples
(19b) Audit (including new and established processes)	For example, non-conformance identified during audit of new or established processes
(19c Research (including local and national trials)	Failure to comply with research protocol

Reporter feedback noted a requirement to include further descriptors to reduce ambiguity across some pathway subcodes. Table 4 includes further descriptor and examples for these.

Table 4. Examples of pathway subcodes (text in teal denotes additions in terms of descriptors and new codes)

Pathway subcodes	Further description and examples
(0e) IT infrastructure (includes change or failure in hardware, software, upgrades, network changes, archive process, system compatibility, data transfer)	Failure of IT network system resulting in delays, interruptions in transfer of, or loss of images or data
(3i) Regular preventative maintenance and repair programme	For example, BCON cylinder volume not checked as scheduled
(11i) Target and organ at risk delineation (including incorrect growing of volume and auto contouring)	Volume delineation inaccuracies, incorrect growing of volume, inappropriate margins requested, peer review not completed when required
(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)	Image review not completed, image review inaccurate, image matched to inappropriate reference image
(13cc) Management of variations, unexpected events (including on-treatment equipment failure (not associated with on-set imaging), management of replans, migration of fiducials, transfer between treatment machines)	Equipment malfunction during treatment, not to be confused with equipment malfunction during on-set imaging
(13d) Explanation, instructions to patient	For example, bladder filling not explained appropriately before treatment commenced. Explanation of procedure not appropriate leading to patient movement during treatment

Pathway subcodes	Further description and examples
(13f) Assessment of patient prior to treatment (including pre-medication prior to treatment, for example, analgesia, antiemetics and so on, cardiac implanted electronic device (CIED) status, MRI safety)	For example, assessment of patient bladder before treatment not appropriate
(13g) Patient positioning (including the use of tools such as surface guidance technology)	Incorrect limb positioning leading to inaccurate patient positioning
(13i) On-set imaging: compliance with local image guidance protocols (including frequency and timing of imaging)	Imaging according to protocol, includes omitting verification imaging or undertaking verification imaging not in accordance with protocol (timing or modality)
(13l) Movements to isocentre (including from reference marks)	Including application of incorrect couch movements, incorrect isocentre shift calculations performed or the use of surface guided radiotherapy (SGRT) that incorrectly defines the treatment position
(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, on-set imaging equipment failure)	Inappropriate exposure used, image not captured, CBCT filter left in for kV image, equipment malfunction during verification image production, unsuitable positioning of imaging panel
(15l) Validation of applicator, source position	Tags marked for the channel for skin treatment, measurement for distance
(20a) Availability of staff with competency appropriate to procedure (including engineers, IT, medical, nursing, physics, radiographer and so on)	Competent staffing unavailable to undertake procedure

To reflect contemporary radiotherapy practice the 2016 pathway taxonomy was reviewed to highlight unused pathway subcodes. Feedback from RTE reporters and the ASR working party identified those pathway subcodes which could be merged. Thirteen pathway subcodes were merged into 4 new pathway subcodes, this change has been reflected in Appendix 2 and is summarised in Table 5.

Table 5. Merged pathway subcodes (text in teal denotes additions in terms of descriptors and new codes)

Updated merged pathway subcodes	Archived subcodes
(2j) Installation and testing before clinical use	(2b) Manufacturer's tests (2c) Acceptance tests (2d) Critical examination under IRR
(3m) Daily consistency checks	(3a) Daily consistency checks – geometric parameters (3b) Daily consistency checks – dosimetric calibration (3c) Daily consistency checks – safety
(3n) Planned QA programme checks	(3e) Planned QA programme checks – geometric parameters (3f) Planned QA programme checks – dosimetric calibration (3g) Planned QA programme checks – safety (3h) Planned QA programme checks – image quality parameters
(13ll) Setting of collimator angle, jaw position, asymmetry	(13n) Setting of collimator angle (13o) Setting of jaw position (13p) Setting of asymmetry

End of process checks

End of process checks (EOPC) are a subset of the pathway taxonomy and can often be allocated as a failed safety barrier or method of detection. A review of the EOPC was conducted in September 2022 (12). This indicated that the EOPC occurring at the end of each discrete part of the pathway may include further subcategories, whilst minimum criteria for checking across EOPC may differ. For example, EOPC within the treatment unit process (13hh) may include:

- in-room checks (such as confirming the correct patient position and immobilisation, correct treatment site identified, laterality, correct move to isocentre, correct FSD, gantry clearance, CBCT filters and so on)
- pre-exposure checks (such as confirming the correct imaging or MU, energy, inclusion of MLC): points 1 and 2 may also be considered as paused and checked criteria, further guidance on pause and check procedures is available (13)
- checks on completion of treatment exposures (such as confirming all fields are treated and complete, confirming the recording of additional information)

To allow for additional granularity within the EOPC subcodes 2 of the EOPC subcodes have been expanded for pretreatment imaging and treatment activities. Previous EOPC subcodes 10l and 13hh have been archived and been replaced by 3 additional pathway subcodes as demonstrated in Table 6.

