Inspection Report

4 September 2024

Antrim Hospital Breast Screening Department

Address: Bush Road, Antrim, BT41 2RL
Telephone: 028 9442 4000 Ext-332561

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: Northern Health and Social Care Trust (NHSCT)	**Department Inspected:** Antrim Hospital –Breast Screening Department (AHBS)
Name of Employer: Ms Jennifer Welsh Chief Executive NHSCT	**Interim Clinical Services Manager (CSM):** Ms Paula McNaughton

Brief description of how the service operates:

The Antrim Hospital Breast Screening (AHBS) department provides a service Monday to Friday between 9am and 5pm to clients and patients. There is no scheduled out of hours service.

Before the inspection Ms McNaughton, CSM, and her team were asked to complete a self-assessment form (SAF). The submitted SAF confirmed that within AHBS (known as the static site) there are two mammography units (one capable of stereotactic biopsy) and three ultrasound suites. The department also has film reading stations for clinical evaluation. There are two mobile units both of which have been replaced recently. These units move between various sites in the NHSCT. The sites are typically main hospital sites, for example Antrim, Whiteabbey, Ballymena and the Mid Ulster. The mobiles can also be stationed at local health and care centres such as Larne. The mobile unit will typically remain at a site for 12-18 months. A breast screening service in accordance with the National Health Service Breast Screening Programme (NHSBSP) is delivered largely from the mobile units. A regional very high risk (VHR) breast screening service is provided to around 600 clients by the AHBS. A symptomatic breast screening service is also provided at AHBS site. In the past year the non-breast screening service carried out 16,542 mammograms, 267 digital breast tomosynthesis (DBT); 90 magnification views; 78 stereotactic vacuum biopsies and 8 stereotactic vacuum excisions. The symptomatic breast screening service carried out 5795 mammograms; 248 DBT; 62 magnification views; 64 stereotactic vacuum; 15 stereotactic vacuum excisions and 21 stereotactic localisations.

Radiographers rotate between the static site in AHBS and the mobile units. There are 1.2 whole time equivalent (WTE) interventional radiography advanced practitioners; 10.56 WTE radiographers (a range of bands) and 1.6WTE assistant practitioners. The service currently has seven breast radiologists. All have completed breast specialist training. All radiologists undertake symptomatic and screening work. The majority of the radiologists also include breast MRI in their scope of practice. The radiologists are also general radiologists with dedicated sessions for breast screening, assessment clinics, symptomatic imaging, multidisciplinary team meetings (MDTs) and administrative/management duties as required by their specific role.

On the mobile units, staff can contact the static unit for support via phone call. All mobile units are connected to the Trust electronic network. Staff have access to phone numbers for the consultant radiologist and the radiologist rotas are available online. These rotas outline the location and availability of the radiologist. The rota also identifies the radiologist covering screening, red flag and assessment clinics.

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

2.0 Inspection summary

On 4 September 2024, 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 AHBS, 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 breast screening 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 breast imaging unit, clients/patients were awaiting or immediately recovering from breast screening and/or assessment procedures, it was deemed inappropriate to seek to speak to these clients/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 AHBS 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.

The range of breast imaging pathways were discussed to establish the referral process for each.

Breast screening in accordance with the NHSBSP

If a client is registered with a General Practitioner (GP) in Northern Ireland (NI) then their details will be supplied via the National Health Application and Infrastructure Services (NHAIS) for screening managed by the Health and Social Care Business Service in NI. Clients who are in the eligible age range (49-70 years old) for screening receive an invitation letter to attend for breast screening which is signed by the Director of Screening who acts as the referrer for these exposures. Clients who receive their last mammogram before they reach 70 years are given information on how to seek further mammograms in accordance with NHSBSP guidelines. They may request further mammograms which triggers an invitation letter which is signed by the Director of Screening who acts as the referrer. Where a client attends without an invitation letter, the administrative team are contacted to confirm the individual has been invited for screening (and thus received the invitation letter). Where an individual attends without an invite to screening the individual is advised to contact the administrative team. It was confirmed that clients who have not received an invite do not receive screening examinations. An invitation letter will be issued when appropriate.

Employers Procedure (EP) B, entitlement, outlined the referrer duty holder role and it was noted that it did not fully reflect the purpose of invitation letter for breast screening and an area of improvement has been made on this matter.

