Inspection Report

20 March 2024

Belfast Health and Social Care Trust (BHSCT) Breast Screening Centre - Linenhall Street

Address: 12-22 Linenhall Street, Belfast, BT2 8BS
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Information on legislation and standards underpinning inspections can be found on our website https://www.rqia.org.uk/ and The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 known as IR(ME)R

1.0 Service information

Organisation/Registered Provider: Belfast Health and Social Care Trust (BHSCT)	**Department Inspected:** Breast Screening Centre – Linenhall Street
Name of Employer: Dr Cathy Jack Chief Executive Officer (CEO) BHSCT	**Imaging Services Manager (ISM):** Sean O'Conaire **Breast Service Manager (BSM):** Ms Noelle Clerkin
Director of Screening and Lead Breast Radiologist: Dr Louise Bamford	**Medical Physics Expert (MPE):** Mr Adam Workman

Brief description of how the service operates:

The BHSCT Breast Screening service is provided at three sites, Breast Screening Centre Linenhall Street, one mobile unit and a limited service based in Belfast City Hospital (BCH). This inspection relates to the breast screening service provided at the Breast Screening Centre based in Linenhall Street (LHS).

There are three mammography rooms in the department, however a risk based approach equipment replacement programme is underway and at the time of inspection only two mammography rooms were operational. This is further discussed in section 5.2.5 of this report. The service is provided Monday to Friday 8.30 am to 4.30pm.

BHSCT Breast Screening Service also provides all breast screening services for South Eastern Health and Social Care Trust (SEHSCT) clients. A new static unit providing breast screening is to be opened in Newtownards in May 2024, which is based in the SEHSCT area however operational services will be provided by staff from BHSCT. This inter Trust arrangement is further discussed in the body of the report.

Before the inspection Ms Clerkin, Breast Screening Manager (BSM), 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). A symptomatic breast screening service is not provided at LHS. The site provides an assessment clinic on Tuesdays when breast screening recalls, technical recalls assessment and technical repeats are undertaken. Over the past year 30584 2D breast screening mammograms were provided by BHSCT breast screening services and 433 digital breast tomosynthesis (DBT) with 144 clients receiving a stereotactic biopsy.

The service is staffed by five BHSCT breast consultant radiologists providing 10 PAs (programmed activities - blocks of time in which contractual duties are performed) and five SEHSCT breast consultant radiologists who provide nine PAs.

Two interventional radiography advanced practitioners, 21 radiographers and 2 assistant practitioners work across the LHS, BCH (breast screening) sites and the mobile unit providing the breast screening.

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 20 March 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 the BHSCT Breast Screening Centre at LHS, as part of RQIA's IR(ME)R inspection programme.

For the 2023/24 inspection year, the inspections will focus on four key themes:

- Entitlement of staff focusing particularly on those duty holders outside of the radiology department and inter Trust duty holders
- Clinical evaluation including arrangements for peer review
- Clinical audit including robust interpretation of findings and action plans
- Patient identification including pause and check
- Any other areas identified through the review of the submitted self-assessment form 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; 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 clients/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, clients were awaiting or immediately recovering from breast screening and/or assessment procedures, it was deemed inappropriate to seek to speak to these patients on the day of the inspection.

5.0 The inspection

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

A previous inspection had not been undertaken of the BHSCT Breast Screening Centre at LHS under the current IR(ME)R legislation.

5.2 Inspection findings

5.2.1 Does the service adhere to legislation in relation to the entitlement of duty holders including assessing training and competency?

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.

There was evidence of induction, training, competency assessment and continuing professional development for all grades of staff. Most records reviewed were reasonably well completed. However, review of an induction record for a radiologist, which had been completed days before the inspection, was found to have no name clearly outlined, it had been signed by the individual but not co-signed by the individual providing and overseeing the induction. The record did not provide evidence of a robust meaningful induction. An area of improvement has been identified to revise the induction record for radiologists to ensure it clearly outlines the name and designation of the individual undertaking the induction, the name of the individual providing and overseeing the induction and that co-signatures of these individuals are evident throughout.

