

Inspection Report of Compliance with the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018

14 November 2019



Antrim Area Hospital, Diagnostic and Interventional Radiology Department

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Assurance, Challenge and Improvement in Health and Social Care

It should be noted that this inspection report should not be regarded as a comprehensive review of all strengths and areas for improvement that exist in the service. The findings reported on are those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not exempt the service from their responsibility for maintaining compliance with legislation, standards and best practice.

1.0 What we look for



RQIA has employed refreshed inspection methodology in relation to compliance of radiology services with The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018, known as the IR(ME)R regulations. The regulations came into force on 6 February 2018.

The inspection had a particular focus on the key changes to the regulations including:

- Communication of benefits and risks
- Diagnostic reference levels (DRL's)
- Accidental and unintended exposures
- Equipment
- Carers and comforters
- Medical physics expert advice
- Non-medical imaging using medical radiological equipment

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

Medical exposures

- 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
- To carers and comforters
- To asymptomatic individuals
- Non-medical exposures using medical radiological equipment

2.0 Service details

Name of Establishment: Antrim Area Hospital	Department Inspected: Diagnostic and Interventional Radiology Department
Name of Employer: Dr Tony Stevens, Chief Executive Northern Health and Social Care Trust (NHSCT)	Radiology Services Manager: Mr Matt Mallon
Clinical Director of Radiology: Dr Myles Nelson	Medical Physics Expert: Mr Philip Doyle

3.0 Profile of services

The self-assessment form submitted prior to the inspection confirmed that each year, Antrim Area Hospital diagnostic and interventional radiology department carries out approximately:

81,982	General radiology (plain film)
1,101	General fluoroscopy
21,594	General computed tomography (CT) scanning
177	Interventional CT
342	Dental
3,450	Symptomatic mammogram
24,269	Ultrasound scan (US)
9,073	Magnetic resonance imaging (MRI)
1,761	Antenatal US
107	CT (Bowel Cancer Screening programme)

US and MRI services were not inspected, as these services do not involve the use of ionising radiation and therefore are not subject to the IR(ME)R regulations.

Antrim Area Hospital radiology department employs:

- 20.52 Consultant Radiologists (9.11 WTE Consultant Radiologists vacant posts)
 - 4 Specialist Registrars
 - 3 Plain film reporting radiographers
- 65.96 Radiographers (6 WTE radiographers vacant posts)
 - 3 Diagnostic Radiology Medical Physics Experts(MPEs) under contract from the Belfast Health and Social Care Trust

It was confirmed that the effect of vacant radiographer and Consultant radiologist posts had been challenging and had impacted waiting times which led to the use of third party providers. The senior management outlined the ongoing measures being taken to recruit suitably skilled and qualified individuals.

4.0 Methodology

On 14 November 2019, warranted IR(ME)R inspectors from RQIA, with advice being provided by Public Health England (PHE) staff, visited Antrim Area Hospital, diagnostic and interventional radiology department, as part of RQIA's IR(ME)R inspection programme.

Prior to the inspection, the service was requested to complete a self-assessment form and provide RQIA with all relevant policies and procedures. This information was shared with PHE prior to the inspection visit, and was used to direct discussions with key members of staff working within the radiology department, and provide guidance for the inspection process.

NHSCT staff and Medical Physics Expert (MPE) staff in attendance for part or all of the inspection:

Dr Tony Stevens	Chief Executive Officer
Ms Margaret O'Hagan	Director Surgery and Clinical Services
Mr Myles Nelson	Clinical Director of Radiology
Dr Barry Patterson	Chair of The Radiation Safety Committee
Ms Cora Regan	Assistant Clinical Services Manager (Radiology)
Mr Matt Mallon	Radiology Services Manager
Mrs Cristiona Logan	Quality Assurance (QA) Radiographer
Mr Philip Doyle	MPE

The inspection team reviewed relevant documentation and patient records. A tour of some areas of the diagnostic and interventional radiology department was undertaken and the inspectors took the opportunity to speak with five members of staff including general and CT radiographers and a MPE.

5.0 Inspection outcome

	Regulations
Total number of areas for improvement	15

Details of the Quality Improvement Plan (QIP) were discussed with senior management as part of the inspection process. The timescales for completion commence from the date of inspection.

