

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

5 March 2020



Altnagelvin Area Hospital, Cardiology Department

Address: Glenshane Road, Londonderry, Co. Londonderry, BT47 2SB Inspectors: Winifred Maguire & Stephen O'Connor Public Health England (PHE) Advisor: Yvonne Sullivan

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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 to:

- 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; and
- non-medical exposures using medical radiological equipment.

2.0 Service details

Name of Establishment: Western Health and Social Care Trust (WHSCT) - Altnagelvin Area Hospital	Department Inspected: Cardiology Department
Name of Employer: Dr Catherine Mc Donnell, Medical director (WHSCT)	Radiology Services Manager : Mr Dan McLaughlin (at the time of inspection)
Clinical Lead Cardiology: Dr Paul McGlinchey	Medical Physics Expert: Mr Philip Doyle

3.0 Profile of services

The self-assessment form submitted prior to the inspection confirmed that each year, Altnagelvin Area Hospital cardiology department carries out approximately:

2078 Cardiology – catheterisation, angioplasty

Altnagelvin Hospital cardiology department employs:

- 8 Consultant Cardiologists
- 1 Specialist Registrar
- 7 Radiographers (rotational basis from main radiology department)
- 1 Clinical Specialist Catheterisation Laboratory Radiographer
- 1 Catheterisation Laboratory Managers (Nursing)
- 5 Nurses
- 9 Clinical Physiology Team (8 on a rotational basis)
- 3 Medical Physics Experts (MPEs) under contract from the Belfast Health and Social Care Trust (BHSCT) (for all WHSCT Radiology services)

There are two cardiac catheterisation laboratories, lab two within the cardiology department and lab one in main theatres. The service is provided 9am to 5.15pm Monday to Friday with an on call service for emergency work.

4.0 Methodology

On 5 March 2020, warranted IR(ME)R inspectors from RQIA, with advice being provided by Public Health England (PHE) staff, conducted an announced inspection to Altnagelvin Hospital, cardiology department, as part of RQIA's IR(ME)R proactive 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, and was used to direct discussions with key members of staff working within the cardiology and radiology departments, and provide guidance for the inspection process.

WHSCT staff and MPE staff in attendance for part or all of the inspection:

Ms Una Cardin	Assistant Director Acute Services Cancer and Diagnostics
Dr Paul McGlinchey	Clinical Lead Cardiologist
Mr Dan McLaughlin	Radiology Services Manager
Ms Tracey McIvor	Radiology Department Manager
Mr Pearse McDonald	Service Manager Cardiology
Mr Fergal Doherty	Clinical Specialist Catheterisation Laboratory Radiographer
Ms Amanda Brown	Clinical Specialist Radiographer
Mr Philip Doyle	MPE

The inspection team reviewed relevant documentation and patient records. A tour of some areas of the cardiology department was undertaken and the inspectors took the opportunity to speak with the clinical lead reporting radiographer, clinical specialist radiographer and a MPE.

5.0 Inspection outcome

	Regulations
Total number of areas for improvement	14

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

WHSCT Altnagelvin Hospital 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 changes are necessary.

We found that the information provided within the submitted self–assessment form and discussion with senior management in relation to the cardiology department arrangements for compliance with IR(ME)R was not fully reflected in the Employer's Procedures. An area of improvement was identified to ensure that the Employer's Procedures are fully reflective of the provision of radiology services within the cardiology department.

A Radiation Safety Policy had been issued in February 2019 and is currently under review. The policy 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 Catherine Mc Donnell, WHSCT, Medical Director and her subsequent responsibilities are clearly set out. The Radiology Services Manager confirmed he had met with Dr McDonnell to ensure she had a full understanding of her duty holder role as Employer.

The Radiation Safety Policy outlined governance and reporting structures in relation to the use of ionising radiation. Clarification was sought on these structures in relation to the inclusion of the cardiology service. We found that the radiography team support the provision of the cardiac catheterisation service. It is a Cardiologist led service with the roles required under IR(ME)R clearly identified in the Employer's Procedures. For example, the Cardiologist for each session has a role as the Referrer, Practitioner and Operator.

The radiographer input is to provide the technical expertise for safe operation of the system and to ensure optimisation of the dose for each individual patient. There is a small dedicated radiography team who provide in hours services on a rotational basis and 24 hour cover is provided on an on-call basis by the same team. All staff working in the cardiology unit undergo a period of induction, training, mentorship and supervision before being entitled to act as an Operator. There is no direct involvement by Consultant radiology staff with the cardiac catheterisation service.

