Healthcare Improvement Scotland | Inspections and reviews
To drive improvement

Announced Inspection Report: Ionising Radiation (Medical Exposure) Regulations 2017

Service: South West Scotland Breast Screening Centre, Ayrshire Central Hospital

Service Provider: NHS Ayrshire and Arran

19–20 August 2025

NHS SCOTLAND

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1 A summary of our inspection

Background

Healthcare Improvement Scotland (HIS) has a statutory responsibility to provide public assurance about the quality and safety of healthcare through its inspection activity.

Our focus

The focus of our inspections is to ensure each service is implementing Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017. Therefore, we only evaluate the service against quality indicators that align to the regulations. We want to find out how the service complies with its legal obligations under IR(ME)R 2017 and how the services are led, managed and delivered.

About our inspection

We carried out an announced inspection to NHS Ayrshire and Arran, South West Scotland Breast Screening Centre (SWSBSC), Ayrshire Central Hospital on Wednesday 19 and Thursday 20 August 2025. We spoke with several staff, including clinical directors, consultant radiographer, superintendent radiographer, head of imaging, medical physics experts (MPEs), radiographers, assistant practitioners (APs). We spoke to staff in both mobile and static screening sites. This was our first inspection to this service.

The SWSBSC provides breast screening imaging and assessment clinic services to those in Ayrshire and Arran, and Dumfries and Galloway. NHS A&A use two mobile units for screening. Approximately 24,000 women are screened per year in the region.

The inspection team was made up of three inspectors.

What action we expect NHS Ayrshire and Arran to take after our inspection

The actions that HIS expects NHS Ayrshire and Arran to take are called requirements and recommendations.

- **Requirement:** A requirement is a statement which sets out what is required of a service to comply with the Regulations. Requirements are enforceable at the discretion of Healthcare Improvement Scotland.

- **Recommendation:** A recommendation is a statement that sets out actions the service should take to improve or develop the quality of the service but where failure to do so will not directly result in enforcement.

This inspection resulted in two requirements and three recommendations. Requirements are linked to compliance with IR(ME)R.

Implementation of IR(ME)R requirements	
Requirements	
1	The South West Scotland Breast Screening Centre must include in their Employers procedures or similar document the referral guidelines for when secondary imaging is required and the type of imaging recommended. (Regulation 6(5)(a)) (see page 10).
2	The South West Scotland Breast Screening Centre must clearly define in the employers procedure or similar documents at what point justification is occurring when as referral is made on the SBSS system. (Regulation 11(b)) (see page 11).
Recommendations	
a	The South West Scotland Breast Screening Centre should document in employers procedure or similar documents where relevant medical history and imaging is stored on the SBSS system to assist the justification process (see page 11).
b	The South West Scotland Breast Screening Centre should document in their procedures the understanding of the term “Routine Recall” in relation to the production of a clinical evaluation (see page 15).
c	The South West Scotland Breast Screening Centre should document their clinical audit programme (see page 17).

An improvement action plan has been developed by the NHS board and is available on the Healthcare Improvement Scotland website.

NHS Ayrshire and Arran must address the requirements and make the necessary improvements as a matter of priority.

We would like to thank all staff at NHS Ayrshire and Arran, South West Scotland Breast Screening Centre for their assistance during the inspection.

2 What we found during our inspection

Safety Culture and Leadership

Key questions we ask:
How clear is the service's vision and purpose?
How supportive is the culture and leadership of the service?

Our findings

A strong safety culture and environment was seen, with the necessary understanding and implementation of IR(ME)R demonstrated to the inspectors.

Safety culture

A strong safety culture can help to strengthen safety in the use of radiation technology, preventing injuries and reducing unnecessary or unintended radiation dose to patients. The safety culture is demonstrated through the measures in place to ensure the appropriate entitlement and scope of practice, Employers Procedures (EPs), optimisation practices, quality assurance systems, as well as the audit and governance arrangements in place.

Staff advised that they are a part of a safe environment that enables them to openly communicate any concerns and reflect on the learning of incidents. Procedures are in place for reporting through local procedures via DATIX and to National Services Scotland (NSS) to the Scottish Breast Screening Programme (SBSP) MPEs.

