The Regulation and Quality Improvement Authority

Inspection Report

18 February 2026

Craigavon Area Hospital, Glenanne Suite Breast Screening 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: Southern Health and Social Care Trust (SHSCT)	**Department Inspected:** Craigavon Area Hospital, Glenanne Unit Breast Screening Service (GU)
Name of Employer: Mr Steve Spoerry Interim Chief Executive SHSCT	**Interim Head of Diagnostics Services (IHDS):** Ms Lorraine Hynds

Brief description of how the service operates:

The Southern Health and Social Care Trust (SHSCT) Breast Screening service, located in the Glenanne Unit at Craigavon Area Hospital, provides essential breast cancer screening for eligible individuals, often as part of the regional screening program. The service involves screening and symptomatic breast imaging services. The service operates from 8.15am to 5.00pm Monday to Friday. Additional Saturday services have been undertaken, once a month to cover the red flag symptomatic service. Two breast screening mobile vans located at Lurgan Hospital and Drumalane House in Newry are managed and staffed from the Glenanne Unit (GU).

Before the inspection Ms Lorraine Hynds, IHDS, and her team were asked to complete a self-assessment form (SAF). The submitted SAF confirmed that a breast screening service is in accordance with the National Health Service Breast Screening Programme (NHSBSP). In the last year the GU has carried out 18223 breast screening mammography, including 506 Digital Breast Tomosynthesis (DBT), 100 Magnification Views, 112 Stereotactic Vacuum Biopsies and three Stereotactic Vacuum Excisions. The GU also provide a symptomatic breast screening service with 5754 mammograms including 1740 DBT, 48 Magnification Views, 77 Stereotactic Vacuum Biopsies, 25 Stereotactic Vacuum Excisions and 64 Stereotactic Localisations provided in the last year.

The service is staffed by four breast consultant radiologists (3.6 whole time equivalent WTE), seven advanced practice radiographers (5.93 WTE), one QMS radiographer (0.88 WTE), three reporting radiographers (2.51 WTE), ten radiographers (7.72WTE) and one assistant practitioner in training.

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 18 February 2026, 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 breast screening service provided in the GU, as part of RQIA's IR(ME)R inspection programme.

For the 2025/26 inspection year the inspections will focus on the following key themes:

- IR(ME)R governance, including arrangements for compliance with IR(ME)R, services provided outside of the main department, communication with other departments, commissioning of new services.
- Justification and authorisation process including use of authorisation guidelines where appropriate
- Management of equipment performance
- Patient identification including pause and check
- Nuclear medicine therapies and radiotherapy - the study of risk
- Radiotherapy – focus on the breast pathway
- 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 breast screening unit, patients/clients were awaiting or immediately recovering from breast screening procedures, it was deemed inappropriate to seek to speak to these patients/clients 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?

There have been no previous IR(ME)R inspections carried out to this service under the current legislation.

5.2 Inspection findings

5.2.1 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 SHSCT is held by the Interim Chief Executive.

The SHSCT Radiation Protection Policy sets out the organisational structures, lines of accountability and governance structures. It was advised that IR(ME)R documentation including Employer's Procedures accurately reflect the current Employer details. Management gave assurances on this matter and confirmed the Employer's Procedures were scheduled for review.

It was confirmed that the Employer is part of the senior leadership team (SLT) and is a member of the Trust board. The Diagnostic Radiology and Nuclear Medicine committee (DRNM) reports to the Radiation Safety Committee (RSC) which is chaired by the Clinical Director of Radiology. The RSC reports to the Standards, Compliance and Regulation steering group which in turn reports to the Risk Assurance group (also known as Senior Leadership Team, (SLT)). They feed into the Governance committee who in turn feedback to the Trust Board. The RSC meet twice a year and the DRNM committee also meet twice a year, one month in advance of the RSC. The modality lead radiographer for breast services attends the DRNM on behalf of the breast imaging services. However, it was noted that the RSC had not met between June 2024 and November 2025. The Clinical Director advised that there were changes in leadership over that period which impacted the frequency of the meetings. Assurances were provided that going forward the frequency of RSC meetings would return to six monthly. A review of the RSC minutes noted that the breast services did not feature has a stand-alone item on the agenda as is the case for other modalities. Management confirmed the breast imaging services were discussed however this was not reflected in the records of the RSC meetings. An area of improvement has been identified to include the breast imaging service as item on the agenda on the RSC meeting.

