CONTROLLED DOCUMENT

University Hospitals Birmingham
NHS Foundation Trust

Ionising Radiation (Medical Exposure) Regulations 2017

Procedure 5: Quality Assurance Programmes for Procedures, Protocols and Equipment used for Exposures to Ionising Radiation

Required under IR(ME)R 2017 Regulation 6, 15 & Schedule 2 (d)

CATEGORY:	Procedure
CLASSIFICATION:	Health & Safety, Clinical Governance
PURPOSE:	To ensure that quality assurance programmes in respect of written procedures, written protocols, and equipment are followed.
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Version Number:	3.0
Controlled Document Sponsor:	Chief Operating Officer
Controlled Document Lead:	Radiation Protection Committees
Approved By:	Radiation Safety Board
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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. All staff.

Contents

Version Control

Version	Title	Issue Date
1.0	The Procedure to Ensure that Quality Assurance programmes are Followed with Respect to IRMER Procedures	01/07/2013
1.4	The Procedure to Ensure that Quality Assurance Programmes are Followed with Respect to IRMER Documentation	04/07/2016
1.5	The Procedure to Ensure that Quality Assurance programmes are Followed with Respect to IRMER Procedures, IRMER Protocols and Relevant Equipment	21/09/2018
3.0	Quality Assurance Programmes for Procedures, Protocols and Equipment used for Exposures to Ionising Radiation	04/10/2022

1 Procedure Statement

1.1 The purpose of this procedure is to ensure that there is a quality assurance programme in place to review written IR(ME)R Employer's Procedures, modality specific standard operating procedures and protocols for radiological practice.

1.2 This procedure also aims to ensure that there is a quality assurance programme in place for radiological equipment.

1.3 The quality assurance programme will:

- Support safe service delivery
- Promote a consistent approach to service delivery
- Provide assurance of service quality
- Ensure up-to-date documents are accessible
- Drive continual service improvement through review

2 Scope

2.1 All written IR(ME)R Employer's Procedures, modality specific standard operating procedures and protocols for radiological practice as defined in Regulations 6(1), 6(4) and Schedule 2 of IR(ME)R 2017 with respect to the Trust.

2.2 All equipment which:

- delivers ionising radiation to a person undergoing exposure or;
- directly controls or influences the extent of the exposure.

2.3 The procedure applies to all exposures within the IR(ME)R 2017 regulations including medical imaging, non-medical imaging, research exposures, exposures of carers and comforters, and therapies with radioactive materials undertaken by Nuclear Medicine, and Radiotherapy localisation and treatment.

3 Documentation

Responsibilities

3.1 University Hospitals Birmingham NHS Foundation Trust is responsible for ensuring that the written IR(ME)R Employer's Procedures, modality specific standard operating procedures and protocols for radiological practice as defined in Regulations 6(1), 6(4) and Schedule 2 of IR(ME)R 2017 are in place.

3.2 Clinical Service Leads are responsible for ensuring that the necessary protocols for radiological practice are in place, reviewed, updated and

authorised for their department (refer to 3.4 for delegation)

3.3 The Radiation Safety Board is responsible for ensuring that the necessary IR(ME)R 2017 Employer's Procedures are in place, reviewed, updated and authorised. It will delegate the review process including checking of the accuracy of content to appropriate subject matter experts.

3.4 When necessary, the task of writing protocols for radiological practice and review of the accuracy of content is delegated to:

- Imaging Modality Managers (as determined by the General Manager of Imaging).
- Staff within Nuclear medicine (as determined by the Head of Nuclear Medicine).
- Staff within Radiotherapy (as determined by the Radiotherapy Clinical Service lead, Radiotherapy Lead Manager, QAO, Head of Radiotherapy Physics)
- Senior BMD Physicist (WTCRF).
- Staff within the Dental and Community Dental Departments (as determined by the Clinical Service Lead for Dental).
- Staff within the Maxillofacial Dept. (as determined by the Clinical Service Lead for Maxillofacial).
- Staff within Cardiology (as determined by the Clinical Service Lead for Cardiology)
- Staff trained in the use of the Fluoroscan (as determined by the Clinical Service Leads for Podiatric/Orthopaedic Surgery and for Hand Surgery).
- Staff within the Urology Dept. (as determined by the Clinical Service Lead for Urology).

3.5 All staff should report to their Line Manager any instances where IR(ME)R Employer's Procedures, modality specific standard operating procedures or protocols for radiological practice are not adhered to. Failures should be regarded as an incident and reported within the Trust Incident Reporting platform; DATIX.

3.6 The Line Manager should report any non-compliance or need for changes to documentation to the relevant General Managers who, in turn will report to the Radiation Safety Board.

3.7 All staff can report to their Line Manager feedback or suggestions for improvement related to IR(ME)R Employer's Procedures, modality specific standard operating procedures and protocols for radiological practice

Practice

3.8 All IR(ME)R Employer's Procedures, modality specific standard operating procedures and protocols for radiological practice must be formally controlled documents i.e., with version numbers, author, issue and review dates and

authorisation date.

3.9 The development and review of documentation must conform to Trust and/or local procedures and must follow a defined governance process prior to publication.

3.10 Documentation must be subject to regular review to ensure it remains up to date and to identify any necessary amendments:

- IR(ME)R Employer's Procedure review must be undertaken at least every 3 years, or sooner if there are changes in legislation or guidance.
- Modality specific standard operating procedures and protocols for radiological practice must be reviewed at a minimum of 3 years or sooner when new equipment, techniques or procedures are introduced or changed.

