



Healthcare
Improvement
Scotland

Inspections
and reviews
To drive improvement

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

The Balfour, Kirkwall
NHS Orkney

23-24 November 2022

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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 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 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 the Ionising Radiation (Medical Exposure) Regulations (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 Balfour, Kirkwall (NHS Orkney) on Wednesday 23 and Thursday 24 November 2022. We spoke with a number of staff including the lead radiographer, radiologists and radiographers. The inspection team was made up of two inspectors.

The Balfour offers plain film and computerised tomography (CT). The focus of this inspection is the imaging department. NHS Orkney has a service level agreement in place with NHS Grampian to provide radiology and medical physics experts.

What we found

What the service did well

- We were told about strong leadership in the NHS board and saw an effective management team in place in relation to IR(ME)R.
- We were told about innovative examples, such as the use of a portable x-ray machine that enables exposures to be carried out, outside hospital settings in remote health centres.
- We are assured a strong working relationship is in place between NHS Orkney and NHS Grampian.
- A robust training plan was in place.

What the service needs to improve

- The NHS board must ensure all staff who refer have individual entitlement and a clearly defined scope of practice.
- NHS Orkney must ensure it is clear who is responsible for referrals submitted on behalf of responsible consultants.

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

What action we expect NHS Orkney to take after our inspection

This inspection resulted in two requirements and eight 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

NHS Orkney 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, The Balfour, 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 peoples' 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 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 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 an individual can carry out, such as the types of referrals and their roles. Their scope of practice depends on the individual's qualifications, role, training and experience. It can also change over time following additional training or moving to a new role. An individual's scope of practice is usually set out formally by the operational IR(ME)R lead and aligned training document. The individual is required to work within their scope of practice.

Employer's procedure EP1 (Entitlement of GMC registered medical staff and GDC registered dental staff to interpret images) and RA1 (To entitle practitioners and operators in radiology) provide guidance on the entitlement process. The chair of the radiation protection committee is responsible for entitling medical and dental staff to refer patients for medical exposures.

Radiographers, depending on their training, are entitled as operators to carry out justifications. One radiographer is carrying out training to allow them to

carry out clinical evaluations on plain film. Radiographers are entitled to fulfil their roles by the department responsible person.

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 specially trained to interpret diagnostic images, such as x-rays and CT scans. The NHS board has a service level agreement in place with NHS Grampian to provide radiologist services – they are entitled by the department responsible person to act as practitioners.

Another group of staff who are entitled to make referrals are non-medical referrers, healthcare professionals who are not doctors or dentists. Applications for non-medical referrers are first approved by their clinical lead. The department responsible person then receives relevant training records and evidence to support the application. The departmental responsible person is responsible for deciding whether to approve the application and establishing their scope of practice.

Referral

Electronic referrals are received by the radiology department from a variety of sources from within the hospital and from NHS Grampian. Paper referrals are received from GPs and non-medical referrers from within NHS Orkney.

A referral can only be made by a person who is entitled to do so. The role of the referrer is clearly recorded on the referral. A non-medical referrer's entitlement is currently recorded on a spreadsheet. We were told it is not always easy to find the relevant referrers scope of practice. A new process is being developed that will make the process easier. The new system should be in place by 31 March 2023.

Justification

RA2 (Justification and authorisation of radiological procedures) provides guidance on the justification of exposures. This includes which staff groups can justify medical exposures and that it must be aligned to their entitlement.

All staff told us a patient's clinical information is reviewed before a referral is justified. If insufficient information is provided, the referral is returned and a new referral must be submitted. If an exposure is urgent, such as an acutely unwell patient, the radiographer will accept verbal information to allow the exposure to be carried out quickly. Radiographers check the radiology information system for any previous exposures or duplicate referrals before carrying out an exposure.

All justifications are recorded on the radiology information system and the practitioner who made the decision is clearly identified. We are assured staff would choose the correct protocol for the exposure and processes are in place to demonstrate staff are entitled to justify and they are adequately trained to do so.

Employer's procedure RA6 (Evaluation of radiological images) describes the scope of practice of those who can evaluate clinical images. The NHS board does not have any reporting radiologists – this is covered by the service level agreement with NHS Grampian. We were told radiologists review images and report their findings. All staff we spoke with could describe the process and where this information is recorded.

Records

We saw information recorded on the radiography information system and noted staff had documented:

- the correct patient information
- details of the referrer and operator
- identification checks
- pregnancy checks
- the recorded dose
- justification, and
- clinical evaluation.

Radiography staff told us about the checks they would carry out before recording information and where they would get the dose information.

