



Healthcare
Improvement
Scotland

Inspections
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To drive improvement

Announced Inspection Report: Ionising Radiation (Medical Exposure) Regulations

Service: University Hospital Crosshouse, Kilmarnock

Service provider: NHS Ayrshire & Arran

8-10 August 2023

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Contents

1	A summary of our inspection	4
<hr/>		
2	What we found during our inspection	6
<hr/>		
	Appendix 1 – About our inspections	15
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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 University Hospital Crosshouse, Kilmarnock, on Tuesday 8 and Thursday 10 August 2023. We spoke with staff, including the medical physics experts, radiologists and radiographers. University Hospital Crosshouse provides iodine therapy and diagnostic nuclear medicine.

The inspection team was made up of two inspectors.

What action we expect NHS Ayrshire & Arran to take after our inspection

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

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

Direction	
Requirements	
1	NHS Ayrshire & Arran must ensure that the maxillofacial surgeon administering the radiopharmaceutical into the patient's tongue is entitled to do so (see page 8). <i>Regulation 17 Ionising Radiation (Medical Exposure) Regulations 2017</i>
2	NHS Ayrshire & Arran must implement a process to gain assurance that referrals from NHS Dumfries & Galloway only come from those who are entitled to do so (see page 8). <i>Regulation 2 Ionising Radiation (Medical Exposure) Regulations 2017</i>
Recommendation	
a	NHS Ayrshire & Arran should consider implementing the guidance from the UK Radiopharmacy Group, and have a second person present to witness the preparation of radiopharmaceuticals (see page 8).

Implementation and delivery	
Requirement	
3	NHS Ayrshire & Arran must ensure that processes are in place to provide assurance to the IR(ME)R lead that all IR(ME)R processes are being followed, including ensuring training records for the surgeons using the gamma probe are available (see page 10). <i>Regulation 17 Ionising Radiation (Medical Exposure) Regulations 2017</i>
Recommendation	
b	NHS Ayrshire & Arran should have a formalised protocol which outlines the training and competency requirements that it currently uses to train relevant staff to authorise under protocol (see page 11).

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 Ayrshire & Arran must address the requirements and make the necessary improvements as a matter of priority.

We would like to thank all staff at University Hospital Crosshouse 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 a positive safety culture in which staff were confident to report incidents, and that learning from these is promoted. NHS Ayrshire & Arran has a positive approach to optimisation, and has delivered tangible improvements in dose reduction. NHS Ayrshire & Arran must ensure that all staff are correctly entitled, including the maxillofacial surgeon, and referrers from other NHS Health boards.

Entitlement

NHS Ayrshire & Arran's Employer's procedure NM3 (Entitlement of practitioners and operators and medical physics experts in nuclear medicine) 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 the Administration of Radioactive Substances Advisory Committee (ARSAC) licence holders to ensure they are regularly performing the tasks that they are entitled to perform, and have access to ongoing continuing professional development to maintain their skills. The radiography staff also had comprehensive training records which demonstrated competence in the activities that they undertake.

What needs to improve

Technologists are entitled to perform injections of radiopharmaceuticals (pharmaceutical drugs that contain radioactive isotopes). However, in NHS Ayrshire & Arran, maxillofacial surgeons administer injections of radiopharmaceuticals into the tongue of the patient, under the supervision of the technologists. The procedure must only be performed by staff who are entitled to do so (requirement 1).

Requirement 1

- NHS Ayrshire & Arran must ensure that the maxillofacial surgeon administering the radiopharmaceutical into the patient's tongue is entitled to do so.

Referrals into the service are received from several medical specialities in NHS Dumfries & Galloway. However, no system is in place to enable the operators in NHS Ayrshire & Arran to be assured that those who refer are entitled to do so (requirement 2).

Requirement 2

- NHS Ayrshire & Arran must implement a process to gain assurance that referrals from NHS Dumfries & Galloway only come from those who are entitled to do so.

Safety culture

All staff we spoke with told us about a supportive and positive safety culture in place. This included 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 this. We were assured staff are supported during an investigation and any sharing of learning that follows.

