The Regulation and Quality Improvement Authority

Inspection Report

15 January 2025

Musgrave Park Hospital Radiology Services

Address: Stockman's Lane, Belfast, BT9 7JB
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Information on legislation and standards underpinning inspections can be found on our website https://www.rqia.org.uk/ and The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 known as IR(ME)R

1.0 Service information

Organisation/Registered Provider: Belfast Health and Social Care Trust (BHSCT)	**Department Inspected:** Musgrave Park Hospital (MPH)–Radiology Department
Name of Employer: Ms Maureen Edwards Interim Chief Executive BHSCT	**Imaging Services Manager (ISM):** Mr Sean O'Conaire

Brief description of how the service operates:

The MPH radiology services is provided Monday to Friday 8.45am to 5pm supporting an elective musculoskeletal services to adults and paediatrics. With a general radiology and computed tomography (CT) on call out of hours (OOH) service.

Before the inspection Mr O'Conaire, ISM and his team were asked to complete a self-assessment form (SAF). The submitted SAF confirmed that MPH radiology service in the last year provided; 25177 general radiology images, 1807 fluoroscopy in the MPH main radiology department,1456 fluoroscopy procedures in theatres, 3627diagnostic computed tomography (CT), 49 CT Biopsies, 52 CT guided injections, 7 CT guided ablations and 6499 Dual-energy x-ray absorptiometry (DXA) (adult only).

MPH imaging service consists of five general radiology rooms, two CT scanners, two DXA scanners, one fluoroscopy machine and two portable X-ray machines. In theatres there are three image intensifiers (C-Arms) which are owned by the radiology department. There are two further C-Arms and three mini C-Arms which are owned by MPH theatres and this is further discussed in the body of the report.

There are 11 consultant radiologists who work across BHSCT sites, with a number based in MPH. The MPH radiology service is provided by seven CT radiographers and 15 general radiographers who also provide an on-call OOH service.

The team is supported by Medical Physics Experts (MPEs) contracted from Regional Medical Physics Service (RMPS) based in BHSCT.

2.0 Inspection summary

On 15 January 2025, warranted Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) inspectors from the Regulation and Quality Improvement Authority (RQIA), with advice being provided by the United Kingdom Health Security Agency (UKHSA) staff, carried out an IR(ME)R inspection of the MPH radiology department, as part of RQIA's IR(ME)R inspection programme.

For the 2024/25 inspection year the inspections will focus on the following key themes:

- Referral process
- IR(ME)R governance, including arrangements for compliance with IR(ME)R, radiology services provided outside of the radiology department, communication with other departments, and commissioning of new services
- Equipment quality assurance including radiology equipment held outside the radiology department
- The study of risk (radiotherapy and nuclear medicine therapies only)
- Brachytherapy (radiotherapy only)
- Any other areas identified through the review of the submitted SAF and supporting documentation

The purpose of our focus is to minimise risk to service users and staff, whilst being assured that ionising radiation services are being provided in keeping with IR(ME)R (Northern Ireland) 2018.

Previous areas for improvement (if applicable) will also be reviewed.

The service was notified of the inspection date and time; and requested to complete and submit a SAF and include supporting documentation to be reviewed in advance of the inspection. The site inspection process included:

- Discussion with management and staff
- Examination of relevant radiology documentation
- Review of the department and facilities
- Review of patient records to ensure compliance with IR(ME)R
- Discussion with patients/representatives (where appropriate)

IR(ME)R is intended to protect individuals undergoing exposure to ionising radiation as follows:

- Patients as part of their own medical diagnosis or treatment
- Individuals as part of health screening programmes
- Patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes
- Carers and comforters
- Asymptomatic individuals
- Individuals undergoing non-medical imaging using medical radiological equipment

3.0 How we inspect

RQIA is responsible for monitoring, inspecting and enforcement of IR(ME)R. The inspection process includes the gathering and review of information we hold about the service, examination of a variety of relevant written procedures, protocols and records, and discussion with relevant staff. RQIA inspection reports reflect on how a service was performing at the time of inspection, highlighting both good practice and any areas for improvement.

The information obtained is then considered before a decision is made on whether the service is operating in accordance with the relevant legislation and professional standards. Examples of good practice are acknowledged and any areas for improvement are discussed with the relevant staff in charge and detailed in the quality improvement plan (QIP).

As already stated, prior to the inspection, the service was requested to complete a SAF and provide RQIA with all relevant supporting information including written policies and procedures. This information was shared with UKHSA prior to the inspection and was used to direct discussions with key members of staff working within the radiology department and provide guidance for the inspection process.

It is the responsibility of the Employer to ensure compliance with legislation, standards and best practice, and to address any deficits identified during our inspections.

4.0 What people told us about the service

As this was a busy radiology department and patients were awaiting or immediately recovering from radiology procedures, it was deemed inappropriate to seek to speak to these patients on the day of the inspection.

5.0 The inspection

5.1 What has this service done to meet any areas for improvement identified at or since the last inspection?

A previous inspection had not been undertaken of the MPH under the current IR(ME)R legislation.

5.2 Inspection findings

5.2.1 Does the service adhere to legislation in relation to the referral process?

A referral is a request for an exposure to be performed, not a direction to undertake an exposure. A referral must be made by an appropriately entitled registered health care professional as defined by IR(ME)R. The referrer must supply sufficient medical data for the practitioner to enable justification. The referrer must also supply accurate up to date information to enable the operator to correctly identify the individual to be exposed.