3.11 Current versions of the UHB IR(ME)R Employer's Procedures will be held within the Trust's controlled document system. Read-only versions are published electronically for staff to access.

3.12 Modality specific standard operating procedures and protocols for radiological practice will be held within local departments Quality Management Systems. Read-only versions are available for staff to access through these systems.

3.13 Examination protocols, embedded in the radiological equipment, require additional management to ensure they are locked and changes cannot be made by unauthorized staff. Software updates may change agreed examination protocol settings, therefore copies of protocols must be backed up.

3.14 Staff are notified of changes to documents via team meetings, email notification, Trust wide communication bulletins on the Intranet.

3.15 Old versions of IR(ME)R Employer's Procedures, modality specific standard operating procedures and protocols for radiological practice protocols must be archived in accordance with the Trust's general policy for retention of records.

Audit

3.16 Audit will take place to verify compliance to the requirements of IR(ME)R Employer's Procedures; these will be registered on the Trust Clinical Audit Registration and Management System (CARMS) of which the Trust Compliance team have central oversight.

3.17 Audit results are reported within CARMS and presented at the relevant Radiation Protection Committee on a quarterly schedule from each Division across the Trust where applicable.

3.18 Where audit findings indicate that improvements are required, the Radiation Protection Committee will oversee completion of action plans and will share any learning at Radiation Safety Board meetings.

3.19 The Radiation Safety Board will provide details of audit compliance within the quarterly radiation report presented to the Trust Health, Safety and Environment Committee. They will escalate any concerns to the committee to ensure oversight at Trust Board level.

4 Equipment

Responsibilities

4.1 The responsibility for undertaking quality assurance tests on radiological equipment and taking appropriate action is defined within the Trust's Radiation Safety Policy (refer to summary table in Appendix 1)

4.2 The Relevant Departmental General Manager is responsible, with contribution from an appointed Medical Physics Expert, for ensuring that:

- Any equipment will be selected, installed and maintained so that it is capable of restricting the exposure in accordance with the intended purpose.
- Preventative maintenance, local quality assurance tests (i.e. type A tests carried out by their staff) and routine type B tests and commissioning/acceptance tests (MPE to delegate for this to be undertaken by medical physics staff) are carried out at the appropriate intervals.
- Establishing acceptable performance criteria.
- Recommendations made following inspections of their radiation equipment and facilities are followed up and actioned as necessary.
- An inventory of their own ionising radiation equipment is kept and all such equipment both satisfies radiation safety requirements and is included in appropriate replacement programmes.

4.3 The relevant branch of the Radiation Protection Committee will review the equipment quality assurance programme and highlight any exceptions to the Radiation Safety Board.

4.4 The Radiation Safety Board will report on the equipment quality assurance programme within the quarterly radiation report provided to the Trust Health, Safety and Environment Committee.

Practice

4.5 All equipment that can impact the exposure to an individual is subject to a programme of quality assurance following the advice of a Medical Physics Expert.

X-ray:

4.6 Maintenance tests will be performed by engineers and outside contractors.

Written reports will be submitted.

4.7 Following maintenance or repairs by an engineer or outside contractor, it should be identified by the engineer and operator accepting equipment back into use whether type A or type B tests are required.

4.8 Type A regular quality assurance tests will be undertaken by department staff. Results are recorded and monitored locally. If test values fall outside specified tolerances the Radiation Protection Service (RRPPS) should be informed so the matter can be investigated and further advice from the MPE can be sought.

4.9 Type B tests, commissioning and acceptance tests will be undertaken by staff within the Radiation Protection Service (RRPPS). A formal report with recommendations will be produced.

Nuclear Medicine:

4.10 Maintenance tests will be performed by outside contractors. Written reports will be submitted.

4.11 Quality assurance, commissioning and acceptance tests will be undertaken by department staff. If test values fall outside specified tolerances the local MPE will provide further advice.

Radiotherapy:

4.12 Maintenance tests will be performed by in-house engineers and outside contractors. Written reports will be submitted by external contractors, in-house records maintained electronically.

4.13 Following maintenance or repairs by an engineer, (in-house or external) it should be identified by the engineer and operator accepting equipment back into use (where necessary) as to the level of quality assurance tests required. Advice from the MPE can be sought.

4.14 Regular quality assurance tests will be undertaken by department staff. Results are recorded and monitored locally. If test values fall outside specified tolerances in the QMS, the local MPE will provide further advice

4.15 Commissioning/acceptance tests are carried out at appropriate intervals managed by an MPE. Any relevant tests will be undertaken by staff within the Radiation Protection Service (RRPPS) and a formal report with recommendations will be produced.

5 Contingencies

5.1 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.

6 Appendices

Appendix 1 – Equipment Quality Assurance Programme

Task	Responsibility	Performed By	Frequency
Preventative maintenance	Departmental / Service Manager	Manufacturer/ Outside Service Contractor In-house clinical technologists (radiotherapy equipment)	As recommended by Equipment supplier
Radiation Protection & equipment performance Surveys	Departmental / Service Manager	RRPPS	Community dental: 3 yearly Hospitals x-ray: annually Mammography: 6 monthly Radionuclide facilities: annually
		Radiotherapy Physics Service	Radiotherapy Equipment: As specified in radiotherapy procedures
Calibration of radiation protection instrumentation	Departmental / Service Manager	RRPPS	Annually
Quality assurance test by department	Departmental / Service Manager	Nominated departmental staff	As determined by local protocols
Commissioning test	Departmental / Service Manager	RRPPS	Before use on patients
Critical examinations	Equipment Installer	Equipment Installer	Before use