Table 6. Expanded end of process checks (text in teal denotes additions in terms of descriptors and new codes)

Table 6a. Pretreatment activities, imaging (10l) End of process checks – archived

Expanded pathway subcodes	Descriptors
(10u) In-room end of process checks	Confirming patient position, immobilisation, treatment site identified, laterality, markers visible and so on.
(10v) Pre-exposure end of process checks	Confirmation of localisation of intended volume, scanning protocol.
(10w) Completion of pretreatment exposure end of process checks	Confirming the correct area is localised, confirming the information is stored and exported, timeliness of sending scans to planning.

Table 6b. Treatment unit process (13hh) End of process checks – archived

Expanded pathway subcodes	Descriptors
(13mm) In-room end of process checks	Confirming patient position, immobilisation, treatment site identified, laterality, moves to isocentre, FSD, gantry clearance, CBCT filters and so on.
(13nn) Pre exposure end of process checks	Confirming the imaging, MU, energy, inclusion of MLC and so on.
(13oo) Completion of treatment exposure end of process checks	Confirming all fields are treated and complete, confirming the recording of additional information.

In total there are 213 pathway subcodes.

Assigning pathway coding

RTEs are often multifaceted with multiple pathway subcodes assigned to each RTE. Providers are asked to include the primary pathway subcode and all other relevant pathway subcodes to illustrate all tasks involved during the RTE.

When assigning a pathway subcode consideration should be given to the failure of the specific task being completed, rather than the area it occurred. For example, a RTE occurring on the treatment unit during adaptive workflows may involve planning processes (deformable registration, auto segmentation, contour editing, plan generation and assessment). The entire pathway coding taxonomy should be considered before assigning an ‘other’ code from the

taxonomy to facilitate appropriate thematic learning. To that end, descriptions of numerous pathway subcodes have been updated to reduce ambiguity.

Safety barriers

Safety barriers (SB) are additional tasks undertaken across the radiotherapy pathway with the primary purpose of identifying and mitigating an event. These process steps are over and beyond core tasks undertaken as part of the planning and delivery of radiotherapy treatment.

These are included in the pathway coding and will be used by UKHSA in the RTE analysis. Providers are not required to indicate SB when assigning the pathway taxonomy for national reporting.

Method of detection

Method of detection (MD) is the process or point in the pathway where an event was identified. It is recommended that the entire pathway coding should be considered when assigning an MD. All RTE reports require the inclusion of an MD. An MD which detects an event and prevents its progression to a radiation incident is defined as a good catch (Level 4).

To indicate MD within a report the letters ‘MD’ should prefix the pathway subcode. The full pathway taxonomy can be seen in Appendix 2. Further guidance on the allocation of an MD within an RTE report can be seen in the submission procedure section.

Contributory factors taxonomy

The use of a contributory factor (CF) taxonomy enables identification of problems or contributory factors that could precipitate a range of different incidents (14). Systems Engineering Initiative for Patient Safety (SEIPS) is a framework for understanding outcomes within complex healthcare systems such as radiotherapy. It advocates a systems approach and emphasises that there are often multiple factors that will contribute to any particular event. Therefore, it is appropriate to consider all potential CF when reporting RTE.

Multiple CF can be assigned to a single RTE, and the entire CF taxonomy should be considered when allocating CFs. Consideration should be given to the associated CF for each pathway subcode identified. The CF taxonomy can be seen in Appendix 3. In keeping with the systems approach, the totality of CF should be included in RTE trend analysis.

Modality taxonomy

RTE review via the national RTE database is completed utilising the nationally agreed taxonomies. To date it has been difficult to differentiate between treatment techniques or modalities, with RTE analysis limited to keyword searches. The introduction of a modality (D)

taxonomy allows the identification of trends within the RTE data specific to the type of treatment (modality).

To minimise the burden on RTE reporters the new modality taxonomy has been developed to align with existing national taxonomies (15). The full modality taxonomy can be seen in Appendix 4. When submitting a modality, a D should prefix the modality code.

Submission procedure of RTE for national analysis

Radiotherapy providers are asked to apply the coding taxonomies to their local reporting and learning system. The voluntary submission of RTE reports nationally does not negate the requirement to report all SAUE (7 to 10) to the appropriate inspectorates and any equipment malfunctions to the relevant regulatory agency and manufacturers.