It was confirmed that all referrals made to MPH radiology department are managed through the Encompass ordering, NIECR and Sectra order management. The majority of referrals are electronic with hard copy referrals being scanned onto the system. Referrals to MPH radiology department are from medical practitioners such as consultant radiologists, consultant orthopaedic surgeons and general practitioners (GPs). There are a range of non-medical referrers (NMR) such as orthopaedic outpatient nurses and MPH ward nurses, all of whom are entitled with a defined scope of practice. The Integrated Clinical Assessment and Treatment Service (ICATS) orthopaedic physiotherapists also acts as NMRs. It was good to note there is a robust application process and training on the role and responsibilities of a referrer in accordance with IR(ME)R. We were informed that the majority of GP referrals will go to ICATS for triage and referral made where appropriate. Inter Trust referrals are accepted from entitled referrers which largely relate to specialist orthopaedic imaging.

Clear entitlement arrangements for referrers including NMR were described by management and reflected in the Employers Procedure (EP) B, entitlement. It was positive to note that incorporated into the newly introduced Encompass referral system is the 'hard stop' on NMR which prevents referrals by non-entitled individuals. Also positive to see the robust NMR audit process, which is carried out regularly and actioned as necessary.

Referrers entitlement records were reviewed and most were well completed and outlined a clear scope of practice. However, review of a MRI radiographer's entitlement record noted it outlined that they had been entitled as an operator for clinical evaluation of intra-orbital foreign objects imaging. However, it did not reflect their duty holder role as a non-medical referrer for these types of images. An area of improvement has been identified to ensure the entitlement record for the MRI radiographers are amended to include their role as NMR. Management confirmed referrers are informed of entitlement and their scope of practice and the imaging service has a dedicated page on the Trust website with link to EP's.

The Employer has the responsibility for putting referral guidelines in place and making sure these are available to referrers. Referral guidelines set out the conditions in which an individual would typically be referred for a specific type of exposure and must include an estimate or indication of the radiation dose associated with the exposure. It was confirmed that referrers within the Trust are provided with the Trust referral criteria, iRefer – Making the best use of clinical radiology. This includes non-medical referrers. iRefer is the main referral criteria for diagnostic procedures within the BHSCT. iRefer guidelines are available across the Health and Social Care (HSC) network and on the BHSCT intranet. The use of these guidelines have been communicated throughout the Trust via the local intranet. Outside the Trust, GPs are informed how to access iRefer via the primary care network. Access to iRefer is also available on the GP portal. As stated previously DXA scans are undertaken on this site and iRefer does not include DXA scans. There were no formally agreed referral guidelines in place for DXA scans. An area of improvement has been identified to establish DXA referral guidelines and make them available to referrers.

The management and staff clearly outlined arrangements for referrals in relation to prioritising, timing future examinations and the referral cancellation process. The measures in place to minimise the possibility of receiving duplicate referrals were reviewed. Staff confirmed they check the radiology information system (RIS) for any prior approval or request and check for any pending appointments or previous scans. If a duplicate is found, radiographers contact the referrer to inform them. EP A Referral Process, is in place and outlines clear instructions in relation to the referral process, however it was advised to consider including the need for operators to check previous imaging prior to the exposure and on receipt of a referral. This direction should also be outlined in other relevant documents such as authorisation guidelines which are discussed further in section 5.2.4 of this report.

On review of patient radiology records there was evidence of referrals in place for most radiology imaging. It was confirmed that Mini C-Arms used in theatre had not been subject to appropriate referrals in accordance with IR(ME)R. The use of Mini C-Arms in theatre and their compliance with IR(ME)R is further discussed in section 5.2.2 of this report.

There is evidence to show that incidents involving a referral of the wrong patient, are among the largest percentage of all diagnostic errors notified to IR(ME)R regulators. The MPH radiology service has robust systems in place to report, record, investigate and learn from incidents and near misses.

Referral processes within the Trust have been strengthened using learning from referral errors and near misses; such as checking previous images, the implementation of Pause and Check, further staff training, raising referrer awareness of their responsibilities and liaising with other departments to promote safe practice.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that the MPH radiology service have good arrangements with respect to the referral process for imaging undertaken in the radiology department and are enthusiastic to ensure these arrangements are regularly reviewed and if necessary, make improvements. The areas of improvement outlined will help strengthen the referral process. The inspection team acknowledge the commitment of staff in this regard.

5.2.2 Are there appropriate IR(ME)R governance arrangements in place to ensure compliance with the legislation?

Organisational Structures and Governance Committees

The overall responsibility for ensuring compliance with IR(ME)R lies with the Employer. The role of IR(ME)R Employer in the BHSCT is held by the Chief Executive. Currently there is an Interim Chief Executive who it was confirmed has been briefed of their role and responsibilities in relation to IR(ME)R. It was good to note that they were available remotely for feedback at the conclusion of the inspection.

The BHSCT Radiation Safety Policy approved in February 2019 sets out the organisational structures, lines of accountability and governance structures. This policy was due for review in January 2024 and is further discussed later in this section of the report.

The task of implementing IR(ME)R has been delegated to the Chair of the Radiation Protection Committee (RPC) and is responsible to the Chief Executive for the implementation of the Employer's duties under the IR(ME)R.

Management described the governance frameworks relating to IR(ME)R, the Trust Board is responsible for establishing the organisation's strategic direction and aims in conjunction with the Executive Management Team. The Chair of the Trust Board works closely with the Employer (Chief Executive) to ensure the effectiveness of the Assurance Framework.

The Assurance Committee provides oversight of governance and assurance through review of information from the steering groups to support the Trust Board of Directors. The Safety and Quality Improvement Steering Group acts on behalf and reports to the Assurance Committee. Facilitating the implementation of Ionising (Radiation) and Non-Ionising Radiations regulations and overseeing the development, implementation and review of the Trust Radiation Safety policy.

