The Regulation and Quality Improvement Authority

Inspection Report

22 July 2026



Altnagelvin Hospital
Cardiology Interventional Imaging

Address: Glenshane Road, Derry, BT47 26SB
Telephone: 028 7161 1322

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

1.0 Service information

Organisation/Registered Provider: Western Health and Social Care Trust (WHSCT)	**Department Inspected:** Altnagelvin Hospital – Cardiology Interventional Imaging Department
Name of Employer: Dr Brendan Lavery WHSCT Medical Director	**Radiology Services Manager:** Ms Seana Nolan

Brief description of how the service operates:

The Cardiology Interventional Imaging Department operates within defined core hours with an on-call service for emergency work. The service has two cardiac catheterisation laboratories (cath labs). Each cath lab has different equipment in terms of manufacturer and one of the cath labs has recently undergone equipment replacement. The interventional radiology room eight, provides contingency if the cath labs cannot not be used.

The Western trust is one of two sites for primary percutaneous coronary intervention (PPCI). The trust delivers a third of the PPCI in Northern Ireland and receives transfers from Causeway Hospital, Northern Health and Social Care Trust (NHSCT); Omagh Hospital and the South West Acute Hospital (SWAH), WHSCT. The service also provides a PPCI service for County Donegal, Republic of Ireland. The patient cohort is patients aged over 16 years.

Prior to the inspection, the radiology services manager (RSM), Ms Nolan and her team completed a self-assessment form (SAF). The submitted SAF confirmed that the cardiology interventional service had carried out 1809 cardiology procedures and 146 interventional computed tomography (CT) scans in the last year.

There are five full time substantive interventional cardiologists and two visiting interventional cardiologists (one based in Letterkenny Hospital, Co Donegal and one based in the NHSCT). Both visiting cardiologists cover PPCI and on-call for the service in the WHSCT. All cardiologists cover sessions during normal working hours.

Radiographer support is provided by a clinical specialist radiographer (cath lab lead radiographer) and seven radiographers who rotate through interventional radiology, the general radiology department and the cath labs. This group of radiographers provide an on-call service ensuring full continuous day and overnight cover. A radiographer is assigned to a cath lab each day (9.00am – 5.00pm) with one radiographer providing on-call cover from 5.00pm onwards.

The service has 10 funded sessions per week in one of the cath labs for PPCI, and three funded sessions per week in a second cath lab for additional PPCI and pacing.

A Medical Physics Expert (MPE) contracted from Regional Medical Physics Service (RMPS) based in the Belfast Health and Social Care Trust (BHSCT) supports the team.

2.0 Inspection summary

On 22 July 2026, 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 Altnagelvin Hospital, cardiology interventional imaging department, as part of RQIA's IR(ME)R inspection programme.

For the 2026/27 inspection year the inspections focused on the following key themes:

- Entitlement
- Clinical Audit and IR(ME)R audit
- Diagnostic Reference Levels (DRLs)
- Management of Significant Accidental or Unintended Exposures (SAUE), incidents and near misses
- The administration of radioisotopes (Nuclear Medicine only)
- Breast radiotherapy pathway (Radiotherapy only)
- Any other areas identified through the review of the submitted SAF and supporting documentation

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

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.

The service was notified of the inspection date and time, and requested to complete and submit a SAF and include supporting documentation, which was 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 cardiology 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 cardiology department, patients were awaiting or immediately recovering from cardiac procedures, it was deemed inappropriate to seek to speak to these patients on the day of the inspection.

5.0 The inspection

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

Areas for improvement from the last inspection on 05 March 2020		
Action required to ensure compliance with The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018		**Validation of compliance**
Area for Improvement 1 **Ref: Regulation 6(1)** **Stated: First time**	The Employer shall ensure that the Employer's Procedures are fully reflective of the provision of radiology services within the cardiology department.	**Met**
	Action taken as confirmed during the inspection: The submitted quality improvement plan for the inspection on 5 March 2020 outlined that Employer's Procedures version 1.4 contained edits recommended by inspection team, including referencing cardiology responsibilities within WHSCT Employer's Procedures. The most current Employer's Procedures in place is version 2.8 which reflects cardiology interventional imaging services.	
Area for Improvement 2 **Ref: Regulation 6(2)** **Stated: First time**	The Employer shall develop formal structures and clear lines of accountability between the cardiology and radiology service to ensure compliance with IR(ME)R regulations; which must be reflected within the Radiation Safety Policy.	**Met**
	Action taken as confirmed during the inspection: The Radiation Safety Policy and the Radiology Quality Manual sets out the governance structures for the radiology service including cardiology. It was noted that the cath lab lead radiographer represents cardiology interventional imaging on a range of governance committees establishing formal links between radiology and cardiology.	

