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

Raigmore Hospital, Inverness
NHS Highland

1-2 December 2020
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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 the 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.
More information about the quality framework and quality of care approach can be found on our website:

Summary of inspection

About our inspection

We carried out an announced inspection to the Raigmore Hospital, Inverness, on Tuesday 1 and Wednesday 2 December 2020. We spoke with a number of staff including the deputy chief executive, IR(ME)R lead, radiologists and radiographers. The inspection team was made up of two inspectors.

Raigmore Hospital offers x-ray, computerised tomography (CT), mammography and nuclear medicine. The focus of this inspection is the radiology department.

What we found

What the service did well

• We saw a positive culture for the reporting and learning from incidents.
• Staff had a clear understanding of employer’s procedures, which were easily accessible.
• Clear governance structures are in place and positive radiology leadership in terms of IR(EM)R.

What the service needs to improve

• Medical staff must be provided with a copy of their personal scope of entitlement.
• Maintain an up-to-date list of non-medical referrers including their scope of entitlement.

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

What action we expect NHS Highland to take after our inspection

This inspection resulted in three requirements and six 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. www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/independent_healthcare.aspx.
NHS Highland 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, Raigmore 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 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

NHS Highland employer’s procedure EP2 (Identification of Referrers, Practitioners, Operators including Medical Physics Experts) sets out the scope of practice for the each staff group depending on their qualifications and experience to act as a referrer, operator and/or a practitioner. An individual’s scope of practice can change over time following additional training or moving to a new role.

A radiologist is a doctor who is specially trained to interpret diagnostic images such as x-rays and CT scans. All radiologists who are Fellows of the Royal College of Radiologists are entitled to carry out justifications and clinical evaluations. Radiographers are entitled, depending on their training, to act as an operator and carry out justifications of x-rays.

Practitioners, operators and non-medical referrers (such as advanced nurse practitioners or physiotherapists) agree their initial scope of entitlement with a designated manager. Their scope of practice is reviewed when required. Employer’s procedure EP1 (Entitlement of Duty Holders for Medical Exposures) states:
• ‘Entitlement of registered healthcare professionals as medical referrers for medical exposures carried out in NHS Highland shall be by staff group, rather than by identification of individuals. Entitlement of registered healthcare professionals as non-medical referrers shall be by identification of individuals.’

This means that medical referrers are not individually entitled. NHS Highland maintains a database of medical staff who can make referrals, which all staff can access. The database is updated continuously. A similar database is also maintained for non-medical referrers that includes their scope of entitlement, however this database is not continuously updated. These list is available to radiology staff.

**Referral**
A referral can only be made by a person who is entitled to do so. Referrals will come into the radiology department from a variety of sources within Raigmore Hospital and the community. Referrals are made internally through the electronic radiology information system or paper referrals. External referrals are received by email or paper referrals. Paper referrals are scanned onto the radiology information system by the clerical staff.

**Justification**
Radiologists review all referrals other than conventional x-ray. They can only justify an exposure if there is sufficient clinical information provided by the referrer. Where an exposure cannot be justified, they would contact the referrer by phone or email. The radiographers were keen to ensure that they offered meaningful feedback about the reason the referral cannot be justified, whether it is a clinical reason or handwriting, that it is a learning opportunity for the referrers. Radiologists cover all general referrals and each has a specialty area. They described themselves as a supportive team. They told us they would consider non-ionising radiation options where possible and support referrers to choose the most appropriate imaging technique. When justifying an exposure they would choose the correct protocol for that procedure. They described referrers as receptive to any feedback.

Radiographers justify conventional x-ray exposures and fluoroscopy and follow the same procedures as the radiologist. They can authorise an agreed set of CT examinations using justification guidelines. The radiologist who wrote the guidelines remaining the practitioner.

**Records**
We looked at the information recorded on the radiology information system. All records we viewed were appropriately completed and included:
• the correct patient information
• details of the referrer and operator
• identification checks
• pregnancy checks
• the recorded dose
• justification, and
• clinical evaluation, including details of the reporting radiologist or radiographers.