The RPC is the overarching strategic committee on all matters pertaining to ionising radiation and non-ionising radiation and any other subsequent legislation. The RPC reports its activities to the Safety and Quality Improvement Steering Group.

The Diagnostic Radiology & Nuclear Medicine (DRNM) committee meet biannually to discuss reports and ensure the Trust is compliant with IR(ME)R. The DRNM committee has been constituted by the RPC to provide assurance to the Employer through providing oversight on meeting statutory duties in relation to ionising radiation.

Imaging sub-groups report to DRNM, which includes Image Optimisation teams (IOTs), Radiation Incident Governance Group and IR(ME)R Equipment Quality Assurance Group.

The RPC plays a key role in the IR(ME)R governance arrangements and is supposed to meet twice a year. However, the RPC has not met since 2023. A RPC meeting is scheduled for March 2025. Management outlined that the RPC had not met due to the demands on the service through the implementation of the Encompass electronic platform. Management confirmed that a co-chair appointment was to be introduced for the RPC, it's terms of reference has been reviewed and membership widened to include representation from other departments outside of radiology where radiology services are delivered for example, theatres. It was disappointing to note that the RPC had not met in since 2023, therefore robust IR(ME)R governance had not been implemented to offer assurance on compliance with IR(ME)R. An area of improvement has been identified to ensure the RPC meets at least twice a year to offer assurance to the Employer through providing oversight on meeting statutory duties in relation to IR(ME)R.

RQIA were notified in December 2024 by the BHSCT that the management had been made aware that use of Mini C-Arms in MPH theatres were not compliant with IR(ME)R. An action plan was submitted with the notification to address the matter. During the inspection an update on the implementation of the action plan was discussed at length. It was noted there had been some action taken such as application training for consultant orthopaedic surgeons and specialist theatre nurses in early January 2025 and an audit of clinical evaluation for images taken using the Mini C-Arms. However, there remained significant non-compliance with IR(ME)R, including equipment QC, entitlement of duty holders, IR(ME)R referrals, justification and authorisation of the images, recording of patient dose and the storage of images on picture archiving communications system (PACS). In light of the discussions on the matter the management confirmed verbally during inspection and subsequently via email that the Mini C-Arms in MPH theatres would be taken out of clinical service with immediate effect until full compliance with IR(ME)R can be evidenced. Management were requested to submit an updated action plan by 22 January 2025 which should outline clear actions taken or to be taken with timescales for the actions and outline those individuals responsible for ensuring actions are carried out. This was submitted to RQIA on 22 January 2025 and on review found to reflect steady progress on the matter. An area of improvement has been identified to ensure that the Mini C-Arms in MPH theatres are no re-introduced to clinical service until full compliance with IR(ME)R has been evidenced and ongoing compliance with IR(ME)R is monitored.

The governance arrangements for ensuring IR(ME)R is complied with for ionising radiation services provided outside of the radiology department was discussed. As a result of the issues arising in MPH theatres management confirmed the following:

- A Trust investigation was ongoing
- A Shared Learning letter was published advising other services within the Trust of the requirement for services outside of Radiology service that provide imaging services to be compliant with IR(ME)R legislation.
- A Regional Shared Learning letter to be shared with the Strategic Performance and Planning Group (SPPG) advising other Trusts of the requirement for services outside the Radiology service that provide imaging services to be compliant with IR(ME)R legislation

Whilst this is positive reactive action, it was evident the Trust IR(ME)R governance structures for imaging services provided outside of the radiology department were not robust. There was lack of clarity on roles and responsibilities particularly where a piece of imaging equipment is not owned by the radiology department.

An area of improvement was identified to review and strengthen IR(ME)R governance structures for imaging services provided outside of radiology departments, to establish a robust radiation safety policy outlining clear roles and responsibilities on this matter.

It was confirmed there is no formal IR(ME)R lead for the Trust. To consolidate IR(ME)R governance it was suggested to consider appointing an IR(ME)R lead and devising an annual IR(ME)R report to reflect a complete overview of IR(ME)R compliance for all ionising radiation services provided within the Trust.

Communication

Management and staff confirmed there was good communication within the MPH radiology department. Face to face daily safety huddles take place with a formal template completed and uploaded to the staff intranet. Monthly meetings and weekly team briefs are utilised for communication. Minutes are disseminated to staff, updates are shared via email and the opportunity to add items to the agenda are also put forward. There is a central point in the staff area for access to procedures and other relevant information. The team can also contact each other via email and the team can also contact each other electronically. The management described clear communication escalation procedures. ISM can contact the director via telephone and will if required inform the Employer.

As discussed previously IR(ME)R governance arrangements for ionising radiation services provided outside of the radiology department must be reviewed and strengthened, this should include formal communication between the radiology service and such departments.

The Employers Procedures (EPs) and other IR(ME)R documents are ratified at DRNM or RPC meetings. A draft is sent to the membership ahead of the meeting for review and then ratified during the meeting. The document is then updated on SharePoint and made available for operational use. Previous versions are taken off Sharepoint once the most recent version has been added. A fortnightly Imaging Briefing Paper ensures changes and updates are appropriately communicated across all Trust imaging staff, with an electronic read receipt included. It was advised other departments providing ionising radiation services would benefit from access to the Imaging Briefing Paper and should be considered for inclusion in the distribution list.

