

## **Inspection Report**

## 13 September 2023



# Royal Belfast Hospital for Sick Children Diagnostic Radiology Department

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Assurance, Challenge and Improvement in Health and Social Care

Information on legislation and standards underpinning inspections can be found on our website <u>https://www.rqia.org.uk/</u> and <u>The Ionising Radiation (Medical Exposure)</u> <u>Regulations (Northern Ireland) 2018</u> known as IR(ME)R

### **1.0** Service information

Organisation/Registered Provider:	Department Inspected:
Belfast Health and Social Care Trust	Royal Belfast Hospital for Sick Children
(BHSCT)	(RBHSC)
Name of Employer:	Imaging Services Manager (ISM):
Dr Cathy Jack, Chief Executive (BHSCT)	Sean O'Conaire
Clinical Director of Radiology:	Medical Physics Expert:
Dr Mark Worthington	Adam Workman

#### Brief description of how the service operates:

The RBHSC diagnostic radiology department provides a 24 hour, seven days a week radiology service to patients aged between 0 and 16 years. The radiology service operates 9am to 5pm with an out of hour's service for X-ray, fluoroscopy and computed tomography (CT). Dual-energy X-ray absorptiometry (DXA) scans for patients up to 18 years old are undertaken on a regional basis.

Before the inspection Mr O'Conaire (ISM) and his team were asked to complete a selfassessment form (SAF). The submitted SAF confirmed that each year, the RBHSC radiology department provides 22,800 general radiography exams, 1500 computed tomography (CT) scans, 168 dual X-ray absorptiometry (DXA) scans, 784 fluoroscopy exams and 30-40 forensic imaging (X-ray and CT). The department has two general radiology rooms, one in the main department and one in the emergency department; three portable X-ray machines, 2 Carms, two general fluoroscopy units, one CT scanner and one DXA machine.

The department is staffed by 22.78 whole time equivalent (WTE) permanent radiographers including 0.8 WTE reporting radiographer; 8.8 WTE consultant radiologists and 1-2 WTE specialist registrars (trainees).

The team is supported by a Medical Physics Expert (MPE) from Regional Medical Physics Service (RMPS) based in the BHSCT.

### 2.0 Inspection summary

On 13 September 2023, warranted Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) inspectors from the Regulation and Quality Improvement Authority (RQIA), with advice being provided by the United Kingdom Health Security Agency (UKHSA) staff carried out an IR(ME)R inspection of RBHSC diagnostic radiology department, as part of RQIA's IR(ME)R inspection programme.

For the 2023/24 inspection year the inspections will focus on four key themes:

- Entitlement of staff focusing particularly on those duty holders outside of the radiology department and inter Trust duty holders
- Clinical evaluation including arrangements for peer review
- Clinical audit including robust interpretation of findings and action plans
- Patient identification including pause and check
- Any other areas identified through the review of the submitted self-assessment form and supporting documentation

The purpose of our focus is to minimise risk to service users and staff, whilst being assured that ionising radiation services are being provided in keeping with IR(ME)R (Northern Ireland) 2018.

Previous areas for improvement (if applicable) will also be reviewed.

The service was notified of the inspection date and time; and requested to complete and submit a SAF and include supporting documentation to be reviewed in advance of the inspection. The site inspection process included:

- Discussion with management and staff
- Examination of relevant radiology documentation
- Review of the department and facilities
- Review of patient records to ensure compliance with IR(ME)R
- Discussion with patients/representatives (where appropriate)

IR(ME)R is intended to protect individuals undergoing exposure to ionising radiation as follows:

- Patients as part of their own medical diagnosis or treatment
- Individuals as part of health screening programmes
- Patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes
- Carers and comforters
- Asymptomatic individuals
- Individuals undergoing non-medical imaging using medical radiological equipment

#### 3.0 How we inspect

RQIA is responsible for monitoring, inspecting and enforcement of IR(ME)R. The inspection process includes the gathering and review of information we hold about the service, examination of a variety of relevant written procedures, protocols and records, and discussion with relevant staff. RQIA inspection reports reflect on how a service was performing at the time of inspection, highlighting both good practice and any areas for improvement.

The information obtained is then considered before a decision is made on whether the service is operating in accordance with the relevant legislation and professional standards. Examples of good practice are acknowledged and any areas for improvement are discussed with the relevant staff in charge and detailed in the Quality Improvement Plan (QIP).

