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Learning from ionising radiation dose errors, adverse events and near misses in UK clinical imaging departments

Working party user guidance

June 2019

Contents

The purpose of this document

The primary aim of this **user guidance** is to help UK clinical imaging staff to minimise future potential ionising radiation exposures errors/near misses while enhancing ongoing patient safety. This user guidance is intended to provide a **practical approach** to implementing the *standard categorisation system* for the identification of errors and near misses – this includes the primary process coding (Tiers 1 and 2 of the coding taxonomy) and any contributory factors with instructions on using the reporting template (an information technology [IT] system to report final codes). It involves a clear objective methodology for highlighting, categorising and recording errors and near misses involving ionising radiation that may occur during any phase of the clinical imaging patient pathway. The guidance is covered by pages 4–14 but also includes supporting information within appendices.

In addition to this user guidance, a full and comprehensive report from the working party to the UK clinical imaging board is available.[1] This report includes a review of the global literature surrounding this issue, the approach to implementing the *standard categorisation system*, recommendations for implementation as well as the agreed taxonomies and reporting methodologies, which mirror the various patient pathways in clinical imaging services. The report also details information about the development of the taxonomy over time, the pilot phase of the work (involving a sample of clinical imaging departments across the UK), the results of the pilot (including consistency checking and resultant codes of control scenarios) as well as the final changes made to the coding taxonomy (including contributory factors) and the reporting template. Resultant codes for further scenarios are included in the report to support a deeper understanding of the *standard categorisation system*.

The report and this user guidance are wide-ranging and do not undermine an employer's legal responsibilities for reporting accidental or unintended radiation exposures 'clinically significant' to the appropriate authority under the Ionising Radiation (Medical Exposure) Guidelines (IR(ME)R).[2,3] It is envisaged that the use of the *standard categorisation system* may also support UK clinical imaging departments in fulfilling their responsibilities under Regulation 8(3) of IR(ME)R (2017 and 2018). [2,3]

It is advisable that the full report is read before using this guidance.

1. Categorisation methods

The coding taxonomy

When reading this guidance, please refer to the associated spreadsheet entitled **'Final coding taxonomy 08102018'.**[4]

Each clinical imaging department is advised to print out the final coding taxonomy, laminate it and make it available in relevant area(s) to be a source of reference. The taxonomy is colour coded for ease of use.

To support the development of a system that identifies, classifies, codes and reports errors, adverse events and near misses involving ionising radiation, the working party, created this *coding taxonomy*. The complex nature of radiological and nuclear medicine services caused widespread discussion. It was important that this taxonomy identified each element of the typical patient pathways found in both radiological and nuclear medicine services, and that the resultant code could identify the root cause and any contributory factors leading to errors, adverse events and near misses. Incidents often involve a complex chain of events. While an oversight or certain action may be viewed as the immediate cause of an incident, subsequent analysis will often expose a series of events or deviations from safe practice.

Root cause – an identified event that leads to anticipated operational occurrences or accident conditions.

Contributory factor – the latent weakness that allows or causes the observed cause of an initiating event to happen, including the reasons for the latent weakness.

The final version of the coding taxonomy is described in detail here (refer also to the spreadsheet which includes further detail).[4]

The coding taxonomy describes each part of the patient pathway from point of referral to final report. It provides options for the user to choose from to identify the nature of the error or near miss (hereafter referred to as the 'incident' for simplicity):

- The **severity** level (1–3)
- The **exposure type** (1–4)
- The **performed modality** (1–7)
- The **intended modality** (A–I)

Severity:

- Level 1: Error – reportable to appropriate authority under IR(ME)R.[2,3] These are incidents that are notifiable to the appropriate enforcing authority.
- Level 2: Error – non-reportable (statutorily). These are incidents that do not meet the criteria for notification. These incidents should still be investigated locally.
- Level 3: Near miss – These are near-miss situations where the error was detected BEFORE the patient was exposed to ionising radiation. They should still be investigated locally.

Exposure type:

1. Medical exposure
2. Non-medical imaging using medical radiological equipment
3. Research
4. Health-screening programmes

Examples of **non-medical exposures** include X-rays performed for employment, insurance or immigration purposes. This category also includes general radiography or computed tomography (CT) scans performed to identify concealed objects within the body and the use of dual-energy X-ray absorptiometry (DXA) to assess body composition when performed outside of a patient care pathway.

