



Healthcare
Improvement
Scotland

Inspections
and reviews
To drive improvement

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

Royal Hospital for Children and Young People,
Edinburgh
NHS Lothian

26-27 July 2022

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About our IR(ME)R inspections

Our approach

Healthcare Improvement Scotland has a statutory responsibility to provide public assurance about the quality and safety of healthcare through its inspection activity.

The quality of care approach and the quality framework together allows us to provide external assurance of the quality of healthcare provided in Scotland.

- **The quality of care approach** brings a consistency to our quality assurance activity by basing all of our inspections and reviews on a set of fundamental principles and a common quality framework.
- **Our quality framework** has been aligned to the Scottish Government's *Health and Social Care Standards: My support, my life* (June 2017). These standards apply to the NHS, as well as independent services registered with Healthcare Improvement. They set out what anyone should expect when using health, social care or social work services.

We have aligned the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017 to the quality framework.

How we inspect services that use ionising radiation for medical exposure

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

What we look at

We want to find out:

- how the service complies with its legal obligations under IR(ME)R 2017 and addresses the radiation protection of persons undergoing medical exposures, and
- how well services are led, managed and delivered.

After our inspections, we publish a report on how well a service is complying with IR(ME)R and its performance against the Healthcare Improvement Scotland quality framework.

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

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

Summary of inspection

About our inspection

We carried out an announced inspection to the Royal Hospital for Children and Young People, NHS Lothian, on Tuesday 26 and Wednesday 27 July 2022. We spoke with a number of staff including the IR(ME)R lead, lead paediatric radiologist, radiographers. The inspection team was made up of two inspectors.

Royal Hospital for Children and Young People offers plain film, computerised tomography (CT) and nuclear medicine. The focus of this inspection is the imaging department. The hospital carried out approximately 21,747 plain film image, 1,152 CT scans and 314 nuclear medicine images in the last 12 months.

We previously carried out an inspection to St John's Hospital, Howden on 10 and 11 March 2021 and made three requirements and four recommendations for NHS Lothian. We followed up any requirements relevant to the Royal Hospital for Children and Young People.

What we found

What the service did well

- Optimised paediatric imaging and application of specific paediatric protocols and techniques.
- A positive safety culture is in place and learning from previous incidents is shared to improve services.
- Staff had good knowledge of paediatric imaging techniques.

What the service needs to improve

- Ensure all staff are appropriately entitled.
- Ensure procedures around justification of pre-booked patients is clearly documented.
- Ensure all training is document to demonstrate competences are in place when carrying out paediatric imaging.

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

What action we expect NHS Lothian to take after our inspection

This inspection resulted in three requirements and three recommendations. Requirements are linked to compliance with IR(ME)R. See Appendix 1 for a full list of the requirements and recommendations.

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

https://www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/ionising_radiation_regulation.aspx

NHS Lothian 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, Royal Hospital for Children & Young People, for their assistance during the inspection.

What we found during our inspection

Outcomes and impact

This section is where we report on what key outcomes the service has achieved and how well the service meets people's needs.

Domain 1 – Key organisational outcomes

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

IR(ME)R requires that those who refer for a patient to be exposed to medical radiation (medical and non-medical), those who operate equipment and those healthcare professionals 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 (NHS board).

What we found - fulfilment of statutory duties and adherence to national guidelines

Entitlement

The process of entitlement sets out the scope of practice an individual can carry out, such as the types of referrals and their roles. Their scope of practice depends on the individual's qualifications, role, training and experience. The types of referrals an individual can make, is linked to their role. It can also change over time following additional training or moving to a new role. An individual's scope of practice is clearly defined and aligned to training and qualifications. The individual is required to work within their scope of practice.

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. They can also carry out specialist procedures using imaging, such as fluoroscopy (imaging that uses x-rays to allow real-time visualization of body structures).

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

NHS Lothian has clear entitlement processes in place, which is the same for radiographers and radiologist working in the paediatric service. They must also carry out specialist paediatric training.

Referral

Referrals are received by the radiology department from a variety of sources from within NHS Lothian, including from the community (such as GPs) and other NHS boards. Referrals are made using an electronic referral systems.

