Healthcare Improvement Scotland | Inspections and reviews
To drive improvement

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

Service: Forth Valley Royal Hospital, Larbert

Service Provider: NHS Forth Valley

25–26th October 2023

NHS SCOTLAND

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First published January 2024

www.healthcareimprovementscotland.org

Contents

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 Forth Valley Royal hospital on 25-26th October 2023. We spoke with staff, including the Consultant Radiologist (ARSAC Licence holder), Consultant Endocrinologist, Consultant Breast Surgeon, Consultant Clinical Scientists, medical physics experts, Radiology Service Manager, team lead and radiographers. Forth Valley Royal hospital provides iodine therapy, diagnostic nuclear medicine and sentinel lymph node biopsies.

The inspection team was made up of two senior IR(ME)R inspectors.

What action we expect NHS Forth Valley 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 three requirements and one recommendation. Requirements are linked to compliance with IR(ME)R.

Direction	
Requirements	
1	NHS Forth Valley must ensure that all staff who act as a referrer, operator or practitioner outside the nuclear medicine department are appropriately entitled to do so. An individual entitlement letter or equivalent requires to be provided to staff who act in those roles. (see page 9). *Regulation 6* *Ionising Radiation (Medical Exposure) Regulations 2017*

Implementation and delivery	
Requirements	
2	NHS Forth Valley must ensure that training records or equivalent for the surgeons using the gamma probe are available. (see page 12). *Regulation 17* *Ionising Radiation (Medical Exposure) Regulations 2017*
3	NHS Forth Valley must ensure its workforce plans outline the medical physics expert resource required to meet the predicted service need. It should include how the NHS board intends to address any identified shortfall in staff in the short and long term. (see page 15) Regulation 14 Ionising Radiation (Medical Exposure) Regulations 2017
Recommendations	
a	NHS Forth Valley should update the employers' procedures to link to clinical audits undertaken by endocrinologists and clearly document the frequency and purpose of clinical audits in SLNBs. (see page 16).

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 Forth Valley, must address the requirements and make the necessary improvements as a matter of priority.

We would like to thank all staff at Forth Valley Royal 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 a positive safety culture in which staff were confident to report incidents, and that learning from these is promoted. NHS Forth Valley must ensure that all staff are correctly entitled, including the breast surgeons and endocrinologist.

Entitlement

NHS Forth Valley's Employer's procedure EP-1 and L2 NM 13 Nuclear Medicine Entitlement outlines the process for entitlement across the NHS board. The policy clearly states who assesses competency of staff and who issues entitlement. All radiology staff who are entitled to act as a referrer, practitioner or operator are issued a written record of their scope of practice. A list of non-medical staff in the nuclear medicine department identifies who has been entitled by the IR(ME)R lead to act as IR(ME)R duty holders.

We saw evidence of regular review of the Administration of Radioactive Substances Advisory Committee (ARSAC) licence holder 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

Entitlement documentation was only available for staff in the nuclear medicine department. Staff outside the radiology department and nuclear medicine department were acting as referrers and practitioners but had not been provided with individual entitlement letters or similar documentation. NHS Forth Valley need to have a system in place to appropriately entitle those who act as a referrer, operator, or practitioner. (requirement 1)

Requirement 1

- NHS Forth Valley must ensure that all staff who act as a referrer, operator or practitioner outside the nuclear medicine department are appropriately entitled to do so. An individual entitlement letter or equivalent requires to be provided to staff who act in those roles.

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.

The consultant radiologist and ARSAC holder is a sole practitioner in the nuclear medicine department. As a result, they do not have a forum to discuss nuclear medicine imaging specifically as part of the NHS Forth Valley radiology events and learning meetings (REALM) meetings where they can discuss radiological discrepancies reviewed alongside examples of excellence. Consideration should be given to how the NHS Board can support the consultant radiologist (nuclear medicine) engage learning from their peers.

Optimisation

The Gamma camera is over ten years old, and the types of imaging undertaking has been fixed for several years. Imaging protocols have been consistent and dose optimisation has therefore not been necessary in recent years. NHS Forth Valley are in the process of replacing the gamma camera with a Single-photon emission computed tomography (SPECT). When the SPECT is being set up the dose optimisation group will be once again be undertaking further dose optimisation. NHS Forth Valley has links with NHS Greater Glasgow and Clyde for shared learning in optimising the SPECT.

