



Healthcare  
Improvement  
Scotland

Inspections  
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To drive improvement

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

**Service:** Ninewells Hospital, Dundee

**Service provider:** NHS Tayside

16- 17 January 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 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 Ninewells Hospital, Dundee, on Tuesday 16 and Wednesday the 17 January 2024. We spoke with staff, including the IR(ME)R lead, radiologists (ARSAC licence holders), plastic surgeon, clinical scientist, technologists, and medical physics staff.

The focus of this inspection was on nuclear medicine diagnostic and therapy services. The inspection was carried out by one inspector.

## What action we expect NHS Tayside 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 but where failure to do so will not directly result in enforcement.

This inspection resulted in 8 requirements and 4 recommendations.  
Requirements are linked to compliance with IR(ME)R.

Direction	
Requirements	
1	<p>NHS Tayside 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 these roles. (see page 7).</p> <p><i>Regulation 6(1)(a)</i> <i>Ionising Radiation (Medical Exposure) Regulations 2017</i></p>
Recommendations	
a	<p>NHS Tayside should introduce a mechanism to monitor and progress areas of improvement identified in the annual IR(ME)R report to the radiation safety committee. (see page 10).</p>

Implementation and delivery	
Requirements	
2	<p>NHS Tayside must maintain and make available up to date training records for all staff groups in the nuclear medicine department. (see page 14).</p> <p><i>Regulation 6(2)(b) &amp; 17</i> <i>Ionising Radiation (Medical Exposure) Regulations 2017</i></p>
3	<p>NHS Tayside must ensure up to date training records are in place for plastic and breast surgeons using the gamma probe. (see page 14)</p> <p>Regulation 17 Ionising Radiation (Medical Exposure) Regulations 2017</p>
4	<p>NHS Tayside must have an employer's procedure in place to ensure that equipment QA is implemented and equipment is maintained in line with best practice or where it deviates this part of a clear governance process. (see page 21).</p> <p>Regulation 15 Ionising Radiation (Medical Exposure) Regulations 2017</p>

5	NHS Tayside must be able to demonstrate that equipment has been appropriately commissioned and acceptance testing completed. That documentation is available to demonstrate that equipment has been tested before it is first used and the protocols and set up is optimised. (see page 22)  Regulation 15 Ionising Radiation (Medical Exposure) Regulations 2017
6	NHS Tayside must keep an up-to-date inventory of all medical equipment, including ancillary devices that can directly control to influence the exposure of radiation. (see page 22)  Regulation 15 Ionising Radiation (Medical Exposure) Regulations 2017
7	NHS Tayside must ensure that it has the facilities to undertake the quality assurance of the gamma probes. (see page 22)  Regulation 15 Ionising Radiation (Medical Exposure) Regulations 2017
8	NHS Tayside must detail in the employer's procedure when and how clinical audits that involve a review of practices are carried out. (see page 22)  Regulation 7 Ionising Radiation (Medical Exposure) Regulations 2017
<b>Recommendations</b>	
b	NHS Tayside develop guidance or similar detailing the arrangements for escalating concerns regarding sub optimal imaging. (see page 13).
c	NHS Tayside should clearly describe how training records are to be stored and this is included in the employer's procedures. (see page 14).
d	It is recommended that the equipment register is reviewed on a set frequency. (see page 19)

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/>

[Ionising Radiation \(Medical Exposure\) Regulations \(IR\(ME\)R\) – Healthcare Improvement Scotland](#)

NHS Tayside, must address the 8 requirements and make the necessary improvements as a matter of priority.

We would like to thank all staff at Ninewells 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 Tayside must ensure that all staff are correctly entitled, including the plastic and breast surgeons and endocrinologist.

#### Entitlement

NHS Tayside Employer's procedure 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 technologist 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 either a referrer, operator or practitioner but had not been provided with individual entitlement letters or similar documentation. NHS Tayside need to have a system in place to entitle those who act as a referrer, operator, or practitioner. (Requirement 1)



## **Requirement 1**

- NHS Tayside 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 these roles.

## **Safety culture**

The overarching governance for radiation safety is managed through the radiation safety committee, chaired by the IR(ME)R policy lead. An annual report is produced by the head of medical physics from the radiation safety committee to the NHS Tayside board Care Governance Committee; this includes compliance with IR(ME)R.

