Healthcare Improvement Scotland | Inspections and reviews
To drive improvement

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

Service: South East Scotland Breast Screening Centre, Ardmillan House

Service Provider: NHS Lothian

22-23 October 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 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 Lothian South East Scotland Breast Screening Centre (SESBSC) on Wednesday 22 and Thursday 23 October 2025. We spoke with a number of staff, including clinical director, QA lead radiologist, medical physics experts, radiology manager, QA lead radiographer, breast screening services manager, radiographers and assistant practitioners (APs). We spoke to staff in both mobile and static units. This was our first inspection of this service.

Based in Ardmillan house in Edinburgh, the SESBSC provides breast screening imaging and assessment clinic services to those in southwest and central Fife, Scottish Borders, Eastern Forth Valley, Edinburgh and the Lothians and Biggar in South Lanarkshire, who fit the national screening criteria. NHS Lothian have the use of six mobile units for screening. Approximately 55,000 women are screened per year in the named areas.

The inspection team was made up of two inspectors and one observer.

What action we expect NHS Lothian to take after our inspection

The actions that HIS expects NHS Lothian SESBSC 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 HIS.

- **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 three requirements and four recommendations. Requirements are linked to compliance with IR(ME)R.

Safety Culture and Leadership	
Requirements	
	No requirements.
Recommendations	
	No recommendations.

Implementation of IR(ME)R requirements	
Requirements	
1	The South East Scotland Breast Screening centre must articulate in their employer's procedures or similar documents the role of the clinical director and the IR(ME)R duties they are undertaking by signing the invitation letter. Regulation 6(1)(a) Schedule 2(b) (see page 12).
2	The South 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 14).
Recommendations	
a	It is recommended that South East Scotland Breast Screening Centre instruct staff on the location of level one employer's procedures (see page 9).
b	It is recommended that South 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 14).

c	It is recommended that South East Scotland Breast Screening Centre should document the steps that should be taken in the event that a Local Diagnostic Reference Level (LDRL) is exceeded by an agreed factor (see page 15).
d	It is recommended that South 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 18).

Risk and communication	
Requirements	
3	NHS Lothian must add in reference to the SESBSC process for risk communication to the NHS Lothian, Employer Procedures document EP8 (Level 1 procedure). Regulation 6(1)(a) Schedule 2 (i) (see page 22).
Recommendations	
	No recommendations.

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

NHS Lothian SESBSC, must address the requirements and make the necessary improvements as a matter of priority.

We would like to thank all staff at NHS Lothian SESBC 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

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, Employer's Procedures (EPs), optimisation practices, quality assurance systems, as well as the audit and governance arrangements in place.

Staff at the SESBSC reported an open environment to reporting incidents and raising queries. Governance for reporting incidents and outcomes are reported following department procedures and are escalated to the Scottish Breast Screening Programme (SBSP) in National Services Scotland (NSS) as required. Incidents are also reported locally through Datix. Staff we spoke to were aware of the reporting procedures and pathways. Staff members involved in incidents raise the Datix's themselves post incident. Staff we spoke to felt comfortable to raise any issues to senior members of staff and reported an open culture for reporting and discussion of incidents.

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 SESBSC is aligned to the NHS Lothian governance structure for the development of IR(ME)R procedures.

There are three distinct levels of documentation in NHS Lothian. The EPs provided to the inspection team were a sample of level one, level two and level three documents. Level one documentation applies to the whole NHS board, covering all modalities, level two documents are modality specific, in this case covering breast screening. Level three documents in SESBSC are standing operating procedures (SOPs) or work instruction documents, that are procedures focused on breast imaging services within the SESBSC

The review of documents is carried out on a two-year basis. All the breast screening EPS we reviewed were in line with their review dates. Document headers and footers for level one EPs state the review dates and versions of each document. The review date and document version numbers for level two and three documents are available on the online quality management system.

These documents are developed with a multi-disciplinary approach from senior radiographers, MPEs and radiologists as required.

What needs to improve

Staff were not familiar with location of level one EPs and were unable to locate them during the inspection.

Requirement

- No requirements.

Recommendation a

- It is recommended that South East Scotland Breast Screening Centre instruct staff on the location of level one employer's procedures.

Training

All Staff working within breast screening must have a Post Graduate Certification (PG Cert) in Mammography. It is also required that all 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 image reading and reporting of images. They also carry out refresher training with staff members across all breast screening centres in Scotland at various times. Staff members who require additional training in scenarios where their technical rates are higher than 3% can also be referred back to SABI for additional support. The appropriate certifications were found to be in place for qualified staff members.