Area for Improvement 3 **Ref: Regulation: 6(1)** **Stated: First time**	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.	**Met**
	Action taken as confirmed during the inspection: The Standard Operating procedure was reviewed and amended to reflect actions recommended by the Inspection Team.	
Area for improvement 4 **Ref: Regulation: 6(1) Schedule 2.1(e) (f)** **Stated: First time**	The Employer shall ensure 'Employer's Procedures K and J' includes reference to the cardiology service.	**Met**
	Action taken as confirmed during the inspection: Both procedures have been updated to reference the cardiology service.	
Area for improvement 5 **Ref: Regulation 6(1) Schedule 2.1(i)** **Stated: First time**	The Employer shall ensure that 'Employers Procedure R' is amended as outlined in the main body of the report.	**Met**
	Action taken as confirmed during the inspection: Employer's procedure R amended as outlined in the previous inspection report.	
Area for improvement 6 **Ref: Regulation: 14(1) Schedule 2.1(b)** **Stated: First time**	The Employer shall ensure the entitlement of Medical Physics Experts is strengthened to include formal inclusion of individual MPEs scope of practice and include the cardiology service.	**Met**
	Action taken as confirmed during the inspection: The entitlement records of Medical Physics Expert includes the cardiology service where relevant.	
Area for improvement 7 **Ref: Regulation 6(3) Schedule 2.1(b)**	The Employer must ensure that Employers Procedure B is amended to accurately reflect the entitlement process for all duty holders.	**Met**

Stated: First time	**Action taken as confirmed during the inspection**: Employer's Procedure B has been amended to reflect entitlement arrangements.	
Area for improvement 8 **Ref: Regulation 6(5)(a)** **Stated: First time**	The Employer shall consider devising specific referral guidelines for cardiology which should then be referenced in Employer's Procedure B.	**Met**
	Action taken as confirmed during the inspection: It was confirmed that the clinical lead cardiologist and clinical specialist radiographer worked on devising referral guidelines for cardiology following the inspection in March 2020. Referral guidelines for cardiology is further discussed in section 5.2.5 of this report	
Area for Improvement 9 **Ref: Regulation 11(1) (b)(c)(f), 11(2),11(3)(d),11(4) (5)** **Stated: First time**	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 Radiology Information System (RIS).	**Met**
	Action taken as confirmed during the inspection: Following the inspection in March 2020 management confirmed that cardiologists were aware of roles under IR(ME)R. A consultant cardiologist agreed to act as cardiology representative at Radiation Protection Sub Group which meets quarterly. This was to enhance communication between the two teams. Radiographers were reminded of the role of cardiologists as IR(ME)R practitioners. The matter is further discussed in section 5.2.1 of this report	

Area for Improvement 10 **Ref: Regulation: 6(1) Schedule 2.1(i)** **Stated: First time**	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.	**Met**
	Action taken as confirmed during the inspection: The consent process and corresponding documentation fully reflects the benefits and risks associated with the radiation dose.	
Area for Improvement 11 **Ref: Regulation: 6(1) Schedule 2.1(i)** **Stated: First time**	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.	**Met**
	Action taken as confirmed during the inspection: Employers Procedure W has been amended to reflect additional improvements to patient communication via patient leaflet, posters and also written consent process.	
Area for improvement 12 **Ref: Regulation: 12(9)** **Stated: First time**	The Employer shall ensure that cardiology services are included in the clinical evaluation audits.	**Met**
	Action taken as confirmed during the inspection: This was actioned following inspection. This is further discussed in section 5.2.2 of this report.	
Area for improvement 13 **Ref: Regulation 8** **Stated: First time**	The Employer shall ensure that Employer's Procedure Q is amended as outlined in the main body of the report.	**Met**
	Action taken as confirmed during the inspection: Employer's Procedure Q has been amended as outlined in the previous inspection report.	

Area for improvement 14 **Ref: Regulation: 6(1) Schedule 2.1(k)** **Stated: First time**	The Employer shall ensure that Employer's Procedure P is further developed to include cardiology.	**Met**
	Action taken as confirmed during the inspection: Employer's procedure P has been updated to include cardiology.	

5.2 Inspection findings

5.2.1 Are there appropriate Entitlement arrangements in place to ensure compliance with the legislation?

Entitlement
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.

The WHSCT has a formal entitlement process to ensure that all referrers, practitioners and operators are appropriately entitled to undertake their roles in accordance with IR(ME)R. This process is defined within the Trust's Employer's Procedure B.

The WHSCT medical director, as IR(ME)R Employer, holds overall responsibility for entitlement. Tasks associated with entitlement responsibilities can be formally delegated to named senior staff member including the clinical lead cardiologist, RSM, assistant RSM (ARSM) and modality leads.

These individuals act as Entitler within their defined areas of responsibility and are themselves appropriately trained, competent and formally entitled.