Entitlement

Entitlement is the term used to describe the process of endorsement by an appropriate and specified individual within an organisation. They must have the knowledge and experience to authorise on behalf of the Employer, that a duty holder or group of duty holders, have been adequately trained and deemed competent in their specific IR(ME)R duty holder roles.

Evidence of induction, training, competency and continuing professional development for radiographers, MPEs, consultant radiologists and NMRs was reviewed and found to be in line with duty holder roles.

Systems are in place to check the professional qualifications and registration of all employees with their appropriate professional bodies. It was confirmed comprehensive systems were in place to provide annual appraisals for all grades of staff and individual development needs are identified as part of this process. The consultant radiologists have their appraisals undertaken by an approved medical appraiser. Any changes to entitlement or scope of practice are identified during appraisal and brought to the clinical director for radiology.

The clinical director is responsible for reviewing the entitlement arrangements for medical staff. There are clear oversight arrangements for entitlement of radiology staff and some staff outside of radiology such as NMRs. However, has previously highlighted the entitlement of duty holders in relation to the use of the Mini C-arms was not in place and an area of improvement has already been made on this matter.

Individual entitlement records for consultant radiologists, radiographers and NMRs were reviewed. The group entitlement record for MPEs was also reviewed. It was noted that entitlement records were well completed.

Clinical Audit

IR(ME)R tells us that clinical audit means the systematic examination or review of medical radiological procedures which seek to improve the quality and outcome of patient care through a structured review, whereby medical radiological practices, procedures, and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where indicated and the application of new standards, if necessary.

An annual multidisciplinary imaging audit schedule is in place which includes clinical and IR(ME)R audits. Management outlined that each modality directs the clinical audits required for their respective area based on clinical practice, needs of the service and results of other audits.

When an audit is completed a standardised audit outcome and action plan form is completed by the auditor and manager of the area. Depending on the type of clinical audit, duty holders involved may include operators (radiographers), practitioners (radiologists) and referrers. Management and staff confirmed that there is a tracker for all audits which is reviewed weekly to show compliance. Monthly compliance reports are used as reference points across modalities and sites. If required there are three monthly re-audits for non-compliance. A biannual audit summary report is provided to the imaging service on compliance with the audit schedule including compliance with target outcomes and outstanding actions. This report is shared with the DRNM committee and RPC as part of the Trust assurance framework for communication with the Employer Examples of clinical audit were reviewed including:

- Percentage of Rosenberg knee x-rays with overlap of femur onto tibia making it suboptimal, October 2024
- Percentage of Rosenberg knee x-rays with overlap of femur onto tibia making it suboptimal, December 2024
- Retrospective review of radiographer intra-orbital foreign body reports.

Overall they were found have a well structured layout with a clear outline of findings. However, on discussion with management and staff on the action taken as a result of the findings it was noted the robust action taken was not fully reflected in the audit report and therefore not formally captured for monitoring purposes. An area of improvement has been identified to include in the clinical audit report a detailed action plan reflecting all aspects of the findings.

There is a rolling programme of IR(ME)R audits performed. Examples were reviewed:

- NMR entitled referrers
- Acceptance of a referral
- Referral- Justification and authorisation
- Patient dose audit

- Pregnancy checks
- Radiologist equipment competency for fluoroscopy equipment

Most IR(ME)R audits reviewed demonstrated high level of compliance. However, dose audits demonstrated a discrepancy in dose levels across Trust sites, some doses were found to be higher than the National DRLs which were adopted as local DRLS. Discussion with the MPE confirmed that this had been highlighted and will be discussed at the next IOT meeting. An area of improvement has been identified to formally investigate the findings of the dose audits and implement any action necessary.

Management outlined how the audit results are fed back to the ISM and sent out to senior management team (SMT) and through the governance chain.

Incident and near miss management

There are clear arrangements in place to report, record, investigate and learn from radiology incidents or near misses in the radiology department. If an incident occurs the radiographer completes a Datix form which details a description of the incident, dose to the patient and other relevant details. The patient and ISM would be informed. The MPE would be informed with the appropriate details to support the dose risk assessment.

Management confirmed that radiation exposure incidents and near misses are recorded on the radiation incident log on Microsoft Teams. The log is a dashboard demonstrating the current status of each investigation including detail on whether the incident is notifiable to RQIA and progress in relation to this. Taxonomy is also used to highlight source(s) and cause(s) of error coded in accordance with the causative factors by modality leads of relevant areas.

The Radiation Incident Governance Group (RIGG) meets weekly. The purpose of RIGG is to provide robust service direction for the reporting and investigation of IR(ME)R related incidents in areas using X-rays or radiopharmaceuticals. Each week modality leads, senior management and the Trust MPE attend the RIGG meeting. The agenda for RIGG includes new notifiable radiation incidents in the previous seven days, new non-notifiable radiation incidents over the last 14 days across certain modalities, update on RQIA notifiable incidents and MPE update. The minutes of RIGG are shared at the weekly divisional governance huddle which is chaired by the Co–Director and chair of division.

The Imaging Service Improvement Lead and MPE produce a radiation incident report in advance of each six monthly DRNM Committee meeting. The DRNM reports to the Trust RPC. One of the responsibilities of the Co- Chair of the RPC is to discuss thematic review of the radiation incidents.

The radiation incident report is also available to all imaging staff for shared learning electronically on the Imaging Services Hub. The report analyses the range of incidents and near misses, categorising them by exposure event, modality and primary source of error. Common themes and compliance with radiation incident policy and Significant Accidental Unintended Exposure (SAUE) guidance is reviewed. An action plan is included at the end of the report based on the findings of the report. As stated this report is presented at the biannual DRNM meeting. The Radiation Incident Report for April 2024-September 2024 was reviewed and found to be well constructed with robust analysis. It demonstrated how incidents and near misses are used for shared learning and drive improvement leading to positive changes in practice.