APs that are signed off as entitled, work under indirect supervision from radiographers. 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.

The SESBSC adopt a way of working whereby two APs may work on a mobile unit without a radiographer present. This remote working has set procedures in place and certain criteria must be met by each AP in order to work under these circumstances. Decisions that require radiographer input for example a technical repeat, must still be authorised by a radiographer. APs will contact the static site to request any imaging or clarify any issues.

Staff we spoke to explained the training requirements and processes that they undertake. We saw evidence of training records and certificates of qualifications. We were shown examples of a variety of AP's and radiographers training records. Staff we met were aware of where to find their training records, were able to access them and were aware of their own individual scope of practice. Individual training records and competencies are reviewed regularly.

The SESBSC employ advanced practitioner radiographers who undertake breast screening reporting, refer and justify secondary screening investigations. To become and maintain competency in image reading, radiographers in training must undertake a review of a minimum of 3000 images under supervision. On completion of their training, they are required to review at least 5000 images a year and have checks on their individual repeat and recall rates to maintain their role and competencies. Post qualifying to read and report on imaging, radiographers may only operate in the first reader role for the first year. New readers will also have their hits and misses reviewed every three months by an appointed mentor.

Radiologists must also undertake a minimum of 5000 images per year to maintain competencies. Arbitration roles are carried out by entitled individuals two to three years post image reading qualification.

Consultant radiologists, consultant radiographers and advanced practitioner radiographers who are involved in the reading of images for breast screening 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), where complex cases are shared with participants and these must be reported back on. Feedback for the cases is also received. This scheme is an element of self-assessment and peer review and is used enhance image interpretation in the screening programme. All individuals in SESBSC that evaluate images are required to take this course once a year and it is part of their QA requirements.

Staff reported having regular access to continuous professional development (CPD) and have sufficient time to undertake learning. They also reported they can request specific time for CPD.

Requirement

- No requirements.

Recommendation

- No recommendations.

Entitlement

Entitlement processes are embedded and defined within the EPs, as per IR(ME)R 2017. A number of these documents, including examples of entitlement letters were shared with the inspection team. There is a clear line of accountability for the entitlement of staff from the employer to the operators.

The clinical director in SESBSC is entitled as the referrer for all those individuals invited for breast screening. The clinical director also has responsibility for entitling other duty holders for their specific roles. The clinical director has provided authorisation to the radiology manager to entitle operators within NHS Lothian SESBSC.

Entitlement documents we viewed were clearly signed by the appropriate persons and available for inspection. The 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. As per the entitlement letters, entitlement is reviewed at staff members annual personal development plan meetings. Training records and entitlement documents are kept centrally for staff to access if required.

Requirement

- No requirements.

Recommendation

- No recommendations.

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 within Scotland.

Women who meet the nationally agreed criteria are invited to attend for breast screening on a rolling three-year basis. The invitation letter is sent from each health board, based on the attendees CHI numbers and registration at a GP practice. The invitation letters from SESBSC are signed by the clinical director. An example of a signed invitation letter was seen at the time of inspection.

Following the review of the screening images, women may be recalled to a review clinic, where their images will be discussed at a clinical assessment meeting. The review clinic lead on the day, who could be a consultant radiologist or consultant radiographer, then decides if the women should go for a secondary investigation which can include the option for tomosynthesis, or other further imaging involving ionising radiation. Referral for assessment clinic is by means of a separate invitation letter, also signed by the clinical director. An example of this type of letter was seen at inspection and signed appropriately. This letter is a form of administration and does not apply as a referral

mechanism. Referral for further imaging in the assessment clinic is the responsibility of the consultant radiologist or consultant radiographer in the review clinic who requests the additional imaging on SBSS. Document BS/S/REVIEW/8 "*Review clinic process"* states that "*women requiring further mammographic assessment, the Consultant Radiographer/Radiologist will act as referrer and practitioner by requesting the examination on SBSS*."

A technical recall is required if the initial image didn't meet the quality standards for a screening image, for example blurring or folds. Referral for technical recall is by means of a new invitation letter from the clinical director. As x-ray imaging will be carried out to complete the initial screening referral, this initial letter is the referral and justification for this repeat imaging.