As already stated, prior to the inspection, the service was requested to complete a SAF and provide RQIA with all relevant supporting information including written policies and procedures. This information was shared with UKHSA prior to the inspection and was used to direct discussions with key members of staff working within the radiology department and provide guidance for the inspection process.

It is the responsibility of the Employer to ensure compliance with legislation, standards and best practice, and to address any deficits identified during our inspections.

### 4.0 What people told us about the service

As this was a busy radiology department paediatric patients were awaiting or immediately recovering from radiology procedures, it was deemed inappropriate to seek to speak to these paediatric patients or their guardians on the day of the inspection.

## 5.1 What has this service done to meet any areas for improvement identified at or since the last inspection?

A previous inspection had not been undertaken of the RHBSC diagnostic radiology department under the current IR(ME)R legislation.

#### 5.2 Inspection findings

## 5.2.1 Does the service adhere to legislation in relation to the entitlement of duty holders including assessing training and competency?

Entitlement is the term used to describe the process of endorsement by an appropriate and specified individual within an organisation. They must have the knowledge and experience to authorise on behalf of the Employer, that a duty holder or group of duty holders, have been adequately trained and deemed competent in their specific IR(ME)R duty holder roles.

Evidence of induction, training, competency assessment and continuing professional development for radiographers and radiologists was reviewed and found to be well completed. Staff spoken with confirmed they had received induction and training in line with their scope of practice. It was noted that an excellent 'Imaging advice paediatric trainee' booklet was in place for specialist radiology trainees (medical staff) as part of their induction and as an ongoing reference. It was suggested that consideration should be given to sharing this booklet with other relevant staff such groups as referrers.

There was evidence available of training and competency assessment for non-medical referrers with a certificate outlining their scope of practice. However, for other non-imaging staff who carry out duty holder roles outside of the radiology department, for example paediatric surgeons, there was no training or competency assessment information in place. This is discussed further within this section of the report.

Systems are in place to check the professional qualifications and registration of all employees with their appropriate professional bodies. It was confirmed comprehensive systems were in place to provide annual appraisals for all grades of staff and individual development needs are identified as part of this process. Consultant radiologists have their appraisals undertaken by an approved medical appraiser. It was confirmed that entitlement is reviewed at annual appraisal and adjusted accordingly if a staff member's scope of practice had changed.

Individual entitlement records for a consultant radiologist, radiographers and non-medical referrers (NMRs) were reviewed. Overall these individual records were found to be mostly well completed. However, the radiographers' entitlement records did not reflect the DXA service where appropriate. The management confirmed they had recently become aware of this oversight and were planning to update the records. An area of improvement has been identified to ensure radiographer's entitlement records reflect their individual scope of practice including the DXA service.

The arrangements for entitlement of NMR were very robust and it was good to evidence that they are subject to regular review. Group entitlement records were reviewed for MPEs; these were found to clearly evidence the entitlement of this group of staff.

The entitlement of staff outside the radiology department such as those who may act as a duty holder in theatres was discussed. Clinical evaluation is an operator task and it was confirmed that some paediatric surgeons carry out clinical evaluation of images in theatre as part of the surgical procedure. A number of nurses and allied health professionals (AHPs) within the Emergency Department (ED) who are entitled as NMRs also carry out clinical evaluation of specific images. However, these paediatric surgeons, nurses and AHPs who carry clinical evaluation have not been entitled as operators under IR(ME)R.

Radiology management are aware that these staff require to be entitled as operators to comply with IR(ME)R and outlined that whilst they were not in their direct line of accountability to carry out the entitlement process or indeed monitor it, they were liaising with the relevant management, offering support and assistance to facilitate the entitlement process. An 'Action Plan for the Entitlement for BHSCT Non-Imaging Duty Holders' dated 30 August 2023 was provided to the inspection team during the inspection. It outlined actions to be taken in relation to progressing the entitlement of duty holders outside of the radiology department, together with responsible persons, timeframes and evidence of completion (most are in the process of being actioned). However, the timeframe for some actions to be completed is 31 March 2024. To assist in further refining this action plan and focusing on a shorter timeframe for completion an area of improvement was identified to ensure non-imaging staff who carry out clinical evaluation of images are entitled as operators and there is evidence of underpinning training and competency assessment in line with their scope of practice.