6.0 The inspection - key findings

6.1 Duties of the employer

Employer's procedures

Antrim Area Hospital, NHSCT had the required Employer's Procedures in place which had been reviewed and updated in accordance with IR(ME)R 2018 and issued in April 2019. The Employer's Procedures are reviewed every two years or more frequently if change is necessary.

A Radiation Safety Policy had been issued in April 2019 and confirmed that the Employer has been clearly identified in line with IR(ME)R legislation. It was established that the overall responsibility for IR(ME)R lies with Dr Tony Stevens, Chief Executive Officer, NHSCT and his subsequent responsibilities are clearly set out.

The Radiation Safety Policy outlined governance and reporting structures in relation to the use of ionising radiation. Clarification was sought on these structures and it was established that new structures had been introduced. A briefing paper provided to the Chief Executive (The Employer) on the new structures was reviewed. The new structures and associated lines of accountability were found to be clear and well thought out. Management demonstrated a good understanding of the respective roles under the new structures. An area for improvement was identified in relation to updating the Radiation Safety Policy to reflect the changes to the organisational structures.

The Chief Executive Officer (CEO), through the Executive team, nominates the Chair of the Radiation Safety Committee with the tasks associated to ensure compliance with the requirements set out in the Radiation Safety Policy and the IR(ME)R regulations.

Review of the submitted documentation, and discussion with the management team, confirmed that systems are in place to ensure that Employer's Procedures are complied with by referrers, practitioners and operators, through audit, induction and training. It was confirmed that the Employer receives reports on the level of compliance.

Document and version control are clearly noted on the Employer's Procedures and inspectors were informed that all relevant policies and procedures can be found on NHSCT intranet.

Quality Assurance programme for written policies and procedures

Review of the documentation, provided to the inspection team, confirmed that a quality assurance system of documentation is in place. It was confirmed that relevant authors are responsible for reviewing the document in the timescale specified according to: current practice, internal audit results, national guidelines, codes of practice and evidence based practice, statutory or regulatory requirements and standards, patient requirements, technological developments and associated competency levels of staff. It was confirmed that changes are communicated to relevant staff via the weekly radiology team brief. All documentation is accessible to all staff via the Radiology Shared drive; RadiologyProtocols.

'Employer's Procedure D', outlines the quality assurance programmes in respect of written procedures, written protocols, and equipment.

Equipment Quality Assurance (QA) is further discussed in section 6.5 of this report.

Diagnostic Reference Levels (DRLs)

The process for establishing, reviewing, and checking compliance with DRLs has been developed in collaboration with the MPEs and is set out in 'Employer's Procedure F'. Dose audits are both site specific and compared across sites. The Radiation Safety Committee endorses existing national DRLs and ratifies any changes to the DRLs proposed by the Image Optimisation Teams (IOTs). The IOTs are tasked with reviewing DRLs audits and ensuring any required changes are actioned.

The work of the IOTs provides information and assurances to the Radiation Safety Committee in line with governance systems.

On inspection it became clear that the IOTs had been co-ordinating dose audits and the collection of data for the establishment of Local DRLs for a number of examinations and modalities. The methodology was discussed at length and it was confirmed that the work was ongoing for establishing Local DRLs, in particular for paediatric imaging. Whilst the work already undertaken is acknowledged, there was no overall action plan with timescales in relation to the establishment of Local DRLs, leading to potential slippage in their establishment and implementation. It was confirmed that it was acceptable to establish and ratify individual Local DRLs on a phased basis within a planned timeframe.

An area for improvement has been identified in relation to the establishment of Local DRLs:

- develop an overall action plan with timescales for the establishment of Local DRLs; and
- prioritise the establishment of paediatric Local DRLs

Dose audits are carried out; a comparison of mean doses for each type of examination with the relevant DRL is undertaken and a report written on the dose survey results that will identify whether any of the dose levels measured either approach or exceed national DRLs.

'Employer's Procedure E' outlines the procedure for assessment of patient dose.

