Northern Devon Healthcare NHS Trust

Document Control

Title			
Minimising the Unintentional Irradiation of Patients - Standard Operating Procedure IR(ME)R 2017			
Author		**Author's job title**	
Gill Kite		Senior Radiographer	
Directorate		**Department**	
Operations		Diagnostic Imaging	

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Main Contact Jane Martin, Principle Radiographer Radiology Department North Devon District Hospital Raleigh Park Barnstaple, EX31 4JB	**Tel: Direct Dial** – 01271 311635 **Tel: Internal** – 3635 **Email**: janemartin4@nhs.net
Lead Director Lead Clinician in Clinical Radiology	
Superseded Documents	

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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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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 the probability and magnitude of accidental or unintentional doses to Patients from radiological practices are reduced so far as is reasonably practicable.

Unexpected incidents can occur, where unintentional irradiation of patients has been delivered; these are notifiable and 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.

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

The Society and College of Radiographers (2012) guide "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 those involved in making ionising radiation exposures.
- Clarify the process involved in the reporting of both unintentional and clinically significant unintentional irradiation of patients.
- Clarify the operational processes in place to reduce unintentional irradiation of patients.

3. Scope

This Standard Operating Procedure (SOP) relates to the following staff groups who may be involved in the making of radiation exposures and those who may be involved following an unintentional irradiation incident:

- 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 Tyrrell 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 over 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 be undertaking a procedure for which (s)he has not received appropriate training.
- All staff should ensure they have up to date CPD and continued training.
- All staff should ensure correct identification of Patient using three forms of identification, according to local identification policy, prior to examination and radiation exposure.
- All staff should ensure that the correct area of interest is being imaging with the patient prior to examination and radiation exposure. Where there is contradiction the referrer must be contacted.
- All staff should ensure equipment is clean and properly maintained.
- All staff should ensure faulty equipment is reported and taken out of use until fault has been investigated and/or fixed.

6.2. Clarify the process involved in the reporting of unintentional irradiation of patients.

- In the event of an unintentional irradiation incident, details of the incident MUST be reported. This can be done:
  - Via the DATIX system.
  - A Radiation Incident report form must also be completed and given to the local Radiation Protection Supervisor.
- If faulty equipment is responsible it must be taken out of use until fault has been rectified or engineer has been contacted and it is considered safe to use.
- Medical Physics may also need to be contacted to test faulty equipment.
- As part of the investigation the patient may also need to be notified of unintentional irradiation incident.
- In the event of a clinically significant unintentional exposure 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. Clarify the operational processes in place to reduce unintentional irradiation of patients.

- Ensuring staff and equipment levels are adequate and appropriate to maintain the workload of the department.
- Adequate training and continued education and development of all operators.
- Equipment is regularly serviced and maintained.
- Regular Quality Assurance (QA) tests are done both by the radiographer responsible for QA and the Medical Physics Department.
- All equipment faults are reported.
- Adherence to local identification policy and procedures.
- Adherences to the incident reporting procedures to ensure that all unintentional exposures are thoroughly investigated.
- Regular monitoring of dose reference levels (DRLs).
- Regular reject analysis of images.

7. References

- Radiology authorisation and IRMER assessment working practice document.
- 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