



Healthcare  
Improvement  
Scotland

Inspections  
and reviews  
To drive improvement

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

Dumfries & Galloway Royal Infirmary, Dumfries  
NHS Dumfries & Galloway

6-7 October 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 IR(ME)R 2017. Therefore, we only evaluate the service against quality indicators that align to the regulations.

## What we look at

We wanted 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](http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/quality_of_care_approach.aspx)

# Summary of inspection

## About our inspection

We carried out an announced inspection to the Dumfries & Galloway Royal Infirmary, NHS Dumfries & Galloway, on Tuesday 6 and Wednesday 7 October 2020. We spoke with a number of staff including the chief executive, IR(ME)R lead, allied health professional (AHP) lead, radiologists and radiographers. The inspection team was made up of one inspector.

Dumfries & Galloway Royal Infirmary offers plain film, computerised tomography (CT) mammography, bone density scanner called DEXA, interventional and nuclear medicine. The focus of this inspection was the imaging department.

## What we found

### What the service did well

- NHS Dumfries & Galloway has a strong programme of audits in place and ensures learning from audit results is implemented.
- We saw good documentation of the risk benefit discussions for patients who may be pregnant and require to have an exposure to ionising radiation.

### What the service needs to improve

- Strengthen links between the IR(ME)R lead and the radiology divisional group.

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

## What action we expect NHS Dumfries & Galloway to take after our inspection

This inspection resulted in two requirements and one recommendation. 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](http://www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/independent_healthcare.aspx).

NHS Dumfries & Galloway 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, Dumfries & Galloway Royal Infirmary, 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

The process of entitlement sets out the scope of practice that an individual can carry out, such as the types of referrals and clinical evaluations. The scope of practice depends on the individual's qualifications, role, training and experience. An individual's scope of practice can change over time, such as following additional training or moving to a new role. An individual's scope of practice is set out in a formal letter from the employer (NHS Dumfries & Galloway). The individual is required to work within this scope of practice.

NHS Dumfries & Galloway's employer's procedures EP1 (Entitlement of duty holders for Medical Exposure) and EP2 (Procedure to identify individuals entitled to act as Referrers, Practitioners, Operators, and Medical Physics Experts and a description of their duties) provides guidance on the entitlement process. The IR(ME)R lead is responsible for entitling all referrers who refer patients for medical or dental exposures to be carried out within NHS Dumfries & Galloway. EP1's appendix (Entitlement of medical staff outside Radiology to interpret images) provides guidance on the scope of entitlement for clinical evaluations, scope of referrals and expected level of training for the different staff groups.



All NHS Dumfries & Galloway medical staff and general practitioners (GPs) registered with the General Medical Council can be entitled to refer, act as a practitioner and/or operator. The scope of practice varies and factors, such as whether the GP is located in the community or based in acute care, specialty and training. EP2 provides clear guidance on the scope of practice based on qualifications and experience.

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.

All radiographers, depending on their training, are entitled as an operator to carry out justifications and clinical evaluations.

Another group of staff that are entitled to make referrals are non-medical referrers, healthcare professionals who are not doctors or dentists. The IR(ME)R lead can entitle a range health care professionals to act as referrers for a range of medical exposures. The IR(ME)R approval panel reviews requests by non-medical referrers and will advise the IR(ME)R lead whether it is appropriate for these individuals to be entitled as detailed under EP2. A full list of all non-medical referrers, including their scope of practice, is available on the NHS board's intranet site for radiographers and radiologists to access.

We reviewed the entitlement process as part of the inspection. We were assured that NHS Dumfries & Galloway has clear processes and procedures in place to demonstrate that entitlement is appropriately managed.

## 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 from within Dumfries & Galloway Royal Infirmary and from the community. Referrals are made using a standard referral card that is then scanned onto the radiology information system. NHS Dumfries & Galloway does not have an electronic referral system.

Radiographers will check the referrer's scope of practice when reviewing a referral. Doctors sign the referral card and detail who they are and their grade. It was clear from our discussions with radiographers, and our review of the referral documentation, that the referrer could not always be identified as a doctor from the information on the referral card. The process relied on local knowledge. Radiographers told us they would phone a doctor if they were unsure who they were and scope of entitlement to refer.

## Justification

NHS Dumfries & Galloway's EP5 (Justification of Medical Exposure) provides guidance on the justification process.

Radiologists review all referrals, other than plain film, to ensure that information is sufficient to justify the referral. Radiographers carry out the majority of justifications for plain film exposure and some CT procedures. Others, such as cardiologists and vascular surgeons are entitled to justify specific exposures as part of their specialty.