Sentinel Lymph Node Biopsy (SLNB)

The Breast surgeons carrying out a biopsy inject patients with 10MBq Technetium-99 Nanocolloid on the morning of the planned surgery. Patients will undergo surgery some time the same day, morning, and afternoon. This results in lower activity at the time of surgery. The ARSAC guidance indicates an activity of 10 MBq at the time of surgery. The surgeons have optimised this process and confirmed positive clinical outcomes, identification of hot nodes, at the time of surgery, using levels below 10MBq.

In addition, iodine-131-metaiodobenzylguanidine (MIBG) uses a radioactive form of iodine which is picked up by the neuroendocrine tumour cells. Measures are taken to reduce the risk to the patient, by reducing the potential uptake in the thyroid and therefore reducing the potential for an unnecessary dose to the thyroid, during this procedure.

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: *How well does the service engage its stakeholders?* *How well does the service manage and improve performance?*		

Our findings

NHS Forth Valley has clear and comprehensive referral and justification guidelines in the form of a table of referral criteria. Referrals are predominantly through speciality teams. All justifications are undertaken by NHS Forth Valley radiologists who authorise under the ARSAC licence holder.

Employer's procedures

NHS Forth Valley has a comprehensive set of employer's procedures for nuclear medicine. These are reviewed every 2 years. Changes are communicated to staff at team meetings and by email.

Training

We saw all clinical scientists/radiographers have up-to-date training records in place. There is also a training matrix in place for departmental staff that is linked to a person's scope of entitlement. This includes training on all the equipment they will use, including the calibrators and QA checks. Training on canulation and the signs of extravasation had also been undertaken. As each person is deemed as competent their training record is signed by a senior member of staff before they can use the equipment independently. Training was provided to all operators to provide advice to careers and comforters and authorise any potential exposures.

Medical staff training is part of their annual appraisal and revalidation every 5 years.

What needs to improve

NHS Forth Valley 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 2).

Requirement 2

- NHS Forth Valley must ensure that training records or equivalent for the surgeons using the gamma probe are available.

Referral for imaging

Referrals are received electronically through an online portal or by email. The employer's procedure L2 NM02 details that referrals are accepted from any hospital doctor who is or is acting on behalf of a Consultant.

Entitled non-medical referrers (NMR), most commonly specialist nurses, for example urology specialist nurses, can also refer for Nuclear Medicine procedures within their scope of practice and only for patients meeting agreed specific criteria. As part of the control on who can make referral, NMR's will only be added to the list of referrers on the radiology information system (RIS) once they have been appropriately entitled.

NHS Forth Valley has clear and comprehensive referral criteria for nuclear medicine. The protocols include the patient's clinical history, and clinical indicators and steps required before referring patients for nuclear medicine.

The radiologist told us that if a referral does not have sufficient clinical information to justify the exposure, the radiologist would contact the referrer by email for further information. If sufficient information is subsequently provided the email response is attached to the referral in RIS and the referral is approved. This system is utilised to reduce potential delays for the patient.

If the clinical information does not warrant the justification of a referral the request would be rejected, and the referrer notified. Referrers have been trained on how to cancel a referral should that be necessary.

Referal for Therapy

All referrals for nuclear medicine therapy come from a multidisciplinary team, with representatives from endocrinology, surgeons, and biochemists. The referral is made on a paper document and will indicate the clinical indication for the referral. The patient pathway to Iodine^{131} therapy can be the result of up to 18 months of treatment before a patient receives Iodine^{131} which is a definitive treatment. The clinical information and history are considered at the MDT to support the decision to refer a patient.

Justification

NHS Forth Valley undertake a variety of diagnostic exposures including lung perfusion, renograms, MIBG and parathyroid scans. In addition, they carry out sentinel node localisation as well as providing therapy. NHS Forth Valley use a variety of radioisotopes for example, Iodine^{123}, Iodine^{131}, Indium^{111}, Krypton^{81} and Technetium^{99m}.

NHS Forth Valley 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. For therapy exposure of Iodine^{131} the endocrinologist has access to the patient medical information including, clinical indicators, such as Grave's disease, previous treatments, and blood results for key markers to ensure the patient is suitable for thyroid ablation.

Breast surgeons will review previous mammography imaging as part of their review of the clinical information as part of their referral to the radiologist for justifying the use of Technetium-99 as part of the breast SLNB.