Implementation of IR(ME)R requirements

Key questions we ask:
How well does the service manage and improve performance?
How does the organisation demonstrate the safe use of ionising radiation (patient exposure)?

Our findings

There was clear systems and processes in place for the development of EPs, entitlement of staff and staff training. Staff were clear on their scope of practice.

Employer's procedures

The SWSBSC is clearly aligned to the NHS A&A governance structure for the development of IR(ME)R procedures. EPs were detailed and thorough and adhered to IR(ME)R regulations. A detailed library of EPs is in place, and a sample of documents were available to the inspection team prior to the inspection.

There are three levels of documents covering the different services. Level one documents applies to the whole of the NHS board, covering all modalities. Level two documents are modality specific. Level 3 documents are service level documents, in this case covering the breast screening services.

There was a clear link of the breast screening specific documents to the wider board procedures.

It was clear that there is a multi-disciplinary team (MDT) approach to the production of all documents and procedures, with varying operational meetings held to discuss documents and agree changes.

Documents are reviewed on a two-year basis. The quality management system alerts staff of review dates and notifies those responsible for the management of documents that require changes or if review is required.

All staff were aware of where to find relevant EPs.

Training

A detailed training programme has been implemented at the SWSBSC. Staff training records are in depth and include various aspects of training, competency and dates achieved. The samples of records that we viewed were complete and signed by the appropriate persons.

The training records included reference to the additional qualifications required to carry out mammography. For a radiographer this is a Post Graduate certification in Mammography (PG Cert), or for an AP this is a Higher Education Certification.

When APs are in training, they practice under direct supervision, where the radiographers are physically in the room and overseeing practice. Radiographers in training follow the same process where they are under direct supervision until deemed competent by the relevant persons.

There is a detailed training pathway for those who read images, and this is included on the training record. Readers must carry out further training and undertake a minimum number of reading images to become and remain competent. Reader's training is overseen by a radiologist who acts as a mentor and appraises their film reading practice. Procedure document BSU-SOP-3007, outlines the standards and protocols for mammography reading in SWSBSC. It states that film readers should report a minimum of 5000 mammograms per year. This document also outlines the requirements to undertake 1st and 2nd reading practices.

HIS standards state that repeat examination rates should be less than 3% in line with NHS Breast Screening Programme consolidated standards. Repeat examination rates are therefore reviewed monthly for each staff member and as a department rate. If a staff members rates are consistently higher than 3%, a procedure is in place, BSU-SOP-3003, to support staff in mentoring sessions, peer review and further training with the Scottish Academy of Breast Imaging (SABI).

Radiologists, consultant radiographers and advanced practitioner radiographers in SWSBSC who are involved in the reading of images are enrolled into the PERFORMS scheme run by the University of Nottingham. This is a national programme, accredited by the Royal College of Radiologists (RCR) that enhances health professionals' interpretation and imaging diagnostic skills. Participants are required to review and report a set of test images including complex cases. The staff receive feedback from PERFORMS on their reporting efforts. This scheme is a positive element of self-assessment and peer review and is used enhance image interpretation in the screening programme.

Continuous professional development (CPD) is a process of continuous learning and ongoing development of skills and addressing learning needs in relation to achieving a higher standard of practice. The Health and Care Professions Council (HCPC) and the General Medical Council (GMC) and RCR outline requirements for undertaking CPD. The radiography and radiologist staff groups reported that time for CPD is available, and a variety of learning activities are provided.

Entitlement

The clinical director is responsible for the referral of individuals and for the justification of an exposure, this is based on the national breast screening criteria. An entitlement letter for the clinical director was available at the time of inspection.

Entitlement for a number of staff was witnessed on the inspection, and each staff member had a physical copy of their entitlement letters. All examples of entitlement letters we saw were signed by the appropriate persons. The entitlement documents outline the scope of practice for each role. All staff we spoke to were aware of their own entitlement and their roles and responsibilities. It was clear that the review of staff entitlement was carried out regularly.

SWSBSC have an assistant specialist surgeon who works in the service. The role is supervised by a consultant. The specialist surgeon attends the assessment clinics which are led by the consultant. They are entitled to report on images as the 1st, 2nd or arbitrator role and can also refer for technical recalls.

