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

Western Isles Hospital, Stornoway
NHS Western Isles

2-3 November 2021
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
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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 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 address 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.

Summary of inspection

About our inspection

We carried out an announced inspection to the Western Isles Hospital, NHS Western Isles, on Tuesday 2 and Wednesday 3 November 2021. We spoke with a number of staff including the medical director, clinical leads, radiation policy lead (IR(ME)R lead), the radiologist and radiographers. The inspection team was made up of one inspector.

Western Isles Hospital offers plain film, computerised tomography (CT) a bone density scanner called DEXA and fluoroscopy. The focus of this inspection was the radiology department.

What we found

What the service did well

• Staff have processes in place to ensure the appropriate patient identification checks are carried out.
• The NHS board has had no reportable incidents in the last 3 years.
• All staff involved in radiology have a close working relationship. This includes those who work in the radiology department based in Western Isles Hospital and others who provide support from NHS Borders, NHS Highland and local GPs.

What the service needs to improve

• The NHS board must ensure it has a clearly defined clinical audit programme.
• The role of the radiologist must be clearly defined when justifying a proposed exposure of an individual who may be pregnant.

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

What action we expect NHS Western Isles to take after our inspection

This inspection resulted in four requirements and two 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.
NHS Western Isles 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, Western Isles 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 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

Entitlement is a process required by the regulations. It sets out the scope of practice an individual can carry out, such as the types of referrals and clinical evaluations. The scope of practice depends on the individual’s role, qualifications, 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 set out in a formal letter from the radiation policy lead.

Radiographers, depending on their training, are entitled to act as operators and carry out justifications of plain film x-rays.

NHS Western Isles recently appointed a full time radiologist. As a fellow of the Royal College of Radiologists, they 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.

Referral

A referral can only be made by a person who is entitled to do so. Referrals are received by the radiology department from a variety of sources, both within the Western Isles Hospital and from the community. Referrals are submitted using...
Paper radiology request forms and transferred onto the electronic radiology information system. DEXA referrals are received electronically.

Paper referrals must clearly identify the referrer as either a doctor, GP or non-medical referrer and include a clinical summary. The form should be completed by one person – this is based on learning from previous incidents. The same form is used to record the justification, pregnancy status checks and patient identification checks. Should a request be rejected and returned to the referrer, it will be noted on the paper referral form.

**Justification**
The radiologist reviews CT and some plain film referrals. Radiographers justify the majority of plan film referrals. Radiographers can also justify, under protocol, some specific head CT’s. As part of the referral, both the radiologist and radiographers ensure sufficient information is recorded to be able to justify the referral. The radiology department and hospital staff have a strong working relationships with referrers. Staff told us they would readily contact referrers to seek further clarity.

Should further clarification be needed, the referrer will be asked to amend the original referral or submit a new one before allowing it to be justified. The radiologist and radiographers told us they are clear on which protocol was appropriate for the exposure.

Staff told us they know how to contact the onsite radiologist for advice and support during regular hours. When a justifications in needed out-of-hours (between 5pm and 11pm) referrals are sent to NHS Borders for authorisation. We were told staff in NHS Borders are readily available and supportive. Referrals issued during the hours of 11pm and 8am are sent to a private contracted company.

**Records**
Radiography staff could describe the checks they would carry out prior to recording information. We saw staff had documented the following on the radiography information system:

- the correct patient information
- identification checks
- scanned documents, such as referrals including pregnancy check
- details of the referrer and operator
- radiation dose
- justification, and
• clinical evaluation.

  ■ No requirements.
  ■ No recommendations.
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 spoke with radiographers, the radiology manager, the consultant radiologist, the radiation policy lead and medical director who all told us about the positive safety culture within the NHS board in relation to IR(ME)R within the radiology department.

The radiology department is small. The radiology manager, radiographers and medical physics expert all told us senior managers in the NHS board are approachable and they feel supported in their roles. All staff we spoke with told us about the open culture and they feel safe to raise concerns. Radiographers feel supported to challenge referrals and told us the radiologist uses these as a learning opportunity for staff training.

Employer’s procedures

NHS Western Isles 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. NHS Western Isles is supported in the development of the employer’s procedure by NHS Highland’s medical physics team.

The NHS board has an overarching radiology safety policy in place for the use of ionising radiation. It sets out how NHS Western Isles will comply with IR(ME)R, including the development of employer’s procedures. NHS Western Isles has three levels of procedures:

- level 1 applies to the whole NHS board
- level 2 are standard operating procedures that are modality specific across the NHS board, and
• level 3 are protocols, including work instructions, data sheets and training records.

