



Healthcare  
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Scotland

Inspections  
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To drive improvement

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

**Service:** Aberdeen Royal Infirmary, Aberdeen

**Service Provider:** NHS Grampian

6–7 November 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 Healthcare Improvement Scotland 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 Aberdeen Royal Infirmary radiotherapy services on Wednesday 6 and Thursday 7 November 2024. We spoke with several staff, including the consultant in clinical oncology and the IR(ME)R department lead, service clinical director medical physics, service manager, radiotherapy manager, head of physics, therapeutic radiographers, quality manager, dosimetrist and the portfolio medical director.

The radiotherapy service has three linear accelerators which provided and treated 1,756 patients in 2023/24. Brachytherapy services are also provided on the site.

The inspection team was made up of three inspectors.

## What action we expect NHS Grampian to take after our inspection

The actions that Healthcare Improvement Scotland expects 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 six recommendations.

Implementation and delivery	
Requirement	
None.	
Recommendations	
a	NHS Grampian should ensure that individual Administration of Radioactive Substances Advisory Committee (ARSAC) licences are readily available and can be provided when requested to do so by the Enforcing Authority (see page 11).
b	NHS Grampian should review the entitlement of medical physics experts in requesting for verification or re-simulation to determine if this is still a requirement of the radiotherapy service and the departmental responsible person (see page 11).
c	NHS Grampian should ensure its workforce plans outline the medical physics expert resources for radiotherapy services. This should include how the NHS board intends to address the shortfall in staff in the short and long-term and mitigate any risks to service provision that are identified (see page 15).
d	NHS Grampian 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 16).
e	NHS Grampian should review the recording of peer reviews taking into consideration the available guidance from the Royal College of Radiologists Clinical Oncology on the recording of the peer review process (see page 18).

Results	
Requirements	
None.	
Recommendations	
f	NHS Grampian should implement a procedure to undertake a pregnancy enquiry immediately before the initial treatment exposure (see page 20).

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

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

We would like to thank all staff at Aberdeen Royal Infirmary 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

**Staff demonstrated a strong understanding and implementation of IR(ME)R in the planning and delivery of external beam radiotherapy and brachytherapy. This included a positive culture and safety values.**

#### 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. Radiotherapy staff 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. The safety culture also demonstrates through the measures in place to ensure the appropriate entitlement and scope of practice, employers' procedures, optimisation practices and quality assurance systems, as well as the audit and governance arrangements.

NHS Grampian has a clear structure for the management of external beam radiotherapy and brachytherapy services. The quality assurance radiotherapy (QART) committee is the primary governance group for the service. The committee provides advice and guidance on regulatory compliance with the IR(ME)R 2017 legislation. There are links to the divisional clinical governance structure as part of an escalation route.

The radiotherapy department has achieved accreditation against the 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
<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 Grampian has a comprehensive set of employer’s procedures and demonstrated their implementation throughout the patient pathway.**

#### Employer’s procedures

We saw a well-defined structure for the development and updating of the employer’s procedures which have been split into four levels and a fifth level for risk assessments. NHS Grampian have a comprehensive set of employer’s procedures for the radiotherapy department. 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 radiotherapy department’s ISO accredited quality system has many management procedures and work instructions that detail all routine procedures, as well as to ensure compliance with IR(ME)R. The documents are managed and overseen by the QART committee and provide departmental oversight to the development of specific radiotherapy employer’s procedures. The department’s responsible person is accountable for level 2 employer’s procedures and other levels could be delegated. The quality manager is responsible for ensuring that the employer’s procedures are uploaded and up to date on the document management system. Changes to the employer’s procedures are communicated to staff via meetings and email.

The radiotherapy department also undertakes an audit of employer’s procedure compliance every 2 years to demonstrate regulatory compliance and identify areas of improvement.

## Training

NHS Grampian has a clear system for training, development and assessment of competencies for staff working in radiotherapy. Training and entitlement records define 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 continuing professional development. NHS Grampian is a member of the radiotherapy board which included all radiotherapy centres in Scotland. A national approach for the type and amount of continuing professional development has been agreed. Oncology staff confirmed they have access to ongoing continuing professional development to maintain their skills. All medical staff also undertake medical revalidation every 5 years.