We found that that whilst there was some understanding of the lines of accountability with regards to ensuring compliance with IR(ME)R within the cardiac catheterisation service by senior management, this was not reflected clearly in the formal structures. For example, there was no representation from the cardiology service on the radiology sub groups. An area of improvement was identified in relation to devising formal structures and clear lines of accountability between the cardiac catheterisation service and radiology service to ensure compliance with IR(ME)R, which must be reflected within the Radiation Safety Policy.

Review of the submitted documentation and discussion with the senior management team outlined that systems are in place to ensure that Employer's Procedures are complied with by Referrers, Practitioners and Operators through audit, induction and training as outlined above; these will be strengthen by the introduction of formal structures.

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 the WHSCT intranet.

Quality Assurance programme for written policies and procedures

We confirmed that a quality assurance system of documentation is in place through the radiology quality management system (QMS) Q Pulse.

It was confirmed that relevant authors are responsible for reviewing the documents 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 radiology QMS. Notification of changes are communicated directly to those in the specialty, via Q pulse emails, discussed within teams by the Clinical Specialist radiographers and shared at staff and governance meetings if required. We found that cardiology staff do not have access to Q Pulse and therefore as highlighted previously formal structures need to be developed to ensure robust and timely communication of information.

We found that a standard operating procedure (SOP) for the cardiac catheterisation lab was in place. However, some information/instructions were not consistent with the Employer's Procedures, for example, the pregnancy enquiry age range was different. It also did not include the requirement to provide benefit and risks information to patients. An area of improvement was identified to ensure that there is consistency in the information provided in the SOP for cardiac catheterisation lab and the Employer's Procedures.

'Employer's Procedure I', outlines the quality assurance programmes in respect of written procedures, written protocols and equipment. We were advised that they are currently working towards The Quality Standard for Imaging (QSI) accreditation.

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 MPEs and is set out in 'Employer's Procedure K'. The Radiation Safety Committee endorses existing national DRLs and ratifies any changes to local DRLs proposed by Image Optimisation Teams (IOTs). The IOTs are tasked with reviewing DRLs and dose audit data and ensuring any changes needed are actioned.

The work of the IOTs provides information and assurances to the Radiation Safety Committee in line with the governance systems. We found that within the 'Employer's Procedure K' there was no reference to the cardiac catheterisation service, however pertinent information in relation to this matter was clearly outlined in the self-assessment form provided prior to the inspection.

Dose audits are carried out and a comparison of mean doses for each type of examination is compared with the relevant DRL. Dose survey results are used to identify whether any of the dose levels either approach or exceed national DRLs. Senior management confirmed that dose audits had led to changes in practice, for example, they now record patient height and weight for all cardiac catheterisation lab procedures.

We found that dose audits relating to the cardiology service had not been made known to the clinical lead for cardiology. As highlighted previously formalising structures including communication between cardiology and radiology will strengthen this area.

'Employer's Procedure J' outlines the procedure for assessment of patient dose. We found it did not reflect the cardiology service. An area of improvement was identified to ensure 'Employer's Procedures' K and J includes reference to cardiology.

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 cardiology department.

Clinical audit

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

Audit is managed through the Radiology QMS and as previously stated the service is working towards QSI accreditation. This process requires an agreed audit schedule to be established and we found that a planned Radiology Audit Schedule is being developed. The inspection team reviewed audits carried out in the radiology and cardiology service and it was good to note that where areas of non-compliance where identified, there was evidence of a re-audit being carried out within a specified timeframe. This resulted in increased compliance rates. Audits are used to improve and change practice with results being shared at the team meetings, emailed to staff and provided online. However as stated previously the sharing of the findings of relevant audits with the cardiology team requires to be strengthened through the development of formal structures.

Accidental and unintended exposures

Management and staff explained the process for reporting accidental or unintended exposures internally and then to the appropriate enforcing authority. We found that there had been no reported radiology near misses or incidents in Altnagelvin Hospital, Cardiology department.

Staff spoken with demonstrated a good understanding of the action to take in the event of an incident occurring and confirmed learning from other modality incidents is shared at team briefs. Trend analysis arrangements are in place for all radiology incidents.