What needs to improve

Referrers do not receive individual entitlement certificates detailing their individual scope of practice (requirement 1).

Junior doctors make referrals for exposure on behalf of consultants. Referrals should be made within the individual's scope of practice. It is not documented in a procedure how junior doctors demonstrate referrals come from consultants responsible for patients' care (requirement 2).

Radiographers told us they may seek advice from a radiologist on the justification of an exposure. This discussion is recorded on the radiology

information system. We were also told if radiographers receive an urgent referral that does not have adequate clinical information, they would discuss it with the referrer. Any additional information is recorded on the radiology information system. The process of recording these discussions is not reflected in the employer's procedures (recommendation a).

Employer's procedure RA2 (Justification and authorisation of radiological procedures) states some referrals can be justified in advance. This is recorded on radiology information system at the time the patient is booked in and it will also be recorded on the paper referral. Some exposures may be justified again on the day by another radiographer, such as some plain film exposures and recorded on the radiology information system. While clear guidance is in place, staff we spoke with did not have a consistent understanding about who is accountable for the justification. We discussed the possibility on an updated radiology information system as a potential solution (recommendation b).

Requirement 1

- NHS Orkney must ensure all staff who refer have individual entitlement documentation and a clearly defined scope of practice.

Requirement 2

- NHS Orkney must ensure individuals make referrals within their scope of practice and any justifiable exceptions to this practice are detailed in an employer's procedure.

Recommendation a

- NHS Orkney should ensure its employer's procedures are updated to reflect the current practice of recording clinical conversations on the radiology information system.

Recommendation b

- NHS Orkney should ensure all staff understand who is accountable when a referral is justified for pre-booked appointments.

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 saw a positive culture is in place and were told about good relationships with colleagues from NHS Grampian. Staff felt encouraged to report mistakes and near misses and were confident about the procedures for reporting and investigating incidents. While NHS Orkney have not had any recent incidents that met the threshold to report to Healthcare Improvement Scotland, the few incidents that have taken place were investigated and the learning shared to reduce the risk of something similar happening again.

Employer’s procedures

NHS Orkney has 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. Level 1 procedures apply to the NHS board across all modalities and are reviewed every 3 years. Level 2 procedures are developed for the radiology department and are reviewed every 2 years.

Employer’s procedures we saw were mostly clear and up to date. All staff we spoke with were familiar with them and could find them easily. Employer’s procedures are stored on the shared drive. Radiographers told us that a paper copy is held in the department, however radiographers use the online version as their first choice.

Patient identification

Employer’s procedure RA3 (Identification of patients) provides guidance on the three point identification checks to be carried out for all patients before an exposure (name, date of birth and address). These checks are essential to

ensure the correct person is being exposed. All staff we spoke with could clearly describe the checks required. While the employer's procedure only indicates a three point check, staff we spoke with told us they would also 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), the reason for the exposure matched the referral and that this matched the patients understanding.

If a patient is unable to confirm their identification (such as, patients who are cognitively impaired or unconscious) staff told us that they would check their wristband to confirm their identification. Verbal confirmation from another member of staff who can identify the patient, can be accepted. However, staff prefer to use the wristband. Radiographers were clear on the process of recording patient identification on the radiology information system.

If any discrepancies are identified during the identification checks, radiographers told us they would contact the referrer and await a new referral with the correct details.

Risk benefit conversations

Employer's procedure RA17 (Provision of information relating to the benefits and risks of an exposure) 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, in changing facilities and treatment rooms to inform patients of the low risk of an exposure. Operators also discuss risks with patients when appropriate, however they do not have access to equivalent background radiation comparisons (or similar information) to support the discussion.

Making enquiries of individuals who could be pregnant

Employer's procedure RA4 (Making enquiries of pregnancy status) provides guidance for carrying out pregnancy checks before any exposure. All radiographers we spoke with were familiar with the employer's procedure. They told us individuals aged between 12 and 55, for exposures where appropriate, are asked the pregnancy status questions. All radiographers we spoke with confirmed pregnancy checks are always carried out.

RA4 clearly states pregnancy must be ruled out before carrying out any exposure. If a patient is confirmed to be pregnant, the referring clinician will record their decision to proceed on a dedicated part of the referral form. If pregnancy is suspected and the referrer has not completed this part of the

form, radiographers were clear they would seek advice from the referrer or radiologists whether to proceed with the exposure.