However it was noted the most current version of SAUE guidance was not outlined, it was advised to ensure the current version of SAUE is in operation and relevant documents updated.

Staff confirmed they were kept informed of incidents, near misses and are made aware of any learning and changes to practice. EP Kii radiation investigation and reporting, was in place, on review it outlined it should be read in conjunction with EP L Clinically Significant Accidental Unintended Exposure(CSAUE) and the policy and procedure for reporting and the investigation of IR(ME)R related incidents in areas using X-rays for diagnostic and interventional procedures. On review EP Kii was noted to lack detail and an area of improvement was identified to amend EP Kii to ensure it reflects a more robust framework for radiation incidents and near misses and include a definition of a CSAUE.

The policy and procedure for reporting and the investigation of IR(ME)R related incidents in areas using X-rays for diagnostic and interventional procedures was reviewed and overall found to be a detailed policy and procedure. However, there were some inaccuracies such as 'Unintended multiple patient's' states to 'maybe' report to RQIA but this should be 'yes' in accordance with SAUE guidance, interventional sections need to be updated to the latest SAUE guidance and Appendix 7 Taxonomy codes also need to be updated. An area of improvement has been identified to amend the policy and procedure for reporting and the investigation of IR(ME)R related incidents in areas using X-rays for diagnostic and interventional procedures to ensure it accurately reflects current IR(ME)R guidance.

The decision making process for clinical CSAUE and informing relevant stakeholders was clearly outlined by management, and reflected in the EP L - CSAUE.

Risk register

The arrangements for ensuring the Trust risk register reflects risks associated with non-compliance with IR(ME)R was reviewed. The management outlined clear information to ensure that the Trust's risk registers are examined, and updated, to ensure all identified IR(ME)R risks are appropriately captured and that specific actions to mitigate the risks are identified and appropriate systems of assurance are put in place. Management confirmed that the non-compliance with IR(ME)R in relation to the Mini C-arms in MPH theatres had been added to the Trust risk register.

The ratification process for Employers Procedures (EPs) and other IR(ME)R documentation

The EPs and other IR(ME)R documents are ratified at the DRNM and RPC meetings. A draft is sent to the membership ahead of the meeting for review and then ratified during the meeting. The document is then updated on SharePoint and on BHSCT Imaging Office 365; and made available for operational use. It was noted that the EPs had not been signed by the Employer. An area of improvement has been identified to ensure the EPs are signed by the Employer.

Written examination protocols for radiological were in place. On review they were found to be overall very well written and subject to strict version control. A number of minor amendments were advised for consideration including ensuring the diagnostic reference levels (DRLs) outlined are the current version. Management were responsive to the advice.

The introduction of a new radiology service involving ionising radiation

Management outlined the arrangements for the introduction of any new imaging services within the radiology department and outside of the radiology department.

The arrangements were found to lack clarity and an area of improvement has been identified to devise a robust procedure for the introduction of a new radiology service within the Trust including where a third-party provider may be involved in the provision of new imaging service.

Management confirmed the governance arrangements for the new service would be fully reviewed including ensuring compliance with IR(ME)R. Once a new service is introduced it would be subject to routine audit.

Review of the submitted SAF supporting documentation and discussion with key staff during the inspection evidenced that there are good governance arrangements with respect to the radiology department and these arrangements are regularly reviewed and, if necessary, improvements are made. However, governance arrangements for imaging services provided outside of the radiology department require to be strengthened. It is hoped the areas of improvement made will enhance governance systems to ensure a more collective approach to radiology governance through the Trust. The inspection team acknowledge the commitment of management and staff in this regard.

5.2.3 Does the service adhere to legislation with regard to equipment Quality assurance?

The Employer must keep an up-to date inventory of all medical radiological equipment including ancillary devices that can directly control or influence the exposure.

It was noted that the radiology equipment inventory did not fully reflect all information required under IR(ME)R. An area of improvement was identified to ensure the equipment inventory must be fully completed in relation to the year of installation and year of manufacture for all radiology equipment and must also include the Mini C-Arms in MPH theatre. Management and staff confirmed there is an appropriate amount of equipment available for the workload of the MPH radiology service.

There is a formal, written equipment quality assurance (QA) programme in place. The MPE was involved in the design of the QA programme. Radiographers have been entitled as trained and competent operators to perform daily, weekly and monthly Quality Checks (QC) testing. QA co-ordinators hold local folders and input onto an overarching Excel spreadsheet on equipment QC. An overarching tracker for QC testing is reviewed at RIGG meetings. Biannually equipment QC audit is carried out and a report shared through DRNM. Evidence was reviewed of overarching QC records provided and were found to be very robust and showed equipment across the sites for comparison.

Management and the MPE confirmed some level B testing had been carried out. However, as reported on in previous inspections, this continues not to be in accordance with the Institute of Physics Engineering in Medicine (IPEM) recommended frequency of level B testing due to limited MPE resources. A risk-based approach to level B testing continues and the matter continues to be on the Trust risk register.

Review of evidence of level B testing was found to be unclear and lacked the necessary detail to identify the specific equipment being tested. An area of improvement has been made to ensure the records of level B testing includes full details of the equipment including name and serial number to provide complete clarity and ongoing management.

As stated previously the Mini C-Arms in MPH theatres had not been included in the equipment QA programme and an area of improvement has been made on this in section 5.2.2 of this report.

