



Healthcare
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Scotland

Inspections
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To drive improvement

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

Service: Victoria Hospital, Kirkcaldy

Service Provider: NHS Fife

27 and 28 February 2024

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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 allow 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.

- **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.
- Further information about the framework can also be found on our [website](#).

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 Victoria Hospital, Kirkcaldy on Wednesday 27 and Thursday 28 February 2024 to review nuclear medicine services and activities. We spoke with the Administration of Radioactive Substances Advisory Committee (ARSAC) licence holder, a surgeon, IR(ME)R Policy Lead, radiography and the medical physics experts.

Based in Kirkcaldy, Victoria Hospital provides a variety of imaging including bone and renal. In addition, sentinel lymph node biopsies (SLNB) are carried out at Queen Margaret Hospital.

The inspection team was made up of two inspectors.

What action we expect NHS Fife to take after our inspection

The actions that Healthcare Improvement Scotland expects NHS Fife 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 no requirements and 2 recommendations. Requirements are linked to compliance with IR(ME)R.

Direction	
Recommendations	
a	NHS Fife should ensure that the audit of activity levels in MAG3 imaging is commenced immediately.

Implementation and delivery	
Recommendations	
b	NHS Fife should ensure that all relevant staff are informed of clinical audits undertaking and the results of these, including the IR(ME)R board.

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

<https://www.healthcareimprovementscotland.scot/inspections-reviews-and-regulation/ionising-radiation-medical-exposure-regulations-irmer/>

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

2 What we found during our inspection

Direction

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

NHS Fife has an excellent approach to the entitlement which means all staff have clear documentation which are aligned to their scopes of practice and competencies. There are very good collaborative working relationships between NHS Lothian and NHS Fife which have resulted in an excellent safety culture.

Entitlement

NHS Fife has a clear policy for entitlement of medical and radiography staff (EP2 Entitlement of IR(ME)R Practitioners and IR(ME)R Operators). All of the radiography staff working in nuclear medicine had up to date entitlement records and clearly defined scopes of practice which aligned to their training records and competency.

The breast surgeons undertaking SLNB are entitled by NHS Fife as operators. They had appropriate entitlement certificates. The surgeons authorise the use of radionuclides under the protocols of the ARSAC licence holders. These protocols have all been approved and agreed by the ARSAC licence holder.

Employers and practitioners who administer radioactive substances require an appropriate licence from the ARSAC. The licensed practitioner is then entitled by the employer. In NHS Fife the ARSAC licence holders are employed by NHS Lothian, and work under an honorary contract in NHS Fife. This includes the entitlement for the administration of ^{99m}Tc and ^{123}I . 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.

NHS Fife has a comprehensive policy for the entitlement of non-medical referrers (NMR) (EP2/RAD/1 Entitlement of registered non-medical professionals). At the time of the inspection there were 4 NMRs referring to the nuclear medicine team. Prior to being issued with entitlement to refer, each staff member had to demonstrate that

relevant training had been undertaken and that the scope of entitlement sought was consistent with their clinical expertise. A regular audit of the NMR referrals is conducted to monitor how many are rejected and whether all aspects of the scope of their referral are used. If any issues are identified, then these are addressed.

Safety culture

We saw evidence of a very good and supportive culture in NHS Fife. All staff we spoke with understood the safety protocols in nuclear medicine and told us of a supportive and positive safety culture. This included an open culture for reporting incidents, and a focus on learning from errors and sharing learning across the team. There was confidence that Victoria Hospital has a positive culture which promotes learning from near misses and incidents.

NHS Fife receive the vials of Tc-99m from NHS Lothian. Comprehensive procedures are in place for the storage and dispensing of radiopharmaceuticals. All staff we spoke with were clear about ordering protocols and ensuring that the sticker from the vial was attached to the corresponding patient's prescription, to provide an audit trail of the radionuclide administered. All staff were confident about the activity tolerance levels of each radiopharmaceutical. They advised us that they would not proceed if the activity tolerance level had fallen out-with an acceptable level. The exact amount of activity administered is measured by, measuring the activity in the syringe before giving it to the patient, and then measuring the remaining dose in the syringe afterwards.

