Healthcare Improvement Scotland | Inspections and reviews
To drive improvement

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

**Service:** Edinburgh Cancer Centre, Western General Hospital, Edinburgh

**Service Provider:** NHS Lothian

22-23 April 2025

NHS SCOTLAND

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



First published July 2025



www.healthcareimprovementscotland.scot

# Contents

# 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 (QA) system and QA 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 as amended 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 Edinburgh Cancer Centre (ECC), Western General Hospital on Tuesday 22 and Wednesday 23 April 2025. We spoke with several staff, including the consultant clinical oncologist and radiotherapy lead, head of oncology physics, head of therapeutic radiography, clinical service manager, principal radiographers, head of dosimetry, head of treatment planning and mould room, head of technology and computing and the head of brachytherapy.

Based in Edinburgh, the ECC Western General Hospital provides a radiotherapy service and has seven external beam linear accelerators which is the second largest department in Scotland. In addition, there is a high dose rate and low dose rate, brachytherapy service provided on the site. In 2023/24 the service treated 3759 patients many of which received multiple fractions.

The inspection team was made up of three inspectors and one observer.

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

The actions that Healthcare Improvement Scotland expects NHS Lothian 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 three requirements and two recommendations. Requirements are linked to compliance with IR(ME)R.

| Direction | |
|---|---|
| **Requirements** | |
| | None. |
| **Recommendations** | |
| | None. |

| Implementation and delivery | |
|---|---|
| **Requirements** | |
| **1** | NHS Lothian must be able to demonstrate the employer has been provided with information regarding the Medical Physics Expert (MPE) provision within radiotherapy services as benchmarked against the Institute of Physics and Engineering in Medicine (IPEM) guidance or equivalent, including the outcomes and control measures in place. Regulation 14 (1) (see page 16) |
| **2** | NHS Lothian must have an employer's procedure (EP) or alternative documentation available to demonstrate that radiotherapy equipment quality assurance testing and frequency is in line with best practice. Regulation 15 (6) (see page 18) |
| **3** | NHS Lothian require to demonstrate that the inventory of equipment and software to be implemented contains the information as detailed in Regulation 15 (1)(b). (see page 18) |
| **Recommendations** | |
| **a** | NHS Lothian should provide the documentation that demonstrates that a review of the MPE provision as benchmarked against the |

| | |
|---|---|
| | Institute of Physics and Engineering in Medicine (IPEM) guidance or equivalent has been undertaken and the outcomes from the review. (see page 16) |
| **b** | NHS Lothian should implement an operating procedure or similar on how it will ensure MPE provision is available outside the standard working day when patients are undergoing radical treatments. (see page 16) |

| **Results** | |
|---|---|
| **Requirements** | |
| | None. |
| **Recommendations** | |
| | None. |

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 Lothian must address the requirements and make the necessary improvements as a matter of priority.

We would like to thank all staff at the Edinburgh Cancer Centre, Western General 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:**<br>*How clear is the service's vision and purpose?*<br>*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. Staff advised us that it is a collaborative learning environment and the culture within the department is one of openness and transparency, and that all staff are encouraged to speak up. Staff confirmed that there is a positive radiation safety culture, and they can challenge any areas that require clarification. Oncologists undertake peer reviews as part of the patient care pathways which supports quality and safety. The safety culture is also demonstrated through the development of comprehensive oncology management system and a document management system that have clear instructions and checks in place, the development of clinical management guidelines, QA systems, as well as a range of clinical audits.

The radiotherapy department is certified against BS EN ISO 9001 quality standard for the treatment prescription, treatment planning and delivery of radiotherapy within clinical oncology at Edinburgh Cancer Centre. The certification was undertaken by an external assessor from the British Standards Institution (BSI). This certification 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.

There is an organisational structure in place from the radiotherapy department to the NHS Lothian Board. In this structure there is an IR(ME)R Board that connects into the NHS Lothian Radiation Protection Committee, this committee links in with the NHS Lothian Health and Safety Committee. The IR(ME)R policy lead, head of oncology physics and head of therapeutic radiography attend the Radiation Protection Committee. In the radiotherapy department the Radiotherapy Management Group and Cancer Services Radiation Protection Committee have a role in providing oversight of IR(ME)R 2017 implementation. There is also a variety of other groups including the Cancer Services Clinical Management Team, the NHS Lothian Clinical Management Group, the Radiotherapy Services Committee and Radiotherapy Incident Group that each have a responsibility in patient safety and aligning these to aspects of IR(ME)R 2017. As well as connecting with the radiation protection groups, clinicians undertake clinical oncology meeting, Cancer Services Clinical Board and link into the Acute Clinical Management Group through the associate medical director.