NHS Ayrshire & Arran order individual vials of the radiopharmaceuticals required for the patients attending the next day. Comprehensive procedures are in place for the storage and dispensing of radiopharmaceuticals. Staff were confident with how to do the calibration, and about the activity tolerance levels of each radiopharmaceutical before administration. They told us they would not proceed if the activity tolerance level had fallen outwith these. All staff we spoke with were also aware of the risks of extravasation (the leakage of radioactive material at the injection site) and the potential for this to change the radiopharmaceutical activity the patient receives. They told us that they would measure the dose left in the vial, re-site the cannula and recommence with the required activity.

What needs to improve

The calibration and preparation for administration of radiopharmaceuticals is delivered by one person. The UK Radiopharmacy Group recommends that two members of staff witness the preparation of radiopharmaceuticals to provide an independent check to reduce the risk of errors (recommendation a).

Recommendation a

- NHS Ayrshire & Arran should consider implementing the guidance from the UK

Radiopharmacy Group, and have a second person present to witness the preparation of radiopharmaceuticals.

Optimisation

NHS Ayrshire & Arran's multidisciplinary dose optimisation group has representation from all modality leads, including nuclear medicine. The group has delivered tangible improvements in nuclear medicine. For example, a recent optimisation project took place to reduce the dose in gallium scans. These are primarily used when patients have an infection of an unknown origin. This is one of the highest dose procedures, and required a pregnancy test to be completed for patients of child bearing age. As a result of the optimisation project, the dose was reduced by 10%. The dose to the uterus is now less than 10mGy, and so below the pregnancy check limit.

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 Ayrshire & Arran has clear and comprehensive referral and justification guidelines. A thorough approach is taken to training staff to authorise under protocol, though written guidance to ensure consistency of the training is required. NHS Ayrshire & Arran have detailed and practical guidance to support staff selecting and implementing protocols.

Employer's procedures

NHS Ayrshire & Arran has a comprehensive set of employer's procedures for nuclear medicine. These are reviewed every 2 years. The consultant physicist leads the review, and has support from relevant clinical specialists as required. The procedures are circulated to all members of the IR(ME)R compliance group for approval. Changes are communicated to staff at team meetings, operational meetings and by email. A printed copy kept in each department is updated by administration staff under the guidance of the consultant physicist.

What needs to improve

We were told the employer's procedures are going to be updated to ensure that the language clearly indicates when a stage in the protocol is required and not optional. For example, NM4 advises that the

"parathyroid protocol is the initial investigation and should be a combined I-123 and Tc-99m sestamibi subtraction study followed by a delayed SPECT/CT study using NM-ISOP-PARI."

This is not optional, and must be done, rather than should be done. NHS Ayrshire & Arran will update the language in this and similar instances to reflect when actions are required.

The employer's procedures will also be updated to make clear that hospital doctors are entitled to refer for nuclear medicine. The current wording could incorrectly indicate that hospital doctors are referring on behalf of senior medical staff.

Training

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

What needs to improve

NHS Ayrshire & Arran was not able to provide assurance or evidence that the surgeons using the gamma probe have been trained to do so, and did not have up-to-date training records in place for this staff group (requirement 3).

Requirement 3

- NHS Ayrshire & Arran must ensure that processes are in place to provide assurance to the IR(ME)R lead that all IR(ME)R processes are being followed, including ensuring training records for the surgeons using the gamma probe are available.

Referral

Referrals are received electronically through an online portal or by email. The employer's procedure NM2 clearly identifies which groups of staff can refer for each nuclear medicine procedure. Referrers are trained in how to use the picture archiving and communication system (PACS), IR(ME)R and how to cancel referrals.

NHS Ayrshire & Arran has clear and comprehensive referral criteria for nuclear medicine. These have been developed with relevant clinical specialists. The protocols include the patient's clinical history, and clinical indicators and steps required before referring patients for nuclear medicine.

All staff told us that if a referral does not have sufficient clinical information to justify the exposure, it would be returned. We saw evidence of a referral being returned because the referral had not been signed.

Justification

NHS Ayrshire & Arran undertake a variety of diagnostic exposures, including cardiac, renal, bone, lung and thyroid scans, as well as providing therapy. NHS Ayrshire & Arran use I-123, I-131, Gallium-67, Thallium-201, Selenium-75 and Technetium-99.

