



Healthcare  
Improvement  
Scotland

Inspections  
and reviews  
To drive improvement

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

**Service:** Borders General Hospital, Melrose

**Service provider:** NHS Borders

15-16 May 2023

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# 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.

The quality assurance system and the quality assurance framework allows us to provide external assurance of the quality of healthcare provided in Scotland. We have aligned the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017 to the quality assurance framework.

## 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 well services are led, managed and delivered.

## About our inspection

We carried out an announced inspection to Borders General Hospital, Melrose on Monday 15 and Tuesday 16 May 2023. We spoke with staff, including the radionuclide consultant, radiologists and radiographers. The service provides iodine therapy and diagnostic nuclear medicine.

The inspection team was made up of two inspectors.

## What action we expect NHS Borders to take after our inspection

The actions we expect NHS board 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 and where failure to do so will not directly result in enforcement.

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

Implementation and delivery	
Requirement	
<b>1</b>	<p>NHS Borders must ensure they have access to training records that demonstrate the competency of the surgeon entitled as an operator to use the gamma probe based (see page 13).</p> <p><i>Regulation 17</i> <i>Ionising Radiation (Medical Exposure) Regulations 2017</i></p>
Recommendations	
<b>a</b>	NHS Borders should update its employer's procedure to include which staff groups are authorised to assess competency (see page 14).
<b>b</b>	NHS Borders should calculate the provision of medical physics expert required to safely deliver nuclear medicine (see page 14).

An improvement action plan has been developed by the NHS board and is available on the Healthcare Improvement Scotland website.  
[https://www.healthcareimprovementscotland.org/our\\_work/inspecting\\_and\\_regulating\\_care/ionising\\_radiation\\_regulation.aspx](https://www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/ionising_radiation_regulation.aspx)

NHS Borders, must address the requirement and make the necessary improvements as a matter of priority.

We would like to thank all staff at Borders General Hospital for their assistance during the inspection.

## 2 What we found during our inspection

### Direction

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

Domain 1: Clear vision and purpose

Domain 2: Leadership and culture

#### 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

**We saw evidence of an excellent safety culture in place within the nuclear medicine service. Strong leadership and effective collaboration with NHS Lothian, who provide medical physics experts and nuclear medicine consultants.**

#### Entitlement

Employer's procedure EP1 (Entitlement of duty holders for medical exposures) is a comprehensive procedure that outlines the process for entitlement across the NHS board. The policy clearly states who assesses competency of staff and who issues entitlement. All staff who are entitled to act as a referrer, practitioner or operator are issued a written record of their scope of practice.

We saw evidence of regular review of staff training and practice to ensure their competency for entitlement. For example, a radiographer's role had changed and they were no longer involved in nuclear medicine – their scope of practice was updated to reflect this change.

#### Safety culture

All staff we spoke with told us about a supportive and positive safety culture in place. We heard about an open culture for reporting incidents and a focus on learning from errors and sharing learning across the team.

In the event of an incident or near miss, staff felt confident to report it. We are assured staff are supported during an investigation and any sharing of learning that follows.

Robust procedures are in place for the storage and dispensing of radiopharmaceuticals (pharmaceutical drugs that contain radioactive isotopes).

This is essential to ensure patient doses are the correct prescription at the right activity level. We saw staff comply with these procedures as they carried out daily calibration checks, which were then recorded. We also saw staff measure and confirm the activity level for the second time immediately before being administered to the patient. This was then recorded and confirmed by a second radiographer. All staff we spoke with were clear about the activity tolerance levels of each radiopharmaceutical and told us they would not proceed if the activity level had fallen outwith these.

All staff we spoke with were aware of the risks of extravasation (the leakage of radioactive material) and the potential for it to change the radiopharmaceutical activity the patient receives. Staff told us that a small spillage would result in the cannula being moved to a fresh site. However, a tissue cannula (when a cannula makes its way out of the vein and the radioactive fluid builds up in the surrounding tissue) is immediately reported to senior staff and the planned exposure cancelled, in line with policy. They told us if a small amount of the radiopharmaceutical accumulates at the injection site, this would be noted on radiology information system. This ensures the radiologist is aware when evaluating the image.