To support national learning through a standardised approach, radiotherapy providers are asked to apply the following key metrics to local analysis and include them in each RTE report submitted to UKHSA to support national learning.

This includes the:

- **TSRT9 trigger code** for those reporting through the NHS England (NHSE), Learning from Patient Safety Event system
- **classification level –** describes the severity of the RTE
- **primary pathway subcode –** describes where in the pathway the event was initiated
- **additional pathway subcode –** describes subsequent points in the pathway where events may have occurred. There can be multiple pathway subcodes assigned
- **method of detection (MD) –** describes how the RTE is identified
- **contributory factor (CF) –** describes a system failure or condition that precipitated the RTE; there can be multiple contributory factors assigned
- **modality (D) –** describes the type of radiotherapy treatment

An associated text description should include the following for each RTE to ensure there is sufficient information to classify and code an RTE locally and nationally:

- anatomical site involved in the RTE
- prescribed dose and fractionation of treatment
- intended dose for exposure and actual dose delivered
- if appropriate, magnitude of geographic misplacement
- a brief description of the circumstances surrounding the incident which could include:
    - contributory factors leading to the RTE

- how the event was detected, and any preceding points at which the RTE should have been detected
- implications for the patient and any correct or preventative action taken
- where applicable, equipment related information

The following is an example.

Classification level: Level 3
Primary pathway subcode: 13g
Additional pathway subcodes: 13mm
Method of detection: 13aa
Contributory factors: CF1d
Modality: D04

RTE taxonomy for submission:

TSRT9/ Level 3/ 13g/ 13mm/ MD13aa/ CF1d/ D04 *text description of event*.

Examples of incident coding

The following are examples of scenarios with the taxonomy coding:

Scenario 1

TSRT9/ Level 1/ 13z/ 13mm/ MD13aa/ CF2c/ CF1c/ D03

The fourth day of treatment for breast patient receiving 26Gy in 5 fractions over 1 week. Daily verification image required for confirmation of patient positioning. First 3 treatment fractions treated correctly. The patient was set up for the fourth treatment, the image panel was positioned by operator A but not independently checked according to local protocol by operator B. The verification image was acquired, leading to only part of the image captured due to image panel misalignment. The image panel was repositioned, and an additional image acquired. The second image was also not appropriately captured, the image panel had been moved too far in the opposite direction. A reset of the image panel for a third image was completed. The image was correctly acquired, matched and the patient treated.

The patient received 3 verification exposures.
For the above scenario the following taxonomy coding applies:

Classification: Level 1 ‘Reportable radiation incident’
Primary pathway subcode: 13z ‘on-set imaging: production process’
All subsequent pathway subcodes: 13mm ‘In-room end of process checks’
Method of detection: 13aa ‘on-set imaging: approval process’

Contributory factors: CF2c ‘adherence to procedures or protocols’ and CF1c ‘slips and lapses’
Modality: D03 ‘IMRT (static field)’

RTE taxonomy for submission:

TSRT9/ Level 1/ 13z/ 13mm/ MD13aa/ CF2c/ CF1c/ D03 *text description of event.*

Scenario 2

TSRT9/ Level 3/ 13cc/MD13cc/ CF3a/ D04

Patient receiving 60Gy in 20 fractions over 4 weeks for prostate treatment. During treatment of day 6 an equipment fault occurred. The patient had received a verification CBCT image which indicated the positioning was correct. The first arc treatment was completed. However, before the second arc could be started a fault occurred on the treatment unit. The engineers were called and could not clear the fault.

The patient was removed from the treatment room and taken to another treatment unit. Due to the transfer an additional verification CBCT was required. The patient was set up on the second treatment unit, verified for treatment using a second CBCT and the second arc of treatment was completed.

For the above scenario the following taxonomy coding applies:

Classification: Level 3 ‘non-reportable minor radiation incident’
Primary pathway subcode: 13cc ‘management of variations, unexpected events’
All subsequent pathway subcodes: None
Method of detection: 13cc ‘management of variations, unexpected events’
Contributory factors: CF3a ‘equipment or IT network failure
Modality: D04 ‘Rotational IMRT’

RTE taxonomy for submission:

TSRT9/ Level 3/ 13cc/ MD13cc/ CF3a/ D04 *text description of event.*

Summary

The use of the taxonomies outlined within this document supports trend analysis which can be replicated at national, regional and local level. Providers are encouraged to report all levels of RTE to generate a comprehensive national dataset that is locally led and data-driven to support local and national learning and service improvement.

It is important that an RTE report contains sufficient information to confirm relevant codes and classification from the current taxonomy guidelines.