An induction pathway process is in place for medical physics and therapeutic radiography staff. Competency assessors ensure that staff members achieve the necessary skills and knowledge for their role. Once they are deemed competent, the assessor will sign them off as competent. This is used to inform the entitlement process. Staff training records we viewed were up to date.

## Entitlement

NHS Grampian have a robust process for the entitlement of staff to undertake the role of a referrer, practitioner and operator. NHS Grampian's employer's procedure RT02-MP31 process for compliance with IR(ME)R 2017 (Entitlement) outlines the process for entitlement across the NHS board. Procedures clearly outline who is authorised to entitle staff to act as a referrer, practitioner or operator. This employer's procedure cross references to the list competencies against which duty holders will be assessed. The scope of practice depends on the individual's qualifications, role, training and experience.

For example, justification of treatments and imaging, treatment planning, use of equipment or dosimetry. This can also change over time following additional training, for example the oncology registrar entitlement and scope of practice change as they progress through their 5-year training programme to become a consultant. Therapeutic radiographers are entitled, depending on their training, to act as operators for the treatment of site-specific tumours. The employer's procedures indicate what should be included in the scope of practice for each staff group. All staff are issued with their scope of entitlement and are clear on their personal scope of practice.

The QART committee monitor the implementation of the appropriate entitlement and implementation of staff groups' scope of practice.

NHS Grampian have the appropriate employers' and practitioners' ARSAC licenses in place. Procedures are in place to ensure practitioner licenses are up to date and aligned to the employer's site license. All ARSAC licenses are also available on the document management system and every nuclear medicine procedure is linked to an ARSAC license.

Entitlement records are in place and detail the entitlement and scope of practices of all staff groups.

### **What needs to improve**

Individual employee ARSAC licenses were not readily available at the time of inspection. Copies of the individual's license were not available on the document management system and supervising staff could not easily provide them (recommendation a).

Medical physics expert are entitled to refer for verification or re-simulation imaging. During the inspection, it was not clear under what circumstances a medical physics expert undertake such a referral (recommendation b).

### **Recommendation a**

- NHS Grampian should ensure that individual Administration of Radioactive Substances Advisory Committee (ARSAC) licences are readily available and can be provided when requested to do so by the Enforcing Authority.

### **Recommendation b**

- NHS Grampian should review the entitlement of medical physics experts in requesting for verification or re-simulation to determine if this is still a requirement of the radiotherapy service and the departmental responsible person.

### **Referral**

NHS Grampian have a clear and comprehensive referral criteria for specific tumour sites. Oncologists undertake all referrals for radical and palliative patients and some brachytherapy treatments. The oncologists confirmed they have access to the relevant clinical information when considering a patient for referral for treatment. The management of newly diagnosed patients is discussed through the relevant site specific multi-disciplinary team meeting and other referrals are brought for multi-disciplinary discussion when required. Referrals are made through the electronic referral system.

## Justification

NHS Grampian 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 patients. The oncologist will review patients' clinical history, clinical information and check any previous imaging.

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

In radiotherapy, once a referral has been justified, an appropriate clinical protocol is selected or modified. The clinical protocols used at NHS Grampian have been agreed by the oncologist and ensure a consistent approach to patient treatment. Oncologists who are the leads for site-specific tumours develop protocols for their area of expertise. If required, an oncologist will seek peer support from colleagues in other NHS boards. We were told how the protocols are evidence based and referenced, for example against guidance from the Royal College of Radiologists (oncology) and medical publications.

Should the patient's treatment need to be replanned at any point, this requires 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.

Optimisation seeks to reduce the dose to as low as reasonably practicable to both the target volumes and normal tissue. The oncologist contours the gross target volume (GTV) for all tumour sites to identify the delivery site of the desired dose of radiotherapy. The GTV is expanded to form the clinical and planning target volumes by the oncologist for each individual patient.