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

Carers and comforters procedures

Employer's procedure RA18 (Carers and comforters) provides clear guidance on the authorisation of an exposure to a carer or comforter, such as the mother of a child. All staff could describe the measures they would take to encourage carers and comforters to reduce their exposure or leave the room if possible. If a carer or comforter is present, a detailed record is kept including the role of the person, the effective dose and this is monitored over time.

General duties in relation to equipment

Radiographers receive training on equipment from the application specialist or the department's 'super user' (a member of staff who has received specialist training and deemed competent to provide training to others). Staff are assessed before using any equipment for the first time, even if they have experience in previous roles.

Quality assurance checks on equipment are completed by radiographers. They are carried out on all equipment and the frequency required is clearly documented. The CT scanner is checked weekly and plain film equipment monthly.

Radiographers told us if an equipment fault is suspected during clinical use, additional quality assurance checks are carried out. If the quality assurance check indicates an issue, a senior member of staff is informed. If a fault is confirmed the engineer and medical physics experts are informed.

An equipment register records the name of the manufacture, serial number, year of manufacture for all equipment and replacement cost of all equipment. A maintenance programme is also in place for all equipment.

Optimisation

Dose optimisation is the balance between the lowest dose and the image quality that is clinically suitable. The equipment used to expose patients to ionising radiation have a variety of protocols to help deliver standardised

exposures. Staff we spoke with were confident about modifying exposures for adults and children and taking account of different body sizes.

The medical physics expert carries out dose audits. This information is used to set local dose reference levels. Should the recorded value of an exposure be outside agreed limits, an investigation will be carried out. The investigation will consider the patient details, the quality of the image taken, the protocol used and scan range.

Radiologists offer relevant feedback to the radiographers on image quality to facilitate optimisation. If any concerns are raised, they are passed to the medical physics expert. NHS Orkney is also part of NHS Grampian's CT users group. This group considers optimisation of images on regularly. There is no equivalent group for plain film.

We were told about a culture of improvement. We saw an example of the NHS board taking services to the patient. A process was developed to get the portable x-ray equipment to remote health centres for patients who are unable to travel to The Balfour. The radiography team, led by the departmental responsible person and the medical physics expert, worked together to deliver this service. They described how they developed the scope of imaging for the portable x-ray machine, the optimisation process to ensure the dose was as low as practical and deliver the desired image quality.

Accidental or unintended exposure

Employer's procedure EP5 (Procedure for reporting adverse radiation events and near misses) details the procedure to follow when an error takes place. This includes a link to the Royal College of Radiologists guidance on clinically significant unintended or accidental exposures.

The process of reporting and investigating incidents was well understood by all staff we spoke with. We were told about a culture that encourages and supports the reporting of incidents and sharing lessons learned. Incidents and learning from them are shared through team meetings.

What needs to improve

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

Training received by staff to carry out quality assurance checks on equipment is not recorded (recommendation d).

We saw some gaps in the compliance with the frequency of the audit schedule (recommendation e).

We did not see any PAUSE posters displayed as recommended by the Society of Radiographers (recommendation f).

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 RA4 (Making enquiries of pregnancy status) should be updated to reflect the new legislation that individuals of child bearing capacity are asked about pregnancy status.
- RA22 (Applying to become a non-medical referrer for x-ray, ultrasound and CT examinations) should include expected standards and training of professionals applying to become non-medical referrers.
- Update EP6 (Radiation protection training requirements) to reflect the NHS board's current approach to training that can only be provided by application specialists and super users.
- Include the frequency of quality assurance checks for CT equipment in EP4 (Procedure for ensuring quality assurance of documents relating to IR(ME)R compliance), to be consistent with NHS Orkney's written guidance.
 - No requirements.

Recommendation c

- NHS Orkney should ensure its employer's procedure 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 (part and side of the body to be exposed).

Recommendation d

- NHS Orkney should ensure training records are complete for staff to demonstrate they are trained to carry out quality assurance checks on equipment.

Recommendation e

- NHS Orkney should ensure it complies with the frequency of equipment quality assurance checks as set out in its employer's procedure.

Recommendation f

- NHS Orkney should display PAUSE posters to ensure staff take time to carry out appropriate checks before an exposure.

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. NHS Orkney's medical director is the IR(ME)R lead – they are supported by the departmental responsible person and the interim radiology services manager. We were told about strong leadership and saw evidence of an effective management team that proactively ensures the implementation of IR(ME)R.

We also saw the departmental responsible person took a proactive approach to the revision of the employer's procedures. Changes were made when required, with the support of the medical director, the interim radiology services manager and the medical physics expert.

What we found - risk management, audit and governance

We saw an effective governance structure in place, supporting committees and groups that support safety in relation to IR(ME)R.