The following key learning points have been collated to assist in the identification, reporting and analysis of RTE locally:

- RTEs can be events of omission (not performing an element in the radiotherapy pathway), or of commission (performing an element incorrectly). However, the RTE classification has been designed as an outcome-based system and is therefore not dependent on this differentiation
- not all RTE lead to patient safety incidents. The RTE may be detected prior to the patient being irradiated
- all RTEs – radiation incidents, good catches or non-conformances – should be reported locally and nationally
- the full taxonomy, including classification, pathway subcodes, method of detection and contributory factors should be used to support trend analysis
- most RTEs are multifactorial, but each starts 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 pathway subcode. Secondary points will be those that followed from this primary point; further events which occurred in the pathway stemming from this primary point
- occasionally a similar event may affect multiple individuals, or a recurring event may affect multiple individuals. In each case a RTE report should be submitted for each individual affected

If any UK radiotherapy reporting provider has feedback on these taxonomies or would like further clarification, please email radiotherapy@ukhsa.gov.uk.

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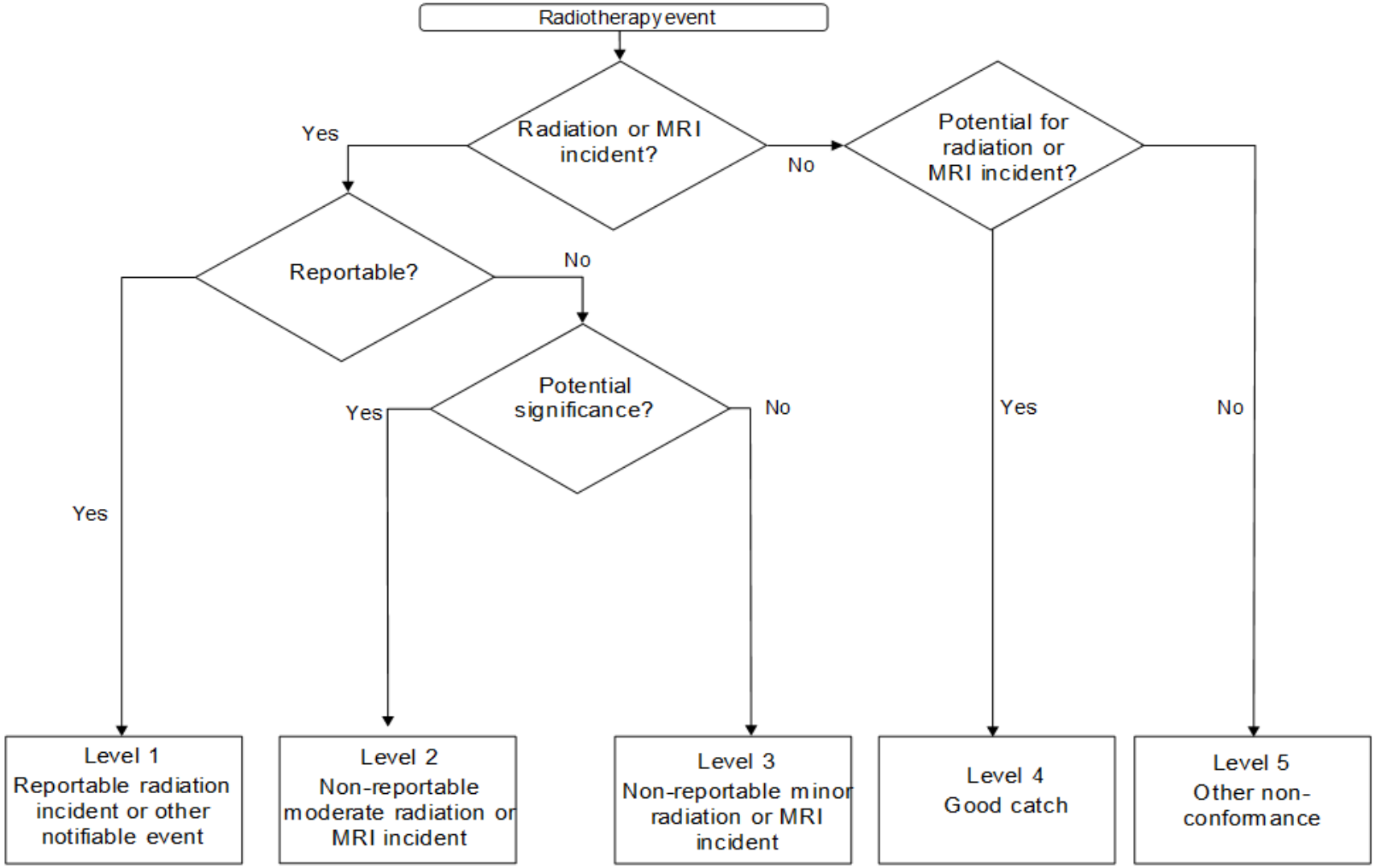
Appendix 1. Classification taxonomy



Appendix 2. Pathway taxonomy

In the tables that follow, text in teal denotes additions to the pathway coding in terms of descriptors and new codes.