'Employer's Procedure Q' for Radiation Incident Investigation and Reporting is in place. It provided a sound framework to manage incidents however a number of issues were discussed to strengthen this procedure including:

- the list of information on page 35 may need a title change as this may only be the initial information for the MPE and not what RQIA require;
- the term 'Much Greater Than Intended' has been superseded by 'accidental and unintended' as outlined in the Significant Accidental or Unintended Exposures (SAUE) guidance;
- it may be worth including the SAUE list in this procedure, to ensure staff record the required information from the outset if the incident is notifiable;
- consider updating the word "Client" which is used in this Employer's Procedure; and
- near miss incidents on page 36 include procedural error and the need for further training.

An area of improvement has been identified to update 'Employers Procedure Q' as outlined above.

'Employers Procedure R' for Clinically Significant Accidents or Unintended incidents was in place. It was confirmed that clinically significance is determined by the MPE not the clinical lead.

We found that it largely reflected the SAUE guidance, however it requires further development to be clearer on arrangements for clinically significant incidents such as; who determines the incident is clinically significant, who is responsible for informing the patient and/or their representative and ensuring cardiology is reflected in this procedure. An area of improvement was identified on this matter.

All radiation incidents are collated and sent to the Radiology Safety Committee 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 there are comprehensive systems in place to provide annual appraisals for all grades of staff. It was further confirmed that training and development needs are identified for individual staff as part of the appraisal process. Consultant cardiologists 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, training and competency and entitlement forms for radiographers and cardiologists. Training and competency records for radiographers were of a satisfactory standard. Minor amendments were suggested in relation to including individual signatures on the competence section of the entitlement form. It was noted the cardiologist's entitlement forms had been recently completed and there had been no previous entitlement forms in place. The arrangements for entitlement of cardiologists must be fully embedded in practice and subject to regular review.

Radiology staff confirmed that they had received update training from the MPE on the regulations. Cardiologists have undertaken IR(ME)R online training, the MPEs have provided advice on the necessary sections that need to be completed as a minimum. It was confirmed that staff are provided with information of their duties under IR(ME)R during induction; including junior doctors.

The senior team reported that radiographers and cardiologists had been appropriately entitled according to their training, competencies and individual scope of practice. Entitlement is recorded and reviewed three yearly, discussed at annual appraisal and adjusted accordingly if a staff member's scope of practice had changed.

MPEs are presently entitled under a group entitlement approach. Evidence was provided of an entitlement letter but this was not signed and needed to have a defined scope of practice to make clear the MPEs area of expertise. Cardiology was not listed as an area covered by the MPE appointment letter. We were informed it is classed as diagnostic radiology. An area of improvement has been identified to ensure the entitlement of MPEs is strengthened to include formal inclusion of individual MPEs scope of practice and reference to cardiology.

'Employers Procedure B', entitlement, did not fully reflect the entitlement process outlined during the inspection and an area of 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 WHSCT intranet.

The Cardiologist described the referral guidelines used within the cardiology service, this was based on i-refer; NICE and other guidance; and clinical judgment. This approach was not reflected in the 'Employers Procedure B', making a referral. Currently there are not specific referral guidelines in place and discussion on devising specific referral guidelines for cardiology took place. We advised that this could be accomplished by including referral criteria within the written protocols or devising stand-alone referral guidelines for cardiology. An area of improvement was identified to consider devising specific referral guidelines for cardiology which should then be referenced in 'Employer's Procedure B'

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.

6.2 Justification and authorisation of individual medical exposures

Justification and authorisation of individual medical exposures was discussed with staff, who demonstrated some understanding of the process and described how justification and authorisation is recorded electronically on the radiology information system (RIS). We found that there was some confusion regarding the justification and authorisation process in relation to cardiology services and the recording of this process. The cardiologist acts as the Referrer, Practitioner and Operator and the radiographer acts as the Operator. The cardiologist is always present during these procedures to justify and authorise the exposures and must be recorded as doing so. The radiographer is acting as an operator but is not authorising the exposure, as the exposure has already been authorised by the cardiologist. Radiographers are recording on RIS that they are authorising yet there are no authorisation guidelines used in cardiology. An area of improvement was identified to ensure complete understanding of the duty holders' roles in relation to the justification and authorisation of medical exposures and ensuring that this is accurately recorded on RIS.

The justification of carers and comforters exposures was discussed and it was confirmed that carers and comforters would not be present during cardiac catheterisation procedures.

