



Healthcare
Improvement
Scotland

Inspections
and reviews
To drive improvement

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

BMI Kings Park Hospital, Stirling
BMI Healthcare

7 December 2021

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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 address the radiation protection of persons undergoing medical exposures.
- 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 virtual inspection to the BMI Kings Park Hospital, Stirling, BMI Healthcare on Tuesday 7 December 2021. We also visited the hospital on Tuesday 14 December 2021. We spoke with a number of staff including the imaging lead, medical physics expert, corporate medical physics expert, national lead for imaging and diagnostics, director of clinical services and the executive director. The inspection team was made up of two inspectors.

BMI Kings Park Hospital offers plain film. The focus of this inspection is the imaging department.

What we found

What the service did well

- We saw a positive safety culture in place and staff felt confident to report incidents and near misses.
- A pregnancy check is completed for all adults between the ages of 12 and 55 and is not limited by gender.
- The risk benefit conversation is robust and includes equivalent background radiation comparisons to help the patient understand the radiation exposure.

What the service needs to improve

- BMI Healthcare must be assured that mechanisms are in place to ensure referrals are made by staff who are entitled to do so.
- Ensure all radiography staff have a clear record of entitlement, which is aligned to their competency.
- Documentation should be in place to demonstrate that radiographers are trained in all equipment used in BMI Kings Park and that those offering training are deemed competent to do so.
- Dose reference levels should be developed for all equipment (including mobile x-ray equipment).

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

What action we expect BMI Healthcare to take after our inspection

This inspection resulted in three requirements and five 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 hospital and is available on the Healthcare Improvement Scotland website.

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

BMI Healthcare 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, BMI Kings Park Hospital, for their assistance during the inspection.

What we found during our inspection

Outcomes and impact

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

Domain 1 – Key organisational outcomes

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

IR(ME)R requires that those who refer 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. The individual is required to work within this scope of practice.

Employer's procedure EP2B (Procedure to identify individuals entitled to act as referrer or practitioner or operator within a specific scope of practice) provides guidance on the entitlement process. It also provides clear guidance on the roles and responsibilities and the scope of practice within each role.

The executive director entitles medical referrers, including consultants within BMI Kings Park Hospital and other NHS boards to allow them make referrals for an exposure. The scope of practice for consultants working in the service is set out in a formal letter.

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 specifically trained to interpret diagnostic images, such as x-ray and CT scans.

BMI Kings Park do not accept non-medical referrals.

Referral

EP2B (Procedure to identify individuals entitled to act as referrer or practitioner or operator within a specific scope of practice) provides guidance on what is to be shared with referrers. Referrals are received by the radiology department from referrers within the service and GPs from the community. Internal referrals are received on paper referral forms, which are scanned into the electronic radiology information system. External referrals are made electronically and signed by the referring GP.

Justification

The radiologist previously justified all plain film exposures. Training has recently been implemented to enable radiographers to also justify plain film. The imaging lead and one bank radiographer are now entitled to justify exposures. Training is also being rolled out to other bank radiographers to ensure they are be appropriately entitled to make justifications in the future. We are assured relevant staff are entitled to make justifications as required.

Radiographers review all clinical information provided in order to justify an exposure. We were told that if insufficient clinical information is provided, the radiographer would contact the referrer to seek additional information. If adequate information is provided to justify the exposure, this is handwritten on the original referral, signed and scanned into radiology information system. If the information provided is not clear the referral will be rejected.

Before carrying out any exposures, the radiographer will check any previous clinical imaging carried out by the service. Staff do not have access to any exposures carried out by any NHS board and they rely on the patient informing them if any previous imaging has been done elsewhere.

When an exposure is justified it is recorded on the radiology information system and the authorising practitioner is clearly identified. If the radiographer requires support from the radiologist to confirm a justification, the radiologist is then identified as the practitioner.