The responsibility for the development of employer’s procedures is detailed in document EP19 (Document control). Level 1 employer’s procedures must be authorised by the radiation policy lead. Level 2 procedures are developed by different teams and authorised by the clinical lead or radiology manager. Changes to level 2 and 3 employer’s procedure are discussed at the radiation safety committee and signed off by the radiology manager, clinical leads and radiation policy lead.

All radiographers we spoke with confirmed they are informed of any updates to the employer’s procedures. Any changes are communicated through:

• the NHS board’s intranet
• message board
• staff meetings, and
• email.

The implementation of the employer’s procedures is monitored through observation of practice by the radiology manager.

**Patient identification**

Employer’s procedures EP7 (Patient identification) provides guidance on patient identification checks and different ways to confirm a patient’s identity. This includes patients that are unconscious or in emergency situations. All radiographers we spoke with could clearly describe how to carry out identity checks and are familiar with the employer’s procedures.

Radiographers told us they pay particular attention when carrying out patient identification checks due to the common surnames on the island. They also told us they usually have time to sit and speak with patients to ensure the correct patient is identified and the clinical information. An exposure would not proceed if patient identification checks could not be completed, or there was a query about the justification of an exposure.

**Risk benefit conversations**

Employer’s procedures EP6 and RAD 2.2 both include instructions for patients who are to receive an x-ray. Patients with an appointment for a procedure that requires preparation are sent an information leaflet in advance. Information posters are also displayed in prominent places throughout the radiology department and patients are encouraged to ask any questions when they arrive.
Staff have access to an interpreter service should they need it to communicate the risk and benefit of an examination.

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

Risk benefit conversations are required when making enquiries of individuals who could be pregnant between 12 and 55, for exposures between the lower diaphragm and upper thigh are directly in the primary beam, would be asked the pregnancy status questions. The referral form is used to document that patients have been asked the relevant questions and confirm the patient is not pregnant.

Radiographers told us that should a patient be confirmed as pregnant, or think they might be, advice would be sought from the radiologist. The radiologist will provide guidance on the most appropriate imaging option and whether the exposure could wait until the patient was no longer pregnant. If an exposure is to go ahead, the radiographer would ensure confirmation is received from the referrer and radiologist and the decision is recorded in the radiology information system.

**Carers and comforters procedures**

Employer’s procedures EP23 and level 2 RAD2.9 (Carers and comforters) both detail the procedure for authorising an exposure to a carer or comforter, such as the mother of a child. If an exposure is to go ahead, it will be recorded in the radiology information system. All radiographers we spoke with are clear they would try to avoid exposure of a carer or comforter where possible. All carers and comforters must be 16 and over.

**General duties in relation to equipment**

One radiographer is trained to carry out routine quality assurance checks on all equipment. Other radiographers do carry out some quality assurance, however they have not been formally trained in this role. The radiology manager told us the procedure when results from these checks are outside the expected parameters.

Staff told us they report any faults to the radiology manager who can escalate to the manufacturer if necessary. Handover documents are completed by the service engineer after every visit. Quality assurance is carried out after every piece of equipment is handed back. The engineer will indicate whether additional quality assurance check are required before the use of x-ray equipment. All staff we spoke with were aware of the procedure when a service engineer is on site and what documentation is used as part of the handover. We saw documentation from the service engineer and quality assurance records were in place.
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 has a variety of protocols that help deliver standardised exposures. Exposures can be modified for adults and children and take account of different body sizes. All the operators we spoke with could describe how they would select the correct protocol for the intended purpose.

Medical physics staff use dose audit information to set local dose reference levels. Where local dose reference levels are not available, UK dose reference levels are used. All local dose reference levels are lower than the national levels as a result of work carried out by medical physics expert and radiology manager.

Employer’s procedure EP13 (Optimisation of Exposure) states that imaging protocols are reviewed by a multidisciplinary team at least every 2 years. The NHS board have not managed to fully implement this due to the lack of a full time radiologist. This work was previously been led by the medical physics expert and radiology manager.

The radiologists told us they have been working with the clinical lead to drive consistency in both dose and optimisation.

Accidental or unintended exposure

NHS Western Isles employer’s procedure EP15 (Reporting and investigation of accidental and unintended exposure to patients) sets out the procedure for reporting incidents and carrying out any investigation. All incidents are reported to the medical physics expert who provides guidance on whether or not an incident meets the criteria for a statutory notification. The radiology manager plays a key role in their link to the medical physics expert and they ensure that all incidents are reported.

