



Healthcare
Improvement
Scotland

Inspections
and reviews
To drive improvement

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

Service: University Hospital Monklands, Airdrie

Service Provider: NHS Lanarkshire

3 and 5 July 2023

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

© Healthcare Improvement Scotland 2023

First published September 2023

This document is licensed under the Creative Commons Attribution-Noncommercial-NoDerivatives 4.0 International Licence. This allows for the copy and redistribution of this document as long as Healthcare Improvement Scotland is fully acknowledged and given credit. The material must not be remixed, transformed or built upon in any way. To view a copy of this licence, visit <https://creativecommons.org/licenses/by-nc-nd/4.0/>

www.healthcareimprovementscotland.org

Contents

1	A summary of our inspection	4
<hr/>		
2	What we found during our inspection	7
<hr/>		
	Appendix 1 – About our inspections	17
<hr/>		

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 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 University Hospital Monklands, Airdrie on Monday 3 and Wednesday 5 July 2023. We spoke with radiologists and nuclear medicine staff, an endocrinology consultant and the medical physics expert.

Based in Airdrie, University Hospital Monklands provides diagnostic and therapeutic nuclear medicine.

The inspection team was made up of two inspectors.

What action we expect NHS Lanarkshire to take after our inspection

The actions that Healthcare Improvement Scotland expects the 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 but where failure to do so will not directly result in enforcement.

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

Direction	
Requirements	
1	NHS Lanarkshire must ensure up-to-date entitlement documentation is in place for all staff who are entitled to act as practitioners and operators. This includes endocrinologists, plastics (melanoma) and breast surgeons (sentinel node work) (see page 8). <i>Regulation 6 Ionising Radiation (Medical Exposure) Regulations 2017</i>
Recommendations	
a	NHS Lanarkshire should ensure robust processes are in place to provide assurance to the IR(ME)R lead that all IR(ME)R processes are being followed, including entitlement and training (see page 9).
b	NHS Lanarkshire should review its workforce planning to ensure a second person is always present to carry out independent checks when administering radiopharmaceuticals (see page 9).

Implementation and delivery	
Requirement	
2	NHS Lanarkshire must ensure up-to-date training records are in place for all staff, including plastic and breast surgeons using the gamma probe (see page 14). <i>Regulation 17(4) Ionising Radiation (Medical Exposure) Regulations 2017</i>
Recommendations	
	None.

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

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

We would like to thank all staff at University Hospital Monklands 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 an excellent safety culture in place – staff are aware of their responsibilities and strive for excellence.

Entitlement

Employer's procedure EP1 (entitlement of duty holders for medical exposure) outlines the process of entitlement. EP2 (Procedure to identify individuals entitled to act as referrers, operators and medical physics experts) outlines the roles and responsibilities of those who are entitled. This policy is comprehensive and clearly sets out who is responsible for assessing competency and authorising each scope of practice and entitlement.

Nuclear medicine staff all received entitlement documents, which matched their training records and activities they had been assessed as competent to carry out.

What needs to improve

Surgical and endocrinology staff did not all have up-to-date entitlement documents that matched their ARSAC licenses (requirement 1).

No assurance processes were in place to ensure the IR(ME)R lead was confident that IR(ME)R is being implemented consistently (recommendation a).

Safety culture

All staff we spoke with understood the safety protocols in nuclear medicine. Specialist training is provided that includes how to respond to an event of extravasation (the leakage of radiopharmaceutical materials out of the enclosed space into the surrounding area of the body).

All staff we met with told us of a supportive and positive safety culture. In the event of a near miss or incident they all felt confident to report this. We were assured they would be supported during an investigation and any learning is shared. All of the staff we spoke with assured us previous imaging is always considered before a nuclear medicine exposure would be justified.

Robust procedures were 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 member of the nuclear medicine staff. All staff we spoke with were clear about the ARSAC DRLs of each radiopharmaceutical and told us they would not proceed if the activity level had fallen outwith these.

ARSAC DRLs were clearly on display. All staff we spoke with were clear about the activity tolerance levels of each radiopharmaceutical. Staff demonstrated good knowledge and understanding. This was particularly evidence while preparing individual patient doses for dispensing and ensuring activity levels were within tolerance before proceeding with the administration.

