The Regulation and Quality Improvement Authority

Inspection Report

5 February 2025

Alliance Medical Holywood, Radiology Department

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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: Alliance Medical	**Department Inspected:** Alliance Medical Holywood Road Belfast (AMHB), Diagnostic Imaging
Name of Employer: Mr Malcolm Banks, Alliance Medical Diagnostic Imaging(AMDI) Limited NI Managing Director	**Quality Manager:** Ms Amy Owens Quality Manager (QM)

Brief description of how the service operates:

The AMHB radiology department provides a service from Monday to Friday between 7.30 am and 8.00 pm to adult patients. A planned limited radiology service is provided at weekends between 8.00 am and 8.00 pm as required. There is no scheduled out of hours service.

Prior to the inspection Ms Amy Owens (QM) and her team were asked to complete a self-assessment form (SAF). The submitted SAF confirmed that the AMHB radiology department has a general digital radiography room, a C-Arm fluoroscopy unit, a computed tomography (CT) scanner and a Dual Energy X-Ray Absorptiometry (DXA) scanner.

AMHB provided 152 general radiology images, 54 fluoroscopy procedures, 9030 CT scans and 25 DXA scans in the past year.

The department is staffed by eight multimodality radiographers with four to five radiographers on site each working day. Radiologist support is provided by a bank of AMHB radiologists through a radiologist of the day rota. The radiologists can be on site for sessional work, offer remote support, be available for medical cover for contrast work and carry out clinical evaluation on site or remotely.

The team is supported by a Medical Physics Expert (MPE) contracted from the Regional Medical Physics Service (RMPS) based in the Belfast Health Social Care Trust.

2.0 Inspection summary

On 5 February 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 AMHB radiology department, as part of RQIA's IR(ME)R inspection programme.

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

- Referral process
- IR(ME)R governance, including arrangements for compliance with IR(ME)R, nuclear medicine 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, patients were awaiting or immediately recovering from radiology diagnostic 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 AMHB radiology department 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 there are two main referrals pathways to the AMHB radiology department, which are National Health Service (NHS) referrals and the private referrals. Both types are managed through the Northern Ireland Picture Archiving and Communications System (NIPACS). The referrals are accepted via an electronic referral form; in a signed letter in electronic form or a hard copy referral which are scanned on to NIPACS. Referrals are excepted from medical practitioners based in the NHS and the Republic of Ireland (ROI), general practitioners(GPs), private doctors and from a small number of non-medical referrers (NMRs) based in NHS Trusts.

Entitlement arrangements for referrers were described by management and largely reflected in the Employers Procedure (EP) 1.

The NHS Trust medical referrers and GPs are entitled through group entitlement arrangements. ROI referrers is on an individual basis. The NMRs are entitled under group entitlement arrangements, however it was noted there are a small number of NMRs and they have different scopes of practice which is not adequately captured by the group entitlement approach. An area for improvement has been identified that AMHB entitle NMRs individually with a clear defined scope of practice. Entitlement is further discussed in section 5.2.2 of this report.

The Employer has responsibility for ensuring referral guidelines are in place and 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. A range of referral criteria was outlined in EP 1 which included iRefer and the National Institute for Health and Care Excellence (NICE) guidelines where applicable. This referral guideline is reflected on the entitlement forms for referrers. Management confirmed that DXA International Society for Clinical Densitometry (ISCD) guidance is used as DXA referral guidelines. However, this was not reflected in the EP 1 or the entitlement forms. It was noted that authorisation guidelines are shared with referrers to assist in the referral process. The purpose of authorisation guidelines as part of the justification and authorisation of exposures was discussed at length and clarification was sought on their provision to referrers to use these guidelines as referral criteria.

There was confusion on the distinct purposes of authorisation guidelines and referral criteria as outlined under IR(ME)R. An area for improvement has been identified to amend EP 1 acceptance of referrals, and the referrer entitlements forms to include details of the DXA referral guidelines and replace the wording of authorisation guidelines outlined in the EP with 'referral guidelines'.