It was good to note that the mammography service has established an image optimisation team (IOT) which is a multi-disciplinary group that meets twice per year. The meetings were found to be well attended with robust scrutiny being applied to the matters discussed.

Communication

Management and staff confirmed there was good communication within the breast services department**.** Radiographers confirmed communication was good and they felt well supported in their role.

There are monthly radiography team meetings which are minuted and the minutes shared. Other methods of communication with staff include emails, a WhatsApp group and a communication board in the Glenanne Unit . Staff in the mobile vans can contact the Glenanne suite electronically or via telephone for advice or support. Consultant radiologists for breast services attend fortnightly breast business meetings. The monthly directorate meeting includes all radiologists involved in the breast screening programme. It was positive to note that there are weekly multidisciplinary meetings to discuss breast services which include consultant radiologists, mammographers/ advance practice radiographers, surgical colleagues and pathology staff.

Updates to standard operating procedures or any new documents are disseminated amongst staff via Q-Pulse. All staff have access to Q-Pulse, which also hosts audit results, PowerPoints and educational material.

A six-weekly meeting on governance and performance for all modalities takes place. This meeting focuses on performance, commissioning levels, and feedback from equipment controllers. Management confirmed it was a positive development. Clear escalation processes were described by management and staff should a serious issue arise.

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 largely in line with duty holder roles. It was noted that the competency records for radiographers who had been entitled as operators to authorise breast imaging in line with authorisation guidelines did not have this component of competency outlined in the competency forms. An area of improvement has been identified on this matter

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

Individual entitlement records for consultant radiologists for breast imaging, advanced practitioners, a band 7 radiographer and a radiographer were evidenced. Group entitlement records for non-medical referrers (named radiographers) and MPEs were also reviewed. It was noted that entitlement records were overall well completed. As stated previously Employer's Procedure C, entitlement states the entitlement process must be reviewed annually. However, the MPE entitlement arrangements and record had not been formally reviewed since 2023. An area of improvement was identified to review the MPEs entitlement arrangements and update record accordingly.

Discussion and review of records relating the duty holder roles across the breast screening service, screening assessment and symptomatic clinics were fully reviewed. There was clarity on the IR(ME)R pathway for breast screening programme and the screening assessment. However, it was less clear for the symptomatic clinics, with some confusion over the role of referrer and practitioner for this service. An area of improvement has been identified to review the IR(ME)R pathway and entitlement arrangements for the symptomatic breast service, so it is clear who is acting as the referrer, practitioner and carrying out the operator tasks associated with this breast imaging service. This should then be fully reflected in the Employer's procedures.

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 patient /client centred service improvement.

A clinical audit programme is developed by the clinical audit lead and is approved by the clinical director who is responsible for radiology clinical audit inclusive of the breast imaging service. The programme is presented to the Trust's clinical reference group for ratification each year.

The Breast Imaging service follow the Trust's clinical audit policy, which includes completing a registration form detailing clearly defined audit aims and objectives, the method, the standard measure against which performance is being assessed, based on the best available evidence and references.

Members of staff are updated with the clinical audit spreadsheet on Q-Pulse which includes completed presentations. Complete audits are shared with all stakeholders. Clinical audits may be presented in the radiologist audit meeting/directorate meeting.

The Trust clinical audit team maintains oversight of all clinical audits and feeds back to the clinical audit committee which informs the Trust board and overall accountability lies with the Employer.

Work is continually ongoing to ensure that all clinical audits are being centrally registered with the Trust clinical audit team, with a record also being maintained by the quality coordinator. Educational emphasis is being placed on planned rather than ad hoc audit completion.

Breast radiology audit records are maintained locally on Q-Pulse audit module for radiographers, and an electronic alert will be sent to the auditor at the time of re-audit according to the Q-Pulse schedule.

Monthly audit reports are produced by the lead auditor and shared within breast imaging services.

The Trust clinical audit team maintain a database of all Trust audits and will notify an auditor when an audit is due for submission. The lead auditor within the department will also track on the Q-Pulse module.

The Trust clinical audit reference group will monitor the implementation of any actions, ensuring that any identified required changes are incorporated into practice and relevant business plans and/or risk registers as appropriate.