Staff spoken with demonstrated a clear understanding on the use of DRLs and what action to take in the event of DRLs being consistently exceeded. National DRLs for adults and National/European DRLs for paediatrics were noted to be displayed in the radiology department.

Clinical audit

It was evident that 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.

A planned Radiology Audit Schedule is in place and evidence of audits was provided. These were found to be multi-professional and included areas of compliance under IR(ME)R. The findings of audits are shared through weekly team briefs, monthly multi-professional meetings, and quarterly audit meetings. There was evidence of how the audits influenced practice. It was noted 'The clinical evaluation of the current x-ray Imaging Pathway for possible hip/pelvis fractures audit' had led to a change in the Hip Imaging Protocol. The protocol was changed to reflect NICE guidelines and indicated the non-requirement for a second x-ray. This was rolled out in practice and provided a benefit to the patient and the evolution of the service.

The Trust has entered into third party contracts with Everlight and Yourworld to provide radiological services. On discussion it was confirmed that formal auditing arrangements in relation to these services has been developed.

Accidental and unintended exposures

Management and staff explained the process for reporting internally and then to the appropriate enforcing authority. Review of a random sample of incident records indicated that there was a delay in the reporting of incidents to RQIA in line with 'Significant accidental and unintended exposures (SAUE) under IR(ME)R – Guidance for employers and duty-holders 'June 2019. A lengthy discussion took place in relation to the reporting of incidents and clarification was provided on the SAUE guidance. 'Employer's Procedure Q' (incident reporting) did not reflect the latest guidance and the current requirements in relation to the reporting of radiology incidents. An area for improvement has been identified to ensure incidents are reported in accordance with SAUE guidance and the legislation. The system for reporting must be strengthened to ensure clear lines of accountability and governance arrangements on this important matter. It was agreed that a full review of all incidents in the last year would be undertaken to ensure all reportable incidents have been reported to the appropriate enforcing authority.

All radiation incidents are recorded on DATIX either as a near miss or radiation incident within 24 hours by the reporting staff member. The appropriate sections of the radiation incident investigation form are completed within 72 hours. Radiation incident forms are forwarded to the site or modality lead radiographer to carry out a preliminary investigation and subsequently complete the appropriate sections of the radiation investigation form. This is then forwarded to the Departmental Lead Governance Radiographer and MPE for review and dose analysis. Radiation incidents are reviewed at the monthly Incident Review Group which ensures that all corrective action has been completed including recommendations. A quarterly radiology error report is collated and communicated at the departmental Image Optimisation Group, Radiation Safety Committee and departmental Governance Steering Group.

These structures are outlined in 'Employer's Procedure Q', however as previously discussed, the organisational structures have changed and may not reflect the current position. An area for improvement was identified to update 'Employer's procedure Q' in accordance with current organisational structures and the SAUE guidance. Consideration should be given to changing the layout of the procedure to ensure it is easier to follow.

Staff spoken to demonstrated a good understanding of the action to take in the event of an incident occurring and confirmed learning from incidents is shared at weekly team briefs.

The identification of clinically significant incidents was discussed with management and the MPE. The Trust system outlined did not fully reflect the legislation on informing the patient and in turn it was not reflected fully in 'Employer's Procedure L'. An area for improvement has been identified in relation to establishing formal systems for the identification of clinically significant incidents, outlining the decision making process, the recording of the decision process and the informing of the individual exposed or their representative and these should be fully outlined in 'Employer's Procedure L'. All radiation incidents are collated and sent to the Radiation Safety Committee and through the governance framework as previously described.

Training, competence and entitlement

There was evidence of induction, training and continuing professional development for all grades of staff. Systems are in place to check the professional qualifications and registration of all employees with their appropriate professional bodies.

It was confirmed that there are comprehensive systems in place to provide annual appraisals for all grades of staff and individual development needs are identified as part of the appraisal process. Consultant radiologists have their appraisals undertaken by an approved medical appraiser. All grades of staff are responsible for maintaining their own portfolio of evidence to maintain their individual professional accreditation.

The inspection team reviewed a number of completed induction programmes for radiographers and competency and entitlement forms. Training and competency records for radiographers were found to be of a high standard.

Staff confirmed that they had received update training from the MPE on the IR(ME)R regulations 2018.