Surveillance pathway

Two surveillance pathways were described by the Director of Breast Screening– oncology surveillance and high risk surveillance (not Very High Risk). For oncology surveillance this includes patients who have had a previous diagnosis of breast cancer. The guidelines for this cohort are within the self directed aftercare (SDA) pathway. After their diagnosis patients are referred by the surgical team. The referral is completed by either a breast surgeon, breast care nurse or breast speciality doctor all of whom have been entitled as referrers. The referral includes detail on diagnosis and previous surgeries. Patients within this cohort are offered annual mammography for five years or until they are 50. If they were previously in the cohort of high risk family history, they will be offered mammography until 60 years of age. If the referrer provides appropriate information, the Director of Breast Screening will extend the period of mammography screening to 60 years of age. A referral is completed for the screening period. The radiologist justifying the screening will document the month to start and end and frequency (annually). This is evidenced in the clinical vetting notes.

If a patient is diagnosed with cancer during this screening period, a new referral is submitted as the patient will move back to year one of the surveillance period. The five year time frame will then restart, and the referral will be treated as a new referral for surveillance screening.

For the high risk surveillance, this cohort is identified by the National Institute of Clinical Excellence (NICE) guidelines. They do not come under the cohort of Very High Risk. Family history can be further broken down into moderate risk, which requires annual surveillance from 40 years - 50 years, and high risk, which requires annual surveillance from 40 years to 60 years. Annual surveillance can be extended to 70 if the referrer provides appropriate information and the practitioner deems it justified.

Very High Risk (VHR)

As stated previously the VHR breast screening service is provided on a regional basis by the NHSCT breast imaging unit. The Lead Radiologist for VHR is the NHSCT Director of Radiology. If a patient is considered VHR the Lead Radiologist receives notification of VHR via a notification form received from the genetics department or a breast surgeon. The Lead Radiologist reviews the information and adds the patient to the VHR database. The individual receives an invite to VHR screening. The Lead Radiologist is evidenced as the referrer on this invitation letter. The Lead Radiologist acts as the practitioner for these referrals which are all individually justified. The pathway follows national guidelines. Imaging typically starts around 25 years of age which is usually magnetic resonance imaging (MRI) until 40 years of age when individuals are offered annual mammography. The individual is added to NBSS and a separate additional database for monitoring.

Discussion on the justification and authorisation process for VHR breast imaging service provided a clear outline of the process however this was not fully reflected in the VHR justification and authorisation procedure. An area of improvement has been identified to further develop the VHR justification and authorisation procedure to ensure it is reflective of practice.

Out of area screening (OOA)

For VHR, clients may request to have the mammogram performed at their local breast imaging unit, this is known as out of area screening. The VHR pathway is a regionally agreed process. The MRI component of the pathway must be performed at Antrim Area Hospital. Where the individual seeks the mammogram locally, the Lead Radiologist for VHR remains the referrer. Clinical evaluation remains with the performing (local) Trust. The results go to the GP and the client.

The Lead Radiologist noted they also act as the IR(ME)R practitioner for these referrals in the OOA setting. It was unclear how this justification is recorded within the individual's local Trust (outside NHSCT). An 'Appoint and review' form is completed for each client. This is not the IR(ME)R referral but the service noted this form evidences locally within NHSCT justification and authorisation. It did not explicitly state on the form that the signature evidenced justification and authorisation. An area of improvement has been identified to add further detail in this form to explicitly evidence justification and authorisation, and update relevant procedures to reflect this process, including the invitation letter serving as the IR(ME)R referral.

The Employer has 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.

Within the NHSCT, the IR(ME)R Lead has been delegated the task to identify referral criteria and ensure the criteria is available to the referrer. It was good to note that the Director of Breast Screening and the Lead Radiologist for VHR breast imaging have devised referral criteria for the breast imaging service in liaison with the MDT. These were found to be of a very good standard.

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.

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 AHBS department has 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 AHBS department have good arrangements with respect to the referral process 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 NHSCT is held by the Chief Executive. The Chief Executive was presented with a briefing paper, in regards to IR(ME)R and the role and responsibilities of the Employer, upon her appointment as Chief Executive in the NHSCT. The NHSCT Radiation Protection Policy sets out the organisational structures, lines of accountability and governance structures. However, it was noted that an approval date, an operational date and a review date had not been completed on the version control page of this policy. An area of improvement has been identified to ensure the approval, operational and review dates are included on the Radiation Safety Policy

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

Management described the lines of accountability for the breast imaging service, the breast imaging staff report to the assistant clinical services manager (ACSM) in breast imaging. The ACSM reports to the clinical services manager (CSM) for radiology, who reports to the assistant director. The assistant director reports to the director, who reports to the director of operations, who reports to the chief executive.