Employer's procedure EP2J (Procedure for carrying out and recording of an evaluation for each exposure including, where appropriate, factors relevant to patient dose) identifies staff are entitled to evaluate exposures. Clinical

evaluations are either carried out by the radiologist or other entitled medical staff, such as orthopaedic surgeons. The radiologist records their evaluations on the radiology information system. Other staff record their evaluations, if required, in the clinical notes. It will be noted on the radiology information system where these evaluations are recorded.

Records

We looked at the information record on the radiography information system and noted that staff had documented:

- the correct patient information
- comprehensive identification checks
- scanned documents, such as pregnancy check questionnaires
- details of the referrer and operator
- radiation dose
- justification, and
- clinical evaluation.

Radiography staff told us about the checks they would carry out before recording information.

What needs to improve

We were told not all referring GPs are currently entitled, however the imaging lead has started the process of entitlement for all referring GPs, starting with 50 who most commonly refer (requirement 1).

Employer's procedure EP2B states the imaging lead will issue a letter of entitlement to each radiographer. However, radiographers are currently entitled as a group and not trained to a defined scope of practice. Such as, all radiographers are entitled to justify plain film exposures. We were told the training of radiographers has recently started to allow them to become practitioners. The radiologist carries out peer review and signs training records to confirm they are competent. The imaging lead now intends to develop individual entitlement records for each radiographer, which will reflect their entitlement on completion of the training (requirement 2).

Radiography staff could describe how they carry out all identification checks and pregnancy checks. However, there was an absence of any guidance to ensure recording of this information is consistent. For example, pregnancy information checks can be recorded on the referral or the enquiry of childbearing potential form (recommendation a).

The paper referral form should be updated to include reference to IR(ME)R 2017.

Requirement 1

- BMI Healthcare must ensure referring GPs are appropriately entitled to do so, either individually or by GP practice.

Requirement 2

- BMI Healthcare must ensure that all operators and practitioners are entitled to carry out roles for which they are trained and competent to do so.

Recommendation a

- BMI Kings Park should develop guidance to ensure all staff record information consistently on the radiology information system.

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 the positive safety culture in BMI Kings Park Hospital and staff feel confident to report mistakes. A national flash report is shared with staff from all BMI Healthcare hospitals, which includes learning from all IR(ME)R incidents.

The imaging lead is supported by colleagues from another nearby BMI Healthcare hospital and they feel supported to discuss any emerging issues or concerns with them. The radiologist also provides advice and guidance as required to radiographers. Bank radiographers are supported by the imaging lead.

We saw two PAUSE posters prominently displayed in the radiology department to remind staff to take the time when carrying out appropriate checks before carrying out an exposure. Radiographers and radiologist told us they are encouraged to take the time needed to carry out their role safely.

Employer’s procedures

The employer 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 employer’s procedures are developed by the radiation protection advisory board for all BMI Healthcare hospitals, with local modifications made by each hospital as appropriate. This is supplemented by local rules which outline site based operational approaches.

Employer's procedures are stored on a shared drive and paper copies are kept in the service. The imaging lead ensures these are the most up to date copies. All new staff are expected to read the employer's procedures and record they have done so. Any updates to procedures are also shared with staff.

Patient identification

Employer's procedure EP2A (Procedure to correctly identify the individual to be exposed to ionising radiation) provides guidance about identification checks to be carried out before any exposure. The procedure states three checks required to be carried out; name, address and date of birth. The procedure also recommends using The Society of Radiographers pause and check guidance, which includes a further three checks to ensure the correct patient is being exposed; site, laterality and timing. We are assured that this process is embedded in practice. In discussion with the corporate team it was agreed that consideration be given to embedding the six point check in the procedure.

If any discrepancies are identified during the identification checks, the radiographer told us they would contact the referrer for clarification. The radiographer would record any changes on the original referral or a new referral is made.