Performed/intended modality:

Performed modality:

1. General radiography
2. Computed tomography (CT)
3. Nuclear medicine single-photon emission computed tomography(SPECT)/positron emission tomography CT (PET-CT)
4. Fluoroscopy
5. Mammography
6. Dual-energy X-ray absorptiometry (DXA)
7. Interventional radiology

Intended modality:

A. General radiography
B. Computed tomography
C. Nuclear medicine single-photon emission computed tomography(SPECT)/positron emission tomography CT (PET-CT)
D. Fluoroscopy
E. Mammography
F. Dual-energy X-ray absorptiometry (DXA)
G. Interventional radiology
H. Magnetic resonance imaging (MRI)
I. Ultrasound

The **computed tomography (CT) only** category should not be used for radiotherapy planning errors and near misses.

Errors and near misses involving nuclear cardiology should be classified using the **nuclear medicine and SPECT/PET-CT** category.

The **interventional radiology** category includes gastrointestinal (GI), neurology, vascular and cardiac procedures. This category also includes situations where an error occurred when using fluoroscopy to guide the insertion of a radioisotope as part of a nuclear

medicine procedure as is the case for Y-90 microsphere administrations. This could go in either fluoroscopy or interventional.

Duty holders:

This section relates to the IR(ME)R duty holder (the individual) who made the error. The **'None'** category should only be used for incidents that were purely as a result of equipment or patient issues.

Duty holder:

- The employer
- The referrer
- The practitioner
- The operator
- None

The duty holder is then further categorised (a, b, c and so on) according to role or pathway. These categories depend on the duty holder. For example:

Practitioner:

A. Consultant radiologist
B. Practitioner licence holder
C. Radiology SpR
D. Cardiologist
E. Radiographer
F. Other: free text

Once the duty holder is established, incidents are sub-categorised to identify the **root cause** as follows:

Tier 1 (Primary code): the point in the pathway that the error first occurred.

Tier 2 (Secondary code): the detail of the error – what went wrong?

Error/near miss classification – application of error taxonomies

It is intended that both the root cause (Tier 1 and 2) and contributory factor taxonomies are applied by individuals with a clear understanding of radiology, cardiology and nuclear medicine processes, and who will have received some training on the application of the taxonomies. Ideally these individuals would include (and be supported by) a multidisciplinary team consisting of medical physicists, radiographers and radiologists.

Tier 1: Employer's responsibility

The **lack of procedures** category relates to a lack of IR(ME)R employer's procedures. **Equipment not fit for purpose** includes out-dated equipment that is, equipment that exceeds European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) recommendations for equipment life span.[5]

Tier 1: Referrer

Wrong timing applies to examinations that were performed earlier/later than required.

Referral information – insufficient/inaccurate clinical information includes failure to provide information regarding contrast allergies, blood test and/or pathology results and missing patient preparation information.

Referral information – illegible handwriting includes a referrer signature that cannot be read or identified.

Patient preparation – psychological preparation (including consent) includes providing patients with adequate information relating to benefits and risks.

Patient preparation – physical preparation could include situations such as inserting the nasogastric (NG) tube before completing a referral for a post NG tube check X-ray or cannulation, oral prep, starvation or prophylactic hydration.

An example of **working outside of scope of practice** would be an emergency department (ED) nurse who is entitled to refer patients for X-rays of the extremities but actually refers a patient for a chest X-ray (CXR).

Non-entitled referrer would include situations such as a radiographer working in MRI referring a patient for a ? FB orbit X-ray when s/he is not entitled to refer for plain radiographs; or a general practitioner (GP) surgery receptionist completing a referral for a patient to have an X-ray.

Tier 1: Practitioner

The **justification** category should be used when the examination should not have been justified at all. This is different from when the examination was justified but should have been performed using a different modality. If the latter situation applies to the error/near miss then the **modality** category should be used.

An example of **incorrect protocol timing** would be where the practitioner wrote 'arterial phase' instead of 'portal venous phase' or they failed to specify phase and there was no existing protocol.