The process of justification and authorisation is further discussed in section 5.2.4 of this report. Management confirmed referrers are directed to Society of Radiographers (SoR) Pause and Check posters for operators when completing referrals. It was advised that these posters would have limited assistance for referrers and it was suggested SoR Pause and Check posters for referrers would be more applicable. Management were receptive to this advice and agreed to follow this up. It was good to note that an audit is carried out to ensure referrers are using the correct referral guidelines.

The management and staff clearly outlined the 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 that they ask the patient if they have had any previous imaging in the last three months. AMHB do not have access to the patients Northern Ireland Electronic Care Record (NIECR) or the NHS radiology information system (RIS) to check for any prior approval or request and to check for pending appointments or previous scans. This has been highlighted as a risk and is listed on the Alliance Medical Diagnostic Imaging Limited (NI) risk register. Management confirmed they have shared this position with the NHS trusts and advised similar arrangements are made in relation to recording the risks.

There was evidence to show that incidents involving referral of the wrong patient are among the largest percentage of all diagnostic errors notified to IR(ME)R regulators. The radiology department have robust systems in place to report, record, investigate and learn from incidents and near misses. Referral processes 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 AMHB radiology department have good arrangements with respect to the referral process and are enthusiastic to ensure these arrangements are regularly reviewed and if necessary, improvements are made. The areas for 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 AMHB is held by the Managing Director. Management confirmed that the Employer and the senior management team (SMT) have received IR(ME)R training in relation to the role and responsibilities of the Employer. The AMHB Radiation Safety (NI) Policy approved in January 2025 sets out the organisational structures, lines of accountability and governance structures.

Management outlined the mechanisms in place to offer assurance with IR(ME)R compliance to the Employer. The AMDI SMT and the AMDI Medical Director report directly to the Employer. The SMT hold regular integrated governance and risk committee meetings and the Quality and Patient Safety department report to this committee.

The Radiation Safety Committee (RSC) which is co-chaired by the radiation protection supervisors (RPSs) reports to the Quality and Patient Safety department. The RSC meet twice a year with a set agenda. Membership of the RSC includes SMT, unit managers, clinical specialist radiographers representing all modalities, the MPE and the lead practitioner (consultant radiologist). On review of minutes for the RSC meetings and discussion on the governance role of the RSC, it was noted that the minutes did not reflect the governance role clearly. The terms of reference (ToR) for the RSC were also not fully reflective of such areas as review of audits and incidents. An area for improvement has been identified to review the ToR for the RSC and ensure they clearly outline the robust governance role which includes scrutiny of audit findings and incidents; and this is fully reflected in the minutes of the RSC meetings which should include an action plan where necessary.

Management and staff confirmed that monthly clinical governance committee meetings and monthly quality meetings are held across the organisation. It was good to note that the radiology service is establishing an image optimisation team (IOT) which will be a multi-disciplinary group including the MPE that will meet twice a year. There are clear terms of reference for this group which focuses on optimisation strategies which includes a review of diagnostic reference levels (DRLs) and dose audits. Both of these important areas are discussed further in this section of the report. The augural IOT meeting is planned for the end of March 2025. It was strongly advised to ensure that the meeting and the vital image optimisation work of the IOT is fully implemented in a timely fashion.

Communication

Management and staff confirmed there was good communication within the radiology department**.** Daily briefing meetings, weekly meetings, a weekly Quality Call which involves all sites and SMT, monthly team meetings are held and a team WhatsApp group is also in place.

Staff confirmed minutes of meetings are available on the organisation's SharePoint/Qpulse. There is a radiologist of the day rota in place and it was confirmed the radiologist is easily contactable for support. Radiographers confirmed communication was good and they felt well supported in their role.

Updates to standard operating procedures or any new documents are disseminated amongst staff through Qpulse. All staff have access to Qpulse, which also hosts audit results, PowerPoint and educational material.

It was confirmed there are formal monthly contract review meetings with the NHS Trusts and formal structures to report and discuss incidents. Management described having good working relationships with the Trusts.

