



Healthcare
Improvement
Scotland

Inspections
and reviews
To drive improvement

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

The Edinburgh Clinic
Aspen Healthcare Limited

3 March 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 2017 to the quality framework.

How we inspect services that use ionising radiation for medical exposure

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

What we look at

We want to find out:

- how the service complies with its legal obligations under IR(ME)R 2017 and 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 Edinburgh Clinic, Aspen Healthcare Limited, on Thursday 3 March 2022. We spoke with a number of staff including the hospital director, imaging manager, medical physics expert, radiologists and radiographers. The inspection team was made up of one inspector.

The Edinburgh Clinic offers plain film and computerised tomography (CT). The focus of this inspection is the imaging department.

What we found

What the service did well

- The Edinburgh Clinic has designated trainers who are trained by the radiography applications specialists and are approved to disseminate training.
- A robust audit cycle is in place, including clinical and non-clinical audits and action plans are developed from these.
- A positive safety culture is in place, underpinned by mandatory training.
- The process to quality assure equipment was clear and robust, with training being disseminating by competent trainers. A handbook is also being developed to support this process.

What the service needs to improve

- GPs who refer must be provided with their entitlement paperwork.

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

What action we expect Aspen Healthcare Limited to take after our inspection

This inspection resulted in one requirement. Requirements are linked to compliance with IR(ME)R.

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

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

Aspen Healthcare Limited must address the requirement and make the necessary improvements as a matter of priority.

We would like to thank all staff at the radiology department of The Edinburgh Clinic 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, 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, operate equipment and undertake clinical evaluations. The scope of practice depends on the individual's qualifications, role, training and experience and can change over time, following additional training or moving to a new role. Radiographers are entitled, depending on their training, to act as operators and practitioners. Medical staff are entitled as referrers, practitioners and operators. An individual is required to work within their scope of practice.

The Edinburgh Clinic employer's procedures clearly set out the process of entitlement for referrers, operators and practitioners within a specific scope of practice. This includes a list of entitled staff, their role, scope of practice and professional registration details.

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.

Employer's procedure 6 (Entitlement of practitioners within a specific scope of practice) and EP7 (Entitlement of operators within a specific scope of practice) state that staff must be deemed competent to carry out specific tasks and recorded in their scope of practice document. We saw these documents in place for radiographers and radiologists.

Referral

Referrals are received by the radiology department from a variety of sources from within the hospital, the community and from NHS Lothian. Referrals are usually received electronically. Paper referral forms are available if needed. Referrals from medical staff include their GMC number.

Employer's procedure 2 (Referral criteria) states referrers must take into account the Royal College of Radiologists 'Making the Best use of Clinical Radiology Services' when making a referral. Locally adopted referral criteria can be developed if deemed necessary, however we did not see these in place. iRefer is readily available in the clinic to ensure access is available to all referrers. This national guidance is designed to make the best use of clinical radiology by providing recommendations for everyday use of clinical imaging services.

Another group of staff who are entitled to make referrals are non-medical referrers, healthcare professionals who are not doctors or dentists. Each non-medical referrer has a record of their entitlement. A full list of all non-medical referrers, including their scope of practice and whether they are actively registered as a health professional with a professional body, is available.

Employer's procedures 5 (Entitlement of referrers within a specific scope of practice) states GPs who have sufficient knowledge, appropriate training and experience can also be entitled to refer patients for radiological exposures.

Justification

Employer's procedure 6 (Entitlement of practitioners within a specific scope of practice) provides clear guidance on who can justify medical exposures. Radiologists can review all referrals to ensure sufficient information is available to allow the referral to be justified. Radiographers can review plain film and CT dental scans for dental implants. All were aware how to choose the correct protocol for the relevant exposure. All protocols are available within the department. We are assured that the processes in place demonstrate that only staff who are entitled to justify are appropriately trained to do so.

If a referral is received that does not have sufficient clinical information, or the information is not correct, the referral is returned along with an explanation of

what is required. A new referral must be submitted. If a referral is received from an external referrer, it must be justified before the patient is offered an appointment to attend the hospital.

Radiographers check previous clinical history before carrying out any exposures and patients are asked about any previous imaging. An image exchange portal is in place so radiographers can obtain previous exposures from other hospitals, including NHS hospitals. If the patient attended an outpatient clinic, this can be found quickly to prevent duplicate exposures.

When an exposure is justified it is recorded on the radiology information system and the authorising practitioner is clearly recorded.

Following an exposure, the radiologist or consultant will review the image and reports their findings. Employer's procedure 15 (Reporting radiological images) provides guidance on exposures that can be evaluated by each group of medical staff. Radiologists can evaluate diagnostic radiology examinations; individually identified surgeons evaluate exposures as a necessary part of the surgical procedures within their specialty; and dentists can evaluate CT dental scans in line with a written agreement.