Risk benefit conversations

Employer's procedure EP2I (Procedure for radiation risk and benefit) details how information is made available for patients on risks and benefits associated with the medical exposure. We were told the radiographer will discuss possible risks and explain the comparable background radiation. We saw information posters displayed in prominent places throughout the hospital and in the changing areas.

Making enquiries of individuals who could be pregnant

Employer's procedure EP2C (Procedure for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breastfeeding). We were told that all individuals between the ages of 12 and 55 who are to undergo a radiological examination below the diaphragm or above the knee are to complete the enquiries of childbearing potential form.

The procedure clearly states that pregnancy must be ruled out before proceeding with any exposure. If the patient is unconscious, such as in theatre, the theatre nurse will ensure the checks have been carried out, recorded and will advise the radiographer before any exposure takes place.

If a patient is confirmed to be pregnant, the radiographer would have a discussion with the radiologist to decide if the exposure should go ahead. We

were told that it is very unlikely that an exposure would go ahead in these circumstances.

The radiographer told us completed pregnancy check forms are scanned into the radiology information system. Records we saw had relevant checks recorded.

Information posters are displayed in the changing room of the diagnostic department also highlighted the need to inform a member of staff of any possibility that a patient may be pregnant.

Carers and comforters procedures

Employer's procedure EP2N (Procedure to establish appropriate dose constraints and guidance for the exposure of carers and comforters) provides clear guidance on the authorisation of an exposure to a carer or comforter. While we were told it is extremely rare that a carer or comforter would be required due to the nature of the patients being seen by the service, the radiographer told us they understood the procedure.

General duties in relation to equipment

Quality assurance checks are carried out on all equipment every day, every 2 months and every 6 months. This is a locally designed approach by the service. Checks are currently carried out by the imaging lead and bank radiographers.

Faults in equipment are identified by staff. The radiographer told us faults are escalated to the engineer and the medical physics expert. The radiographer was clear about the process to handover equipment to the engineer as well as the need to quality assure equipment before it is put back in use. There is no guidance to specify at what level of dose consistently above the national dose reference level would require the radiographer to report the equipment to the medical physics expert. The medical physics expert told us that they will discuss the need for this to be developed at the next radiation protection advisors meeting.

No system is currently in place to automatically replace older equipment. The mobile x-ray equipment has been in place for 25 years. It has been on the radiation protection action plan for 1 year to replace the mobile unit. However, when local dose reference levels are developed it will allow the radiographers to ensure it is operating below the UK dose reference levels and is considered safe to use.

Optimisation

Image optimisation is the balance between the lowest dose and the image quality that is clinically suitable. Medical physics experts use dose audit information to set local dose reference levels. Where local dose reference levels are not available, the service can develop cross-organisation levels by working in collaboration with other BMI Healthcare hospitals, or use UK or European dose reference levels.

At the time of the inspection the medical physics expert was supporting the imaging lead to develop local dose reference levels for the new x-ray room and the theatre scanner.

The operator told us how they would select the correct protocol for the intended exposure, as well as how they calculate image quality with as low as dose as was reasonably practical. The equipment used to expose patients to ionising radiation have a variety of protocols that help deliver standardised exposures. Exposures can be modified for adults and children and take account of different body sizes.

A close working relationship between the radiographer and radiologist allows any image quality issues to be identified during the clinical examination. Issues can then be raised immediately with the radiographer and solutions sought.

A dose audit is carried out each year by the medical physics expert. This is more often than the minimum standard of an audit every 3 years as specified in the employer's procedure.

Accidental or unintended exposure

Employer's procedure EP2L (Procedure for unintended and accidental exposures) provides guidance on reporting incidents. It provides information on roles and responsibilities, how to carry out an investigation, the reporting mechanism and how to ensure the investigation has been carried out appropriately.

The procedure also highlights the need to report near misses and references the criteria for making statutory notifications. Staff we spoke with described a positive culture of reporting near misses and incidents. We were told that learning from near misses and incidents is shared to help prevent incidents in the future. While no incidents or near misses have been reported in the previous year, the procedures for reporting, investigating and learning from these was clearly understood by the imaging lead.

