Healthcare Improvement Scotland | Inspections and reviews
To drive improvement

Announced Inspection Report: Ionising Radiation (Medical Exposure) Regulations 2018

Service: Ninewells Hospital, Dundee

Service Provider: NHS Tayside

10–11 December 2024

NHS SCOTLAND

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https://www.healthcareimprovementscotland.scot/

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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 the services are led, managed and delivered.

About our inspection

We carried out an announced inspection to Ninewells Hospital, Dundee on Tuesday 10 and Wednesday 11 of December 2024. We spoke with a variety of staff including the clinical lead radiotherapy, clinical lead oncology, head of medical physics, therapeutic radiographers, head of radiotherapy physics and head of therapeutic radiography services.

The inspection team was made up of two inspectors.

What action we expect NHS Tayside to take after our inspection

The actions that Healthcare Improvement Scotland expects NHS Tayside 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 one requirement and four recommendations. Requirements are linked to compliance with IR(ME)R 2017.

Direction	
Requirements	
	None.
Recommendations	
	None.

Implementation and delivery	
Requirements	
	None.
Recommendations	
a	NHS Tayside should implement an operating procedure or similar on how it will ensure medical physics expert provision outside the standard working day when patients are undergoing radical treatments (see page 14).
b	It is recommended that NHS Tayside produce a programme of clinical audits (see page 16).
c	NHS Tayside should review the recording of peer reviews, taking into consideration the available guidance from the Royal College of Radiologists, Clinical Oncology, for the recording of the peer review process (see page 16).

Results	
Requirements	
1	NHS Tayside must a undertake a study risk in respect to radiotherapeutic practices and record the analyses of the events involving potentially accidental or unintended exposures, proportionate to the radiological risk. (Reg8(2)) (see page 18).
Recommendations	
d	It is recommended that NHS Tayside retain a copy of the signed consent form from patients undergoing radiotherapy (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/

NHS Tayside must address the requirement 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

Safety culture

A radiation safety culture can help to strengthen safety in the use of radiation technology, preventing injuries and reducing unnecessary or unintended radiation dose to patients. Staff members in radiotherapy told us about the supportive and positive culture for reporting and learning from incidents. They also told us of the collaborative learning environment. We were told that the culture within the department is one of openness and transparency, and that all staff are encouraged to speak up. Oncologists also undertake peer reviews which support quality and safety.

The safety culture was also demonstrated through the measures in place to ensure the appropriate entitlement and scope of practice, employer's procedures, optimisation practices, quality assurance systems, as well as the audit and governance arrangements in place.

The radiotherapy department is accredited against BS EN ISO 9001 quality standard for radiotherapy services. The accreditation was undertaken by an external assessor from the British Standards Institution (BSI). This accreditation supports a quality management system which is a framework for an organisation to control its processes and to meet its statutory and regulatory requirements applicable to the radiotherapy service.

Implementation and delivery

This is where we report on 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: *How well does the service engage its stakeholders?* *How well does the service manage and improve performance?*		

Our findings

Employer's procedures

We saw a defined structure for the development and updating of the employer's procedures. NHS Tayside have a comprehensive set of employer's procedures (EPs) which are split into four levels for the radiotherapy department. The radiotherapy department's ISO 9001 system provides the document control framework for the radiotherapy departments employer's procedures. The employer's procedures we reviewed were all clear, up to date and cross-referenced as required. The employer's procedures are available to staff on the internal electronic document management system.

The quality management team has responsibility for the operational aspects of IR(M)ER implementation. The team is responsible for the quality management system, provides departmental oversight to the development of specific radiotherapy employer's procedures, implementing IR(M)ER related policies, procedures and the collation and review of audits and incidents. The team links into the radiotherapy coordination group which oversees the governance of radiotherapy services. Changes to the employer's procedures are communicated to staff at meetings and by email.

The radiotherapy department also undertakes an audit of employer's procedure compliance every year to demonstrate regulatory compliance and identify areas of improvement.