Clinical images are reviewed by radiologists and recorded on the radiology information system. Evaluations carried out when a patient is in theatre, or by a cardiac consultant, are recorded in the patient's notes. It is clearly noted on the radiology information system where each are recorded.

Records

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

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

Radiography staff could describe the checks they would carry out before recording information and where they would get the dose information.

What needs to improve

GPs are not issued letters or certificates confirming their individual entitlement (requirement 1).

A contract is in place that allows NHS Lothian to accept referrals and justify exposures before radiographers (operators) from The Edinburgh Clinic carry out these exposures. The images are then returned to NHS Lothian to be evaluated. No process is in place for each organisations to be assured that staff are appropriately entitled to carry out their roles. We were told a new governance arrangement is being developed to ensure these processes are in place. We will welcome this being in place at our next inspection.

Requirement 1

- The Edinburgh Clinic must ensure all referrals are made from medical staff who are entitled to do so.

- No recommendations.

Service delivery

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

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

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

What we found - safe delivery of care

Safety culture

We were told about a positive culture and staff felt confident to report mistakes. Staff must attend a mandatory training programme, which encourages them to report any concerns to prevent future incidents. All staff we spoke with understood the procedures for reporting, investigating and learning from incidents. One incident had been reported in 2021 and we were assured learning and action taken following this incident had been shared across the radiography team. While formal methods of sharing learning at team meetings and using email, the team is small. This means the imaging manager can speak with each individual member of staff to ensure they are aware of learning from mistakes.

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.

Employer’s procedures

The Edinburgh Clinic 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 of systems and processes to ensure statutory requirements are being met.

Template employer’s procedures are supplied by St George’s as part of a service level agreement. These are amended by the imaging manager for local use and approved by the hospital director. One level of employer’s procedures are in place, supported by comprehensive local rules outlining site based operational approaches displayed in the department. Employer’s procedures are reviewed

every year, however changes can be made between reviews if identified by the imaging manager or the medical physics expert. The imaging manager is responsible for the implementation of the employer's procedures.

Employer's procedures are stored on a shared drive and a paper copy is kept in the department. The imaging manager is responsible for ensuring that the paper copies are up to date. All new staff must read the employer's procedures and sign to confirm this has taken place. Existing staff must also record they have read any revisions or updates to the procedures.

Patient identification

Employer's procedure 1 (Identification of patients) provides guidance about identification checks to be asked of all patients before any exposure are carried out. It clearly sets out an eight point check, which includes site, laterality (part of the body to be exposed and side of the body), image modality and previous exposures. All staff we spoke with were clear about the identification and recording process. The radiology information system allows the recording of the six checks, however staff were confident that all eight are always carried out.

If any discrepancies are identified during the identification checks, radiographers told us they would return the referral to the referrer and request a new referral be submitted.

Risk benefit conversations

Employer's procedure 27 (Providing benefit and radiation risk information to patients) details how information is made available for patients about the risks and benefits associated with an exposure. Radiographers proactively offer specific information about risks and benefits, however they will answer any questions raised by a patient. We saw information posters displayed in waiting areas and patient information leaflets were available.

Making enquiries of individuals who could be pregnant

Employer's procedure 9 (Enquiries of persons of child bearing potential) provides guidance on carrying out pregnancy checks before any exposure. Radiographers told us they ask everyone between 12 and 55 if there is a possibility that they are pregnant. If a person of child bearing potential who is to undergo a radiological exposure below the diaphragm, or above the knee, must sign a pregnancy declaration form.

If a patient is confirmed to be pregnant, the radiologist or referring clinician will decide whether to proceed. However, the procedure clearly states pregnancy must be ruled out before carrying out any exposure. All staff we spoke with told us that an exposure would not be justified if a patient was confirmed to be pregnant.

A patient's pregnancy status must be confirmed before any surgery is carried out. Radiographers can check their pregnancy status to confirm it is appropriate to proceed with an exposure if the patient is already in theatre.

We saw completed pregnancy declaration forms are scanned onto the radiology information system.

We saw information posters displayed in the changing areas, highlighting the need to inform a member of staff of any possibility that a patient may be pregnant.

Carers and comforters procedures

Employer's procedure 26 (Carers and comforters) provides clear guidance on the authorisation of an exposure to a carer or comforter. We were told it would be extremely rare that a carer or comforter would be required due to the nature of the patients seen. However, radiographers understood the procedure, were able to accurately describe the checks required and where to record this.

General duties in relation to equipment

Quality assurance checks are carried out on all equipment by radiographers who are been trained and entitled to do so. The frequency of the required checks is clearly documented and complied with.

The service has a designated expert trainer who received extensive training from the radiography application specialist on the use of the equipment and quality assurance. This designated trainer has a clear scope of practice setting out their entitlement to train other radiographers on the specific equipment in the department. Radiographers have a clear record of entitlement outlining their scope of practice to allow them to operate each piece of equipment.