It was positive to see SESBSC have a level three SOP outlining the referral criteria for assessment clinic imaging. 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

It was clarified at inspection that the invitation letter for breast screening is the referral mechanism, and the exposure has been justified and authorised by the clinical director, who acts as the referrer and practitioner for breast screening. However, these roles were not clearly outlined in the EP's.

Requirement 1

- The South East Scotland Breast Screening centre must articulate in their employer's procedures or similar documents the role of the clinical director and the IR(ME)R duties they are undertaking by signing the invitation letter. Regulation 6(1)(a) Schedule 2(b).

Recommendation

- No recommendations.

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 an agreed national population and criteria. The justification for exposure is assumed to be applied at the invitation stage of the screening process by means of an invitation letter. Clinical justification is carried out in the clinical setting by entitled operators prior to exposure.

When a woman attends for screening, the previous imaging is reviewed to ensure that no images have been taken in the previous six months. Staff have access to Scottish Breast Screening System (SBSS) and Picture Archiving and Communication System (PACs) and national PACS to check the imaging history. In addition, the women are asked about any previous imaging including any that was taken outside of Scotland or in private healthcare. If there are any doubts imaging will not be undertaken. Staff on the mobile units can contact the static units to check previous imaging if PACs is not available.

Technical repeats are additional images taken when the initial images do not meet the quality standards and are deemed inadequate by entitled radiographers.

Further imaging can also be justified based on a review of the screening images by entitled consultant radiologists, consultant radiographer or advanced practitioners following a review of the screening images. As images are reviewed by the readers on monitors with a much greater pixelation they will be able to identify areas of blurring that may not have been visible on the mobile unit. Readers determine if further imaging or examinations are required such as a tomosynthesis, stereotactic biopsy exposures, technical recall and technical repeat. A reason for further imaging is recorded in the SBSS system.

The consultant radiologist or consultant radiographer will define which imaging is required and justify these as the practitioner. The views being added to SBSS is evidence of justification.

In the review clinic, each individual case is discussed each morning and the women requiring further imaging are identified. The consultant radiologist or consultant radiographer act as the referrer and the practitioner for further imaging taken in 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. The system records the referrer and there is an assumption that this is also the justifier. In relation to assessment clinic imaging the document EP2/BSP/04 Justification and authorisation of medical exposures states "*The Radiologist or Consultant radiographer will define which imaging is required and justify these as the practitioner. The views being added to SBSS is evidence of justification."*

Although a staff discussion was had for each woman attending the assessment clinic, it was unclear where the relevant clinical history for justification of secondary image is documented for each person.

Requirement 2

- The South 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).

Recommendation b

- It is recommended that South 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 SESBSC have adopted the Scottish DRLs as set by NSS. NSS have developed a range of four DRL's that cover 80% of women, in comparison the national DRL only has one DRL range that covers 10% of women. We were told that due to the comprehensive DRLs it is not common for the operators to exceed the DRLs when imaging. DRL charts were visible at the operator console at the static and mobile sites. Staff were aware of the use of DRLs when questioned.

The dose for each image is recorded on the individual image on PACs and dose factors can be retrieved on the console of the x-ray unit. Operators can also see the given dose on exposure to the women.

What needs to improve

On inspection, exposure charts for the recommended values were visible on the walls in the static centre and mobile unit. Level one document EP9 Diagnostic Reference Levels (DRLs) states *that "examinations for which the DRL is significantly exceeded and for which there is no apparent reason for the increased dose due for example to patient size, the Operator should consider whether there may have been an equipment or procedural error and if so that should be reported as a radiation incident in accordance with EP11."* There is no information in the EPs that clarifies or defines what constitutes as "significantly exceeding" the DRL, where there is no apparent reason for the increased dose and which requires further investigation.

Requirement

- No requirements.

Recommendation c

- It is recommended that South East Scotland Breast Screening Centre should document the steps that should be taken in the event that a Local Diagnostic Reference Level (LDRL) is exceeded by an agreed factor.

Operator

There are a set of operator procedures in place. Staff were familiar with the operators' procedures and could locate them if required. Staff were familiar with the 4 national DRLs. Staff described the process for imaging women including the need to review previous imaging, ID checks, accurately position the women and breast, number of views, adequate compression and imaging women with breast implants or implantable devices.

