The Regulation and Quality Improvement Authority

Inspection Report

25 January 2023

Altnagelvin Hospital, Breast Screening Service

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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: Western Health and Social Care Trust (WHSCT)	**Department Inspected:** Breast Screening Service
Name of Employer: Dr Brendan Lavery, Medical Director (WHSCT)	**Radiology Services Manager (RSM):** Ms Tracey McIvor **Assistant Radiology Service Manager (ARSM)-Breast Service:** Ms Marietta Connor
Clinical Lead Radiologist for Breast Screening: Dr Paul Farry	**Medical Physics Expert:** Mr Adam Workman

Brief description of how the service operates:

The WHSCT Breast Screening service is provided by a department based on the Altnagelvin Hospital site and two mobile units. There are three mammography rooms in the Altnagelvin Hospital department and the mobile units provide breast screening services from eight locations around the WHSCT covering a large geographical area from Coleraine to Enniskillen. The service is provided Monday to Friday 8.30 am to 5pm with extended hours if a patient assessment deems it necessary.

Before the inspection Ms McIvor, RSM, and her team were asked to complete a self-assessment form (SAF). The submitted SAF confirmed that a breast screening service in accordance with the national breast screening programme and a symptomatic breast screening service is provided. Over the past year 20994 clients were invited for a breast screening mammogram with 2490 mammograms for family history and recalls and 63 receiving a stereotactic biopsy. There were 2978 mammograms and 45 stereotactic biopsies for symptomatic patients.

The service is staffed by two whole time equivalent (WTE) consultant radiologists working between the main radiology department and the breast screening unit. There is also a part time locum consultant radiologist. Specialist registrars rotate through the breast unit. One WTE consultant radiographer, two WTE advanced practice radiographers (film readers), two WTE advanced practice radiographers performing stereotactic biopsies, 11.31 WTE radiographers and 2.8 WTE assistant practitioners work across the department and the mobile units providing the breast screening programme and a symptomatic service.

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 25 January 2023, 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 Altnagelvin Hospital Breast Screening Service, as part of RQIA's IR(ME)R inspection programme. Remote IR(ME)R inspections had been conducted for inspection years 2020/21 and 2021/22 in line with COVID -19 restrictions. A decision has been taken to resume site based IR(ME)R inspections for the 2022/23 IR(ME)R inspection programme.

For the 2022/23 inspection year the inspections will focus on four key themes:

- Incident management with a focus on audit/action plans and shared learning
- Optimisation including establishing local Diagnostic Reference Levels (LDRLs)
- Entitlement of staff to include training and competency with a focus on those duty holders outside of the radiology department
- Equipment quality assurance (QA) programmes
- Any other areas identified through the review of the submitted self-assessment form and supporting documentation

The purpose of our focus was to minimise risk to service users and staff, whilst being assured that ionising radiation services were 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
- To carers and comforters
- To asymptomatic individuals
- To 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 and patients 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 Altnagelvin Hospital Breast screening service under the current IR(ME)R legislation.

5.2 Inspection findings

5.2.1 Does the service manage ionising radiation incidents in accordance with the legislation, professional standards and guidance?

Management and clinical staff described the internal process for reporting accidental or unintended exposures and how notifiable incidents are reported to the appropriate enforcing authority.

It was confirmed that this department have not had any reportable radiology incidents however it was evidenced that clear robust procedures are in place to ensure that they are reported and investigated, with the findings shared, and any necessary action taken to prevent reoccurrence.

There was a very good awareness of incident reporting across all types of incidents: notifiable, non-notifiable and near misses. The findings of previous IR(ME)R inspections to other WHSCT radiology departments concerning the reporting and recording of near misses has been implemented.

It was clear as to who makes the clinical decision as to when an incident should be classified as clinically significant. This was discussed with staff and it was confirmed that the clinical lead radiologist for Breast screening is responsible for classifying an incident as clinically significant, taking into consideration the medical physics report generated by the MPE. It was advised to ensure this is fully reflected in the EPs.

It was confirmed that there two sets of Employer's Procedures for the breast service, one set for the Breast screening programme service - Employers Procedures for WHSCT Breast Screening Programme January 2023; and one for symptomatic screening/assessment - the 'Employers Procedures for Diagnostic /Interventional Radiology' June 2022. For the purpose of this report the Employers Procedures referred to are those for the Breast screening programme. However the matter is further discussed in section 5.2.5 of this report.

There is a clear incident reporting procedure which is linked to Employer's Procedure (EP) L 'investigation and reporting of accidental and unintended exposures'.