It was noted that a number of competence forms for radiographers had basic competencies recently signed despite the duty holders being entitled for some time and therefore it was difficult to be assured that the competence assessment was carried out prior to entitlement and in line with the duty holder's scope of practice. An area of improvement has been identified to revise the competence form and ensure it includes the name of the staff member and relevant dates for ongoing sign off to underpin the entitlement process and ensure competence assessment for the duty holder is carried out prior to entitlement.

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. 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 including SEHSCT consultant radiologists, an advanced practitioner radiographer, radiographers (mammographers), assistant practitioners and group entitlement records for the MPEs were reviewed. The group entitlement records for MPEs were found to be an old version of their entitlement record. However, the most up to date group entitlement record was provided during the inspection and it was noted to clearly evidence the entitlement of this group of staff. It was advised that up to date entitlement records should be readily available in the department and previous versions archived in accordance to Trust record management policy.

It was good to note that the individual entitlement records for radiographers reflected the individual site including the mobile unit and equipment quality checks competencies for each location. However, some detail outlined was less clear and there was confusion around the various duty holder roles and the individual duty holders' scope of practice. This included entitling an assistant practitioner as an IR(ME)R practitioner despite the individual not being a registered health care professional as required. Radiographers were entitled as practitioners and operators who authorise exposures in accordance with authorisation guidelines. Through discussion it was acknowledged the radiographers do not act as practitioners. Patient identification was listed as a practitioner task however under IR(ME)R this is an operator task.

Individual duty holders described a specific scope of practice which was not reflected in their entitlement records.

An area of improvement has been identified to review entitlement arrangements for duty holders and ensure their roles are compliant with IR(ME)R; that there is a clear, specific, individual scope of practice which is reflected in entitlement records and to ensure all staff fully understand their duty holder role and responsibilities.

The advanced practitioner's role was discussed in relation to carrying out biopsies and clinically evaluating the associated images. We were informed that the advanced practitioner did not carry out clinical evaluation of these images and was not entitled as an operator to clinically evaluate these images. However, on review of client records it was evidenced that one advanced practitioner was carrying out clinical evaluation of images associated with biopsies. An area of improvement has been identified to ensure that the advanced practitioner is entitled as an operator to carry out clinical evaluation in line with their scope of practice.

Breast consultant radiologists' entitlement records were found to clearly outline duty holder roles for the provision of the breast screening service. It was good to note that SEHSCT breast consultant radiologists had been entitled by the BHSCT Breast Clinical Lead Radiologist as referrers, practitioners, and operators with a defined scope of practice and are clearly subject to BHSCT employers procedures (EPs) and protocols. There were clear inter Trust entitlement arrangements in place.

It was confirmed that for breast biopsy procedures a breast consultant radiologist acts as referrer. One radiologist takes the lead on the day of the assessment clinic, and this individual is the practitioner justifying all of the imaging that day. They are named on the report and documented on the assessment form. However, on review of client records and discussion with staff they were unable to identify the signature of the radiologist on the assessment forms they provided for a particular assessment clinic and therefore were unsure who the practitioner was for those exposures. An area of improvement was identified to ensure there is clear identifiable evidence of the practitioner for all images undertaken.

Review of client records noted that the written referral is captured within the client form generated for the assessment clinic. This is completed by the radiologist and includes clinical examinations required, preliminary discussions had with screening images present and additional imaging such as Tomosynthesis or magnification views are requested on this form. A multidisciplinary team (MDT) approach was evident, and laterality checks are completed and documented on this form specifying right or left breast to be imaged. We were informed the referral criteria used is iRefer and NHSBSP guidelines, if required iRefer referral guidelines are used for additional imaging.