What needs to improve

We found multiple occasions where the employer's procedures should be updated. These include:

- The term 'should' is used to describe activities that are required, such as 'aids for communication needs should be provided, IR(ME)R practitioners should be asked to justify pregnancy'. The language should be updated to reflect these requirements 'must' be carried out throughout.
- Some employer's procedures make reference to other guidance that is not embedded. Such as, the Society of Radiographers pause and check guidance and the Care Quality Commission's SAUE guidance on significant accidental and unintended exposures. These should be detailed and embedded rather than cross-referenced.
- Clarify language to ensure it is clear that only staff who are entitled to act as operators will be able to clinically evaluate images and not all referrers are able to do so.
- An error was noted stating the radiographer should use patient notes to confirm the identity of patients who are unable to confirm their own identification. This was administrative error and should be changed to reflect the use of wristbands, not patient notes, for any identification checks of unconscious patients.
- Contact details for Healthcare Improvement Scotland should be updated.
- The outdated term medio legal should be replaced (recommendation b).

While we have no current concerns about image optimisation, we saw no evidence of a multidisciplinary approach to dose optimisation either locally at the service or corporately. COMARE 16¹ recommends dose optimisation teams are established to provide a multidisciplinary approach to dose optimisation (recommendation c).

While we are assured that local dose reference levels are being developed for the new x-ray room, no levels are being considered for the mobile x-ray equipment as it is rarely used. Employer's procedure EP2F (Procedure for diagnostic reference levels for radiodiagnostic examinations falling within regulation 3 a, b and c) clearly states that local dose reference levels will be displayed in the x-ray room and attached to the mobile x-ray equipment (recommendation d).

¹ Committee on Medical Aspects of Radiation in the Environment (COMARE): 16th Report. Public Health England. 14 August 2014.

While we saw the service carried out quality assurance of all equipment, this was not underpinned by any procedure or policy to indicate the regularity of the checks.

- No requirements.

Recommendation b

- BMI Kings Park should update its employer's procedures to ensure any inaccuracies or out-of-date terminologies and contact details are updated.

Recommendation c

- BMI Healthcare should create an image optimisation team to ensure effective dose optimisation.

Recommendation d

- BMI Kings Park should ensure dose reference levels are developed for all equipment, including the mobile x-ray equipment.

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

BMI Healthcare has identified an imaging lead who is responsible for the implementation of IR(ME)R in each of its hospitals. This is set out in its IR(ME)R implementation procedure. All hospitals are all supported by a corporate team who have expertise in medical physics and radiation protection.

What we found - risk management, audit and governance

The local radiation protection committee is chaired by the imaging lead. It meets once each year and reviews implementation of IR(ME)R, any near misses and incidents. It is attended by the radiologist, medical physics expert and director of clinical services. The group also links with the following.

- The corporate radiation protection advisory board (MPE). This meeting takes place every 3 months and includes medical physics experts representing their BMI hospitals in which they oversee as regionally appointed medical

physics experts. Review of employer's procedures are undertaken with board members - the next review is scheduled for January 2022.

- The corporate national radiation protection committee includes core membership from the medical director, consultant radiologist, corporate medical physics expert, radiation protection advisor and the national lead for imaging and diagnostics. The minutes of these committee meetings are shared with the imaging lead at Kings Park Hospital.
- The national radiation protection committee is aligned with, and feeds up to, the corporate national health and safety committee.

IR(ME)R is also discussed at the BMI Kings Park clinical governance meeting that takes place every 2 months. This is attended by all departments in the hospital.