The following three examples help to illustrate this section:

1. *A trauma CT study is justified and authorised as an arterial and portal venous phase CT thorax, abdomen and pelvis (TAP). An arterial TAP followed by a portal venous phase TAP is performed. An error is reported as the practitioner had intended the protocol to be interpreted as arterial TAP followed by portal venous phase abdomen and pelvis.*
2. *A follow-up post neurosurgical CT head study is justified and authorised as a CT head plus contrast. The patient receives a pre- and post-contrast CT head. An error is reported as the practitioner had intended for this to be a post-contrast only study.*
3. *A CT scan request querying whether the patient has a pulmonary embolus is justified, authorised and protocolled by the radiologist (practitioner) as an arterial phase post-contrast CT scan of the thorax. The radiographer (operator) follows the protocol and the patient undergoes a CT thorax with arterial phase contrast. An error is reported as there is sub-optimal enhancement of the pulmonary artery and the patient requires further imaging.*

An example of **working outside of scope of practice** would include situations such as a registrar justifying a fluoroscopy referral when s/he is only entitled to justify 'plain film' exposures.

An example of a **non-entitled practitioner** would be a radiographer 'justifying' an X-ray examination when s/he is only entitled (as an operator) to authorise under guidelines.

Tier 1: Operator

Patient safety checks – unknown/undeclared pregnancy applies to situations where it is discovered after the examination has been performed that the patient was pregnant at the time of the examination. This category should only be used where all checks were made correctly, in line with the IR(ME)R employer's procedure for making pregnancy enquiries. For instances where the IR(ME)R procedure for making pregnancy enquiries was not followed the **patient safety checks – failure to check pregnancy** should be used.

Patient safety checks – failure to check breast-feeding only applies to nuclear medicine examinations. This category should not be used for MRI or CT contrast agent checks.

Clinical history – check patient information given and consent given refers to the clinical information provided about the patient and ensuring the patient understands what imaging examination they are having and why, so they are able to consent. This includes routine examinations, for example, does the patient understand the benefits and risks?

Exam authorisation – wrongly authorised – wrong timing applies to examinations that would have been perfectly fine to authorise if they were done at the correct time (or interval since last examination), for example, a screening mammogram performed less than six months after a previous mammogram.

Pre-exposure safety checks – wrong patient position/set-up includes situations where the patient should have been positioned head first/feet first, prone/supine or using the internal/external lights on the CT scanner.

Pre-exposure safety checks – wrong anatomy/anatomy missed should not be used for technical repeats where the error would not have been identified at the pre-exposure check.

Examples of **pharmaceutical/contrast preparation – wrong timing** include situations where oral preparation is not given at the correct time and the wrong expiry times put on radiopharmaceuticals.

Pharmaceutical/contrast administration – wrong timing includes situations where the wrong contrast delay is set or where the region of interest (RoI) is placed in the wrong area resulting in poor bolus tracking. This also includes cases when the radiopharmaceutical is administered at the wrong time compared to the procedure protocol (for example, too early following potassium iodate administration for thyroid blocking).

Pharmaceutical/contrast administration – contrast delivery issue includes issues where the pressure injector doesn't start at the correct time or the operator forgets to connect the injector to the patient. Errors where the contrast and saline chaser are swapped would also fall into this category.

An example of a **pharmaceutical/contrast administration – extravasation/ misadministration** error might include giving contrast arterially in error rather than

intravenously (IV), or extravasating a large amount of the radiopharmaceutical rendering the images undiagnostic.

The **equipment** category in the operator section relates to errors/near misses where the operator fails to use the equipment in an appropriate way or fails to do something that results in image loss; this category should not be used for equipment faults (these would be categorised as duty holder: None errors/near misses)

Equipment – handover issue includes errors/near misses where an engineer carried out work that may impact on patient dose or when an applications specialist changes a protocol without passing this information on to the site.

Equipment – image loss errors are situations where the operator failed to do something which then resulted in an image being lost, for example, failing to check that images have been transferred to picture archiving and communication system (PACS) before deleting the images from the modality.

Equipment – IT error – an example would be computerised radiology information system (CRIS)-modality interface being down, therefore transcription error due to manual data input.

Example:

Errors involving data input or system settings (not related to patient ID information), or failure to follow correct IT procedures that have directly affected image quality or integrity. (These errors will often involve more than one patient, For example, incorrect system changes made to time/date.)

Equipment – local changes to protocol would be used to categorise an error/near miss that was as a result of a protocol change by a member of staff, for example, a super user changing a CT protocol and accidentally switching off mA modulation and setting a fixed mA instead.