Radiography staff told us the checks they would carry out prior to justifying an exposure. In all cases they would check for duplicate referrals, review the patient history and ensure the appropriate clinical information is provided. Everyone was clear what information needed to be recorded in the radiology information system and how to do this.

What needs to improve
As stated in the regulations, the employer must identify individuals to act as a referrer, practitioner or operator. We saw these procedures were in place for non-medical referrers who received an individual scope of entitlement letter. Some medical staff are individually entitled, such as cardiologists and orthopaedic surgeons, however not all medical staff are individually entitled as referrers (requirement 1).

The database that records individual non-medical referrer’s scope of entitlement relies on the entitled referrer informing the person responsible for updating the scope of practice if their roles changes. This could result in a non-medical referrer’s scope of entitlement being out of date on the database (requirement 2).

Radiographers told us of occasions where it was not possible to read the hand writing on paper referral forms. They told us they would go back to the referrer for clarity, or request a new referral was made. Referrals made using the electronic referral do not have this problem.

We were told the current radiology information system could result in delays when justifying time critical referrals from remote services. Administration staff from the referring service must alert Raigmore Hospital of an incoming referral. Raigmore administration staff then alert the radiology team of the time critical referral to request it is reviewed as soon as practicable. The system also makes timely clinical evaluation difficult if the radiologist is working in one of the
remote sites as the radiology information system does not allow clinical evaluation to be entered outwith Raigmore Hospital. Radiology staff welcomed the planned enhanced electronic system.

**Requirement 1**
- NHS Highland must ensure that each medical member of staff is provided with their individual scope of entitlement.

**Requirement 2**
- NHS Highland must maintain an up-to-date list of non-medical referrers that includes details of their current scope of entitlement.

- 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, consultant radiologists, the radiation protection lead and the lead radiologist who were all positive about the safety culture within the radiology department. We were told:

- ‘staff work as a really good team’, and
- ‘it is an open culture’.

We were told that consultants were supportive when staff asked for clarity, or requested further information, if required. Staff told us about the positive culture for reporting and learning from incidents and about the collaborative learning environment. Feedback and reflection from audits results was also encouraged.

Employer’s procedures

NHS Highland 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 Highland has three levels of employer’s procedures:

- level 1 applies to the whole NHS board, including all modalities
- level 2 that are modality specific across various sites, and
- level 3 which are usually site specific within a hospital – locally referred to as level 3 documentation.

The responsibility for the development of employer’s procedures is detailed in document EP19 (Document control).
The employer’s procedures are easily available electronically on a dedicated radiology page of the NHS board’s intranet. All staff we spoke with were familiar with the procedures and could quickly access them. Changes to employer’s procedures are communicated through the NHS board’s intranet, at team huddles, meeting minutes and briefing notes. All the radiographer’s we spoke to confirmed they are informed of any updates.

**Risk benefit discussions**

Information posters were displayed in the radiology department and in changing facilities to inform patients of the low risk of an exposure. The posters also highlighted the need to inform a member of staff of any possibility they may be pregnant.

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

This is required when making enquiries of individuals who could be pregnant. All the radiographers we spoke were familiar with the employer’s procedure EP8 (Exposure of Individuals of Child-bearing Potential) and supporting level 2 procedures.

We were told that anyone of child bearing capacity aged between 12 and 55, for exposures when the primary beam is in the area above the knee and below the diaphragm, would be asked the pregnancy status questions. The practitioner and referrer must review each individual case where a patient is confirmed as being pregnant, or if they are unable to communicate their pregnancy status. The procedures also advise that a radiologist must be consulted when an exposure requires a high dose examinations, such as CT, intravenous pyelogram (IVPs – an x-ray examination of the kidneys, ureters and urinary bladder that uses iodinated contrast material injected into veins) or barium enemas.