Staff reported they will always work in a team of two operators, or an additional member if someone is in training and therefore requires direct supervision. APs have a certain scope of practice and are therefore not entitled to carry out all aspects of the screening process. AP staff were aware of their responsibilities and role when seeking help and authorisation from radiographers for example when requesting a technical repeat. The SESBSC employ a system whereby two APs may work together on a mobile unit. Procedures are in place to ensure that it is routine screening only that is carried out in this scenario. If women attend for screening and have breast implants or implantable devices, they are reappointed as APs cannot undertake these tasks. A level three SOP is in place, BS/S/SCREENING/14 "*Assistant Practitioner Scope of practice...*" which outlines the criteria both the APs must fit in order to work in these circumstances for example must be qualified a minimum of two years and have a technical recall

rate of <3%. Should assistance be required for APs in the remote working environment, a phone call is made to the static unit whereby confirmation can be received. This phone call discussion is documented on SBSS including the involved radiographer's unique identification number.

Requirement

- No requirements.

Recommendation

- No recommendations.

Records

SESBSC uses an online QMS system for upkeep and management of all EPs. Documents were accessible at the mobile unit, with paper copies also available for some documents in the event of failure to access the internet in remote areas. Screening records are held on the national SBSS system and follow the individual's screening pathway and history.

Requirement

- No requirements.

Recommendation

- No recommendations.

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.

For women who require an interpreter, these services are available.

Level one document EP 5 outlines the procedure for identifying patients by asking the clients to recite their information to staff. Level three SOP BS/S/SCREENING/15 and BS/S/SCREENING/16 "*protocol for screening…"* outlines the procedure specific for screening processes and that ID checks and pre-exposure questions are recorded on SBSS.

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

Requirement

- No requirements.

Recommendation

- No recommendations.

Clinical evaluation

Clinical evaluation is the clinical interpretation of an image and the recorded outcome (documentary evidence) of that reading. Clinical evaluation can only be performed by operators who have undertaken specialist training and achieved a recognised qualification in breast image interpretation and are entitled to do this task by the employer. All readers in SESBSC have undertaken training and achieved competencies to be entitled to carry out this role. All the images in SESBSC are read by two readers. The readers are a mix of consultant radiologists, consultant radiographers and entitled advanced practitioner radiographers.

For each image acquired, both readers are required to record their clinical outcome and reach a consensus on the findings. All images are reported on SBSS with an outcome of routine recall or further referral. Where there is a difference of opinion on image reading an arbitrator will review the images to provide a third reading. Systems are in place for the role of the arbitrator, that they must be a minimum of 2-3 years post image reading qualification in order to act in this role.

It was confirmed that no artificial intelligence is used in the reading of breast screening images in SESBSC.

What needs to improve

There are three options available when reading an image in order record the clinical findings at the initial reading. These options include “Routine Recall”, “Technical Recall” and “Assessment Clinic”. As there is no option to write the findings or lack of 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 informs the woman that their images were satisfactory, and they are to be placed back on the routine list for screening. The letter is seen as an outcome from the clinical evaluation. 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.

Requirement

- No requirements.

Recommendation d

- It is recommended that South 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

MPEs from NSS provide the expert physics advice for the screening programme across Scotland. NHS Lothian MPEs are informed of local Datixs 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 of new equipment
- 6 monthly and annual quality assurance of equipment
- dose monitoring and
- analysis of incidents.

NSS MPE provision carry out the procurement and commissioning of all equipment for the SESBSC. There are representatives from NHS Lothian that are included in this process.

NSS MPEs carry out a range of audits and reports, e.g. dose monitoring, image quality. Results from these reports and audits are disseminated back to SESBSC for learning.

Whilst the NSS MPE are not based in the SESBSC, they are readily available for support from both static centre and mobile units via phone or online. Strong collaboration between the employers and services was evident at the inspection between NHS Lothian, SESBSC and NSS MPEs.

Requirement

- No requirements.

Recommendation

- No recommendations.

Contracted services

No locum or agency staff are utilised in the SESBSC. No third-party external imaging reporting services are outsourced for image reading.

Requirement

- No requirements.

Recommendation

- No recommendations.

General duties in relation to equipment

QA procedures, tests and tolerances are set by the NSS MPE provision. A comprehensive QA manual, provided and compiled by NSS MPEs, is available to staff undertaking QA tasks. The QA manual is available online for all staff to access. It was confirmed the most recent version is being used in the SESBSC.

Training for QA testing is delivered by the MPEs to the staff in each centre. All staff in SESBSC are required to be signed off as competent before undertaking the QA checks by themselves. All operators are trained to undertake QA checks apart from needle QA checks where APs are not entitled to carry these out. These include the daily, weekly and monthly tests. The 6 monthly and annual tests are carried out by NSS MPEs. These tests are more comprehensive, and dedicated time is provided for these tests to be undertaken.