Employers Procedure B on entitlement was in place and was found to be detailed. However, it was noted that the entitlement records did not always reflect the entitlement procedure and the individual delegated the task of entitlements outlined in the EP B. It was noted that EP B states that the Chair of the Radiation Protection Committee entitles radiographers. However, entitlement records for this group evidenced that the Site Lead Radiographer for the Breast Imaging Service had signed their entitlement records as the entitler. There were inconsistencies with duty holder roles described and EP B. Radiology practice and the EPs must be aligned. It was noted that EP B made reference to the entitlement of Allied Health Professionals (AHP) as operators in relation to clinical evaluation, this was not prescriptive enough for the breast screening service. An area for improvement has been identified to update EP B on entitlement to reflect any changes as a result of the review of the entitlement arrangements, ensure that it reflects the breast imaging service and that it is complied with thereafter.

The duty holder roles of operator and practitioner were examined in relation to the justification and authorisation of exposures. Justification is the intellectual activity of weighing up the expected benefits of an exposure against the possible detriment of the associated radiation dose and is the primary role of the practitioner. Authorisation is a process separate to justification and is the documentation confirming that the intellectual activity of justification has taken place. It is not always possible for a practitioner to review every imaging referral, so regulations allow for an appropriately entitled operator to authorise an exposure following written authorisation guidelines issued by a named practitioner. The practitioner is responsible for the justification of any exposure that is authorised by an operator following the authorisation guidelines. The operator is responsible for the authorisation and following the authorisation guidelines accurately. Authorisation guidelines must be clearly written using precise statements that are unambiguous in order to allow the operator to confirm whether the referral can be authorised.

Authorisation guidelines were available and a named practitioner was identified. The radiographers are entitled as operators using these authorisation guidelines to authorise breast screening images. It was confirmed that these authorisation guidelines are used for the breast screening service only. The authorisation guidelines were found to be relating to organising the imaging rather than guidelines for operators as to what can and cannot be authorised by them. They were a mixture of work instructions and elements of authorisation guidelines. Discussion about the assistant practitioner's role found information outlined in the authorisation guidelines was not in line with their working practice.

Overall, they were found not to be sufficiently detailed to serve as authorisation guidelines. An area of improvement has been identified to devise comprehensive authorisation guidelines and consider using The National Breast Screening Programme IR(ME)R Guidance authorisation guidelines template to assist in their development.

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 confirmed that this will be taken to a regional radiology meeting for consensus. 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 limits.

There were inconsistencies noted in various documentation where there was mention of C&C processes, including entitlement documents, authorisation guidelines and EP O for C&C. An area of improvement was identified to re-consider the role of the C&C in providing the breast screening programme and update the entitlement processes and EP O accordingly.

To enhance duty holders' understanding of the IR(ME)R framework in particular the entitlement process, an area of improvement has been identified to ensure all duty holders undertake refresher IR(ME)R training to include the roles and responsibilities of duty holders.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced entitlement arrangements require to be strengthened.

Management and staff were receptive to areas of improvement identified and advice provided on the entitlement process. The inspection team acknowledge the commitment of staff in this regard.

5.2.2 Does the service have appropriate arrangements for the clinical evaluation of medical exposures including peer review?

Clinical Evaluation

The employer must ensure that a clinical evaluation of the outcome is recorded for each exposure. Clinical evaluation involves the assessment of an image and the documentation by the suitably trained and entitled operators. In breast screening clinical evaluation can only be performed by operators who have undertaken specialist training and achieved a recognised qualification in breast image interpretation and are entitled to do this task by the employer. A clinical evaluation is not required for individuals who are exposed while being a carer or comforter.

Clinical evaluation is reported electronically on the Picture Archiving and Communication System (PACS) National Breast Screening System (NBSS), which is available to all staff who have the appropriate permissions. In some scenarios, for example where a biopsy is performed, clinical evaluation may be written by the operator in the client's clinical notes. The dose factors may also be recorded in the clinical evaluation, if required. Each process for documenting clinical evaluation has been clearly described in EP H and includes a process for the management of repeat and rejected images of non-diagnostic quality and partial mammography.