The radiologist or radiographer will review the clinical information that accompanies a referral and use this information to make a decision whether the referral is appropriate and can be justified. They will look for any previous imaging history for recent images and potential duplication.

When a referral is justified, the radiographer or radiologist will sign the referral card, or complete the appropriate electronic record on the radiology information system, to show that they have authorised the exposure. If the radiologist provides verbal justification, the operator will record the name of the radiologist in the radiology information system. When the justification is made, the correct protocol for the medical exposure of ionising radiation is selected.

We were told that if a referral was received with insufficient information, the radiologist or radiographer would contact the referrer to request further information. If more information was required to allow a justification to be made, a request for a new referral card with all details completed will be requested. If further clinical information is not available, or the information did not warrant an exposure, the referral would be declined and the referrer informed. Both radiographers and radiologist confirmed that this process worked well.

A record of justification is always made. Other than for specialist exposures, the justification is recorded in radiology information system.

## Records

During our inspection, we looked at the information recorded on the radiography information system and noted staff had documented:

- scanned documents
- the correct patient information
- details of the entitled referrer and operator
- identification and pregnancy checks, and

- the dose, justification and clinical evaluation.

Radiography staff could describe the checks they would carry out prior to recording this information, how they would review clinical history to check it matched the patient information and where they would get the dose information. Radiographers have access to translation services if required when communicating with patients.

Radiographers are the final check to ensure that the right patient gets the right exposure. They are positively encouraged to be vigilant.

### **What needs to improve**

Referral cards do not include contact details for the referring doctors, or their grade that links to scope of entitlement (requirement 1).

### **Requirement 1**

- NHS Dumfries & Galloway must ensure radiology staff who review referrals from clinicians can identify the referrer and confirm their scope of entitlement to make referrals.
- 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.

NHS Dumfries & Galloway 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. Each organisation must appoint an IR(ME)R lead who will take responsibility for the implementation systems and process to ensure statutory requirements are being met.

#### What we found - safe delivery of care

NHS Dumfries & Galloway’s associate medical director reports to the chief executive and is responsible for the governance and assurance of the implementation of IR(ME)R and the corresponding employer’s procedure. The AHP lead manages the implementation of IR(ME)R on an ongoing basis with the support from the IR(ME)R documentation co-ordinator and staff from the radiology department.

Radiology governance is discussed at the radiology divisional group. We were told this group links into the acute management Board and the radiation safety committee (chaired by the IR(ME)R lead). These links were not clear in the supporting documentation. These groups also connects to the acute clinical governance group.

The membership of the radiology divisional group is multidisciplinary with representatives from key staff groups including radiologists, radiographers, modality leads and managers. IR(ME)R related issues are discussed at these meeting and we saw evidence of discussions taking place about near misses and DATIX reports. Incidents are summarised and sent to the radiation safety committee. A review of radiation near misses and incidents since January 2020 has helped identify areas of improvement. Six incidents were reported to the medial physics expert, however none of these met the criteria to notify

Healthcare Improvement Scotland. Any serious concerns are brought to the attention of the senior executive team and chief executive.

The head of dental services is a member of the radiation safety committee and has responsibility for IR(ME)R in dental services. The image optimisation team is clearly linked with the radiology divisional group and radiation safety committee.

### Safety culture

Everyone we spoke to during the inspection was positive about the safety culture within the NHS board. The chief executive and IR(ME)R lead were clear that radiation safety was a priority and they wanted to reduce the exposures where possible. Radiographers are supported in their role to challenge and question referrals to ensure they are appropriate. The radiologist considers non-radiation imaging technique where possible. The staff involved in radiology all spoke about the culture of reporting near misses and incidents to drive improvements.

We saw a PAUSE poster prominently displayed in the radiology department to remind staff to take time when carrying out the appropriate checks before patient exposure. All staff we spoke to confirmed that they were supported to take the time needed to carry out all the appropriate checks.

### Employer's procedures

All NHS boards have a duty under IR(ME)R to develop written procedures in line with schedule 2 of IR(ME)R 2017. These procedures are referred to as employer's procedures. NHS Dumfries & Galloway has three levels of employer's procedures:

- level 1 applies to the whole NHS board, including all modalities
- level 2 are standard operating procedures that are modality specific across various sites, and
- level 3 are called department protocols, which are usually site specific within a hospital.

The responsibility for the development of employer's procedures is detailed in document EP19 (Document control). It was confirmed that level 2 and 3 documents would be developed by different teams and authorised by the relevant manager, clinical director or specialty team. Level 1 employer's procedures are required to be authorised by the IR(ME)R lead. Radiographers, a radiologist and the medical physics expert all confirmed they had been involved in reviewing employer's procedures.