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 and consultant radiologists 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 that 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. It was confirmed that entitlement is reviewed at the annual appraisal and adjusted accordingly if a staff member's scope of practice had changed.

There are oversight arrangements for entitlement of radiology staff and staff outside of radiology such as NMRs.

Referrer group entitlement records for NHS consultants, independent sector consultants, GPs, NMRs and individual entitlement records for consultant radiologists and various grades of radiographers were reviewed. The entitlement records for radiographers outlined a wide range of duty holder roles and operator tasks. It was noted that entitlement records outlined that the radiographers were acting as practitioners for a range of imaging and that they carried out the operator task of clinical evaluation for a range of images. On discussion with management and staff it was evident that the individual entitlement records did not accurately reflect the duty holder roles carried out by the radiographers. It was confirmed that they were only practitioners for carers and comforters and did not carry out the operator task of clinical evaluation of images. An area for improvement has been identified to review the entitlement of radiographers and ensure entitlement records accurately reflect their duty holder roles and scope of practice.

The consultant radiologist's entitlement records were generally well completed however they did not fully reflect an individual scope of practice such as the clinical evaluation of specific types of imaging for example cardiac computed tomography (CT). An area for improvement has been identified to ensure that the consultant radiologists entitlement record includes an individual scope of practice.

On discussion it was noted that referrals from the NHS Trust are justified by medical practitioners in the Trust who are entitled by the NHS Trust, however are not entitled by the AMDI Employer. An area for improvement has been identified to entitle NHS Trust medical practitioners as practitioners for images carried out in AMDI.

To promote a better understanding of the IR(ME)R, an area for improvement has been identified for management and staff to undertake formal IR(ME)R training to include duty holder roles and responsibilities; and the justification and authorisation process. As stated previously justification and authorisation is further discussed in section 5.2.4 of this report.

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.

It was evident that the radiology service has an underpinning culture of quality improvement. Management and staff demonstrated an inclusive, enthusiastic and proactive approach to patient centred service improvement. Review of the radiology clinical audit programme noted it be focused on IR(ME)R compliance and was therefore not a clinical audit programme. Management had recognised the need to develop a clinical audit programme and confirmed a new strategy was issued recently. Sites were given sample audits, tools and templates for each site to choose their own clinical audits. This is a site-based need approach to audits however, it is at the early stages of implementing this process. To consolidate this clinical audit initiative an area for improvement has been identified to develop a multidisciplinary clinical audit programme.

An IR(ME)R compliance focused audit programme was reviewed and found to be carried out in a structured way. Management and staff also described regular ‘spot checks’ relating to IR(ME)R compliance which are not formally recorded as part of the IR(ME)R compliance audit programme. An area for improvement has been identified to formalise the ‘spot check’ approach on IR(ME)R compliance and include recording, collating findings, action taken and any shared learning.

A number of IR(ME)R compliance audits were reviewed as follows:

- Dose audit CT abdomen and pelvis scans January – March 2024
- Dose audit CT abdomen and pelvis scans September – December 2024
- Clinically justified and referrer – DXA
- Clinically justified and referrer – fluoroscopy
- Radiation safety audit 2024

Management and staff described the IR(ME)R audit process well however, the action taken with regard to significant findings was less clear. The dose audit noted findings in excess of the national DRLs, these had been re-audited six months later with some improvement. However, there was no evidence to support if the findings had been reviewed by the clinical governance committee, if any action had been taken, who had been informed, and if the findings had been escalated and discussed at the RPC. This issue had not been minuted at the RPC meetings and there was no evidence that a formal decision had been taken on continuation of the service**.**

As stated previously, scrutinising of audit findings and documenting a detailed action plan is vital to robust governance. An area for improvement has been identified to ensure audit findings are fully interpreted and an action plan devised and implemented as necessary.

In addition, a lack of a formalised approach when DRLs are consistently exceeded was evident. EP 7 dose recording, was found to be ambiguous and unclear in places on this matter. An area for improvement has been identified to formalise action to be taken when the DRLs are consistently exceeded and amend EP 7 dose recording, to ensure it provides a clear framework to adhere to on the matter of patient dose.

