Healthcare Improvement Scotland | Inspections and reviews
To drive improvement

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

Service: East Scotland Breast Screening Centre, Ninewells Hospital

Service Provider: NHS Tayside

24–25 September 2025

NHS SCOTLAND

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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 service is led, managed and delivered.

About our inspection

We carried out an announced inspection to East Scotland Breast Screening Centre (ESBSC), Ninewells Hospital on Wednesday 24 and Thursday 25 September 2025. We spoke with several staff during the inspection including a consultant breast radiologist, screening director, screening PACS manager, advanced practitioner radiographer/ quality assurance lead, medical physics experts (MPEs) and specialist radiographers. This was our first inspection to this service.

ESBSC provides two static screening rooms with access to a third room within the centre that is also used for symptomatic mammograms. ESBSC also operates two mobile screening units, and has access, when required, to a further mammography unit at Perth Royal Infirmary. ESBC screens approximately 20,000 to 25,000 patients per year.

The inspection team was made up of two inspectors.

What action we expect NHS Tayside to take after our inspection

The actions that Healthcare Improvement Scotland expects the NHS Tayside ESBSC 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 four recommendations. Requirements are linked to compliance with IR(ME)R.

Safety Culture and Leadership	
Requirements	
	None.
Recommendations	
	None.

Implementation of IR(ME)R requirements	
Requirements	
1	ESBSC must be able to demonstrate the radiographers who work in the breast screening service are adequately trained and have undertaken a post graduate course in mammography. (Regulation 17(1)) (see page 10).
2	The East Scotland Breast Screening Centre must clearly define in the employer's procedures or similar documents at what point justification is occurring when a referral is made on the SBSS system. Regulation 11 (1)(b) (see page 13).
Recommendations	
a	It is recommended that East Scotland Breast Screening Centre promote the learning opportunities available as well as the guidance on protected time to undertake continual professional development (see page 10).
b	The East Scotland Breast Screening Centre should document in employer's procedures or similar documents where the relevant medical history and imaging is stored on the SBSS system to assist the justification process (see page 13).
c	It is recommended that the East Scotland Breast Screening Centre record the steps that should be taken in the event that a Local Diagnostic Reference Level (LDRL) is exceeded by an agreed factor at the time of a patient exposure (see page 14).

d	The East 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 17).
Risk and Communication	
Requirements	
	None.
Recommendations	
	None.

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

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

We would like to thank all staff at NHS Tayside ESBSC 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 was a strong ionising radiation safety culture in place with clear a governance structure and team awareness in place for the implementation of IR(ME)R.

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. There is a clear framework through the Employer's Procedures (EPs), protocols and assurance programmes that support the safe delivery of ionising radiation. There are measures in place to ensure the appropriate entitlement and scope of practice, EPs, optimisation practices, quality assurance (QA) systems, as well as the audit and governance arrangements in place. Staff reported open lines of communication to raise concerns and discuss issues. The staff reported a safe environment to report incidents and described a learning environment and the use of reflection.

Requirement

- No requirements.

Recommendation

- No recommendations.

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

There were 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 ESBSC is clearly aligned to the NHS Tayside governance structure for the development of IR(ME)R procedures. There are four distinct levels of documentation within NHS Tayside. We reviewed a selection of level one, level two and level three EPs documents and ESBSC protocols. Level one documentation applies to the whole NHS board, covering all modalities. ESBSC protocols are focused on breast imaging services, both screening and symptomatic.

The review of documents is conducted annually, and the protocols have been recently updated. These documents are developed with a multi-disciplinary approach from senior radiographers, MPEs and radiologists as required.

Training

All radiographers working within breast screening must have a Post Graduate Certification (PG Cert) in Mammography. It is also required that all advanced practitioners (APs) complete a higher education certification in Mammography. These certifications are provided by Scottish Academy of Breast Imaging (SABI). The courses run by SABI are approved by the College of Radiographers (CoR). SABI provides further training modules in advance practice to enable professional and clinical skills development for those who wish to extend their scope of practice within breast imaging, for example in reading and reporting of images.

They also carry out refresher training with staff members across all breast screening centres in Scotland at various times. When radiographers and APs are

in training, they practice under direct supervision, where the trained radiographers are physically in the room and overseeing practice.

The training records for each staff member are stored in folders and were available for inspection. We were shown examples of a number of radiographers' training records. Staff we spoke to were aware of the link between their training and their own individual scope of practice. Individual training records and competencies are reviewed regularly.

There is a specific training pathway for consultant breast radiographers who as part of their role undertakes breast reporting of both symptomatic and screening images. They undertake a post graduate module in image interpretation. This includes reviewing a minimum of 3,000 screening images under supervision, monitoring cancer detection rates, recall rates and missed cancer rates. This is in addition to the other competencies associated with the role.