Referral

Referral for the breast screening programme is carried out by invitation based on a referral criteria set out by the Scottish Government and UK national screening committee. The SBSP is aligned and evidenced by the breast screening programme in NHS England. All criteria and recommendations are agreed nationally. It is the responsibility of the host board to ensure these criteria are applied locally.

Women who meet the nationally agreed criteria are invited to attend for breast screening on a rolling three-year cycle. The invitation letters are sent from the SWSBSC and are identified by women registered at a GP practice. A letter of invitation, signed by the entitled clinical director, is the mechanism of referral to the SBSP. This letter is generated by SBSS, the breast screening IT system. An example of an invitation letter was seen at inspection and signed appropriately.

Referral to assessment clinic or for a technical recall is also by means of a general invitation letter signed by the clinical director.

A referrer must be a registered healthcare professional, therefore APs as a staff cohort are not entitled to act as a referrer.

The SBSS radiology information system is used to map the patient pathway and record the referral information, secondary imaging and results.

What needs to improve

Staff were able to clearly define when secondary imaging would be applicable and the type of imaging and views that would be appropriate for use in the assessment clinic, however no reference to written procedures were available. There are no documented referral guidelines in place for assessment clinic imaging exposures.

Requirement 1

- The South West Scotland Breast Screening Centre must include in their Employers procedures or similar document the referral guidelines for when secondary imaging is required and the type of imaging recommended. (Regulation 6(5)(a)).

Justification

Justification is the process of weighing up the expected benefit of an exposure to ionising radiation against the potential harms of radiation exposure. In breast screening the benefit of exposure is early detection and treatment of breast cancer, or knowledge that no disease is present.
Radiation exposure through the breast screening programme throughout Scotland is based on agreed national population and criteria. The justification for exposure is applied at the invitation stage of the screening process by means of an invitation letter. Clinical justification is carried out in the boards by entitled operators prior to exposure also.

Justification is a role that can be carried out by registered health professionals only. All image exposures must be justified prior to exposure taking place. In the breast screening setting, as per document BS05 *"the responsibility for justification remains with the Practitioner who will have agreed the guidelines*". In this case it is the clinical director who signs the invitation letter. The entitled operators involved in the practical undertaking of the exposure authorise the exposure under guidelines.

What needs to improve

During inspection there was discussion where the justification for imaging was undertaken. The IT system SBSS does not include a separate “justified by” component. Instead, the “requested by” option on the assessment clinic module on SBSS was the only option and therefore it was assumed that this action covered the IR(ME)R role of justification. There could potentially lead to debate over who had responsibility for justification of images taken in the assessment clinic.

Although initial screening images are viewed prior to assessment clinic it was unclear where the relevant clinical history for justification of secondary imaging is documented for each person.

Requirement 2

- The South West Scotland Breast Screening Centre must clearly define in the employers procedure or similar documents at what point justification is occurring when as referral is made on the SBSS system. (Regulation 11(b))

Recommendation a

- The South West Scotland Breast Screening Centre should document in employers procedure or similar documents where relevant medical history and imaging is stored on the SBSS system to assist the justification process.

Optimisation

The role of optimisation is to ensure that doses to individuals are kept as low as reasonably practicable (ALARP), consistent with the desired clinical results. The SWSBSC have adopted the Scottish diagnostic reference levels (DRLs) as set by NSS. NSS have developed a range of four DRLs that cover 80% of women, in comparison the national DRL only has one DRL range that covers 10% of women. A review of the SBSP 2023 2D patient dose data showed that it is not common for the operators to exceed the DRLs when imaging. This is due to a combination of factors (for example, the use of automatic exposure control, equipment design, staff training and protocols, use of the SBSS flagging system to optimise individual exposures). DRL charts and exposure charts were visible at the operator console at the static and mobile sites.

The Auto AEC mode is utilised for all screening attendees. Document BSU-SOP-3006 outlines the procedure for screening women with pacemakers, implantable devices and 'Popcorn' Calcifications. In these scenarios the auto AEC mode is turned off. The AEC is an inbuilt function on the equipment to ensure that the mammogram has the correct or optimal exposure. A manual selection of the AEC chambers is chosen to ensure the best quality image. Any person who has had a manual selection of an AEC chamber is "flagged" on the SBSS system for future appointments, detailing the AEC position. This is a positive use of the flagging system and good optimisation as may reduce unnecessary exposures at future appointments.