There is regular contact between the IR(ME)R lead, the head of nuclear medicine physics, chief technologist, principal radiopharmacist and radiologists. A weekly multidisciplinary group is used to discuss any radiological issues, including nuclear medicine. Information from the meeting is then cascaded.

There are a variety of forums where IR(ME)R related issues can be discussed such as weekly leads groups, medical physics meetings and daily technologist huddles.

There are two consultant radiologist ARSAC licence holders in the nuclear medicine department. They participate in the NHS Tayside three monthly radiology events and learning meetings (REALM) and a specific PET-CT meeting where they can discuss radiological discrepancies reviewed alongside examples of excellence. Where action is required, an action plan is produced, and the implementation of any agreed action will be monitored at a subsequent meeting. Key points from these two meetings can also be brought to the diagnostic improvement group.

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.

## **What needs to improve**

There was a lack of evidence to demonstrate that areas of improvement highlighted in the biannual report from the nuclear medicine department to the radiation safety committee had been actioned or closed.

## Recommendation a

- NHS Tayside should introduce a mechanism to monitor and progress areas of improvement identified in the annual IR(ME)R report to the radiation safety committee.

## Optimisation

NHS Tayside has only recently restarted the multi-disciplinary image optimisation team in nuclear medicine. The role of the team will be to ensure the dose is as low as possible while answering the clinical question. The group will be carrying out a full review of current practices. Currently there is ongoing optimisation work on the use of Gallium 68 used in PET DOTA scans. In addition, the group will be looking at myocardial perfusion imaging as the current practice is 50% above the national DRL.

### Sentinel Lymph Node Biopsy (SLNB)

Technologists and radiologists, inject patients with <sup>99m</sup>Tc-Albumin Nanocolloid on the morning of the planned surgery as close to the time of surgery. For next day procedures the injection is performed the afternoon prior to the planned day of surgery. The administered activity is increased to accommodate for the time between injection and surgery and provide a retained activity of approximately 10MBq at the time of surgery. The plastic surgeons did not have access to information on the activity levels at the time of surgery. However, the plastic surgeons team undertook an audit of the clinical effectiveness for the identification and removal of sentinel node. The audit confirmed that NHS Tayside plastic surgeon's identification, and removal of sentinel nodes was in line with colleagues in Scotland.

## What needs to improve

NHS Tayside require to demonstrate that dose reference levels are in line with the ARSAC licence guidance note. Where the dose reference levels are above the ARSAC DRL there must be clear governance to support the higher DRL.

NHS Tayside could not locate any information on why the current myocardial perfusion imaging practice should be 50% above the ARSAC DRL. The current myocardial perfusion scan DRL was set before the installation of the most current equipment. A review of optimisation should be carried out on a regular basis and when practices change.

NHS Tayside confirmed that a cardiologist had raised concerns regarding the image quality of myocardial perfusion scans with a medical physics expert. It was confirmed that there was no formal route or process to capture and action

concerns from staff who are not radiologists or part of an image optimisation team.

### Recommendation b

- NHS Tayside develop guidance or similar detailing the arrangements for escalating concerns regarding sub optimal imaging.

## 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
<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

NHS Tayside has clear and comprehensive referral and justification guidelines. The camera acquisition protocol provides comprehensive information on the different types of examination. All diagnostic imaging justifications are undertaken by NHS Tayside ARSAC licence holders. However, NHS Tayside need to be able to demonstrate that equipment quality assurance systems aligns to either nationally agreed or manufacturer guidance and where it does not, demonstrate the governance for the divergence.

### Employer's procedures

NHS Tayside has a comprehensive set of employer's procedures for nuclear medicine. Changes are communicated to staff at team meetings and by email.

### Training

We saw all technologist/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 cannulation 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. The radio pharmacy technologist also had comprehensive training records in place.

Medical staff training and competence is part of their annual appraisal and annual job planning meeting. In addition, all medics undertake medical revalidation every 5 years.

### **What needs to improve**

There was a lack of any available information or training records for medical physics staff in the nuclear medicine department. It was discussed that records may be stored in a location not currently available.