The oncologist will also use the notes filed for any dose restrictions and limitations. Oncologists can select from pre-agreed treatment plans and clinical protocols. They may also use the text box for anything that is not included in the standard planning criteria. The dosimetry staff develop a delivery plan based on

the information supplied by the oncologist and information in the clinical protocol.

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, and
- dosimetry reviews.

The oncologist will review and confirm patients' treatment plans to ensure this meets the treatment intent.

### Operator

Therapeutic radiographers carry out the practical aspects relating to external beam radiotherapy to 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 patient positioning, fraction numbers and the shift details. They also check the selection of the correct treatment plan and clinical protocols. Staff described how they undertake an X-ray and cone beam CT as part of the procedure to match the machine iso centre to the tumours. When present, staff described using patients' tattoos to support patient positioning. We were told that sometimes the matching process must be repeated, for example after emptying the bladder. On-line and off-line matching is undertaken as part of the quality control process to ensure the patient is correctly positioned.

NHS Grampian confirmed that they are looking to install surface guided radiotherapy in 2025.

### Clinical evaluation

All treatment plans are evaluated by an oncologist.

## Records

NHS Grampian have an electronic care pathway that was set up for each patient. This details the requirements at each stage of a patient's journey. This 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, the inclusion of a bolus and the use of immobilisation equipment.

We reviewed the information recorded on the oncology management system and noted staff have documented the following:

- correct patient information
- 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 obtain the dose information.

## Patient identification

All staff that we spoke with clearly described how they carry out identity checks and are 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 and, in most cases, this included a picture of the patient as a secondary check. 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 Grampian's medical physics team support external beam radiotherapy and brachytherapy. The medical physics expert role provides 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 out with tolerance levels

- optimisation
- dose reference levels (CT planning images)
- analysis of incidents, and
- dosimetry.

Documentation is in place to demonstrate that the above activities are undertaken by the medical physics team. The medical physics expert provide advice on whether an incident 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. No complex procedures or radical treatment plans are undertaken at the weekend. Weekend procedures are managed by the oncologist and include planning input from the dosimetrist and is delivered by the therapy radiographer.

### **What needs to improve**

NHS Grampian 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 staff, which included medical physics experts and clinical technologists, was 50% below the staffing levels as recommended by IPEM guidance (recommendation c).

Radical treatment may, on rare occasions, be extended beyond the standard working day during the week, when the medical physics experts were 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 (recommendation d).

### **Recommendation c**

- NHS Grampian should ensure its workforce plans outline the medical physics expert resources for radiotherapy services. This should include how the NHS board intends to address the shortfall in staff in the short- and long-term and mitigate any risks to service provision that are identified.

## Recommendation d

- NHS Grampian 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. Parameters and mechanisms are in place to respond to faults. Employer's procedure RT02-MP19 sets out how NHS Grampian manage equipment quality assurance, 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 acceptable performance criteria.

The radiotherapy department maintains an equipment register. The quality assurance requirements cover 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. The medical physics team have the necessary test equipment to undertake the quality assurance checks, and this equipment had been calibrated. The medical physics team communicated that the quality control had been undertaken successfully using a signage system. The medical physics team must indicate that the equipment is safe to use before radiotherapeutic staff use the equipment. All staff confirmed that this system of communication is well understood and worked well.

All staff who conduct quality assurance have been trained to do so and records are in place. A quality control log is in place to support the implementation of quality assurance for each piece of equipment. This detailed the list of equipment and frequency of quality assurance. We observed quality assurance procedures being undertaken and the recording of the results. When results are outside the expected parameters, remedial action is taken. If a piece of equipment did not pass the quality assurance checks, it is taken out of use until faults are rectified.



The head of dosimetry and quality assurance monitor the implementation of the quality assurance programme.

A service engineer carries out planned maintenance visits three times a year on the external beam radiotherapy equipment.

### Clinical audit

An audit calendar is in place that details the clinical audits undertaken over a 2-year period. For example, audits included reviewing specific patient pathways, or in response to incidents and near misses. The calendar includes re-audits where improvements or changes to processes had been made to determine if changes had been implemented and sustained. Audits undertaken included:

- process audits
- clinical audits
- prostate follow-up audits, and
- training records audits.