Where a radiographer / radiologist suspects that a patient has been exposed to an accidental or unintended dose of radiation the incident is immediately reported to the radiation protection supervisor (RPS) and clinical specialist radiographer. The RPS undertakes a preliminary investigation to determine if an incident has actually occurred which has resulted in an accidental or unintended exposure to a person undergoing medical imaging. The RPS informs the clinical lead and the departmental manager that a suspected incident has occurred. In the absence of the RPS, a senior radiographer undertakes the preliminary investigation. The individual discovering the incident is responsible for ensuring that the incident is recorded on Datix using the Trust Datix incident form. The RPS ensures that all relevant information (documents, emails, reports) relating to the investigation are uploaded to Datix in a timely manner throughout the investigation.

The preliminary investigation includes statements from all staff involved detailing the sequence of events at the time of the incident, exposure factors and dose factors for the examination and any relevant observations. The ARSM contacts the Trust MPE to carry out an assessment of the dose received by the patient. The MPE undertakes a dose and risk assessment and advises the clinical lead and radiology department manager of any requirement to notify RQIA of the incident using the "Significant accidental and unintended exposures under IR(ME)R, guidance for employers and duty-holders" (SAUE) guidance.

Where it is identified that an incident is notifiable to RQIA the departmental manager will inform the local clinical lead and the chair of the radiation protection sub group of the incident and the requirement for reporting. If the cause of the incident is due to an equipment defect or failure, the Northern Ireland Adverse Incident Centre (NIAIC) may also be informed.

It was confirmed there are robust arrangements for the governance and oversight of radiology incidents. Feedback to staff is through the radiology governance structures, including bi-monthly governance meetings, radiology QMS, discussion at staff meetings and by learning alerts circulated by the Trust Risk Management Department. Radiation incidents are reviewed at the six monthly Radiation Protection Working Group meetings and any wider organisational learning or remedial actions identified. Learning from incidents may be shared regionally where there is appropriate learning.

Staff demonstrated a clear understanding of the action to take in the event of an incident occurring and confirmed the arrangements for shared learning.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection, evidenced that the Altnagelvin Hospital Breast Screening Service have robust arrangements with respect to the management of ionising radiation incidents/near misses and are enthusiastic to ensure these arrangements are regularly reviewed and if necessary improvements are made. The inspection team acknowledge the commitment of staff in this regard.

5.2.2 Does the service have appropriate arrangements in relation to optimisation including establishing local Diagnostic Reference Levels (DRLs)?

Optimisation is a key principle of the radiation protection framework within IR(ME)R. The optimisation process is the joint responsibility of the practitioner, operator and MPE. The aim of optimisation is to achieve the image quality required to answer the clinical question using the lowest dose possible.

Staff and management outlined a range of measures in place to ensure that medical exposures are kept as low as reasonably practicable (ALARP). EP K reflected the arrangements in place, these include:

- Applications training
- Modality specific training
- Radiographic protocols
- Standard operating protocols
- Clear instructions to clients during the mammogram
- Employer's procedures
- IR(ME)R documents are subject to review and amendment
- Routine equipment maintenance
- Equipment quality assurance as recommended by the National Breast Screening Programme Guidelines
- Use of local DRLs which are displayed in the relevant department
- Appropriate exposure charts
- Incident management
- Management of near misses
- Dose audits
- A multi-disciplinary audit programme

Staff described clear arrangements in accordance with EPs for the optimisation of exposures where pregnancy cannot be ruled out.

DRLs are radiation dose levels or for nuclear medicine the administered activity for typical diagnostic examinations on standard size adults and children for broadly defined types of equipment for example CT, fluoroscopy or general radiography. DRLs are benchmarks of patient radiation dose, based on dose indices and where certain variables such as equipment type, examination and patient size are standardised to minimise uncertainty. DRLs are often considered the first step in the optimisation process. DRLs should not be consistently exceeded when good and normal practice is applied.

It was good to note that the WHSCT have established local DRLS (LDRLs) for breast screening. The clinical lead for Breast Screening in consultation with the MPEs, ARSM, RPS and QA radiographer established LDRLs and coordinates reviews should they be consistently exceeded.

It was confirmed that the Image Optimisation Team (IOT) is involved in the oversight of establishing and reviewing LDRLs. It was noted that the terms of reference for the IOT is awaiting ratification by the Radiation Protection Committee at the next meeting.

The LDRLs were noted to be displayed in the department and staff demonstrated an excellent understanding of their use and what action to take should they be consistently exceeded.