## 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:<br>Co-design, co-production | Domain 4:<br>Quality improvement | Domain 5:<br>Planning for quality |
|---|---|---|
| **Key questions we ask:**<br>*How well does the service engage its stakeholders?*<br>*How well does the service manage and improve performance?* | | |

## Our findings

**NHS Lothian has a comprehensive set of employer's procedures and associated procedures and demonstrated their implementation throughout the patient pathway.**

### Employer's procedures

NHS Lothian have a comprehensive set of employer's procedures (EPs) and associated documents for the radiotherapy department. The radiotherapy EPs are available for staff to view on the document management system. There are clear mechanisms in place to review documents and update as necessary. Every document has a designated owner who is accountable for ensuring that it is reviewed and updated as necessary. Reviews are undertaken by the appropriate groups such as a clinical management group. Changes to documents can be communicated to staff automatically and they are required to confirm they have reviewed the documents following any significant changes. The document management system is managed by a quality manager who oversees the entire system's processes. The EPs and associated documents we reviewed were all up to date.

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

### Training

The department has a clear procedure for training, development and assessment of competencies for staff working in radiotherapy. Document QMS/6 outlines the scope and objective for the induction and training of staff. Training and entitlement records define the competency description and how it would be assessed and evaluated. Training records are stored either electronically or on paper by line managers. The staff training, qualifications and

knowledge are all linked to the staff members' entitlement and scope of practice.

Consultant oncologist staff training and competence is a part of their annual appraisal and included in their job plan for continual professional development. The medical staff confirmed they have access to ongoing professional development to maintain their skills. In addition, all medical staff undertake medical revalidation every five years. There is a clear progression pathway for specialist registrars for their training and development. Specialist registrars training includes tumour site specific assessments, planning, dosimetry and brachytherapy. The scope of practice for medical staff is recorded in a matrix document that details the different tasks staff can undertake.

There are clear processes for the training of therapeutic radiographers and oncology physics staff (clinical scientists and clinical technologists) groups. The department has defined competencies that require staff to achieve for different tasks. For example, staff have a training plan for each task and an assessment of competency. The tasks are linked to an individual's scope of practice. Designated trainers for oncology physics and therapeutic radiographers have a role to ensure that staff members achieve the necessary skills and knowledge for their role, as detailed in the training plan document. Once staff are deemed competent, the designated trainer will sign the staff member off as competent. This information is then linked to an individual's entitlement.

Staff training is recorded in matrix documents that detail the level of training and entitlement for different tasks for all staff. The document is also used to demonstrate which staff are entitled to perform the task, which staff can act as a task assessor, and which are trained to act as a trainer. Staff training records we viewed were up to date.

### Entitlement

NHS Lothian have a robust process for the entitlement of staff to undertake the role of a referrer, practitioner and operator. There are clear 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, role, training and experience. Document R/1 roles and responsibilities provides details for different staff groups at different stages of a patient pathway. The documents also clearly define the level of qualifications that the clinical oncology doctors are required to have to be entitled for various roles.

Consultant oncologists are entitled to refer for all radiotherapy procedures. Referrals can be for palliative treatments or radical treatments, with radical

referrals being applicable to site specific tumour sites. The oncology specialists in training are entitled for palliative treatments and require sign off for radical treatments. Consultants are entitled to undertake tumour specific sites and entitled to act as an assessor or trainer.

Therapeutic radiographers are entitled, depending on their training, to act as operators and for the treatment of site-specific tumours. NHS Lothian have one consultant therapeutic radiographer. Their scope of practice is supported by a training, competency and governance framework in line with the Society of Radiographers' (SOR) education and Career Framework and SOR Scope of Practice document is in place.

