Healthcare Improvement Scotland | Inspections and reviews
To drive improvement

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

Breast Screening Programme

NHS National Services Scotland

11 June 2025

NHS SCOTLAND

Healthcare Improvement Scotland is committed to equality. We have assessed the inspection function for likely impact on equality protected characteristics as defined by age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation (Equality Act 2010). You can request a copy of the equality impact assessment report from the Healthcare Improvement Scotland Equality and Diversity Advisor on 0141 225 6999 or email his.contactpublicinvolvement@nhs.scot

First published August 2025

www.healthcareimprovementscotland.scot

Contents

1 A summary of our inspection

Background

Healthcare Improvement Scotland 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 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 National Services Scotland (NSS), Scottish Breast Screening Programme (SBSP) on Wednesday 11 June 2025. During the inspection we spoke with the national clinical advisor/deputy director of screening, IR(ME)R lead, portfolio lead, quality assurance leads for radiologists and radiographers and the medical physics experts (MPEs) for SBSP. This was our first inspection to this service.

The SBSP manage the framework for the commissioning and delivery of breast screening services throughout six screening centres in Scotland. These services are delivered at fixed centre locations, however most of the screening is undertaken via the specialist mobile breast screening units. The SBSP set the national standards for the quality assurance (QA) of all breast screening equipment and the QA of the services delivered, adhering to NHSBSP standards where possible.

The inspection team was made up of three inspectors.

What action we expect NSS Scottish Breast Screening Programme to take after our inspection

The actions that Healthcare Improvement Scotland expects the NSS Scottish Breast Screening Programme 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 no requirements and four recommendations.

Implementation of IR(ME)R requirements	
Recommendations	
a	It is recommended that NSS Scottish Breast Screening Programme (SBSP) document the involvement of any or other professionals as part of the review or development of employer's procedures, to demonstrate a multidisciplinary approach, when necessary. (see page 7)
b	It is recommended that the service level agreement (SLA) between the local boards and NSS is reviewed and updated to include the entitlement of staff who undertake the lead role of quality assurance as identified. (see page 8)
c	It is recommended that a multidisciplinary optimisation group be established within the Scottish Breast Screening Programme (SBSP) to aid standardisation and consistency across all centres. (see page 10)
d	It is recommended that NSS is given the full spectrum of information of incidents, from all breast screening centres, to allow for trend analysis and service improvements on a national basis. (see page 13)

An improvement action plan has been developed by the NHS NSS Scottish Breast Screening Programme and is available on the Healthcare Improvement Scotland website. The NHS NSS Scottish Breast Screening Programme should address the recommendations and make the necessary improvements.

We would like to thank all staff involved for their assistance during the inspection.

2 What we found during our inspection

Safety Culture and Leadership

This is where we report on how clear the service's safety culture and how supportive its leadership and culture is.

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

There is a strong safety culture for the use of ionising radiation with systems and processes in place for the implementation of IR(ME)R and mechanisms to support quality assurance across Scotland.

Safety culture

The safety culture is demonstrated through the appropriate competence of staff, employer's procedures (EP's), supporting documents, audits, and the governance arrangements in place.

NSS has a clear governance structure for the management of IR(ME)R in relation to the services delivered within NSS in collaboration with the six NHS Boards that deliver breast screening services.

The IR(ME)R advisory group (IAG) has a pathway through the clinical governance committee and radiation safety committee to the NSS Board. Screening Oversight and Assurance Scotland (SOAS) is responsible for providing oversight and assurance of Scotland's national screening programmes. Although SOAS does not carry out the operational delivery of screening, it provides coordination, support and expert advice to the health boards. The SBSP is accountable through the National Screening Oversight Board (NSOB) to the Scottish Screening Committee (SSC), chaired by an NHS Chief Executive.
The NSOB and SCC together provide national which has accountability for the national oversight and assurance of screening programmes.

Throughout the governance structure there are available routes of escalation for raising incidents, and to support the services alignment to IR(ME)R and HIS breast screening standards.

Implementation of IR(ME)R requirements

This is where we report on how well the service implements the requirements of IR(ME)R and manages and improves performance.

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

NSS have clear processes in place for the commissioning and quality assurance of equipment. NSS have governance arrangements and procedures in place for the quality assurance of services delivered by NHS Boards.

Employer's procedures

NSS has a duty under IR(ME)R to develop written procedures commonly referred to as EP's. These are intended to provide a framework under which professionals can practice. NSS demonstrated that they have a clear pathway for developing and updating their EP.

The services provided by the NSS Medical Physics team are within the scope of registration for ISO 9001:2015 Quality Management System, which includes IR(ME)R documentation.
Level one documents are the responsibility of the IAG, and level two documentation is the responsibility of the medical physics expert (MPE) staff within the SBSP. The reviewing of documents is an agenda item of the IAG. An audit of the documentation is undertaken every year. EP's are available to view on the QMS and are reviewed regularly, with revision dates recorded on each document. The EP's we reviewed were comprehensive and up to date.