Training

The department has a clear system for training, development and assessment of competencies for staff working in radiotherapy. Training and entitlement records defined the competency description and how it would be assessed and evaluated. Training records are held by line managers. The staff training, qualifications and knowledge are linked to their entitlement and scope of practice.

Medical staff training and competence is a part of staff's annual appraisal, in job plans and continual professional development. Oncology staff confirmed they have access to ongoing professional development to maintain their skills. In addition, all medical staff undertake medical revalidation every 5 years.

There are clear processes for the training of staff. The department has workbooks that define staff competencies that require to be achieved for different tasks. For example, medical physics staff have a training plan for each task and an assessment of competency. The tasks are linked to an individual's scope of practice. Competency assessors for medical physics and therapeutic radiography staff have a role to ensure that staff members achieve the necessary skills and knowledge for their role as detailed in the workbook. Once they are deemed competent, the assessor will sign the staff member off as competent. This is used to inform the entitlement process.

Staff training is recorded in matrix documents that details the level of training for different tasks for all staff. The document is also used to demonstrate which staff are trained, trained to supervise and trained to be an assessor. Staff training records we viewed were up to date.

Entitlement

NHS Tayside have a robust process for the entitlement of staff to undertake the role of a referrer, practitioner and operator. There are clear procedures lines of accountability of who can entitle staff to act as a referrer, practitioner or operator. The entitlement and scope of practice is linked to the competencies of the staff member as demonstrated by their qualifications and role, training and experience.

The entitlement of oncologists is tumour site specific for radical treatments and all oncologists are entitled for the treatment of palliative treatments. The oncology registrars are entitled for palliative treatments and require sign off for radical treatments. Therapeutic radiographers are entitled, depending on their training, to act as operators and for the treatment of site-specific tumours. NHS Tayside have advanced practice therapeutic radiographers. The competency

framework has been developed, and we were told it aligns to the Society of Radiographers' education and career framework. All staff are issued with their scope of entitlement and are clear on their personal scope of practice.

The quality management team monitor the implementation of the appropriate entitlement and implementation of staff groups' scope of practice.

NHS Tayside have the appropriate employers and practitioners' Administration of Radioactive Substances Advisory Committee (ARSAC) licenses in place. Procedures are in place to ensure practitioner licenses are up to date and aligned to the employer's site licence. In addition, all ARSAC licenses were available, and every nuclear medicine procedure is linked to an ARSAC license.

There is an annual review of all entitlements. There are records in place that detail the entitlement and scope of practices of all staff groups.

Referral

NHS Tayside have comprehensive referral criteria for specific tumour sites. Oncologist consultants or oncologist registrars as entitled, undertake all referrals for radical and palliative patients and some brachytherapy treatments. The oncologists confirmed they have access to all the relevant clinical information when considering a patient for referral for treatment. Referrals are discussed at a multidisciplinary team meeting. Referrals are made through the electronic referral system which is uploaded to the oncology management system. The referral system has mandatory fields that require to be completed.

Justification

NHS Tayside have comprehensive justification protocols in place, which are regularly reviewed and updated. As part of the justification process, consideration is given to the risks and benefits for the patients. The oncologist reviews the patients' clinical history, clinical information and check any previous imaging. The justification process will confirm the prescription and the clinical protocol to be used.

Clinical protocol will detail the dose tolerance of the organs at risk and the desired dose to the tumour. The clinical protocol ensures a consistent approach to patient treatment. Clinical protocols are developed as part of a multi-disciplinary team involving oncologist, medical physics and therapeutic radiographer. Oncologists who are the leads for site-specific tumours led on the development of protocols for their area of expertise. We were told how the protocols are evidence based and referenced, for example against guidance from the Royal College of Radiology (oncology) and medical publications. Oncologists can approve a deviation from an approved clinical protocol in rare

occasions where a protocol has not previously been used to treat a rare tumour site. This involves the use of an already agreed protocol for a similar site that may require minor alteration for a rare tumour site. After a deviation from a clinical protocol has been used once, a revised new protocol will then go through the standard approval process for inclusion in the clinical protocols for future reference.

