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Inspections
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To drive improvement

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

Ninewells Hospital: NHS Tayside, Dundee

29 August 2024

Healthcare Improvement Scotland is committed to equality. We have assessed the inspection function for likely impact on equality protected characteristics as defined by age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation (Equality Act 2010). You can request a copy of the equality impact assessment report from the Healthcare Improvement Scotland Equality and Diversity Advisor on 0141 225 6999 or email his.contactpublicinvolvement@nhs.scot

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Summary of the follow-up inspection

Previous inspection

Healthcare Improvement Scotland (HIS) previously inspected Ninewells hospital on 16 and 17 January 2024. This inspection resulted in 8 requirements and 4 recommendations. As a result of the inspection, NHS Tayside produced an improvement action plan and HIS, acting on behalf of the regulatory body for Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R) are responsible for ensuring that providers are implementing the requirements and actions as per the agreed action plan. The inspection report is available on the Healthcare Improvement Scotland website at: [Ionising Radiation \(Medical Exposure\) Regulations \(IR\(ME\)R\) – Healthcare Improvement Scotland](#)

About our follow-up inspection

We carried out a follow-up inspection to Ninewells hospital on 29 August 2024. The purpose of the inspection is to follow up on the progress NHS Tayside has made in addressing the 8 requirements and 4 recommendations since the initial inspection was carried out on 16 and 17 January 2024.

We spoke with the clinical leads for Nuclear Medicine, head of medical physics, head of nuclear medicine physics, principal radiopharmacist and lead technologist during the inspection.

The inspection team was made up of 2 inspectors.

The actions that Healthcare Improvement Scotland expects the NHS board to implement are called requirements and recommendations.

- **Requirement:** A requirement is a statement which sets out what is required of an independent healthcare provider to comply with the National Health Services (Scotland) Act 1978, regulations or a condition of registration. Where there are breaches of the Act, regulations or conditions, a requirement must be made. Requirements are enforceable.
- **Recommendation:** A recommendation is a statement which sets out what a service should do in order to align with relevant standards and guidance.

Summary of Requirements

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 is required to be provided to staff who act in these roles.
Findings	
	NHS Tayside have undertaken a full review of entitlement and have introduced ongoing monitoring to review entitlement documents for all staff. The employers' procedures have been reviewed and updated. The level 2 procedures NM-PO2.1-L2 has been revised and includes a procedure for the entitlement of surgical staff working within nuclear medicine non- imaging procedures. The clinical lead signs off the entitlement for this staff group based on an interview, where records of training and competency for the relevant modality are reviewed. The record of entitlement NM-PO2.1-L3 details the areas of competence and scope of entitlement. Records are available to demonstrate that all staff, including surgical staff, are now appropriately entitled to include a summary of entitlement documents of medical staff in nuclear medicine and PET-CT.
Has the requirement been met?	
	Yes.

Requirement	
2	NHS Tayside must maintain and make available up to date training records for all staff groups in the nuclear medicine department.
Findings	
	Employer's procedure (EP) NM-P13.1-L3 details nuclear medicine training. The comprehensive EP provides detail on how NHS Tayside ensure that all staff are appropriately trained, the training is documented and records are readily available. A full review of all staff has been undertaken. A revised training matrix was developed and is in place for all nuclear medicine staff. The training matrix demonstrates the current competency of each member of the team. The matrix is based on assessment and allocates a range of roles from 'competent to undertake a task' to 'authorised to sign off others as

	<p>competent to undertake a task'. For those staff that training records were not available, new training records have been produced based on observation of practice and discussions. Training records were viewed at the time of inspection</p> <p>The training record audit programme for nuclear medicine staff is a standing agenda item on the medial physics senior staff meeting agenda. This provides ongoing monitoring to give assurance to NHS Tayside that the new system is being implemented and maintained.</p>
Has the requirement been met?	
	Yes.

Requirement	
3	NHS Tayside must ensure up to date training records are in place for plastic and breast surgeons using the gamma probe.
Findings	
	Training records for plastic and breast surgeons are now in place.
Has the requirement been met?	
	Yes.