NHS Tayside is required to keep training records for all practitioners and operators. These should be available for inspection. Training records should be subject to regular review as equipment and techniques change. Training records and scope of practice records should be reviewed and updated as part of any appraisal process.

There was no clear procedure on the storing of training records to ensure that supervising staff can provide them when required to do so. The relevant information on staff training and competencies requires to be made available at the time of inspection. For example, online records/spreadsheets and training folders.

Training records were not in place for the plastic and breast surgeons on the use of the gamma probe (Requirement 2 & 3).

### **Requirement 2**

- NHS Tayside must maintain and make available up to date training records for all staff groups in the nuclear medicine department.

### **Requirement 3**

- NHS Tayside must ensure up to date training records are in place for plastic and breast surgeons using the gamma probe.

### **Recommendation b**

- NHS Tayside should clearly describe how training records are to be stored and this is included in the employer's procedures.

## What needs to improve

### Referrals

Referrals can be received by paper copy or electronically. All electronic referrers must complete a mandatory confirming they are entitled to refer. The electronic referral system can be modified to ensure that mandatory information is provided. The system reduces the likelihood on none entitled staff from making nuclear medicine referrals.

NHS Tayside has clear and comprehensive referral criteria for nuclear medicine produced by the ARSAC licence holders.

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.

### Pan Scotland referrals

NHS Tayside is the national centre for FDG-PET imaging under general anaesthetics for paediatric patients with epilepsy. There is a pan Scotland group with experts from multiple NHS Boards. The groups discuss the patients' needs and decides which patients require a FDG-PET. A consultant from NHS Tayside on the group acts as the referrer of the patient to the imaging service at Ninewells hospital. The results of the imaging are then shared with the group by the NHS Tayside consultant. This mechanism ensures that referral is from an appropriately entitled individual. NHS Tayside are currently considering alternative mechanism to facilitate referrals from other NHS Boards.

When a referral is made for an FDG scan the person justifying the imaging and the operator administering the radiopharmaceutical have access to additional clinical information relating to chemotherapy to ensure that the scan is on the appropriately date after the chemotherapy.

### Justification

NHS Tayside undertake a wide variety of diagnostic and therapy exposures including, sentinel lymph nodes, lung perfusion, renograms, MIBG, parathyroid, neuroendocrine, and thyroid. NHS Tayside use a variety of radioisotopes for example, Gallium 68, Iodine123, Iodine131, Indium111, Fluorodeoxyglucose 18, and Technetium99.

NHS Tayside 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 or undertaken before nuclear medicine is justified. The ARSAC license holders have developed a framework for justification for other consultant radiologists. The framework provides clear guidance for the consultants to enable them authorise exposures which meet the required criteria.

### Examinations

NHS Tayside has a guidance document on the acquisition protocols for each type of examination. The document provides a wide scope of information and includes the DRL, administered dose, effective dose, ARSAC licence code, ARSAC licence holder, patient protocols and information to be recorded. The documents also provide links to relevant employer's procedure.

NHS Tayside order individual vials of radiopharmaceuticals required for the patients attending the next day. Some of the radiopharmaceuticals are manufactured in the in-house pharmacy and delivered to the department in individual syringes. The onsite radiopharmacy prepares patient-specific-unit dose - radiopharmaceuticals within the activity range; 95-105% of the LDRL, referenced for the patients booked administration time. (85% of which are released within the 95-100% LDRL range. Procedures are in place for the storage and dispensing of radiopharmaceuticals. Each patient specific syringe is shielded within a lead syringe container, the lead container contains a label detailing the specifics of the radiopharmaceutical, and including the patient's full name and CHI.

The document that accompanies the syringe provides details of the radio pharmaceutical, activity at the time of production. Operators must follow local guidelines on administration, which require recording pre-administration activity, residual syringe activity and administered activity on the RIS system. Staff were confident with how to do the calibration, and about the activity tolerance levels of each radiopharmaceutical. Only one patient is injected at a time and two staff members will always be present in the department when administering a radiopharmaceutical. Administered activity will be subject to monthly review as part of the liquid waste calculations.