It was good to confirm that the MPE involvement in optimisation includes the following;

- Involved with and attends IOT meetings
- Provides guidance on dose audits and DRLs, ensuring an consistent approach
- Advice on protocols and on equipment
- Increasingly involved with procurement of equipment and commissioning.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that the breast screening department have good arrangements with respect to optimisation of medical exposures and are enthusiastic to ensure these arrangements are regularly reviewed and if necessary improvements are made. The inspection team acknowledge the commitment of staff in this regard.

5.2.3 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. It was noted that the competence form for one staff member did not have the name of the staff member on the front, it was not dated and therefore 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.

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 a consultant radiologist, an advanced practitioner radiographer, two mammographers, an assistant practitioner and group entitlement records for the MPEs were reviewed. Group entitlement records for MPEs were found to clearly evidence the entitlement of this group of staff. The individual entitlement records were 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 a referrer despite the individual not being a registered health care professional and individual duty holders describing specific scope of practice for equipment quality checks (QC) which was not reflected in their entitlement records. The breast screening service has two distinct pathways for the breast screening programme and the symptomatic breast screening service which again was not reflected in the 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 the entitlement records and ensure all staff fully understand their duty holder role and responsibilities.

EP B on entitlement, sets out the arrangements for entitlement and it was suggested to ensure accuracy of terminology in keeping with IR(ME)R and update to reflect any changes as a result of the review of the entitlement EP.

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.

There were two sets of authorisation guidelines in place for the breast screening programme, one within the EP's (Appendix 5) January 2023 and the other devised in December 2022. It was not clear which was in use. The authorisation guidelines within the EPs did not have a named practitioner. The other authorisation guidelines were brief and would not be sufficiently detailed to serve as authorisation guidelines. An area of improvement has been identified to devise comprehensive authorisation guidelines, which clearly outline a named practitioner for the medical exposures to be carried out using the guidelines.

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 and patients 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/patient during a medical exposure. This is outlined within EP N. It also states that a careful risk assessment of each individual case would likely result in the examination being cancelled and recorded as ' attended not screened in National Breast Screening Service (NBSS) as benefit would be difficult to identify. An area of improvement was identified to re-consider the role of the C&C in providing the breast screening programme.

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.

5.2.4 Does the service adhere to legislation with regard to equipment quality assurance (QA)?

An inventory of radiological equipment was supplied which contained all of the information as specified within the legislation. This list of equipment will be kept under constant review and will be updated when there is a change.

The inspection team sought to ensure that all QA equipment tests are undertaken and to schedule; that the results of the tests are recorded and interpreted in a suitable manner and that any actions necessary as a result of the tests are followed through appropriately. In addition Trust staff liaise with external providers of QA and advise on performance and optimisation. e.g. RMPS.

The equipment QA programme should specify two levels of testing, level A which is carried out internally by the radiology staff and level B testing which is carried out by an external provider, RMPS.

As part of the service level agreement (SLA) between the WHSCT and the RMPS a programme for external QA is undertaken using recommended QC test methods and at a frequency advised by The Institute of Physics and Engineering in Medicine (IPEM). The IPEM set the 'Recommended Standards for the Routine Performance Testing of Diagnostic X-ray Imaging Systems' in their IPEM Report 91. The National Health Service Breast Screening Programme (NHSBSP) recommends QC checks to be conducted for equipment involved in the breast screening service.

A MPE report dated November 2021 outlining the findings of an equipment quality control audit conducted for July – December 2020 in line with the NHSBSP was reviewed. It was noted that the report of the findings was issued a year after the audit was conducted. On discussion with management in relation to the report and actions taken to address the findings, it was evidenced that whilst some actions had been taken to address the findings of the report, it was not clear if all actions within the report had been actioned. The responsibilities around following up on the findings in this report were not clear and governance structures concerning this could be strengthened. An area of improvement has been identified to review the MPE audit report fully, set out a clear action plan to address the findings and strengthen governance structures in relation to the role and responsibilities for follow up to a MPE audit and any findings.

A robust level A QC testing schedule was evidenced with clear work instructions in place for each piece of equipment. A number of QA radiographers have been trained and assessed as competent for the department. Staff involved in performing QA testing had evidence of training and a competency assessment to undertake this role. However, as stated previously in section 5.2.3 it was not evident that they had been entitled to do so.

Review of level A QC test records found they were up to date, well completed and comprehensive. Staff outlined clearly what action to take if issues with a level A test were outside of baselines; including informing the RPS and the QA radiographer; repeating the test; seeking advice from the MPE and manufacturer; and if necessary removing the equipment from service on the advice of MPE.

A robust equipment QA audit process was in place. The QA radiographer carries out monthly and quarterly equipment QA audits and reports the findings to the ARSM which are reported if serious through the Trust governance structures. It was confirmed the Employer is part of the Trust governance board.