It was confirmed that an entitled radiographer is always present in theatres to carry out the practical aspects of the exposure and the paediatric surgeon does not carry out the imaging unless a radiographer is present.

It was strongly reiterated the importance of ensuring all staff including those outside of the radiology who carry out the tasks of a duty holder must be entitled under IR(ME)R to do so.

The governance arrangements concerning the entitlement of staff outside of the radiology department was found to be unclear. The action plan referred to the appointment of a Trust IR(ME)R lead for services outside of radiology by 31 January 2024. There requires to be clear lines of accountability in relation to offering assurance to the Employer that IR(ME)R is being complied with throughout the Trust. An area of improvement has been made to ensure robust governance arrangements are established and implemented to include clear lines of accountability which offer assurance to the Employer that IR(ME)R has been complied particularly for non-imaging services such as within theatres and ED.

Employers Procedures (EP) B on entitlement, sets out the arrangements for entitlement and provides a sound framework for the entitlement process. It was good to note that a number of amendments had been completed following a recent IR(ME)R inspection of another BHSCT radiology department. It was advised to keep this EP updated in line with changes to entitlement arrangements as a result of this inspection.

### **Justification and Authorisation**

The duty holder roles of operator and practitioner was examined in relation to the justification and authorisation of exposures. Justification is the intellectual activity of weighing up the expected benefits of an exposure against the possible detriment of the associated radiation dose and is the primary role of the practitioner. Authorisation is a process separate to justification and is the documentation confirming that the intellectual activity of justification has taken place. It is not always possible for a practitioner to review every imaging referral, so regulations allow for an appropriately entitled operator to authorise an exposure following written authorisation guidelines issued by a named practitioner. The practitioner is responsible for the justification of any exposure that is authorised by an operator following the authorisation guidelines. The operator is responsible for the authorisation and following the authorisation guidelines accurately. Authorisation guidelines must be clearly written using precise statements that are unambiguous in order to allow the operator to confirm whether the referral can be authorised.

It was confirmed that within the RBHSC radiology department the radiographers act as operators and authorise exposures using authorisation guidelines. A range of authorisation guidelines were reviewed and most were found to have sufficient detail to act as authorisation guidelines and the identity of the practitioner for exposures undertaken using the authorisation guidelines was evident from the guidelines. However, 'the authorisation guidelines for Fluoroscopy in the operating theatres in RBHSC' did not include sufficient detail in relation to the clinical indications for the specific examinations. An area of improvement was identified on this matter.

It was confirmed that carers and comforter's (C&Cs) exposures are included in the authorisation guidelines. Radiographers acting as operators authorise these images using the relevant authorisation guidelines. The C&Cs support form was reviewed and it was found to contain detailed information for the C&C to read. It was suggested to facilitate this information in a more accessible form consider using a bullet point format. It was suggested that EP N is updated to include how this information is made available to a non-English speaking C&C or a C&C with sensory deprivation.

The justification and authorisation process was found to be clear on the roles of the operator and practitioner and staff displayed a very good understanding of their IR(ME)R roles and responsibilities. It was confirmed there are excellent working relationships within the radiology team with ongoing support from the consultant radiologists to facilitate patient centred delivery of the radiology service.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced overall clear and robust entitlement arrangements are in place. However, entitlement of some staff groups outside of the radiology department requires to be strengthened. Management and staff were receptive to advice on the entitlement process. The inspection team acknowledge the commitment of staff in this regard.

# 5.2.2 Does the service have appropriate arrangements for the clinical evaluation of medical exposures including peer review?

### **Clinical Evaluation**

The employer must ensure that a clinical evaluation of the outcome is recorded for each exposure. Clinical evaluation involves the assessment of an image and the documentation by the suitably trained and entitled operators. Clinical evaluation is most commonly considered to be a documented radiology report, which is usually recorded on Radiology Information System (RIS). Other methods of clinical evaluation include written records in patient notes. It is considered that evaluation is the final step in the justification process. A clinical evaluation is not required for individuals who are exposed while being a carer or comforter.