We previously recommended NHS Lothian should ensure the referrers' role is clearly identified in all referrals at our inspection to St Johns in March 2021 (a referral can only be made by a person who is entitled to do so). We saw the referrer can now be clearly identified as doctor or non-medical referrer. When a referral is received by a non-medical referrer, radiographers check the referrer's scope of practice against the list of non-medical referrers. A non-medical referrer is a registered healthcare professional who can request certain types of examinations as part of their role. Radiographers told us this process works well and the list is easy to access. If a referral has been received, which is out with an individual's scope of practice, it is rejected.

Justification

Radiographers can justify plain film exposures. Consultant radiologists (paediatric specialists) can justify all type of examinations.

All staff we spoke with told us a patient's clinical information is reviewed as part of the justification process. If insufficient clinical information is provided, radiographers and radiologists will contact the referrer. They may ask for a new referral to be submitted with suitable clinical information to allow the request to be justified. The referral will be rejected if sufficient information is not provided. They may also recommend a non-ionising radiation imaging, such as an ultrasound. Radiographers told us this works well and they felt empowered to challenge referrals and clinicians are happy to discuss why a referral did not meet the required criteria to be justified.

All justifications are recorded on the radiology information system and the practitioner who made the decision is clearly recorded. We are assured justifications are made using the correct protocol for the medical exposure.

Radiologists review all images and report their findings (clinical evaluation). The report is attached to a patient's examination in the radiology information system. The radiologist (operator) who carried out the clinical evaluation is identified on the report.

Radiographers do provide an initial assessment following an exposure, such as when an object is ingested or for fractures, which is recorded on the radiology information system. A full report from a radiologist will then be provided. The radiologist told us there is a high degree of accuracy between the radiographers' initial assessment and the full report produced by the radiologist.

Records

We saw staff had documented the following on the radiography information system:

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

What needs to improve

We saw three members of staff who work in orthopaedics and rheumatology departments had not been appropriately entitled as practitioners and operators to use the mini C arm, which is used in theatres (requirement 1). It is important to ensure IR(ME)R procedures are appropriately implemented and recorded, particularly for these members of staff who have been making referrals (recommendation a).

Staff were not clear whether referrals should be justified at the time when an appointment is made, or at the time when the exposure is carried out. While we are assured information is always reviewed again at the time of exposure, it was agreed with staff that the radiographer would review and justify the referral at the time of booking an appointment. The radiographer, who then carries out the exposure, will then check the clinical information has not changed (requirement 2).

Radiologists are provided with a paper copy of the referral that includes all the necessary clinical information. They then complete another paper form, which includes a tick box to identify the radiologist and confirm their justification; it also includes the desired protocol. This is then attached to the original printed referral. The paper form is used by radiographers when carrying out the exposure. The information from this form is then transferred to the radiology information system and the paper form is destroyed after the examination. We were told this system is not practical and time consuming.

This system has potential weaknesses, including:

- lack of traceability for all CT examinations justified by radiologists as the original papers form is destroyed
- transcription errors, and
- the paper form with the justification can become detached.

We were also told the current radiology information systems does not have all the functionality required to support best practice. Staff told us it was not practical to scan documents onto the system as it took too long. It is also time consuming when reviewing past examinations for previous requests or duplicate referrals. Discussions are taking place to source an upgraded system (recommendation b).

Requirement 1

- NHS Lothian must ensure staff working in orthopaedics and rheumatology are appropriately entitled for the roles they carry out.

Requirement 2

- NHS Lothian must update its employer's procedures to ensure the point of which exposures are justified for pre-booked patients is clearly documented for plain film examinations.

Recommendation a

- NHS Lothian should review a sample of previous justifications for those members of staff who were not appropriately entitled.

Recommendation b

- NHS Lothian should consider a new or updated integrated radiology information system to support the radiology department and maximise the effectiveness of IR(ME)R related processes.

Service delivery

This section is where we report on how well the service is delivered and managed.

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

High performing healthcare organisations are focused on safety and learning to take forward improvements, and put in place appropriate controls to manage risks. They provide care that is respectful and responsive to people’s individual needs, preferences and values delivered through appropriate clinical and operational planning, processes and procedures.

