



Healthcare
Improvement
Scotland

Inspections
and reviews
To drive improvement

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

Gilbert Bain Hospital, Lerwick
NHS Shetland

15-16 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. 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 Gilbert Bain Hospital, Lerwick, NHS Shetland, on Tuesday 15 November and Wednesday 16 November 2022. We spoke with a number of staff including the IR(ME)R lead and radiographers. The inspection team was made up of two inspectors.

Gilbert Bain Hospital offers plain film and computerised tomography (CT). The focus of this inspection is the imaging department. NHS Shetland 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

- A positive safety culture is in place with respect to reporting and learning from incidents and near misses.
- The NHS board has a strong clinical audit cycle in place, which is completed regularly.

What the service needs to improve

- Ensure individuals make referrals within their scope of practice.
- Ensure a system is in place to demonstrate non-medical referrers are appropriately entitled.
- Training expectations must be identified for all non-medical referrers.
- Employer's procedures should be developed to ensure all relevant areas of practice are covered.

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

What action we expect NHS Shetland to take after our inspection

This inspection resulted in three requirements and nine 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 Shetland 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, Gilbert Bain Hospital, 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 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 formally set out by the operational IR(ME)R lead and aligned training document. The individual is required to work within their scope of practice.

The chair of the radiation safety committee is responsible for entitling medical and dental staff to make referrals. A range of employer's procedures (EP1, EP2, RA01 and RA1A) sets out the entitlement process in the medical imaging department and includes dental staff.

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. A service level agreement is in place with NHS Grampian to provide radiologists, who are appropriately entitled.

Another group of staff who are entitled to make referrals are non-medical referrers, healthcare professionals who are not doctors or dentists. Some non-medical professionals, such as physiotherapists, may ask their clinical lead if they can apply to become non-medical referrers. Once this is agreed, the department responsible person then confirms their entitlement within a defined scope of practice. A full list of all non-medical referrers, including their scope of practice, is available in a folder held in the radiology department.

Referral

Referrals are received by the radiology department from a variety of sources, including from within Gilbert Bain Hospital and the community, such as GPs. Referrals are usually made using paper forms. NHS Grampian receive electronic referrals through its radiology information system – these are then forwarded to NHS Shetland.

A referral can only be made by a person who is entitled to do so. The role of the referrer is recorded on the referral and can be checked against their entitlement. When a referral is received from a non-medical referrer, a radiographer checks their scope of practice against the list of non-medical referrers. We were told if a referral is received that is outwith an individual's scope of practice, it is rejected.

We saw the NHS board introduced a new entitlement record for non-medical referrers. However, we noted the new paperwork is not as clear as the previous version.

Justification

Employer's procedure RA2 (Justification and authorisation of radiological procedures) provides guidance on the justification process for exposure to ionising radiation. This includes which staff groups can justify medical exposures and that it must be aligned to their entitlement.

Radiographers we spoke with 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.

All justifications are recorded on the radiology information system and the practitioner who made the decision is clearly identified. Radiographers check the radiology information system for any previous exposures or duplicate referrals before carrying out an exposure. We are assured staff would choose the correct protocol for the medical 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 (Clinical 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. In order to reduce the number of clinical evaluations being carried out by NHS Grampian, NHS Shetland is currently training a radiographer to produce clinical evaluations within a defined scope of practice.

Records

Radiography staff told us how they would record the following:

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

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

While we saw processes in place for the entitlement of non-medical referrers, no training criteria had been identified to ensure this group of staff are competent to be entitled to carry out their duties (requirement 1).

The current process for entitling non-medical referrers requires their clinical lead (who may be outwith the radiology department) to review evidence and confirm they are competent to make referrals. The department responsible person then counter-signs the scope of practice as submitted by the applicant's clinical lead. The department responsible person has no role in quality assuring any aspects of the application and does not receive any evidence to demonstrate that entitlement is appropriate and is clinically required. We saw one example where a non-medical referrer had approved their own application as clinical lead (requirement 2).

We saw an example where a clinical oncologist sent information to a specialist nurse to complete the referral on their behalf – this is outwith the specialist nurse's scope of practice. We were also told junior doctors may also make

referrals out with their own scope of practice on behalf of consultants. Individual should only make referrals within their defined scope of practice. However, when this is not practical, due to aspects of remote working unique to NHS Shetland, this process must be clearly detailed in an employer's procedure (requirement 3).

NHS Shetland recently introduced a new way of recording non-medical referrers' scope of practice, which did not clearly define the extent of their roles within which they can make referrals. We saw older paperwork, which clearly demonstrated the scope of practice (recommendation a).