A range of clinical audits had been undertaken over the last year. The inspection team reviewed excellent examples of audit of practice and techniques where staff were achieving 100% in most cases.

A recurrent IR(ME)R audit programme is carried out. It was good to note that the IR(ME)R audit programme uses a range of methodologies, including observational audit. The audit template includes a section for actions, responsible staff and target date for completion.

Urgent findings from audits are shared with the IHDS and escalated, as required. Any issues arising from audit, which require the Employer to be aware of, are reported via the governance structures outlined previously or directly to the Employer, if deemed high risk.

A review of completed IR(ME)R audits noted that they were overall carried out robustly and it was noted that the analysis of the findings was detailed and meaningful, with learning shared.

The standard of clinical and IR(ME)R audits is to be commended. They provide thorough and robust frameworks to drive improvement and offer assurance on compliance with IR(ME)R.

Employer's Procedure Q audit was found to provide clear direction on the breast imaging service audit. However, it outlined that on a two-yearly basis compliance with IR(ME)R legislation is audited by the MPE. The MPE advised that this MPE audit was aspirational and had not been fulfilled due to MPE resource issues. An area of improvement has been identified to amend Employer's Procedure Q audit to accurately and realistically reflect MPE audit of the breast imaging service.

Incident and near miss management

There are clear arrangements in place to report, record, investigate and learn from radiation incidents or near misses in the breast imaging service. 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 the Employer's Procedure (EP) I – Incident investigation and reporting. The definitions of an accidental and unintended exposures were discussed with advice being provided that SAUE guidance was being updated to provide greater clarity on this matter. The timing of MPE reports following suspected SAUE was explored. The MPE confirmed that in line with a regionally agreed risk-based approach to MPE services, it is aimed to have a MPE report relating to suspected SAUE devised within a week of receiving the notification.

The decision making process for clinically significant accidental or unintended exposures (CSAUE) and informing relevant stakeholders was clearly outlined by management and reflected in the EP J - CSAUE. It was confirmed that the modality lead or deputy for the service area is responsible for analysing individual incidents within their modality or area.

A review of incidents and near misses occurs at the six weekly IHDS governance meetings, attended by the senior breast imaging staff. An ongoing review of Datix records is available to the divisional governance group who meet weekly and the chair of the RSC (clinical director) attends. IR(ME)R incident details are logged by the radiology incident investigation team lead (which is a new post) who conducts and presents trend analysis, based upon the findings of investigators. The breast imaging service share incidents with the central Datix system. It was positive to note that near miss incident form has been devised for the breast imaging service which is recorded locally. A near miss Datix is also completed. However, near misses in the breast imaging service Datix records are not shared with the central Datix system. An area of improvement has been identified to ensure all near misses are shared with the central Datix system to allow centralised oversight.

Management confirmed that work is ongoing to ensure incidents are coded and analysed using the Clinical Imaging Board's Coding Taxonomy for ionising radiation dose errors, adverse events and near misses in UK clinical imaging departments. Also, that a more systems-based approach to investigation and analysis is conducted. Incident trend analysis reports are devised which are discussed at IOT, DRNM and at directorate meetings

Incident reports are available on Q-Pulse for staff to view. However, it was advised to actively share these valuable reports with staff. Management outlined that there are plans to publish a monthly newsletter for staff which would include information on incidents. There is already a newsletter published post IOT meeting in diagnostic radiology but does not include the breast imaging service.

Employer's Procedure K to ensure that the probability and magnitude of accidental, unintended doses to patients from radiological practice is reduced as far as reasonably practicable, was noted to outline the objective to be preventing an accidental or unintended radiation dose to clients/patients. Under responsibilities it outlined referrers, practitioners and operators, however then only outlined in detail operator responsibilities. An area of improvement has been identified to amend Employer's Procedure K to include referrer and practitioner responsibilities.

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 risks associated with IR(ME)R compliance are appropriately captured and that specific actions to mitigate the risks are identified and appropriate systems of assurance are put in place.

There is a department risk register where risks can be recorded. Where it is considered appropriate to place a risk on the Trust risk register, the appropriate forms must be completed before corporate service will add it to the register. The IHDS is responsible for placing risks on the directorate risk register and escalating to the assistant director for inclusion on the corporate risk register. Risks are reviewed locally at the six weekly IHDS meeting.

The Employer would be made aware of any additions to the risk register through the previously described governance structures.