It was confirmed that staff are provided with information regarding their duties under IR(ME)R during induction; including junior doctors.

The senior team reported that radiographers and radiologists had been appropriately entitled according to their training, competencies and individual scope of practice. Entitlement is reviewed at annual appraisal and adjusted accordingly if a staff member's scope of practice has changed. The entitlement process for radiologists was discussed and a radiologist's entitlement documentation was reviewed.

The process of entitlement for non-medical referrers was discussed at length. It was confirmed that some issues had arisen in relation to non-medical referrers attempting to refer outside of their scope of practice. As a result the Trust had undertaken a full review of non-medical referrers entitlement. There are three categories of non-medical referrers: NHSCT non-medical referrers, external non-medical referrers and primary care non-medical referrers. Review of the entitlement arrangements for each of these categories found that some work had been done to ensure enhanced processes were in place. Ensuring that non-medical referrers are appropriately trained and competent requires to be strengthened together with their understanding of their duty holder role under IR(ME)R. An area for improvement has been identified to ensure the strengthening of the application process and introduction of a robust review and scrutiny of training and competency records for non-medical referrers as part of the entitlement process. These records should be available for inspection.

It was confirmed that third party radiology staff are subject to the entitlement process and this process was outlined to the inspection team. An area for improvement has been identified in relation to ensuring the entitlement process for third party radiology staff includes evidence that they are suitably qualified, trained and competent to carry out their duty holder role.

MPEs are presently entitled under a group entitlement approach. An area for improvement has been identified to ensure the entitlement of MPEs is strengthened with the formal inclusion of individual MPEs scope of practice.

'Employers Procedure B', entitlement, did not fully reflect the entitlement process outlined during the inspection and an area for improvement has been identified to update the procedure to reflect accurately the entitlement process for all duty holders.

Advice was provided on the entitlement process in relation to ensuring there is evidence of robust adherence to the Trust's procedures and legislation; management were receptive to this advice.

Referrals

The referral guidelines currently being used are the Royal College of Radiologists i-Refer Guidelines Making the Best Use of Clinical Radiology 8th edition. Referral guidelines are available on the NHSCT intranet.

Staff described how diagnostic referrals are made to the department, including prioritising referrals and specifically timed future examinations.

A clear process was evidenced for returning/rejecting referrals which are incomplete, inappropriate or unjustified. Cancelling referrals was discussed including how referrers are made aware of the process to cancel a referral they have made. An area of improvement has been identified to include a timeframe to inform the referrer of a cancellation of the request within the work instruction.

'Employer's Procedure O' (accepting a referral for a medical exposure) was in place and found to provide clear information.

6.2 Justification and Authorisation of individual medical exposures

Justification and authorisation was discussed with staff, who demonstrated an understanding of the process and described how justification and authorisation is recorded electronically on the radiology information system (RIS). This was evidenced in a randomly selected number of patient records.

It was confirmed that radiographers act as operators and authorise under guidelines in general radiology and CT. The justification process during out of hours was discussed with staff who demonstrated a clear understanding on the matters relating to CT imaging.

Authorisation guidelines were in place for general radiology and CT examinations which identified the practitioner for these medical exposures.

The justification of carers and comforters exposures was discussed and it was confirmed that the justification of the patients exposure as outlined in the authorisation guidelines extended to the carers and comforters. This is not in accordance with the legislation in relation to carers and comforters exposures which should be justified and authorised in their own right. An area of improvement has been identified to amend the authorisation guidelines in relation to carers and comforters or consider entitling radiographers as practitioners for carers and comforters exposures. Staff confirmed that they verbally outline the benefits and risks of the exposure to the carer or comforter. They complete a carers and comforters record form which includes written information on the benefits and risks, a pregnancy enquiry form if relevant is signed by the carer or comforter and the radiographer.

'Employer's Procedure N' (carers and comforters) was reviewed and an area of improvement has been identified to update the procedure to reflect the justification and authorisation process in relation to carers and comforters exposures.

Non-medical exposures using medical radiology equipment

Staff confirmed that non-medical imaging exposures are clearly identified on the referral form and these exposures are justified using clinical criteria by an entitled practitioner. 'Employer's Procedure M', which outlines the arrangements in place for non-medical imaging, was reviewed and found to be satisfactory.