In accordance with NHSBSP, BHSCT LHS has a robust system of double reporting in place. This involves two breast consultant radiologists independently providing clinical evaluation on a set of images. BHSCT and SEHSCT breast consultant radiologists carry out clinical evaluation for breast screening images. It was confirmed that all clinical evaluations take places on site. If two breast consultant radiologists do not reach consensus from the initial clinical evaluation, then a process called arbitration is instigated. In the BHSCT breast screening services arbitration requires the images to be read by a third breast consultant radiologist. Each breast consultant radiologist is responsible for entering their results using direct entry onto NBSS.

For the assessment clinic, the breast consultant radiologist at each clinic ensures that the images are clinically evaluated and the outcome entered onto NBSS. All details are recorded on the assessment form which is saved on PACS.

As discussed in section 5.2.1 of this report, a review of client records noted that an advanced practitioner was carrying out clinical evaluation of images associated with biopsies and had not been entitled. An area of improvement has been made on this matter as outlined in section 5.2.1 of this report.

It was good to note that there is a robust audit programme in relation to clinical evaluation in place in accordance to NHSBSP guidelines.

Peer Review

Peer review in radiology means an assessment of the accuracy of a written report (clinical evaluation) issued by another radiologist/radiographer (entitled operator).

As previously outlined, within the breast screening service there is a built-in peer review mechanism with double reporting and the arbitration approach. It was good to note that BHSCT and SEHSCT breast consultant radiologists take part in the PERFORMS programme which involves clinically evaluating a test set of images which are then compared to the national standards. This is to be commended. The lead breast consultant radiologist chairs Radiology Events and Learning Meetings (REALMS) which includes reviewing and discussing images with the breast consultant radiologists in attendance. There are robust peer review arrangements in place.

Artificial Intelligence (AI)

As AI systems are beginning to make their way into clinical radiology practice, it is crucial to ensure that their use is compliant with IR(ME)R and safe clinical practice. Currently, the use of AI has not been approved by the UK National Screening Committee (UK NSC) for use within the NHSBSP. Management confirmed that AI is not used to assist or support clinical evaluation of breast screening images carried out in BHSCT breast screening service.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that the radiology department have very good arrangements with respect to clinical evaluation and peer review. The inspection team acknowledge the commitment of staff in this regard.

5.2.3 Does the service adhere to legislation with regard to clinical audit including robust interpretation of findings and action plans?

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 screening service is striving for a culture of quality improvement. Management and staff confirmed they continue to develop an inclusive, enthusiastic and proactive approach to client centred service improvement.

A clinical audit plan 2022-24 for the breast screening service was in place. The plan was devised taking account of clinical practice, needs of the service, the outcomes of previous audits and includes recurrent audits for IR(ME)R and the NHSBSP. The plan was approved by senior management. It was good to note that a MDT approach is taken to carrying out audits, with evidence of radiographers and radiologists involvement.

Evidence of nine clinical audits was provided which involved BHSCT breast screening service and included:

- Justification audit 2022
- Justification audit 2023
- NBSS signs and symptoms 2023
- Breast Implants January 2024
- Breast Implants September 2023
- YPAST technical recall/technical repeat November 2023
- YPAST technical recall/technical repeat February 2024
- Screen detected Breast Cancers diagnosed following Arbitration of discordant double reading opinions – April 2021
- Breast screening audit cases –four cases reviewed 2021

The audits carried out by the radiographers were conducted and recorded using a Trust wide audit template. It was well laid out and provided a sound framework for recording audits. The radiologists did not use this framework for their clinical audits. Their audits were found to be less structured leading to an informal approach to outcomes and learning. It was suggested that the Trust wide audit template should be used by all members of the MDT involved in clinical audit.

Review of the audits carried out by the radiographers found most were well completed outlining outcomes /results, dissemination of results, audit status and had action plans. The action plan identified the action, implementation date, staff member responsible, responsible manager and change stage key 1-4, with 4 being full implementation completed. However, it was noted that in number of audits sections had not been completed such as results of compliance achievement and audit status. Also noted is that the re-audit date was not always complied with, one re-audit noted to have been scheduled for September 2022 was not carried out until January 2023.