The RSM provides a risk governance report to the Trust Board. If equipment is taken out of use and there will be an impact on service delivery report, the RSM will escalate the service delivery challenges to relevant directorates and the Trust Board.

It was good to note that level A QC testing is up to date, robust processes are in place, and there is clear management oversight.

It is the Employer's responsibility to ensure that an equipment QA programme is in place. The task of implementing QA programme for all applicable imaging equipment has been delegated to RSM as set out in the WHSCT Radiology Equipment QA procedure.

Staff and management demonstrated an understanding of their roles and responsibilities in relation to equipment QA with the exception of the MPE audit.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced a clear and robust level A equipment QA programme is in place and the management were receptive to the area for improvement identified in relation to follow up to the MPE audit. 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.

Clinical Audit

It was good to note a comprehensive breast service annual audit schedule was in place for 2022/23. The schedule included clinical audit and IR(ME)R compliance audits. A range of audits were reviewed and found to be of an overall good standard. It was noted one audit was untitled and not dated. It was confirmed as being an audit in relation to technical recall and technical repeat January 2021 – April 2021 and the report outlined that it had been had been carried out as part of The Screening Quality Assurance Service (SQAS) which ensures breast screening programmes are safe and effective by checking national standards. Following the inspection we were informed that the equivalent body to SQAS in Northern Ireland is known as Young Person and Adult Screening Team (YPAST).The results of the audit were discussed. In particular the language used in the report with regards to 'justified mammograms' led to a confusing picture in relation to compliance with IR(ME)R.

The findings also highlighted the need for supervision of trainee staff when making the decision to repeat an image. Whilst the matter was clarified, an area of improvement has been identified to ensure:

- all audits are titled and dated
- re-audit the technical recall and technical repeat images
- the correct supervision of trainee staff until fully competent
- ensure robust follow up to audit findings

Employers Procedures

As stated previously, management confirmed that there were two sets of Employer's Procedures (EPs) operational for the breast service, one set for the breast screening programme service – 'Employers Procedures for WHSCT Breast Screening Programme' January 2023; and another set for symptomatic screening/assessment - the 'Employers Procedures for Diagnostic /Interventional Radiology' June 2022.

On discussion with staff in the department they were not aware of the two sets of EPs and described one set of EPs covering the breast screening programme and the symptomatic breast screening service. Management advised the inspection team that it is their intention to have one set of EPs for both breast screening services and that this may have led to confusion on the matter from staff.

It was emphasised that EPs are important legal frameworks which must be made available to and complied with by duty holders. Management agreed to direct staff in relation to the present provision of two sets of EPs. In addition the EPs for the breast screening programme were found to be confused in the use of some IR(ME)R terminology. An area of improvement has been identified to consider devising one set of EPs for the breast screening service to include the breast screening programme and the symptomatic breast screening service, which must outline the correct use of IR(ME)R terminology; and be made available and complied with by duty holders.

Research

There is EP in place for the exposure of patients or other persons voluntarily participating in medical or biomedical diagnostic or therapeutic research. It sets out a clear framework to ensure that all medical exposures for research purposes require special consideration and special procedures in addition to those generally applicable to medical exposures.

The WHSCT breast screening service is involved in a research – a 'Small Trial'. This trial is for clients taking part in the National Breast Screening Programme, who have an early biological breast cancer - detected early. The trial compares standard surgery outcomes with clients who have vacuum assisted excision biopsy performed using radiological guidance instead of surgery. Referrals to the trial are identified at multi-disciplinary team meetings. Clients are subsequently either randomised in or out, of the use of Stereo excisional biopsy for removal of 'B3' lesions.

The operation of this trial within the department was discussed with management, including such matters as the referrer for each research exposure, who justifies research exposures, how the operator identifies those clients as part of the research trial and if there are specific written examination protocols for the research trial.

Whilst radiology staff were knowledgeable in relation to the research trial, it was noted there was no formal research protocol for the roles and responsibilities of radiology staff for this research trial. An area of improvement has been identified to establish a research protocol outlining roles and responsibilities for radiology staff and any specific examination protocols to follow.

6.0 Conclusion

There were eight areas of improvement identified as a result of this inspection. These are fully outlined in the appended quality improvement plan (QIP).