A justification includes a specific number of cone beam CT verification images removing the need to justify every image as part of the patient's treatment pathway. Should this number be exceeded, additional cone beam CT verification imaging would need to be justified.

The justification process does not have a limit on the number of the lower dose imaging used to confirm the setup of the patient and ensure that the tumour is in the isocentre of the external beam equipment. There are procedures in place which included a need to escalate any problems with the patient set up that require three or more lower dose images. The escalation will involve reviewing all the available information and set equipment before proceeding with further imaging. The procedure also allows for the treatment to be paused, and the positioning of the patient replanned. For example, because of an anatomical change in the patient. Should the patient's treatment need to be replanned at any point, this would require a new justification.

All brachytherapy justifications are undertaken by the ARSAC license holders. Brachytherapy treatments are linked to the ARSAC guidance notes.

Optimisation

All patient treatments are individually planned in terms of the expected radiation dose. Treatment plans take into consideration the anatomical position of the site of exposure and nearby organs at risk, previous exposures and the treatment intent.

The oncologist contours the gross target volume (GTV) for all tumour sites. Identifying the delivery site of the desired dose of radiotherapy. The GTV is expanded to form the clinical and planning target volumes. (CTV and PTV) The outlining of the CTV and PTV in some circumstances is an isotropic expansion, in most cases the oncologist will modify the volumes for individual patients.

Therapeutic radiographers who have received additional training and are appropriately entitled will undertake the initial delineation of the organs at risk as part of the dosimetry stage and develop the treatment plan based on the clinical protocol. All treatment plans are reviewed by entitled medical physics operators.

Further measures in place to ensure that medical exposures are kept as low as reasonably practicable include:

- operator training which includes applications training
- routine equipment maintenance
- daily quality assurance
- treatment plans, and
- dosimetry reviews.

The oncologist will review and approve the treatment plan to confirm the delivery of radiation dose to the tumour site and organ at risk, confirming it meets the treatment intent.

Operator

Therapeutic radiographers carry out the practical aspects relating to external beam radiotherapy to the patients. Every patient has a patient checklist on the document management system that the radiographers review before they speak with the patient. The checklist includes information on fraction numbers, patient positioning, patient immobilisation devices and the shift details. They also check the selection of the correct treatment plan and clinical protocols. Staff described how they undertake kilovoltage x-ray imaging as part of the patient set and one cone beam CT to ensure the machine isocentre has been matched to the tumour and it's anatomical position. Therapeutic radiographers described using patients' tattoos to support position. We were told that sometimes the matching process must be repeated, for example after emptying the bladder.

Online and offline matching is undertaken as part of the quality control process to ensure the patient is correctly positioned. Offline images are not reviewed by the same individual on consecutive fractions or by the person who undertook the online matching.

Clinical evaluation

All treatment plans are evaluated by an oncologist.

Records

NHS Tayside have an electronic care pathway and is set up for each patient. It details the requirements at each stage of a patient's journey. It includes a checklist to be completed before the system would move onto the next stage of the patient's journey. For example, selection of the clinical protocols and the use of immobilisation equipment.

We reviewed the information recorded on the referral system and radiography information system and noted staff have documented the following:

- correct patient information and pregnancy capacity
- details of the referrer, practitioner and operator
- identification checks
- scanned documents, such as pregnancy check questionnaires
- justification, and
- dose monitoring.

Radiography staff described the checks they undertake before recording information and where they get the dose information.

Patient identification

All staff that we spoke with clearly described how they carry out identity checks and were familiar with the relevant employer's procedures. They told us they ask the patient their name, date of birth and one further identification check before any exposures. Interpreter services are available when required. Patients' details are available to staff in the treatment room. All inpatients must also have a wristband in place. An exposure would not proceed if there were any concerns about the patient's identification.

Expert advice

NHS Tayside have a medical physics team to support external beam radiotherapy and brachytherapy. The medical physics expert role provide support with:

- commissioning of new equipment
- acceptance testing of new equipment
- establishing baselines for quality assurance
- calibration of equipment
- quality assurance
- investigation if quality assurance is outwith tolerance levels
- optimisation
- dose reference levels (CT planning images)
- analysis of incidents, and
- dosimetry review.