What we found - safe delivery of care

Safety culture

We were told about a positive safety culture and staff felt safe to report mistakes and near misses. We were told:

- a multidisciplinary approach was in place to ensure a safe culture in the department
- all staff were approachable, and
- staff worked well together.

Staff were confident about the procedures for reporting and investigating incidents and were clear that learning from incidents is shared to reduce the chance of something similar happening again.

We saw PAUSE posters prominently displayed in each clinical room in the radiology department to remind staff to take the time when carrying out appropriate checks before carrying out patient exposures. Staff also assured us they are never pressured to rush an exposure.

Employer’s procedures

NHS Lothian 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. The NHS board has three levels of employer’s procedures:

- level 1 applies to the whole NHS board, including all modalities
- level 2 are modality specific across various sites, and
- level 3 are department protocols.

Employer's procedures we reviewed were all clear, up to date and cross-referenced. All staff we spoke with were familiar with the employer's procedures and could find them easily.

Patient identification

Employer's procedure EP5 (Patient identification) provides guidance on the three point identification checks to be carried out for all patients before an exposure.

The service is often required to carry out exposures on patients who are too young to identify themselves, or answer all the relevant identification questions. Carers or comforters, such as a parent or guardian, help confirm identification. Staff also check patient identifications bands. Ward staff may accompany a child who is unable to provide identification themselves. Theatre staff can also help identify the patient.

Staff told us they are familiar with the different ways to identify patients. They review the patient's clinical history to check it matched the clinical information received. They would check the site, laterality (part and side of the body to be exposed) and reason for exposure matched the referral. If any discrepancies are identified during the identification checks, radiographers told us they would not carry out the exposure until details could be confirmed. Once the patient identification checks are complete, this is recorded the radiology information system.

Risk benefit conversations

Employer's procedure EP8 (Provision of information relating to the benefits and risks of an exposure) details the procedure for providing information on the risks and benefits associated with the radiation dose from medical exposures. We saw information posters displayed in the radiology department and in changing facilities to inform patients (and their carer or comforter) of the low risk of an exposure. Leaflets are also sent out with appointment letters to patients, or their carer or comforter, are to receive higher dose exposures. Operators will also discuss the risks with patients, when appropriate.

Making enquiries of individuals who could be pregnant

Employer's procedure EP2/RAD/06 (Establishing whether female patients may be pregnant) provides guidance for carrying out pregnancy checks before any exposure. All radiographers we spoke with were familiar with the procedure. They told us everyone aged between 12 and 55, for an exposure where anatomy in between the lower diaphragm and upper thigh are directly in the primary beam, are asked the pregnancy status questions.

Carers and comforters procedures

Most patients admitted to the service need to be seen with a carer or comforter, usually the child's parent or guardian. They play an active role in supporting children who requires an exposure.

Employer's procedure EP21 and EP2/RAD/010 provide clear guidance on the authorisation of an exposure to a carer or comforter and dose constraints are in place. Parents may need to hold a child, during an exposure, or be in close proximity of the beam and they would be provided with lead aprons. All staff could describe the measures they would take to reduce their exposure as far as possible. This included:

- excluding anyone where there is a possibility they were pregnant
- ensuring different carers or comforters supported the child where practical, and
- ensuring carers and comforters stand as far as possible away from the equipment, or behind the control screen or outside a room.

A written record, identifying the specific carers or comforters for each child is recorded in the radiology information system.

Information posters are displayed in the diagnostic department also highlighted the need to inform a member of staff of any possibility that the patient may be pregnant. Which also include a carer or comforter.

General duties in relation to equipment

Quality assurance checks are carried out on all equipment and the frequency required is clearly documented. All staff carrying out quality assurance checks have been trained to do so. Quality assurance is routinely carried out by radiographers and medical physics experts.

Optimisation

Dose optimisation is the balance between the lowest dose and the image quality that is clinically suitable.

Radiologists and radiographers told us they would always consider an alternative to ionising radiation in the first instance. A positive culture around dose optimisation was in place and all operators we spoke with could describe how they select the correct protocol for the intended purpose. We also saw a wide range of paediatric specific protocols in place.