What needs to improve

We were told it is standard practice is to have a second person present at the time of drawing radiopharmaceuticals, but staff told us it was not always possible due to staff shortages. It is recommended by the UK Radiopharmacy Group that two members of staff witness the drawing up of radiopharmaceuticals to provide an independent check to reduce the risk of errors (recommendation b).

Optimisation

NHS Lanarkshire has robust approach to image optimisation. Multidisciplinary groups are in place that regularly review optimisation of images and consider lower doses in diagnostics. A nuclear medicine group is also being set up.

Requirement 1

- NHS Lanarkshire must ensure up-to-date entitlement documentation is in place for all staff who are entitled to act as practitioners and operators. This includes endocrinologists, plastics (melanoma) and breast surgeons (sentinel node work).

Recommendation a

- NHS Lanarkshire should ensure robust processes are in place to provide assurance to the IR(ME)R lead that all IR(ME)R processes are being followed, including entitlement and training.

Recommendation b

- NHS Lanarkshire should review its workforce planning to ensure a second person is always present to carry out independent checks when administering radiopharmaceuticals.

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
Key questions we ask: <i>How well does the service engage its stakeholders?</i> <i>How well does the service manage and improve performance?</i>		

Our findings

NHS Lanarkshire have comprehensive employer's procedure in place. We saw good approaches to training and audit as well as robust referral pathways.

Employer's procedures

NHS Lanarkshire have level 1 and 2 employer's procedures cover all modalities. A comprehensive set of employers procedures are also in place to provide detailed policies for nuclear medicine.

Employer's procedures are reviewed every 2 years by the head of nuclear medicine and other relevant parties as required, such as any specialist services. All changes are communicated to staff verbally.

Training

All nuclear medicine staff training records were up to date. Application specialists train the nuclear medicine staff to use equipment and carry out quality assurance checks. They are also trained to use the calibrators and carry out cannulation and responding efficiently in the event of extravasation. Each member of nuclear medicine staff are deemed as competent by a senior member of staff and their training record signed off before they use any equipment on their own.

All members of the nuclear medicine team carry out regular training. Attendance at conferences is promoted and learning shared across the team.

What needs to improve

Training records were not in place for the plastic and breast surgeons using the gamma probe (requirement 2).

Referral

Referrals are received electronically using an online clinical system or by email from a variety of sources. Clear clinical guidelines are in place for referral, and staff will consider alternatives before referring for an exposure with high doses of radiation. Staff told us if a referral does not have sufficient clinical information to justify an exposure it would be returned.

The head of nuclear medicine plans to circulate a newsletter to highlight the referral pathways for nuclear medicine. This will be shared with all NHS Lanarkshire staff.

Justification

Diagnostic nuclear medicine covers a variety of exposures. NHS Lanarkshire use technetium-99m and selenium-75 for diagnostic scans. Justifications are carried out by medical staff, with the exception of the administration of radiopharmaceuticals for the localisation of sentinel nodes. These are justified by radiographers under protocol. Staff we spoke with were very clear on what clinical information was required for justification.

Radioiodine is used in therapeutic nuclear medicine interventions. Only the endocrinologists are entitled to justify these procedures.

All staff we spoke with were clear about justification of lung scans during pregnancy. A protocol is in place that supports clinicians balancing these risks and benefits of exposing the foetus.

Records

The radiology information system has a separate nuclear medicine tab. This facilitates recording of the dose, time, isotope administered and the name of the operator who carried out the initial and the secondary checks.

We saw information recorded on the radiology information system included the following:

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

- clinical evaluation.

Patient identification

All staff we spoke with could describe the patient identification checks carried out and included name, date of birth, address, name of the referrer and the reason for referral. We also saw staff carry out these checks.

We were assured if a patient could not identify themselves, and were not accompanied by an adult who could do so for them, the exposure would be cancelled. All staff were aware of communication aids available to assist communication.

Expert advice

Medical physics expertise is provided by the head of the nuclear medicine department. He has an appointment letter and is registered with RPA2000 (certified competent in IR(ME)R protection practice).