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 of incidents.

Optimisation

NHS Fife participates in an optimisation group which encompasses NHS Fife, NHS Borders and NHS Lothian. The optimisation group will benefit from having a full time MPE working in nuclear medicine who can direct relevant audit activity.

What needs to improve

NHS Fife intend to undertake an audit to explore whether the 30MBq used in MAG imaging is as effective as the 100MBq recommended by ARSAC and used in neighbouring boards. As the activity level in NHS Fife differs so significantly from the ARSAC guidance, and there is no recent research or audit supporting this decision, the audit should be commenced imminently (recommendation a).

Recommendation a

- NHS Fife should ensure that the audit of activity levels in MAG imaging is commenced immediately.

Implementation and delivery

How well the service engages its stakeholders and 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 Fife have robust approaches for referral to nuclear medicine, including for non-medical referrers. Justification protocols are in place which have been reviewed and approved by the ARSAC licence holder. Additionally, NHS Fife have good training records which clearly identify individual's competencies and those who can deliver training.

Employer's procedures

NHS Fife has a comprehensive set of employer's procedures which covers all modalities including nuclear medicine. These include level 2 procedures which relate to nuclear medicine. These are reviewed every 2 years. The responsible manager leads the review with input and support from all relevant staff. The procedures are circulated to the IR(ME)R board.

A printed copy of the employer's procedure is kept in the radiology department. Document control procedures are in place to ensure that this is always up to date and reflects any changes introduced to the procedures.

The employer's procedures are supplemented by the SNLB Theatre IR(ME)R procedures. This is a detailed guidance of IR(ME)R roles and responsibilities for all theatre staff involved in SLNB surgery. Any changes to the procedures are communicated to staff verbally and by email.

Training

All staff have up to date training records which are aligned to their scope of practice. The training records show assessment of competency, and this also includes a record of when staff have been deemed competent to train others. The training records were also specific to the equipment being used in NHS Fife.

The surgeons have been trained to use the gamma probe used in NHS Fife, and training would be organised if new equipment was procured.

All medical staff have completed the online IR(ME)R module which is part of mandatory training. They also have the opportunity to share clinical cases at the REALM meetings.

Referral

NHS Fife has clear and comprehensive referral criteria for nuclear medicine. Referrals are received electronically through TRAK or SCI Gateway if from a GP. Referrals received from non-medical referrers are clearly identifiable. All staff were clear about accessing the spreadsheet to check whether the referral is within the referrers scope of entitlement.

There is clarity about the procedure if a referral does not have sufficient clinical information to justify the exposure. The ARSAC licence holder would check the patients' clinic history and check the results of tests including an antibody or thyroid function test. They would also contact the referrer by email. If sufficient justification is provided then this is recorded on CRIS.

Justification

NHS Fife undertake a variety of diagnostic exposures, including lung perfusion, renal, bone, lung and thyroid scans,, oesophageal/gastric/intestinal motility studies as well as SLNB. NHS Fife use 99mTc.

The ARSAC licence holder justifies the majority of nuclear medicine exposures. NHS Fife has authorisation protocols in place for trained radiographers to justify nuclear medicine exposures for exams which require to be approved urgently. These justification protocols are regularly reviewed and updated. Training for staff to authorise under protocol is provided, and competency is assessed by the ARSAC license holder. Regular audits of images justified under authorisation are conducted by the ARSAC licence holder to provide assurance of competency. This is captured in EP3NM29 Generic Authorisation Guidelines - Training Procedure.

SLNB are justified under protocol by the breast surgeons. If a patient is seen by the surgeon and identified for SLNB there is a multi-disciplinary discussion before SLNB is confirmed. At the time of surgery, in line with the ARSAC guidance, the surgeons expect to inject radionuclide with an activity level no lower than 10MBq. If the activity level does drop, advice is then sought from the ARSAC licence holder and a decision is made on whether or not to proceed.

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 patients' prescription is scanned and uploaded to the radiology information system (CRIS). This includes the sticker from the vial and a written confirmation of ID.