An area of improvement has been identified to ensure that audit forms are comprehensively and accurately completed and re-audit timescales are adhered to.

It was confirmed that all audit findings are shared with staff through monthly meetings, team briefings in their departments and there is a monthly report presented to management and staff. Governance and Quality lead provides an audit report twice a year and these are presented at Breast Image Optimisation Team (IOT) meeting. The audit report is also shared with the Diagnostic & Nuclear Medicine (DI&NM) committee meeting with breast screening staff in attendance. The DRNM committee report to Radiation Protection committee who report to Trust Board level. There are robust governance arrangements in place in relation to clinical audit.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced there are good clinical audit arrangements in place, the recording of clinical audit requires to be further strengthened and developed. Management and staff were receptive to advice on this matter. The inspection team acknowledge the commitment of staff in this regard.

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

IR(ME)R requires the Employer to establish a procedure to correctly identify the individual to be exposed to ionising radiation. The procedure should specify how and when an individual is to be identified. EP A (ii) patient (client) identification, was in place and largely provides a clear and comprehensive framework for staff to follow. However, a number of ambiguous statements were noted such as on the use of a friend or a relative to assist the client in client identification as 'still permissible but not advised by the Trust or professional bodies'. An area of improvement has been identified to amend EP A (ii) to clarify the use of a friend or a relative in assisting with client identification.

Correct identification (ID) of the client 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 client is being examined against the primary data source, which for breast screening is the breast screening client form. The operator signs the form to indicate the client ID has been completed. The client form is scanned on to PACS. The responsibility for correct ID lies with the operator who carries out the medical exposure.

The operator must always check the client's name, address and date of birth on the client screening form. The 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:

- Have you had a mammogram in the last six months?

For other scenarios, for example clients who lack capacity a clear client ID process was outlined for each situation. It was noted that a client ID audit is carried out as part of the rolling programme of IR(ME)R audits.

Staff explained the process for discrepancies in the client ID, for a breast screening discrepancy regarding a client's name/date of birth/ gender requires their GP to provide an update. The screening unit is not able to amend this information. Address, GP Practice or email address that requires updating, can be amended live on the NBSS server by the operator or member of the administrative team at time of appointment. In cases where live NBSS access is not possible, changes can be made on the screening client form for administrative staff to update at a later date. However, it was clear from responses that the exposure would not be undertaken if the client ID could not be confirmed.

There is evidence to show that incidents involving referral of the wrong patient/client are among the largest percentage of all diagnostic/screening errors notified to IR(ME)R regulators. The breast screening service have robust systems in place to report, record, investigate and learn from incidents.

Patient/client ID processes have been strengthened using learning from patient/client 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 client identification processes are in place. The review of EP A (ii) will enhance the client ID process. 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

Equipment replacement programme

As outlined in section 1 of this report the BHSCT breast screening service is undergoing an equipment replacement programme. The ISM described how equipment procurement has been a regional project in collaboration with the medical physics team who have been involved in the specifications. All units will be replaced including all mobiles across the region. At LHS department one room has been installed. Room 2 is having apps training booked in the coming weeks. There is risk based approach to the roll out of the equipment replacement programme, with one unit being replaced at a time at each site. It was confirmed all new units will have tomosynthesis capabilities. This is a positive development in the breast screening service.

Employers Procedures (EPs)

There were EPs for Breast Imaging in place which had been issued in January 2024 and approved by the Policy and External Guidance Assurance Committee at an Executive Team meeting. The EPs were overall found to be well written and relevant to the breast imaging services.

EP C pregnancy enquiries, was found to be detailed and reflected NHSBSP guidance. It also outlined arrangements for pregnancy enquiries for non – screening mammography where knowing the pregnancy status of an individual may be clinically beneficial. It was noted that an otherwise well written EP did not have an age range outlined for pregnancy enquiries. For completeness this should be included. An area of improvement has been identified to include an age range for pregnancy enquiries in EP C.

