



Healthcare
Improvement
Scotland

Inspections
and reviews
To drive improvement

Announced Inspection Report – Ionising Radiation (Medical Exposure) Regulations 2017

ROC Clinic, Aberdeen

17 January 2023

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 contactpublicinvolvement.his@nhs.net

© Healthcare Improvement Scotland 2023

First published April 2023

This document is licensed under the Creative Commons Attribution-Noncommercial-NoDerivatives 4.0 International Licence. This allows for the copy and redistribution of this document as long as Healthcare Improvement Scotland is fully acknowledged and given credit. The material must not be remixed, transformed or built upon in any way. To view a copy of this licence, visit <https://creativecommons.org/licenses/by-nc-nd/4.0/>

www.healthcareimprovementscotland.org

Contents

| | |
|--------------------------------------|----------|
| About our IR(ME)R inspections | 4 |
|--------------------------------------|----------|

| | |
|------------------------------|----------|
| Summary of inspection | 6 |
|------------------------------|----------|

| | |
|--|----------|
| What we found during our inspection | 8 |
|--|----------|

About our IR(ME)R 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 of care approach and the quality framework together allows us to provide external assurance of the quality of healthcare provided in Scotland.

- **The quality of care approach** 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 framework.
- **Our quality 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. 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 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 framework.

More information about the quality framework and quality of care approach can be found on our website:

www.healthcareimprovementscotland.org/our_work/governance_and_assurance/quality_of_care_approach.aspx

Summary of inspection

About our inspection

We carried out an announced inspection to the ROC Clinic, Aberdeen on Tuesday 17 January 2023. We spoke with a number of staff including the chief executive, IR(ME)R lead, radiologist and radiographers. The inspection team was made up of one inspector.

ROC Clinic offers plain film and mammography. The focus of this inspection was the imaging department.

What we found

What the service did well

- Governance arrangements were clear and effective.
- We saw a positive safety culture in place with collaborative working relationships evident.
- A robust training programme was in place with in-house training complimenting training from the application specialist to use equipment.

What the service needs to improve

- Employer's procedures should accurately reflect the requirements for training and identification checks.

Detailed findings from our inspection can be found on page 8.

What action we expect ROC Clinic to take after our inspection

This inspection resulted in no requirements and three recommendations. Requirements are linked to compliance with IR(ME)R. See Appendix 1 for a full list of the requirements and recommendations.

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

https://www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/ionising_radiation_regulation.aspx

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

We would like to thank all staff at the radiology department, ROC Clinic, for their assistance during the inspection.

What we found during our inspection

Outcomes and impact

This section is where we report on what key outcomes the service has achieved and how well the service meets people's needs.

Domain 1 – Key organisational outcomes

High performing healthcare organisations identify and monitor key measures that help determine the quality of service delivery and the impact on those who use the service or work with the service.

IR(ME)R requires that those who refer for a patient to be exposed to medical radiation, those who operate equipment and those healthcare professionals (medical and non-medical) who justify that the procedure is necessary, must be adequately trained and entitled to do so. Entitlement is given to each person involved in the process by the employer.

What we found - fulfilment of statutory duties and adherence to national guidelines

Entitlement

The process of entitlement sets out the scope of practice that an individual can carry out, such as the types of referrals, operate equipment and clinical evaluations. The scope of practice depends on the individual's qualifications, role, training and experience and can change over time, following additional training or moving to a new role. The individual is required to work within this scope of practice.

Employer's procedure EP2 (Entitlement of duty holders) provides guidance on the entitlement process. It also provides clear guidance on the roles and responsibilities and the scope of practice within each role.

All radiologists who are fellows of the Royal College of Radiologists are entitled to carry out justifications and clinical evaluations. A radiologist is a doctor who is specifically trained to interpret diagnostic images, such as x-ray and CT scans. The chief executive has delegated the function of entitling consultants to the lead radiographer. Radiologists receive a formal certificate detailing their scope of practice.

Radiographers are entitled to act as operators and carry out justifications of plain film x-rays and mammography. Each radiographer had a record of entitlement, which clearly described their roles and is aligned to their competency and training. Entitlement is issued by the lead radiographer.