0	Infrastructure
1	Room design
2	New equipment
3	Routine machine QA
4	Referral for treatment
5	Communication of intent
6	Booking process and administration process (pretreatment, planning, treatment and follow up)
7	Process prior to first appointment
8	Pretreatment: preparation of patient
9	Mould room, workshop activities (these activities are not limited to mould room or workshop areas)
10	Pretreatment activities, imaging (to include CT, MRI, simulation, clinical mark-up, reference image production)
11	Pretreatment planning process (including virtual simulation and replans)
12	Treatment data entry, data preparation process
13	Treatment unit process (including external beam radiotherapy, Protons and Superficial)
14	On-treatment review process
15	Brachytherapy (including sealed source and IORT)
16	End of treatment process
17	Follow-up process
18	Timing
19	Research, audit and document management
20	Staff management

0. Infrastructure
(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 or failure in hardware, software, upgrades, network changes, archive process, system compatibility, data transfer)

Equipment-specific activities

1. Room design
(1a) Patient safety (includes alteration of room design or use)
(1b) Staff and public safety (includes alteration of room design, safety feature design such as ferroguard or their use)
(1c) Environmental controls
(1d) Access control (access to control area)
(1e) Other

2. New equipment
(2a) Installation
(2e) Customisation and configuration of equipment (to include the use of assistive artificial intelligence)
(2f) Commissioning (to include assistive artificial intelligence)
(2g) Data recording

(2h) Preparation of data files for planning systems (to include treatment planning systems, virtual simulation, independent dosimetry checking software, assistive artificial intelligence and so on)
(2i) Other
(2j) Installation and testing before clinical use (amalgamated previous codes 2b, 2c, 2d)

3. Routine machine QA
(3d) Daily verification of accuracy of data transfer between TPS, R&V system and treatment equipment
(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)
(3k) Routine radiation safety checks
(3l) Other
(3m) Daily consistency checks (amalgamated previous codes 3a, 3b, 3c)
(3n) Planned QA programme checks (amalgamated previous codes 3e, 3f, 3g,3h)

Patient-specific activities

4. Referral for treatment
(4a) Identification of patient (verification against primary source data)
(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
(4h) Consideration of patient condition, co-morbidities (including CIED, prosthesis, patient unsuitable for IV contrast and changing performance status)
(4i) Choice of other concurrent treatment or interventions and their sequencing or timing (including patient selection criteria or referral criteria not met)
(4j) Consent process and documentation
(4k) Other

5. Communication of intent
(5a) Completion of referral for treatment (including incomplete referral or insufficient data or failure to communicate 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)
(5h) Recording of previous radiotherapy treatment details
(5i) Recording of patient's specific requirements (includes communication, handover, documentation of patient specific information and so on)
(5j) Recording of non-standard information, protocol variants
(5k) Authorisation of exposure (including referrals not signed by appropriately entitled practitioner and authorisation of additional imaging)
(5l) Other

6. Booking process and administration processes (pretreatment, planning, treatment and follow-up)
(6a) Bookings made according to protocol
(6b) Bookings made according to referral details (including additional requirements and 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)
(6g) Use of electronic task lists (quality check list, care pathway)

7. Processes prior to first appointment
(7a) New patient: registration with healthcare organisation's patient administration system (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
(7e) Old patient: location of department notes, previous treatment details (including availability of archived materials)
(7f) Availability of reports, imaging required by protocol for treatment (including requirements for these at all points on the pathway)
(7g) Availability of consent documentation
(7h) Other

8. Pretreatment: preparation of patient
(8a) Confirmation of ID
(8b) Confirmation of consent

(8c) Confirmation of fertility, pregnancy status
(8d) Advice on procedure (including training on breath hold, bladder or bowel preparation, CIED or electronic device status, information on pre-medication, fiducial insertion, MRI safety and so on)
(8e) Other

9. Mould room, workshop activities (these activities are not limited to mould room or workshop areas)
(9a) Confirmation of ID
(9b) Pre mould room diagnostics, interventions
(9c) Production of immobilisation devices
(9d) Checking, fitting of immobilisation devices
(9e) Production of other accessories, personalised beam shaping device
(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 and so on)
(9i) Instructions to patient
(9k) End of process checks
(9l) Other

