



Healthcare  
Improvement  
Scotland

Inspections  
and reviews  
To drive improvement

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

**Service:** Spire Murrayfield Hospital, Edinburgh

**Service Provider:** Spire Healthcare

27 and 28 September 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 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 at: [The Quality Assurance System \(healthcareimprovementscotland.org\)](https://www.healthcareimprovementscotland.org)

## 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 Spire Murrayfield Hospital, Edinburgh on Wednesday 27 and Thursday 28 September 2023 to review nuclear medicine services and activities. We spoke with the Administration of Radioactive Substances Advisory Committee (ARSAC) licence holder, a surgeon, theatre staff, radiography and hospital managers and the medical physics expert.

Based in Edinburgh, Spire Murrayfield Hospital provides sentinel lymph node biopsies (SLNB).

The inspection team was made up of two inspectors.

## What action we expect Spire Healthcare to take after our inspection

The actions that Healthcare Improvement Scotland expects Spire Healthcare 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 three recommendations. Requirements are linked to compliance with IR(ME)R.

Direction	
Recommendations	
a	Spire Healthcare should develop a procedure/protocol which identifies the optimal administered activity level at which the SLNB surgery should proceed, and the requirement for documentation of a clinical decision to proceed out with this level.

Implementation and delivery	
Recommendations	
b	Spire Healthcare should ensure that gamma probe training is captured in a training record.
c	Spire Healthcare should ensure the employers procedure details how and when all programmed clinical audits are carried out.

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)

We would like to thank all staff at Spire Murrayfield 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

**We saw an excellent approach to the entitlement and identification of the scope of practice of the surgeons.**

#### Entitlement

Employers and practitioner who administer radioactive substances require an appropriate licence from the ARSAC. The licensed practitioner is then entitled by the employer. The Spire Murrayfield has entitlement documentation for the ARSAC licence holder for the administration of Tc-99m sulphur colloid as part of the SLNB.

Breast surgeons undertaking SLNB are then entitled under protocol for the use of Tc-99m sulphur colloid. Each Doctor is issued with a personalised letter to entitle them as a referrer, operator and practitioner in SLNB. Referral guidelines which include the clinical indicators for the administration of Tc-99m sulphur colloid are issued by the head of imaging. These are accompanied by a comprehensive scope of entitlement document. All relevant medical staff had up to date entitlement certificates.

#### Safety culture

All staff we spoke with understood the safety protocols in nuclear medicine. They also told us of a supportive and positive safety culture. There was confidence that Spire Murrayfield has a positive culture which promotes learning from near misses and incidents.

Clear procedures were in place for the ordering and dispensing of radiopharmaceuticals (pharmaceutical drugs that contain radioactive isotopes). The ordering and delivering of vials of Tc-99m from an offsite facility, are timed to provide the appropriate level of activity at the planned time of the SLNB

procedure. Each vial arrives with two labels and a printed note with the patient details to provide assurance. All staff we spoke with were clear about ordering protocols and the activity tolerance levels of each radiopharmaceutical.

### **What needs to improve**

Spire Murrayfield do not have a dose meter, so procedures and time are used to ensure that the activity level stays within an accepted range. The ARSAC DRL is 20 MBq, and Spire Murrayfield aim to administer the dose with 15 MBq–20MBq. However, although a recent audit identified an average of 17 MBq over 29 cases, it also showed that one patient had received a dose as low as 10.9. Spire Murrayfield do not have a protocol that identifies the lowest acceptable activity level, or how/when to document a clinical decision to continue with a dose below the target level (recommendation a).

### **Recommendation a**

- Spire Healthcare should develop a procedure/protocol which identifies the optimal administered activity level at which the SLNB surgery should proceed, and the requirement for documentation of a clinical decision to proceed out with this level.



## 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
<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

**Spire Healthcare had comprehensive employer's procedure in place. We saw good approaches to training and justification.**

#### Employer's procedures

Spire Healthcare employer's procedures cover all modalities including nuclear medicine. The employer's procedures are supplemented by working instructions. Specifically, a work instruction for the SLNB procedure that involves intraoperative injection of Tc-99m sulphur colloid into the patients periaoreolar area (the nipple area). This is a detailed guidance, which includes IR(ME)R responsibilities, for all theatre staff involved in patient care working in SLNB.