We saw no evidence of non-medical referrers carrying out regular audits of their referrals, as recommended in the Royal College of Radiographers guidance. A selection of completed audits should be checked by the NHS board to provide assurance that non-medical referrers maintain their competency in line with their scope of practice (recommendation b).

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 and the paper referral at the time the patient is booked in. Some exposures may be justified again on the day by another radiographer, such as some plain film exposures. This resulted in lack of clarity around who is responsible for the justification. It was not clear from the employer's procedure at which point in the process, an individual is accountable for the justification of an exposure. We discussed the possibility of updating the radiology information system so the person accountable for justifying the exposure is clearly identifiable (recommendation c).

Radiographers told us they may seek advice from the radiologist on the justification of an exposure. The radiographer documents this discussion on radiology information system and accepts accountability for the justification under protocol. While we were assured the process works well in practice, this was not reflected in the employer's procedures (recommendation d).

Requirement 1

- NHS Shetland must identify standards and training required to entitle non-medical referrers.

Requirement 2

- NHS Shetland must introduce a system to demonstrate non-medical referrers are appropriately entitled based on competence and clinical need.

Requirement 3

- NHS Shetland 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 Shetland should ensure the scope of practice for all non-medical referrers is clearly recorded.

Recommendation b

- NHS Shetland should ensure non-medical referrers regularly audit their referrals and a sample of these audits are checked.

Recommendation c

- NHS Shetland should ensure its employer's procedures clearly state who is accountable when a referral is justified for pre-booked appointments.

Recommendation d

- NHS Shetland should ensure a protocol is in place to record any discussions between the radiologist and radiographer that supports decisions to justify exposures of patients.

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 in NHS Shetland. Staff felt confident to report mistakes and near misses and were confident about the procedures for reporting and investigating incidents. All incidents have been investigated and the learning shared to reduce the risk of something similar happening again. No incidents have taken place recently that met the threshold to report to Healthcare Improvement Scotland.

We saw PAUSE posters prominently displayed in each clinical room in the radiology department to remind staff to take the time when carrying out appropriate checks before carrying out patient exposures.

Employer’s procedures

NHS Shetland has a duty under IR(ME)R to develop written procedures commonly referred to as employer’s procedures. These procedures provide a framework under which professionals can practice. NHS Shetland has a clear structure for the development and update of its employer’s procedures. Level 1 employer’s procedures apply to the NHS board, including all modalities and should be reviewed every 3 years. Level 2 procedures should be reviewed every 2 years and are modality specific.

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 a shared drive. Staff told us they would use the online version in the first instance. While paper copies are held in the department, radiographers usually use the online version. Radiographers assured us that the paper copies were up to date.

Patient identification

Employer's procedure RA3 (Identification of patients) provides guidance on the three point identification checks (name, address and date of birth) to be carried out for all patients before an exposure. These checks are essential to ensure the correct patient is being exposed. All staff we spoke with could clearly describe the checks carried out before an exposure. While the procedure only states a three point identification check is required, all staff we spoke with told us they would also review a 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 identity (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 is not accepted as adequate confirmation of identification before an exposure is carried out.

If any discrepancies are identified during the identification checks, radiographers told us they would return the referral to the referrer and await a new referral. Once the patient identification checks are complete, this is recorded the radiology information system.

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 and in changing facilities to inform patients of the low risk of an exposure. Operators will also discuss the risks with patients when appropriate and have access to equivalent background radiation comparisons to support these discussions.

Making enquiries of individuals who could be pregnant

Employer's procedure RA04 (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.

RA04 clearly states pregnancy must be ruled out before carrying out any exposure. If a patient is confirmed to be pregnant, the referrer will record their decision to proceed on 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 and not proceed.

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 parent 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

Training for use of the x-ray equipment is delivered by radiographers. Staff are assessed before using any equipment for the first time, even if they have experience in previous roles. Radiographers receive specialist training from the radiography application specialist for the new CT scanner.

Quality assurance checks on equipment are completed by radiographers. They carry out checks on all equipment and the frequency required is clearly documented and complied with. The CT scanner is checked weekly and plain film equipment every 2 months. Training to carry out quality assurance of equipment is provided and competency recorded in the training record.

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

An equipment register records the name of the manufacture, serial number and year of manufacture for all equipment. A maintenance programme is also in place for all equipment. While some equipment is old, the medical physics expert confirmed performance is within acceptable limits of dose for patients.

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. The local dose reference level for exposures for both adults and children was clearly displayed in the relevant rooms. 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.

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

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 reference 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 supports the reporting of incidents and sharing lessons learned. Incidents and learning from them are shared throughout the radiology department.