NHS Lothian have the appropriate employers and practitioners' Administration of Radioactive Substances Advisory Committee (ARSAC) licenses. 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 brachytherapy and nuclear medicine procedure is linked to an ARSAC licence.

Oncology physics staff including clinical scientists and clinical technologists have a robust process for the entitlement of staff to undertake their role. The entitlement and scope of practice is clearly linked to the competencies of the staff member and their qualifications, training and experience.

### Referral

The ECC covers patients from Lothian, Fife and the Borders and other health board areas as required. Patients are discussed at a multidisciplinary team meeting with other clinicians and if radiotherapy is agreed as the most appropriate treatment option the patient will be referred to an oncology clinic. Here the patient will be seen by an NHS Lothian clinical oncologist consultant at which time the consultant will complete the electronic referral process. Clinical consultant oncologists refer for radical and palliative patients and brachytherapy treatments. The oncologists confirmed they have access to all the relevant clinical information when considering a patient for referral for treatment. The referral is raised directly into the oncology management system and a copy of the consent form is scanned into the system. The referral encounter requires the prescription to be selected using a template (unless off-protocol) which populates the dose and fractionation and imaging as per protocol. Other pertinent information can be added in the notes field, for example bolus. The electronic referral system has mandatory fields that require to be completed to ensure the correct key information is provided. Oncology specialist registrars and consultant therapeutic radiographers also refer within their scope of entitlement. NHS Lothian have a defined referral criteria for

different tumour sites.  If an oncologist requires to cancel a referral they can do so at any point in time.

### Justification

NHS Lothian have comprehensive clinical management guidelines that include the justification criteria and authorisation guidelines for additional imaging exposures outside of the clinical protocol. As part of the justification process, consideration is given to the risks and benefits for the patients. As part of the justification and authorisation, the consultant oncologist reviews the patients' clinical history, clinical information and any previous imaging or radiotherapy treatment. The justification confirms the prescription and the clinical protocol to be used.

The clinical management guidelines, which include the site-specific protocols, used at NHS Lothian have been agreed by the consultant oncologists and ensure a consistent approach to patient treatment. Consultant oncologists who are the leads for site-specific tumours develop protocols for their area of expertise in collaboration with other consultants oncologists in the tumour site group. The clinical management guidelines will detail the dose tolerance of the organs at risk (OAR) and the desired dose to the tumour.  We were told how the guidelines are evidenced based and referenced, for example against guidance from the Royal College of Radiologists (RCR) (oncology) and medical publications. These documents are regularly reviewed and updated by site specific specialist oncologists with input from a multidisciplinary team. All brachytherapy justifications are undertaken by the ARSAC license holders and treatments are linked to the ARSAC guidance notes.

When a treatment is justified it will include verification imaging, removing the need to individually justify every image as part of the patient's treatment pathway.

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

### 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 OAR, previous exposures and the treatment intent. A planning scan is taken for all patients prior to external beam radiotherapy. The CT image is used, with other imaging modalities as appropriate, to define the location of the tumour and the surrounding tissues and organs. As part of the planning scan the patient setup will be optimised and

recorded in the oncology information system and used when delivering the patient treatment.

Optimisation seeks to reduce the dose to as low as reasonably practicable to the normal tissue, whilst meeting with the prescribed dose to the target volumes. The consultant clinical oncologist contours the gross target volume (GTV) for all tumour sites to identify the delivery site of the desired dose of radiotherapy. The GTV or ITV 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 clinical oncologist will modify the CTV for individual patients, and expand the PTV from the modified CTV.

The clinical oncologists will check what they have previously entered as a draft prescription at the time of referral, and confirm this (if appropriate) by setting the status of the prescription to 'reviewed'. They review the patient notes and assess if any further dose restrictions are required based on previous treatment history. They can also add notes for anything that is not included in the standard planning criteria.

The treatment planning staff develop a delivery plan based on the information supplied by the oncologist and information in the clinical management guidelines. Each plan is individually developed based on the location of the disease, criteria within the clinical management guidelines on dose and agreed tolerance limits (ionising radiation) for the OAR. Treatment planning staff will develop a plan that delivers the desired outcome and will try to reduce the dose to the OAR as far as reasonably practicable. Where the dose limit for an OAR cannot be achieved, the results are discussed with the consultant oncologist and any alterations are to be agreed and approved. The clinical oncologist or consultant radiographer is the responsible person for the patient treatment plan. They review and confirm patients' treatment plans as prepared by the treatment planning staff to ensure this meets the treatment intent.