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. Radiology incidents and near misses are recorded by the identifying radiographer on AMDI Incident platform (IRIS) and the QM is informed. The management and staff clearly outlined actions to be taken if it suspected significant accidental or unintended exposure (SAUE) has occurred which was fully reflected in relevant employer's procedures. EP 13 incident reporting was well written however, it was advised that it should state its scope applies to all duty holders not just operators as outlined and consider adding detail on analysis of incidents and shared learning. Management were receptive to this advice.

The decision making process for clinical SAUE (CSAUE) and informing relevant stakeholders was clearly outlined by management, which was very well reflected in the EP 14 - CSAUE.

As stated previously the QM and also the Quality department are notified of all incidents and near misses. To provide internal assurances, all incidents are reviewed by another member of staff within the Quality department, and support provided if needed, prior to close out. Near Misses and Minor Incidents will be investigated by the allocated Quality Specialist and then reviewed prior to closure by the allocated Senior Incident Quality Specialist.

Major Incidents will be investigated by the Senior Incident Quality Specialist, with the input of the Quality Manager / Head of Patient Safety and Quality. These are reviewed prior to closure by the QM and/or Head of Patient Safety and Quality.

All minor and major radiation incidents are managed by the QM in their functions as Clinical Lead for Radiation Safety, respectively. All serious reportable events will be investigated, managed and closed out by the Head of Patient Safety and Quality with input from the relevant members of the SMT.

The Quality department responsibilities include:

- Review the case and documentation relating to the incident
- Request further details, if necessary
- Perform root cause analysis using various tools, including the Fish Bone analysis to determine root cause
- Issue specific actions, if necessary
- Identify corrective and preventative actions as necessary to prevent similar incidents occurring in future
- Risk assess and grade all incidents, in accordance with the Risk Management Procedure
- Recommend the adding of any incidents considered to be a potential risk to the local risk register or corporate risk register
- Write a close out report, if required
- Provide feedback to staff on site or feedback to patients, if required.
- All incidents are communicated to the Managing Director and management team on a monthly basis
- All incidents are communicated to the company's insurers and Medical Director on a monthly basis
- All relevant incidents are communicated to the relevant committees or regulatory bodies
- Trends in incident reporting will be undertaken on an ongoing basis.

Learnings from near misses and incidents will be shared within AMDI and relevant stakeholders via RSC meetings to ensure that all staff benefit from knowledge shared and improve the safety of AMDI's service delivery.

Risk register

The arrangements for ensuring the AMDI risk register reflects risks associated with non-compliance with IR(ME)R was reviewed. The management outlined clear information to ensure that the risk registers are examined, updated and mitigated, to ensure all identified IR(ME)R risks are appropriately captured and that specific actions to reduce the risks are identified and appropriate systems of assurance are in place. The Employer would be made aware of any additions to the risk register through the previously described governance structures.

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

It was confirmed that the RSC review draft EPs and protocols. They are held in the relevant folder on the Alliance Medical Holywood Radiology (AM HWR) SharePoint in portable document format (PDF). New documents are uploaded to SharePoint with the older versions archived. Staff confirmed that they are informed of new or updated documents on SharePoint via email. There are a limited number of hard copy procedures which are subject to a clear tracking system to ensure the most up to date version is in place. EP 6 'ensure quality assurance (QA) programmes are followed' includes QA of written documentation. On review it was noted that it lacked detail on version control, author, page numbers and a clear ratification process. An area for improvement has been identified to amend EP 6 to include more detail as outlined above.

A number of written examination protocols were reviewed. The CT examination protocol was found to be an excellent well written and very clear document.

General X-ray examination protocol was detailed and generally well written however, it was noted that the document indicated it is used as authorisation guidelines and the references to the practitioner role was confusing. As stated previously the justification and authorisation process is further discussed in 5.2.4. It was noted that the DXA examination protocols are currently held in two separate documents and on review both require to be more detailed. An area for improvement has been identified to review the General X-ray examination protocol and the DXA examination protocol to ensure they provide detailed and accurate information.