6.3 Optimisation

There are good arrangements in place to ensure that medical exposures are kept as low as reasonably practicable. 'Employer's Procedure P' 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 cardiology service was not fully reflected in the 'Employer's Procedure P' and an area of improvement was identified in relation to further developing 'Employer's Procedure P' to include cardiology.

Image Optimisation Teams (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

We found that benefits and risks of having an exposure to ionising radiation are discussed with patients as part of the written consent process for the cardiac catheterisation procedure. Patients are also given information leaflets. Review of the consent forms noted that there is limited information in relation to the benefits and risks associated with the radiation dose. An area of improvement was identified to include a more detailed statement on the benefits of having the exposure and the risks associated with the radiation dose within the written consent process.

'Employers procedure W' benefits and risks, is in place, however it did not reflect the cardiology service. An area of improvement was identified to amend 'Employer's Procedure W 'to reflect arrangements for communicating on the benefits of having the exposure and the risks associated with the radiation dose in cardiology.

Paediatrics

Paediatric procedures are not carried out in the cardiology department.

Clinical Evaluation

We found that the cardiologist performing the cardiac procedure carries out the clinical evaluation. 'Employer's Procedure G' 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 there is a clear understanding of the clinical evaluation for medical exposures. There are clear arrangements for auditing compliance with IR(ME)R in relation to clinical evaluation within the radiology department and some clinical evaluation which takes place outside of the radiology department such as orthopaedic surgery.

Cardiology is not included in these audits. An area of improvement has been identified to include cardiology services in the clinical evaluation audits.

6.4 Expert advice

The WHSCT retains the services of a MPE on a contractual basis. The MPE was present for part of the inspection. It was confirmed the appointed MPEs are currently recognised by the 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 on 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 acknowledged that direct contact with the cardiology department is largely through annual audit and requests for support from the department. The development of formal structures as outlined previously will strengthen links between the cardiology department and the MPE service.

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; and training of Practitioners and other staff on radiation protection and compliance with regulations. It was confirmed the lead MPE had provided training to cardiac radiographers in relation to IR(ME)R 2018.

6.5 Equipment

A screen shot of the inventory of radiological equipment was submitted to RQIA which did not contain all of the legislative information. However we found the electronic inventory of radiological equipment reviewed during the inspection to be in line with legislation. Management and staff confirmed there is an appropriate amount of equipment available for the workload of the cardiology department.

As stated previously 'Employer's Procedure I' includes information on QA of equipment. It was suggested to update the procedure to reflect the role Q Pulse plays in QA of equipment. We found that equipment QA medical physics reports and in-house QA testing was evidenced on Q Pulse. A robust QA system is in place, with alerts sent to the lead radiographer when action is required e.g. calling an engineer. The clinical specialist radiographer ensures all QA actions have been fully actioned.

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 radiographer who is acting as an Operator 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) 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 D' 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 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 Altnagelvin Hospital cardiology department.

6.9 Review of environment

The inspection team reviewed the facilities available in Lab Two, in relation to cardiac catheterisation services. The department was found to be clean, tidy and well organised. 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 a cardiologist, radiographers and a MPE 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 most of the other areas discussed. Review of patient records indicated that the correct Employer's Procedures are being followed.

6.11 Conclusion

Radiological practice in Altnagelvin Hospital cardiology 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 has been undertaken to ensure compliance with IR(ME)R 2018 including updating the lonising Radiation Safety Policy and the Employers 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 cardiology 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. However the theme running through this inspection was the formal disconnect between the radiology department and cardiology service which is reflected through the areas of improvement identified. Senior Management were receptive to this and gave assurances that the matters raised would be addressed.

There were 14 areas of improvement identified as a result of this inspection. These are fully outlined in the appended Quality Improvement Plan (QIP).

The management team and staff are to be commended for their commitment and enthusiasm to ensure that the department is striving to operate within the legislative framework and maintaining optimal standards of practice for patients.

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 Quality Improvement Plan (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 <u>bsu.admin@rgia.org.uk</u> 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 (1)	The Employer shall ensure that the Employer's Procedures are fully reflective of the provision of radiology services within the cardiology department.	
Stated: First time	Ref: 6.1	
To be completed by: 5 June 2020	Response by the Employer detailing the actions taken: Employers procedures version 1.4 contains edits recommended by inspection team, including referencing Cardiology responsibilities within WHSCT Employers procedures. Edits complete with the exception of Procedure Q – new version 1.4 requires sign off by Medical Director. This will be completed by 5 th June 2020.	
Area for improvement 2	The Employer shall develop formal structures and clear lines of accountability between the cardiology and radiology service to ensure	
Regulation: 6 (2)	compliance with IR(ME)R regulations; which must be reflected within the Radiation Safety Policy.	
Stated: First time	Ref: 6.1	
5 June 2020	Response by the Employer detailing the actions taken: Radiation Safety Policy review will be completed by 5 th June 2020.	