The working instruction was recently updated with input from all relevant experts and will go to the clinical and care governance forum before being published.

Any changes to the procedures are communicated to staff verbally and by email.

#### Training

Breast surgeons routinely use gamma probes as part of their role and recently Spire Murrayfield Hospital commissioned a new gamma probe for the surgeons to use. A radioactive isotope is injected intra-dermally into the areola, in the quadrant of the tumour and travels through the skin's lymphatic vessels. These are the sentinel lymph nodes. The Gamma Probe is used to identify the areas of radioactive activity, often referred to as hot nodes. The hottest node i.e. the node with the most radioactive activity and any other hot nodes demonstrating greater than 10% of the radioactive activity in comparison to the hottest node are targeted for removal. Training for theatre nursing staff was provide on the

new probe by the manufacture apps specialist. The training included the quality assurance procedure. The familiarisation training is now being disseminated by those who received this training to all medical staff . Medical staff will be trained in the use and functions of the new probe before using it in surgery for the first time.

### **What needs to improve**

Spire Murrayfield are ensuring that all surgeons are trained prior to using the new gamma probe. However, there are no training records for this (recommendation b).

### **Recommendation b**

- Spire Healthcare should ensure that gamma probe training is captured in a training record.

### **Justification**

Spire Murrayfield Hospital use tc-99m sulphur colloid for sentinel lymph node biopsies (SLNB). Justifications are carried out by medical staff. Spire Murrayfield Hospital have a robust approach to justification – Prior to SLNB procedure clinical information is reviewed which includes the mammograms that are clinically evaluated, tumour size and location is discussed at a Multi-disciplinary meeting where decision is agreed to undertake a SLNB. The breast surgeon undertaking the operation is part of the multi-disciplinary meeting. There are emergency exceptions to this, but the procedure for justifying and recording this are very clear.

### **Records**

The pre-operative theatre check provided a record of checks that included those required for IR(ME)R. This includes the patient ID and printed confirmation that a pregnancy test has been conducted and the result is negative.

### **What needs to improve**

The ARSAC licence holder for Spire Murrayfield confirmed that the dose of administered radiopharmaceutical is recorded in the surgeons' notes, but not on the radiology information system. They identified this as an area of improvement and intend to introduce a new protocol to ensure that administered activity levels are recorded in the radiology information system. This would be a positive development as it would provide more accessible information.

### **Patient identification**

All staff we spoke with could describe the patient identification checks carried out. This includes both a verbal check and confirming identification using the two patient ID bands that all patients wear.

All staff we spoke to were clear about access to interpreters of required, and the procedure if the person lacked capacity.

### Expert advice

Medical physics expertise is provided by Integrated Radiological Services. They have an appointment letter and are registered with RPA2000 (certified competent in IR(ME)R protection practice).

The medical physics expert provides support with:

- commissioning of some new equipment,
- dose evaluation,
- advice and support via email or telephone,
- employer ARSAC licence applications, 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

The surgical gamma probes have a regular quality assurance programme in place. Currently the QA process is done weekly as the equipment is new and staff are familiarising themselves with it, this will reduce to fortnightly in line with their policy. Additional QA checks are also done on the days when the probe will be in use.

### Clinical audit

A dose audit was recently conducted as mentioned earlier in the report. A new clinical effectiveness audit is exploring whether each surgery results in the removal of 'hot nodes' – those which the radiopharmaceutical has identified.

### What needs to improve

Spire Murrayfield hospital do not currently detail the programme of audits in their employers procedure (recommendation c).

### Recommendation c

- Spire Healthcare should ensure the employers procedure details how and when all programmed clinical audits are carried out.

#### Accidental or unintended exposure

All staff we spoke with fully understood the significant accidental and unintended exposures 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, clear processes are in place to share learning from any incidents.

## Results

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

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

#### Risk benefit conversations

Risk benefit information is given to patients in a book called “Treatment for Primary Breast Cancer by Breast Cancer Now”. This succinct book provides all relevant information about the radiopharmaceutical used in SLNB.

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

Spire Murrayfield Hospital has not entitled any staff to perform SLNB to patients who are pregnant. Prior to surgery all adults of childbearing age are required to take a pregnancy test. The results of this are checked and the surgeon only proceeds if the test result is negative.

- No requirements.
- No recommendations.

## 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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