Written protocols

A range of breast imaging protocols were reviewed which had been issued in 2021. Overall it was good to note some clear work instructions were outlined. However, it was noted that they could be strengthened by the inclusion of elements of the IR(ME)R breast screening guidance, such as exposure factors, projections, positioning, post processing, image quality assessment, image transfer and dose recording. An area of improvement has been identified to further develop the breast screening image protocols to reflect the IR(ME)R breast screening guidance as outlined above.

Image Optimisation Team (IOT)

It was good to note that Breast Imaging IOT meetings have been held on a six monthly basis.

A review of the minutes of meetings held in August 2023 and February 2024 found that there was a clear terms of reference and valuable discussions had been undertaken. Some discussion resulted in action being proposed however, whilst there was an action column, it was unclear this was adhered to or monitored for completion.

To consolidate this good work, an area of improvement has been identified to include a clear action plan as part of the minutes of the Breast Imaging IOT meeting which identifies action to be taken, who is responsible and a timescale as this will allow robust monitoring of action and if appropriate can be signed off as completed.

6.0 Conclusion

There were 14 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 BHSCT Breast Screening Service at LHS is well managed and operating within the legislative framework; and maintaining optimal standards of practice for clients.

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	14

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 17 **Stated:** First time **To be completed by:** 20 June 2024	The Employer must revise the induction record for radiologists to ensure it clearly outlines the name and designation of the individual undertaking the induction, the name of the individual providing and overseeing the induction and that co-signatures of these individuals is evident throughout. Ref 5.2.1
	Response by Employer detailing the actions taken: Radiologist Induction Competency record has been updated to include the name and designation of the individual undertaking the induction, the name of the individual providing and overseeing the induction and that co-signatures of these individuals is evident throughout.
Area for improvement 2 **Ref:** Regulation 6 Schedule 2 (1) (b) **Stated:** First time **To be completed by:** 20 June 2024	The Employer must revise the competence form for radiographers and ensure it includes the name of the staff member and relevant dates for ongoing sign off to underpin the entitlement process and ensure competence assessment for the duty holder is undertaken prior to entitlement. Ref 5.2.1
	Response by Employer detailing the actions taken: All competency form templates have been revised. Induction packs have been updated to reinforce the requirement for competencies to be undertaken prior to entitlement.
Area for improvement 3 **Ref:** Regulation 6 Schedule 2 (1) (b) **Stated:** First time **To be completed by:** 20 June 2024	The Employer must review entitlement arrangements for duty holders and ensure their roles are compliant with IR(ME)R; that there is a clear specific individual scope of practice which is reflected in the entitlement records and ensure all staff fully understand their duty holder role and responsibilities. Ref 5.2.1
	Response by Employer detailing the actions taken: Entitlement records have been updated to ensure compliance with IR(ME)R, detailing clear specific individual scope of practice. Clarification of the entitlement process has also been improved in the Employer's Procedure B.