Following on from a previous inspection to NSS, an image optimisation group has been established in the SBSP, which will add to optimisation across the Scottish centres.

The SWSBSC has an EP in place for exceeding DRLs. The document, GUID-001, outlines "*the steps that should be taken in the event that a Local Diagnostic Reference Level (LDRL) is exceeded or consistently exceeded***".** For all images the dose data is recorded on the digital imaging and communication in medicine (DICOM) header of each image taken. Regular audits are in place that includes a review of the dose information.

Image quality, including blurriness or artefact presence, is highlighted to the radiography QA lead or senior management by the operators if there was a concern that equipment or image quality was not adequate. Advice would then be given on whether the equipment can remain in use. After investigation further stakeholders such as NSS medical physics and equipment engineers may be notified if required.

It was noted that it is in progress for future equipment purchases, that clinicians will be involved in optimisation by providing clinical judgment on image quality. Staff reported they are content with current quality of images.

Operator

There are a number of EPs and protocols that operators work against. All staff we spoke to were aware of the EPs relevant to them and where they could access them if required. Mammography staff work in the mobile unit and static centre and interchange regularly. Staff were familiar with the processes required for each site.

Operators check the day list for previous mammogram dates as recorded by the administration staff from the various PACs systems to ensure no attendees have had imaging done in the previous six months. This is also confirmed verbally with the ladies in the pre-exposure checks undertaken prior to any imaging taking place. Staff described the process for imaging women including the need to review previous imaging, ID checks, accurately position the women and breast, appropriate number of views, adequate compression and imaging women with breast implants or implantable devices.

Staff described the methods of being under supervision for AP and radiographer roles, and working under direct and indirect supervision. Staff reported they were aware of their scope of practice and did not undertake tasks they were not entitled to carry out.

Records

The SWSBSC use a document management system for the updating and management of all EPs. Staff also use an online application to store breast screening documents as there is no access to the intranet on the mobile units. Documents stored on the online application are reviewed every six months.

The SWSBSC has access to national PACS system and the SBSS PACs system. However, there is no access to PACs on the mobile units. To counteract this previous imaging for attending women is checked prior to attendance. PACS is checked for Ayrshire and Arran, Dumfries and Galloway and any imaging undertaken at Crosshouse Hospital. Admin staff check previous mammogram dates and record this on the day list for reference for the operators.

Patient identification

All staff we spoke to were aware of the patient identification procedures in place. A three-point ID check is used for all patients. The worklist for patients each day is linked from the SBSS IT system to the imaging equipment. Operators record on SBSS that they have carried out the identification process and the details match.

For women who require an interpreter, these services are available.
A quarterly audit is undertaken on patient identification which has returned 100% compliance. These audits are carried out in both the mobile units and the static centre.

Imaging exposures will not be carried out if there are any concerns over patient identification.

Clinical Evaluation

Clinical evaluation is the clinical interpretation of an image and the recorded outcome (documentary evidence) of that reading. All the images in SWSBSC are read by two readers. Document BS10 states "*Clinical evaluation is undertaken by both 1st and 2nd reader (and if required a 3rd reader) to confirm the clinical evaluation*". The readers are a mix of consultant radiologists, consultant radiographers, assistant specialist and entitled advanced practitioner radiographers who completed extra training and qualifications.

For each set of images acquired at this initial screening stage, both readers are required to record their clinical opinion on SBSS and come to a consensus on the findings. Where there is a difference of opinion an arbitrator will review the images to provide a third reading, finalise the consensus and confirm the outcome for the woman on SBSS.

What needs to improve

There are three options available when reading an image to clinically evaluate the findings at the initial reading. These options include "Routine Recall," "Technical Recall" and "Review Required." As there is no option to write in depth the findings in the routine recall option on SBSS, it is assumed by generation of a letter to the women and placement back on the routine call list, that there was no suspicious finding on the images. The letter is seen as an outcome from the clinical evaluation. We were advised that a routine recall is equivalent to a clinical evaluation whereby no suspicious pathology was evident. As per the NHS breast screening IR(ME)R guidance, the processes for clinical evaluation, arbitration, and the recording of the outcome of the assessment should be clearly described in the employer's procedure.