The introduction of a new radiology service

Management outlined the process to be followed when new a radiology service is introduced. This would typically come through from the commissioners and a business case would be developed, mapping from capital to revenue to identify needs. Design teams would be created, which would involve the MPE and the relevant modality leads/expertise would also be involved. The MPE will be involved in commissioning and performing the relevant tests as well as setting up protocols and giving sign off for the equipment to be used clinically. The equipment is then added to the equipment inventory and assigned a unique identification (ID). Application training is provided by the vendor and the vendor will have remote access for additional support.

The governance arrangements for the new service will be fully reviewed including ensuring compliance with IR(ME)R. Once a new service is introduced it will be audited.

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 AMHB radiology service and these arrangements are regularly reviewed and, if necessary, improvements are made. It is hoped that addressing the areas for improvement will further enhance the governance systems. The inspection team acknowledge the commitment of staff in this regard.

5.2.3 Does the service adhere to legislation with regard to equipment QA?

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 equipment inventory did not fully reflect all of the information required under IR(ME)R. An area for improvement has been identified on this matter.

Management and staff confirmed there is an appropriate amount of equipment available for the workload of the radiology department.

There is a formal, written equipment QA programme in place. It was confirmed that the MPE had been involved in devising the equipment QA procedures which were found to be generally well written. However, it was noted that the submitted SAF outlined very pertinent detail relating to what to do if there are discrepancies in results. It was advised it would be helpful to have this information included in the QA procedures. Management were receptive to this advice.

It was confirmed that daily and monthly quality checks (QC) of the radiology equipment are carried out by appropriately trained and entitled operators.

A review of equipment QC records evidenced that they were performed with no gaps in testing.

EP 6- equipment QA, is in place which was found to be a comprehensive and clear framework for staff to follow.

It was noted there is clear governance and oversight of the equipment QA programme. Staff and management demonstrated understanding of their roles and responsibilities in relation to equipment QA.

Management confirmed there is no radiology equipment held in AMHB outside of the radiology department.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that a clear and robust equipment QA programme is in place. The inspection team acknowledge the commitment of 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

Justification and authorisation

The duty holder roles of operator and practitioner were 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.

As stated previously there was a lack of clarity on the process of justification and authorisation of imaging undertaken in AMHB. Radiographers were outlined as practitioners for a range of imaging in their entitlement records. On discussion it was confirmed they only act as practitioners for carers and comforters. Authorisation guidelines were in place, however on review they were found to have insufficient detail on areas such as clinical indications or whether they were for adults or paediatrics. The DXA authorisation guidelines were particularly limited and included body composition imaging, which is not a justified practice. Fluoroscopy authorisation guidelines were available however, it was confirmed a radiologist acting as an entitled practitioner is always present during this type of imaging to individually justify and authorise each fluoroscopy procedure therefore, authorisation guidelines should not be required. The use of terminology such ‘approving’ and ‘vetting’ throughout the authorisation guidelines and within other IR(ME)R documents has compounded confusion in relation to justification and authorisation of referrals.

It is hoped the previously outlined area for improvement in relation to IR(ME)R training for staff will assist in developing a better understanding of the justification and authorisation process.

In addition, an area for improvement has been identified to review all authorisation guidelines, their use and ensure IR(ME)R terminology is used throughout to avoid confusion.

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 outlined that benefits and risks information is provided where practicable prior to an exposure taking place, to the individual to be exposed or their representative. This takes the form of benefit-risk posters on display within patient waiting areas and inside of individual examination rooms. In addition, appointment letters sent to patients highlight that an exposure or a scan involves radiation. Further information is also available on the AMDI website which is noted in the patient letters. Radiographers confirmed they had training delivered by the MPE via AMDI on the provision of benefits and risks information. This was reflected EP 16 benefits and risks.

