Northern Devon Healthcare NHS Trust

Document Control

Title			
Reporting and Investigation of Over-Exposures Standard Operating Procedure - IR(ME)R 2017			
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Consulted with the following stakeholders: (list all)

- Clinical Audit lead Radiology
- Radiologists
- Radiographers
- Practitioner Referrers
- Medical Physics

Approval and Review Process

- Lead Clinician in Clinical Radiology

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CONTENTS

1. Introduction

The Ionising Radiation (Medical Exposure) Regulations {IR(ME)R} 2000 were introduced to protect patients against the hazards associated with the use of ionising radiation in medical settings. It is a requirement of IR(ME)R 2000 that all notifiable incidents should be reported.

Notifiable incidents under IR(ME)R are those where a dose "*much greater than intended*" has been delivered to an individual and should be reported to the appropriate authority.

Under-doses are not notifiable but must still be locally investigated.

IR(ME)R 2000, "Regulation 4(5) requires Employers to *"make an **immediate preliminary investigation**" of incidents and then "**forthwith notify the appropriate authority.**"* A detailed investigation and dose assessment is required and it is presumed that notification to the appropriate authority will take place unless the Employer is certain that no exposure much greater than intended has occurred.

The Society and College of Radiographers (2012) guidance states: "It is imperative that there are no undue delays in notifying the IR(ME)R appropriate authority (the IR(ME)R Inspector) of a reportable incident following the local preliminary investigation. This is obviously important in learning from errors but also in protecting the patient / public".

Following the update of IR(ME)R 2017 it is the Employers duty to ensure "that the referrer, the practitioner, and the patient or their representative are informed of the occurrence of any relevant clinically significant unintended or accidental exposure, and of the outcome of the analysis of this exposure".

Guidance as to what constitutes a 'clinically significant' unintended, or accidental exposure has been taken from a British Journal of Radiology commentary. A clinically significant unintended or accidental exposure has been taken to include:

1. Any incident that has resulted in demonstrable clinical harm. An example of this would include missing diagnosis by imaging the wrong body part, for instance a broken foot.
2. A reportable radiation safety incident resulting in an additional effective dose to the patient affected of 20mSv or more.
3. A reportable radiation safety incident that has resulted in an additional skin absorbed dose of 2Gy or more, or an eye lens absorbed dose of 0.5Gy or more.

2. Purpose

The Standard Operating Procedure (SOP) has been written to:

- Identify the roles and responsibilities of the Operator (Radiographer) in reporting incidents where an over-exposure has occurred.
- Clarify the processes involved in the reporting of, and investigation of over-exposures and clinically significant unintentional exposures.
- Adhere to the Guidelines for notification of over-exposures.

3. Scope

This Standard Operating Procedure (SOP) relates to the following staff groups who may be involved in making radiation exposures and those who may be involved following an incident where over-exposure, or a dose much greater than intended (MGTI) has occurred:

- Radiographers (Operators)
- Radiologists (Practitioners)
- Medical Physics
- Medical Staff
- Allied Health Professionals

4. Location

This Standard Operating Procedure applies to the Radiology Departments at the North Devon District Hospital, Barnstaple; Bideford and District Hospital, Bideford; and Tyrell Hospital, Ilfracombe.

Staff undertaking ionising radiation exposures at these sites must be able to demonstrate competence as per the organisations policy on assessing and maintaining competence.

5. Equipment

All Radiology imaging equipment on the above sites including General and A+E x-ray units, AMX Mobile imaging machines, Dental imaging equipment, Mobile Image Intensifiers, Interventional fluoroscopy equipment, CT and DEXA.

6. Procedure

6.1. Roles and Responsibilities of Staff.

- No Operator/Radiographer should undertake a procedure for which (s)he has not received appropriate training.

- All staff should ensure they have up to date CPD and continued training.