Recommendation b

- The South West Scotland Breast Screening Centre should document in their procedures the understanding of the term "Routine Recall" in relation to the production of a clinical evaluation.

Expert advice

MPEs from NSS provide the expert physics advice for the screening programme. NHS Ayrshire and Arran MPEs are informed of local Datixes however NSS MPE provision carry out investigations on reportable incidents. Local MPEs contribute to the development of the local EPs and provide advice on compliance to IR(ME)R.

In relation to the equipment NSS provide MPE input and are responsible for the following:

- commissioning and procurement of new equipment
- 6 monthly and annual quality assurance of equipment
- dose monitoring and
- analysis of incidents.

While NSS MPEs are responsible for the procurement and commissioning of all equipment for the SWSBSC, there are representatives from NHS Ayrshire and Arran that are included in this process.

The NSS MPEs are not based in the SWSBSC however, they are readily available for support from both static centre and mobile units via phone or online. A strong working relationship was evident at the inspection between NHS Ayrshire and Arran, SWSBSC and NSS MPEs.

Contracted services

There are currently no locum or agency staff hired in the screening service. However, an EP for locum induction (BS-IOP-MAM-TR-AC-2) is in place if required.

No third-party external imaging reporting services are used for image reading, or cross border reporting is carried out.

General duties in relation to equipment

The guidelines for implementing IR(ME)R guidelines in the breast screening pathway report that "*QA programmes including that documentation must be regularly reviewed, it is followed by staff, it reflects current clinical practice and that only the latest version is available*". The QA manual, compiled and provided by NSS MPE provision, was available at the time of inspection and it was

confirmed the most up to date version was in circulation. A printed manual is kept on the mobile units, and it is the responsibility of the QA lead radiographer to ensure this is kept up to date. NSS MPEs also routinely check in their QA visits that the manual available is the most up to date version being used.

All staff are trained to undertake the daily and monthly QA tests on the mammography equipment. The training for this is cascaded from NSS MPEs to local QA lead staff and through to the mammographers and assistant practitioners. Training records must be signed as competent for staff to undertake these tasks by themselves. The mammography equipment has the daily and monthly QA tests scheduled internally thus highlighting to staff that the tests must be carried out on a certain day. The equipment will not allow images to be acquired without these tests being completed. Results from each test is recorded onto a live spreadsheet. This is accessible by NSS MPEs for review and to aid in any test failures. Should there be any faults or failure of QA tests, staff were aware of the procedures to follow, the routes of escalation and who to contact. In the scenario where equipment is taken out of clinical use due to test failure, the appropriate out of clinical use signs were available. There are additional QA tests to be carried out when equipment is returned to use and after any engineer has been on site to carry out work, along with a handover form.

As part of the maintenance and annual service of mammography screening equipment BS 23 outlines that "*physics checks are performed 6 monthly by NSS Medical Physics with reports and any action trackers being sent to the Superintendent Radiographer and departmental QA radiographer*".

It was confirmed that there is dedicated time in the day to undertake QA tests as required on a daily basis and post engineer check or post movement of the mobile unit.

As part of the SBSP there are dedicated QA roles appointed in each screening centre. The radiography QA lead and radiology QA lead in SWSBSC link with the other national QA leads to aid in the standardisation of practice across the SBSP.

The monitors used to undertake clinical evaluations also have a QA programme in place.

Clinical audit

A clinical audit programme is a tool to identify and improve healthcare outcomes across the breast screening pathway. SWSBSC undertake a comprehensive range of audits as part of the screening program and locally.

All mammography staff undertake a self-assessment audit on previous images they have taken using the Perfect, Good, Moderate Inadequate (PGMI) image evaluation system established by the National Health Service Breast Screening Programme (NHSBSP). Operators self-assess 20 images per month. The radiography QA lead will also audit a further 100 images across the department. Through the PGMI system technical recall and technical repeats are monitored. These rates must be below 3% consistently, there are procedures in place to assess if additional refresher training is required or to check reasons behind increased rates.