6.3 Optimisation

There are good arrangements in place to ensure that medical exposures are kept as low as reasonably practicable. 'Employer's Procedure K' outlines the arrangements in place, these include:

- applications training;
- radiographic protocols;
- standard operating protocols;
- routine equipment maintenance;
- appropriate exposure charts;

- patient dose surveys; and
- daily quality assurance.

The range of optimisation measures taken in the radiology department was not fully reflected in the 'Employer's Procedure K' and an area of improvement was identified in relation to further developing 'Employer's Procedure K' to include Image Optimisation Teams (IOTs) and establishing Local DRLs.

As stated previously, IOTs are established and terms of reference were provided to the inspection team. Staff were aware of the work of the IOTs and displayed an understanding of their role in the optimisation of exposures.

The MPE described their involvement on the IOT and confirmed that they are involved in dose audits; the establishment of Local DRLs; setting up of protocols and risk assessment.

Communication of benefits and risks of having an exposure to ionising radiation

Staff displayed clear understanding in relation to the process of providing the individual (or their representative) to be exposed with adequate information on the benefits of having the exposure and the risks associated with the radiation dose. It was confirmed that staff had training from the MPE in relation to providing benefits and risks information.

It was good to note information posters prominently displayed in the waiting areas of the imaging department. Inspectors reviewed written patient information and preparation leaflets which had been developed and found them to be well written.

Paediatrics

Paediatric imaging is provided by the radiology department. It was noted that special attention is paid to optimisation when undertaking exposures of children. This includes:

- paediatric exposure charts;
- modified views;
- alternative techniques not involving ionising radiation where appropriate;
- use of European paediatric DRLs; and
- use of lead protection, where justified and appropriate.

The IOT is leading a trust wide audit focusing on paediatric dose, compliance with European DRLs and the appropriateness and efficiency of current equipment. Specific equipment has been identified and optimised to be used for paediatric imaging demonstrating good practice and compliance with Regulation 12(8)(a).

Clinical Evaluation

'Employer's Procedure O' is in place for the clinical evaluation for medical exposures and it outlines that 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.

There is an audit trail in the Radiology Information System (RIS) which identifies which exposures have not yet been reported on. It was confirmed that there are instances where clinical evaluation is recorded directly in the patients clinical notes.

6.4 Expert Advice

The NHSCT retains the services of a MPE on a contractual basis. The MPE was present for the duration of the inspection. It was confirmed the appointed MPEs are currently recognised by Department of Health and are entitled as operators who are competent and appropriately trained for their scope of practice. As stated previously an area of improvement has been made regarding the entitlement of MPEs.

The MPE provides ongoing advice and support to the management team on a range of issues including dosimetry and evaluation of dose, QA matters relating to radiation protection, and radiological equipment.

The MPE is involved in high dose CT services. The MPEs contribute to radiation protection of patients and others; DRLs analysis; QA of the equipment; acceptance testing of equipment; installation design and technical specification of equipment; analysis of accidental or unintended exposures; selection of equipment for radiation protection measurements; training of practitioners and other staff on radiation protection and compliance with regulations. It was confirmed the lead MPE had provided training to staff on IR(ME)R regulations 2018.

6.5 Equipment

An inventory of radiological equipment was submitted to RQIA which contained all of the legislative information. Management and staff confirmed there is an appropriate amount of equipment available for the workload of the radiology department.

As stated previously 'Employer's Procedure F' includes information on QA of equipment. The quality assurance records for three pieces of radiology equipment were reviewed. The records viewed were incomplete and did not provide assurances that the equipment was being checked in line with manufacturer's instructions and QA procedures. The MPE confirmed that these checks are carried out by radiographers following training from the MPE however competence had not been confirmed.

The inspection team discussed this matter with senior management in relation the inadequacy of the QA checks, the training and competence of staff undertaking QA of equipment checks, the governance arrangements for compliance with the QA of equipment procedures and the need for an immediate response to ensure radiology equipment is clinically safe to use. The senior management gave immediate assurances that the matter would be robustly addressed. An action plan was requested to be submitted to RQIA within one week of the inspection outlining action taken and action proposed to ensure all QA of radiology equipment is fully compliant with QA procedures, including governance arrangements.