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

Clinical evaluation

All NM images are reported by the sole consultant radiologist (ARSAC license holder) in nuclear medicine. A second full time equivalent (FTE) consultant radiologist has joined the team will be providing additional capacity to report. As part of their role, they also work 2 sessions per week for the PET service in NHS Greater Glasgow and Clyde.

We were told that the imaging staff would highlight any potential factors to the radiologist that would affect imaging, such as extravasation and patient movement.

Nurse specialists in endocrinology carry out follow up with patients to review the clinical effective of treatments delivered.

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 Forth Valley have service level agreement with NHS Greater Glasgow and Clyde for the provision of medical physics experts (MPE). All MPE's 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
- commissioning and acceptance testing of new equipment (new SPECT due in the first quarter of 2024)

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

Currently there is 0.65 FTE MPE provision that supports the full range of duties. The workload is indicative of the site operating one gamma camera. The planned installation of a new SPECT will increase the scope of activities that can be undertaken and impact on the workload of the MPEs. Therefore, NHS Forth Valley need to calculate a revised provision of MPE services for the installation, commissioning, and operation of the new SPECT. (requirement 3)

Requirement 3

- NHS Forth Valley must ensure its workforce plans outline the medical physics expert resource required to meet the predicted service need. It should include how the NHS board intends to address any identified shortfall in staff in the short and long term.

General duties in relation to equipment

NHS Forth Valley have a quality assurance (QA) and maintenance schedule as part of their nuclear medicine procedures. All quality assurance checks carried out are documented, along with the activity tolerance levels. All staff told us that if the quality assurance is out with tolerance levels, the quality assurance check is repeated. If it continues to be out with tolerance, the equipment is removed from use and the medical physics expert and team lead informed.

As part of the gamma camera QA uniformity checks, a Technetium-99 flood source, is used. The flood source requires to be prepared each morning at a measured activity of 20MBq.

Gamma probes used by the breast and plastic surgeons are also calibrated in the department. Staff have been trained to calibrate the probes against a Cobolt^{57} source to ensure the probes are working within agreed tolerance levels.

The medical physics experts also conduct regular quality assurance of equipment.

Dose

Dose reference levels are displayed in the dispensing room which are based on the ARSAC baseline levels.

NHS Forth Valley order individual vials of the radiopharmaceuticals required for the patients attending the next day and Iodine ^{131} tablets as required.

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. Daily QA is undertaken on the calibrator, using a Caesium^{137} source, to ensure it is working within the set parameters. 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. We were told that where the intended administered dose was below the optimal activity then in discussion with medical physics the time for the image acquisition could be extended to produce clinical useful images.

Clinical audit

The procedure L2 NM 11 Clinical Audit details how NHS Forth Valley will clinical audits. It details the frequency of the different audits and the responsible person. It covers,

- entitlement
- staff training records
- DRL's
- carer and comforters
- incidents, and
- optimisation.

An audit of nuclear medicine administered activities against Local DRLs in 2022 delivered several recommendations including the need for further operator training.

In endocrinology an audit is undertaken every two years to evaluate the clinical cure rate of thyroid ablation. A nurse specialist undertakes the review, and the outcome help manages patient care.

There have been no recent clinical evaluation audits for SLNB. (Recommendation 3)

Recommendation a

- NHS Forth Valley should update the employers' procedures to link to clinical audits undertaken by endocrinologists and clearly document the frequency and purpose of clinical audits in SLNBs.

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.

The most recent incidents have involved break downs in the gamma camera. Due to the age and number of breakdowns the gamma camera will only be used until it is replaced in the new year. In response to the breakdowns the department has changed its protocols on injecting patients with radiopharmaceuticals. Only one patient will be injected and scanned at a time. Therefore, limiting the number of patients who could be affected in the event of a breakdown. Should a patient be injected and the camera breaks, there is potential for patients to be sent to NHS greater Glasgow and Clyde for imaging.

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: *What difference has the service made?* *What has the service learned?*	

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.

The endocrinologist will describe to the patient, in person, the risk and benefits of thyroid ablation. Providing the patient with an opportunity to raise any questions. Patients will also be provided with an information booklet.

Making enquiries of individuals who could be pregnant.

All staff we spoke with told us that all patients of childbearing 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.

All patients who undergo Iodine^{131} therapy will require to have a pregnancy test. If a patient is pregnant then the therapy will be halted.

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 quality assurance framework.

Further information about the framework can also be found on our website at: [The Quality Assurance System (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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