Area for improvement 3 Regulation: 6 (1)	The Employer shall ensure that there is consistency in the information provided in the Standard Operating Procedure for the cardiac catheterisation lab and the Employer's Procedures.
Stated: First time	Ref: 6.1
To be completed by: 5 June 2020	Response by the Employer detailing the actions taken: Standard Operating procedure reviewed and amended to reflect actions recommended by Inspection Team.
Area for improvement 4	The Employer shall ensure Employer's Procedures' K and J includes reference to the cardiology service.
Regulation: 6 (1) Schedule 2 (e) (f)	Ref: 6.1
Stated: First time	Response by the Employer detailing the actions taken: Both procedures updated in version 1.4 to reference Cardiology
To be completed by: 5 June 2020	service.
Area for improvement 5	The Employer shall ensure that 'Employers Procedure R' is amended as outlined in the main body of the report.
Regulation: 6 (1) Schedule 2 (i)	Ref: 6.1
Stated: First time	Response by Employer detailing the actions taken: Employers procedure R edit complete.
Stated: First time To be completed by: 5 June 2020	Response by Employer detailing the actions taken: Employers procedure R edit complete.
Stated: First time To be completed by: 5 June 2020 Area for improvement 6	Response by Employer detailing the actions taken: Employers procedure R edit complete. The Employer shall ensure the entitlement of Medical Physics Experts (MPEs) is strengthened to include formal inclusion of individual MPEs
Stated: First timeTo be completed by:5 June 2020Area for improvement 6Regulation: 14 (1)Schedule 2 (b)	Response by Employer detailing the actions taken: Employers procedure R edit complete. The Employer shall ensure the entitlement of Medical Physics Experts (MPEs) is strengthened to include formal inclusion of individual MPEs scope of practice and include the cardiology service. Def: 6.1
Stated: First timeTo be completed by: 5 June 2020Area for improvement 6Regulation: 14 (1) Schedule 2 (b)Stated: First time	Response by Employer detailing the actions taken: Employers procedure R edit complete. The Employer shall ensure the entitlement of Medical Physics Experts (MPEs) is strengthened to include formal inclusion of individual MPEs scope of practice and include the cardiology service. Ref: 6.1
Stated: First time To be completed by: 5 June 2020 Area for improvement 6 Regulation: 14 (1) Schedule 2 (b) Stated: First time To be completed by: 5 June 2020	Response by Employer detailing the actions taken: Employers procedure R edit complete.The Employer shall ensure the entitlement of Medical Physics Experts (MPEs) is strengthened to include formal inclusion of individual MPEs scope of practice and include the cardiology service.Ref: 6.1Response by the Employer detailing the actions taken: Will be completed by 5 th June 2020.
Stated: First time To be completed by: 5 June 2020 Area for improvement 6 Regulation: 14 (1) Schedule 2 (b) Stated: First time To be completed by: 5 June 2020 Area for improvement 7	Response by Employer detailing the actions taken: Employers procedure R edit complete.The Employer shall ensure the entitlement of Medical Physics Experts (MPEs) is strengthened to include formal inclusion of individual MPEs scope of practice and include the cardiology service.Ref: 6.1Response by the Employer detailing the actions taken: Will be completed by 5 th June 2020.The Employer shall ensure that 'Employers Procedure B' is amended to accurately reflect the entitlement process for all duty holders.
Stated: First time To be completed by: 5 June 2020 Area for improvement 6 Regulation: 14 (1) Schedule 2 (b) Stated: First time To be completed by: 5 June 2020 Area for improvement 7 Regulation: 6 (3) Schedule 2 (b)	Response by Employer detailing the actions taken:Employers procedure R edit complete.The Employer shall ensure the entitlement of Medical Physics Experts(MPEs) is strengthened to include formal inclusion of individual MPEsscope of practice and include the cardiology service.Ref: 6.1Response by the Employer detailing the actions taken:Will be completed by 5 th June 2020.The Employer shall ensure that 'Employers Procedure B' is amended to accurately reflect the entitlement process for all duty holders.Ref: 6.1
Stated: First timeTo be completed by: 5 June 2020Area for improvement 6Regulation: 14 (1) Schedule 2 (b)Stated: First timeTo be completed by: 5 June 2020Area for improvement 7Regulation: 6 (3) Schedule 2 (b)Stated: First time	Response by Employer detailing the actions taken: Employers procedure R edit complete. The Employer shall ensure the entitlement of Medical Physics Experts (MPEs) is strengthened to include formal inclusion of individual MPEs scope of practice and include the cardiology service. Ref: 6.1 Response by the Employer detailing the actions taken: Will be completed by 5 th June 2020. The Employer shall ensure that 'Employers Procedure B' is amended to accurately reflect the entitlement process for all duty holders. Ref: 6.1 Response by the Employer detailing the actions taken: Will be completed by 5 th June 2020.