Radiographers told us if a piece of equipment is suspected to be faulty during clinical use, additional quality assurance checks are carried out. If the quality assurance check indicates an issue, the engineer is informed. A handbook is being developed that includes specific guidance about equipment warning lights, faults and the contact details of the engineers.

An equipment inventory records the name of the manufacture, serial number and year of manufacture for all equipment. While all the equipment is older than 10 years, radiographers were able to demonstrate the dose from each machine was below the national dose reference level for each of the commonly used procedures. The hospital is about to be purchased by Nuffield Health and the new commissioning team will look to replace all of the equipment.

Optimisation

Image optimisation is the balance between the lowest dose and the image quality that is clinically suitable. Optimisation is discussed at the medical exposure committee every year. This meeting has representation from radiographers, radiologists and medical physics experts. While there has not been any optimisation issues, the lead radiologist told us about the positive working relationships within the service, which facilitates any timely identification of any issues.

Medical physics experts use dose audit information to set local dose reference levels for all equipment. These are prominently displayed beside relevant equipment. National dose reference levels and tolerance levels are also available. A dose audit is carried out each year by the medical physics expert. This is more than the minimum standard of every 3 years as specified in national guidance.

Accidental or unintended exposure

Employer's procedure 18 (Accidental or unintended medical exposure to ionising radiation) provides guidance on reporting incidents and near misses. It provides information on roles and responsibilities, how to carry out an investigation and the reporting mechanism. The medical physics expert provides a report for the imaging manager that includes the assessment of dose and information regarding the radiation risk. It also advises whether a notification should be referred to Healthcare Improvement Scotland.

Staff told us they were encouraged to report near misses and incidents and learning is shared to help prevent future incidents. Staff we spoke with were all clear on the procedures for reporting, investigating and learning from incidents. The incident that was reported in 2021 resulted in actions to mitigate against any further occurrence, as well as formal and informal dissemination of learning for all staff.

What needs to improve

Employer's procedure 9 (Enquiries of persons of child bearing potential) initially describes pregnancy checks for all people of child bearing years, however it later mentions females. It should be updated to reflect gender neutral.

- 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

The hospital director has been delegated all responsibility of the implementation of IR(ME)R. They are supported by the imaging manager.

What we found - risk management, audit and governance

The hospital director told us they were assured about the implementation of IR(ME)R through regular audits, monitoring of incident reporting and regular communication with the imaging manager and clinical lead.

Regular groups and committee meetings support safety in relation to IR(ME)R including:

- radiation protection meetings each year with representation from service managers and the medical physics expert
- radiation and laser committees are once each year with representation from all the services within Aspen Healthcare Limited
- radiology management meetings take place every 3 months, which are run corporately
- a medical exposures group meets every year to review incidents and optimisation, and
- the group radiation protection committee has a role in the consultation and sign-off for policies.

Regular staff meetings also take place where frontline staff learn from near misses and any policy changes.

Clinical audit

Staff told us recent changes to the approach to audits across the Aspen Healthcare Limited led to a more robust audit programme and an increased focus on clinical audit. We saw evidence of audits results being shared with staff and actions implemented. The audit programme includes:

- reviews of recording of exposures
- observing clinical practice, and
- practical activities, such as reject analysis.

- 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

Medical physics expertise is contracted from St George's Hospital. They are appointed in writing by The Edinburgh Clinic and provide expert advice in relation to compliance with IR(ME)R. They are involved in a variety of areas such as:

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

The medical physics experts provide an annual report on the services they provide. They also provide advice as required, including advice on whether or not an incident requires to be reported to Healthcare Improvement Scotland.

We are assured the medical physics expert resource meets the needs of service. Staff told us they were easily contactable and available for advice and support, and responds very quickly.

Training

Radiographers are provided with an induction and ongoing training once qualified. We saw comprehensive training records in place for staff involved in IR(ME)R.

We were told operators must be trained on each specific piece of equipment and we saw evidence of this in training records. Training had been provided by a designated expert who was trained by the radiography application specialists on each piece of equipment in use.

Radiographers maintain their own continual professional development as part of their professional registration. Student radiographers are provided with observational placement, however they do not have an active role in carrying out exposures.

A radiologist's training and continual professional development is managed through their annual appraisal and medical revalidation process with their respective NHS board. This includes mandatory completion of IR(ME)R specific training in the NHS board, the results of which is shared with The Edinburgh Clinic as part of the appraisal process.

What needs to improve

While we have no concerns about the medical physics expert resource required, no formal calculation had been carried out. The European Federation of Organisations for Medical Physics Policy Statement No. 7.1 provides guidance on the roles, responsibilities and status of the medical physicist including the criteria for the staffing levels in a medical physics department. The guidance can be used to provide detail on how to calculate suitable and sufficient medical physics staffing levels.

- No requirements.
- 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	The Edinburgh Clinic must ensure all referrals are made from medical staff who have been entitled to do so (page 11). <i>Regulation 6(1)a 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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