- It is the responsibility of the Operator to record and report any known or suspected over exposure of a patient using a radiation incident form which then needs to be submitted to the Principle Radiographer. (Forms are available on the radiology public drive in the 'Forms' folder).

- If there is a possibility that the exposure was much greater than expected or intended, or is a potentially clinically significant unintentional exposure then the RPS/Radiology Services Manager must be informed immediately and Medical Physics advised.

- An incident report needs to be made on the Trusts Incident Reporting system ("Datix"). Potential over-exposure should be indicated in the <Description of Incident>, and relevant exposure details included (DRP or DRL, or exposure factors; kVp etc).
- The Principle Radiographer will conduct an investigation (or delegate this responsibility to a suitable person) to ascertain the details of the incident.

6.2. Processes involved in the reporting of, and investigation of over-exposures.

- When an incident of radiation over exposure is reported a preliminary investigation must be undertaken by the employer.

- Medical Physics will determine whether the incident is reportable to CQC as an exposure much greater than intended and also whether the incident constitutes a clinically significant unintended, or accidental exposure. If the incident results in a clinically significant radiation dose to the patient, Medical Physics will evaluate the outcome of this exposure.

- If this preliminary investigation shows that an exposure much greater than intended has occurred then the appropriate IR(ME)R enforcement agency must be notified and arrangements made for a more detailed investigation.

- All staff should ensure faulty equipment is reported.

- If faulty equipment is responsible for a dose MGTI, it must be taken out of use until the fault has been rectified or the engineer has been contacted and it is considered safe to use.

- It is the responsibility of all staff to ensure equipment is properly maintained, visually inspected and regularly cleaned.

- Medical Physics and/or equipment engineers may also need to be contacted to test faulty equipment.

- As part of the investigation the patient may also need to be notified of the radiation over exposure incident.

- The Principle Radiographer will be responsible for ensuring that following an investigation the Referrer, Practitioner and Patient or their representative are informed of the occurrence of any relevant clinically significant unintended or accidental exposure, and of the outcome of the analysis of this exposure.

6.3. Guidelines for notification of over exposure.

6.3.1. Clinically Significant Unintended or Accidental Exposures

Guidance as to what constitutes a 'clinically significant' unintended, or accidental exposure has been taken from a British Journal of Radiology commentary. A clinically significant unintended or accidental exposure has been taken to include:

1. Any incident that has resulted in demonstrable clinical harm. An example of this would include missing diagnosis by imaging the wrong body part, for instance a broken foot.
2. A reportable radiation safety incident resulting in an additional effective dose to the patient affected of 20mSv or more.
3. A reportable radiation safety incident that has resulted in an additional skin absorbed dose of 2Gy or more, or an eye lens absorbed dose of 0.5Gy or more.

Medical Physics will determine whether an incident constitutes a clinically significant unintended, or accidental exposure. If the incident results in a clinically significant radiation dose to the patient, Medical Physics will evaluate the outcome of this exposure.

6.3.2. Exposure Much Greater than Intended

- **Examples of exposures MGTI that require notification are shown in the table 1 and 2 below. These have been taken from the document:**

Guidance on investigation and notification of medical exposures much greater than intended (2017) available from:
https://www.gov.uk/government/publications/the-ionising-radiation-medical-exposure-regulations-2000

According to the Guidance on investigation and notification of medical exposures much greater than intended (2017) document:

"Notification is **not** required where the exposure is:
(I) less than intended, or
(ii) greater than intended, but less than the relevant guideline factor in Table 2".