All radiographer's we spoke with confirmed they are informed of any updates. Changes to employer's procedures are communicated through:

- the NHS board's intranet (that can be accessible by Dumfries & Galloway Royal Infirmary and community staff)
- team huddles
- meeting minutes, and
- briefing notes.

The implementation of the employer's procedures is monitored through observation of practice, audits and monitoring of incidents.

### Risk benefit conversations

Risk benefit conversations are 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 females of childbearing potential). EP8 includes a diagram detailing when to seek clinical justification. We were told that anyone of child bearing capacity aged between 12 and 55, for exposures where the lower diaphragm and upper thigh are directly in the primary beam, would be asked the pregnancy status questions.

If a patient was confirmed to be pregnant, and the exposure is to proceed, a document must be signed by the referrer, radiologist and patient prior to any exposure. Radiographers told us if a patient was pregnant they would only proceed with routine exposures with this document in place. All the records we reviewed confirmed these discussions took place with the appropriate patients. Radiologists and referrers can authorise an exposure in emergency circumstances.

Information posters were displayed in the diagnostic 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 that the patient may be pregnant.

### Carers and comforters procedures

NHS Dumfries & Galloway has clear guidance on the authorisation of an exposure to a carer or comforter, for example the mother of a child. All radiographers have received training on the authorisation of an exposure to a carer or comforter. If an exposure is authorised, it will be recorded on a separate sheet and scanned into the radiology information system. These sheets are also kept in a separate folder for ease of auditing. Audits are carried out to ensure that no individuals acting as a carer or comforter are being

regularly exposed. All the radiographers we spoke with were very clear that they would try and avoid exposure of a carer or comforter where possible.

### General duties in relation to equipment

NHS Dumfries & Galloway has a large amount of new equipment. The medical physics expert undertook acceptance testing for all this new equipment.

Staff carry out routine quality assurance checks and could describe to us the procedure if results from these checks were outside the expected parameters. Staff told us they can go direct to the manufacturer if required and medical physics experts could also be contacted for advice. All staff could describe the procedure when a service engineer is on site and what documentation is to be used. When we visited the department 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. All the operators we spoke with could describe how they would select the correct protocol for the intended purpose. Many exposures have a dose reference level that provides an indicator of the level of expected exposure.

The medical physics experts use dose audit information to set local dose reference levels. Where local dose reference levels are not available, NHS Dumfries & Galloway can use information from medical physics experts who have access to data for the west of Scotland. Scottish and UK dose reference levels are also available that provide a reference point on what the expected dose from an exposure should be. Recently national data for Scotland was published for mammography services and this has been implemented.

The equipment used to expose patients to ionising radiation has a variety of pre-set protocols that help deliver standardised exposures. These can be modified for adults and children and take account of different body sizes. All operators we spoke with could describe how they would select the correct protocol for the intended purpose and were aware of the dose reference levels. Should the recorded value of an exposure be outside agreed limits without reason, an investigation will be carried out. The investigation would consider the patient details, the quality of the image taken, the protocol used and scan range.

The radiologists we spoke with described the balance between image quality and the dose to obtain clinically effect images. They also told us they would always consider an alternative to ionising radiation.

NHS Dumfries & Galloway have an imaging optimisation team chaired by the AHP lead who is also the general manager for diagnostics. The group includes members from all modalities, medical physics experts and specialist leads. The audit data and reviews the data and discussed the implementation of revised dose reference levels are discussed at the group.

### **What needs to improve**

The IR(ME)R lead had recently changed. Communication between the radiology divisional group and the IR(EM)R lead is no longer clear and should be strengthened (recommendation a).

The majority of NHS Dumfries & Galloway employer's procedure are in paper form. It would be beneficial to utilise a document management system as a means to ensure that staff have access to the most up to date information. In addition, it would support the staff who have to maintain the documents and make them more accessible.

- No requirements.

### **Recommendation a**

- NHS Dumfries & Galloway should ensure clear communication between the radiology divisional group and IR(ME)R lead to ensure the IR(ME)R lead is engaged with any developments and discussion at the radiology divisional group.

## **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 - risk management, audit and governance**

#### **Outsourced services**

NHS Dumfries & Galloway use a private company to provide radiologist cover between 8pm and 8am. NHS Dumfries & Galloway carry out their own quality assurance and clinical audits of the service provided. Any discrepancies are discussed with the company. Radiographers and medical staff can contact the company for advice. All justifications are assigned to an individual and their details recorded on the radiology information system. The radiologists provided



by the private company will justify exposures and provide clinical evaluations of images.