EP I - equipment QA, is in place which was found to be a comprehensive and provide a clear framework for staff to follow.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced an equipment QA programme is in place for the radiology department which has clear and robust oversight arrangements. It is hoped areas of improvement made will ensure all radiological equipment is subject to a robust equipment QA programme. The inspection team acknowledge the commitment of management and staff in this regard.

5.2.4 Additional areas reviewed - other areas identified through the review of the submitted self-assessment form and supporting documentation

Benefits and Risks

The provision of information on the benefits and risks prior to an exposure taking place to the individual to be exposed or their representative (where practicable) is required under IR(ME)R.

Information may take the form of posters, leaflets, verbal discussions and appointment letters or be in a written consent.

Management and staff confirmed that patients are sent an information leaflet which documents the benefits and risks of having a procedure, and includes the relevant information regarding benefits and risks of the radiation exposure. Radiographers, during identification checks, also confirm with the patient that they have received information regarding benefits and risks of the exposure and checks if the patient has any further questions. It was noted that there were posters on the benefits and risks of the exposure in the waiting rooms.

The process was less clear for patients receiving ionising radiation in theatre. An area of improvement has been identified to ensure formal arrangements are in place to provide patients receiving ionising radiation in theatre with information on the benefits and risks of having an exposure and outlined in EP I.

Management outlined that the Trust provide training to the radiographers on benefit and risks of the radiation exposure. On discussion with staff it was not clear if all radiographers in MPH have received this training. An area of improvement has been identified to ensure all radiographers undertake benefits and risks of a radiation exposure training.

Justification and authorisation

The duty holder roles of operator and practitioner was examined in relation to the justification and authorisation of exposures.

Justification is the intellectual activity of weighing up the expected benefits of an exposure against the possible detriment of the associated radiation dose and is the primary role of the practitioner. Authorisation is a process separate to justification and is the documentation confirming that the intellectual activity of justification has taken place.

It is not always possible for a practitioner to review every referral, so regulations allow for an appropriately entitled operator to authorise an exposure following written authorisation guidelines issued by a named practitioner. The practitioner is responsible for the justification of any exposure that is authorised by an operator following the authorisation guidelines. The operator is responsible for the authorisation and following the authorisation guidelines accurately. Authorisation guidelines must be clearly written using precise statements that are unambiguous in order to allow the operator to confirm whether the referral can be authorised.

Management and staff described the process of justification and authorisation clearly and demonstrated a good understanding of their role and responsibilities. As outlined previously in section 5.2.1 of this report the checking of previous imaging by the operator prior to authorisation should be included in authorisation guidelines. Overall authorisation guidelines reviewed were well written. However, advice was provided to review the list of operators outlined table 4.6 in the CT authorisation guidelines, as some are dated from 2005; and review the inconsistencies on the use of lead protection in the general radiography authorisation guidelines.

The use of fluoroscopy authorisation guidelines was discussed and it was confirmed the radiologist carrying out the examination is the practitioner who will justify and authorise the examination. Management and staff recognised the need to change the title of this document to clarify it's use as a booking guide and not to authorise examinations. Management gave assurances on this matter.

Carers and comforters

The arrangements for carers and comforters were reviewed and it was good to note staff demonstrated a very good understanding of their role on this matter. It was noted that carers and comforters dose constraint information in the CT authorisation guidelines was inconsistent with the dose constraint outlined in EP N, Carers and Comforters. An area of improvement has been identified to ensure accurate and consistent dose constraint information in relation to carers and comforters in all relevant documentation.

DXA service

As previously stated, this site provides DXA scans to adults. Discussion with staff involved in the provision of the DXA service confirmed that they had recently been invited to attend the IOT meetings which is a positive development. The process of clinical evaluation of the DXA scans was well described by staff. A number of DXA radiographers are appropriately trained and competent entitled operators to carry out clinical evaluation of DXA scans. However, the EP J clinical evaluation, did not fully reflect the arrangements for clinical evaluation of DXA scans.

An area of improvement has been identified to amend EP J, clinical evaluation to fully reflect the DXA service.

National Diagnostic Reference Levels (NDRLs) were noted to be referenced in a number of IR(ME)R documents; however, they were not the current version.

An area of improvement has identified to ensure references to DRLs are accurate and reflect current guidance. It was noted that there are no DRLs established for DXA scans and an area of improvement has been made to establish DRLs for DXA scans and amend the EPs to reflect their implementation.

The EPs in general did not fully reflect the DXA service and an area of improvement has been identified to review the EPs to ensure they are reflective of the DXA service.

Pregnancy checks

Staff clearly described pregnancy checks carried out in the radiology department and where they are recorded. Review of patient records found pregnancy checks had been completed. However, the pregnancy checking process in theatres was less clear. An area of improvement has been identified to review the process for carrying out pregnancy enquiries in theatre, ensure they are recorded and EP C pregnancy enquiries, is amended to fully reflect the arrangements for pregnancy enquiries in theatre.

6.0 Conclusion

There were 20 areas of improvement identified as a result of this inspection. These are fully outlined in the appended QIP.

The management team and staff are to be commended for their ongoing commitment and enthusiasm to ensuring that the MPH is well managed and largely operating within the legislative framework; and maintaining optimal standards of practice for patients.

The inspection team would like to extend their gratitude to the management team and staff for their contribution to the inspection process.

7.0 Quality Improvement Plan/Areas for Improvement

Areas for improvement have been identified where action is required to ensure compliance with The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 known as IR(ME)R and other published standards which promote current best practice to improve the quality of service experienced by patients.

Total number of areas for improvement	20

Areas for improvement identified during this inspection are detailed in the QIP. Details of the QIP were discussed with senior management as part of the inspection process. The timescales commence from the date of inspection.