Medical physics experts carry out dose audits. This information is used to set local dose reference levels. Where local dose reference levels are not available,

national dose reference levels are used. We saw local dose reference levels displayed near equipment in the radiology department. Should the recorded value of an exposure be outside agreed limits, an investigation will be carried out. The investigation will consider the patient details, the quality of the image taken, the protocol used and scan range.

Examples of the optimisation work include:

- protocols for different age ranges and body mass depending on the area to be exposed for children aged 0-16 years old
- a low dose protocol was developed for foreign bodies in the abdomen
- the number of projections for specific examinations was reduced
- collimation used to reduce the radiation beam
- ensure appropriate use of scatter grids, and
- the production of paediatric exposure charts for local dose reference levels.

A new CT scanner has been sourced, which has significantly increased the speed of some scans and lowered the dose. This has led to a reduction in sedating some patients.

A multidisciplinary team considered lower dose examinations, such as for the examination of a foreign object swallowed by a child. The team set up a new protocol with a lower dose, which still delivers the clinical information required to spot a foreign body. This examination is a lower dose in comparison to the standard examination of the abdomen.

Accidental or unintended exposure

Employer's procedure EP11 (Recording and investigating accidental and unintended exposures) details the procedure to follow when an error has taken place. Staff we spoke with understood the process of reporting and investigating incidents. We were told about a culture that supports the reporting of incidents. Incidents are shared throughout the radiology department.

Data are gathered and analysed about any near misses. Any areas of improvement are shared within the department. The radiology department has introduced a 'near miss week' four times each year to capture these events.

- No requirements.
- 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

Each organisation must appoint an IR(ME)R lead who is responsible for the implementation of systems and processes to ensure statutory requirements are being met.

The IR(ME)R policy provides clear structure about how IR(ME)R is implemented. It includes the roles and responsibilities from the chief executive to department staff. The IR(ME)R lead, who is appointed by the chief executive, is responsible for ensuring that the IR(ME)R policy is implemented.

We recommended NHS Lothian should ensure the IR(ME)R lead be provided with a comprehensive induction to support them in their role at our inspection to St John's Hospital. The current IR(ME)R lead was appointed in March 2020 and told us they had received a full induction, which supported them to undertake their role.

What we found - risk management, audit and governance

NHS Lothian IR(ME)R lead chairs the IR(ME)R Board where they are provided with assurance that IR(ME)R is being implemented, which includes Royal Hospital for Children and Young People. The group links to the NHS board's radiation protection committee, chaired by a member of the executive team.

Contracted services

NHS Lothian do not use any external radiologist services.

Clinical audit

The Royal College of Radiologists describes clinical audits as a tool for reviewing and improving healthcare outcomes and ensuring patient care is provided in line with best practice standards. Employer's procedure EP14 (Provision for IR(ME)R audit) includes the following:

- compliance with employer's procedures
- compliant with IR(ME)R procedures and protocols
- patient referrals
- dose reference levels

- entitlement, and
- incidents and near misses.

What needs to improve

While NHS Lothian has been significantly impacted by the pandemic, which has affected the amount of audit activity carried out, staff do carry out a variety of audits that are not currently collated. This includes, neonatal image quality and GI tube insertion (recommendation c).

- No requirements.

Recommendation c

- NHS Lothian should ensure all annual audit activity is recorded to demonstrate the scope of IR(ME)R related activity.

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

The medical physics expert role includes the provision of advice in relation to compliance with IR(ME)R. They are involved in a variety of areas such as:

- commissioning of new equipment
- acceptance testing of new equipment
- local dose reference levels
- dose monitoring
- deliver staff training, and
- analysis of incidents.

Staff told us medical physics experts regularly visit the service and they are easily contactable for advice and support. They also provide advice on whether an incident requires to be reported to Healthcare Improvement Scotland. They attend the IR(EM)R Board meetings and are part of multidisciplinary image optimisation team.

While no specific peer review programme of clinical evaluations is being carried out, a variety of clinical evaluations are being double read. Double reading takes place for clinical evaluations for child protection cases, at multidisciplinary review meetings and radiology and learning events.

