



Healthcare
Improvement
Scotland

Inspections
and reviews
To drive improvement

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

Forth Valley Royal Hospital, Diagnostic
Department
NHS Forth Valley

17–18 September 2019

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

© Healthcare Improvement Scotland 2019

First published December 2019

This document is licensed under the Creative Commons Attribution-Noncommercial-NoDerivatives 4.0 International Licence. This allows for the copy and redistribution of this document as long as Healthcare Improvement Scotland is fully acknowledged and given credit. The material must not be remixed, transformed or built upon in any way. To view a copy of this licence, visit <https://creativecommons.org/licenses/by-nc-nd/4.0/>

www.healthcareimprovementscotland.org

Contents

What we found during our inspection	8
Appendix 1 – Requirements and recommendations	19
Appendix 2 – Who we are and what we do	21

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 of care 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.
- The framework has areas of focus called domains. Each domain has a number of quality indicators. These cover all aspects of a service's work to improve the quality of care provided for all users of services.

How we inspect IR(ME)R services

The focus of our inspections is to ensure each service is implementing the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R). Therefore, we only evaluate the service against quality indicators which align to the regulations.

What we look at

We want to find out how:

- organisations and individuals working within healthcare organisations implement the legal obligations to ensure that patients undergoing medical exposures to ionising radiation are appropriate and safe, and
- services are led, delivered and managed in relation to IR(ME)R.

After our inspections, we publish a report on how well a service is performing against IR(ME)R in line with our domains and quality indicators.

More information about the quality framework and quality of care approach can be found on our website:

www.healthcareimprovementscotland.org/our_work/governance_and_assurance/quality_of_care_approach.aspx

Summary of inspection

About our inspection

We carried out an announced inspection to the diagnostic department of the Forth Valley Royal Hospital on Tuesday 17 and Wednesday 18 September 2019. We spoke with a number of staff including the IR(ME)R lead manager, diagnostic staff, quality team leader and the consultant radiologist. This was the first Healthcare Improvement Scotland IR(ME)R inspection to this service.

The inspection team was made up of two inspectors.

What we found

What the service did well

- The service has a positive safety culture for the delivery of IR(ME)R.
- All staff we spoke with had clear roles and responsibilities and a clear scope of practice.
- There were clear employer's procedures and protocols in place and staff could demonstrate their implementation.
- There were clear guidelines for justifications under protocol for radiography staff.
- There was good evidence of clinical audits being undertaken and mechanisms to share learning.

What the service needs to improve

- The service must ensure that when an outsourced company is used to provide a justification, the record of that justification must be able to identify the individual practitioner.
- The record of the justification for a patient known to be pregnant must demonstrate that a discussion had been undertaken on the net benefit to the patient and exposure to the foetus had been considered.

What action we expect NHS Forth Valley to take after our inspection

This inspection resulted in four requirements and no recommendations. Requirements are linked to compliance with IR(ME)R. See Appendix 1 for a full list of the requirements.

An improvement action plan has been developed by NHS Forth Valley and is available on the Healthcare Improvement Scotland website.

NHS Forth Valley must address the requirements and make the necessary improvements as a matter of priority.

We would like to thank all staff at the diagnostic department at Forth Valley Royal 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 the quality of service delivery.

Domain 1 – Key organisational outcomes

High performing healthcare organisations identify and monitor key measures that help determine the quality of service delivery and the impact on those who use the service or work with the service.

IR(ME)R requires that those who refer for a patient for an x-ray or scan, those who operate the x-ray equipment/scanners 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

Expert advice

IR(ME)R requires that an employer must appoint a suitable medical physics expert (MPE). NHS Forth Valley has a contracted service with NHS Greater Glasgow and Clyde. Although there is a lead MPE for NHS Forth Valley, more than one MPE is appointed and may step in depending on availability and/or expertise. They have access to an MPE 5 days a week. An MPE is appropriately involved in a variety of areas including optimisation, dose surveys, quality assurance, and providing advice and commissioning of new equipment. They also estimate the patient dose for any notification and advise NHS Forth Valley if an incident requires to be notified to the regulator. An MPE is a member of the Ionising Radiation advisory group and radiation safety committee.