What needs to improve

The procedure for reviewing or developing EPs can involve different professional groups, however this involvement is not recorded in the documented procedure.

Recommendation a

- It is recommended that NSS Scottish Breast Screening Programme (SBSP) document the involvement of any or other professionals as

part of the review or development of employer's procedures, to demonstrate a multidisciplinary approach, when necessary.

Entitlement

NSS EPs on entitlement demonstrate the process of entitlement and illustrate lines of accountability. NSS entitle MPEs and have clear documentation in place that identifies who can act as an operator. NSS does not deliver breast screening services and therefore there is no need to entitle staff to act as a referrer.

Varying levels of entitlement are assigned across the physics provision, in line with their roles and responsibilities. Staff are appropriately entitled and are aware of the scope of practice in accordance with their role. Examples of physics staff entitlement forms and training records were available for the inspection team to review. NSS were able to provide documents to demonstrate the competence of staff in the different activities undertaken. Staff entitlement and their scope of practice is clearly linked to training, skills and knowledge.

What needs to improve

Through a service level agreement (SLA) NSS utilises a consultant radiologist and a radiographer to lead, direct and deliver the quality assurance programme for radiological performance for SBSP. NSS should review the activities that these individuals are undertaking and determine if they require to be entitled for any part of their role. Such as making an assessment on image quality, providing any form of reporting or directing required care based on an image.

Recommendation b

- It is recommended that the service level agreement (SLA) between the local boards and NSS is reviewed and updated to include the entitlement of staff who undertake the lead role of quality assurance as identified.

Referral

Referral for the SBSP is carried out by invitation to the individual identified for screening, 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. The invitation letter originates from each of the six NHS boards who have responsibility for delivering breast screening services.

Justification

Exposure through the SBSP is based on an agreed national population and criteria. Justification is applied at the invitation stage of the screening process. Clinical justification is carried out in the NHS boards by entitled operators prior

to exposure. HIS will undertake further investigation into justification process during site inspection visits, including the justification for further imaging and assessment.

One of the criteria for individuals who have been identified for breast screening is that they have had no previous imaging carried out in the previous six months. Currently operators are required to review two different PACS systems to check the individual's history of imaging. The standalone screening PACS system and the national PACS system where all other imagining is stored. NSS confirmed that they are involved in the process of developing an integrated PACS system. This will reduce the likelihood of individuals receiving unnecessary breast screening imaging while the patient is undergoing treatment with associated breast imaging.

Optimisation

Dose optimisation is the balance between the lowest dose and the image quality that is clinically suitable. The service has implemented robust optimisation practices including clinical audits to assess dose and image quality. NSS have an established QA manual and schedule for equipment testing. The equipment used to expose individuals to ionising radiation has a variety of protocols that help deliver standard and optimised exposures to all persons who undergo breast screening in Scotland. An audit programme involving a QA lead radiographer and QA lead radiologist enhance the optimisation efforts and image quality.

NSS collect national dose data from all breast screening equipment across Scotland. Dose reference levels (DRLs) are regularly reviewed by MPEs. The MPEs use the dose audit information to set national DRLs. A positive finding from the audit was that screening doses in Scotland are lower than the UK national guidelines. As a result, a revised DRL has been adopted in Scotland that is lower than the national DRL. This demonstrates a positive safety culture and adherence to as low as reasonably practicable (ALARP) principles.

What needs to improve

While many positives were seen in the optimisation of the screening programme including undertaking clinical audits, training of equipment and established quality assurance programmes. It was concluded that the optimisation primarily involved MPEs and a focus on dose and adherence to manufacture parameters. Optimisation should also ensure the optimal management and implementation of protocols. It was acknowledged that this position was changing to include end users of images, namely the radiologist and radiographers as part a multidisciplinary approach to the optimisation. However, the process was not fully implemented in the NSS SBSP and there was

no formal image optimisation team (IOP) in place. An IOP can support improvements on existing safe practices, support the introduction of new equipment into the screening programme and maintain an awareness of current research and technological developments in the speciality area.

Recommendation c

- It is recommended that a multidisciplinary optimisation group be established within the Scottish Breast Screening Programme (SBSP) to aid standardisation and consistency across all centres.

Expert advice

MPE provision is provided on a national basis through the programme. MPE support is provided by NSS MPEs to the breast screening centres with input from local MPEs in each board according to local agreements. It was confirmed that there is a strong working relationship between breast screening departments and the national MPEs.

The MPEs are involved in a variety of areas such as:

- commissioning of new equipment
- acceptance testing of new equipment
- local dose reference levels
- dose monitoring, and
- analysis of incidents.
- advice in relation to compliance with IR(ME)R
- provide training to breast screening centres to undertake quality assurance testing

They also provide advice on whether an incident should be reported to HIS.