Post-processing – no/insufficient images on PACS category should be used when a patient needs to be recalled due to insufficient or no images on PACS resulting in a repeat exposure.

Post-processing – images in wrong patient folder should only be used if a repeat exposure is needed to provide assurance that the image is indeed in the wrong folder. Consider inclusion of near misses here.

Post-processing – wrong image date/time, for example, the wrong accession number is selected from a worklist.

Post-processing – wrong laterality markers should only be used if a repeat exposure is required to provide assurance that the wrong marker was used.

Working outside of scope of practice examples might include an assistant practitioner who X-rays a child when they are only entitled to X-ray adults or a new radiographer performing a mobile CXR on a ward without supervision before s/he has been signed off as competent to undertake mobile imaging.

Non-entitled operator would include situations where someone who is not entitled to undertake any operator roles does so, for example, an operating department practitioner (ODP) in theatre operating a mini-C-arm.

Tier 1: None

Equipment related – these are errors/near misses that are simply the result of an equipment failure/fault and all duty holders carried out their tasks correctly. This category should not be used if an individual uses the equipment incorrectly/inappropriately.

Patient related – should be used when all duty holders carried out their tasks correctly but either the patient did something or their condition caused an error to occur, for example, patient did not follow breathing instructions for a CT scan resulting in undiagnostic images or in cases when the patient has been administered the radioisotope but the delayed imaging fails, either due to patient not turning up for the scan or patient being taken ill before the scan has completed, rendering the study undiagnostic.

Contributory factors:

The coding taxonomy also identifies potential **contributory factors (CF).** While not the root cause, these are factors that contribute to an incident and may be related to weaknesses in systems or processes. For any given incident, there may be one or more contributory factors. The working party felt inclusion of contributory factor taxonomies would enhance trend analysis. The coding taxonomy facilitates the inclusion of up to three contributory factors per event. Future work on the analysis of incidents would seek to improve the learning from these events, subsequently improving patient safety. Contributory factors are categorised as follows:

Contributory factors:

- **CF1** – Individual
- **CF2** – Procedural
- **CF3** – Technical
- **CF4** – Patient related
- **CF5** – Teamwork/management/organisational
- **CF6** – Environmental
- **CF7** – Other

For any given incident, selection of the appropriate categories within the coding taxonomy results in an alphanumeric code specific to that incident. Recording of this code on a suitable IT system (such as the reporting template detailed later) supports the identification of patterns of errors and near misses.

Application of contributory factor taxonomy

Several studies have shown there is often a complex chain of events that may lead to an adverse outcome. 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. The contributory factor taxonomy has been designed so that each of these events can be captured.

Definitions and examples of contributory factor taxonomy

CF1: Individual

The field of human factors concerns the interaction between humans and the system in which they work.[6] 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; 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 which skills to apply to a situation; an 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 practised, proceeding without much conscious involvement; may be associated with tasks of a repetitive nature or preoccupation or distraction; may include physical stress or fatigue; involuntary automaticity; skill-based errors occurring in a pressurised work environment; non-adherence to procedures or protocols.
- CF1d – communication includes those errors associated with human interaction failures within the team; poor or 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 includes deliberate actions by an individual; knowingly acting outside scope of practice; deliberately not following procedures /protocols.

CF2: Procedural

Procedural factors are associated with the failure of a procedure or process designed 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/or 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/or technologies.
- CF2c – process design includes impractical and inefficient processes that cannot be performed properly in the allotted time.

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 or IT network failure contributes to an error; failure of accessory equipment; machinery that appears 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, for example, lack of communication and lack of a 'do not use sign' on malfunctioning equipment which leads to the equipment being inappropriately used again.

- CF3b – commissioning/calibration/maintenance/handover is defined as inappropriate or incomplete commissioning, calibration, maintenance or handover of equipment (hardware and software) or accessory equipment; includes situations where incorrect data were provided by the vendor or supplier; where equipment was incorrectly calibrated or protocols were adjusted 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's physical condition is particularly complex or serious including an 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 and comprehension difficulties; where lack of communication, or miscommunication, results in the patient misunderstanding 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 his/her own volition or through an unknown inability to comply; where cultural, religious and social issues affect the ability of a patient to comply with pre-conceived expectations; compliance of paediatric patients; where a patient has chosen purposefully to ignore advice which has directly led to an incident – for example, deliberately withholding knowledge of a pregnancy.