Any incidents and the results of audits are shared at the radiation safety committee. Any relevant information about IR(ME)R is also shared at the health and safety committee. The departmental responsible person can raise any concerns about the IR(ME)R implementation at the executive management team meetings.

Contracted services: governance arrangements

NHS Orkney has a service level agreement in place with NHS Grampian and we found a positive working relationship between the two NHS boards. NHS Grampian provide medical physics expertise and radiologist services and are responsible for the out-of-hours contracts on behalf of NHS Orkney.

Clinical audit

Employer's procedure EP3 (Departmental IR(ME)R and clinical audit) describes NHS Orkney's approach to clinical audits. The following audits are carried out:

- entitlement
- referrals
- employer's procedures
- dose levels
- justification under protocol, and
- the use of 'red dots' by radiotherapists to highlight potential areas of clinical significance in the image.

We saw effective improvements put in place following audits. Such as, an audit of referrals received from non-medical referrers in accident and emergency highlighted that nurses were carrying out clinical reporting on images that was not included in their scope of practice. The employer's procedures and associated guidance were immediately updated to ensure all non-medical referrers were operating within their scope of practice.

We saw evidence of peer review taking place in NHS Orkney. It is part of a radiographer's training to carry out clinical evaluation and justification under protocol. Peer review also takes place in specialist clinical groups.

What needs to improve

Employer's procedure RA15 (Induction and training for radiographic staff working in The Balfour radiology department) states an individual can be deemed competent to use equipment either by their previous experience or training. However, an individual can only be deemed competent by previous training, not on experience alone (recommendation g).

- No requirements.

Recommendation g

- NHS Orkney should update its employer's procedure to ensure competency to use equipment is only determined by training and assessment.

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 contracted from NHS Grampian. 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.

The medical physics experts provide an annual report to the radiation protection committee. They also provide advice on whether an incident should be reported to Healthcare Improvement Scotland. Staff told us the medical physics experts are easily contactable and available for advice and support.

Training

We found comprehensive training records in place for staff involved in medical exposure to radiation. Once a radiographer qualifies, an application specialist provides induction and ongoing training.

We were told operators must be trained on each specific piece of equipment. All the radiographers we spoke with told us they had received appropriate training and all training records we saw were up to date.

NHS Orkney offers student placements for radiographers. All staff we spoke to were clear that student radiographers can only work while being supervised by a qualified radiographer. Radiographers knew they were accountable for the actions of a student during an exposure.

What needs to improve

We saw a robust training programme in place to train radiographers to carry out justification and reporting (clinical evaluation), including an audit of the decision making. However, this is not detailed in an employer's procedure (recommendation h).

- No requirements.

Recommendation h

- NHS Orkney should ensure a procedure is in place to reflect the training and auditing requirements to enable radiographers to report and provide justification under protocol.

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	
1	NHS Orkney must ensure all staff who refer have individual entitlement documentation and a clearly defined scope of practice (see page 11). <i>Regulation 6 Ionising Radiation (Medical Exposure) Regulations 2017</i>
2	NHS Orkney must ensure individuals make referrals within their scope of practice and any justifiable exceptions to this practice are detailed in an employer’s procedure (see page 11). <i>Regulation 6 Ionising Radiation (Medical Exposure) Regulations 2017</i>
Recommendations	
a	NHS Orkney should ensure its employer’s procedures are updated to reflect the current practice of recording clinical conversations on the radiology information system (see page 11).
b	NHS Orkney should ensure all staff understand who is accountable when a referral is justified for pre-booked appointments (see page 11).

Domain 5 – Service Delivery	
Requirements	
None	

Domain 5 – Service Delivery (continued)

Recommendations

- c** NHS Orkney should ensure its employer’s procedure 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 (part and side of the body to be exposed) (see page 16).
- d** NHS Orkney should ensure training records are complete for staff to demonstrate they are trained to carry out quality assurance checks on equipment (see page 16).
- e** NHS Orkney should ensure it complies with the frequency of equipment quality assurance checks as set out in its employer’s procedure (see page 17).
- f** NHS Orkney should display PAUSE posters to ensure staff take time to carry out appropriate checks before an exposure (see page 17).

Domain 6 – Policies, planning and governance

Requirements

None

Recommendation

- g** NHS Orkney should update its employer’s procedure to ensure competency to use equipment is only determined by training and assessment (see page 19).

Domain 7 – Workforce management and support

Requirements

None

Recommendation

- h** NHS Orkney should ensure a procedure is in place to reflect the training and auditing requirements to enable radiographers to report and provide justification under protocol (see page 20).

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

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