Staff assured us previous imaging is always considered before a nuclear medicine exposure is justified.

### Optimisation

Appropriate methods were used to ensure the dose is as low as reasonably practicable when carrying out nuclear medicine exposures. This included prescriptions for potassium iodide before dopamine transporter (DAT) scan to ensure the radiopharmaceutical do not enter the thyroid. Additionally, hydration is encouraged before nuclear renal scans to reduce the risk of the radiopharmaceutical gathering in the kidney.

Both NHS Borders and NHS Lothian demonstrated a collaborative approach to optimisation. Audits are carried out to align protocols across the two NHS boards and to compare doses and image quality across sites with the same equipment. When any issues are identified with the gamma probe, a comparison audit is carried out on NHS Borders and NHS Lothian data. This would result in an action plan and optimisation of the gamma probe.

### **What needs to improve**

COMARE 16<sup>1</sup> recommends multidisciplinary dose optimisation teams are established. While NHS Borders has a formal multidisciplinary dose optimisation group with representation from all modality leads including nuclear medicine, there is no nuclear medicine medical physics expert represented on the group. We were told this is being progressed.

- No requirements.
- No recommendations.

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<sup>1</sup> Committee on Medical Aspects of Radiation in the Environment (COMARE): 16th Report. Public Health England. 14 August 2014



## Implementation and delivery

This is where we report on how well the service engages its stakeholders and also how it manages and improves performance.

Domain 3: Co-design, co-production	Domain 4: Quality improvement	Domain 5: Planning for quality
<b>Key questions we ask:</b> <i>How well does the service engage its stakeholders?</i> <i>How well does the service manage and improve performance?</i>		

### Our findings

**We saw evidence of a robust approach to the implementation of IR(ME)R underpinned by clear and comprehensive procedures, staff training and specialist input.**

#### Employer's procedures

Level 1 and level 2 employer's procedures are in place, which cover all modalities. Level 3 employer's procedures are a comprehensive set of local rules that provides detailed policies for nuclear medicine.

All employer's procedures are reviewed every 2 years, carried out by the lead radiographer with support from relevant clinical specialists as required. Level 3 policies are reviewed by the modality lead. Any changes to employer's procedures are discussed and agreed at the radiation and MRI safety committee. All confirmed changes are communicated to staff at team meetings and by email. Changes can be made outwith the regular review period if a clinical need is identified.

#### What needs to improve

We saw a general procedure indicated unlicensed products can be justified. However, we are assured NHS Borders are addressing this error.

#### Training

We saw all radiographers have up to date training records in place. These include training on each piece of equipment they will use, including the calibrators. Each radiographer is deemed as competent and their training record signed by a senior member of staff before they use the equipment independently.

Nuclear medicine consultants and medical physics experts who provide services in NHS Borders are trained by NHS Lothian. We are assured this training is carried out and is reviewed at appraisals each year.

### **What needs to improve**

We saw evidence of a surgeon who was entitled as an operator to use the gamma probe based on their training and experience in NHS Lothian. NHS Borders do not have access to this training record (requirement 1).

While we were assured staff were being appropriately assessed as competent to be entitled to carry out their duties, the employer's procedures did not identify which staff groups can authorise competency (recommendation a).

### **Referral**

Referrals are received electronically through an online portal or by email. A link between the online portal and the radiology information system allows clinicians to cancel referrals, which will notify the radiology department. Referrals are printed off so that the administered isotope can be printed directly on to the request form.

Referrals for radioiodine therapy can only be made by endocrinologists. Referrals for diagnostic nuclear medicine are received from a variety of sources. We saw clear clinical guidelines for referral, including steps to take to consider alternative lower dose options before referring for nuclear medicine. We were told about a few occasions when a DAT nuclear medicine study was requested without a CT scan first taking place. The DAT scan would be refused and the CT scan requested. Only if the clinical indications from the CT scan confirm the need for a DAT scan would it be authorised.