Clinical audit

Clinical audits carried out are set out in an employer's procedure. Local audits also take place including an audit of referral information and orthopaedic checks. A national audit of compliance with the employer's procedures takes place every month. The results are provided to both senior managers in BMI Kings Park and those in the corporate team. BMI Kings Park could consider a difference scope of audits. Examples can be found on the Royal College of Radiologists on webpage AuditLive. It provides an audit framework identifying best practice in key stages of the audit cycle.

- 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 in London. The medical physics expert is appointed by letter. They provide expert 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, and
- analysis of incidents.

Medical physics experts provide advice on whether or not an incident requires to be reported to Healthcare Improvement Scotland. They told us they were currently involved in establishing dose reference levels for the new x-ray equipment and will provide support to establish dose reference levels for the theatre x-ray and the mobile x-ray equipment.

The medical physics experts provide an annual report to BMI Kings Park following their onsite visit.

Staff told us the medical physics experts are easily contactable and available for advice and support.

Training

We found training records in place for staff involved in medical exposure to radiation. These are held by the imaging lead and easily accessible.

Staff are offered corporate IR(ME)R training and radiographers are encouraged to attend. We were also told that the Society of Radiographers website is accessed for training.

The service does not provide placements for any student radiographers.

The radiologist's training and continual professional development is managed through their annual appraisals and medical revalidation process with NHS Forth Valley, the NHS board they are substantively employed by.

What needs to improve

Operators should be trained on each specific piece of equipment, both to use it and to quality assure it. The imaging lead at BMI Kings Park has been deemed competent to train others in the use of equipment, and its quality assurance whilst in previous employment. However, this does not cover all of the equipment used in BMI Kings Park. The documentation must be extended to ensure there is signed documentation confirming that all radiographers are deemed competent to use and quality assure the equipment and that the imaging lead is at Benner competency level 6 (as outlined in EP2B) in the use and quality assurance of the specific pieces of equipment used in BMI Kings Park (requirement 3).

We saw evidence of continual education for radiologists and radiographers, however specific IR(ME)R related training was not mandatory. It was also unclear what continual education was needed for staff outside radiology, who have obligations under IR(ME)R (recommendation e).

Requirement 3

- BMI Healthcare must ensure that paperwork is completed for all staff to demonstrate their competence to use, and quality assure, each piece of equipment on site and their competence to deliver training to others, if appropriate.

Recommendation e

- BMI Kings Park should ensure specific IR(ME)R related training is included as part of its continual professional development.

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	BMI Healthcare must ensure referring GPs are appropriately entitled to do so, either individually or by GP practice (see page 11). <i>Regulation 6(1)a Ionising Radiation (Medical Exposure) Regulations 2017</i>
2	BMI Healthcare must ensure that all operators and practitioners are entitled to carry out roles for which they are trained and competent to do so (see page 11). <i>Regulation 17(1) Ionising Radiation (Medical Exposure) Regulations 2017</i>
Recommendation	
a	BMI Kings Park should develop guidance to ensure all staff record information consistently on the radiology information system (see page 11).

Domain 5 – Safe, effective and person-centred care delivery	
Requirements	
None	

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

Recommendations

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|----------|---|
| b | BMI Kings Park should update its employer's procedures to ensure any inaccuracies or out-of-date terminologies and contact details are updated (see page 17). |
| c | BMI Healthcare should create an image optimisation team to ensure effective dose optimisation (page 17). |
| d | BMI Kings Park should ensure dose reference levels are developed for all equipment, including the mobile x-ray equipment (see page 17). |

Domain 7 – Workforce management and support

Requirement

- | | |
|----------|--|
| 3 | BMI Healthcare must ensure that paperwork is completed for all staff to demonstrate their competence to use, and quality assure, each piece of equipment on site and their competence to deliver training to others, if appropriate (see page 20). |
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Regulation 17(1)

Ionising Radiation (Medical Exposure) Regulations 2017

Recommendation

- | | |
|----------|---|
| e | BMI Kings Park should ensure specific IR(ME)R related training is included as part of its continual professional development (see page 20). |
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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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