The ratification process for Employer's Procedures (EPs) and other IR(ME)R documentation

Employer's Procedures are reviewed and updated on a two-yearly basis by the Director of Screening. This will be carried out with the involvement of Breast Imaging Services Modality Lead, Director of Screening, QMS Lead Radiographer and other staff as appropriate such as the MPE. It was confirmed that RSC reviews draft EPs and protocols. They then go to a scrutiny board before sign off by the Employer. DRLs are set and reviewed by the IOT. They are then ratified by the DRNM. There is a quality management system (QMS) in place for all electronic documents which are held on Q-Pulse. Newly ratified documents will be uploaded to Q-Pulse with the older versions archived. Staff will be informed of the new documents on Q-Pulse. It was confirmed that staff also have access to Q-Pulse on the mobile vans. 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. Compliance with hard copies within the department is audited.

The introduction of a new radiology service

Management outlined the process to be followed when a new radiology service is introduced. This would typically come through from the commissioners, and a business case would be developed and mapping from capital to revenue to identify needs.

Design teams would be created, which would involve the MPE who is also involved in the procurement process. 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 signing off the equipment for clinical use. The equipment is then added to the equipment inventory and assigned a unique ID. Application training is provided by the manufacturer.

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 subject to 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 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.

5.2.2 Does the service adhere to legislation in relation to the justification and authorisation of ionising radiation procedures?

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.

The duty holder roles of operator and practitioner was examined in relation to the justification and authorisation of exposures. It is not always possible for a practitioner to review every imaging referral, so regulations allow for an appropriately entitled operator to authorise an exposure following written authorisation guidelines, issued by a named practitioner. 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.

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.

The range of breast imaging pathways were discussed to establish the justification and authorisation process for each.

Breast screening in accordance with the NHSBSP

Where clients are registered with a General Practitioner (GP) in Northern Ireland (NI), 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 within 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 if they wish to, in accordance with NHSBSP guidelines. They may request further mammograms which triggers an invitation letter from the Director of Screening who acts as the referrer. It was advised to ensure the invitation letter for all breast screening is signed by the Director of Breast Screening as the referrer.

The Practitioner who justifies screening exposures is the Director of Breast Screening. It is not practicable for the Director of Breast Screening to authorise each exposure and so signed breast screening Authorisation Guidelines have been issued by the Director of Breast Screening. Appropriately trained and entitled radiographers and advanced practitioners to act as operators to authorise breast screening imaging in accordance to the authorisation guidelines.

Referral guidelines are required under IR(ME)R and must be made available to referrers. Authorisation guidelines and referral guidelines have two distinct functions. An area of improvement has been made to ensure that referral guidelines for breast screening is established separate from authorisation guidelines and made available to referrers.

Staff outlined that the day before a breast screening clinic an entitled operator will check each client form against NIPACS to establish any mammography history outside of screening. The client will be contacted for further information, if required. These are recorded on the client form by the operator completing the checks. Previous imaging history is checked and also verbally checked with the patient before any imaging is undertaken during the authorisation process, as detailed within the Authorisation Guidelines.

The Operator acting under authorisation guidelines, authorises the examination by initialling beside the patient details on the SASP2 client form and electronically on NBSS. This confirms both the patient identification check and the exposure authorisation. Management confirmed that NBSS has no functionality to record 3-point ID. It was advised that nationally there is work ongoing on the NBSS to ensure compatibility with the IR(ME)R framework. However, in the meantime, as patient identification and authorisation are two separate functions under IR(ME)R there must be separate evidence of completion for each function. An area of improvement has identified on this matter. Patient identification is further discussed in section 5.2.4 of this report.

Assessment

If assessment is required, the client will be recalled to the assessment clinic. The required imaging will fall outside the agreed Authorisation Guidelines for Breast Imaging (Screening), therefore, the breast radiologist (known as the responsible assessor) at the assessment clinic will act as practitioner and justify individual exposures, as required. The imaging will be detailed on the 'Breast Imaging Exam Form', and on NBSS. The Practitioner records justification by initialling the 'Imaging Assessment form'. The Practitioner is detailed in the request notes on RIS/PACS by the Operator. The Operator carries out the pre-exposure checks and completes the examination requested. On addition of the approval code the "logged in" username is automatically populated in the signature box. Each RIS user has a unique account which can only be accessed with their name and password. If further views are required during assessment, these are justified and authorised by one of the breast radiologists in the department.