Area for improvement 8	The Employer shall consider devising specific referral guidelines for
Population: 6 (5) a	cardiology which should then be referenced in 'Employer's Procedure
Regulation. 0 (5) a	В.
Stated: First time	Ref: 6.1
To be completed by 5 June 2020	Response by the Employer detailing the actions taken: Clinical Lead Cardiologist and Clinical Specialist Radiographer currently working on this recommendation. Radiology service have agreed access for Cardiology staff to Qpulse system as a pilot project. This will improve communication between the 2 teams regarding polices and procedures relevant to both services.
Area for improvement 9 Regulation: 11(1) (b) (c) (f), 11(2), 11(3) (d), 11(4) (5)	The Employer shall ensure that duty holders have complete understanding of their roles in relation to the justification and authorisation of medical exposures and that this is accurately recorded on RIS. Ref: 6.2
Stated: First time To be completed by: 5 June 2020	Response by the Employer detailing the actions taken: Cardiologists aware of roles under IRMER, but these will be re inforced via qpulse. Consultant Cardiologist has agreed to act as Cardiology representative at Radiation Protection Sub Group which meets quarterly. This will further enhance improved communication between the 2 teams. Further to feedback from the inspection, Radiographers have been reminded of the role of Cardiologist as IRMER Practitioner.
Area for improvement 10 Regulation:6 (1) Schedule 2 (i)	The Employer shall ensure that a more detailed statement on the benefits of having the exposure and the risks associated with the radiation dose is included within the written consent process. Ref: 6.3
Stated: First time To be completed by: 5 June 2020	Response by the Employer detailing the actions taken: A review of the consent has been completed to include edits recommended by Inspection team.
Area for improvement 11 Regulation: 6 (1) Schedule 2 (i)	The Employer shall ensure that 'Employer's Procedure W' is amended to reflect arrangements for communicating the benefits of having the exposure and the risks associated with the radiation dose in cardiology. Ref:6.3
	Response by the Employer detailing the actions taken:
To be completed by: 5 June 2020	Procedure W has been amended to reflect additional improvements to Patient communication via Leaflet, Posters and also written consent process.

Area for improvement 12	The Employer shall ensure that cardiology services are included in the clinical evaluation audits.
Regulation: 12 (9)	Ref: 6.3
Stated: First time	Response by the Employer detailing the actions taken: We will update re clinical audit plan by 5 th June 2020.
To be completed by: 5 June 2020	
Area for improvement 13	The Employer shall ensure that Employer's Procedure Q is amended as outlined in the main body of the report.
Regulation: 8	Ref: 6.1
Stated: First time	Response by the Employer detailing the actions taken: Edit will be completed by 5 th June 2020.
To be completed by: 5 June 2020	
Area for improvement 14	The Employer shall ensure that Employer's Procedure P is further developed to include cardiology.
Regulation: 6(1) Schedule 2(k)	Ref: 6.3
Stated: First time	Response by the Employer detailing the actions taken: Procedure P has been updated to include Cardiology.
To be completed by: 5 June 2020	

Please ensure this document is completed in full and returned via bsu.admin@rqia.org.uk





The Regulation and Quality Improvement Authority 9th Floor Riverside Tower 5 Lanyon Place BELFAST BT1 3BT

Tel028 9536 1111Emailinfo@rqia.org.ukWebwww.rqia.org.ukImage: Colored colored

Assurance, Challenge and Improvement in Health and Social Care