All staff told us that if a referral does not have sufficient clinical information to justify the exposure, it will be returned.

### **Justification**

Diagnostic nuclear medicine covers a variety of exposures. NHS Borders use technetium-99 for cardiac ventriculography, bone scans, sentinel node, thyroid, parathyroid and renal scans and lung scans. We saw a clear and comprehensive policy outlining the examination type that can be justified by each staff group. These have been developed in line with the Society for Nuclear Medicine Guidelines, the British Nuclear Medicine Society guidelines, the Royal College of Radiologists and the Administration of Radioactive Substances Advisory Committee (ARSAC) notes for Guidance.

Radioiodine is used in therapeutic nuclear medicine interventions in NHS Borders. Only the endocrinologist is entitled to justify these procedures. The same endocrinologist is also involved in overseeing the therapy.

Hyperthyroidism has a complex patient pathway to be followed before nuclear medicine exposure is justified. We saw the stages of this pathway set out in a local policy. We also saw a clear policy to support staff in balancing the risks of exposing a foetus to a high dose of radiation during a lung scan, which requires complex decision making.

### **What needs to improve**

Only the endocrinologist, who is the ARSAC license holder, is entitled to justify iodine therapy. This can lead to delays in justification when they are on periods of leave.

### **Records**

We looked at the information recorded on the radiography information system and noted that staff had documented:

- the correct patient information
- details of the referrer and operator
- identification checks
- pregnancy checks
- the recorded dose
- the radiopharmaceutical
- justification, and
- clinical evaluation.

The radiology information system allows staff to record information specific to nuclear medicine, including the activity level of the radiopharmaceutical as it was dispensed.

### **Patient identification**

All staff we spoke with told us patient identification checks are always carried out, which includes name, date of birth, address, who made the referral and the reason for the procedure. We were told the employer's procedure is being updated and will reflect all of these factors.

We were told if a patient could not identify themselves, and were not accompanied by a person who could do so for them, the exposure would not

proceed. All staff were aware of communication aids, such as language line, to provide support to any communication barriers.

### Expert advice

Medical physics expertise is provided by NHS Lothian as part of a service level agreement. NHS Borders has an appointment letter for the medical physics expert and they are registered on RPA2000.

The medical physics expert provide support with:

- commissioning of new equipment, including the SPECT CT, gamma probe and calibrator
- acceptance testing of new equipment
- local dose reference levels
- establishing baselines for quality assurance
- training in quality assurance
- monthly calibration of equipment
- investigation if quality assurance is outwith tolerance levels
- exploring software solutions
- optimisation, and
- development of employer's procedures.

They also provide support on the analysis of incidents and advice on whether an incident requires to be reported to Healthcare Improvement Scotland.

Staff told us the medical physics experts are easily contactable and available for advice and support.

### What needs to improve

The medical physics expert resource provided by NHS Lothian is based on historical arrangements – no assessment has been carried out to check if it meets the current need (recommendation b).

### General duties in relation to equipment

The medical physics expert conducts regular quality assurance of equipment. They also provide training for radiographers to carry out checks every month on the gamma probe and daily checks of the SPECT scanner. A record of all quality assurance checks is kept on a spreadsheet, which highlights if the results fall outwith the tolerance range. All staff told us if this happens, the quality assurance check is repeated. If it continues to be outwith tolerance, the

equipment is removed from use and the medical physics expert and lead radiographer are informed. All staff we spoke with also told us that quality assurance checks must be carried out following a visit from an engineer.

Dose reference levels are displayed in the dispensing room. They have been developed using the ARSAC baseline levels and local optimisation is carried out regularly.

### Clinical audit

A comprehensive audit is carried out every 3 months where 20 patient records are selected to review the following.

- Whether the ARSAC baseline dose reference levels has been exceeded.
- The code for the operator and justifier are correct and within their scope of practice.
- Two radiographers have completed all checks.
- Pregnancy status checked are carried out, if relevant.
- Whether any non-medical referrers have made referrals within their scope of practice.
- That the clinical evaluation has been completed.
- Any concerns about the clinical information in the referral are investigated.