Symptomatic

Management outlined that the director of breast screening acts as the practitioner for symptomatic imaging and has issued authorisation guidelines for symptomatic mammography. If any further views are required, these are also justified and authorised on a case-by-case basis by the Consultant Radiologist or Consultant Radiographer / during the symptomatic clinic. The Operator performing the medical exposure authorises the examination using the authorising guidelines. Operators check NIPAC/RIS to confirm that the mammogram is performed at the appropriate time interval, as requested by the Referrer. It was advised that repeat exposures could be included in authorisation guidelines and/or examination protocols. As stated previously there was some confusion noted on this matter and an area of improvement has been outlined in relation to this matter in section 5.2.1 of this report.

Out of area (OOA)

The Northern Health and Social Care Trust (NHSCT) breast screening service provide a regional breast imaging service for very high risk (VHR) clients. 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 NHSCT Lead Radiologist for VHR remains the referrer. The Lead Radiologist (NHSCT) act as the IR(ME)R practitioner for these referrals in the OOA setting. Clinical evaluation remains with the performing (local) Trust. The results go to the GP and the client. Management and staff described and understood the justification and authorisation process for OOA screening.

Employer's Procedure D justification and authorisation was reviewed and found to not fully reflect the justification and authorisation process as described by staff. An area of improvement has been identified to update Employer's Procedure D justification and authorisation, to clearly reflect practice.

Exposures to carers and comforters require individual justification. Justification of the exposure of carers and comforters who knowingly and willingly provide help and support should consider both the direct benefit to the health of the individual undergoing the medical exposure as well as the indirect benefit to the carer or comforter. The exposure of a carer or comforter should only be permitted when this net benefit can be clearly identified. The role of carers and comforters (C&C) to support individuals undergoing breast screening was discussed with the management and staff.

They outlined the skilled approach they take with clients to ensure compliance with the breast screening exposure and that it would be extremely unlikely that a C&C would be asked to support a client during a medical exposure. However, on discussion around whether the service should provide for C&C, it was advised to consider inclusivity for the cohort who need screening but could not manage without a C&C.

The Breast Screening IR(ME)R guidance provides information on how to manage C&Cs including benefits and risks information, pregnancy checks recording and dose constraint . An area of improvement was identified to consider the role of the C&C in providing the breast screening programme and update the entitlement processes and Employer's Procedure R accordingly.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that justification and authorisation process is reasonably well understood by staff and largely fully implemented in accordance with the employer's procedures.

The areas of improvement will assist on this matter. 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 breast imaging 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, comprehensive written breast imaging equipment quality assurance (QA) programme in place which is available on QPulse. It was confirmed that daily, weekly and monthly quality control (QC) checks of the breast imaging equipment are carried out by appropriately trained and entitled operators following the national guidance and standards from NHSBSP and Institute of Physics and Engineering in Medicine (IPEM). In addition, the MPE carries out QC testing and audits the QC testing carried out by the entitled operators within the breast imaging service. It was confirmed the MPE QA programme is up to date.

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

Employer's Procedure I, reporting radiation incidents, is in place which was found to be a comprehensive and clear framework for staff to follow. However, it noted that it included reference to reporting defective and equipment failure incidents to Northern Ireland Adverse Incident Centre (NIAIC) which is no longer operational and has been replaced by a department within the Medicines and Healthcare Products Regulatory Agency (MHRA). Management gave assurances to update the Employer's Procedure I accordingly.

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 QC.

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 staff in this regard.

5.2.4 Does the service adhere to legislation with regard to patient identification including pause and check?

IR(ME)R requires the Employer to establish a procedure to identify correctly the individual to be exposed to ionising radiation. The procedure should specify how and when an individual is to be identified.

Employer's Procedure B - patient identification, is in place and provides a clear comprehensive framework for staff to follow. Correct identification (ID) of the patient or individual to be exposed is an operator task and must be undertaken prior to any exposure.

Management and staff confirmed that it is the responsibility of the operator to ensure the correct patient is being examined against the referral. Whilst multiple staff may be involved with the patient/client, the responsibility for correct ID lies with the operator who carries out the medical exposure.