The administration of radiopharmaceutical is weight based for all paediatric patients. The department has calibrated scales to ensure that they have the most up to date weight prior to calculating the volume to be administered. ALL measured paediatric activities is checked by two technologists/radiographers

prior to administration and both sign the referral form confirming the activity is correct for the weight of the child

Staff were clear about the risks of extravasation (the leakage of radioactive material at the injection site). We were told that the diagnostic test would only proceed if adequate activity had been successfully injected, and that the 'hot spot' would be clearly marked on the patients notes to ensure this would not affect the clinical evaluation. 20 bone scans a month are audited for signs if extravasation.

### Clinical evaluations

Clinical evaluations are undertaken by a the two, consultant radiologist, ARSAC license holders with three other radiologists working under protocol. In addition, cardiologist will report on their area of work.

### What needs to improve

Clinical evaluations for FDG-PET imaging of paediatric patients with epilepsy is being undertaken by a consultant who is a national specialist in this area and works outside NHS Tayside. It must be ensured that staff undertaking clinical evaluations outside NHS Tayside have the appropriate arrangements in place to ensure that they are entitled to undertake their role. It was discussed that this may be in the form of service level agreement with the NHS Trust or another mechanism to entitle the individual.

Following a concern raised by a cardiologist, NHS Tayside has identified the acquisition protocols on one of the gamma cameras that is used for cardiac images was significantly different from the manufacturing default. Investigations have identified that the poor image quality has resulted in patients undergoing further examinations which on retrospect were not required. See the equipment section for further information.

### Records

The radiology information system is used to record the referral through to the clinical evaluation.

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.

The radiology information system allows staff to record information specific to nuclear medicine, including the activity level of the radiopharmaceutical as its 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.

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.

#### Expert advice

NHS Tayside have a medical physics team in place and have recently added a head of medical physics.

The medical physics expert roll is to provides support with:

- commissioning of new equipment
- acceptance testing of new equipment
- establishing baselines for quality assurance
- calibration of equipment
- 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

Any new equipment bought by the department will undergo a commissioning process, led by a medical physics expert. The commissioning process will involve the setting up of protocols and optimisation of doses and testing the equipment before it is first used.

Quality assurance checks to be carried out are documented in the employers' procedures. The quality assurance defines the equipment testing, specific interval and defines acceptable performance levels. All clinical technologists had been trained to undertake quality assurance and training records were in place. NHS Tayside have a quality assurance and maintenance schedule as part of their nuclear medicine procedures. There is a combination of daily and weekly test undertaken by staff. 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 quality assurance uniformity checks, a Technetium-99 flood source is used. The flood source requires to be prepared each morning at a measured activity by the pharmacy. These are produced specifically for the different gamma cameras due to the difference on where the flood sources are placed in the room.

Staff would also undertake equipment quality assurance following a visit from an engineer if the works could affect the operation of the equipment.

The nuclear medicine department has undertaken a review of the quality assurance undertaken on the equipment in the department which was triggered by the investigation into the image quality of myocardial scans. The review identified that the quality assurance programme in numerous areas was not in line with national publications on quality assurance programmes or the wider nuclear medicine community with no justification for deviation recorded.

### What needs to improve

Some of the quality control tests or appropriate frequencies for radiological and ancillary equipment did not align to benchmarked standards. Some equipment undertakes quality control at a lower frequency, some tests were not being completed and in one case where a quarterly test was identified it was not being completed quarterly according to the records seen. Daily quality assurance was in place and staff were completing daily records, however there were some gaps in the documentation.

NHS Tayside identified a failure in the governance of the quality assurance programme as a result of the investigation into the recent statutory notification. They identified that imaging protocols deviated from the manufacturers recommendations without documented justification, and as a result patients may have been subject to unnecessary follow up imaging.

There was also lack of commissioning/acceptance documentation for some equipment on the department and gaps in the criteria used when setting up protocols.

NHS Tayside must ensure that there is a robust system in place to provide assurance that equipment is being suitably commissioned and quality assurance in place, is responsive and wide ranging with clear records maintained. The quality assurance programme must be measured and re-evaluated against best practice standards using nationally agreed benchmark publications and from the wider nuclear medicine community.

NHS Tayside have an equipment register, however, it has been identified that the register is not up to date and does not include all equipment.