Requirement	
4	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 is part of a clear governance process.
Findings	
	NHS Tayside have undertaken a systematic review of all the quality control undertaken in the nuclear medicine department. A gap analysis was undertaken cross-referencing quality control tests with manufacturers and national and international standards. EP's have been amended to strengthen the quality assurance mechanisms in place. NM p19.0 L2 details the roles and responsibilities, system and structure to ensure factors which could impact the radiation dose delivered to the patient are regularly reviewed. As an outcome of the work undertaken to address the requirement, NHS Tayside have developed a robust process to demonstrate that equipment has been

	<p>commissioned safely and is maintained in line with best practice. Any divergence from the guidance is managed through a clear governance process and achieves the appropriate patient outcomes.</p> <p>There is a dedicated location for the storing of commissioning and quality assurance of all radiological equipment.</p>
Has the requirement been met?	
	Yes.

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.
Findings	
	<p>All equipment has been recommissioned and the appropriate records are in place. This requires a commitment from senior management as the commissioning process is comprehensive.</p> <p>As part of the recommissioning process all equipment has undergone a review, to optimise both the equipment and also the image acquisition protocols and patient pathway. The results are shared with the image optimisation group. Clinicians are allocated different types of examinations as the lead reviewer. The review of the patient pathway considers the appropriateness of examinations using ionising radiation in comparison to non-ionising radiation options. As a result, some patient pathways have been modified to offer non-ionising radiation options where clinically appropriate. The reviews are undertaken by a multidisciplinary team focusing on clinical outcomes and involved clinical staff from other directorates. Although some reviews are ongoing the process is now embedded.</p>
Has the requirement been met?	
	Yes.

Requirement	
6	NHS Tayside must keep an up-to-date inventory of all medical equipment, including ancillary devices that can be directly controlled to influence the exposure of radiation.
Findings	
	An up-to-date equipment inventory is now in place. EP NM P17.0-L2 sets out the system of managing the equipment inventory in Nuclear Medicine. The procedure includes all nuclear medicine equipment used for the diagnostic or therapeutic nuclear medicine procedures.
Has the requirement been met?	
	Yes

Requirement	
7	NHS Tayside must ensure that it has the facilities to undertake the quality assurance of the gamma probes.
Findings	
	NHS Tayside are working towards constructing a bespoke piece of equipment. The equipment will provide housing for the sealed source and gamma probe and deliver a consistent approach to quality assuring the gamma probes.
Has the requirement been met?	
	In progress.

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.
Findings	
	NHS Tayside have revised the level 1 EP NM-P15.0-L2 to define clinical audits. Since the inspection the clinical leads have introduced a system where they identify clinical audits to be undertaken. In addition, individual clinicians can highlight audits recommended to be

	<p>undertaken. A MS Teams channel has been created for the tracking of all audits, where the progress and outcomes are recorded. The audit results are also shared at radiology forums attended by clinicians and other staff groups.</p> <p>NHS Tayside presented information on the range and scope of undertaken since the initial inspection.</p>
Has the requirement been met?	
	Yes.

Summary of Recommendations

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.
Findings	
	The radiation safety report pro forma includes issues not completed from the previous meeting. This includes items highlighted at the meeting for action and added to the agenda for the next meeting to monitor their implementation. The report is co-produced with the radiation physics team and used to capture all radiation-related information including IR(M)ER-related issues.
Has the recommendation been met?	
	Yes.

Recommendation	
b	NHS Tayside develop guidance or similar detailing the arrangements for escalating concerns regarding sub optimal imaging.
Findings	
	Concerns are to be escalated through line managers or shared with a member of the nuclear medicine senior leadership team. In addition, a nuclear medicine generic group email has been created to allow concerns to be sent by email. If a concern is raised directly with a staff member, this is escalated to a senior manager. Concerns and emails will be discussed at the senior leadership team meetings.

Has the recommendation been met?	
	Yes.

Recommendation	
c	NHS Tayside should clearly describe how training records are to be stored and this is included in the employer's procedures.
Findings	
	The employer's procedure NM-P13.0-L2 and L3 have been updated to provide guidance on where training records are located. For staff in the nuclear medicine department there are dedicated folders in the IT systems for the uploading and storage of training records. Training is discussed at an annual personal development meeting. Clinicians undertake an appraisal meeting annually and a revalidation every 5 years. This will include discussions on continual professional development.
Has the recommendation been met?	
	Yes.

Recommendation	
d	It is recommended that the equipment register is reviewed on a set frequency.
Findings	
	The register will be reviewed annually.
Has the recommendation been met?	
	Yes.

Next steps and actions

NHS Tayside have addressed and have made satisfactory progress against all requirements and recommendations.

We would like to thank all staff at Ninewells hospital for meeting with us to discuss the implementation of the action plan following the previous inspection of this service.

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 allow 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 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.

Complaints

If you would like to raise a concern or complaint about an IR(ME)R service, you can directly contact 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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