On review of the department, there were posters displayed in the patient waiting area however they did not contain information on benefits and risks. Review of the individual examination and changing rooms noted that there were no benefits and risks posters in place. In addition, review of an example of a patient appointment letter noted that it did not reflect information on the benefits and risks of having an examination that involves ionising radiation.

An area for improvement has been identified to ensure 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) as required under IR(ME)R and amend EP 16 benefits and risks accordingly.

Employer's Procedures (EPs)

Employer's procedures in place were generally well written however, it was noted that the DXA service was not fully reflected in the EPs.

EP 5 pregnancy enquires, was reviewed and found to be a sound framework for duty holders to follow however, it was noted that there was no link to safeguarding arrangements should a safeguarding matter arise.

An area for improvement has been identified to review the EPs to ensure they fully reflect the DXA service and update EP 5 pregnancy enquiries, to include a safeguarding link.

6.0 Conclusion

There were 17 areas of improvement identified as a result of this inspection. This is 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 AMHB radiology department is well managed and 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. 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	17

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 (1) Schedule 2.1 (b) **Stated:** First time **To be completed by:** 5 April 2025	The Employer must ensure that Non-Medical Referrers are individually entitled with a clear defined scope of practice. Ref 5.2.1
	Response by Employer detailing the actions taken: Non-Medical Referrer entitlement has been reviewed, with scope of practice defined.
Area for improvement 2 **Ref:** Regulation 6 (1) **Stated:** First time **To be completed by:** 5 April 2025	The Employer must amend EP 1 acceptance of referrals, and the entitlements forms to include details of the DXA referral guidelines and the authorisation guidelines outlined in the EP are replaced by referral guidelines details. Ref 5.2.1
	Response by Employer detailing the actions taken: EP 1 has been reviewed and updated in line with area for improvement.

Area for improvement 3 **Ref:** Regulation 6 (2) and Regulation 8 (3) **Stated:** First time **To be completed by:** 5 April 2025	The Employer must review the Terms of Reference (ToR) for the Radiation Safety Committee (RSC) and ensure they clearly outline the robust governance role which includes scrutiny of audit findings and incidents; and this is fully reflected in the minutes of the RSC meetings which should include an action plan where necessary. Ref 5.2.2
	Response by Employer detailing the actions taken: Terms of Reference have been updated to further delineate the role that the RSC has in audit findings and incidents. Future minutes will ensure accurate and comprehensive information is captured from discussions held with specific actionable items listed.
Area for improvement 4 **Ref:** Regulation 6 (2) Schedule 2.1 (b) **Stated:** First time **To be completed by:** 5 April 2025	The Employer must review the entitlement of radiographers and ensure entitlement records accurately reflect their duty holder roles and scope of practice. Ref 5.2.2
	Response by Employer detailing the actions taken: Radiographer entitlement has been reviewed to accurately reflect duty holder roles and scope of practice.
Area for improvement 5 **Ref:** Regulation 6 (1) Schedule 2.1 (b) **Stated:** First time **To be completed by:** 5 April 2025	The Employer must ensure that the consultant radiologists entitlement record includes an individual scope of practice. Ref 5.2.2
	Response by Employer detailing the actions taken: Radiologist entitlement has been reviewed to include an individual scope of practice.
Area for improvement 6 **Ref:** Regulation 6 (1) Schedule 2.1 (b) **Stated:** First time **To be completed by:** 5 May 2025	The Employer must entitle NHS Trust medical practitioners as practitioners for examinations carried out in AMDI. Ref 5.2.2
	Response by Employer detailing the actions taken: Entitlement underway - will be completed by 30th April 25.
Area for improvement 7 **Ref:** Regulation 6 (3) Schedule 3	The Employer must ensure management and staff undertake formal IR(ME)R training to include duty holder roles and responsibilities; and the justification and authorisation process. Ref 5.2.2