It is the responsibility of the Employer to ensure that all areas for improvement identified within the QIP are addressed within the specified timescales.

The QIP should be completed and detail the actions taken to address the areas for improvement identified. The Employer should confirm that these actions have been completed and return the completed QIP via BSU.Admin@rqia.org.uk for assessment by the inspector.

Quality Improvement Plan

Action required to ensure compliance with The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018

Area for improvement 1 **Ref:** Regulation 6. Schedule 2.1 (b) **Stated:** First time **To be completed by:** 15 March 2025	The Employer must ensure the entitlement record for the MRI radiographers are amended to include their role as non-medical referrer (NMR). Ref 5.2.1
	Response by Employer detailing the actions taken: The Entitlement form for Radiographer under IR(ME)R includes non-medical referrer function for orbital x-ray examinations. The MRI radiographer has completed and signed the entitlement form for NMR of orbit x-rays and clinical evaluation of orbit x-ray examinations. The competency and entitlement form for MRI radiographer reporting of IOFB radiographs prior to MRI has been amended as a competency form only which will provide evidence and assurance when entitling the radiographer via the Entitlement form for Radiographer under IRMER.
Area for improvement 2 **Ref:** Regulation 6(5)(a) **Stated:** First time **To be completed by:** 15 April 2025	The Employer must establish DXA referral guidelines and make them available to referrers. Ref 5.2.1
	Response by Employer detailing the actions taken: Guidelines for DEXA Referrals have been established and made available to referrers through the Trust LOOP intranet. The Trust is undergoing work with regional colleagues on how best to communicate DEXA referral guidelines with primary care colleagues in the way iRefer applies to all of Northern Ireland.
Area for improvement 3 **Ref:** Regulation 6 **Stated:** First time **To be completed by:** 15 March 2025	The Employer must ensure the Radiation Protection Committee meets at least twice a year to offer assurance to the Employer through providing oversight on meeting statutory duties in relation to IR(ME)R Ref 5.2.2
	Response by Employer detailing the actions taken: The Radiation Protection Committee met on 3rd March 2025 and have scheduled further meetings on 3rd June and 11th November this year. The terms of reference stipulate the RPC must meet bianually.

Area for improvement 4 **Ref:** Regulation 6 **Stated:** First time **To be completed by:** 15 February 2025	The Employer must ensure that the Mini C-Arms in MPH theatres are not re-introduced to clinical service until full compliance with IR(ME)R has been evidenced and ongoing compliance with IR(ME)R is monitored. Ref 5.2.2
	Response by Employer detailing the actions taken: The mini c-arms are not re-introduced to clinical service at present in MPH theatres. An action plan has been developed by the Orthopaedic service to achieve full compliance with IR(ME)R and this continues to be reviewed weekly with support from the Imaging Service and Medical Physics Service. The Orthopaedic Service have also submitted the Trust investigation and action plan and MPE report to RQIA for W486257 on the 12th March 2025.
Area for improvement 5 **Ref:** Regulation 6 **Stated:** First time **To be completed by:** 15 March 2025	The Employer must review and strengthen IR(ME)R governance structures for imaging services provided outside of radiology department and establish a robust radiation safety policy outlining clear roles and responsibilities on this matter. Ref 5.2.2
	Response by Employer detailing the actions taken: The Trust Radiation Safety Policy has undergone a thorough review and was reviewed by the Radiation Protection Committee on 3rd March 2025. The policy outlines the IR(ME)R Governance structure, including service areas outside of radiology, and clear roles and responsibilities, including management of radiation equipment. In line with Trust policy approval processes, the Radiation Safety Policy will be presented to Policy and External Guidance Committee in May 2025. The Trust will continue to work to the current published version of the policy until final approval.
Area for improvement 6 **Ref:** Regulation 7 **Stated:** First time **To be completed by:** 15 March 2025	The Employer must ensure clinical audit reports includes a detailed action plan reflecting all aspects of the findings. Ref 5.2.2
	Response by Employer detailing the actions taken: The re-audit of Rosenberg x-rays action plan was reviewed and updated with the specific actions carried out to reflect all work completed. A re-audit was completed on 3rd March 2025 as per the action plan which demonstrated compliance was met and improvements made. Communication was shared to staff to ensure all detailed actions are included within the audit outcome form. This was shared via the weekly RIGG meeting on 12th March 2025 and through the fortnightly briefing paper due for publication on Friday 14th March 2025.

Area for improvement 7 **Ref: Regulation 6 (7)** Regulation 12(1) **Stated:** First time **To be completed by:** 15 March 2025	The Employer must formally investigate the findings of the dose audits and implement any action necessary. Ref 5.2.2
	Response by Employer detailing the actions taken: Action plans have been developed to investigate the findings from the MPE dose audits and reviewed via RIGG and further discussion will be held at the established Image Optimisation Team meetings as required.
Area for improvement 8 **Ref:** Regulation 8 Schedule 2(1)(l) **Stated:** First time **To be completed by:** 15 April 2025	The Employer must amend Employers Procedures Kii to ensure a more robust framework for radiation incidents and near misses and include a definition of a Clinically Significant Accidental Unintended Exposure (CSAUE). Ref 5.2.2
	Response by Employer detailing the actions taken: Employer's Procedure K(ii) reviewed and amended. A definition of a CSAUE added.
Area for improvement 9 **Ref:** Regulation 8 **Stated:** First time **To be completed by:** 15 April 2025	The Employer must amend the policy and procedure for reporting and the investigation of IR(ME)R related incidents in areas using X-rays for diagnostic and interventional procedures to ensure it accurately reflects current IR(ME)R guidance. Ref 5.2.2
	Response by Employer detailing the actions taken: Policy reviewed and amended in line with current SAUE guidance and Taxonomy coding.
Area for improvement 10 **Ref:** Regulation 6 Schedule 2.1 **Stated:** First time **To be completed by:** 15 February 2025	The Employer must ensure the Employers Procedures are signed by the Employer. Ref 5.2.2
	Response by Employer detailing the actions taken: The Employer's Procedures have been signed by the Employer.
Area for improvement 11 **Ref:** Regulation 6 **Stated:** First time **To be completed by:**	The Employer must devise a robust procedure for the introduction of a new radiology service within the Trust including where a third-party provider may be involved in the provision of new imaging service. Ref 5.2.2