10. Pretreatment activities, imaging (to include CT, MRI, simulation, clinical mark-up, reference image production)
(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 size (including production of reference images)
(10f) Production of images demonstrating correct detail (including incorrect scanning protocol and production of reference images)
(10g) Labelling of imaging dataset (including pre-scan data entry, for example, ID format, orientation and so on and production of reference images)
(10h) Saving of planning geometry data
(10i) Recording of radiation data
(10j) Documentation of instructions, information
(10k) Marking of patient or immobilisation device
(10m) Identification of staff (appropriate training, competency, entitlement)
(10n) Other
(10o) Assessment of patient prior to exposure
(10p) Use of contrast (including unplanned event such as leaking out, extravasation, timing of contrast and so on)
(10q) Use of gating (including discrepancy between intended treatment technique and pretreatment scan, scan acquisition, construction of image sequence or application of gating equipment and so on)
(10r) Monitoring of patient during pretreatment activity exposure
(10s) Assessment of patient after exposure (including RF burns for MRI)
(10t) Management of variations, unexpected events (including pretreatment equipment failure)
(10u) In-room end of process checks
(10v) Pre exposure end of process checks
(10w) Completion of pretreatment exposure end of process checks

11. Pretreatment planning process (including virtual simulation and replans)
(11a) Verification of patient ID, orientation and data entry format to include all patient data, imaging and so on
(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, for example, MRI, PET, angio, contrast, pre-op, post op data and so on
(11f) Choice of dose and fractionation inputs
(11g) Availability of source data
(11h) Choice of technique (including IMRT, volumetric, ART, superficial or protons and so on)
(11i) Target and organ at risk delineation (including incorrect growing of volume and auto contouring)
(11j) Generation of plan for approval (to include DVH, incorrect labelling, inappropriate beam arrangement, replans or missing plan information and so on)
(11k) Authorisation of plan
(11l) Verification of plan, identification of responsible staff (including patient specific quality control checks)
(11m) Recording of definitive treatment prescription
(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
(11s) Calculation checking process for non-planned treatments

(11t) End of process checks
(11u) Identification of responsible staff (appropriate training, competency, entitlement)
(11v) Other

12. Treatment data entry, data preparation process
(12a) Pre-data entry verification (including OMS data import)
(12b) Choice of data entry method (input vs. transcription)
(12c) Use of correct data
(12d) Correct ID of patient, all patient input data
(12e) Correct ID of patient output data
(12f) Accuracy of data entry (including field sequencing and image scheduling and any required amendments)
(12g) End of process checks (including OMS data import)
(12h) Identification of responsible staff (appropriate training, competency and entitlement)
(12i) Other

13. Treatment unit process (including EXBRT, Protons and Superficial
(13a) Availability, timeliness of all required documentation and data
(13b) Patient ID process
(13c) Patient data ID process
(13d) Explanation, instructions to patient
(13e) Confirmation of pregnancy, fertility status

(13f) Assessment of patient prior to treatment (including pre-medication prior to treatment, for example, analgesia, antiemetics and so on, cardiac implanted electronic device (CIED) status, MRI safety)
(13g) Patient positioning (including the use of tools such as surface guidance technology)
(13h) Use of IVD according to local protocol
(13i) On-set imaging: compliance with local image guidance protocols (including frequency and timing of imaging)
(13j) Transfer of marks
(13k) ID of reference marks
(13l) Movements to isocentre (including from reference marks)
(13m) Setting of treatment machine parameters (including overrides)
(13q) Setting of couch position, angle (including 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, on-set imaging equipment failure)
(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)
(13cc) Management of variations, unexpected events (including on-treatment equipment failure (not associated with on-set imaging), management of replans, migration of fiducials, transfer between treatment machines)
(13dd) Communication between treatment unit and V&R
(13ee) Recording of patient attendance
(13ff) Recording of delivered treatment data
(13gg) Recording of additional information
(13ii) Identification of responsible staff (appropriate training, competency, entitlement)
(13jj) Other
(13kk) Monitoring of patient during treatment exposure
(13ll) Setting of collimator angle, jaw position, asymmetry (amalgamated previous codes 13n, 13o, 13p)
(13mm) In-room end of process checks
(13nn) Pre exposure end of process checks
(13oo) Completion of treatment exposure end of process checks

14. On-treatment review process
(14a) On-treatment review of patient according to protocol by RT staff
(14b) On-treatment review of patient according to protocol by other professional
(14c) On-treatment review of notes, data according to protocol (including omission of weekly chart checks)
(14d) Actions following on-treatment review
(14e) Other