A range of governance sub groups are in place which feed into the radiation safety committee (RSC) which is chaired by the IR(ME)R lead. The RSC submits a report twice a year to the safety and quality care steering group which is chaired by the director of operations. This then feeds into the risk assurance group. On occasions where appropriate, the Trust board will request the attendance of the CSM for radiology to attend meetings and discuss particular issues.

It was good to note that the breast imaging service has established an image optimisation team (IOT) which is a multi-disciplinary group. There are clear terms of reference for this group which focuses on dose optimisation strategies and quality improvement. The MPE generally attends the IOT meetings.

Communication

Management and staff confirmed there was good communication within the breast imaging department**.** Monthly meetings and weekly team briefs are utilised for communication within the breast imaging team. 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, clinics for the weeks ahead and other relevant information. The team can also contact each other via email and the team can also contact each other electronically.

There are range of meetings held to promote robust communication and good governance including twice yearly Trust Screening Quality Assurance (QA) meetings, a monthly meeting between cancer services and the imaging services managers and weekly MDT which includes attendance from breast surgeons and breast radiologists. It was confirmed that there is close communication between the outpatients and the breast imaging unit. The symptomatic clinic is a collaborative clinic between the surgeons and the radiologists.

Regionally, there is communication via email and a working group for VHR which meets twice a year. There is a breast QA group which is led by the breast QA radiology lead and the Public Health Agency (PHA) lead for screening and they meet twice a year. On an annual basis there is an interval cancer workshop organised by Young Person and Adult Screening Team (YPAST) and the breast QA lead. This is an opportunity for teams to discuss any issues and is typically an educational meeting.

Within the YPAST framework there are surgical and radiology groups which liaise back to the central group. This allows dissemination of learning via quarterly meetings. The Trust meets with YPAST in relation to QA follow up meetings twice a year. The Trust also meet with the MPEs on a weekly basis to discuss incidents.

The management described clear communication escalation procedures which included sending an email to the core group: breast surgeons, breast radiologists and breast middle grade doctors. CSM can contact the director via telephone and will if required inform the Employer.

Updates to standard operating procedures or any new documents are disseminated amongst staff via document management system(DMS). All staff have access to DMS, which also hosts audit results, PowerPoint presentations and educational material.

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 advanced practitioners , radiographers, assistant practitioners and consultant breast 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 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 breast radiologists and surgeons have their appraisals undertaken by an approved medical appraiser. Breast radiologist entitlement is reviewed at annual appraisal, breast surgeon's entitlement is reviewed by the Surgery CSM annually following request for review from radiology and may be adjusted accordingly if a staff member's scope of practice had changed. There are clear oversight arrangements for entitlement of radiology staff and staff outside of radiology such as non medical referrers (NMRs) and breast surgeons.

Individual entitlement records for consultant breast radiologists, an advanced practitioner, radiographers, an assistant practitioner and NMRs were reviewed. The group entitlement record for MPEs was also reviewed. It was noted that entitlement records were in the main well completed. However, it was noted that the scope of practice for consultant breast radiologists did not fully reflect specialisms in relation to interventional procedures. It was also noted that the entitlement record did not reflect the review of entitlement which was confirmed as taking place annually at appraisal. An area of improvement has been identified to ensure that the consultant breast radiologists entitlement record is further developed to reflect the consultant breast radiologists scope of practice and the review process.

As previously discussed the radiographer's entitlement records were largely well completed and reflective of the duty holders role. However, it was noted that the operator task of authorising carer and comforters imaging was not included in their entitlement records. Staff confirmed they undertake this role and demonstrated a very good understanding of their responsibility in this regard. An area of improvement has been identified to ensure the authorisation of carers and comforters exposures is included as an operator function in the radiographers entitlement records.

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 the breast imaging service has an underpinned culture of quality improvement. Management and staff demonstrated an inclusive, enthusiastic and proactive approach to client/patient centred service improvement. It was good to note that the provision of clinical audit within the breast imaging service had been subject to a structured robust approach.