Staff confirmed that the operator must always check the patient/client's name, address and date of birth on the referral on RIS. The patient/client must be asked to state their name, address and date of birth rather than confirm these details. They outlined the following questions:

- What is your name?
- What is your address?
- What is your date of birth?

It was confirmed that supplementary safety checks are also carried out such as:

- Why are you here?
- Have you been scanned recently?

Staff confirmed that the professional guidance on Pause and Check is used and promoted in the breast imaging department. It was good to note that Pause and Check notices were displayed in the department.

For breast screening clients the identity of any individual attending for breast screening must be checked against the clinic control sheet (SASP1) and the SAPE function on NBSS. Although a client may be identified at more than one stage in the process, the responsibility for a final identity check lies with the operator carrying out the exposure. The operator will tick the screening form (SASP2) at the three relevant lines. The operator will sign their initials on SASP2 to indicate that identity and authorisation has been completed. As stated previously in section 5.2.1 of this report an area of improvement has been identified in relation to having separate records for patient identification confirmation and authorisation.

On review of patient and client records it was noted that the client SASP2 form is not scanned onto the patient/client notes but held in an administrative folder on a share drive.
An area of improvement has been identified to ensure this client SASP2 form which acts as a primary source document for client identification is held as part of the client records.

Staff confirmed for symptomatic breast imaging the 3-point patient identification process is followed as previously outlined and recorded within the examination page in PACS, the operator records the method of patient identification confirmation and documents this by inputting their username and password.

For other scenarios, for example such as patients who lack capacity or communication difficulties a clear patient/client ID process was outlined for each situation.

Review of a random sample of patient records confirmed that patient/client ID had been recorded as checked for all those reviewed.

A patient ID audit is carried out as part of the rolling programme of IR(ME)R audits. There was a very high compliance level noted.

Staff explained the process for discrepancies in the patient ID, this included; check if known as any other name, check with carer/relative, check on (PACS), make a record of the changes required, and send a request to PACS team to change the demographics. There is a section in RIS for incorrect demographics. However, it was very clear from responses that the exposure would not be undertaken if the patient/client ID could not be confirmed.

There is 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 breast imaging services have robust systems in place to report, record, investigate and learn from incidents and near misses. Patient ID processes have been strengthened using learning from patient ID incidents and near misses, such as the implementation of Pause and Check; further staff training, raising 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 clear and robust patient identification processes are in place. The inspection team acknowledge the commitment of staff in this regard.

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

Benefits and Risks

IR(ME)R requires that wherever practicable information on the benefits and risks of an ionising radiation exposure should be provided to clients/patients prior to the exposure.

The breast imaging service have a range of information leaflets they provide to clients and patients and display a general radiology benefit and risk information posters in the department. Review of the information noted that whilst most was clear, there was some inconsistencies in how the dose of radiation was described across a number of documents. An area of improvement has been identified to review benefit and risk information and ensure it is consistent in describing the dose of radiation and to also consider displaying the Society of Radiographers (SoR) benefits and risks symptomatic mammograms posters in the department.

6.0 Conclusion

There were thirteen 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 breast imaging service 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.

7.0 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	13

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 **Stated:** First time **To be completed by:** 18 May 2026	The Employer should include the breast imaging service as item on the agenda on the RSC meeting. Ref 5.2.1
	Response by Employer detailing the actions taken: Breast service has always been included on the agenda for RSC meeting, will ensure minutes of future meetings reflect this.
Area for improvement 2 **Ref:** Regulation 6 Schedule 2 (1) (b) **Stated:** First time **To be completed by:** 18 May 2026	The Employer must ensure the competency records for radiographers who had been entitled as operators to authorise breast imaging in line with authorisation guidelines have this component of competency outlined in the competency forms. Ref 5.2.1
	Response by Employer detailing the actions taken: Radiographer entitlement forms have been updated to reflect the above requirement. Authorisation guidelines for all exposures are available on Q-Pulse. all operators read and acknowledge these guidelines which demonstrate compliance.