Area for improvement 4 **Ref:** Regulation 6 Schedule 2 (1) (b) **Stated:** First time **To be completed by:** 20 May 2024	The Employer must ensure that the advanced practitioner is entitled as an operator to carry out clinical evaluation in line with their scope of practice. Ref 5.2.1
	Response by Employer detailing the actions taken: Employer's Procedure B and the Radiographer Entitlement form have been updated to include IR(ME)R Operator function 'Competent to provide clinical evaluation for associated images in line with scope of practice. (Breast Advanced Practitioners only)'
Area for improvement 5 **Ref:** Regulation 11 (1) & (5) **Stated:** First time **To be completed by:** 20 April 2024	The Employer must ensure that the practitioner is clearly identified for all images undertaken. Ref 5.2.1
	Response by Employer detailing the actions taken: The Practitioner or Authorising Operator is now recorded on the Client/ Screening form.
Area for improvement 6 **Ref:** Regulation 6 Schedule 2 (1) (b) **Stated:** First time **To be completed by:** 20 June 2024	The Employer must update employer's procedure (EP) B on entitlement to reflect any changes as a result of the review of the entitlement arrangements and ensure it is complied with thereafter. Ref 5.2.1
	Response by Employer detailing the actions taken: EP B has been updated to reflect clarified entitlement arrangements. Entitlement is reviewed annually at Staff Development Reviews.
Area for improvement 7 **Ref:** Regulation 11 (5) **Stated:** First time **To be completed by:** 20 June 2024	The Employer must devise comprehensive authorisation guidelines and consider using a Breast Screening Guidance authorisation guidelines template to assist in their development. Ref 5.2.1
	Response by Employer detailing the actions taken: The service is revising the Authorisation Guidelines in accordance with the national Breast Screening Guidance template, and in collaboration with UK Health Security Agency advisors. Planned revision to be completed and republished by 20 June 2024.
Area for improvement 8 **Ref:** Regulation 11 (3) (b) Regulation 6 Schedule 2 (n)	The Employer must re-consider the role of the carer & comforter (C&C) in providing the breast screening programme and update the entitlement processes and EP O accordingly. Ref 5.2.1

Stated: First time **To be completed by:** 20 July 2024	**Response by Employer detailing the actions taken**: The Trust have adopted the role of carer and comforter in the Breast Imaging service, and have now included the process in Employer's Procedure O, and updated the entitlement form accordingly.
Area for improvement 9 **Ref:** Regulation 6 Schedule 2 (b) **Stated:** First time	The Employer must ensure all duty holders undertake refresher IR(ME)R training to include the roles and responsibilities of duty holders. Ref 5.2.1
To be completed by: 20 May 2024	**Response by Employer detailing the actions taken**: Refresher IR(ME)R training was performed with all Breast imaging staff on 14 May 2024.
Area for improvement 10 **Ref:** Regulation 7 **Stated:** First time	The Employer must ensure that audit forms are comprehensively and accurately completed and re-audit timescales are adhered to. Ref 5.2.3
To be completed by: 20 April 2024	**Response by Employer detailing the actions taken**: Refresher Audit training has been performed with all Breast imaging staff.
Area for improvement 11 **Ref:** Regulation 6 Schedule 2 (1) (a) **Stated:** First time	The Employer must amend EP A (ii) to clarify the use of a friend or a relative to assist in client identification. Ref 5.2.4
To be completed by: 20 May 2024	**Response by Employer detailing the actions taken**: EP A (ii) updated to include, 'If a patient is unable to answer the three point ID questions, ID can be confirmed with the assistance of adult carer/ relative/ friend or ID band. This is recorded on Sectra RIS.'
Area for improvement 12 **Ref:** Regulation 6 Schedule 2 (1) (c) **Stated:** First time	The Employer must include an age range for pregnancy enquiries in EP C. Ref 5.2.5
To be completed by: 20 May 2024	**Response by Employer detailing the actions taken**: EP C now includes the age range for pregnancy enquiries, 10-55years.
Area for improvement 13 **Ref:** Regulation 6(4) **Stated:** First time	The Employer must further develop the breast screening image protocols to include details provided in the IR(ME)R breast screening guidance as outlined in section 5.2.5. Ref 5.2.5

To be completed by: 20 June 2024	**Response by Employer detailing the actions taken**: The service is revising the Breast screening image protocols in accordance with the IR(ME)R Breast Screening Guidance, and in collaboration with UK Health Security Agency advisors. Planned revision to be completed and republished by 20 June 2024.
Area for improvement 14 **Ref:** Regulation 12 **Stated:** First time **To be completed by:** 20 July 2024	The Employer must include a clear action plan as part of the minutes of the Breast Imaging IOT meeting which identifies action to be taken, who is responsible, a timescale as this will allow robust monitoring of action and if appropriate can be signed off as completed. Ref 5.2.5
	Response by Employer detailing the actions taken: IOT Meeting minutes template updated to include Action Plan denoting 1) Action to be taken, 2) Responsible person, 3) Timescale, and 4) Current status.

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