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 QA, and
- dosimetry reviews.

### Treatment Delivery

Therapeutic radiographers carry out the practical aspects relating to external beam radiotherapy to the patients. Every patient has a checklist on the

oncology management system that the radiographers review before they speak with the patient. The daily treatment encounter includes information on the area of treatment, number of fractions, patient positioning, patient immobilisation devices and any isocentre shift details. They also check the selection of the correct treatment plan based on the clinical information. Should there be any doubt, staff described how they would seek clarification. As part of the discussion with the patient prior to treatment delivery, staff will confirm with the patient the area of treatment and the fractionation.

Staff explained how they undertake cone beam Computed Tomography (CBCT) or Kilovoltage (kV) imaging to ensure the machine isocentre has been matched to the planned isocentre. We were advised that sometimes the matching process must be repeated, for example after emptying the bladder. Radiographers are entitled to authorise taking additional radiation exposures as required under protocol. There is an escalation process to allow for further verification imaging to be undertaken by radiography staff which is detailed in the employer's procedures.

Online and offline matching is undertaken as part of the quality control process to ensure the patient is correctly positioned. A record of who undertook these checks is recorded in the oncology management system. Online matching is undertaken by two therapeutic radiographers. Offline matching must be undertaken prior to the next fraction. If offline matching identifies any concerns, there is an escalation process in place that staff are familiar with.

### Clinical evaluation

All treatment plans are evaluated by a clinical oncologist or a consultant radiographer.

It is routine practice for the oncologists to write a letter to the patient's general practitioner at the conclusion of treatment.

### Records

NHS Lothian have an electronic care pathway for each patient. It details the requirements at every stage of the patient's journey. It includes a checklist to be completed before moving onto the next stage.

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

- details of the referrer, practitioner and operator
- correct patient information and pregnancy status
- justification and authorisation

- check lists throughout the care pathway
- peer review
- planned prescription
- treatment plan development and sign off
- identification checks
- scanned consent document including pregnancy status
- patient immobilisation,
- treatment delivery
- online and offline review and
- dose monitoring.

Radiotherapy staff described the checks they undertake and where they obtain the information to check the fractionation and dose delivered.

### Patient identification

All staff that we spoke with clearly described how they carry out identity checks and are familiar with the relevant EPs. They told us they ask the patient their name, date of birth and address before any exposures. Interpreter services are available when required. Staff also described the procedure to identify patients who could not confirm their identity and the role of carers and guardians. Patients' details are available to staff in the treatment room. If an inpatient is to receive treatment, they must also have a hospital identification wristband in place. An exposure does not proceed if there are any concerns about the patient's identification.

### Expert advice

NHS Lothian's oncology physics team support external beam radiotherapy and brachytherapy. The MPE role provides support with:

- commissioning of new equipment
- acceptance testing of new equipment
- establishing baselines for QA
- calibration of equipment
- QA records
- optimisation
- dose reference levels (Computed Tomograhy (CT) planning images)
- analysis of incidents, and
- dosimetry.

Documentation is in place to demonstrate activities that are undertaken by the oncology physics team. The MPE provides advice on whether any incidents are required to be reported to Healthcare Improvement Scotland.

### What needs to improve

There is a potential that a radical treatment on rare occasions, be extended beyond the standard working day during the week, when the MPEs may not be in the department. An informal arrangement is in place to contact an MPE by phone, out of hours if there is no MPE team member on site. An MPE should be available for advice, at least by telephone, at all times that radical radiotherapy patients are being treated.

NHS Lothian discussed that a review had been undertaken of the MPE and clinical scientist staff provision. The review when undertaken benchmarked provision against the calculator published by the Institute of Physics and IPEM. We were informed the outcome of the review indicated that the current provision of oncology physics staff, which included MPEs, and clinical technologists was below the IPEM guidance however, it was determined that the current workforce fulfilled the requirements of Regulation 14, provision of expert advice. While it was confirmed that the review had been undertaken there was no documented information available to demonstrate the decision-making process and outcome. The IR(ME)R Board on behalf of the employer has a role to ensure responsibilities under IR(ME)R 2017 have been appropriately discharged. It was not clear if information had been shared with the IR(ME)R Board as a mechanism to demonstrate that the employer has been assured that the MPE staffing complement meets the requirements as per Regulation 14 (1).