Training

Once a radiographer qualifies, NHS Lothian provide an induction and ongoing training. Radiographers training records are in place for staff involved in medical exposure to radiation and showed relevant training had been provided. Staff told us about a recent talk by the medical physics team are part of their ongoing IR(ME)R related training. A radiographer's training record is closely linked to their entitlement.

Operators must be trained on each the specific piece of equipment. All radiographers we spoke with confirmed they had received appropriate training and all training records we saw were up to date. Records were in place to demonstrate staff are trained to justify referrals.

Radiographers have received specialist training to work in the paediatric services. This includes:

- optimisation
- specific protocols tailored for the patients age and size
- specific local dose reference levels for paediatric services
- understanding where the number of views/phases can be reduced
- the use of specific low dose examinations
- immobilisation techniques to avoid unnecessary repeat examinations, and
- managing exposure to careers and comforters.

Radiologists also receive specific training relevant to paediatrics. This includes a 4 month radiology training induction and Royal College of Radiologists specialty training, which can take 12 months. An IR(ME)R specific module is also included as part of their training. During the training period the degree of autonomy increases and trainees will start justifying imaging based on their training progression. Although all reports are double read until they are qualified.

Radiologists' continual professional development is managed through their annual appraisals and medical revalidation. They also attend radiology events and meetings where radiological discrepancies are reviewed. The meetings are used to share learning and improve outcomes for patients.

Student radiographers can only work under the supervision of a qualified radiographer. They are allowed more autonomy to carry out tasks as they progress through their training and demonstrate their competencies. We were told students would never be left in a room unsupervised when delivering ionising radiation.

What needs to improve

The paediatric specific training for the radiographers was not recorded in their training records, which is required to demonstrate appropriate skills, knowledge and assessed competencies (requirement 3).

The NHS board calculated the medical physics expertise resource required using an internationally recognised tool. The identified shortfall and mitigation is not outlined in a workforce plan, or similar. We understand the workforce has been discussed at the IR(ME)R Board meeting and the workforce has increased. We understand the shortfall has been highlighted and discussions have taken place on how to meet the predicated service need – we will review this again at a future inspection.

Requirement 3

- NHS Lothian must ensure all training is recorded to demonstrate appropriate competences are in place to carry out paediatric imaging.

- 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	
Requirements	
1	<p>NHS Lothian must ensure staff working in orthopaedics and rheumatology are appropriately entitled for the roles they carry out (see page 11).</p> <p><i>Regulation 6(2)</i> <i>Ionising Radiation (Medical Exposure) Regulations 2017</i></p>
2	<p>NHS Lothian must update its employer’s procedures to ensure the point of which exposures are justified for pre-booked patients is clearly documented for plain film examinations (see page 11).</p> <p><i>Regulation 10(2)</i> <i>Ionising Radiation (Medical Exposure) Regulations 2017</i></p>
Recommendations	
a	<p>NHS Lothian should review a sample of previous justifications for those members of staff who were not appropriately entitled (see page 11).</p>
b	<p>NHS Lothian should consider a new or updated integrated radiology information system to support the radiology department and maximise the effectiveness of IR(ME)R related processes (see page 11).</p>

Domain 6 – Policies, planning and governance	
Requirements	
None	
Recommendation	
c	NHS Lothian should ensure all annual audit activity is recorded to demonstrate the scope of IR(ME)R related activity (see page 17).

Domain 7 – Workforce management and support	
Requirement	
3	NHS Lothian must ensure all training is recorded to demonstrate appropriate competences are in place to carry out paediatric imaging (see page 19). <i>Regulation 17(4)</i> <i>Ionising Radiation (Medical Exposure) Regulations 2017</i>
Recommendations	
None	

Complaints/Concerns

If you would like to raise a concern or complaint regarding any aspect of the inspection then please discuss this with the lead inspector in the first instance.

If there is a concern or complaint about the conduct of an inspector please contact Kevin Freeman-Ferguson, Head of Service Review, kevin.freeman-ferguson@nhs.scot in the first instance to discuss your concerns in more detail.

Alternatively, Healthcare Improvement Scotland has a complaint and feedback service that can be contacted directly. Details can be found on our webpage.

http://www.healthcareimprovementscotland.org/about_us/contact_healthcare_improvement/complaints.aspx

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