It was confirmed that radiologists including specialist trainees provide clinical evaluation in the form of a written report available on RIS. The specialist trainee clinical evaluation reports are also reported on by the radiologist (known as double reporting) until the trainee has completed their 'certificate of completion of training'(CCT), which confirms a doctor has completed an approved UK training programme and is eligible for entry onto the General Medical Council (GMC) specialist register. Clinical evaluation is carried out by one entitled radiographer in line with their scope of practice and another is undergoing training.

As stated in section 5.2.1 in theatres the performing surgeon clinically evaluates images undertaken as part of the operation/procedure, a number of nurses and AHPs in ED clinically evaluates images and records this in the patient notes.

The clinical evaluation of DXA scans was examined and it was noted that an auto analysis system document (a technical report) is generated. There is no agreed standard paediatric analysis for DXA. A radiographer reviews this report and inputs specific data on a template which has been developed by a consultant radiologist. There is no entitled operator involved and review of the completed template confirmed that this approach is not a clinical evaluation in accordance with IR(ME)R. Management acknowledged this and outlined that it had been planned to enrol a number of radiographers on specialist DXA course to provide them with the training and competency to undertake clinical evaluation of DXA scans, which would then lead to their entitlement as operators for this task. However, this course has been withdrawn by the providers and an alternative is not yet available. Whilst this is acknowledged, the requirement for clinical evaluation remains and an area of improvement has been identified to ensure DXA scans are clinically evaluated by an entitled operator.

It was confirmed that around 50% of DXA scans are virtual fracture analysis (VFA) and are clinically evaluated by consultant radiologists. A consultant radiologist confirmed the complexities of clinically evaluating paediatric DXA scans and outlined that VFA DXA scans image quality are checked, clinically evaluated and a detailed report provided on RIS.

It was confirmed that double reporting for suspected physical abuse (SPA) imaging and forensic imaging was undertaken by consultant radiologists.

All imaging examinations must be evaluated as rapidly as possible and procedures are in place to ensure the most clinically urgent are prioritised.

The timeframe for providing clinical evaluation was discussed, management outlined the following:

- Red flag reported within 48 hrs
- 100% of exposures within 28 days

Within imaging, procedures are in place to identify any examinations that are awaiting an evaluation with trigger points and an escalation process to ensure that they are reported within the appropriate timeframes. All specialised examinations are reported or verified on RIS by a consultant radiologist / specialist registrar with access to consultant advice. The completion of clinical evaluation is subject to regular audit.

As stated there are instances where clinical evaluation is recorded directly in the patient's clinical notes, the arrangements for assuring this has happened was unclear. An area of improvement was identified to establish and implement governance arrangements for clinical evaluation outside of the radiology department including regular audit.

'EP J' is in place for the clinical evaluation for medical exposures which outlines a documented clinical evaluation is produced for all medical exposures. Discussions with management and staff confirmed a clear understanding of the clinical evaluation for medical exposures within the radiology department. However outside of the radiology department as previously outlined it was less well understood. An area of improvement was identified to ensure arrangements for clinical evaluation outside of the radiology department is clearly outlined in EP J and fully implemented.

### **Artificial Intelligence (AI)**

As AI systems are beginning to make their way into clinical radiology practice, it is crucial to ensure that their use is compliant with IR(ME)R and safe clinical practice. It was confirmed that 'BoneXpert' software is in use in the department which automatically measures a child's bone age from a child's hand X-ray image. This is not viewed as clinical evaluation and a consultant radiologist confirmed whilst it was very valuable in assisting clinical evaluation, these images were also reviewed by the consultant radiologist and clinically evaluated with a written report.

### **Peer Review**

Peer review in radiology means an assessment of the accuracy of a written report (clinical evaluation) issued by another radiologist/radiographer/health care professional (entitled operator).

The Regional Medical Imaging Board are currently developing a regional peer review process with the involvement of BHSCT radiology service who will implement it in due course.

At present it was confirmed that peer review is included at Multi-Disciplinary Team (MDT) meetings and at Radiology Events and Learning Meetings (REALM), which now includes learning and peer review of images. These meetings also include locum radiologists. As stated previously a number of clinical evaluation reports are double reported.