The radiography QA lead and radiology QA lead feed into the NSS regional QA leads to provide information on the centre. The regional QA leads write a report which is sent to the clinical director, the departmental QA lead, NSS programme board and Screening Oversight and Assurance Scotland (SOAS). Feedback from the QA report is provided.

All readers participate in the review of images for interval cancers cases. Each case is scored, and the results are collated before being discussed at annual team meetings. The local Interval cancer rate is audited annually by the local Radiology QA Lead. Figures are pulled from SBSS. The audit forms part of the evidence submitted prior to the annual QA visit. Rates are discussed at the visit and go towards national data.

What needs to improve

There is a wide range of clinical audits being undertaken, however there is no document that describes the overarching programme of clinical audits in place and how they are being used to provide assurance and identify areas for improvement.

Recommendation c

- The South West Scotland Breast Screening Centre should document their clinical audit programme.

Accidental or unintended exposure

The SWSBSC centre follows the IR(M)ER procedure for the notification of incidents as outlined in their EPs.

The SWSBSC has a standing agenda item at the radiation safety protection group which is held every two months. This group discusses radiation incidents and shared learning with other radiation services. Incidents from breast screening are also discussed locally in the SWSBSC and nationally at the SBSP.

National discussion includes breast screening QA leads from all centres, and NSS MPEs.
All staff we spoke to were aware of how and when to raise a Datix. Datix is unavailable on the mobile units, therefore paper forms are in place to record the details when in this setting. It was reported that staff members are involved in deciding the learning points in relation to the incidents which shows a collaborative approach.

Locally learning from incidents is communicated through a monthly newsletter to all staff and at staff meetings.

Risk and Communication

This is where we report on what difference the service has made and what it has learned.

Key questions we ask:

How well does the organisation communicate with service users?

Our findings

It is required under IR(ME)R that adequate information is provided to individuals prior to exposure relating the risks and benefits of radiation exposure from imaging. Systems are in place to communicate this information to eligible individuals.

Risk benefit conversations

As the screening programme is delivered nationally, information leaflets from NHS Scotland and Public Health Scotland are provided to the centres to be given to the women with their invitation letter. The leaflets provided include the risks and benefits of screening. The invitation letter contains a phone number for the department should they have further questions. The opportunity is available for women to speak to a staff member in person, in the department should they have further questions prior to imaging.

Making enquiries of individuals who could be pregnant

Enquiries to individuals who may be pregnant are not routinely carried out in the SBSP. As stated in the breast screening IR(ME)R implementation guidance, there is no requirement from a radiation dose perspective to routinely enquire about pregnancy prior to the exposure for routine breast screening imaging. Document BS8 removes the requirement of EP8 “Exposure of individuals of

child-bearing potential" in SWSBSC "*as pregnancy is NOT a contraindication for Mammography examinations*".

The guidance also notes that mammography is not routinely performed when a woman is breastfeeding, due to the density changes in the breast tissue.

Carers and comforters procedures

Carers and comforters are not utilised in the screening service. Individuals who are not able to comply with screening procedures by themselves are not imaged. These individuals will receive an information leaflet specifically for people who do not receive any imaging as part of the breast screening service. The EP BS22 removes the requirements outlined in the board level 2 document EP22 for carers and comforters as they will not be present in controlled areas during imaging exposure.

If during the process a person cannot complete their screening appointment mammograms will be marked on SBSS for future reference as a "partial mammogram", and individuals will receive an information leaflet for incomplete imaging.

Appendix 1 – About our inspections

Our approach

Healthcare Improvement Scotland has a statutory responsibility to provide public assurance about the quality and safety of healthcare through its inspection activity.

How we inspect services that use ionising radiation for medical exposure

The focus of our inspections is to ensure each service is implementing IR(ME)R 2017. Therefore, we only evaluate the service against quality indicators that align to the regulations.

What we look at

We want to find out:

- how the service complies with its legal obligations under IR(ME)R 2017 and addresses the radiation protection of persons undergoing medical exposures, and
- how well services are led, managed and delivered.

Complaints

If you would like to raise a concern or complaint about an IR(ME)R service, you can directly contact us at any time. However, we do suggest you contact the service directly in the first instance.

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