Audit priorities are agreed by the Senior Management Team which includes: the Radiology Clinical Services Manager, Assistant Clinical Services Manager for Breast Imaging, Governance Lead Radiographer, Clinical Director, in liaison with the Consultant Radiologist Audit Leads. The team identifies departmental objectives to plan, prioritise and record the rolling Breast Imaging Audit Schedule.

The annual rolling Breast Imaging Audit Schedule is drafted and prioritised considering the various factors, for example clinical priorities, as part of incident investigations, risk management, departmental or corporate objectives, to evidence compliance with IR(ME)R and documented processes, and to facilitate continuous quality improvement.

IR(ME)R audits are predominantly scheduled annually, however audits may be scheduled more or less frequently dependent on patient risk, available staffing resources, availability of suitable sample sizes and previous audit outcomes.

Outcomes of audit are communicated in the weekly radiology team brief, presented at the relevant audit meetings (Radiology and the referring service where applicable), discussed at breast imaging meetings, Radiology Directorate, IOT and RSC. The Audit Schedule, templates, outcomes and action plans are available to all staff on the Breast Imaging Documentation shared drive. Hard copies of audits are also available for staff reference.

It was good to note a MDT approach to audit and a number of audits were reviewed which included:

Radiographers Clinical Audits –

- Stereo Guided Wire Localisation Accuracy
- Audit of Technical Recalls and Repeats
- Audit of Partial Mammography

Radiologists Clinical Audit

- A retrospective audit of Interval cancers screened 2019-2020 carried out April 2024

IR(ME)R compliance Audit

- Employer Procedure A
- Employer Procedure C (December 2023 and March 2024)
- Appropriateness of referrals

The clinical and IR(ME)R audits were found to be very robust with an indepth analysis particularly on the understanding of staff. The audit template in use was found to provide an excellent framework to capture meaningful audit and drive improvement.

Incident and near miss management

There are clear arrangements in place to report, record, investigate and learn from incidents or near misses in the breast imaging department. There is an incident review group weekly meeting to manage and ensure oversight of incidents and near misses. The management and staff clearly outlined action to be taken if it suspected significant accidental or unintended exposure (SAUE) has occurred, and this was fully reflected in relevant employer's procedures.

The decision making process for clinical SAUE (CSAUE) and informing relevant stakeholders was clearly outlined by management, and reflected in the EP L - CSAUE. However, EP L does not reflect what happens if the decision is made not to inform the individual. An area of improvement has been identified to amend EP L to clearly reflect the action required if the decision not inform the individual of a CSAUE is taken.

Radiology participates in the monthly Surgery and Clinical Services Divisional Governance Meeting. Review of SAUEs in particular is a standing agenda item.

The analysis of incidents and near misses is co-ordinated by the Incident Review Group and provides a quarterly Radiology Error report which is shared through the Trust Governance Assurance Framework including Image Optimisation Group, RSC, Departmental governance meeting and the Safety and Care Quality Steering Group. Incidents are presented annually at the radiology audit meetings. Learning themes are shared and communicated with all relevant stakeholders within and external to the organisation.

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 Trusts 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.

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

It was confirmed that RSC reviews draft EPs and protocols for ratification. If documents require ratification prior to the scheduled RSC meeting then they are emailed to the IR(ME)R Lead for ratification. Diagnostic Reference Levels (DRLs) are set and reviewed by the IOT. They are then ratified by the RSC. It was good to note two local DRLs are in place. There is a quality management system (QSM) in place for all electronic documents which are held on DMS. Newly ratified documents will be uploaded to DMS with the older versions archived. Staff will be informed of the new documents on DMS. 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.

The introduction of a new breast imaging service

Management outlined the process to be followed when a new breast imaging service is introduced. This would not be a Trust led introduction and would be in accordance to the National Breast Screening programme and Public Health Agency for Northern Ireland.

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 will be audited.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that there are robust governance arrangements with respect to the breast imaging service and these arrangements are regularly reviewed and, if necessary, improvements are made. It is hoped the areas of improvement made will enhance 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 reflected all information required under IR(ME)R. Management and staff confirmed there is an appropriate amount of equipment available for the workload of the breast imaging service.

There is a formal, written equipment quality assurance (QA) programme in place. Radiographers have been entitled as trained and competent operators to perform daily, weekly and monthly QC testing. There is a nominated QA radiographer in the department who liaises closely with medical physics. There are regular QA meetings which ACSM attends with the governance lead radiographer. Trust wide QA coordinators meetings are held quarterly. The QA coordinators provide reports at these meetings to allow oversight. QA compliance is not directly reported to the Employer except by exception, for example where a deficit is found.