If a patient is confirmed to be pregnant, and the exposure is to proceed, written consent must be documented prior to any exposure to confirm the risk benefit discussion has taken place. Radiographers told us they would only proceed with routine exposures with this document in place. All records we reviewed confirmed that these discussions took place with the appropriate patients. Radiologist and referrers can authorise an exposure in emergency circumstances.

**Carers and comforters procedures**

We saw clear procedures in place for managing careers and comforters who require to be in a room with a patient when an exposure is carried out. All staff could describe the measures they would take to encourage carers and
comforters to leave the room, if possible, and how to reduce their exposure if not.

**General duties in relation to equipment**

NHS Highland have a central register of all radiological equipment. The list details the location of every piece of equipment, serial number and age. When considering whether equipment should be replaced, the following is considered:

- age of equipment
- previous safety audits, and
- radiation safety.

The register can be used to identify equipment that is reaching its end of life. This information is used to support the purchase of new equipment. Medical physics equipment safety audits are also considered when a piece of equipment needs replaced or taken out of use. The senior executive we spoke to confirmed that radiation safety would be a factor when considering any replacement of equipment.

We were told about the quality assurance procedures for equipment and shown records of quality assurance checks. A variety of quality assurance checks are carried out by radiography staff either daily, weekly and monthly. Staff were able to describe the process when a piece of equipment fails a quality assurance check. This includes asking for support from the medical physics expert and calling the engineer out to repair a piece of equipment.

We saw that when an engineer visits to repair x-ray equipment, quality assurance is carried out by radiographers prior to it being put back into service. All staff could describe this handover procedure and completed records were available on the department. The majority of the handovers sheets and audit records where up to date.

**Optimisation**

Dose optimisation is the balance between the lowest dose and the image quality that is clinically suitable. Radiologists we spoke with described how they calculate image quality with as low a dose as was reasonably practical when justifying an exposure. They also told us they would always consider if there is an alternative to ionising radiation.

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.

We were told of a recent work undertaken by a consultant radiologist who completed an optimisation project looking at CT of the neck using contrast. The outcome was a reduction in the need for additional imaging and a reduction in the overall patient dose of ionising radiation.

**Accidental or unintended exposure**
Employer’s procedure EP15 (Reporting of incidents and near-misses involving radiation) provides the details of how investigations are undertaken and who would be involved. Both radiologist and radiographers told us there was a positive culture for the reporting of incidents.

**What needs to improve**
Radiologists could demonstrate a comprehensive understanding of clinically significant incidents and described who they would involve in the decision making process. The employer’s procedures, did not reflect this level of detail but did refer to the Royal College of Radiologists guidance. The radiologists were familiar with the guidance (recommendation a).

NHS Highland communicates the benefits and risk of x-ray and CT through information posters only. This means that posters are used for all patients, of all ages, for all types of examinations. NHS Highland policy only requires the discussion of the risks benefit with the patient as part of any cardiology and intervention procedures, which involves exposure to ionising radiation. The way in which this information is delivered should vary depending on the type of examination and the individual being exposed. It should take account of the diverse delivery of service provision. The information can be given in various forms, such as posters, leaflets, verbal discussions and appointment letters, or be part of written consent (recommendation b).

We were told when an engineer repairs CT equipment it is the engineer who quality assures the equipment prior to it being put back into use, unless the repair involves the tube. In this instance the medical physics expert would conduct a quality assurance check prior to the equipment being used. Radiography staff do not undertake quality assurance checks following an engineer visit (recommendation c).

- No requirements.
Recommendation a

- NHS Highland should update its employer’s procedures when deciding if an incident meets the criteria of clinically significant. It should include details of who should be involved in the process and the roles and responsibility of each staff group.

Recommendation b

- NHS Highland should vary the way risk benefit information is provided depending on the type of examination, including CT and x-ray, and the individual being exposed and not rely solely on the provision of information posters.

Recommendation c

- NHS Highland should ensure all CT equipment is quality assured following an engineer’s visit prior to being used on patients.

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 Highland has a clear structure in place for the governance of IR(ME)R. This included IR(ME)R subgroups and a CT user group with links to the radiation safety committee.