Another group of staff who are entitled to make referrals are non-medical referrers, healthcare professionals who are not doctors or dentists. ROC Clinic has not yet needed to entitle any non-medical referrers. However, a training programme is being developed and any future applicants will be required to complete this training before they can be entitled.

Referral

Referrals are received by the radiology department from a variety of sources from within the clinic, from other hospitals and from the community. External referrals are made on a paper form. These are scanned and attached to the patients' clinical notes. Referrals from within ROC Clinic are received by email.

A referral can only be made by a person who is entitled to do so. Employer's procedure EP1 (Entitlement and responsibilities of medical and dental referrers for medical exposure) sets out the process and provides guidance about the clinical information required to be included. The role of the referrer is recorded on the referral form. If any referrals are received outwith an individual's scope of practice, we were told these would always be rejected.

Justification

Radiographers review all referrals to ensure there is sufficient information to be able to justify the referral. They would also choose the correct protocol for the medical exposure of ionising radiation. The protocols for plain film were recently reviewed and updated by the radiologist. Processes are in place to ensure staff are entitled to justify and they are adequately trained to do so. A radiologist is always available to support the radiographers if needed.

All staff told us a patient's clinical information is reviewed when a referral is justified, in line with EP7 (Justification and authorisation of radiological procedures). Radiographers ask the patient if they have had any previous exposures to prevent any duplication. If they have, these can be sought, including images taken in the NHS.

Records

We looked at the information recorded on the patients record and noted that staff had documented:

- the correct patient information

- details of the referrer and operator
- identification checks
- pregnancy checks
- the recorded dose, and
- justification.

Radiography staff could describe the checks they would carry out before recording information and where they would get the dose information.

What needs to improve

All medical referrers are entitled to refer for plain film x-ray and mammography. However, staff told us that in practice referrals for mammography would only be received from the breast clinic. It is important that IR(ME)R referrals are only made by those who have the clinical knowledge to request the exposure (recommendation a).

- No requirements.

Recommendation a

- ROC Clinical should ensure mammography referrals are only requested by those with the expert knowledge to make the request.

Service delivery

This section is where we report on how well the service is delivered and managed.

Domain 5 – Safe, effective and person-centred care delivery

High performing healthcare organisations are focused on safety and learning to take forward improvements, and put in place appropriate controls to manage risks. They provide care that is respectful and responsive to people’s individual needs, preferences and values delivered through appropriate clinical and operational planning, processes and procedures.

What we found - safe delivery of care

Safety culture

We were told about a positive safety culture and saw evidence of strong working relationships. Staff felt confident to report mistakes and near misses and were clear about the procedures for reporting and investigating incidents. Staff were also clear that learning from incidents is shared to reduce the chance of something similar happening again.

We saw PAUSE posters prominently displayed in the clinical rooms in the radiology department to remind staff to take the time when carrying out appropriate checks before carrying out exposures. Staff also told us they are never pressured to rush an exposure.

Employer’s procedures

Employers have a duty under IR(ME)R to develop written procedures commonly referred to as employer’s procedures. These are intended to provide a framework under which professionals can practice. We saw a clear structure for the development and review of the employer’s procedures.

Employer’s procedures we reviewed were all clear and up to date. All staff we spoke with were familiar with the employer’s procedures and could find them easily. We heard that any updates are shared by email and all staff must sign to confirm they have familiarised themselves with the latest version.

Patient identification

Employer’s procedure EP8 (Identification of patients) provides guidance on the three point identification checks to be carried out for all patients before an exposure. These checks are essential to ensure the correct person is being exposed.

All staff we spoke with could clearly describe the checks carried out before an exposure (full name, date of birth and address). Radiographers check with the patient if any previous images have been taken. If they have, they would consult with the referrer to confirm whether a new exposure is required.

Radiographers told us that they always review the patient's clinical history to check it matched the clinical information received. They would check the site, laterality (part and side of the body to be exposed) and reason for exposure matched the referral and ensure this matched the patients understanding. These checks are recorded on the referral form. Radiographers told us they would return the request to the referrer and await a new referral if any discrepancies are identified during these checks. As referrals are received by email this can be done very quickly so that there is no delay for the patient.