A six monthly audit of QA is carried out and the results are shared via email, discussed at staff meetings and team briefs.

EP D - 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.

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

Employers Procedures (EPs)

It was good to note EPs for the NHSCT Breast Imaging Service where in place which had been issued in August 2024 and are due for review August 2026. They had been signed by the Employer on 13 August 2024. Overall they were found to be provide a sound framework for the delivery of the breast imaging service and largely reflected practice.

It was noted that EP I benefits and risks, did not fully reflect the robustness of the process in place which staff described to the inspection team.

Clinical evaluation was reviewed and was very well described by the Director of Breast Screening including the process of arbitration. However the arbitration process was not outlined in detail in EP J clinical evaluation.

An area of improvement has been identified to amend the EPs as follows:

- EPI benefits and risks, amend to reflect the robust process for ensuring the provision of information to clients/patients on the benefits and risks of breast imaging.
- EPJ clinical evaluation, amend to include full details of the arbitration process.

Record keeping

As part of the inspection of the breast imaging service client/patient records were reviewed to ensure compliance with IR(ME)R. Overall the standard of record keeping was very high.

However, it was noted that for all but one client/patient records reviewed a radiation dose record was available.This was discussed with management who gave immediate assurances to review client/patient records to ensure this is not a widespread issue and remind staff of the requirement to record dose. An area of improvement has been identified to ensure there is a record of radiation dose for each exposure outlined clearly in client/patient records.

The client screening forms were reviewed and it was noted that one signature covers both the identification check and confirmation of authorisation. It is not possible to determine compliance with EPs in relation to these two separate aspects as a single initial is used. An area of improvement has been identified to provide separate signatures to confirm client identification and authorisation of the exposure on the client screening form.

On review of the 'Pink' assessment clinic form it was noted that there is a single area to evidence authorisation. However patients attending assessment may have multiple exposures and it is therefore difficult to determine what exact exposure is authorised. An area of improvement has been identified to clarify this approach to ensure it is clear who has justified and authorised each exposure.

6.0 Conclusion

There were 11 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 AHBS is well managed and operating within the legislative framework; and maintaining optimal standards of practice for clients/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	11

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:** 4 December 2024	The Employer must ensure that Employers Procedure (EP) B, entitlement, reflects the purpose of the invitation letter in relation to the referrer for breast screening. Ref 5.2.1
	Response by Employer detailing the actions taken: NHSCT Breast Imaging EP B has been updated to reflect that Clients receive a screening invitation letter which acts as the referral for imaging. This is signed by the Director of Screening who is entitled by the Employer to act as the referrer for these exposures.
Area for improvement 2 **Ref:** Regulation 11 **Stated:** First time **To be completed by:** 4 November 2024	The Employer must further develop the VHR justification and authorisation procedure to ensure it is reflective of practice. Ref 5.2.1
	Response by Employer detailing the actions taken: NHSCT Breast Imaging EP B has been updated to detail the process for VHR screening. Information has been included to indicate the staff member who is the referrer and practitioner for VHR screening. This has also been detailed on the updated

	'Appoint and Review' form for VHR screening. This form fulfils IR(ME)R requirements and is available to view on the NBSS record when a client is seen out-of-area. The relevant work instruction has been updated to reflect the process.
Area for improvement 3 **Ref:** Regulation 11 **Stated:** First time **To be completed by:** 4 November 2024	The Employer must add further detail in the 'Appoint and Review' form to explicitly evidence justification and authorisation, and update relevant procedures to reflect this process, including the invitation letter serving as the IR(ME)R referral. Ref 5.2.1
	Response by Employer detailing the actions taken: The 'Appoint and Review' form has been updated to include IR(ME)R requirements, detailing the staff member who has justified and authorised the required imaging. NHSCT Breast Imaging EP B has been updated to reflect that clients receive a VHR screening invitation letter which acts as the referral for imaging and is signed by the Breast Radiologist Lead for VHR BSP who is entitled by the Employer to act as the referrer for these exposures.
Area for improvement 4 **Ref:** Regulation 6 Schedule 2.1(d) **Stated:** First time **To be completed by:** 4 November 2024	The Employer must ensure the approval, operational and review dates are included on the Radiation Safety Policy. Ref 5.2.2
	Response by Employer detailing the actions taken: The Radiation Safety Policy has been updated and reissued following discussion with RPA. In future the document will be managed timely and reviewed through the Radiology Document Management System and via Trust Policy Library.
Area for improvement 5 **Ref:** Regulation 6 (1) Schedule 2.1 (b) **Stated:** First time **To be completed by:** 4 December 2024	The Employer must ensure that the consultant breast radiologists entitlement record is further developed to reflect the consultant breast radiologists scope of practice and the review process. Ref 5.2.2
	Response by Employer detailing the actions taken: The Consultant Radiologist Entitlement form has been updated with more detailed information to accurately reflect the scope of practice for Radiologists. The 'Annual Medical Entitlement and Competency Checklist' form is completed annually at appraisal to ensure that no amendments are required to the Radiologists scope of practice.