It was identified that there is no quality assurance undertaken on the gamma probes used by the plastic and breast surgeons. A cobalt 57 source is commonly used to calibrate the probes to ensure the probes are working within agreed tolerance levels. It was confirmed that NHS Tayside did not have equipment to calibrate the gamma probes. In addition, it was identified that there was no documentation on the commissioning of the gamma probe.

#### **Requirement 4**

- NHS Tayside must have an employer's procedure in place to ensure that equipment quality assurance is implemented, and equipment is maintained in line with best practice or where it deviates this is part of a clear governance process.

#### **Requirement 5**

- NHS Tayside must be able to demonstrate that equipment has been appropriately commissioned and acceptance testing completed. That documentation is available to demonstrate that equipment has been tested before it is first used and the protocols and set up is optimised.

#### **Requirement 6**

- NHS Tayside must keep an up-to-date inventory of all medical equipment, including ancillary devices that can directly control or influence the exposure of radiation.

## Requirement 7

- NHS Tayside must ensure that it has the facilities to undertake the quality assurance of the gamma probes.

## Recommendation c

- It is recommended that the equipment register is reviewed on a set frequency.

## Clinical audit

NHS Tayside have an audit schedule for the completion audit as detailed in NM-P15-L2 Audit of the Compliance with IR(ME)R Policy and Procedures. The audit focuses on compliance with the regulatory requirements of IR(ME)R. Monthly audits are undertaken by a technologist and are collated for inclusion in the nuclear medicine report to the radiation safety committee.

It was highlighted clinical audits undertaken to review practices against peers and clinical standards had been undertaken by the plastic surgeons involved in the sentinel lymph node biopsy. The outcome of the audit demonstrated that the detection rate was in line with peers nationally.

## What needs to improve

Following a concern raised by a cardiologist, NHS Tayside undertook a reactive audit and identified the variance in recall rates of patients undergoing the same examination but on different equipment. The results demonstrated that one of its gamma cameras used for cardiac images had a significantly higher rate of recall results than the other cameras on the department. While it is positive that the audit was undertaken, and improvement implemented, it has highlighted there is a lack of coordinated clinical audits being undertaken ensuring patient care is provided in line with best practice.

## Requirement 8

- NHS Tayside must detail in the employer's procedure when and how clinical audits that involve a review of practices are carried out.

## 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 of incidents. All staff we spoke to confirmed the learning from incidents was cascaded at a variety of forums.

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

### Our findings

#### Risk benefit conversations

Written information is provided to all patients at the time of booking their appointment who attend hospital for an appointment. This includes guidance for carers as well as the individual being exposed. For in patients, it is the responsibility of the referrer to provide the relevant information. In addition to the written information, radiography staff will discuss the risk benefit information with patients.

Information posters are also displayed in the department prompting patients to ask staff if they have any questions regarding exposure to radiation. The posters also ask patients to highlight to staff if they are pregnant.

NHS Tayside confirmed that they will be undertaking a review the information resources available for in patients prior to an examination.

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

All staff we spoke with told us that all patients of childbearing capacity will be asked to confirm their pregnancy status. Those who are not pregnant are asked to sign a form to confirm and this is then scanned on to the RIS system. If a patient is unsure about their pregnancy status, they will be asked to complete a pregnancy test. All patients who are of child bearing capacity attending for iodine therapy are asked to take a pregnancy test to ensure iodine therapy is not provided to anyone who is pregnant.

If a patient is pregnant and the referrer has deemed the exposure essential – the technician would query this and seek assurance prior to proceeding.

If the patient states that they are breast-feeding, the Duty Scientist must be contacted prior to administration, to discuss the implications of the test with the patient. If the patient decides to proceed, written advice will be given by the

Clinical Scientist on any requirement for interruption of feeding, based on the radiopharmaceutical being used and the information contained in the current ARSAC Notes for Guidance.

#### Carers and comforters procedures

Employers' procedures on carers and comforters, provides guidance about the justification of exposure of carers and comforters who undergo diagnostic and therapy procedures. The dose constraint applied to a carer and comforter exposure is 5 mSv.

The employer's procedure also states advice on conduct after administration of a radiopharmaceutical is given in the Patient Information Leaflet sent to the patient with their appointment letter.

## 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 \(healthcareimprovementscotland.org\)](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**

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