### Clinical audit

NHS Dumfries & Galloway has a strong programme of audits in place. The consultant radiographer (audit co-ordinator) co-ordinates the delivery of the audit programme on behalf of the AHP lead. The scope of audits are included in employer's procedure EP21 (Staff who are trained to do so undertake) and DR-SOP4 (Clinical Audit) that details the following.

- Radiology department audits will be performed in a standardised way, using guidance from the Royal College of Radiologists' Clinical Audit in Radiology publication.
- Audits of the IR(ME)R employer's procedures will take place in their entirety every 3 years. This will be accomplished by auditing at least six procedures each year.
- The audit co-ordinator will arrange for a monthly general audit to ensure referral procedure, justification, patient identification, pregnancy status, clinical evaluation, carer and comforter documentation are being adhered to.
- Audits of radiographers in general x-ray working under protocols.

NHS Dumfries & Galloway carries out clinical audits for radiologist services that are provided by external organisations. They review 30 justifications each month. The audits review justifications to ensure they are comparable with the justification criteria within NHS Dumfries & Galloway.

Images taken by specialist, such as orthopaedic surgeons, record justifications in the patient's notes. Audits are also carried out of these clinical notes to ensure consistently is being applied. We were told that the outcome was positive.

All audits results are sent to the radiological divisional group for review. During our inspection, we reviewed the comprehensive audits carried out that covered a wide variety of topics and included the remedial action to be taken. We saw evidence that information and guidance had been produced as a result of audit findings.

- No requirements.
- No recommendations.

## Domain 7 – Workforce management and support

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

### What we found - staff recruitment, training and development

#### Expert advice

NHS Dumfries & Galloway contracts medical physics expertise from NHS Greater Glasgow and Clyde. Medical physics experts are appointed by letter by the IR(ME)R lead, which was provided in evidence. The medical physics experts provides advice to NHS Dumfries & Galloway in relation to compliance with IR(ME)R. They are involved in a variety of areas including:

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

They review audits carried out by NHS Dumfries & Galloway staff and are available for support and advice. The medical physics experts also provides advice on whether an incident requires to be reported to Healthcare Improvement Scotland. Staff we spoke with confirmed that the medical physics experts were easily contactable and available for advice and support.

Medical physics experts told us they are currently working with radiologists to review dose and image quality for plain film chest x-rays to ensure the dose used is as low as possible.

The medical physics experts report to the radiation safety committee every 6 months on the services they have provided.

#### Training

We found comprehensive training records in place for staff involved in medical exposure to radiation. Once a radiographer qualifies, NHS Dumfries & Galloway provides induction and ongoing training. We saw records that demonstrated the relevant training had been provided. We saw clear training records for operators of equipment in the department and this included CT and plain film equipment.

A radiographer's training record is closely linked to their entitlement. We reviewed a sample of records and saw the entitlement records corresponded to the training record. Training records for the last 3 years demonstrated that IR(ME)R topics were covered in each of these years. We also saw evidence of learning as a direct result of finding from audits. It is the responsibility of the radiographer to maintain their own continual professional development as part of their professional registration. Radiographers confirmed to us that they attend an annual presentation on IR(ME)R.

We were told that operators must be trained on each of the difference types of equipment. All the radiographers we spoke with told us they had received appropriate training. All training records we inspected were up to date.

Radiologist training and continual professional development is managed through their annual appraisals and medical revalidation process which occurs every 5 years.

### **What needs to improve**

While we saw evidence of continual education for radiologists and radiographers, it was not always possible to identify training that relates specifically to IR(ME)R. It was also unclear what continual education was needed for staff outside radiology, who have obligations under IR(ME)R (requirement 2).

### **Requirement 2**

- NHS Dumfries & Galloway 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 1 – key organisational outcomes	
Requirement	
1	NHS Dumfries & Galloway must ensure radiology staff who review referrals from clinicians can identify the referrer and confirm their scope of entitlement to make referrals (see page 11).  <i>Regulation 6(2) Ionising Radiation (Medical Exposure) Regulations 2017</i>
Recommendations	
None	

Domain 5 – Safe, effective and person-centred care delivery	
Requirements	
None	
Recommendation	
a	NHS Dumfries & Galloway should ensure clear communication between the radiology divisional group and IR(ME)R lead to ensure the IR(ME)R lead is engaged with any developments and discussion at the radiology divisional group (see page 16).

## Domain 7 – Workforce management and support

### Requirement

- 2** NHS Dumfries & Galloway must develop a procedure that details the continual education requirements for all who work within the scope of IR(ME)R (see page 19).

*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.freemanferguson@nhs.net](mailto: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](http://www.healthcareimprovementscotland.org/about_us/contact_healthcare_improvement/complaints.aspx)

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