Patient identification

NHS Fife has a comprehensive procedure for the identification of patients (EP2/FIFE/RAD 5 Identification of patient). All staff we spoke with could describe the patient identification checks carried out. It is the responsibility of the staff member dispensing the radionuclide to confirm the patient ID. All staff we spoke to were clear about access to interpreters if required, and if it was a child who are too young to confirm their details.

NHS Fife are developing a training video to demonstrate patient identification in various circumstances.

Expert advice

NHS Fife medical physics experts (MPE) are provided by NHS Lothian using honorary contracts. 0.2 WTE was provided, until a calculation identified that 1 WTE was required to safely deliver nuclear medicine services. A full time MPE has now been appointed. They have an honorary contract and are registered with RPA2000 (certified competent in IR(ME)R protection practice). NHS Fife have updated their Employer's procedure (EP2/FI|FE/RAD/2 Entitlement of IR(ME)R Practitioners and IR(ME)R Operators) to reflect an annual check of the RPA2000 register, to be completed by the responsible manager to ensure that the MPE's registration is current.

The MPE provides support with:

- equipment procurement
- dose evaluation
- advice and support
- quality assurance of equipment
- employer ARSAC licence applications, and

- investigation of incidents.

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

General duties in relation to equipment

An equipment inventory is maintained, and reviews are undertaken when equipment is due for renewal.

There is a quality assurance (QA) programme in place for all equipment. These either follow the IPEM guidance or the manufacturers guidance. All quality assurance checks carried out are documented, along with the activity tolerance levels. The results are recorded on a spreadsheet, along with the weekly and monthly tests undertaken by the radiographers, and the less frequent tests conducted by the MPE are now also included. The spreadsheet highlights any results which are out-with the tolerance levels. Staff told us that if the result is out with tolerance the medical physics expert is informed and their advice is followed.

Clinical audit

NHS Fife have undertaken several clinical audits. We witnessed evidence that these have delivered tangible improvements in patient care. Examples of the audits undertaken are:

- monitoring of patients following sentinel node surgery to identify any cases of a recurrence of cancer within 10 years. Positively NHS Fife are within clinically acceptable rates
- an audit of bone scans was conducted to evaluate whether more clinically useful results were derived from scanning with SPECT CT, rather than the equipment in NHS Fife which does not have CT. The audit demonstrated that further imaging is required more frequently for those whose imaging did not include CT and,
- one specific group of patients with prostate issues often had a full bladder which was impacting on imaging. To reduce the need for imaging after the scan, the radiographer now checks the patients records for any recent imaging of the pelvis. If there are none, then a SPECT acquisition is performed to gather the relevant clinical information.

Additionally, IR(ME)R compliance audits are conducted, which include live observation of frontline staff. The result of the audits are shared with the IR(ME)R board.

What needs to improve

NHS Fife do not share the clinical audits undertaken with all relevant staff (recommendation b).

Recommendation b

- NHS Fife should ensure that all relevant staff are informed of clinical audits undertaken and the results of these, including the IR(ME)R board.

Results

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 is in place to ensure patients who are pregnant would not be exposed to nuclear medicine imaging.

Risk benefit conversations

Risk benefit information is given to patients in a leaflet, and this is sent to the patient before attending their appointment. This leaflet includes basic information about exposure to radiation and invites patients to contact the department if they have any concerns or queries.

Making enquiries of individuals who could be pregnant

NHS Fife has a comprehensive procedure for checking pregnancy status before exposure to nuclear medicine (Establishing whether patients of childbearing potential are or may be pregnant or breast-feeding). Patients are given written information ahead of the imaging which includes the need to advise the department if the patient is or could be pregnant, or is breast feeding. All staff we spoke with told us that all patients of childbearing age are 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, or there is potential that they are, then the radiologist and the referrer decide whether the exposure should proceed.

Carers and comforters procedures

Staff were clear on the procedures for carers and comforters being present during nuclear medicine exposures. No one who is pregnant can fulfil this role without special consideration and justification from the ARSAC Practitioner. Risk benefit information is

provided to carers and comforters. This includes the risks to them and advice on reducing their risk of exposure.

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.

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