The Clinical services manager-radiology, submitted a quality improvement plan to RQIA on 20 November 2019 which outlined specific action already taken and action proposed in relation to the QA equipment findings of the inspection. It included the following:

- Review and amend Equipment Quality Assurance Procedure to include unambiguous roles and responsibilities associated with the QA Programme, and clear lines of communication throughout the Trust Clinical Governance Framework;
- An immediate cycle of MPE supervised QA was carried out on the X-ray equipment within the department, to ensure the equipment is safe for clinical use, and relevant baselines are correctly set and recorded;
- Subsequently a cycle of Regional Medical Physics Service(RMPS) supervised QA will be carried out on all X-ray equipment within the Antrim Area Hospital Radiology Department, to ensure the equipment is safe for clinical use and baselines have been calculated and recorded correctly;
- Review of the application and implementation of the X-ray QA Programme:
 - Training format to be reviewed by RMPS, to include a training competency matrix (which shall highlight escalation processes), with the recording of assessment, by an appropriate assessor. Core staff are to be re-trained utilising the training matrix by the appropriate MPE or RMPS representative.
- Training shall highlight the necessity and importance of ensuring that the QA programme not only records test results, but also that results must be assessed against tolerances and/or baselines, in order to provide appropriate assurances.
- Equipment QA should be undertaken by a core team of experienced staff members, trained and assessed as competent by RMPS:
 - A review of staff training, and the supporting documentation was undertaken and concluded that the supporting documentation was ambiguous and ineffective. As a result, it will be reviewed, updated, verified by frontline staff members, ratified by the relevant MPE and issued.
- Senior management oversight shall be enhanced by ensuring a designated member of staff is identified as each modality or site QA Co-ordinator. This has been recorded in QA procedures. The relevant QA Co-ordinator will carry out monthly checks on the QA Programme results, to ensure tests are carried out, results are recorded, compared against appropriate baselines, and a record of assessment of results QA will be added as a standing agenda item to modality, site and management meetings. QA Co-ordinator will collate results and provide a report:
 - The report will subsequently be communicated throughout the Trust Clinical Governance and Assurance Framework.
 - A Trust-wide review of the application and implementation of the X-ray QA Programme will be undertaken to ensure the programme has been safely and effectively implemented on all sites. Training, documentation, communication and senior management oversight will be replicated as listed above; and
- A reminder will be communicated to all staff via the radiology weekly team brief, to highlight the importance of good record keeping.

To ensure the full implementation of all the measures set out above by the Trust and an area of improvement has been identified to ensure the equipment QA procedures are robustly complied with by suitably qualified, trained and competent staff and associated governance arrangements are rigorously implemented.

6.6 Patient identification

'Employer's Procedure A' is in place to correctly identify individuals to be exposed to ionising radiation. The procedure references the three point patient identification process. It clearly outlines that it is the responsibility of the operator who carries out the medical exposure to ensure that the correct patient receives the correct medical exposure according to the referral.

Staff outlined the patient identification procedure and that the operator responsible must sign their name beside the identity (ID) check on the referral form or sign electronically in RIS as appropriate. Review of a sample of patient records confirmed an ID check had been recorded.

6.7 Pregnancy Enquiries

'Employer's Procedure C' for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breast feeding was in place and found to be adequate. It was good to note pregnancy enquiries had been included for such situations as transgender men and gender non-conforming individuals.

Staff interviewed demonstrated a very good understanding of making pregnancy enquiries, describing clearly what they would do in a range situations and where to record details of these enquiries. Pregnancy enquiry forms for different clinical situations were made available and are in use.

"Inform the radiographer if you are pregnant" posters were displayed in the changing areas in the department.

6.8 Research

The management team confirmed that no research is currently being conducted in Antrim Area Hospital diagnostic and interventional radiology department.

'Employer's Procedure G' was in place for research exposures. It was reviewed and found to provide high level information which may not be adequate for operators should research be undertaken in the future or at any other sites when the trust. An area of improvement has been identified to provide more detail on the operators functions and role within Employer's Procedure G'.