15 April 2025	**Response by Employer detailing the actions taken**: Trust medical devices policy available to all staff detailing steps to take when introducing new radiological equipment, this includes involvement of medical physics and relevant specialists prior to procurement. Staff were reminded to comply with this policy. The organisation is working on a procedural document to support the introduction of ionising radiation equipment within the Trust which will refer to the medical devices and radiation safety policies for clear roles and responsibilities. Once drafted, this procedure will have to go through the appropriate Trust's approval process.
Area for improvement 12 **Ref:** Regulation 15(2) **Stated:** First time **To be completed by:** 15 March 2025	The Employer must ensure the equipment inventory is fully completed in relation to the year of installation and year of manufacture for all radiology equipment and must also include the Mini C-Arms in MPH theatres. Ref 5.2.3
	Response by Employer detailing the actions taken: The equipment inventory includes the mini c-arms in MPH theatres and is fully completed in relation to the year of installation and year of manufacture as per Employer's Procedure D(ii).
Area for improvement 13 **Ref:** Regulation 15 **Stated:** First time **To be completed by:** 15 February 2025	The Employer must ensure the records of level B testing outlines full details of the equipment including name and serial number to provide complete clarity and ongoing management. Ref 5.2.3
	Response by Employer detailing the actions taken: Level B testing records held by medical physics provides full details of the equipment including serial number and name for identification.
Area for improvement 14 **Ref:** Regulation 6 Schedule 3 **Stated:** First time **To be completed by:** 15 April 2025	The Employer must ensure all radiographers undertake benefits and risks of a radiation exposure training. Ref 5.2.4
	Response by Employer detailing the actions taken: Benefits and risks of a radiation exposure is part of staff training and is included within the relevant competencies. Confirmed reading of communication of benefits v risks by staff is recorded and reviewed by the relevant manager. Further information and shared learning has been provided to staff via the fornightly briefing paper in January, February and March 2025.

Area for improvement 15 **Ref:** Regulation 6 Schedule 2.1 (i) **Stated:** First time **To be completed by:** 15 March 2025	The Employer must ensure formal arrangements are in place to provide patients receiving ionising radiation in theatre with information on the benefits and risks prior to having an exposure and outline in Employers Procedure I. Ref 5.2.4
	Response by Employer detailing the actions taken: Benefit versus Risk information will be incorporated within appointment letters pre-procedure for theatre as per Employer's Procedure I.
Area for improvement 16 **Ref:** Regulation 6 Schedule 2.1(n) **Stated:** First time **To be completed by:** 15 March 2025	The Employer must ensure accurate and consistent dose constraint information in relation to carers and comforters in all relevant IR(ME)R documentation. Ref 5.2.4
	Response by Employer detailing the actions taken: CT authorisation guidelines reviewed and dose constraint information amended in line with Employer's Procedure N.
Area for improvement 17 **Ref:** Regulation 12(9) Regulation 6 Schedule 2.1(j) **Stated:** First time **To be completed by:** 15 April 2025	The Employer must amend Employers Procedure J, clinical evaluation to fully reflect the DXA service. Ref 5.2.4
	Response by Employer detailing the actions taken: Emplyer's Procedure J reviewed and amended to reflect DEXA.
Area for improvement 18 **Ref:** Regulation 6 Schedule 2.1 **Stated:** First time **To be completed by:** 15 April 2025	The Employer must review the Employers Procedure to ensure they are reflective of the DXA service. Ref 5.2.4
	Response by Employer detailing the actions taken: The Employer's Procedures have been reviewed and amendments made to EP E and J. Further amendments will be made to the Employer's Procedures once local DRLs are established.
Area for improvement 19 **Ref:** Regulation 6(5)(c) Schedule 2.1 (f) **Stated:** First time	The Employer must establish diagnostic reference levels for DXA scans and amend the Employers Procedures to reflect their implementation. Ref 5.2.4

To be completed by: 15 April 2025	**Response by Employer detailing the actions taken**: Diagnostic reference levels are in the process of being established for DEXA. Local dose data will be collected and shared with the MPE to review. Once DRLs are established, the Employer's Procedures will be reviewed.
Area for improvement 20 **Ref:** Regulation 6 (8), 12 (8)(d), Schedule 2.1 (c) **Stated:** First time **To be completed by:** 9 March 2025	The Employer must review the process for carrying out pregnancy enquiries in theatre, ensure they are recorded; and Employers Procedure C pregnancy enquiries, is amended to fully reflect the arrangements for pregnancy enquiries in theatre. Ref 5.2.4
	Response by Employer detailing the actions taken: Pregnancy enquiry is carried out as per Employer's Procedure C in theatre and recorded on encompass via the pre operative checklist when a radiographer has not been present to complete pregnancy enquiry prior to patient being anaesthetised.

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