Stated: First time **To be completed by:** 5 April 2025	
	Response by Employer detailing the actions taken: Additional training has been arranged to be delivered by MPE.
Area for improvement 8 **Ref:** Regulation 7 **Stated:** First time	The Employer must develop and implement a multidisciplinary clinical audit programme. Ref 5.2.2
To be completed by: 5 May 2025	**Response by Employer detailing the actions taken**: Clinical audit programme to be devised in conjunction with the Image Optimisation Team - programme will be agreed upon by 30th April 2025.
Area for improvement 9 **Ref:** Regulation 6 (2) **Stated:** First time	The Employer must formalise the 'spot check' approach on IR(ME)R compliance and include recording, collating findings, action taken and any shared learning. Ref 5.2.2
To be completed by: 5 May 2025	**Response by Employer detailing the actions taken**: Spot checks have been converted to a rolling IR(ME)R compliance programme, results of which will be disseminated to the Employer.
Area for improvement 10 **Ref:** Regulation 7 **Stated:** First time	The Employer must ensure audit findings are fully interpreted and an action plan devised and implemented as necessary. Ref 5.2.2
To be completed by: 5 May 2025	**Response by Employer detailing the actions taken**: All audits will now follow a standardised report template, containing structured, actionable items which have a responsible person and close out date allocated.
Area for improvement 11 **Ref:** Regulation 6 (7) Schedule 2.1. (f) **Stated:** First time	The Employer must formalise action to be taken when the DRLs are consistently exceeded and amend EP 7 dose recording, to ensure it provides a clear framework to adhere to on the matter of dose. Ref 5.2.2
To be completed by: 5 April 2025	**Response by Employer detailing the actions taken**: EP 7 has been amended to reflect points raised as area for improvement.

Area for improvement 12 **Ref:** Regulation 6 (1) Schedule 2.1(d) **Stated:** First time	The Employer must review EP 6 include details of quality assurance programmes in respect of written procedures and protocols such as version control, author, page numbers and a clear ratification process. Ref 5.2.2
To be completed by: 5 May 2025	**Response by Employer detailing the actions taken**: EP6 has been updated to reflect the existing AMDI Document Control procedure.

Area for improvement 13 **Ref:** Regulation 6 (4) **Stated:** First time **To be completed by:** 5 April 2025	The Employer must review the General X-ray examination protocol and the DXA examination protocol to ensure they provide detailed and accurate information. Ref 5.2.2
	Response by Employer detailing the actions taken: Protocols have been reviewed for clarification and accuracy.
Area for improvement 14 **Ref:** Regulation 15 (2) **Stated:** First time **To be completed by:** 5 April 2025	The Employer must ensure the equipment inventory fully reflects all information required under IR(ME)R. Ref 5.2.3
	Response by Employer detailing the actions taken: The addition of date of manufacturer has been completed.
Area for improvement 15 **Ref:** Regulation 11 (5) **Stated:** First time **To be completed by:** 5 April 2025	The Employer must review all authorisation guidelines, their use and ensure IR(ME)R terminology is used throughout to avoid confusion. Ref 5.2.4
	Response by Employer detailing the actions taken: Review has been undertaken and action is completed.
Area for improvement 16 **Ref:** Regulation 6 (1) Schedule 2.1(i) **Stated:** First time **To be completed by:** 5 May 2025	The Employer must ensure 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) as required under IR(ME)R and amend EP 16 benefits and risks accordingly. Ref 5.2.4
	Response by Employer detailing the actions taken: Further risk versus benefit information is now displayed across the department. Appointment letters now direct patients to a specific page of the AMDI website which includes more detailed information to assist patients or their representative in making an informed decision. Radiographers remain available at any time to speak to a patient and/or their representative.
Area for improvement 17 **Ref:** Regulation 6 (1) Schedule 2.1 (c) **Stated:** First time **To be completed by:** 5 May 2025	The Employer must review the EPs to ensure they fully reflect the DXA service and update EP 5 pregnancy enquiries, to include a safeguarding link. Ref 5.2.4
	Response by Employer detailing the actions taken: A review of the EPs has been undertaken to ensure DXA is fully reflected. EP5 now includes reference to AMDI Safeguarding procedures.

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