Optimisation

When using ionising radiation in diagnostics, the employer will try and get the dose as low as is reasonably practicable. To do this, employers set dose reference levels (DRLs), which exposures of 'average' patients should be consistently below. An MPE at NHS Forth Valley is a member of the image optimisation team. The team sets the local DRL's which are based on a review of national information and feedback from the MPE on dose surveys. Radiologists are also part of the team and ensure that the image quality continues to be

clinically effective. The DRL's were being used appropriately in NHS Forth Valley.

Clinical Audit

NHS Forth Valley has an audit schedule. They have clinical evaluation audits and have undertaken them in the emergency department. As part of the review, they will look at if the image provided was acted on clinically. If it was not then the image would not have been appropriate. This year, NHS Forth Valley looked at the rejected justifications in relation to neurology. As part of the review they were looking for trends or outliers for areas of improvement.

Requirement

- No requirements.

Recommendation

- 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

The Lead IR(ME)R consultant radiologist told us about the positive culture within the hospital. They described how radiologists felt empowered to challenge and to participate in investigations of radiation incidents. We were told by a variety of staff, including radiologists and radiographers, that there was a positive safety culture in the diagnostic department. Staff told us that implementation of the employer's procedures and protocols were core to the safe delivery of medical exposure. Staff spoken with told us they felt empowered to challenge any deviation from employer's procedures and staff were open to challenge.

We were told that there was 'great teamwork' within radiology, between all the professions which was supporting the delivery of service. The collaboration with other NHS boards was also positive, and links developed with another NHS board have made the mammography service more robust.

Reporting and investigation of accidental and unintended exposure
NHS Forth Valley Radiology Department has a level 2 procedure that provides the practical aspects of reporting and investigation of accidental unintended exposure of patients. The policy was clear and provided step by guidance. The procedure had been updated to include notifications to Healthcare Improvement Scotland. In the event of an accidental unintended exposure of patients, a radiation incident form and adverse event form is completed. The investigation will be started and it will be determined if the incident meets the criteria to be reported to HIS as the regulator. Internally those involved are asked to provide reflective comments on the circumstances of the incident. The investigation is led by the IR(ME)R lead manager and, if required, the clinical dental director. An MPE provides information on the dose estimate of any notification.

Depending on the learning or seriousness of the event, the findings will be passed to the ionising radiation advisory group. This group may then pass the incident on to the radiation safety committee and consultant radiologist IR(ME)R lead, as required. Finally information may be passed to the radiation safety committee, chaired by the medical director. Radiology management are required to log all events as part of the process to review trends which can then be addressed. As part of the process, the patient will be contacted to advise them of the incident. An MPE provides a bi-annual report to the ionising radiation advisory group and an annual report to the radiation safety committee. These reports are noted at the radiology clinical governance group meetings. We were shown evidence of recent reviews of incidents during our inspection. Even in the event of an accidental or unintended exposure the image will still be reviewed by a consultant radiologist. To support shared learning from incidents, an MPE will provide an annual report based on many of the NHS boards in the West of Scotland.

NHS Forth Valley have identified correct referral area and side (of the body) as an area of improvement in their fracture and orthopaedic clinics. Although this would be relevant to a requirement under IR(ME)R, it was not specific to IR(ME)R. NHS Forth Valley have worked to improve referrals and reduce the number of incorrect referrals with body part or incorrect side requested. As a result, staff have made changes to the patient identification procedure and this has improved referral patient identification.

Employer's duties

NHS Forth Valley has clear procedures for the development and sign off of employer's procedures and includes a delegation of responsibilities. The IAG group is responsible for signing off level 2 and 3 employer's procedures. Level 1 procedures will be agreed at the group but will require to be signed off by the medical director. The IAG group includes representatives from clinicians and the medical physics expert. There is a review of employer's procedures every 2 years. Level 1 Employer's Procedures are on NHS Forth Valley Intranet for all staff groups to access and level 2 and 3 can be found on a shared drive.

NHS Forth Valley has an employer procedure to identify individuals entitled to act as a referrer, practitioner or operator within a specific scope of practice. This includes being able to justify exposures. Entitlement is supported by training which demonstrates the competence of an individual to carry out certain functions. An individual will have a scope of entitlement which documents what functions they can undertake. For example, a doctor in training can refer for an x-ray/scan but not interventional radiology. NHS Forth Valley maintain a database of the staff who are entitled.

