CONTROLLED DOCUMENT

University Hospitals Birmingham
NHS Foundation Trust

Ionising Radiation (Medical Exposure) Regulations 2017

Procedure 13: Actions Required after an Accidental or Unintended Exposure to Ionising Radiation

To Comply with IR(ME)R 2017 Regulations 6 & 8 and Schedule 2 (i)

CATEGORY:	Procedure
CLASSIFICATION:	Health & Safety, Clinical Governance
PURPOSE:	To ensure that the referrer, the practitioner, and the individual exposed or their representative are informed of the occurrence of any relevant significant or clinically significant unintended or accidental exposure, and of the outcome of the analysis of this exposure.
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Distribution: Essential Reading for: Information for:	 Staff who are designated as an IR(ME)R duty holder, defined as referrer, practitioner and/or operator. The people listed in section 5 All staff.

Contents

Version Control

Version	Title	Issue Date
1.0	The procedure to detail actions in the event of a radiation incident and to ensure that the referrer, practitioner, the individual exposed or their representative are informed of the occurrence of any relevant clinically significant unintended or accidental exposure, and the outcome of the analysis of this exposure	21/09/2018
2.0	Actions Required after an Accidental or Unintended Exposure to Ionising Radiation	04/10/2022

1. Procedure Statement

1.1. To clarify the arrangements in the event of a radiation incident and, when there has been a significant or clinically significant unintended or accidental exposure, ensure that the referrer, practitioner, individual exposed or their representative and the appropriate regulatory authority are informed of the occurrence and the outcome of the analysis of this exposure.

2. Scope

2.1. Any accidental or unintended radiation exposure carried out by the Trust, as defined in Section 3.

2.2. Where a practitioner or operator considers that it is clinically appropriate to increase an exposure e.g. extend the length of a CT scan or continue an interventional procedure beyond the level that might cause tissue effects, this is deemed a change in the individual's management and not an incident.

2.3. This procedure will be applied to exposures resulting from equipment failure as well as those due to human error.

2.4. A foetal exposure where there has been no procedural failure is not considered SAUE. However, these may be notifiable as a clinically significant event.

3. Definitions

3.1. **Accidental exposure:** an individual has received an exposure in error, when no exposure of any kind was intended

3.2. **Unintended exposure:** although the exposure of an individual was intended, the exposure they received was significantly greater or different from that intended.

4. Practice: Significant accidental or unintended exposures ("SAUE")

4.1. The Care Quality Commission (CQC) provide definitions of "significant" on their website at: SAUE: Criteria for making a notification (cqc.org.uk) and in the document "Significant accidental and unintended exposures under IR(ME)R: Guidance for employers and duty-holders", available on the same webpage

4.2. SAUE are defined in terms of radiation dose. A medical physics expert should be asked for advice on whether or not an exposure is "significant". If an accidental or unintended exposure is significant, the CQC must be notified via their website at Notifying us - Care Quality Commission (cqc.org.uk)

5. Practice: Clinically significant accidental or unintended exposures ("CSAUE")

5.1. An accidental or unintended exposure that causes or has the potential to cause

"moderate harm" to the individual exposed would be considered clinically significant.

5.2. It is possible that the exposure would not be considered significant under the SAUE guidance.

5.3. Guidance on what could be considered clinically significant has been provided by professional bodies. The guidance is outlined in Appendix 2 and available in full via the following documents:

IR(ME)R: Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine | The Royal College of Radiologists (rcr.ac.uk)

Ionising Radiation (Medical Exposure) Regulations: Implications for clinical practice in radiotherapy Guidance from the Radiotherapy Board (rcr.ac.uk)

5.4. A clinician – in most cases, the practitioner– should decide whether an incident is clinically significant taking account of this Employer's Procedure and the relevant guidance named above

5.5. If an exposure is considered to be CSAUE CQC must be notified via their website at Notifying us - Care Quality Commission (cqc.org.uk)

6. Practice: Responsibilities of the Operator - All Radiation Incidents including Near Misses

6.1. If the incident is caused by equipment error, make the equipment safe by following contingency plans in Local Rules. Do not turn off faulty equipment unless this is necessary to make safe. Record any error messages on equipment.