Where necessary, action plans are generated and implemented. All audits and action plans are shared with QART committee and are escalated to the clinical governance committee as necessary. An example of the outcome of an audit was the identified need to provide additional contact time with patients who underwent a prostate treatment.

The audit template, as detailed in employer's procedure 3, requires to be completed every 2 years and focuses on IR(M)ER compliance. The department's responsible person for radiotherapy is responsible for ensuring that audits are completed. The audit reviewed a wide range of IR(ME)R related activities including entitlement of staff, ARSAC licenses, training records, referral criteria, justification of imaging and clinical evaluation. The template also captured any other clinical audits that had been undertaken.

### 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 Grampian oncologists undertake peer reviews of specific tumour sites and of complex sites as identified by the leading oncologist. The peer review is undertaken before the first treatment plan.

### **What needs to improve**

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

### **Recommendation e**

- NHS Grampian should review the recording of peer reviews taking into consideration the available guidance from the Royal College of Radiologists Clinical Oncology on 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 RT02-MP10 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 is identified, local protocols for recording and reporting any near misses or incidents are implemented. The incident type dictates 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 Grampian recorded all near misses and incidents. These are discussed and monitored at the QART meeting.

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, this is communicated via email 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
<b>Key questions we ask:</b> <i>What difference has the service made?</i> <i>What has the service learned?</i>	

### Our findings

**Clear procedures for the management of risks and communication of risk and benefits with patients are in place.**

#### Study of risk of accidental or unintended exposures

Regulation 8(2) requires the employer to implement a quality assurance programme of radiotherapeutic practices that includes a study of the risk of accidental or unintended exposures. NHS Grampian have an IR(ME)R compliance statement level document that details the study of risks undertaken. The assessments follow the patient pathway from referral to treatment delivery. The study detailed the types of risk considered and the control measure in place to address the highlighted concerns.

When introducing new technologies or techniques a study of risk is also undertaken as detailed in RT02-MP30. The evidence base for the new technologies or processes are discussed at the QART committee. An example was shared of a recent discussion on the risks and benefits of introducing an updated oncology information system.

#### 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 Grampian use the Royal College of Radiologists consent forms that had been developed to support these conversations. The cancer site-specific forms include details of the radiotherapy, short- and long-term side effects and confirm if patient information leaflets had been provided. Patients sign the form to confirm the conversation and that they understood the risks. Examples of the patient consent forms were found to be in place.

NHS Grampian provide treatment review clinics to ensure appropriate and effective clinical assessment of the patient's condition while they receive radiotherapy. These clinics also provide an opportunity for a patient to ask questions relating to their care, including clarity on the risks and benefits.

NHS Grampian also provide a link to a video of the service and information booklets provided by Macmillan Cancer Support.

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

NHS Grampian work instruction RT02-MP37 details the responsibilities of the referrer, practitioner and operators in establishing and communicating pregnancy status. All staff we spoke with were familiar with the procedure and how it is implemented in their department.

NHS Grampian use the Royal College of Radiologists consent form which includes a question confirming that there was no risk that the patient was pregnant and confirmation that the patient was aware they should not become pregnant during treatment. Patients are again asked to confirm their pregnancy status before the initial planned exposure.

#### **What needs to improve**

The pregnancy status of a patient is established during initial discussions with the oncologist and patients were advised not to become pregnant before and during treatment. The emphasis is on the patient to inform staff at the initial treatment exposure about any changes to their pregnancy status since they initially met with the oncologist. The pregnancy status of a patient is asked before the initial treatment exposure (recommendation f).

#### **Recommendation f**

- NHS Grampian should implement a procedure to undertake a pregnancy enquiry immediately before the initial treatment exposure.

#### **Carers and comforters' procedures**

NHS Grampian have a strict policy on carers and comforters as detailed in its management procedure, RT02-MP14: '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 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/publications/the-quality-assurance-system-and-framework/>

### 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](mailto:his.irmer@nhs.scot)

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