The radiation safety committee is chaired by a consultant radiologist. The radiation policy lead, who also acts as the IR(ME)R lead, is a member of the group. The radiation safety committee reports to NHS Highland’s health and safety group, which reports to the Board committees groups (clinical governance committee and staff governance committee). This ensures the executive team, including the chief executive, are provided with assurance that IR(ME)R is being implemented. The deputy chief executive confirmed that any concerns from the radiation safety committee would be escalated up through this reporting structure, such as incidents involving radiology services. We were told about a recent incident that had been brought to their attention involving radiology services.

The radiation safety committee is provided with results from audits and incident data from service leads from different radiological services. This information is
used to monitor effective implementation of employer’s procedures and compliance with IR(ME)R. The arrangements for the development and sign-off of employer’s procedures was documented in the radiation safety policy.

**What we found - audit**

**Outsourced services: governance arrangements**

NHS Highland use outsourced services to provide out-of-hours radiology services. We discussed the arrangements for this service with the radiology service lead and the chair of the radiation safety committee, both radiologists. All radiologists provided by the service must be registered with the General Medical Council. The service undertakes its own quality assurance and clinical audits and provides NHS Highland a copy of the results.

Radiographers and medical staff can contact the outsourced service for advice during out of hours. The radiologists will justify exposures and provide clinical evaluations of images. All justifications are recorded against an individual radiologist and their details recorded on the radiology information system.

**Clinical audit**

NHS Highland has a clear policy on the audit activity to be undertaken. The radiology service lead and radiation policy lead described how the audit information is used to provide assurance that IR(ME)R is being implemented. The service lead for radiology is responsible for ensuring that clinical audits are carried out for their service. Results are submitted to the radiation policy lead for inclusion in reports to the NHS Highland’s radiation safety committee and the health and safety committee. The report includes all radiology sites across NHS Highland.

The scope of the annual audits is included in employer’s procedure EP21 (Clinical Audit) and covers:

- entitlement process
- competences of entitled practitioners and operators
- referrals resulting in a medical exposure
- making sure radiation dose is not consistently in excess of the dose reference levels, and
- equipment inventory and equipment quality control checks.

If any aspect of the annual audit fails, remedial action will be taken. The area will be audited again 6 months later.
Further audits are detailed in the level 2 clinical audit document, such as an audit of at least 20 patient referral forms every 6 months. If any of these audits falls below the required standard, it is fed back to clinicians and the audit is repeated. The minimum information to be audited on each referral is:

- patient details including patient name, address and CHI number or date of birth
- adequate clinical information so that the examination can be justified
- name of the referrer
- signature of referrer
- date of referral
- appropriate justification/authorisation of the examination
- completion of pregnancy check, and
- any examinations for research purposes.

**What needs to improve**

Employer’s procedure EP21 (Clinical Audit), states that outsourced services must be audited as part of the annual audit of services outside the radiology department. However, the employer’s procedure did not detail what should be included in the audit, such as number of records (recommendation d).

- No requirements.

**Recommendation d**

- NHS Highland should update its employer’s procedures to include details of the required frequency of audits and scale of audits when using outsourced radiologist services.

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**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 Highland’s radiation safety policy states that the radiation policy lead is responsible for ensuring that suitable and sufficient medical physics experts are
appointed. Current medical physics experts staffing levels are based on historical numbers and no workforce plan is in place that includes staffing requirements.

Medical physics experts are appointed by NHS Highland and provide advice in relation to compliance with IR(ME)R. They are involved in a variety of areas including:

- commissioning of new equipment
- quality assurance of equipment
- dose monitoring
- dose optimisation
- training, and
- analysis of incidents.

They also provide advice on whether an incident requires to be reported to Healthcare Improvement Scotland.

Staff told us the medical physics experts were easily contactable, regularly visited the department and available for advice and support.

**Training**
When a radiographer qualifies, NHS Highland provides induction training, which is recorded in a booklet. These booklets seems to be in place for newer members of staff. Any staff members who were employed over 3 years ago, did not have their training records readily available at the time of inspection. The team leads we spoke with had already identified this and were considering how to address it.