Area for improvement 3 **Ref:** Regulation 6 (1) (a) Schedule 2 (1) (b) **Stated:** First time **To be completed by:** 18 May 2026	The Employer must review the MPEs entitlement arrangements and update record accordingly. Ref 5.2.1
	Response by Employer detailing the actions taken: Review has ben undertaken and records have been updated accordingly.
Area for improvement 4 **Ref:** Regulation 6 (1) (a) Schedule 2 (1) (b) **Stated:** First time **To be completed by:** 18 May 2026	The Employer must review the IR(ME)R pathway and entitlement arrangements for the symptomatic breast service so it is clear who is acting as the referrer, practitioner and carrying out the operator tasks associated with this breast imaging service. This should then be fully reflected in the Employer's procedures. Ref 5.2.1
	Response by Employer detailing the actions taken: Employers procedures have been updated to reflect this and when signed off will be reissued
Area for improvement 5 **Ref:** Regulation 6 **Stated:** First time **To be completed by:** 18 May 2026	The Employer must amend Employer's Procedure Q audit to accurately and realistically reflect MPE audit of the breast imaging service. Ref 5.2.1
	Response by Employer detailing the actions taken: Employers procedure Q has been updated and MPE 2 yearly audit has been removed according to MPE advice.
Area for improvement 6 **Ref:** Regulation 8 **Stated:** First time **To be completed by:** 18 May 2026	The Employer must ensure all near misses are shared with the central Datix system to allow centralised oversight. Ref 5.2.1
	Response by Employer detailing the actions taken: WR.M-140, Near miss incident form has been updated to include the Radiology incident investigation team lead. All near miss forms will now also be sent to team lead and discussed at leads meeting. Mammography staff informed of such at next staff meeting.
Area for improvement 7 **Ref:** Regulation 6 Schedule 2(1)(k) **Stated:** First time **To be completed by:** 18 May 2026	The Employer must amend Employer's Procedure K probability and magnitude to include referrer and practitioner responsibilities Ref 5.2.1
	Response by Employer detailing the actions taken: Employers procedures have been updated to reflect this and when signed off will be reissued

Area for improvement 8 **Ref:** Regulation 6 (5) (a) **Stated:** First time **To be completed by:** 18 May 2026	The Employer must ensure that referral guidelines for breast screening is established separate from authorisation guidelines and made available to referrers. Ref 5.2.2
	Response by Employer detailing the actions taken: Referral guidelines for breast screening have been established and shared with the referrer, i.e director of breast screening.
Area for improvement 9 **Ref:** Regulation 11 **Stated:** First time **To be completed by:** 18 April 2026	The Employer must ensure there is separate evidence of completion for patient identification and authorisation. Ref 5.2.2
	Response by Employer detailing the actions taken: A separate signature is now being used on all client screening forms to ensure authorisation is completed. Separate signatures on screening forms for identification and authorisation.
Area for improvement 10 **Ref:** Regulation 11 **Stated:** First time **To be completed by:** 18 May 2026	The Employer must update Employer's Procedure D justification and authorisation, to clearly reflect practice. Ref 5.2.2
	Response by Employer detailing the actions taken: Employers Procedure D has been updated to reflect this. A separate signature is now being used on all client screening forms to ensure authorisation is completed. Separate signatures on screening forms for identification and authorisation
Area for improvement 11 **Ref:** Regulation 11 (3) (b) Schedule 2 (1) (n) **Stated:** First time **To be completed by:** 18 May 2026	The Employer must consider the role of the carers and comforters in providing the breast screening programme and update the entitlement processes and Employer's Procedure R accordingly. Ref 5.2.2
	Response by Employer detailing the actions taken: SHSCT breast imaging services has considered the role of carers and comforters and Employer Procedure R reflect this.
Area for improvement 12 **Ref:** Regulation 6 Schedule 2 1) (a) **Stated:** First time	The Employer must ensure this client SASP2 form which acts as a primary source document for client identification is held as part of the client records. Ref 5.2.4

To be completed by: 18 May 2026	**Response by Employer detailing the actions taken**: All client SASP 2 forms will now be held centrally on the NIPACS system. These will be scanned on by the operator post exposure for each screening episode. WR.M-4 has been updated to reflect this. Scanners are currently in process of being ordered.

Area for improvement 13 **Ref:** Regulation 6 Schedule 2(1)(i) **Stated:** First time **To be completed by:** 18 May 2026	The Employer must review benefit and risk information and ensure it is consistent in describing the dose of radiation and to also consider displaying the Society of Radiographers (SoR) benefits and risks symptomatic mammograms posters in the department. Ref 5.2.5
	Response by Employer detailing the actions taken: Risk/benefit information has been reviewed and corraleted. SOR Mammography poster are now also displayed in department

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