Documentation is in place to demonstrate that the above activities are undertaken by the medical physics team. The medical physics expert also provide advice on whether an incident is required to be reported to Healthcare Improvement Scotland.

The medical physics team is available onsite Monday to Friday when patients undergo radical treatment plans during the standard working day. Radiotherapy is not undertaken at the weekend.

What needs to improve

Radical treatment may, on rare occasions, be extended beyond the standard working day during the week, when the medical physics experts are not in the department. An informal arrangement is in place to contact medical physics staff out of hours if required. A medical physics expert should be available for advice, at least by telephone, at all times that radical radiotherapy patients are being treated.

NHS Tayside conducted a calculation of the medical physics expert requirement using the calculator published by the Institute of Physics and Engineering in Medicine (IPEM). The result of the calculation indicated that the current provision of medical physics experts was adequate, however the provision of support staff, such as clinical technologists, is below the recommended levels.

Recommendation a

- NHS Tayside should implement an operating procedure or similar on how it will ensure medical physics expert provision outside the standard working day when patients are undergoing radical treatments.

General duties in relation to equipment

A planned system of quality assurance is in place to maintain equipment that performed within acceptable parameters and mechanisms were in place to respond to faults. Employer's procedure sets out how NHS Tayside manage equipment quality assurance and dosimetry and fault rectification. Daily, weekly and monthly checks are in place.

As part of the commissioning process of any piece of equipment, the medical physics staff develop the quality assurance requirements. Quality assurance is benchmarked against published guidance such as IPEM reports and manufacturer's guidance to ensure it meets the acceptable performance criteria.

The radiotherapy department maintains their own equipment register. We were assured that the quality assurance requirements covered all equipment on the register that can deliver ionising radiation to a person or directly control or influence the extent of the exposure.

Quality assurance is undertaken of the external beam radiotherapy equipment by medical physics staff at the beginning of each day and before any patient treatments. We were assured that the medical physics team have the necessary test equipment to undertake the quality assurance checks, and this equipment is calibrated. The medical physics team communicated that the quality control is undertaken successfully using a handover form and signage system on the wall next to the control area of each external beam radiotherapy equipment. The medical physics team must indicate that the equipment is safe to use before therapy radiographers use the equipment. All staff confirmed that the handover system is well understood and worked well.

All staff who conduct quality assurance have been trained to do so and records are in place. There is a quality assurance programme that references the quality control checks to be undertaken. We observed quality assurance procedures being undertaken and the recording of the results. When results are outside the expected parameters, remedial action would be taken. If a piece of equipment did not pass the quality assurance checks, it is taken out of use until any faults were rectified.

Medical physics staff have received additional training and are authorised to undertake some aspect of the manufacturers servicing on the external beam radiotherapy equipment. Therefore, the manufacturer service engineer is only required to carry out an annual planned maintenance visit.

Clinical audit

Clinical audit is a quality improvement process that is central to patient care and involves the review of the delivery of healthcare to ensure that best practice is being carried out. It was confirmed that clinical audits are conducted, and examples of audits were discussed during the visit. We were assured that the outcomes or a summary of audit results are shared with the quality management team.

What needs to improve

NHS Tayside undertake a variety of clinical audits, however there is no programme of audits. Audits are undertaken based on suggestions from staff or incidents.

Recommendation b

- It is recommended that NHS Tayside produce a programme of clinical audits.

Peer review

The Royal College of Radiologists encourages regular planned peer review meetings and supports peer reviews that are undertaken on an on-demand basis. NHS Tayside oncologists undertake peer reviews of specific tumour sites and of complex sites as identified by the leading oncologist at multidisciplinary groups. All thoracic tumour sites are peer reviewed, and a record of the review is detailed in the patient notes. We were told other tumour site-specific peer review meeting were regularly taking place and it was estimated it would meet the 10% recommendation from the Royal college of Radiologists.

What needs to improve

It was acknowledged that the recording of peer reviews is not consistent. The Royal College of Radiologists recommends that both approaches, planned and on demand, reviews should be documented in the same way.