6.9 Review of environment

The inspection team reviewed the facilities available in relation to diagnostic and interventional imaging. The department was found to be clean, tidy and well organised. There were posters to provide patients with information regarding the benefit and risk of the exposure and pregnancy posters were displayed. There was a well-appointed waiting area for inpatients and changing cubicles for outpatients.

6.10 Staff discussion and review of patient records

The inspection team met with radiographers and discussed: the application of the Employer's Procedures; the role and responsibilities of duty holders; patient identification; the use of authorisation guidelines; induction; continued professional development; the use of DRLs as a reference tool; equipment QA procedures and the action to be taken if they thought a patient had received an accidental or unintended exposure. Staff demonstrated a good working knowledge of the Employer's Procedures and the most of the other areas discussed. As previously stated knowledge, and application of equipment QA procedures required improvement. Review of patient records indicated that the correct Employer's Procedures are being followed.

6.11 Conclusion

Radiological practice in Antrim Area Hospital diagnostic and interventional radiology department was found to be safe, effective and largely in line with the principles of IR(ME)R and good practice guidelines.

The staff were found to be knowledgeable and professional. It is acknowledged the work that has been undertaken to ensure compliance with the IR(ME)R regulations 2018 including: updating the Ionising Radiation Safety Policy and the Employer's Procedures; the MPE providing training on the new regulations to management and staff and developing posters and information leaflets for the communication of the benefits and risks of medical exposures to patients (and/or their representative).

As stated previously, it was evident the radiology department has an underpinning culture of quality improvement. Management and staff demonstrated an inclusive, enthusiastic and proactive approach to patient centred service improvement. The staff feedback provided on the day of inspection confirmed this approach.

Inspectors concluded that there was one identified concern regarding the delivery of the service which related to the QA of equipment which required immediate attention from the Trust. The prompt and robust response to this matter from senior management and staff is acknowledged and the action plan provided following the inspection serves to offer assurance that appropriate action has and will be taken.

There were 15 areas for improvement identified as a result of this inspection. These are fully outlined in the appended Quality Improvement Plan (QIP).

The inspectors would like to extend their gratitude to the management team and staff for their hospitality and contribution to the inspection process.

7.0 Quality improvement plan

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.

7.1 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.

7.2 Actions to be taken by the service

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

Quality Improvement Plan	
Action required to ensure compliance with The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 and other published standards which promote current best practice to improve the quality of service experienced by patients.	
Area for improvement 1 Regulation: 6 Stated: First time To be completed by: 14 January 2020	<p>The employer shall ensure the Radiation Safety Policy is updated to reflect the changes to the organisational and governance structures.</p> <p>Ref: 6.1</p> <p>Response by the employer detailing the actions taken:</p>
Area for improvement 2 Regulation: 6(5)(c) Stated: First time To be completed by: 14 February 2020	<p>The employer shall ensure the following in relation to the establishment of Local DRLs:</p> <ul style="list-style-type: none"> • develop an overall action plan with timescales for the establishment of Local DRLs • prioritise the establishment of paediatric Local DRLs <p>Ref: 6.1</p> <p>Response by the employer detailing the actions taken:</p>
Area for improvement 3 Regulation: 8 (4) (b)(iv) Stated: First time To be completed by: 14 December 2019	<p>The employer shall ensure significant accidental or unintended exposures are reported in accordance with SAUE guidance and the legislation. The system for reporting must be strengthened to ensure clear lines of accountability and governance arrangements on this matter.</p> <p>Ref: 6.1</p> <p>Response by the employer detailing the actions taken:</p>
Area for improvement 4 Regulation: 8(4) Stated: First time To be completed by: 14 January 2020	<p>The employer shall further develop Employer's Procedure Q to incorporate the organisational governance structures and link to the SAUE guidance. Consideration should be given to reviewing the format and ordering of the procedure to ensure it is easier to follow.</p> <p>Ref: 6.1</p> <p>Response by the employer detailing the actions taken:</p>
Area for improvement 5	<p>The employer shall ensure that the following formal systems are established:</p>