In addition to clinical audits, radiologists use clinical forums for peer review and learning. The radiology event and learning meeting (REALM) allows staff the opportunity to review scans and clinical reporting. Multidisciplinary review meetings also provide an opportunity for exposures to be peer reviewed. If any discrepancies are found in the clinical evaluation, they are recorded on radiology information system to inform clinical decision making and learning.

### Accidental or unintended exposure

All staff we spoke with fully understood the SAUE guidance and the local protocols for recording and reporting any near misses of incidents. While no nuclear medicine incidents or near misses have taken place in the last 2 years, we saw clear processes in place to share learning from any incidents.

### Requirement 1

- NHS Borders must ensure they have access to training records that demonstrate the competency of the surgeon entitled as an operator to use the gamma probe based.

### **Recommendation a**

- NHS Borders should update its employer's procedure to include which staff groups are authorised to assess competency.

### **Recommendation b**

- NHS Borders should calculate the provision of medical physics expert required to safely deliver nuclear medicine.

## Results

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

Domain 6: Relationships	Domain 7: Quality Control
<b>Key questions we ask:</b> <i>What difference has the service made?</i> <i>What has the service learned?</i>	

### Our findings

**We saw evidence of a robust approach to sharing of risk benefit information.**

#### Risk benefit conversations

We saw evidence of a robust approach to sharing risk benefit information with patients. Written information is provided with the appointment letter. On the day of the procedure, the radiographer will discuss risk benefits with the patient and check they have read and understood the information sent with the appointment letter. If not a copy will be shared before proceeding. Family members or carers are included in the discussion as needed. The discussion will include any actions required following treatment to reduce exposing other people to the radiation.

#### Making enquiries of individuals who could be pregnant

All staff we spoke to told us that all patients of child bearing age will be asked to confirm their pregnancy status. Those who are not pregnant will be asked to sign a form to confirm this. In the event pregnancy is suspected, the exposure is delayed until the patient can confirm they are not pregnant.

If a patient is pregnant, and an exposure is essential, a detailed protocol is followed to reduce the dose and the risk to the foetus.

#### Carers and comforters procedures

Risk benefit information is provided to carers and comforters. This includes the risks to them and advice in reducing the risk of exposure. If a child does require a carer or comforter during the procedure, this is recorded in the patients' notes and further information provided on the day.

- No requirements.
- 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.

The quality assurance system and the quality assurance framework together allows us to provide external assurance of the quality of healthcare provided in Scotland.

- **The quality assurance system** brings a consistency to our quality assurance activity by basing all of our inspections and reviews on a set of fundamental principles and a common quality assurance framework.
- **Our quality assurance framework** has been aligned to the Scottish Government's *Health and Social Care Standards: My support, my life* (June 2017). These standards apply to the NHS, as well as independent services registered with Healthcare Improvement. They set out what anyone should expect when using health, social care or social work services.

We have aligned the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017 to the framework.

Further information about the framework can also be found on our website at: [The Quality Assurance System \(healthcareimprovementscotland.org\)](https://www.healthcareimprovementscotland.org)

### 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.



After our inspections, we publish a report on how well a service is complying with IR(ME)R and its performance against the Healthcare Improvement Scotland quality assurance framework.

## Complaints

If you would like to raise a concern or complaint about an independent healthcare service, you can complain directly to us at any time. However, we do suggest you contact the service directly in the first instance.

Our contact details are:

### **Healthcare Improvement Scotland**

Gyle Square  
1 South Gyle Crescent  
Edinburgh  
EH12 9EB

**Telephone:** 0131 623 4300

**Email:** [his.irmer@nhs.scot](mailto:his.irmer@nhs.scot)

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## Healthcare Improvement Scotland

Edinburgh Office  
Gyle Square  
1 South Gyle Crescent  
Edinburgh  
EH12 9EB

0131 623 4300

Glasgow Office  
Delta House  
50 West Nile Street  
Glasgow  
G1 2NP

0141 225 6999

[www.healthcareimprovementscotland.org](http://www.healthcareimprovementscotland.org)