Advanced practitioner mammography radiographers undertake breast screening reporting and assign clients to routine recall, technical recall or further assessment. As part of the training this staff group also must undertake a review of a minimum of 3,000 images under supervision to be able to carry out clinical evaluations. On completion of their training, they are required to review at least 5000 images a year to maintain their role and competencies.

Radiologists, consultant radiographers and advanced practitioner radiographers in ESBSC 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.

EP P13 Training and Continuing Professional Development (CPD) training lays out the requirements for operators and practitioners. Training record documents were available that detailed specific areas/equipment that staff were deemed competent and the date competency was reached. As a requirement to carry out mammography services, a Post Graduate Certification for radiographers or a Higher Education certificate for APs is necessary to be achieved. This is in line with staff entitlement as duty holders.
Under IR(ME)R regulation 6 (3)(b) every employer is to ensure that every practitioner or operator undertakes continual professional development.

Continuous professional development 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. In addition, it is the responsibility of the radiographer to maintain their own continual professional development as part of their professional registration.

Radiologist training and continual professional development is managed through staff annual appraisals The radiologist reported that time for CPD is available, and a variety of learning activities are provided. Some staff informed the inspection team they had undertaken CPD and have attended events relevant to their role. Events included training on implantable devices, sign language and a talk from an equipment supplier.

What needs to improve

At the time of inspection, the Post Graduate Certification Mammography for radiographers working in the breast screening service was not available for all staff. All radiographers we spoke to confirmed that they had completed their Post Graduate Certification.

There were varying degrees of awareness from radiographers of the CPD opportunities and the amount of time made available to undertake CPD. Staff also commented team meetings could be used to discuss learning and development.

Requirement 1

- ESBSC must be able to demonstrate the radiographers who work in the breast screening service are adequately trained and have undertaken a post graduate course in mammography. (Regulation 17(1)).

Recommendation a

- It is recommended that East Scotland Breast Screening Centre promote the learning opportunities available as well as the guidance on protected time to undertake continual professional development.

Entitlement

NHS Tayside have a robust process for the entitlement of staff to undertake the role of a referrer, practitioner and operator. There are clear lines of accountability of who can entitle staff to act as a referrer, practitioner or operator. The entitlement and scope of practice is linked to the competencies of the staff member as demonstrated by their qualifications and role, training and experience. An individual's scope of practice can change over time, for example following additional training or moving to a new role. NHS Tayside have individualised training records to link to training to an individual scope of practice.

Entitlement records were reviewed for several staff and examples of entitlement letters were available on inspection. The entitlement documents outlined the scope of practice for each role. The staff we spoke to were aware of where to find their training records and their scope of practice. An annual review had also been undertaken of staff entitlement and scope of practice.

Referral

The letter of invitation to women to attend for screening is sent from the screening director (consultant breast radiologist), who is the entitled by NHS Tayside as the referrer. The referral criteria are set out by the Scottish Government and UK national screening committee.

When further investigation is required, screening images and the initial findings from the screening are discussed at an assessment clinic. If necessary, the lead assessor, which may be a consultant radiologist or consultant radiographer functions as the referrer and the practitioner for further imaging. The clinical director of East Scotland Breast Screening confirmed that they would refer for different images depending on the investigations undertaken, seeking a non-ionising radiation where practicable. When further investigation is required, the referrer completes the referral on the SBSS system. The system details who the referrer was, and the examination requested.

Justification

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 by entitled operators prior to exposure.

When a woman attends for screening, the previous imaging history is reviewed to ensure that no images have been taken in the previous six months. Staff

reported they ask the women verbally as part of the pre-exposure tasks, if they had any previous imaging. Staff have access to SBSS, screening and symptomatic Picture Archiving and Communication System (PACs) and CRIS to check the imaging history if there is any ambiguity in the verbal response. If there is any further doubt, imaging will not be undertaken.

Technical repeats, which can be undertaken at the time of screening, are further images taken if the image quality is deemed inadequate by appropriately entitled operators. Operators can carry out a technical repeat as part of the original justification for the mammogram.

When screening images are read this is undertaken on monitors with much greater resolution, this can result in the identification of areas of blurring not visible at the time of screening. If blurring is identified the entitled reader can determine if a technical recall is required and which views requires repeats. Other reasons requiring a technical recall may also become apparent at this stage. The reason for review and which view is required for technical recall is recorded on SBSS and is visible to the operator when the client reattends screening for their technical recall.

Screening images that require further investigation are referred to the assessment clinic. In the assessment clinic, the cases are discussed by the leads and the mammography radiographers each morning and the women requiring further imaging are identified. When a woman is referred to the assessment clinic, further imaging can be justified based on the assessment by the consultant breast radiologist or consultant radiographer who leads the clinic. Further imaging can include adapted views, tomosynthesis, magnification views, cone views and stereo biopsy. NHS Tayside have developed referral criteria for the type of imaging appropriate to the type that would be discussed at the assessment clinic.