The management team and staff are to be commended for their ongoing commitment and enthusiasm to ensuring that the Altnagelvin Hospital Breast Screening Service is well managed and operating within the legislative framework; and maintaining optimal standards of practice for clients and 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	8

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 (3) Schedule 2 (b) **Stated:** First time **To be completed by:** 25 April 2023	The Employer must review competency assessment forms to ensure they include the name of the staff member and relevant dates for ongoing sign off to underpin the entitlement process. Ref 5.2.3
	Response by Employer detailing the actions taken: A review has been undertaken of the competency forms in the unit to ensure inclusion of staff member name and to comprise dates for sign off of competency. The forms will be completed over the next month by staff to appropriately record their competency in line with the recommendation from RQIA.

Area for improvement 2 **Ref:** Regulation 6 Schedule 2.1 (b) **Stated:** First time **To be completed by:** 25 April 2023	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 5.2.3
	Response by Employer detailing the actions taken: A review of the entitlement documentation for the unit is ongoing . The use of the draft IR(ME)R guidance for the screening programme to ensure documentation of compliance of roles as well as clearly defined scope of practice for each individual has enhanced the previous documentation. This document will be sent to medical physics for their oversight prior to completion before the 25th April 2023.
Area for improvement 3 **Ref:** Regulation 11 (5) **Stated:** First time **To be completed by:** 25 April 2023	The Employer must develop comprehensive authorisation guidelines, which clearly outline a named practitioner for the medical exposures to be carried out using the guidelines. Ref 5.2.3
	Response by Employer detailing the actions taken: Authorisation guidelines are under review in accordance with the draft guidelines for IR(ME)R(August 2022) and will cover all elements of breast imaging in the service. These are expected to be finalised before the 25th April 2023.
Area for improvement 4 **Ref:** Regulation 11 (3) (b) **Stated:** First time **To be completed by:** 25 April 2023	The Employer must re-consider the role of the carer and comforter in providing support to an individual undergoing an exposure within the breast imaging service. Ref 5.2.3
	Response by Employer detailing the actions taken: The role of carer and comforter is being reconsidered and steps have been taken to create a carer and comforter consent form along with an ammended carer and comforter procedure within the Employers procedures as well as provision of authorisation guidelines for carer and comforter exposures in the breast imaging service authorisation guidelines.These documents will be sent to medical physics expert for review prior to 25th April 2023.
Area for improvement 5 **Ref:** Regulation 14 (3) **Stated:** First time	The Employer must review the Medical Physics Expert (MPE) audit report fully, set out a clear action plan to address the findings and strengthen governance structures in relation to the role and responsibilities for follow up to a MPE audit and any findings.

To be completed by: 24 April 2023	Ref 5.2.4
	Response by Employer detailing the actions taken: After discussion with medical physics on 24/02/2023, a regional template is to be drawn up for actions and responses relating to the QC audits undertaken by medical physics as part of the NHSBSP. This is to be discussed at the next regional radiography QA meeting. Within the unit the previous QC audit undertaken by medical physics is under review and actions will be documented on the outcomes from that review by 24th April 2023.
Area for improvement 6 **Ref:** Regulation 7 **Stated:** First time **To be completed by:** 25 April 2023	The Employer must ensure : • all audits are titled and dated • re-audit technical recall and technical repeat images • the correct supervision of trainee staff until fully competent • ensure robust follow up to audit findings Ref 5.2.5
	Response by Employer detailing the actions taken: Audit template has been used to undertake a re audit of repeat images, this includes title and date information displayed at the beginning of the documentation. The correct supervision of trainiees is to be outlined in the entitlement documentation where trainee (level 1- with supervison) and fully competent (level 2- without supervision or for AP indirect supervision) is detailed. This is in progress and is expected to be completed by 24/04/2023.
Area for improvement 7 **Ref:** Regulation 6 (1) **Stated:** First time **To be completed by:** 25 April 2023	The Employer must consider devising one set of Employers Procedures for the breast screening service to include the breast screening programme and the symptomatic breast screening service, which outlines the correct use of IR(ME)R terminology; and be made available and complied with by duty holders. Ref 5.2.5
	Response by Employer detailing the actions taken: The review of employers procedures has been initiated with a meeting to discuss with medical physics again planned for 15/04/2023 to begin in depth analysis of requirements.
Area for improvement 8 **Ref:** Regulation 6 Schedule 2.1 (g) **Stated:** First time **To be completed by:** 25 April 2023	The Employer must establish a research protocol outlining roles and responsibilities for radiology staff and outline any specific examination protocols to follow. Ref 5.2.5
	Response by Employer detailing the actions taken: A draft research protocol has been created to cover aspects of the SMALL trial relating to radiology. This document has been discussed with reprsentatives from the research group for the

	trial and as a locally held copy it was deemed that it would not need to be ratified through the group. The protocol is scheduled for the next radiology governance meeting in March 2023 for final sign off.

The Regulation and Quality Improvement Authority

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