<p>Regulation:8(1)</p> <p>Stated: First time</p> <p>To be completed by: 26 November 2019</p>	<ul style="list-style-type: none"> the identification of clinically significant incidents; the outlining the decision making process; and the recording of the decision process and the informing of the individual exposed or their representative. <p>These systems should be fully outlined in 'Employer's Procedure L'.</p> <p>Ref: 6.1</p>
<p>Area for improvement 6</p> <p>Regulation: 6(2)</p> <p>Stated: First time</p> <p>To be completed by: 14 December 2019</p>	<p>Response by employer detailing the actions taken:</p>
<p>Area for improvement 7</p> <p>Regulation: 6(3)</p> <p>Stated: First time</p> <p>To be completed by: 14 December 2019</p>	<p>The employer shall strengthen the application process and introduce a robust review and scrutiny of training and competency records for non-medical referrers as part of the entitlement process and these records should be available for inspection.</p> <p>Ref: 6.1</p>
<p>Area for improvement 8</p> <p>Regulation: 6(3)</p> <p>Stated: First time</p> <p>To be completed by: 14 December 2019</p>	<p>The employer shall ensure that the entitlement process for third party radiology staff includes evidence that they are suitably qualified, trained and competent to carry out their duty holder role.</p> <p>Ref: 6.1</p>
<p>Area for improvement 9</p> <p>Regulation: 6(3)</p> <p>Stated: First time</p> <p>To be completed by: 14 December 2019</p>	<p>The employer shall ensure the entitlement of MPEs is strengthened to include formal inclusion of individual MPEs' scope of practice.</p> <p>Ref: 6.1</p>
<p>Area for improvement</p>	<p>The employer shall ensure that 'Employers Procedure B' is updated to reflect accurately the entitlement process for all duty holders.</p> <p>Ref: 6.1</p>
	<p>Response by the employer detailing the actions taken:</p>

<p>10</p> <p>Regulation: 6(5)</p> <p>Stated: First time</p> <p>To be completed by: 14 January 2020</p>	<p>cancellation of the request within the work instruction.</p> <p>Ref: 6.1</p> <p>Response by the employer detailing the actions taken:</p>
<p>Area for improvement 11</p> <p>Regulation: 11(3)(b)</p> <p>Stated: First time</p> <p>To be completed by: 14 January 2020</p>	<p>The employer shall amend the authorisation guidelines to specify authorisation guidelines for exposures to carers and comforters or consider entitling radiographers as practitioners for justifying exposures to carers and comforters.</p> <p>Ref:6.2</p> <p>Response by the employer detailing the actions taken:</p>
<p>Area for improvement 12</p> <p>Regulation: 6, Schedule 2</p> <p>Stated: First time</p> <p>To be completed by: 14 January 2020</p>	<p>The employer shall update the 'Employer's Procedure N' to reflect the justification and authorisation process in relation to carers and comforters.</p> <p>Ref: 6.2</p> <p>Response by the employer detailing the actions taken:</p>
<p>Area for improvement 13</p> <p>Regulation: 12</p> <p>Stated: First time</p> <p>To be completed by: 14 January 2020</p>	<p>The employer shall amend 'Employer's Procedure K' to include Image Optimisation Teams (IOTs) and establishing Local DRLs.</p> <p>Ref: 6.3</p> <p>Response by the employer detailing the actions taken:</p>
<p>Area for improvement 14</p> <p>Regulation: 15(1)(a)</p> <p>Stated: First time</p> <p>To be completed by: 14 December 2019</p>	<p>The employer shall ensure that the equipment QA procedures are robustly complied with by suitably qualified, trained and competent staff and that the associated governance arrangements are rigorously implemented.</p> <p>Ref: 6.5</p> <p>Response by the employer detailing the actions taken:</p>

<p>Area for improvement 15</p> <p>Regulation: 6, Schedule 2(g)</p> <p>Stated: First time</p> <p>To be completed by: 14 January 2020</p>	<p>The employer shall provide more detail on the operator's functions and role within 'Employer's Procedure G' Research.</p> <p>Ref: 6.8</p> <hr/> <p>Response by the employer detailing the actions taken:</p>
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Please ensure this document is completed in full and returned via BSU.Admin@rqia.org.uk



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