Risk benefit conversations

Employer's procedure EP16 (Risk communication) details the procedure for providing information on the risks and benefits associated with the radiation dose from medical exposure. We saw information posters displayed in the radiology department and in changing facilities to inform patients of the risk of an exposure. The posters describe the risk benefit discussion and includes equivalent background to provide valuable information to the patient.

Making enquiries of individuals who could be pregnant

Employer's procedure EP9 (Making enquiries of pregnancy status) provides guidance for carrying out pregnancy status checks before any exposure. All radiographers we spoke with were familiar with the procedure. They told us that all women are asked the required pregnancy check questions aged between 12 and 55, for exposures where the lower diaphragm and upper thigh are directly in the primary beam. They must sign a form to confirm they are not pregnant. If a patient thinks they might be, a test can be taken before going ahead with the exposure.

Information posters are displayed in the diagnostic department also highlighted the need to inform a member of staff of any possibility that the patient may be pregnant.

Carers and comforters procedures

Employer's procedure EP10 (Carers and comforters) provides clear guidance on the authorisation of an exposure to a carer or comforter, such as the mother of a child. The nature of the service means a carer or comforter has not been needed.

General duties in relation to equipment

Quality assurance checks are carried out on all equipment and the frequency required is clearly documented and complied with.

An equipment register records the details of all equipment. A maintenance programme is also in place.

Optimisation

Dose optimisation is the balance between the lowest dose and the image quality that is clinically suitable. All operators we spoke with could describe how they would select the correct protocol for the intended purpose.

The medical physics expert carries out dose audits. This information is used to compare the doses in ROC Clinic with those of neighbouring NHS boards. We saw local dose reference levels displayed near equipment. Should the recorded value of an exposure be outside agreed limits, an investigation will be carried out.

Accidental or unintended exposure

Employer's procedure EP5 (Procedure for managing and reporting adverse radiation events and near misses) details the procedure to follow when an error has taken place. The process of reporting and investigating incidents was well understood by all staff we spoke with. We were told about a culture that supports the reporting of incidents and sharing lessons learned.

What needs to improve

While we were assured staff review clinical history and laterality as part of their patient identification checks, this is not reflected in the employer's procedures (recommendation b).

Employer's procedure EP2 (Entitlement of duty holders) states an individual can be deemed competent to use equipment either by their previous experience or training. However, an individual should only be deemed competent by previous training, not on experience alone (recommendation c).

While the current approach to optimisation is good and includes comparison of doses against neighbouring NHS boards, there is no multidisciplinary approach to dose optimisation. COMARE 16¹ recommends dose optimisation teams are established to provide a multidisciplinary approach to dose optimisation.

¹ Committee on Medical Aspects of Radiation in the Environment (COMARE): 16th Report. Public Health England. 14 August 2014

While most employer's procedures were comprehensive and clear, we saw areas where the clinical practice was good, however the employer's procedures did not reflect this. These include the following.

- Language in EP9 (Making enquires of pregnancy status) should be updated to reflect the new legislation that individuals of child bearing capacity are asked about pregnancy status.
 - The language in EP1 (Entitlement and responsibilities of medical and dental referrers for medical exposures) should be revised to ensure it is clear which independent dentists and doctors are entitled and that consultant radiologists are deemed competent and awarded entitlement and do not assess their own competency.
- No requirements.

Recommendation b

- ROC Clinic should ensure its employer's procedure EP8 (Identification of patients) includes the full scope of identification checks staff carry out to ensure consistency and reduce the risk of identification errors. This should include clinical information and laterality.

Recommendation c

- ROC Clinic should update its employer's procedure EP2 (Entitlement of duty holders) to ensure competency to use equipment is only determined by training and assessment.

Domain 6 – Policies, planning and governance

High performing healthcare organisations translate strategy into operational delivery through development and reliable implementation of plans and policies, and have effective accountability, governance and performance management systems in place.

What we found - policies and procedures

Each organisation must appoint an IR(ME)R lead who is responsible for the implementation of systems and processes to ensure statutory requirements are being met. ROC Clinic's lead radiographer is the IR(ME)R lead – they are supported by the medical physics experts.