What needs to improve

All radiographers we spoke with described carrying out patient identification checks that included laterality (part and side of the body to be exposed) and checking clinical information with the patient. However, the full scope of checks is not reflected in the employer's procedure (recommendation e).

While processes were in place to ensure pregnancy status checks are carried out, the employer's procedure does not reflect the current legislation. All employer's procedures should also be gender neutral.

- No requirements.

Recommendation e

- NHS Shetland 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.

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 Shetland has appointed the medical director as the IR(ME)R lead. They are responsible for the implementation of IR(ME)R and supported by the departmental responsible person (the imaging lead). Both IR(ME)R lead and department responsible person are relatively new to the role.

What we found - risk management, audit and governance

NHS Shetland has a radiation safety committee, which restarted following the pandemic in April 2021. The medical physics expert's annual report are shared with this group.

Contracted services

NHS Shetland has a service level agreement in place with NHS Grampian, who provide medical physics expertise and radiologist services. NHS Grampian also contract out-of-hours services, which is accessible to NHS Shetland.

Clinical audit

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

- entitlement
- referrals
- employer's procedures
- quality assurance checks
- dose audits
- red dot audits, and
- justification under protocol.

What needs to improve

Employer's procedure RA15 (Induction and training for radiographic staff working in the medical imaging 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 f).

- No requirements.

Recommendation f

- NHS Shetland 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 safety 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, NHS Shetland provides induction and ongoing training. We saw records demonstrating relevant training had been provided.

We were told operators must be trained on each specific piece of equipment. All the radiographers we spoke with said they had received training and all training records we saw were up to date. Radiographers who are entitled to operate CT scanners are trained by an application specialist.

NHS Shetland offers student placements for radiographers. All staff we spoke with were clear that student radiographers only work while being supervised by a qualified radiographer. Radiographers are aware they are 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) that includes an audit of their decision making. However, this is not detailed a procedure (recommendation g).

Training to carry out quality assurance checks and the use of equipment in plain film is delivered by radiographers who have not been assessed as competent to deliver this training (recommendation h).

The current IR(ME)R lead was not provided with appropriate support to ensure they were aware of the full range of responsibilities under IR(ME)R and ensure the organisation was compliant with the regulations. While we saw a robust approach to induction for most staff, we did not see formal induction for senior staff who are accountable for IR(ME)R (recommendation i).

- No requirements.

Recommendation g

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

Recommendation h

- NHS Shetland should ensure all radiographers who provide training on quality assurance and how to use equipment, are appropriately trained to do so.

Recommendation i

- NHS Shetland should ensure all staff who are accountable for the implementation of IR(ME)R, receive a formal induction on the required responsibilities to be compliant with the regulations.

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 Shetland must identify standards and training required to entitled non-medical referrers (see page 11). <i>Regulation 6 Ionising Radiation (Medical Exposure) Regulations 2017</i>
2	NHS Shetland must introduce a system to demonstrate non-medical referrers are appropriately entitled based on competence and clinical need (see page 11). <i>Regulation 6 Ionising Radiation (Medical Exposure) Regulations 2017</i>
3	NHS Shetland 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 12). <i>Regulation 6 Ionising Radiation (Medical Exposure) Regulations 2017</i>
Recommendations	
a	NHS Shetland should ensure the scope of practice for all non-medical referrers is clearly recorded (see page 12).
b	NHS Shetland should ensure non-medical referrers regularly audit their referrals and a sample of these audits are checked (see page 12).

Domain 1 – Key organisational outcomes (continued)	
Recommendations continued	
c	NHS Shetland should ensure its employer’s procedures clearly state who is accountable when a referral is justified for pre-booked appointments (see page 12).
d	NHS Shetland should ensure a protocol is in place to record any discussions between the radiologist and radiographer that supports decision to justify exposures of patients (see page 12).

Domain 5 – Service Delivery	
Requirements	
None	
Recommendation	
e	NHS Shetland 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 (see page 16).

Domain 6 – Policies, planning and governance	
Requirements	
None	
Recommendation	
f	NHS Shetland should update its employer’s procedure to ensure competency to use equipment is only determined by training and assessment (see page 18).

Domain 7 – Workforce management and support	
Requirements	
No requirements	
Recommendations	
g	NHS Shetland 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 19).

Domain 7 – Workforce management and support

Recommendations continued

- | | |
|----------|---|
| h | NHS Shetland should ensure all radiographers who provide training on quality assurance and how to use equipment, are appropriately trained to do so (see page 19). |
| i | NHS Shetland should ensure all staff who are accountable for the implementation of IR(ME)R, receive a formal induction on the required responsibilities to be compliant with the regulations (see page 19). |

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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