6.2. Notify the appropriate Modality Lead or Service Manager immediately

6.3. In Radiotherapy, incidents are escalated according to the Standard Operating Procedure held in the Quality Management System

6.4. Complete Incident Report Form (Datix) in accordance with normal Trust procedure.

6.5. Provide any further information necessary for the incident to be investigated fully.

7. Practice: Responsibilities of the Modality / Service Lead - All Radiation Incidents including Near Misses

7.1. Where applicable, remove any faulty equipment from service and arrange investigation and/or repair, if appropriate

7.2. Manage the incident on Datix and start logging actions.

7.3. Carry out an immediate preliminary investigation to establish exactly what happened.

7.4. Liaise with MPE for advice on classification of the incident

7.5. Request advice from a Medical Physics Expert on:

- whether the incident is SAUE
- whether the unintended radiation exposure is “moderate”, in which case the incident may be CSAUE

7.6. For diagnostic and interventional radiology, the MPE is contacted using the form provided by RRPPS and held within the RRPPS quality management system, at UHB.RRPPSMPE@nhs.net

7.7. In Nuclear Medicine and Radiotherapy the relevant specialist MPE should be contacted.

7.8. Notify the IR(ME)R practitioner and request advice on whether the incident has resulted in “moderate harm”, as defined in the guidance mentioned inspection 0, in which case it may be CSAUE

7.9. If the incident is likely to be SAUE or CSAUE, notify the Relevant General Manager that it might be notifiable to the CQC

7.10. If the incident is determined to be CSAUE, ensure that the incident is classed as “moderate” or higher on Datix

8. Practice: Responsibilities (on request) of the Medical Physics Expert - All Radiation Incidents including Near Misses

8.1. Estimate and advise on doses and risks associated with the exposure to determine whether the incident is SAUE (see section 3).

8.2. Advise on the appropriate code to use when notifying the CQC provides a list of codes to be used when reporting a significant accidental or unintended exposure.

8.3. If there is a suspicion that the exposure may be a CSAUE (see section 3), provide dose and risk information

8.4. Advise on appropriate corrective and/or preventative actions

9. Practice: Responsibilities of the IR(ME)R practitioner - All Radiation Incidents including Near Misses

9.1. Liaise with the referrer and the Medical Consultant responsible for the individual exposed to determine whether the outcome of an accidental or unintended exposure is clinically significant (see section 3); advice should be sought from an MPE where required.

9.2. Advise the Medical Consultant responsible for the individual of the need to inform the individual and/or their representative if the incident proves to be determined as a SAUE or CSAUE incident.

9.3. Liaise with the Medical Consultant responsible for the individual exposed to ensure that they understand the doses and risk being quoted.

10. Practice: Responsibilities of the Relevant General Manager - All Radiation Incidents including Near Misses

10.1. If it is determined that a significant or clinically significant accidental or unintended exposure has occurred after discussion with the relevant Director of Operations , notify the CQC via the online form at:

http://www.cqc.org.uk/content/reporting-IR(ME)R-incidents

10.2. Responsibility for notification may be delegated to the Head of Nuclear Medicine, Head of Radiotherapy Physics or Imaging Modality Manager as appropriate.

10.3. Notification should be immediately after the preliminary investigation. CQC expect notification within 2 weeks of incident at the latest, with follow-up reports if necessary.

10.4. If appropriate, (i.e. for equipment faults or pharmaceutical errors) notify the MHRA using their medical device adverse incident on-line notification system https://yellowcard.mhra.gov.uk/.

10.5. Ensure that a formal detailed investigation is carried out (see Appendix 3)

10.6. Ensure the implementation of recommendations which would prevent a similar incident / accident in the future

10.7. Ensure that a record is kept of any investigations for period for at least two years; the Datix record is sufficient for these purposes.

10.8. Ensure that a copy of the detailed investigation is sent to the IR(ME)R referrer, IR(ME)R practitioner, and consultant with responsibility for the individual exposed.

11. Practice: Responsibilities of the Consultant Responsible for the Individual Exposed - All Radiation Incidents including Near Misses

11.1. Ensure that the individual exposed (or their representative) is informed of the occurrence of any clinically significant unintended or accidental exposure. This should be done urgently if follow-up exposures or recalls are required.

11.2. Ensure compliance with the Trust's Duty of Candour policy.

12. Practice: Responsibilities of the Divisional Director of Operations - All Radiation Incidents including Near Misses

12.1. Ensure that the Chief Operating Officer and appropriate and committees within the Trust are informed of any significant or clinically significant accidental or unintended exposures

12.2. Make arrangements for any communications with the media if necessary following any significant incident.

13. Contingencies

13.1 Any failure in compliance with this procedure must be reported to the relevant Divisional General Managers or Medical Physics Expert in their absence. Failure to comply with the above procedure may result in the Trust's Disciplinary Policy being invoked.