It was good to note the reporting radiographer is subject to peer review of clinical evaluation by a consultant radiologist. It was confirmed the results are discussed with the radiographer and the target is 95% accuracy rate in line with Royal College of Radiologists(RCR) targets. Any discrepancies are discussed with the reporting radiographer's consultant radiologist mentor.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that the RBHSC radiology department have good arrangements with respect to clinical evaluation within the radiology department and are enthusiastic to ensure these arrangements are regularly reviewed and if necessary, improvements are made. However clinical evaluation arrangements need strengthened for non-imaging services. The inspection team acknowledge the commitment of staff in this regard.

**5.2.3 Does the service adhere to legislation with regard to clinical audit including robust interpretation of findings and action plans?** 

#### **Clinical audit**

IR(ME)R tells us that clinical audit means the systematic examination or review of medical radiological procedures which seek to improve the quality and outcome of patient care through a structured review, whereby medical radiological practices, procedures, and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where indicated and the application of new standards if necessary.

It was evident the imaging service has an underpinning culture of quality improvement. Management and staff demonstrated an inclusive, enthusiastic and proactive approach to patient centred service improvement.

There is a planned multi-disciplinary clinical audit schedule in place. It was confirmed that each modality directs the clinical audits required in their respective area based on clinical practice, needs of the service and results of other audits. In addition, a recurrent IR(ME)R audit programme is carried out. When the audit is completed a standardised audit outcome and action plan is completed by the auditor, manager of the area and the QA radiographer if relevant. This outlines the responsibilities of the auditor and the manager using a colour coded system. It provides a summary of the audit, results, and whether compliance was noted and if a change to practice is required. A detailed action plan is devised based on the findings, it identifies the actions required for change in practice, how results are communicated and when re-audit must occur. It identifies target deadlines, the staff member responsible for completing the action and the manager responsible. It also documents the change stage. It was good to note re-audit is considered in line with the findings. Usually one to three months if non-compliance noted. On completion of all actions on the action plan the audit can be closed. This is evidenced on the form by the sign off by the auditor and area manager.

A range of clinical and IR(ME)R audits were reviewed:

- · Skeletal Survey audit, on follow up imaging
- · Chest-X-ray audit, on reason for increase in referrals
- Assessment of X-ray knee imaging audit
- Diagnostic Reference Level (DRL) audit
- Equipment quality control (QC) tests audit

It was good to note excellent use of a standard template to log findings and actions required as described above. There was evidence of follow up audits when 100% compliance was not reached, implementing the necessary change, staff being reminded of the importance of technique and a practical tutorial giving information to staff of how to improve and leading to improvements to practice.

Staff described how audits had led to positive changes in practice and demonstrated a knowledge on the importance of audit. Shared learning is facilitated by modality leads/department managers via team meetings and sharing the audit results electronically.

A gap analysis tool is also available on Microsoft Teams which allows the area service managers and the lead QSI radiographer to overview compliance of audits, the audit schedule and outcomes.

The service develops an 'Audit Report' every 6 months which reviews compliance with audit schedule, audit performance, and outstanding actions. This is shared with all imaging staff and senior management team through e-mail communication, a fortnightly briefing paper, and is reported to the radiation protection committee via the diagnostic radiology and nuclear medicine group. The Lead QSI radiographer maintains a dedicated audit record channel on Microsoft Teams, where completed audits are shared.

Management described the clear governance arrangements for ensuring the audit programme is established, implemented, acted upon and used to drive improvement. All demonstrated a sound understanding of the roles and responsibilities associated with clinical audit.

It was suggested to consider sharing this excellent work with the wider radiology community for example by publishing or attending professional conferences.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced clear and robust clinical audit arrangements are in place. The inspection team commend the commitment of staff in this regard.

# 5.2.4 Does the service adhere to legislation with regard to patient identification including pause and check?

IR(ME)R requires the Employer to establish a procedure to identify correctly the individual to be exposed to ionising radiation. The procedure should specify how and when an individual is to be identified. EP A (ii) patient identification, is in place and provides a clear comprehensive framework for staff to follow. Correct identification (ID) of the patient or individual to be exposed is an operator task and must be undertaken prior to any exposure.

Management and staff confirmed that it is the responsibility of the operator to ensure the correct patient is being examined against the request made. Whilst many people may be involved along the patient pathway, the responsibility for correct ID lies with the operator who carries out the medical exposure. Staff described the patient ID process, the operator must always check the patient's name, address and date of birth on the referral. The patient or guardian must be asked to state their name, address and date of birth rather than confirm these details. They outlined the following questions:

- What is your name?
- What is your address?
- What is your date of birth?