General duties in relation to equipment

A rolling programme of the replacement and servicing of mammography equipment is organised through the National Procurement directorate, with input from National Services Division, NSS MPEs and clinical SBSP staff. As part of the programme, the SBSP use a grading system to help decide which mobile equipment to replace, as well as engagement with the NHS Boards of their equipment needs which is based on the age and performance of the equipment. When procuring equipment, it will undergo a technical and practical evaluation by a multidisciplinary team. This will look at capital funding and is performance led across the service. NSS undertake due diligence during the procurement process and oversee provision based on need and timelines. When the new piece of equipment has been procured it will go through a commissioning process undertaken by the MPEs which focus on the technical specifications. Further commissioning on the practical applications is undertaken by the radiologists specialising in mammography.

The SBSP is responsible for setting the national quality assurance programme for all radiological equipment. The type and frequency of testing was developed by the MPEs. This includes the performance testing for both mammographers and medical physics teams. We were advised that the types and frequency of QA tests are benchmarked against the manufacturer and nationally agreed documents such as those from the Institute of Physics and Engineering in Medicine (IPEM), the National Co-ordinating Centre for the Physics of

Mammography (NCCPM) and NHS breast screening programme guidance. Document FAC407-008 is an example of QA tests carried out showing parameters, remedial and suspension levels and the related reference or benchmark documentation.

The SBSP demonstrate a high-level fulfilment of QA duties and regular testing. A QA lead radiologist and QA lead radiographer are in place to assess their areas of expertise and provide oversight to help with consistency and standardisation across all breast screening centres.

There is a detailed QA manual available and is provided to all breast screening centres. Each centre carries out the daily QA tasks and any problems arising from this is raised through the appropriate channels. Physics QA visits are carried out by the medical physics team at six monthly and yearly intervals at the static and mobile units. The results from the tests carried out are shared with the NHS Board who is responsible for managing the service. The results from the QA audit are recorded and monitored for identifying trends to ensure ongoing performance management.

An equipment inventory is held by the SBSP MPEs and updated as necessary. All test kits that are utilised are calibrated on a scheduled basis, and records are kept.

The quality assurance radiography group meet six monthly to discuss quality assurance alongside incident reviews and clinical conformity tests. Additionally, shared learning is promoted through an annual national QA study day, where trends, results and safety are discussed.

Clinical audit

During the inspection it was confirmed clinical audits are carried out in the SBSP and is detailed in the employers' procedures. Clinical audits within the SBSP look at various themes including interval cancer rates and cancer detection rates. The results from clinical audits are used to inform programme learning and to drive improvement nationally. There is joint working with other organisations, for example Public Health Scotland (PHS), to obtain data for analysis.

As part of the quality assurance, the SBSP is provided with information on the technical recall rates and technical repeats at each breast screening centre.

Accidental or unintended exposure

EP's for unintended exposure was as provided to inspectors. NSS MPEs investigate all radiation incidents reported to them. They are then reported to SOAS who assess whether they meet the criteria for a screening incident. If so, a Problem Assessment Group is established. It was reiterated that MPE advice and support is available for all incidents, including local incidents that are not reportable.

What needs to improve

Whilst staff did report a positive reporting culture between the breast screening centres and NSS, not all local incidents are reported to the national MPE if they are not deemed as adverse. Investigations and analysis of incidents and near misses, including remedial actions to prevent or minimise recurrence, undertake trend analysis and share learning. This can support the review for national trends analysis, service improvement opportunities and aid learning on a national level. There is a duty of cooperation that each breast screening centre must adhere to, and therefore it is advised that the SBSP MPEs have access to all incident information if requested.

Recommendation d

- It is recommended that NSS is given the full spectrum of information of incidents, from all breast screening centres, to allow for trend analysis and service improvements on a national basis.

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

Risk benefit conversations

Risk benefit conversations are navigated through patient information provided by the SBSP and public forums, for example NHS Inform. This topic will be inquired further in the clinical site inspection visits as NSS do not provide any clinical imaging services. As per the provided EPs regarding risk and benefit, the MPEs provide advice regarding content for the consent and invitation letter provided to participants.

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.

Our contact details are: his.irmer@nhs.scot

Healthcare Improvement Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

Telephone: 0131 623 4300

Email: his.irmer@nhs.scot

You can read and download this document from our website.
We are happy to consider requests for other languages or formats.
Please contact our Equality and Diversity Advisor on 0141 225 6999
or email his.contactpublicinvolvement@nhs.scot

Healthcare Improvement Scotland

Edinburgh Office	Glasgow Office
Gyle Square	Delta House
1 South Gyle Crescent	50 West Nile Street
Edinburgh	Glasgow
EH12 9EB	G1 2NP
0131 623 4300	0141 225 6999

www.healthcareimprovementscotland.org