What needs to improve

The SBSS radiology system does not clearly use language to identify the person who has justified an exposure at an assessment clinic. 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 is covered by the IR(ME)R role of justification.

Although a staff discussion is undertaken for each woman attending the assessment clinic, and the clinical information on SBSS is reviewed the system does not clearly identify this information as part of their medical history.

Neither was it documented in the EPs or protocols the type of information that was to be regarded as the medical history.

Requirement 2

- The East Scotland Breast Screening Centre must clearly define in the employer's procedures or similar documents at what point justification is occurring when as referral is made on the SBSS system. Regulation 11 (1)(b).

Recommendation b

- The East Scotland Breast Screening Centre should document in employer's procedures or similar documents where the 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 ESBSC 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 with the national DRL that has one DRL range that covers 10% of women. A review of the SBSP 2023 2D patient dose date 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, QA, staff training and protocols and use of the SBSS flagging system to optimise individual exposures. DRL charts and exposure charts were visible at the operator console within the static and mobile site.

NHS Tayside have an optimisation group and can discuss dose optimisation and image quality concern. In addition, following a previous inspection to NSS a national image optimisation group has been established, which will seek to improve optimisation across the Scottish centres.

NHS Tayside procedures for screening allow the mammography staff to choose whether to use the Auto AEC mode or a manual mode when screening women with pacemakers, implantable devices and 'popcorn' calcifications. A document based on the manufacturers' guidance is available at the imaging console to help support staff in choosing the imaging options. 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 for these women 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 it may reduce unnecessary exposures at future appointments.

For all images the dose data is recorded on the digital imaging and communication in medicine (DICOM) header of each image taken. NHS Tayside and NSS have a long standing program of retrospective audit of clinical dose against DRLs with investigation above an agreed action level.

What needs to improve

In the event that the that the DRLs are significantly exceeded at the time of an individual patient exposure, staff advised us there were no formal arrangements in place. Staff told us they would review the factors involved to determine if there are any contributory factors and may highlight the incident to the superintendent and MPE. There is no requirement to highlight or record any incident that excessively exceeds the DRL at the time of an incident.

Recommendation c

- It is recommended that the East Scotland Breast Screening Centre record the steps that should be taken in the event that a Local Diagnostic Reference Level (LDRL) is exceeded by an agreed factor at the time of a patient exposure.

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 who work in the mobile unit and static centre can interchange regularly. Staff were familiar with the processes required for each site. The protocols were clear and provided step by step guidance.

Staff described the process for imaging women including the need to review previous imaging, ID checks, accurate positioning of the breast
the number of views required adequate compression and imaging women with breast implants, or implantable devices. Staff have access to interpreter services if required and question sets are available in different languages.

Staff were familiar with the four national DRLs and posters were displayed close to the operator of screening equipment. Staff described how they work to optimise imaging and use the red flag system to communicate any relevant information for the next appointment. This may include the need to provide additional time to undertake the screening due to mobility issues, confirming implantable devices or implants. If an image had been optimised and any

settings updated. Staff reported they always work in a team of two operators or an additional member if someone is in training and requires direct supervision. Staff reported they are aware of their scope of practice and did not undertake tasks they were not entitled to carry out.

Records

The ESBSC uses a document managing system for the upkeep and management of EPs and protocols of all levels. Documents were accessible online in the mobile unit at the time of inspection. Paper copies of some documents were available in the event of failure to access the internet in remote areas, for example the QA manual. Screening records are held on the national SBSS system and follow the individual's screening pathway and history.

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.

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 ESBSC are read by two readers. The readers are a mix of consultant radiologists and consultant radiographers and advanced practitioners who completed extra training and qualifications.

For each image acquired, both readers are required to record their clinical opinion and arrive at a consensus on the findings. Where there is a difference of opinion an experienced screen reader, who may be a consultant radiologist, consultant radiographer or advanced practitioner will act as an arbitrator and will review the images to provide a third-party independent reading. Arbitration will finalise the consensus and confirm the clinical evaluation outcome.

There are three options available when initially reading an image to clinically evaluate the findings. These options are "Routine Recall," "Technical Recall" and "Assessment Clinic." As there is no option to record the findings and clinical evaluation in the routine recall option on SBSS, it is assumed by generation of a

letter to the women that they will be invited for a routine recall in the future when there are no suspicious findings on the images. The letter is seen as an outcome from the clinical evaluation whereby no suspicious pathology was evident. Staff involved in the process understand their role in relation to IR(ME)R and the implications of the function options to report on images within the SBSS system. The processes for clinical evaluation, arbitration, and the recording of the outcome of the assessment should be clearly described in the EP, providing guidance on the role and responsibilities of staff in relation to IR(M)ER and how this is demonstrated on the SBSS system.