It was confirmed that supplementary safety checks are also carried out such as:

- Why are you being X-rayed/scanned?
- Have you been X-rayed or scanned recently?

Staff confirmed that the professional guidance on Pause and Check is used and promoted in the radiology department. Pause and check notices were observed to be displayed in the department and staff demonstrated a clear understanding of the importance of the use of Pause and Check.

Staff described the patient ID process when more than one operator is involved. For other scenarios such as patients who lack capacity, the unconscious patient and patients in theatre, a clear patient ID process was outlined for each situation.

The patient ID check is recorded on RIS by the operator and validated with their personal password prior to exposing the patient to ionising radiation. Review of a random sample of patient records confirmed that patient ID had been recorded as checked for all those reviewed.

A patient ID audit is carried out as part of the rolling programme of core audits. There was a very high compliance level noted.

Staff explained the process for discrepancies in the patient ID, this included; check if known as any other name, check with carer/relative, check on picture archiving communication system (PACS), make a record of the changes required, and send a request to PACS team to change the demographics. There is a section in RIS for incorrect demographics. However, it was very clear from responses that the exposure would not be undertaken if the patient ID could not be confirmed.

There is evidence to show that incidents involving referral of the wrong patient are among the largest percentage of all diagnostic errors notified to IR(ME)R regulators. The radiology department have robust systems in place to report, record, investigate and learn from incidents and near misses. Patient ID processes have been strengthened using learning from patient ID incidents and near misses, such as the implementation of Pause and Check; further staff training, raising awareness of their responsibilities and liaising with other departments to promote safe practice.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced clear and robust patient identification processes are in place. The inspection team acknowledge the commitment of staff in this regard.

# 5.2.5 Additional areas reviewed - other areas identified through the review of the submitted self-assessment form and supporting documentation

### Optimisation

Optimisation is a key principle of the radiation protection framework within IR(ME)R and is a joint responsibility of the practitioner, operator and MPE. The aim of optimisation is to achieve the image quality required to answer the clinical question using the lowest dose.

IR(ME)R says that the practitioner and operator must pay particular attention to the optimisation of exposures performed on children.

It was confirmed that the following additional optimisation measures are applied to the imaging of children:

- Paediatric protocols, which are either age or weight based are in place
- Paediatric exposure charts
- Paediatric Diagnostic Reference Levels (DRLs), which have been updated recently to reflect the National DRLs
- There are a small number of clinical indication specific protocols which are considered low dose
- For CT and fluoroscopy, the imaging protocol is tailored specifically for the individual clinical query by the practitioner
- Split bolus contrast technique is employed in CT to reduce the number of required imaging acquisitions
- Where multiphase acquisitions are required in CT, effort will be made to reduce the length of some of the image acquisitions
- Operator promotes patient compliance in advance of the exposure, communicating with paediatric patient, explaining to carer and comforter their role in the examination
- Specialist paediatric training for radiographers
- Distraction techniques are used in X-ray
- Positioning aides, such as sponges are in use
- Liaising with other specialists for children who have had a previous challenging experience in hospital
- Involvement of play specialist
- Image optimisation team, who consolidate expertise in order to consistently optimise paediatric imaging examinations for dose and image quality

Staff and management demonstrated a clear understanding of optimisation and it was evident there is a continuous review of practice in relation to optimisation.

### **Employers Procedures (EPs)**

There were comprehensive detailed EPs in place which had been approved in February 2022 by the Employer. It was good to note that they had been updated in May 2023 following a recent IR(ME)R inspection to another BHSCT radiology department.

Discussion took place on the ratification process when minor amendments had taken place. Assurance was given that minor amendments are approved by the radiation protection committee (RPC) and the most recent changes had been approved by the RPC on 4 June 2023.