CF5: Teamwork/management/organisational

Teamwork/management/organisational 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; discouraging constructive challenging of policies; outdated practice; inadequate supervision or consistency; attempting to achieve imposed targets or waiting times without review of available resources; inappropriat planning or management of workload.

- 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 service and associated processes; inadequate service level agreements or contracts.
- CF5c – inadequate capital resources includes: equipment and finance and relates to situations where appropriate funding is not available to run the service as proposed; 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, or out-of-date and poorly maintained risk assessment protocols; ineffective or poorly planned strategies for change management or the introduction of new processes, techniques and technologies.

CF6: Environmental

Environmental factors are associated with the design of the work area and availability of equipment.

- CF6a – physical includes poor design of equipment and poor workplace layout; power cuts; excessive noise.
- CF6b – natural factors include situations where a fire or flood have contributed to the error.

CF7a: Other

If none of the codes above accurately describes the contributory factor for the incident, the contributory factors should be descripbed in the free text to inform a future refinement of the taxonomy.

Scenario using full coding taxonomy (with CF):

The following incident scenario helps to illustrate how the full coding taxonomy is used to create the final alphanumeric code:

An adult patient presented for a skeletal survey X-ray and this was undertaken by a second year student under supervision. On the lateral lumbar spine view the detector was not fully covered by the X-ray beam and a very high exposure – five times the intended dose – was given.

For this incident, the resultant code is: **2/1/1/A/DH4f/T14/T2c/CF1a/**

Severity: Level 2 (Error – non-reportable)

Exposure type: 1 (Medical exposure)

Performed modality: 1 (General radiography)

Intended modality: A (General radiography)

Duty holder: DH4f (Operator, trainee under supervision)

Tier 1: 4 (pre-exposure safety checks)

Tier 2: c (wrong patient position/set up)

Contributory factor: CF1a (organisational, inadequate leadership/supervision)

The reporting template

Please refer to the associated spreadsheet entitled **'Final reporting template 08102018'.**

The working party created the reporting template (RT) to record the full alphanumeric code. This is an Excel spreadsheet with drop down boxes for each element of the final alphanumeric code. Once the categories are agreed, the user enters these into the RT by clicking on the relevant boxes for each column. The intention is that the RT should be a 'live' document that may be used at any time and by any user, preferably whoever codes the incident. Results from the RT may be analysed for patterns of errors and near misses and can be shared locally or nationally. It is hoped that the information from these patterns will be widely disseminated to support ongoing discussion and learning by staff in UK services.

The working party hopes that ultimately this reporting template might be linked to existing management incident reporting systems, for exapmle, Datix to allow ease of use and time saving within already busy clinical imaging departments. Recommendation number four within the full report (page 5) document highlights this aspiration.[1]

References

1. Clinical Imaging Board. *Learning from ionising radiation dose rrrors, adverse events and near misses in UK clinical imaging departments.* London: The Royal College of Radiologists, 2019.
2. Her Majesty's Government. *The Ionising Radiation (Medical Exposure) Regulations 2017*. London: The Stationery Office, 2017.
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5. European Coordination Committee of the Radiological, Electromedical and Healthcare IT industry. *Medical imaging equipment age profile and density.* Brussels: COCIR, 2016.
6. Hinton-Walker P, Carlton G, Holden L, Stone PW et al. The intersection of patient safety and nursing research. *Ann Rev Nurs Res* 2006; 24: 3–15.
7. Society and College of Radiographers. *Pause and check IR(ME)R referrer poster.* London: Society and College of Radiographers, 2016.

Appendix 1.
Patient pathways for all clinical imaging modalities

It should be noted that the specific role of the duty holders under IR(ME)R as stated in this Appendix can vary slightly between different departments and different patient pathways.

Referrer pathway for medical exposures

The diagram below shows the steps involved for the **referrer** as the IR(ME)R duty holder when referring a patient for clinical imaging *(read/print in landscape format)*.

Considering the risk versus benefit principal, 'benefit' can only be established after the referrer has reviewed the results and made a decision regarding treatment or further investigation.