### Requirement 1

- NHS Lothian must be able to demonstrate the employer has been provided with information regarding the Medical Physics Expert (MPE) provision within radiotherapy services as benchmarked against the Institute of Physics and Engineering in Medicine (IPEM) guidance or equivalent, including the outcomes and control measures in place. Regulation 14 (1)

### Recommendation a

- NHS Lothian should provide the documentation that demonstrates that a review of the MPE provision as benchmarked against the Institute of Physics and Engineering in Medicine (IPEM) guidance or equivalent has been undertaken and the outcomes from the review.

### Recommendation b

- NHS Lothian should implement an operating procedure or similar on how it will ensure MPE provision is available outside the standard working day when patients are undergoing radical treatments.

### General duties in relation to equipment

The QA programme provides an assessment of equipment function and performance ensuring equipment meets acceptable performance criteria. A planned system of QA is in place to maintain equipment to ensure it performs within acceptable parameters. A key component of the QA is the measurement of the delivered dose and the detection of any changes. EPs and supporting documentation set out how NHS Lothian manage equipment QA, dosimetry and fault rectification. There is a schedule of QA checks in place that are undertaken at different frequencies.

The radiotherapy department maintain their own equipment register but is currently moving this information to another system. We were assured that the QA covered all equipment that can deliver ionising radiation to a person or directly control or influence the extent of the exposure. We were assured that the oncology physics team have the necessary test equipment to undertake the QA checks. Equipment is calibrated as necessary with traceability back to the UK Primary Standard at the National Physical Laboratory.

QA is carried out on the external beam radiotherapy equipment by oncology physics staff at the beginning of each day and before any patient treatments. The oncology 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 oncology physics team must indicate that the equipment is safe to use before therapeutic radiographers use the equipment. All staff confirmed that the handover system is well understood and worked well. The ongoing QA for the external beam radiotherapy equipment is routinely reviewed by the head of technology.

There is also a programme that includes further comprehensive QA tests undertaken by the oncology physics team on monthly and quarterly basis as detailed in R/Phy/Dos/6 and 7. The policy clearly sets out the roles and responsibilities of the staff groups undertaking QA and the types of tests to be undertaken, cross referencing to work instructions and spreadsheets to be used.

The QA undertaken on the high dose rate afterload for brachytherapy is set out in the EPs R/Phy/Br/43 and is a good example of presenting the QA system in place. It also clearly identifies the range of national and international guidance and papers that have been used to develop the QA system.

All staff who conduct QA have been trained and records are in place. The QA programme references the quality control checks to be undertaken and stated parameters. We observed QA procedures being carried out and the recording of the results. When results are outside the expected parameters, remedial action

is taken. Restrictions on equipment use can be put in place, or the equipment is taken out of use until the faults are rectified. Signage is changed to indicate the equipment parameters in use or if it is out of use.

We were assured the assessment of the dose of ionising radiation that a person may be exposed to, the dose administered, can be accurately determined because of the QA programme in place.

### What needs to improve

We were advised that the types and frequency of QA tests on radiotherapy and ancillary equipment are benchmarked against the manufacturer and nationally agreed benchmark documents such as the IPEM or guidance from the wider radiotherapy community. The documentation to demonstrate the alignment was not readily available on inspection or provided subsequently.

NHS Lothian are in the process of transitioning their equipment inventory database from their current system to a new system. The older system included the information as per Regulation 15 (2) and (2A). The new system currently does not include the category to record the year of manufacture. NHS Lothian will be required to review the options to record the software inventory in line with Regulation 15(2A).

### Requirement 2

- NHS Lothian must have an employer's procedure or alternative documentation available to demonstrate that radiotherapy equipment quality assurance testing and frequency is in line with best practice. Regulation 15 (6).

### Requirement 3

- NHS Lothian require to demonstrate that the inventory of equipment and software to be implemented contains the information as detailed in Regulation 15 (1)(b).