15. Brachytherapy (including sealed source and IORT)
(15a) Ordering of sources (including unexpected wastage)
(15b) Delivery and transportation of sources
(15c) Source calibration
(15d) Sterility, contamination of sources
(15e) Correct applicators, sources (including the use of applicators, channels in delivery)
(15f) Correct and functioning medical equipment (including theatre equipment)
(15g) Initial positioning of applicators, sources
(15h) Planning of treatment (including replans)
(15i) Maintenance of position of applicators, sources (including movement of applicators, seed migration)
(15j) Removing of applicators, sources (including medical complications caused by the removal)
(15k) Other
(15l) Validation of applicator, source position
(15m) Authorisation of plan (including prescription not authorised)
(15n) Management of variations, unexpected events (including treatment equipment failure, anatomical implications such as perforations or management of seed migration)
(15o) Imaging: compliance with local image guidance protocols
(15p) Imaging: production process (including inappropriate exposure used, image not captured, marking or labelling applicators, quality of image, unsuitable positioning of imaging panel)
(15q) Imaging: approval process (including incorrect image acceptance)
(15r) Imaging: recording process (including resultant actions not undertaken)

(15s) End of process check (at each element of the workflow such as pause and check)
(15t) Patient ID Process
(15u) Patient data ID process
(15v) Assessment of patient prior to treatment (including pre-medication, anaesthetic for example, anticoagulation, analgesia, antiemetics and so on, cardiac implanted electronic device (CIED) status)
(15w) Monitoring and assessment of patient during treatment

16. End of treatment process
(16a) Communication of appropriate end of treatment information to patient
(16b) Recording of treatment summary information in notes
(16d) Communication of information to referring clinician, GP, CNS and so on
(16e) Organisation of follow-up appointment according to protocol
(16f) Communication of follow-up to patient
(16g) Other

17. Follow-up process
(17a) Follow-up consultation process and documentation (including follow – up actions required, patient identified unexpected toxicity or potential adverse event)
(17b) Management of non-attendance or non –engagement
(17c) Archiving of details of treatment

18. Timing
(18a) Timing of systemic anti-cancer therapy (SACT), irradiation, surgery

(18b) Transport issues
(18c) Portering issues

19. Research, audit and document management
(19a) Availability of current protocol, procedures, work instructions forms, training and competency documentation
(19b) Audit (including new and established processes)
(19c) Research (including local and national trials)

20. Staff management
(20a) Availability of staff with competency appropriate to procedure (including engineers, IT, medical, nursing, physics, radiographer and so on)

Appendix 3. Contributory factor (CF) taxonomy

Text in teal denotes additions to the contributory factor coding in terms of descriptors and new codes.

Category	Code	Description	Definitions and examples
Category	**CF1**	**Individual**	Occurs when the actions and decisions of individuals result in failures.
Sub-category	CF1a	Failure to recognise hazard (knowledge-based and so on)	Where the person 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 events.
	CF1b	Decision making process (rule-based or old or invalid rule used and so on)	Where, in non-routine events, the decided course of action is inappropriate resulting in an event; flawed or inadequate decision making; or 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 events.
	CF1c	Slips and lapses (skill-based, involuntary automaticity and so on)	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 events occurring in a pressurised work environment.
	CF1d	Communication (inaccuracy or omission of verbal, written and so on)	Includes those events associated with human interaction failures within the team; inadequate, 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 (deliberate action, acting outside scope and so on)	Includes deliberate actions by an individual; knowingly acting outside scope of practice.

Category	Code	Description	Definitions and examples
Category	**CF2**	**Procedural**	Associated with failure of procedure or process to prevent an event.
Sub-category	CF2a	No procedures or protocols (not in place or unavailable and so on)	Where the appropriate supporting documentation is not in place or is unavailable for existing or new processes, techniques and technologies.
	CF2b	Inadequate procedures or protocols	Where the supporting documentation is not sufficient or is out of date for existing or new processes, techniques and technologies.
	CF2c	Adherence to procedures or protocols	Where the locally defined process was not adhered to.
	CF2d	Process design (impractical and inefficient processes and so on)	Includes impractical and inefficient processes that cannot be performed properly in the allotted time; failure to execute the planned action.
Category	**CF3**	**Technical**	Relate to the equipment used which directly contributes to the event
Sub-category	CF3a	Equipment or IT network failure (including immobilisation and accessories)	Includes situations where a machine malfunction leads directly to an event; 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. This does not include power cuts which are included in CF6a Physical. Note: This should not be confused with the inappropriate handling of a machine malfunction that then leads to an event.