Recommendation c

- NHS Tayside should review the recording of peer reviews, taking into consideration the available guidance from the Royal College of Radiologists, Clinical Oncology, for the recording of the peer review process.

Accidental or unintended exposure

Every radiation incident is investigated, and an assessment of the radiation dose made. The radiotherapy department employer's procedure NHST-P12-L1-RR and RT P12 L12 details the process for the management of radiotherapy errors. Staff are clear on the roles and responsibilities of those involved in an investigation, how to carry out an investigation and the reporting mechanisms. When an incident was identified, local protocols for recording and reporting any near misses or incidents are implemented. The incident type would dictate the level of investigation and to whom it should be reported. Staff we spoke with fully understood the criteria for reporting significant accidental or unintended exposures to Healthcare Improvement Scotland. We saw evidence that NHS Tayside record near misses and incidents.

The head of therapeutic radiography services undertakes an analysis of the data on near misses and incidents. The review of the data seeks to identify any trends in the recorded near misses and incidents. The analysis considers a wide range of information such as causative factor, safety barriers, method of detection and the stage in the process where the incident occurred. The analysis which includes data from over the past four years supports the department to identify areas of improvement. The information is discussed at the Quality Management Team meetings to identify areas of increased reports and identify any mitigation to be actioned.

All staff we spoke with described the positive culture of reporting near misses and incidents. We were told that learning from near misses and incidents is shared to help prevent incidents in the future through emails and team meetings.

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

Study of Risk of Accidental or Unintended Exposures

What needs to improve

NHS Tayside have implemented employers' procedures and standard operating procedures which control the radiation risk to patients. However, a specific study of risk of accidental or unintended exposure from radiotherapeutic practices has not been completed. The study should detail the risks, control measures, likelihood and the potential impact on the patient.

Requirement 1

- NHS Tayside must a undertake a study risk in respect to radiotherapeutic practices and record the analyses of the events involving potentially accidental or unintended exposures, proportionate to the radiological risk. (Reg8(2))

Risk benefit conversations

The oncologist discusses the patient's treatment plan with every patient. We found that the benefits and risks of having an exposure to ionising radiation are discussed as part of the consent process. NHS Tayside use the Royal College of Radiologists consent forms that had been developed to support these conversations. The cancer site-specific forms included details of the radiotherapy, short- and long-term side effects and confirmed if patient information leaflets had been provided. We were advised the oncologist records in the patient notes that the risk benefit conversation with the patient has been undertaken. The patient takes home the Royal College of Radiologists consent form. When the patient returns for the planning scan the patient signs a "statement of consent", to confirm they have been provided with risk benefit information.

What needs to improve

Information on the Royal College of Radiologists website suggests that for radiotherapy a copy of the written consent is retained in the patient's records and a copy provided to the patient.

Recommendation d

- It is recommended that NHS Tayside retain a copy of the signed consent form from patients undergoing radiotherapy.

Making enquiries of individuals who could be pregnant

As part of the oncologist's conversation with the patient they are to determine the pregnancy capacity of the patient. This information is recorded in the referral notes for the therapeutic radiographer to review. The oncologist will provide advice on not becoming pregnant and not undergoing treatment when pregnant. The therapeutic radiographer will ask patients who have the capacity to be pregnant to confirm their pregnancy status before the planning CT and first fraction of the planned treatment. If required pregnancy tests are available. The response to the questions is recorded on the treatment sheet which is subsequently filed by the oncology support team. Treatment will not proceed if the patient is pregnant. The emphasis is thereafter on the patient to advice staff if they could potentially be pregnant during further treatment.

Carers and comforters' procedures

It was clearly understood that under no circumstances can any person, including carers and comforters, remain within the Controlled Area during a radiation exposure. Only the patient can remain in the treatment room.

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 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: https://www.healthcareimprovementscotland.scot/inspections-reviews-and-regulation/ionising-radiation-medical-exposure-regulations-irmer/how-we-inspect-irmer-services/

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 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: his.irmer@nhs.scot

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