A radiographer’s training record is closely linked to their entitlement. We saw the record of staff entitlement detailed the scope of entitlement for all radiographers. However, without the accurate training records it was not possible to demonstrate that radiographer’s entitlement matched their training.

Operators must be trained on each specific piece of equipment. All staff were clear they had been trained on appropriate equipment in the department, including CT and x-ray equipment. Staff also told us they received a variety of training and are felt supported to undertake further education. They also had access to peer support if required.

Radiologist training and continual professional development is managed through their annual appraisals and medical revalidation process. It is the
The responsibility of the radiologist to maintain their own continual professional development as part of their professional registration. Radiologists we spoke with confirmed they are supported to undertake continual professional development and take study leave. Radiologists described a supporting learning environment and they have meetings where they discussed imaging and areas of learning.

Non-medical referrers carry out online training modules prior to being entitled as a referrer. While we were told that all junior medical staff will have a 30 minute IR(ME)R induction, we saw no policy to provide local IR(ME)R awareness training for referrers other medical staff. The service lead for radiology did tell us that they engage with a different groups of medical staff, such as primary care staff, to inform them of the services provided by radiology and what referrers can expect from radiology.

What needs to improve

We saw evidence of continual education for radiologists and radiographers. However, it was not always possible to identify the training that related specifically to IR(ME)R. It was also unclear what was the policy for staff outside radiology, who have obligations under IR(ME)R, in relation to their continual IR(ME)R education (requirement 3).

The European Federation of Organisations for Medical Physics. Policy Statement No. 7.1 provides guidance on the roles, responsibilities and status of the medical physicist including the criteria for the staffing levels in a medical physics department. The guidance can be used to provide detail on how to calculate suitable and sufficient medical physics staffing levels for NHS Highland (recommendation e).

The Royal College of Radiologist provides guidance on the training requirements for referrers. It is considered best practice that, where practicable, all referrers complete some form of local awareness training. NHS Highland should ensure its training includes:

- use of the electronic and paper referral system
- how to request, cancel or change a referral (electronic and/or paper)
- local procedures governing the use of IT, and
- how to access referral guidelines, including information on radiation dose (recommendation f).
Requirement 3

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

Recommendation e

■ NHS Highland should outline the medical physics expert workforce required to meet the predicted service needs.

Recommendation f

■ NHS Highland should provide local awareness training for all referrers. Training should align to guidance issued by the Royal College of Radiologists, IR(ME)R Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine.
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.

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<td>1 <strong>NHS Highland must ensure that each medical member of staff is provided with their individual scope of entitlement (see page 11).</strong></td>
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*Ionising Radiation (Medical Exposure) Regulations 2017* |
| 2 **NHS Highland must maintain an up-to-date list of non-medical referrers that includes details of their current scope of entitlement (see page 11).** |
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### Domain 5 – Safe, effective and person-centred care delivery

#### Recommendations

**b** NHS Highland should vary the way risk benefit information is provided depending on the type of examination, including CT and x-ray, and the individual being exposed and not rely solely on the provision of information posters (see page 16).

**c** NHS Highland should ensure all CT equipment is quality assured following an engineer’s visit prior to being used on patients (see page 16).

### Domain 6 – Policies, planning and governance

#### Requirements

None

#### Recommendation

**d** NHS Highland should update its employer’s procedures to include details of the required frequency of audits and scale of audits when using outsourced radiologist services (see page 18).

### Domain 7 – Workforce management and support

#### Requirement

**3** NHS Highland must develop a procedure that details the continual education requirements for all who work within the scope of IR(ME)R (see page 21).

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

#### Recommendations

**e** NHS Highland should outline the medical physics workforce required to meet the predicted service needs (see page 21).

**f** NHS Highland should provide local awareness training for all referrers. Training should align to guidance issued by the Royal College of Radiologists, IR(ME)R Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine (see page 21).
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.freemanferguson@nhs.net 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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