Review of EPs noted the following:

- EP K(II) radiation incident investigation and reporting procedure, refers to an additional policy and procedure for the reporting and investigation of IR(ME)R related incidents. Some of the information outlined in the additional policy and procedure would be better placed for ease of access in the EP K(II). It was noted that EP K(II) made no reference to Significant Accidental and Unintended Exposures (SAUE) guidance April 2023. The EP should reflect this relevant and important guidance
- EP K(I) ensure the probability and magnitude of AUE is reduced as far as reasonably practicable, this EP references the EP K(II) and the policy and procedure for reporting and investigating IR(ME)R related incidents. EP K(I) would benefit from a link to the aforementioned policy and procedure
- EP L Clinically SAUE (CSAUE), requires to clearly specify all CSAUEs are notifiable to RQIA and ensure that CSAUEs are documented in patient notes
- **EP D (I)** QA programme for written protocols, this EP lacked detail on document and version control and the ratification process
- **EP D (ii)** Equipment quality assurance (QA), referred to detailed X-ray Equipment Performance Procedures, however there was no link for ease of access to this important information

An area of improvement has been identified to amend the EPs as outlined above.

### 6.0 Quality Improvement Plan/Areas for Improvement

Areas for improvement have been identified where action is required to ensure compliance with The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 known as IR(ME)R and other published standards which promote current best practice to improve the quality of service experienced by patients.

Areas for improvement identified during this inspection are detailed in the QIP. Details of the QIP were discussed with senior management as part of the inspection process. The timescales commence from the date of inspection.

It is the responsibility of the Employer to ensure that all areas for improvement identified within the QIP are addressed within the specified timescales.

The QIP should be completed and detail the actions taken to address the area for improvement identified. The Employer should confirm that these actions have been completed and return the completed QIP via <u>BSU.Admin@rqia.org.uk</u> for assessment by the inspector.

Quality Improvement Plan		
Action required to ensure compliance with <u>The Ionising Radiation (Medical Exposure)</u> <u>Regulations (Northern Ireland) 2018</u>		
Area for improvement 1 Ref: Regulation 6 Schedule 2.1(b)	The Employer must ensure radiographer's entitlement records reflect their individual scope of practice including the dual- energy X-ray absorptiometry (DXA) service. Ref 5.2.1	
Stated: First time To be completed by: 13 November 2023	Response by Employer detailing the actions taken: The IR(ME)R Entitlement for Radiographers form was revised to include DEXA operator entitlement. Revised Entitlement forms were completed by radiographers who perform DEXA and signed off appropriately.	
Area for improvement 2 Ref: Regulation 6 Schedule 2.1(b)	The Employer must ensure non-imaging staff who carry out clinical evaluation of images are entitled as operators and there is evidence of underpinning training and competency assessment in line with their scope of practice.	
Stated: First time	Ref 5.2.1	
To be completed by: 13 November 2023	<b>Response by Employer detailing the actions taken</b> : Planned presentation to the Trust Executive team on 27th November 2023 to outline each Directorate / service's roles and responsibilities to confirm underpinning training and competency assessment for staff who carry out clinical evaluations. This will be followed up with letters to individual Directors to formally note the requirement and actions agreed and address any lack of understanding within the Trust. A Group Entitlement form for services outside of Imaging where clinical evaluation of images takes place and accompanying letter has been developed by the Imaging service and shared with Trust Risk & Governance, Joint Chairs of the Radiation Protection Committee and Director of Child Health & NISTAR, Imaging Medical Physics & Outpatients for review and subsequent distribution to all specialities.	
Area for improvement 3	The Employer must ensure robust governance arrangements are established and implemented to include clear lines of	
Ref: Regulation 6	accountability which offer assurance to the Employer that IR(ME)R has been complied with, particularly for non-imaging	
Stated: First time	services such as within theatres and emergency department (ED).	

To be completed by: 13 December 2023	Ref 5.2.1
	<b>Response by Employer detailing the actions taken</b> : The Imaging Services Manager met with the Trust Risk & Governance team on 27 October 2023 to highlight gaps in compliance with IR(ME)R by non-imaging services. It was confirmed that risks and concerns would be tabled at the External Reports Review Group (ERRG) meetings, and RQIA report and action plans from relevant services will be discussed in this forum as a means of accountability. Service areas outside Imaging are required to report into the Diagnostic Radiology & Nuclear Medicine (DR&NM) committee and the Radiation Protection Committee (RPC). DR&NM committee's Terms of Reference were reviewed to include membership of Clinical Directors and Service Managers of services outside Imaging where there are IR(ME)R Practitioners and Operators, and an invite extended to the next meeting.