## Accidental or unintended exposure

Every radiation incident is investigated, and an assessment of the radiation dose is made. The radiotherapy department EP details the process for the management of radiotherapy errors. Staff are clear on their roles and responsibilities of those involved in an investigation, how to carry out an investigation and the reporting mechanisms. The oncology physics team completes a report on any incident. Staff we spoke with fully understood the criteria for reporting significant accidental or unintended exposures (SAUE) to Healthcare Improvement Scotland. Clinicians will lead on any discussions with the patient if required.

Incidents are discussed at the multidisciplinary Radiotherapy Incident Group meetings. At these meetings, there is a review of the outcomes from investigations and incidents, and if required recommendations for improvements can be made, such as a change of a form, process or shared learning.

All staff we spoke with described the positive culture around the reporting of near misses and incidents. We were told that learning from near misses and incidents is shared through emails and team meetings, this is to help prevent incidents in the future. Senior radiographers have a meeting once a month and discuss any incidents and shared learning.

## 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:**<br>*What difference has the service made?*<br>*What has the service learned?* | |

### 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 QA programme of radiotherapeutic practices that includes a study of the risk of accidental or unintended exposures. NHS Lothian have a Study of Risk of Accidental and Unintended Exposures at Edinburgh Cancer Centre document that details the study of risks undertaken. The document references national publications that were used during the process to look at ways of reducing errors in radiotherapy which are caused by individual human error or failure of systems of work. The assessment follows the different stages in a patient journey and includes the referral, immobilisation and preparation of the plan and treatment. The study detailed the types of risk considered and the control measures in place to address the highlighted risk.

#### Risk benefit conversations

The clinical oncologist or consultant radiographer discusses the patient's treatment plan with each patient. We found that the benefits and risks of having an exposure to ionising radiation are discussed as part of the consent process. NHS Lothian use the RCR consent forms that are developed to support these conversations. The cancer site-specific forms include details of the radiotherapy treatment, short and long-term side effects and confirm if the patient information leaflets have been provided. Patients sign the form to confirm the conversation and that they understand the risks. Examples of the patient consent forms were found to be in place. The consent form is scanned onto the oncology management system as a record that a risk benefit conversation has been completed. A copy of the form is also provided to the patient.

### Making enquiries of individuals who could be pregnant

NHS Lothian's EP document, EP24, details the responsibilities of the consenting clinical oncologist as the practitioner or 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 Lothian use the RCR consent form which includes a question confirming that there is no risk that the patient is pregnant and confirmation that the patient is aware they should not become pregnant during treatment. Patients are again asked to confirm their pregnancy status before the initial CT planning exposure and prior to the first fraction. The patient signs or initials the form to confirm the conversation has taken place as part of the initial consent process. The radiographer documents within the oncology management system that they have made the enquiry, and the patient is not pregnant to confirm the conversation has taken place prior to the CT and prior to first fraction. A copy of the form is scanned into the oncology management system.

### Carers and comforters procedures

Only the patient can remain in the room during imaging or treatment exposure. NHS Lothian policy does allow the option for a carers and comforter to be in the pre-treatment scanning room and control measures have been detailed. However, to date no carer or comforter has been required to be present in the room during the CT planning imaging.

# 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 QA system and the QA framework together allows us to provide external assurance of the quality of healthcare provided in Scotland.

- **The QA system** brings a consistency to our QA activity by basing all of our inspections and reviews on a set of fundamental principles and a common QA framework.
- **Our QA 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 QA framework.

Further information about the framework can also be found on our website at: https://www.healthcareimprovementscotland.scot/

## 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.

## 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

**Healthcare Improvement Scotland**
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

**Telephone:** 0131 623 4300

**Email:** his.irmer@nhs.scot

You can read and download this document from our website.
We are happy to consider requests for other languages or formats.
Please contact our Equality and Diversity Advisor on 0141 225 6999
or email his.contactpublicinvolvement@nhs.scot

Healthcare Improvement Scotland

| Edinburgh Office | Glasgow Office |
|---|---|
| Gyle Square | Delta House |
| 1 South Gyle Crescent | 50 West Nile Street |
| Edinburgh | Glasgow |
| EH12 9EB | G1 2NP |
| 0131 623 4300 | 0141 225 6999 |

www.healthcareimprovementscotland.org