Patient correctly identified. Verify pregnancy or breastfeeding status. Previous medical history checked including relevant imaging (including duplicate requests). Patient's mobility assessed. Confirm patient understands and consents to the examination and understands when/how they will receive the appointment/urgent examination.	Referral guidelines (*iRefer* or local guidelines) to confirm appropriate examination requested. Non-ionising radiation alternative considered. Adequate relevant clinical information supplied on request form as required and including previous imaging.	Correct region/laterality confirmed. Unique identifier confirmed (signature/electronic signature/correct user login). Ensure correct timing is clearly defined.	Mandatory information completed. Check if this is the CORRECT patient again. Complete and send request. Cancellation procedure for exams no longer required.	EXPOSURE	Make and record clinical evaluation of examination in line with local procedures.**	Ensure clinical evaluation is used in the decision to manage. Consider need for further imaging. Discuss with patient.

*** Note: Some employers have delegated the responsibility of providing a clinical evaluation to the referrer. IR(ME)R cites that the recording of a clinical evaluation is an operator function therefore if this responsibility has been devolved, the referrer must be adequately trained and entitled within local procedures.*

All steps, preceding (light pink box) and proceeding (white box) the medical exposure have been included. Also see SCoR's *IR(ME)R Referrer Pause and Check* poster at SCoR.[7]

Practitioner pathway for medical exposures

The diagram below shows the steps involved for the **practitioner** as the IR(ME)R duty holder when justifying a diagnostic imaging procedure. Consideration must be given to the risk versus benefit principal, such that a sufficient net benefit should result from the medial exposure.

Where no direct medical benefit is expected for the individual (volunteers participating in research exposures) dose constraints should be adhered to.

All steps, preceding the medical exposure have been included.

Please note: In interventional radiology, the practitioner may be a radiologist, cardiologist, vascular surgeon or a radiographer with advanced practice

Please note: In nuclear medicine this is always the Administration of Radioactive Substances Advisory Committee (ARSAC) certificate holder ((b) in Tier 2 of CT). In IR(ME)R, this person must hold a practitioner licence.[1,2]

Other clinicians or radiographers who are entitled (as the operator) may authorise under guidelines produced by the practitioner.

Please note: Some of these stages may be undertaken by the entitled operator using authorisation guidelines developed by the practitioner.

Confirm referrer ID (Confirm referrer is entitled). Patient correctly identified. Match patient data on referral with RIS	Check previous medical history, including all relevant imaging. Enquire whether patient is pregnant or breastfeeding if relevant. Establish intended timing of procedure.	Evaluate clinical information supplied by referrer and consider any appropriate alternative procedure not involving ionising radiation. Balance risk versus benefit of medical exposure and confirm decision.	Assign modality and protocol. Include any specific requirements for the individual exposure.	Assign urgency. Clarify timing of procedure.	Justify the medical exposure. Authorise the medical exposure.

Operator pathway for medical exposures

The diagram below shows the steps involved for the **operator** as the IR(ME)R duty holder when performing the practical aspects of the exposure during a diagnostic imaging procedure.

This pathway assumes that the equipment is fit for purpose, that regular quality-assurance checks have been undertaken and that operators have been adequately trained to use the equipment. Also see SCoR's *IR(ME)R Operator Pause and Check poster*.[7]

Confirm identity of referrer (check they are entitled). Confirm justification of the exposure and identity of entitled practitioner. *OR* Compare referral with guidelines produced by a practitioner and authorise request when entitled. Check previous medical imaging for the patient. Confirm timing of the examination is appropriate. Confirm modality is correct. Check blood results as required for intravenous injections/interventional procedures.	Confirm correct patient identity. Confirm previous medical history and relevant imaging with patient. Explain procedure and confirm patient understands.	Confirm no contraindications to examination (follow pregnancy/ breastfeeding policy and so on). Confirm consent and record where appropriate. Confirm correct body region/ laterality. Confirm patient weight/ height when appropriate. Position patient.	Confirm correct product, date, volume, flow-rate, concentration, activity (where appropriate) and route of administration for any intravenous (IV) contrast agent or radiopharmaceutical associated with exposure. Select appropriate examination protocol and equipment settings. Perform optimisation adjustments with due regard to patient age, sex, pregnancy status, BMI and dose constraints.	EXPOSURE	Complete exposure. Check image quality and confirm no further imaging required. Complete post processing. Attend to aftercare needs of patient including appropriate information regarding results.	Send images to image archive system and confirm complete arrival of images on archive system (where possible before proceeding with next patient).	Record exposure factors Complete clerical duties with regard to all documentation including the administration of contrast agent or radiopharmaceutical. Document a clinical evaluation.