IR(ME)R requires that those who refer for a patient for an x-ray/scan, those who operate the equipment and those healthcare professionals (medical and non-medical) who justify that the procedure as necessary, must be adequately trained and entitled to do so. The scope of entitlement can change as individuals complete more training and develop further skills.

The IT system used to make referrals utilises drop down menus to support the correct referral request. For example, if a referrer chooses an ankle to be x-rayed/scanned, the options will then be aligned to appropriate types of protocols. This reduces the likelihood of inappropriate referral.

Within the community, GPs, advanced nurse practitioners and physiotherapists are entitled to make referrals within their scope of entitlement. The advanced nurse practitioners and physiotherapists are employees of NHS Forth Valley. Within the acute hospital all clinicians can make referrals for plain film and CT. Other healthcare professionals can also make referrals but this would be detailed within their scope of practice. For example, speech and language therapists can refer for swallow tests.

There is a mechanism in place to provide feedback should a referral request be rejected. This may be because of insufficient information or there is a more appropriate technique that avoids exposure to ionising radiation. In such circumstances the GP practice managers are provided with the feedback and the GPs are emailed directly. If a referral is rejected in an acute service the

rejected referral would be noted in the radiology information system. Procedures are in place whereby the clinician would be emailed/telephoned stating why their referral has been rejected. When a referral is made it will be vetted to check the clinical details are available. This will usually be carried out in the department. At this point the reviewer is checking to ensure that the clinical information is aligned. If there are any queries the referrer can be contacted for clarity and a decision can be made if the referral is to be modified or cancelled.

When a patient arrives in the department and is called into the imaging room, the radiographers carry out a number of checks. They will review the radiology information system and confirm the details with the patient if possible. They can check on the reason for having an image, patient ID and pregnancy status.

NHS Forth Valley Radiology Department has a level 2 procedures on correctly identifying the patient. All staff we spoke to were very clear on their role with the procedure. They were all clear what to do in the event that there was any doubt regarding a patient's identification. The patient identification checks were recorded in all the records we reviewed.

There is a procedure for operators to determine the pregnancy status of individuals of child bearing age. Everyone we spoke with were clear when the check would be made and where to record the information.

All staff described:

- where they record the patient dose
- the purpose of the dose reference limits
- the correct exposure protocols for ensuring doses are appropriate, and
- what they would do if the dose reference limits were consistently exceeded.

All records reviewed had this information recorded as relevant.

Record keeping was not clear when a pregnant individual was required to have a CT scan. In this case we were told that the referrer would have had the risk benefit discussion with the individual and the radiologist would have justified the exposure after considering the exposure to the foetus, neither of which are recorded. We were told that the only recorded checks would have been done by the radiographers as part of the pre exposure discussion. The radiographers would record in the radiology information system that the patient told them they had discussed the risks of exposure with their clinician. The radiologist

confirmed that discussions take place with the referrers as part of their decision making process and staff confirmed that patients do confirm they have been advised of the benefit and risk of the exposure. The flow diagram which is part of the employers procedure did not clarify who records the decision making process.

It is important that information can be provided for the operator and to record that the risk benefit discussion has taken place. It is also essential that the radiologist indicates that the exposure to the foetus has been considered.

Justification

The justification process is carried out in the majority of cases by a radiologist. Radiologists can justify all diagnostic imaging. Radiographers can justify specific exposures but these are carried out under protocol. In these circumstances the radiographer is acting under the supervision of a named consultant radiologist.

We saw the guidelines for radiographers to justify under protocol in CT. The guidelines have clear clinical indicators that have to be met to allow the radiographers to justify under protocol. NHS Forth Valley also outsource justification to a third party for out of hour's services. The outsource company only uses radiologists.

The individual who justifies the exposure is required to record this information in the radiography information system. The record will contain information that can identify the NHS Forth Valley radiologist who undertook the justification. The justification information was in place for the records we inspected.

When an outsourced company is used the radiographer will record the conversation in the system to confirm the justification. However, they do not have a mechanism for identifying the radiologist who provided the justification. When we reviewed the records the justification only contained the name of the outsourced company. IR(ME)R requires that the individual who provided the justification must be able to be identified. We were told that the outsourced company would be able to provide this information but it was not routinely available.