Table 1 – Examples of unintended medical exposures that require notification

All Modalities	**When to notify (what constitutes an exposure much greater than intended)**
Wrong patient exposed	All cases – regardless of dose
Wrong radioactive medicinal product administered	All cases – regardless of dose
Unintended planning or verification exposures. Examples include wrong protocol/plan, patients placed in the imaging pathway in error.	All cases – regardless of dose
Wrong examination including incorrect body part or modality. **Excluding diagnostic imaging laterality errors in the anatomy distal to the hip and shoulder. These incidents do not require notification** but should be investigated locally.	Apply guideline factors in Table 2
Timing errors when an additional unintended examination is undertaken e.g. outside clinically acceptable time frame of the intended date	Apply guideline factors in Table 2
Where an incident involves exposure of several people to an extent that is greater than intended (but less than the guideline factors) as a result of a systematic process or clinical failure	All cases – regardless of dose
Failure to follow procedure regarding pregnancy and breastfeeding enquiries resulting in an unintended exposure to the foetus or unintended exposure of a child through breastfeeding	All cases – regardless of dose
Unintended foetal exposure where there was no failure to follow procedure regarding pregnancy enquiries	When the foetal dose is greater than 10 mGy
Any other situation where a patient has been exposed to ionising radiation, which in the judgement of the employer, is much greater than was intended for that patient	All other cases – regardless of dose **at the employer's discretion**

Table 2 – Guideline factors for diagnostic and interventional procedures, including pre-treatment (planning) imaging and during treatment (verification) imaging

Diagnostic and Interventional exposures	Guideline factor applied to intended dose
High dose examinations, where the intended dose is greater than 5mSv, to include interventional radiology, radiographic, and fluoroscopic procedures involving contrast agents, diagnostic nuclear medicine, PET- CT and CT examinations	When the total exposure is at least 2.5 times greater than the intended dose
All radiotherapy planning and verification imaging	When episode dose is 2.5 times the intended whether through multiple repeats or through the unintended use of high dose procedures. Or, when five repeat exposures* (for procedural or human error) have been necessary for an individual patient over a course of treatment.
Intermediate dose examinations, where the intended dose is within the range 0.5 - 5mSv, to include mammography, CT scout examinations, and all other radiographic examinations not referred to elsewhere in this table	When the total exposure is at least 10 times greater than the intended dose.
Low dose examinations, where the intended dose is less than 0.5mSv, to include DEXA, skull, dentition, chest, in-vitro nuclear medicine	When the total exposure is at least 20 times greater than the intended dose.

*The ‘repeat’ criteria are intended to ensure repeated imaging born from poor practice or breakdown in the verification imaging protocol are highlighted.

7. References

- Ionising (Medical Exposures) Regulations 2017. Statutory Instruments 2017 No 1322
  http://www.legislation.gov.uk/uksi/2017/1322/pdfs/uksi_20171322_en.pdf

- Radiology authorisation and IRMER assessment working practice document.

- Guidance on investigation and notification of medical exposures much greater than intended (2017) available from:
  https://www.gov.uk/government/publications/the-ionising-radiation-medical-exposure-regulations-2000

- Care Quality Commission Reporting IR(ME)R incidents. Available form:
  http://www.cqc.org.uk/content/reporting-irmer-incidents

- Ionising (Medical Exposures) Regulations 2000. Statutory Instruments 2000

  No 1059 – http://www.opsi.gov.uk/si/si2000/20001059.htm

- IRMER – Ionising Radiation (Medical Exposures) Amendment Regulations 2006

  http://www.opsi.gov.uk/si/si2006/uksi_20062523_en.pdf

- Society of Radiographers (2012) IR(ME)R 2000 and IR(ME) Amendment Regulations 2006 & 2011 - https://www.sor.org

- Ionising Radiation (Medical Exposure) Regulations 2017. Statutory Instruments 2017.

- Kotre CJ, Walker A. Duty of candour and the definition of moderate harm for radiation overexposure and exposures much greater than intended in diagnostic radiology. Br J Radiol 2014;87:20130555.

8. Associated Documentation

Northern Devon Healthcare NHS Trust Policies for:

- Northern Devon Healthcare NHS Trust Radiation Policy
- Northern Devon Healthcare NHS Trust Identification Policy
- Northern Devon Healthcare NHS Trust Incident Reporting Policy