NHS Western Isles has had no incidents required to be notified to the inspectorate in the last 3 years. This is due to the vigilance of staff in the hospital and the systems in place, particularly around patient identification and staff having the opportunity to discuss clinical information with patients.

What needs to improve

Employer’s procedure EP8 (Exposure of females of childbearing potential) and the decision diagram in RAD3.175 in the level 3 employer’s procedures provide guidance on the process to follow in the event that a pregnant individual needs
to be exposed to ionising radiation. It does not include the role of the radiologist in the decision making process (requirement 1).

The NHS board has one radiographer specifically trained to carry out quality assurance checks on equipment. Other radiographers carry out quality assurance checks after an engineer’s visits, however they have not been formally trained (requirement 2).

With the radiologist now in post, NHS Western Isles should move to a more formal multidisciplinary approach to optimisation. This multidisciplinary team should report to the radiation safety committee (recommendation a).

The radiation safety policy provides details of the role of the radiation protection advisor, who also undertakes the role of the medical physics expert. However, the policy does not detail the role of the medical physics expert (recommendation b).

We saw that a small number of local dose reference levels could not be set due to a lack of available data. NHS Western Isles should consider working with NHS Highland to review combined data to support local dose reference levels that are lower than the national.

**Requirement 1**
- NHS Western Isles must include the role of the radiologist in its employer’s procedure when justifying exposures of individuals who are, or may be, pregnant.

**Requirement 2**
- NHS Western Isles must ensure that staff who undertake quality assurance checks on equipment are appropriately trained to do so.

**Recommendation a**
- NHS Western Isles should develop an imaging optimisation group that includes representation from medical physics experts, radiologists and radiographers. The group should have clear roles and responsibilities to provide governance and co-ordination of any dose optimisation undertaken.

**Recommendation b**
- NHS Western Isles should ensure its radiation safety policy includes the roles and responsibilities of the medical physics expert.
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
NHS Western Isles has an overarching radiation safety policy that clearly sets out the roles and responsibilities of the chief executive officer, radiation policy lead, clinical leads and radiation protection advisor in relation to IR(ME)R.

The radiation policy lead is responsible for the implementation of IR(ME)R and provides continuity for radiation safety. They are supported operationally by the radiology manager, medical physics expert and clinical lead. The medical director receives an annual report from the radiology manager, which includes an overview of radiology services and IR(ME)R implementation. The radiation policy lead can easily contact the medical director and chief executive if required.

The radiation safety committee is chaired by the radiation policy lead. The committee discusses any ongoing issues or developments in relation to IR(ME)R including clinical audits. While the group only meets twice each year, we were told anything that needs immediate attention would be addressed between meetings. The NHS board has a collective approach to the implementation of IR(ME)R and senior managers are readily accessible to discuss IR(ME)R related issues. The committee provides assurance to the medical director and chief executive that the NHS board is meeting its statutory obligations. It also links to the:

- acute clinical care governance committee
- quality planning and quality assurance committee and
- improvement committee.

What we found - risk management, audit and governance
Contracted private services: governance arrangements
NHS Western Isles has an arrangement with NHS Borders for the provision of out-of-hours radiology cover between 5pm and 11pm. During 11pm to 8am radiology support is provided by NHS Borders’ contracted out-of-hours provider. As there is only one substantive radiologist, radiographers and medical staff can contact either NHS Borders radiologists, or the contracted private company, for
advice when required. All justifications are assigned to an individual and their details are recorded on NHS Western Isles’ radiology information system.

NHS Borders’ clinical lead is responsible for the ongoing governance arrangements for the private company that provides out-of-hours services for both NHS boards.

Clinical audit
The radiology manager co-ordinates the delivery of audits on behalf of the clinical lead. The scope of audits are set out in employer’s procedure EP21 (Clinical audit) and cover the following:

- entitlement process
- list of entitled operators and practitioners
- patient request forms completed appropriately, including justification
- adverse incidents, and
- dose reference levels are not consistently exceeded.

The new radiologist recently carried out an audit of 150 patient records to ensure appropriate justifications and clinical evaluations had been carried out by locum radiologists and the private contracted out-of-hours service. A graded scale was used to identify any areas requiring action. The outcome of the audit was reported with the clinical lead.

Other examples of more focused clinical audits include:

- The review of all clinical evaluations of every cancer patient, by a second radiologist (this accounts for 7-10% of all reports in total).
- As part of the DEXA radiographer’s ongoing training and development, all DEXA clinical evaluations are reviewed by a clinician. Once training is complete, DEXA will be included in routine clinical audits.