NHS Forth Valley has a level 2 employer procedure for carers and comforters: instructions for radiology staff. The radiographers, as the operators, are to justify exposures to carers and comforters in plain film. They may also provide written information. They will record why there was a need for a carer or comforter to be exposed and if any information has been provided. In the case of complex issues, then we were told that advice would be sought from the medical physics expert or radiologist before proceeding.

Requirement 1

- NHS Forth Valley must ensure that the documentation demonstrates that the radiologist has been provided with sufficient clinical information to determine the net benefit of the exposure. Such as the individual detriment that the exposure may cause and the benefit and risk.

Requirement 2

- NHS Forth Valley must be able to demonstrate that all ionising radiation medical exposures have been justified and authorised by an entitled practitioner. This could be achieved by including the appropriate person specific information in the radiology information system or an equivalent means to identify the practitioner.

Recommendation

- No recommendations

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 risk management, audit and governance

The medical director is the IR(ME)R lead for NHS Forth Valley. The medical director chairs the annual radiation safety committee which provides overarching governance for radiation safety matters including medical exposure. Members of the group include the consultant radiologist with IR(ME)R responsibility.

To support the work of the committee, IR(ME)R operational aspects are discussed at the bi-annual ionising radiation advisory group. This group includes the IR(ME)R lead manager, the medical physics expert and radiation protection supervisors (radiographers who have received radiation protection supervisor training for Ionising Radiation Regulations 2017. However, in NHS Forth Valley the radiation protection supervisor will also undertake a lead role on IR(ME)R within their speciality). This group provides the strategic overview of the development, implementation and update of the relevant IR(ME)R policies and

procedures. The group will discuss any radiological issues that have been identified.

We were told that there were links with primary care through the community diagnostic users group. The group is chaired by the associate medical director for primary care. The group membership includes representatives from Radiology, Labs, Cardiology and Endoscopy. The Associate Medical Director for Primary care links with the community advanced nurse practitioners and community physiotherapists. The advanced nurse practitioners and physiotherapists are employees of NHS Forth Valley.

We were also told that any concerns or cases can be raised and discussed with the NHS board's clinical governance structure, with departmental meetings every three months.

Radiation protection supervisors and team leaders use team meetings, email and staff huddles to feed back to their teams. There is also a communication book in each department for staff to refer to if, for shift patterns, they are not present at a meeting. During our visit, we saw the communication book in the departments and staff we spoke with confirmed the routes of communication. All staff spoken with confirmed that communication was good and that they were made aware of information relevant to IR(ME)R, such as learning from incidents and changes to procedures.

Communication to radiologists includes monthly consultant meetings, with the meeting minutes available to everyone. We were told that this is not an IR(ME)R-specific meeting but IR(ME)R will be discussed if relevant, for example new protocols or changes to existing protocols. There are also monthly educational meetings where learning from medical exposure incidents could be discussed. The minutes of these meetings are shared at the clinical governance group.

Equipment

The Lead IR(ME)R manager and medical physics expert maintain an inventory of equipment able to expose patients to ionising radiation. All equipment purchased within NHS Forth Valley is included in the inventory.

We were told that there are good relationships within Forth Valley Royal Hospital and that clinical departments seek advice relating to IR(ME)R from service managers prior to purchasing equipment.

We were told that NHS Forth Valley risk assess any equipment that is over 10 years old but that currently none of their equipment is over 10 years old. There

is a level 2 employer's procedure in place for quality assurance procedures of radiology equipment. This includes guidance on:

- annual servicing and maintenance programmes
- dose surveys
- quality assurance testing, and
- the record of information.

We found that everyone was clear on their role in quality assurance and who to contact in the event of any equipment faults. All staff we spoke with said that the system worked well and that support was readily available. We were shown the maintenance records during our inspection.

External providers and clinical audit

Clinical evaluation is the reviewing of diagnostic images and preparation of a report for the referring clinician. NHS Forth Valley uses an external company to provide radiologists for the clinical evaluation of images overnight and at the weekend. The outsourcing company is used for the provision of radiologists. The services are used to undertake the role of justification of exposures out-of-hours and at the weekends.

As part of the governance arrangements, there are quarterly meetings with the providers and at any point 'discrepancies' can be discussed. Discrepancies are events when it would have been reasonable for the radiologist undertaking the clinical evaluation to have identified clinical information from the image.