Area for improvement 6 **Ref:** Regulation 6(1) **Stated:** First time **To be completed by:** 4 November 2024	The Employer must ensure the authorisation of carers and comforters exposures is included as an operator function in the radiographers entitlement records. Ref 5.2.2
	Response by Employer detailing the actions taken: The Radiographer Entitlement form has been updated to include authorisation of 'carers and comforters' as an Operator task. All new staff will be entitled using the new document going forward. All existing entitled staff will be re-entitled at their next appraisal (the normal re-entitlement period).
Area for improvement 7 **Ref:** Regulation 8(1) **Stated:** First time **To be completed by:** 4 December 2024	The Employer must amend EP L to clearly reflect the action required if the decision not inform the individual of a CSAUE is taken. Ref 5.2.2
	Response by Employer detailing the actions taken: NHSCT Breast Imaging EP L has been updated with detail to include the necessary action required in the event of a decision not to inform a patient of a CSAUE. The staff members involved in the decision making process and actions agreed are outlined.
Area for improvement 8 **Ref:** Regulation 6 Schedule 2.1 **Stated:** First time **To be completed by:** 4 December 2024	The Employer must amend the EPs as follows: • EPI benefits and risks, amend to reflect the robust process for ensuring the provision of information to clients/patients on the benefits and risks of breast imaging. • EPJ clinical evaluation, amend to include full details of the arbitration process. Ref 5.2.4
	Response by Employer detailing the actions taken: NHSCT Breast Imaging EP I has been updated to detail the information provided, information displayed and who is responsible for verbally informing clients/patients of benefits and risks for breast imaging. NHSCT Breast Imaging EP J has been updated to include full details of the arbitration process.
Area for improvement 9 **Ref:** Regulation 10 (4) **Stated:** First time **To be completed by:** 4 October 2024	The Employer must ensure there is a record of radiation dose for each exposure outlined clearly in client/patient records. Ref 5.2.4
	Response by Employer detailing the actions taken: An email was sent to RQIA on 3rd October 2024 explaining that the images viewed on the day of the inspection with no

	radiation dose information recorded are post processed images and therefore are not 'true' exposures. All 'true' exposures have radiation dose information recorded.
Area for improvement 10 **Ref:** Regulation 6(1) Schedule 2.1 (a) Regulation 11 **Stated:** First time **To be completed by:** 4 November 2024	The Employer must ensure that separate signatures are provided on the client screening form to confirm client identification and authorisation. Ref 5.2.4
	Response by Employer detailing the actions taken: A stamp is now being used on all client screening forms to ensure Operators can be identified. Separate signatures for identification and authorisation are recorded.
Area for improvement 11 **Ref:** Regulation 11 **Stated:** First time **To be completed by:** 4 November 2024	The Employer should clarify the recording of authorisation on the 'Pink assessment' form to ensure it is clear who has justified and authorised each exposure. Ref 5.2.4
	Response by Employer detailing the actions taken: A stamp has been ordered to use on the 'pink assessment' form. This separately records the Practitioner who has justified and authorised each exposure. This information will be recored on Encompass following roll out. The form will no longer be used following encompass roll out. However it will still be available for staff use with stamp to ensure business continuity during periods of downtime.

The Regulation and Quality Improvement Authority
James House
2-4 Cromac Avenue
Gasworks
Belfast
BT7 2JA

Tel 028 9536 1111
Email info@rqia.org.uk
Web www.rqia.org.uk
@RQIANews