NHS Western Isles refer patients to other NHS boards for a variety of treatments. As a result of the audit, if any discrepancies are identified by the receiving NHS board with an NHS Western Isles image, this is fed back. As the radiologist is the sole practitioner in NHS Western Isles, they have joined the radiology events and learning meetings hosted by NHS Borders. The group provides the opportunity to discuss discrepancies in reports.
**What needs to improve**
Employer’s procedure EP21 (Clinical audit) includes an annual checklist covering a mix of quality assurance and clinical audit. However, a number of clinical audits being carried out were not included in the employer’s procedure. The NHS board should also consider including clinical audits of:

- CT justifications under protocol, and
- justifications and clinical evaluations carried out by surgical staff as part of their role.

While some of the information is transferred on to the radiology information system, it must be recorded in the scope of clinical audit (requirement 3).

**Requirement 3**
- NHS Western Isles must update its employer’s procedure on clinical audit to demonstrate the scope of clinical audits to be undertaken. It should include what should be audited, the frequency and by whom.
- 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**
NHS Western Isles contracts medical physics expertise from NHS Highland. Medical physics experts are appointed by letter from NHS Western Isles’ radiation policy lead. The role of the medical physics expert is well understood by the radiation policy lead and radiology staff. They provide advice in relation to compliance with IR(ME)R. They are involved in a variety of areas including:

- procurement and commissioning of new equipment
- quality assurance of equipment
- dose monitoring and optimisation and
- analysis of incidents.
The medical physics expert also provides advice on whether or not an incident requires to be reported to Healthcare Improvement Scotland. They told us they were currently involved in an ongoing review of local dose reference levels.

The medical physics expert visits NHS Western Isles four times each year and are contactable by telephone and video calling. They are well known to staff and works closely with the radiology manager. We were told us they are easily contactable and available for advice and support. Staff told us the medical physics experts are:

- ‘very helpful’, and
- ‘a great help to me’.

Training

We saw training records were in place for staff involved in medical exposure to radiation. The records showed that relevant training had been provided. We saw clear training records for operators of equipment in the radiology department that included CT, plain film and DEXA equipment.

A radiographer’s training is closely linked to their entitlement. We reviewed a sample of training records and saw the entitlement records corresponded to the training records.

It is the responsibility of the radiographer to maintain their own continual professional development as part of their professional registration. NHS Western Isles provide support to staff through a variety of different learning opportunities. Staff told us they feel supported to take an equivalent of a half day every month for their continual professional development.

A radiologist’s training and continual professional development is managed through their annual appraisals and medical revalidation process.

Employer’s procedure EP22 (Supervision of trainees) describes the role of student radiographers and their supervisor. Student radiographers can only work under the supervision of a qualified radiographer and the supervisor remains responsible for the students practice. All staff we spoke to we clear on their responsibility when working with students.

The DEXA radiographer is currently working with the medical lead for DEXA as part of a fracture liaison service. As part of the training the radiographer undertakes the clinical evaluation and the medical lead does the same, counter signing the original and amending as required. Once the radiographer has
completed their training the medical lead will provide clinical supervision thereafter.

**What needs to improve**

While we saw evidence of continual education for radiologists and radiographers, it was not always possible to identify the training that related specifically to IR(ME)R. It was also unclear what training was required for staff outside radiology who have obligations under IR(ME)R (requirement 4).

**Requirement 4**

- NHS Western Isles must develop a procedure that details the continual education requirements for all who work within the scope of IR(ME)R.

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

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  *Regulation 6(a)*  
  *Ionising Radiation (Medical Exposure) Regulations 2017*

| 2 | NHS Western Isles must ensure that staff who undertake quality assurance on equipment checks are appropriately trained to do so (see page 15). |

  *Regulation 17(6)*  
  *Ionising Radiation (Medical Exposure) Regulations 2017*

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| b | NHS Western Isles should ensure its radiation safety policy includes the roles and responsibilities of the medical physics expert (see page 15). |
### Domain 6 – Policies, planning and governance

**Requirement**

3. NHS Western Isles must update its employer’s procedure on clinical audit to demonstrate the scope of clinical audits to be undertaken. It should include what should be audited, the frequency and by whom (see page 18).

*Regulation 12(9)*  
*Ionising Radiation (Medical Exposure) Regulations 2017*

**Recommendations**

None

### Domain 7 – Workforce management and support

**Requirement**

4. NHS Western Isles must develop a procedure that details the continual education requirements for all who work within the scope of IR(ME)R (see page 20).

*Regulation 6(3)(b)*  
*Ionising Radiation (Medical Exposure) Regulations 2017*

**Recommendations**

None
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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