Appendix 1. Definitions of Clinically Significant Accidental or Unintended Exposures

This appendix provides a summary of the guidance. The full document is available here:

IR(ME)R: Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine | The Royal College of Radiologists (rcr.ac.uk)

Ionising Radiation (Medical Exposure) Regulations: Implications for clinical practice in radiotherapy Guidance from the Radiotherapy Board (rcr.ac.uk)

1. The guidance uses the concept of "moderate harm that would trigger the duty of candour" to determine whether an incident is clinically significant. It refers to the definition from the National Reporting and Learning System (NRLS):

2. Any unexpected or unintended incident that resulted in a moderate increase in treatment, possible surgical intervention, cancelling of treatment, or transfer to another area, and which caused significant but not permanent harm, to one of more persons receiving NHS-funded care.

3. The underlying incident must have been accidental or unintended according to IR(ME)R, so for example the following incident is CSAUE:

    - A request is made for an x-ray of the left foot, but the right foot is imaged in error. Because the right foot is normal, no further investigation is performed and the fracture in the patient's left foot is left undetected and untreated, leading to severe pain and further damage.

4. While this is not CSAUE:

    - A request is made for an x-ray of the left foot, which is imaged as intended. The fracture on the left foot is not detected and is left untreated, leading to severe pain and further damage. Because the exposure was delivered as intended, this is not considered a CSAUE.

5. In the case of an unintended exposure of an embryo or foetus, if the outcome of the exposure is considered to be clinically significant, this would be classed as a CSAUE even if there had been no procedural failure.

6. The guidance also provides definitions in terms of stochastic, deterministic and psychological effects:

    - Stochastic effects: an accidental or unintended exposure that results in a 1 in 1,000 lifetime radiation-induced cancer risk or greater

- Tissue effects (deterministic): an accidental or unintended exposure that results exceeds thresholds for radiation-induced tissue effects

- Psychological harm: an accidental or unintended exposure that affects the individual psychologically to the extent that requires intervention or treatment

7. SAUE in Radiotherapy is defined to be one that has had, or is expected to have, a measurable effect on the patient's tumour control, normal tissue toxicity or quality of life

8. The following often will be CSAUE, but each case should be reviewed individually

    - All total geographic misses of a therapy exposure, including if for a single fraction of a prescription e.g. setting up the wrong marks in external beam RT

    - When the delivered dose to the planned treatment volume is 1.1 times (whole course) or 1.2 times (any fraction) the intended dose

    - When the delivered dose to Organs at risk (OAR) is 1.1 times the tolerance dose as specified locally for that organ for a whole course of treatment

    - When the delivered dose to the planned treatment volume is 0.9 times less than the intended dose(whole course) in external beam RT or brachytherapy

    - When the administered activity is less than 0.9 times the prescribed activity +-10% in molecular RT

    - When there is an unintended clinical impact or compromise in the effectiveness of treatment, regardless of dose due to errors in scheduling the treatment (e.g. patient referred for breast and nodal treatment, treatment delivered to breast only

Appendix 2. Detailed Investigation of Incidents

1. Objectives of investigation

1.1. There are four main objectives in investigating incidents. These are:

- To establish the facts about what happened,
- To identify the defect or malfunction in any radiation equipment involved and to establish its causes or identify the reasons for procedural errors etc.,
- To ensure that appropriate steps have been taken to avoid recurrence by including any lessons learnt, and
- To estimate the dose received by all persons involved in the incident.

2. Persons to involve in the investigation

2.1. It is important to know from the outset the persons who will be involved in the investigation; including those conducting the investigation and those whose evidence is to be considered. It is suggested that the following persons would normally be asked to provide evidence:

- The MPE,
- The person(s) acting as operators for the exposure,
- The practitioner for the exposure,
- The service engineer who examined any equipment following an incident related to equipment error,
- The person who was responsible for quality assurance on the equipment.

3. Sources of information

3.1. The following sources of information may prove helpful both in determination of what happened and in the assessment of the dose received:

- The settings on the equipment or the activity of radioactive substance involved,
- The records of QA measurements,
- Any fault reports and the records of servicing of the equipment,
- Any tests on equipment carried out for the purpose of the investigation,
- Individuals involved.

4. Report of investigation

4.1. It is recommended that the report of the investigation be kept brief but it should include the following:

- The key facts concerning the incident,
- A record of the calculations and measurements that were made,
- The doses received and risk associated with these doses, and
- Any appropriate recommendations to avoid recurrence of the incident.