Operator pathway for studies involving radioactive substances (nuclear medicine and nuclear cardiology including SPECT/CT and PET/CT)

The diagram opposite shows the steps involved for the **operators** when performing the practical aspects of the exposure for studies involving radioactive substances paying special attention to differences/specific requirement that occur in these types of studies compared to other modalities in clinical imaging.

This pathway involves a number of steps and many different professionals. Some of the steps do not directly involve the patient and not all steps are relevant to all patients. More than one operator may be included in each step, for example, when double checking on dispensing or administration is required.

This pathway assumes that the equipment is fit for purpose, that regular quality-assurance checks have been undertaken with regards to the equipment and the radiopharmaceutical and that operators have been adequately trained.

Authorisation under protocol	Requesting Radiopharmaceutical	Preparing and dispensing Radiopharmaceutical	Checking quality of Radiopharmaceutical	Administration of radioactivity	EXPOSURE – ADMINISTRATION	Scanning the patient	EXPOSURE – CT SCANNING AS REQUIRED	Taking radioactive blood samples	Processing of radioactive blood samples
Confirm referrer ID. (Confirm referrer is entitled). Patient correctly identified. Match patient data on referral with RIS. Check previous medical history, including all relevant imaging. Enquire whether patient is pregnant or breastfeeding if relevant and issue advice as appropriate. Evaluate clinical information supplied by referrer and compare with protocol/ guidelines produced by ARSAC holder to establish/ assign procedure to be undertaken. Establish intended timing and radioactivity as per ARSAC holder's protocol/ guidelines. Authorise the medical exposure when entitled.	Confirm authorisation of the exposure and identity of entitled practitioner/ authorising operator. Check previous medical imaging for the patient. Confirm timing of the examination is appropriate. Confirm correct procedure. Check blood results or other safety precautions as appropriate for procedure. Establish any corrections to be made to the radioactivity based on age/height/weight of patient as per ARSAC holder's protocol. Request the correct radioactivity and radiopharmaceutical for the correct time, procedure and patient.	Confirm correct requested radioactivity and radiopharmaceutical for correct procedure. Ensure the correct manufacturing of the radiopharmaceutical product. Make appropriate corrections for radioactivity based on age/height/weight/pregnancy status of patient as per ARSAC holder's protocol. Draw up the correct product, including volume, concentration, and radioactivity for the procedure and ensure this is correct for the requested time of administration. Correctly label the vial/syringe and update records.	Ensure the appropriate chromatography is undertaken for the correct radiopharmaceutical as per local protocol to ensure that the radiochemical purity of the product conforms to the guidelines. Record result as appropriate.	Confirm correct patient identity. Confirm modality is correct. Confirm medical history and clinical information with patient and request. Confirm previous medical imaging for the patient. Confirm timing of the examination is appropriate. Confirm blood results or other safety precautions as appropriate. Confirm consent and record where appropriate. Confirm no contraindications to examination (follow local pregnancy/breastfeeding policy, etc) including patient ability to undergo scan. Confirm advice as appropriate (for example, stop breastfeeding for x hrs) Confirm any corrections made to the radioactivity based on age/height/weight pregnancy status of patient are correct as per ARSAC holder's protocol. Explain procedure and any restrictions to be followed afterwards and confirm patient understands. Confirm correct radiopharmaceutical, date, time, volume, radioactivity and route of administration and record as appropriate.		Confirm correct patient identity. Confirm modality is correct. Confirm correct radiopharmaceutical administration and that timing of the examination is appropriate. Confirm medical history and clinical information with patient and request. Confirm previous/relevant imaging. Explain procedure and confirm patient understands. Confirm correct body region/laterality. Position patient. Select appropriate examination protocol and equipment settings. Perform optimisation adjustments with due regard to patient height/weight or BMI, pregnancy status. Confirm no further imaging required. If further imaging is required ensure appropriate authorisation is obtained.		Confirm correct patient identity. Confirm consent and record where appropriate. Confirm correct procedure. Confirm relevant medical history/clinical information with patient. Explain procedure and confirm patient understands. Confirm correct sampling site. Confirm correct radiopharmaceutical administration and that timing is appropriate and record as appropriate. Ensure samples are labelled correctly with patient, study and timing details.	Confirm correct patient samples Select appropriate protocol and equipment settings as per request. Ensure all samples are subdivided into correctly labelled vials and follow correct local protocol. Prepare standard samples as per local protocol as appropriate. Insert correct patient, procedure, radiopharmaceutical, blood and standard samples data into calculation sheet to obtain the result.