NHS Ayrshire & Arran has authorisation protocols in place for trained staff to justify nuclear medicine exposures. Only tekrotyd, meta-iodobenzylguanidine (mIBG), gallium and SeHCAT require to be authorised by the ARSAC licence holder. Comprehensive training for staff to authorise under protocol is provided, and there was evidence that they sought assistance from the ARSAC licence holders when required.

NHS Ayrshire & Arran has comprehensive justification protocols, which are regularly reviewed and updated. These include steps to reduce the risk of radiation and ensure that lower dose options are considered/completed before nuclear medicine. A recent example was the patient pathway for MIBG. This treatment uses a radioactive form of iodine which is picked up by the neuroendocrine tumour cells. To reduce the risk to the patient, Potassium iodate 130 is used to reduce the uptake in the thyroid.

What needs to improve

Although NHS Ayrshire & Arran has a thorough approach to training staff to authorise under protocol, this is not formally recorded. We were told that written guidelines for this training were being developed during the inspection (recommendation b).

Recommendation b

- NHS Ayrshire & Arran should have a formalised protocol which outlines the training and competency requirements that it currently uses to train relevant staff to authorise under protocol.

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 (RIS) 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. This includes name, date of birth, address, who made the referral and the reason for the procedure.

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 LanguageLine, to support any barriers to communication.

Expert advice

NHS Ayrshire & Arran has an appointment letter for the medical physics experts and they are registered on RPA2000.

The medical physics experts provide:

- support with the development of protocols and employer's procedures
- advice on individual patient procedures
- scientific support
- ARSAC application support
- radioiodine therapy support
- advice for carers and comforters
- support with clinical audit
- local dose reference levels
- training in quality assurance
- monthly calibration of equipment
- investigations if quality assurance is outwith tolerance levels
- exploring software solutions
- optimisation and dose optimisation groups, and
- commissioning and acceptance testing of new equipment

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.

General duties in relation to equipment

The medical physics experts conduct regular quality assurance of equipment. They also provide training for radiographers to carry out a regular programme of checks. All quality assurance checks carried out are documented, along with the activity tolerance levels. All staff told us that if the quality assurance is outwith 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 and lead radiographer 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. Most are based on the ARSAC baseline levels. Local optimisation has led to local dose reference levels (DRLs) for some exposures.

Clinical audit

A comprehensive IR(ME)R audit is carried out every 6 months and includes:

- equipment maintenance and quality assurance
- IR(ME)R licences
- staff training records
- entitlement
- clinical audit
- patient incidents, and
- optimisation.

In addition to the IR(ME)R audit, there are also several clinical audits. These include an informal review of the scope of practice for ARSAC licence holders, dose audits, an audit of clinical decision making in parathyroid studies, and a review of compliance with pregnancy checks, and carers and comforters.

NHS Ayrshire & Arran has a valuable programme of peer review. This is a valuable opportunity for medical staff to learn from their colleagues. 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 or unintended exposures (SAUE) guidance and the local protocols for recording and reporting any near misses or incidents. NHS Ayrshire & Arran use a spreadsheet which records all near misses and incidents. This is a useful approach to monitoring incidents and promoting learning from them.

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

We saw a robust approach to risk benefit, and good information being shared with patients, carers and comforters.

Risk benefit conversations

We saw evidence of risk benefit information being shared with patients. Written information is provided to all patients at the time of booking their appointment. Bespoke information leaflets are provided for each radiopharmaceutical used. This includes guidance for carers as well as the individual being exposed. In addition to the written information, radiography staff will discuss the risk benefit information with patients.

Making enquiries of individuals who could be pregnant

All staff we spoke with 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.

If a patient is pregnant, and an exposure is essential, the patient signs a form to confirm that they understand that the referrer has assessed the benefit of treatment as outweighing the risk.

Carers and comforters procedures

Risk benefit information is provided to carers and comforters. This includes the risks to them and advice in reducing their risk of exposure.

We saw the presence of a carer and comforter recorded on RIS, along with their relationship to the patient.

- 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 Scotland. 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:

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