We were told that there is no employer's procedure which covers the quality assurance mechanism for work outsourced to external companies and that quality assurance was part of clinical governance arrangements within the contract with the provider.

Requirement 3

- NHS Forth Valley must detail in an employer's procedure their quality assurance protocol for outsourced clinical evaluation services. This will provide assurance that clinical evaluations provided by outsourced radiologists are delivered to an appropriate standard and comply with NHS Forth Valley employer's procedures.

Recommendation

- 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

Training

We reviewed the level 2 employer's procedure for 'Radiographer Training and Competency Record.' All radiography staff joining NHS Forth Valley have an induction. On an ongoing basis, staff will attend further training, for example on the different types of equipment and quality assurance.

We spoke to a number of radiographers who worked in a variety of areas, including CT, mammography and plain film (x-ray). All staff spoken with confirmed that since starting their job in the NHS board, they had received the relevant equipment training and were clear that they would not use equipment they had not been trained to use. During our visit, we found comprehensive training records and were assured that there was adequate training for radiographers prior to using any equipment.

We saw evidence of IR(ME)R-related training and the training on human factors. The training is closely linked to someone's scope of practice and although there was ongoing training, it was not clear in the employer's procedures what the procedure or protocol is with regards to continuing education and training. IR(ME)R requires a procedure or protocol that covers continuing education. We found continual professional development sessions were being offered but there was no specific requirement to include IR(ME)R related topics.

As part of the inspection, we reviewed the entitlement process. We saw training records for radiographers and how this linked to their entitlement. A radiographer requires to be trained on each unique piece of equipment. Radiologists training is monitored by the Clinical Director through the medical revalidation process. The appraisal system is the national mechanism for managing medical staff training.

NHS Forth Valley use bank staff to cover services as required and these staff have to undertake the same level of training as NHS Forth Valley staff to maintain their entitlement and scope of practice.

Requirement 4

- No requirement.

Recommendation

- 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	
Requirements	
1	NHS forth Valley must ensure that the documentation demonstrates that the radiologist has been provided with sufficient clinical information to determine the net benefit of the exposure (Regulation 11(b)). Such as the individual detriment that the exposure may cause and the benefit and risk (Regulation 11 (1)(b)) (see page 14).
2	NHS Forth Valley must be able to demonstrate that all ionising radiation medical exposures have been justified and authorised by an entitled practitioner. This could be achieved by including the appropriate person specific information in the radiology information system or an equivalent means to identify the practitioner (Regulation 6(2) & 11(b)) (see page 14).
Recommendation	
None	

Domain 6 – Policies, planning and governance

Requirements

3 NHS Forth Valley must detail in an employer’s procedure their quality assurance protocol for outsourced clinical evaluation services. This will provide assurance that clinical evaluations provided by outsourced radiologists are delivered to an appropriate standard and comply with NHS forth Valley employer’s procedures (Regulation 7) (see page 16).

Recommendation

None

Appendix 2 – Who we are and what we do

Healthcare Improvement Scotland was established in April 2011. Part of our role is to undertake inspections of independent healthcare services across Scotland. We are also responsible for the registration and regulation of independent healthcare services.

Our inspectors check independent healthcare services regularly to make sure that they are complying with necessary standards and regulations. They do this by carrying out assessments and inspections. These inspections may be announced or unannounced. We use an open and transparent method for inspecting, using standardised processes and documentation.

Our work reflects the following legislation and guidelines:

- The Ionising Radiation (Medical Exposure) Regulations 2017
- the National Health Service (Scotland) Act 1978 (we call this ‘the Act’ in the rest of the report)
- the Healthcare Improvement Scotland quality framework, and

This means that when we inspect an independent healthcare service, we make sure it meets the requirements of the Act and the associated regulations. If we find a service is not meeting the requirements of the Act, we have powers to require the service to improve.

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

Our contact details are:

Healthcare Improvement Scotland

Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

Telephone: 0131 623 4300

Email: comments.his@nhs.net

You can read and download this document from our website.
We are happy to consider requests for other languages or formats.
Please contact our Equality and Diversity Advisor on 0141 225 6999
or email contactpublicinvolvement.his@nhs.net

Healthcare Improvement Scotland

Edinburgh Office
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

0131 623 4300

Glasgow Office
Delta House
50 West Nile Street
Glasgow
G1 2NP

0141 225 6999

www.healthcareimprovementscotland.org