Category	Code	Description	Definitions and examples
	CF3b	Commissioning, calibration, maintenance (including immobilisation and accessories)	Defined as inappropriate or incomplete commissioning, calibration or maintenance of equipment (hardware and software) such as an immobilisation device or accessory equipment; includes situations where incorrect data was provided by the vendor or supplier.
	CF3c	Device, product design	Include flaws or inadequacies inherent in the design of equipment or ancillary kit used as part of the exposure or to inform the exposure.
	CF3d	Equipment supplier related (withdrawal of support, servicing, spare parts)	Include withdrawal of support from the equipment supplier, servicing and availability of spare parts.
Category	**CF4**	**Patient related**	Relate to incidents where the actions or individual circumstances of the patient directly contribute to the event.
Sub-category	CF4a	Patient physical or medical condition (inability to remain still and so on)	Relates to where the patient's general health condition is particularly complex or serious; for example, inability to remain still or inability to maintain bladder.
	CF4b	Communication with the patient (language issues, comprehension and so on)	Includes those events 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 event.

Category	Code	Description	Definitions and examples
	CF4c	Patient choice, compliance	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 – that is, tattoos or skin marking and compliance of paediatrics; where a patient has chosen to purposefully ignore advice which has directly led to an incident – that is, deliberately withheld knowledge of a pregnancy.
Category	**CF5**	**Teamwork, Management, Organisational**	Organisational or management factors are associated with inadequate organisational structures and culture. These factors transcend all levels of the organisation from senior management to individual teams working at an operational level.
Sub-category	CF5a	Inadequate leadership (inadequate supervision, congruence or consistency and so on)	Includes absence of a safety culture at a strategic or operational level; where 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 (across the radiotherapy pathway)	At a strategic or operational level includes undefined roles, responsibilities and lines of accountability within the organisational structure and across teams; 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 (equipment in use no longer fit for purpose and so on)	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.

Category	Code	Description	Definitions and examples
	CF5d	Inadequate staffing (insufficient staffing levels or skill mix necessary to meet the demands of a service and so on)	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 (inadequate or lack of training and so on)	Includes inadequate or lack of training on local, new or changed processes, techniques and technologies.
	CF5f	Inadequate risk assessment (inadequate change management and so on)	Includes the absence of, out of date and inadequately maintained risk assessment and ineffective planned change management or introduction of new processes, techniques and technologies.
Category	**CF6**	**Environmental**	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 event.
Sub-category	CF6a	Physical (power cut, control area excessively noisy, distractions and so on)	Includes inadequate design of equipment and inadequate workplace layout; power cuts; area excessively noisy and so on.
	CF6b	Natural factors (fire, flood and so on)	Include situations where a fire, flood and so on have contributed to the event.
Category	**CF7**	**Other**	
	CF7a	Other	If none of the codes above accurately describe the CF for the incident, please describe the CF in the free text to aid future refinements of the taxonomy.

Appendix 4. Modality taxonomy (D)

Text in teal denotes additions to the coding in terms of descriptors and new codes.

Modality code	Descriptor
D01	Simple (direct or parallel opposed fields) and electrons
D02	Conformal
D03	Intensity modulated radiotherapy (IMRT) (static field) excluding more specific definitions
D04	Rotational IMRT including volumetric modulated arc therapy (VMAT) and RapidArc
D05	Intraoperative radiation therapy (IORT)
D06	Total body, skin radiotherapy – including total body irradiation (TBI) and total body electrons (TBE)
D07	Stereotactic ablative body radiotherapy (SABR)
D08	Stereotactic radiotherapy, radiosurgery (SRT, SRS)
D09	Proactive adaptive radiotherapy – predicts changes likely to occur and prepares a choice of plans (library of plans) to compensate for these changes
D10	Real-time adaptive radiotherapy – creates and delivers a new plan online (on the treatment machine with patient in treatment position). Can occur for each fraction or when required
D11	Contact radiotherapy (superficial, orthovoltage, Papillion)
D12	Brachytherapy
D13	Proton beam therapy
D98	Other treatment

Acknowledgements and PSRT steering group membership

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 Patient Safety in Radiotherapy steering group would like to thank all stakeholders for their ongoing commitment to the refinement and update of the RTE taxonomies. We would like to thank:

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- Petra Jankowska (Consultant Clinical Oncologist, Somerset Foundation Trust; Quality and Safety Lead, RCR) (member 2019 to 2024)
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- Josh Mutio (Patient Safety Team, NHSE)
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- Carl Rowbottom (Head of Physics, The Clatterbridge Cancer Centre NHS Foundation Trust)
- Kim Stonell (UKHSA and Secretariat)

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UKHSA is an executive agency, sponsored by the Department of Health and Social Care.

Version 1

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Published: May 2024
Publishing reference: GOV-17882