What we found - risk management, audit and governance

The local radiation protection committee is chaired by the chief executive. It meets twice each year and reviews implementation of IR(ME)R, any near misses and incidents. It is attended by the medical physics expert and radiographers. IR(ME)R is also discussed in the following:

- The clinical governance committee meets every 3 months. This committee is chaired by a member of medical staff and reports are shared regularly with the chief executive.
- The medical advisory committee meets regularly and includes the review of medical staff competency to perform their roles.
- Clinical incident meetings take place each week to discuss any adverse events, which included any IR(ME)R related incidents.

IR(ME)R is also discussed at the weekly operational meetings, which has representatives from each department.

We are assured that the governance arrangements in place provide the chief executive with the necessary assurance about the implementation of IR(ME)R.

Clinical audit

We saw a comprehensive IR(ME)R compliance audit, which is completed every 2 years. The results are used to develop an action plan to drive any required improvement. Examples of audits include review of justification and clinical evaluation of exposures, dose audits and compliance with IR(ME)R. Such as, a recent audit of chest x-rays led to improvements in the quality of images after learning from the audit was shared.

Peer review is encouraged in ROC Clinic. We were told an audit is due to begin shortly and will include review of justification and reporting by both radiographers and radiologists.

- No requirements.
- No recommendations.

Domain 7 – Workforce management and support

High performing healthcare organisations have a proactive approach to workforce planning and management, and value their people supporting them to deliver safe and high quality care.

What we found - staff recruitment, training and development

Expert advice

Medical physics expertise is provided by NHS Grampian. The contract between ROC Clinic and NHS Grampian includes an appointment letter for the medical physics experts. They provide advice in relation to compliance with IR(ME)R. They are involved in a variety of areas such as:

- commissioning of new equipment
- acceptance testing of new equipment
- local dose reference levels
- dose monitoring, and
- analysis of incidents.

We were told that the medical physics experts provide an annual report to ROC Clinic following an onsite visit. Staff told us the medical physics experts are easily contactable and available for advice and support.

Medical physics experts also provide advice on whether or not an incident requires to be reported to Healthcare Improvement Scotland.

Training

We saw a comprehensive training programme in place. Application specialists provide training for radiographers on each piece of equipment. Training has been provided to ensure that all staff are competent to justify referrals and carry out exposures for each part of the body. Training records were in place to reflect this.

IR(ME)R specific training is completed regularly by all radiology staff.

- No requirements.
- No recommendations.

Appendix 1 – Requirements and recommendations

The actions that Healthcare Improvement Scotland expects the independent healthcare service 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.

| Domain 1 – Key organisational outcomes | |
|--|---|
| Requirements | |
| None | |
| Recommendation | |
| a | ROC Clinical should ensure mammography referrals are only requested by those with the expert knowledge to make the request (see page 10). |

| Domain 5 – Service Delivery | |
|-----------------------------|--|
| Requirements | |
| None | |
| Recommendations | |
| b | ROC Clinic should ensure its employer’s procedure EP8 (Identification of patients) includes the full scope of identification checks staff carry out to ensure consistency and reduce the risk of identification errors. This should include clinical information and laterality (see page 14). |
| c | ROC Clinic should update its employer’s procedure EP2 (Entitlement of duty holders) to ensure competency to use equipment is only determined by training and assessment (see page 14). |

Complaints/Concerns

If you would like to raise a concern or complaint regarding any aspect of the inspection then please discuss this with the lead inspector in the first instance.

If there is a concern or complaint about the conduct of an inspector please contact Kevin Freeman-Ferguson, Head of Service Review, kevin.freeman-ferguson@nhs.scot in the first instance to discuss your concerns in more detail.

Alternatively, Healthcare Improvement Scotland has a complaint and feedback service that can be contacted directly. Details can be found on our webpage.

http://www.healthcareimprovementscotland.org/about_us/contact_healthcare_improvement/complaints.aspx

Our contact details are:

Healthcare Improvement Scotland

Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

Telephone: 0131 623 4300

Email: his.comments@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 contactpublicinvolvement.his@nhs.net

Healthcare Improvement Scotland

Edinburgh Office
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

0131 623 4300

Glasgow Office
Delta House
50 West Nile Street
Glasgow
G1 2NP

0141 225 6999

www.healthcareimprovementscotland.org