The medical physics expert provides support with:

- commissioning of new equipment
- acceptance testing of new equipment
- establishing baselines for quality assurance
- calibration of equipment and establishing new methods of calibration of gamma probes
- investigation if quality assurance is outwith tolerance levels
- optimisation
- dose reference levels
- staff training
- development of employer's procedures, and
- analysis of incidents.

The medical physics expert also provides advice on whether or not an incident requires to be reported to Healthcare Improvement Scotland.

General duties in relation to equipment

Staff are trained by application specialists to carry out daily quality assurance checks. All staff we spoke with were clear on the process and how to identify any issues with equipment. We observed the daily quality assurance process, staff were confident and competent in the use of the flood source used for quality control on the gamma camera system. A record of all quality assurance

checks is kept on a spreadsheet and shared with the medical physics expert, who will also carry out more comprehensive checks regularly.

Staff told us if a piece of equipment outwith the accepted tolerance levels, the quality assurance check is repeated. If it continues to be outwith tolerance the equipment is removed from use and the medical physics expert informed. All staff we spoke with also told us that quality assurance checks are carried out either by the nuclear medicine staff or the engineer following a visit.

The surgical gamma probes have a regular quality assurance programme in place. The medical physics expert introduced an additional programme of comprehensive quality assurance for the probe that they will start to carry out shortly.

Clinical audit

A monthly audit is carried out on 10 patient records. Compliance with IR(ME)R is checked on each record. This includes:

- details of the operator and justifier
- any complete pregnancy checks
- patient identification checks
- clinical evaluation
- dose, and
- signed by the referrer.

Radiologists also carry out audits on sentinel node exposures. All staff told us that learning from audits is shared and learning opportunities are identified.

Radiologists utilise multidisciplinary review meetings as an opportunity for exposures to be peer reviewed by other radiologists and specialists. Any discrepancy in the clinical evaluation is recorded on radiology information system. This assists with learning from clinical decision making and radiologists continued learning. Radiology event and learning meetings (REALMs) also provide the opportunity to review scans and clinical reporting.

Accidental or unintended exposure

All staff we spoke with fully understood the significant accidental and unintended exposures (SAUE) guidance and local protocols for recording and reporting any near misses or incidents. While no incidents or near misses had taken place in nuclear medicine in the last 6 months, we are assured clear processes are in place to share learning from any incidents.

Requirement 2

- NHS Lanarkshire must ensure up-to-date training records are in place for all staff, including plastic and breast surgeons using the gamma probe.
- No recommendations.

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
Key questions we ask: <i>What difference has the service made?</i> <i>What has the service learned?</i>	

Our findings

A robust approach to management of risks in nuclear medicine was in place.

Risk benefit conversations

We saw a clear approach in place to sharing risk benefit information with patients. Generic written information is provided with the appointment letter. This includes specific risks relevant to the type of exposure. The letter also clearly explains the benefits of the exposure outweighs the risk.

All patients are given the opportunity to ask any questions of the nuclear medicine staff and discuss the risks and care required after the exposure. This includes actions required after the treatment to reduce exposing other people to the radiation.

Making enquiries of individuals who could be pregnant

All staff we spoke with told us all patients of child bearing age are asked to confirm their pregnancy status. Those who are not pregnant will be asked to sign a form. If pregnancy is suspected, the exposure is delayed until the patient can confirm that they are not pregnant. If a patient is pregnant and the scan is essential (such as a lung scan) a comprehensive protocol is in place to reduce the dose and the risk to the foetus.

Carers and comforters procedures

Clear guidelines for staff are in place if a carer or comforter is required to ensure they understand the risk and can provide informed consent. The appointment letter includes the risks to carers and comforters and advice in reducing the risk during an exposure. Local policies provide guidance on the dose a carer or comforter can be exposed to. This is defined for both diagnostic and therapeutic exposures.

All staff told us if there is a carer or comforter, it is clearly recorded in the patient's notes.

- 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 quality assurance 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

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

Healthcare Improvement Scotland

Edinburgh Office
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