Recommendation d

- The East 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

Medical physics experts (MPEs) from NSS provide the expert physics advice for the screening programme and work in cooperation with NHS Tayside MPEs for breast services. NSS undertake the MPE QA on the two mobile units and the two static rooms that are used predominantly for screening. NHS Tayside MPEs undertake the QA on the two static units, one at Ninewells Hospital and one at Perth Royal Infirmary, that are primarily used for symptomatic patients but can also be used for screening. These NHS Tayside MPE’s QA tests are aligned to the national breast screening QA standards. The reports from the QA test are shared between the MPEs from NSS and NHS Tayside. NSS are informed of local Datixes. NHS Tayside MPEs contribute to the development of the local EPs and provide advice on compliance to IR(ME)R.

In relation to the breast screening equipment the NSS MPE are responsible for the following:

- commissioning and procurement of new equipment
- six monthly and annual QA of equipment
- dose monitoring and
- analysis of incidents.

The analysis of all patient radiation incidents involving NHS Tayside operators and referrers, EPs and symptomatic equipment fault is analysed by NHS Tayside MPEs. NSS MPEs analyse patient radiation incidents arising from screening equipment faults.

All patient incidents are communicated to NSS MPEs by ESBSC following completion of the investigation and analyses.

While NSS MPEs are responsible for the procurement and commissioning of all screening equipment for the ESBSC, NHS Tayside MPEs are included in this process. The NHS Tayside MPEs are responsible for the procurement and commissioning of the two static rooms primarily used for the symptomatic service and involve the NSS MPEs. There is a service level agreement (SLA) detailing the responsibilities of the NSS and NHS Tayside MPEs.

Contracted services

NHS Tayside will use locum services to support the breast screening service when required. When locums are used, they are subject to the same level of training and evaluation as any other member of staff. Any locum will be assessed as part of the process to define their scope of practice.

General duties in relation to equipment

There is a QA program in place that details the equipment to be tested, type of test, the tolerance limits and frequency of testing. A comprehensive QA manual, compiled and provided by NSS MPEs and is available to staff undertaking QA tasks. An information chart which detailed the potential results from QA were available in the mobile unit. Charts indicate the acceptable parameters and the remedial and suspension levels.

All staff had been trained to undertake the daily, weekly and monthly tests. The imaging equipment has the required QA tests programmed for the relevant days. There were clear escalation procedures in place for equipment that was found to be out of tolerance. Staff confirmed that, if required, they could contact the manufacturer or the NSS MPE to resolve issues. QA results are recorded on paper forms and then transferred to online spreadsheets for the daily, weekly and monthly QA tests. The online spreadsheet highlights if a result is out of tolerance. The six monthly and annual tests are carried out by NSS MPEs. Bimonthly tests are more comprehensive, and dedicated time is provided for these tests to be undertaken.

Clinical audit

Clinical audit is a tool used in improving healthcare outcomes across the breast screening pathway. ESBSC undertake a comprehensive range of audits as part of the national screening program and local procedures.

All 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 QA lead radiographer will also audit a further 10 images per staff member.

The QA lead radiographer regularly audits recall and retake rates. This data is monitored, and all staff are provided with feedback on the outcomes of the audits and rates. If a high level of recall or retake was seen, further investigations are carried out.

All readers participate in the review of images for interval cancers. Meetings for discussion of these rates are held twice a year. A report from these figures is produced to go towards the national data on interval cancers.

Accidental or unintended exposure

The ESBSC centre follows the NHS Tayside procedure for the reporting of incidents as outlined in the EPs which also include reference to the statutory notification criteria.

Incidents are reported locally through Datix. Staff we spoke to were aware of the reporting procedures and pathways. The quality lead collates incident data for analysis to identify trends and learning. Governance for reporting incidents and outcomes are reported following the departmental procedures and are escalated to the SBSP in NSS as required. Staff we spoke to were aware of the reporting procedures and pathways. In the last 12 months there has been five incidents, one of which was reportable to the regulator.

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 to 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 along with their invitation letter. The leaflets include the risks and benefits of screening. The invitation letter contains a phone number for women to call the department should they have further questions. The opportunity is available 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

Exposure of individuals of child-bearing potential or pregnancy is not a contraindication for mammography examinations.

Carers and comforters procedures

Whilst there are EPs in place covering the wider radiology service, including breast screening, for comforters and carers, these procedures are not required in the breast screening programme in NHS Tayside. It was reported that if the women are not able or suitable for imaging without the need for a career or comforter being exposed, then they will not be imaged.

Requirement

- No requirements.

Recommendation

- No recommendations.

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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