Appendix 2. Scenario examples using full coding taxonomy (with CF included)

CF1: Individual

The patient was positioned for a CT abdomen/pelvis scan by radiographer A. The topogram was performed and radiographer A positioned the start and end positions to include the required anatomy. The resultant CT scan unexpectedly included a large volume of the lungs and missed the lower portion of the pelvis. Radiographer A noticed the required anatomy was missing and repositioned the start and end positions again using the same topogram. Another two CT abdomen/pelvis scans were performed on the advice of a second radiographer (B) in an effort to demonstrate the required anatomy. It transpired the patient had moved position on the scan table after the initial topogram had been performed. Radiographers A and B realised patient movement should have been considered when the first error was identified and a repeat topogram should have been performed at this point.

Coding: Level 1/1/2B/DH4c/4c/CF1b/CF1c/CF4a

CF2: Procedural

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

A patient was referred for a CT scan of the chest abdomen and pelvis for suspected underlying malignancy. The patient was elderly and had limited capacity but was accompanied by a family member. The patient was correctly identified, prepared and positioned on the CT scanner by the radiographer. It was only when the scan was completed and the patient had left the scan room that the radiographer noticed the patient had undergone a CT chest, abdomen and pelvis three weeks previously as an inpatient. The pause and check procedure had not been followed and it transpired there had been two referrals made for this patient. It transpired there were no procedures in place to identify duplicate referrals prior to scheduling the examination appointment.

Coding: Level 1/1/2B/DH4c/2b/CF2a/CF1c

CF3: Technical

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

There appeared to be a generator fault on a DR X-ray unit. The operator had just taken a chest X-ray but following the generator fault these images were no longer available to review on either the X-ray unit study list or the PACS. Despite the operator performing a full shutdown and reboot of the system the image could not be retrieved. A call was logged with IT and the PACS team were asked to provide support with locating the image. It was established that this was not an issue with PACS but an equipment fault which had erased the image permanently from the X-ray unit.

Coding: Level 2/1/1A/DH5/1a/CF3a

CF4: Patient related

Patient factors relate to incidents where the actions or individual circumstances of the patient directly contribute to the error.

Patient was administered a 0.37MBq capsule in order to perform a nuclear medicine SeHCAT bile study. The patient was scheduled to return one week later for the scan to complete the study but did not attend at the appointment time. The patient was contacted by telephone and agreed to attend for the scan later that day but did not arrive or make contact with the department. They were also contacted the following morning by telephone

but hung up and did not respond to further requests to attend for their scan. The study was aborted without imaging or a diagnosis.

Coding: Level 1/1/3C/DH5 /1b/CF4c

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.

A patient received a CT scan using an incorrect scan protocol to answer the clinical question being asked. The practitioner (SpR radiologist) justified the examination prior to the appointment being scheduled and clearly identified a low dose CT kidneys, ureters and bladder (KUB) protocol. The CT KUB protocol was incorrect as the clinical information provided indicated that a CT urogram would be the appropriate examination. The scan was scheduled for a different radiologist's scanning list. The error was only identified after the CT KUB had been performed and reported. As the protocol should have been for a CT urogram the patient was recalled to have the contrast-enhanced scan element of the protocol. The operator who performed the scan was an agency radiographer on their second day working in the department. The departmental policy states all agency and new staff members must be closely supervised by an experienced radiographer until they have completed their local induction training. On this particular day the supervising radiographer had been called away to another patient on the adjacent scanner, leaving the agency radiographer to continue with the list unsupervised.

Coding: Level 3/1/2B/DH3c/3a/CF5a/CF5d

CF6: Environmental

Environmental factors are associated with the design of the work area and availability of equipment.

During a routine mammogram, the mammographer performed an exposure and then stepped backwards towards the edge of the room. The mammographer accidentally walked into the emergency off switch which was positioned on the wall behind operator panel. This then cut all power to the system and once restarted the patient's images were lost. This room had recently been reconfigured and no guard had been placed on the emergency stop to prevent accidental activation.

Coding: Level 2/1/5E /DH1/1g/CF6a/CF3c

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