<ul> <li>Area for improvement 4</li> <li>Ref: Regulation 11(5)</li> <li>Stated: First time</li> <li>To be completed by: 13 December 2023</li> </ul>	The Employer must ensure the 'authorisation' guidelines for fluoroscopy in the operating theatres in RBHSC' includes sufficient detail in relation to clinical indication for the specific examinations. Ref 5.2.1 <b>Response by Employer detailing the actions taken</b> : The 'Authorisation Guidelines for Fluoroscopy in the operating theatres in RBHSC' were revised to include further detail in
	relation to clinical indication for specific examinations. Republished and shared with staff on 27th October 2023.
Area for improvement 5 Ref: Regulation 12(9)	The Employer must ensure DXA scans are clinically evaluated by an entitled operator. Ref 5.2.2
Stated: First time	<b>Response by Employer detailing the actions taken</b> : The Imaging service plans to build capacity within the
To be completed by: 13 November 2023	radiographer workforce to support the provision of clinical evaluations for DEXA examinations across the service. The University of Derby Programme Lead has confirmed PgCert Bone Densitometry Reporting Course will commence in January 2024 with an estimated completion date of October 2024. Two radiographers from the Imaging service will be supported to complete this course. The service plans for DEXA clinical evaluations in RBHSC to be performed by Consultant Radiologists for an interim period until radiographers are qualified and trained to support this service.
Area for improvement 6 Ref: Regulation 12(9)	The Employer must establish and implement governance arrangements for clinical evaluation outside of the radiology department including regular audit.
Stated: First time	Ref 5.2.2
To be completed by: 13 November 2023	<b>Response by Employer detailing the actions taken</b> : Employer's Procedure J was updated to outline the responsibilities and governance framework when providing clinical evaluation outside Imaging. The Trust's Employer's Procedures were republished and shared with staff on 10th November 2023.
Area for improvement 7 Ref: Regulation 6 Schedule 2.1(j) Stated: First time	The Employer must ensure arrangements for clinical evaluation outside of the radiology department is clearly outlined in employer's procedure (EP) J and fully implemented. Ref 5.2.2

<b>To be completed by:</b> 13 December 2023	<b>Response by Employer detailing the actions taken</b> : Clear systems of Audit of clinical evaluation outside Imaging have now been outlined within Employer's Procedure J. The Trust's Employer's Procedures were republished and shared with staff on 10th November 2023.
Area for improvement 8	The Employer must amend the following EPs:
Ref: Regulation 6 Schedule 2.1 Stated: First time	• EP K(II) radiation incident investigation and reporting procedure, include information from 'policy and procedure for the reporting and investigation of IR(ME)R related incidents' and include details of the SAUE guidance April 2023
To be completed by: 13 December 2023	• <b>EP K(I)</b> ensure the probability and magnitude of AUE is reduced as far as reasonably practicable, include a link to the 'policy and procedure for reporting and investigating IR(ME)R related incidents'.
	• EP L Clinically SAUE (CSAUE), requires to clearly specify all CSAUEs are notifiable to RQIA and ensure that CSAUEs are documented in patient notes
	• EP D (I) QA programme for written protocols, include document and version control and the ratification process
	<ul> <li>EP D (II) Equipment QA, include a link to 'X-ray Equipment Performance Procedures'</li> </ul>
	Ref 5.2.5
	Response by Employer detailing the actions taken: The Trust's Employer's Procedures were updated to include all areas for improvement as stated below and republished on Trust Loop 10 November 2023: EP K (ii) radiation incident investigation and reporting procedure, was updated to include information from 'Policy and procedure for the reporting and investigation of IR(ME)R related incidents' and include details of the SAUE guidance April 2023. EP K9i) ensure the probability and magnitude of AUE is reduced as far as reasonably practicable, was updated to include a link to the 'Policy and procedure for the reporting and investigation of IR(ME)R related incidents'. EP L- Clinically SAUE (CSAUE), was updated to clearly specify that all CSAUEs are notifiable to RQIA and ensure that CSAUEs are documented in patient notes.

<ul> <li>EP D (i) QA programme for written protocols, was updated to include document and version control and the ratification process.</li> <li>EP D(ii) Equipment QA, was updated to include a link to X-ray Equipment Performance Procedures'.</li> </ul>





The **Regulation** and **Quality Improvement Authority** 

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