The imaging equipment has the required QA tests programmed for the relevant days. There are clear escalation procedures in place for equipment that was found to be out of tolerance. Remedial and suspension levels were discussed and tolerances available to staff. Routes of escalation for faults and equipment issues were known by the staff that we spoke to, and clear procedures are in place. Records are in place by means of a fault log and maintained appropriately. Online live spreadsheets are used to input data from the daily, weekly and monthly QA tests, which highlights if a result is out of tolerance. There was evidence of remedial action being taken for faults and issues. QA testing also includes image quality to ensure that the images are clinically optimised.

When QA is undertaken and if an artefact is present and considered as minor, the operator will contact the consultant radiologist to ask whether the location of the artefact will impact on the ability of the reader to carry out a clinical evaluation, until such time as it is rectified.

The SESBSC covers a large geographical area, and the mobile units travel to cover the wider population. As equipment may be affected by the movement, a specific QA checklist is to be completed before screening any patients. Procedures are in place for these post move checks of the mobile unit.

When an engineer requires to visit and undertake a repair, staff confirmed that they would always undertake the daily QA again before putting the equipment back in use. It was confirmed that there is dedicated time in the day to undertake QA. The use of signage is used to visibly see when a unit is not for clinical use, for example if an engineer is on site.

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

Requirement

- No requirements.

Recommendation

- No recommendations.

Clinical audit

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

All staff undertake a self-assessment audit on previous images they have taken using the PGMI (Perfect, Good, Moderate, Inadequate) 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 5 images per staff member. Staff are informed monthly of their individual technical recall rate.

The QA lead radiographer regularly audits recall and retake rates. This data is monitored for all staff, and all staff are provided with feedback on the outcomes of the audits and rates.

Audits on interval cancer rates are used to drive learning and performance improvement. Single reader pick-ups and misses are also reviewed and data is fed back to the individual readers and discussed during their appraisal process. Interval cancer meetings are carried out every three months. A report from these figures is generated to go towards the national data on interval cancers.

QA lead radiologists in the SBSP have a continuous audit programme, which includes all six breast screening centers in Scotland. These audits include visiting the centers in person and having virtual meetings. QA lead radiographers have a similar national audit programme. Information from the annual reports is shared nationally. The QA lead radiologist and QA lead radiographer in SESBSC feed into these national audit programmes.

Requirement

- No requirements.

Recommendation

- No recommendations.

Accidental or unintended exposure

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

Incidents are raised at a local level through Datix. Staff involved fill out the required information including a reflection. Radiation incident forms are also passed on to medical physics. Incidents are raised to NSS MPEs and investigated as required.

An annual report which includes incident details, is sent to the NHS Lothian IR(ME)R board for discussion.

Learning from incidents is shown in a yearly report highlighting any trends. Level three document BS/S/SCREENING/27, states "*All incidents on Datix will be discussed with staff member(s) involved and investigated by the Management Team*." All staff are further informed of incidents at a yearly staff meeting.

Requirement

- No requirements.

Recommendation

- No recommendations.

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

Risk benefit conversations are navigated through patient information provided by the SBSP and public forums for example, NHS Inform. An information leaflet, containing risks and benefits of screening, including the risks from radiation, is sent alongside the invitation letter to all those eligible for screening. The letter contains a phone number for women to call 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. Posters were visible in the department highlighting benefits and risks.

What needs to improve

A level one EP is in place for communication of benefits and risks, however, it does not allude to screening mammography. There are no level two or level three documents in place to cover screening processes.

Requirement 3

- NHS Lothian must add in reference to the SESBSC process for risk communication to the NHS Lothian, Employer Procedures document EP8 (Level 1 procedure). Regulation 6(1)(a) Schedule 2 (i).

Recommendation

- No recommendations.

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.

The guidance also notes that mammography is not routinely performed when a woman is breastfeeding, due to the density changes in the breast tissue. Documentation in NHS Lothian states that three months after breast feeding has stopped, screening can be carried out.

Requirement

- No requirements.

Recommendation

- No recommendations.

Carers and comforters procedures

Whilst there are EPs in place covering the wider radiology service at level one (EP 21), and a level two breast screening specific document (EP2/BSP/10), for comforters and carers, these procedures are reported to not be required in the breast screening programme in NHS Lothian. It was reported that if the women are not able or suitable for imaging 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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