The management described the process of entitlement, noting entitlement is provided following the provision of evidence of training and competency. The entitlement will include a defined scope of practice and this must be agreed between the individual being entitled and the Entitler. This process is documented on individual entitlement forms.

Evidence of induction, training, competency and continuing professional development for radiographers and consultant cardiologists was reviewed and found to be in line with duty holder roles. Systems are in place to check the professional qualifications and registration of all employees with their appropriate professional bodies.

Individual entitlement records for consultant cardiologists, radiographers and non-medical referrers (NMRs) were reviewed. A review was undertaken of group entitlement records for MPEs. The entitlement records were overall well completed.

Radiographers
Radiographers have individual entitlement records with signed competency largely in accordance with the duty holder roles and a defined scope of practice. Radiographers are entitled by the ARSM following competency checks. Radiographers are dual trained and rotate in the general radiology department and the cath labs. Radiographers are entitled as operators for a range of operator functions. Entitlement is reviewed every three years, or as and when different competencies are achieved. Management confirmed entitlement may be discussed during the supervision process.

Examination of the entitlement records highlighted that in one record clinical evaluation had been signed by the radiographer but not by the Entitler. The service confirmed the individual does not perform clinical evaluation. Clarification was also sought around another individual's job title as CT Radiographer, whereby the individual had not been entitled to perform any duty holder roles in CT. The service confirmed the individual had not moved into CT due to staffing challenges. The entitlement records outlined 'scribing' as an operator task. Discussions around the process of 'scribing' took place. The management gave assurances that 'scribing' has not been carried out since May 2025 following the introduction of the Epic (electronic patient record) system. The cardiologists complete the referrals electronically. However, the scribe function was signed June 2025, possibly highlighting the need for regular reviews of entitlement and removing functions that are obsolete.

The service was advised that entitlement is a live process and therefore a regular review of entitlement is required. With this in mind, the service was asked to consider the timeline of the formal review period of entitlement. An area for improvement has been made to consider formally reviewing entitlement arrangements on at least an annual basis. Management are encouraged to integrate the entitlement review into structures already in place (such as the staff annual review) and to evidence this review.

Consultant Cardiologists
Consultant cardiologists based in WHSCT and Causeway Hospital (NHSCT) are entitled by the WHSCT medical director to act as referrers for cardiology interventional imaging services. The clinical lead cardiologist is entitled by the medical director. The clinical lead cardiologist is responsible for entitling consultant interventional cardiologists and visiting consultant interventional cardiologists (as outlined previously) to carry out the duty holder roles of practitioner and operator for interventional cardiology imaging in WHSCT. This process includes reviewing training records, looking at the individual's skill mix, and ensuring GMC registration to include specialist register for interventional cardiology.

All interventional cardiologists scope of practice includes performing diagnostic angiography, PCI and balloon angiography. There are three consultant interventional cardiologists who perform more complex procedures and these entitlement records were examined. It was found the cardiologists' entitlement records did not fully reflect the complexity of some of the scopes of practice as described. An area for improvement has been identified to provide a more comprehensive record of entitlement for consultant interventional cardiologists which fully reflects the individual's scope of practice. The clinical lead cardiologist was receptive to reviewing the process and highlighted how annual appraisal involves reviewing case numbers over the previous year, tying into review of competency.

Cardiac CT is provided by the cardiologists. The consultant cardiologists are entitled to act as the practitioner and operator for clinical evaluation for these scans. This was verified during record keeping checks.

Non- Medical Referrers (NMRs)
There are a number of NMRs known as the PCI nurse activators. This group of staff are cardiology specialist nurses. The NMRs refer specifically for emergency situations during out of hours at which point the cath lab will be alerted to set up for cardiology interventional imaging procedures.

The entitlements for the NMR were reviewed. A clear process of entitlement of non-medical referrers was demonstrated. They complete the standard Trust NMR entitlement application and IR(ME)R training on HSC e-Learning platform which the clinical lead will review and sign if appropriate. The clinical lead radiologist will also review the application. The NMR then has face to face training with one of the ARSMs. This session focuses on the role and responsibilities of the NMR in relation to their entitlement. The RSM then entitle them as a NMR. The application outlines their scope of referral. The application includes a flow chart outlining the exact scenarios which the NMR would refer for. The individual is then added to the Epic system. They must have verification of entitlement from radiology prior to gaining Epic referring privileges. Re-application and re-entitlement occurs every three years, aligned with the mandated training refresh cycle. Any changes in role or scope are required to be declared by the individual. An NMR referral was reviewed during the record keeping checks and found to be accordance with arrangements outlined by management and within the Employer's Procedures.

MPE
The MPE is entitled by the clinical lead radiologist. There is an entitled lead MPE appointed to WHSCT for diagnostic imaging and interventional radiology which includes cardiology. The entitlement process reviewed aligns with what is described in the Employer's Procedures.

Governance of Entitlement
The service demonstrated a quality management system which provides oversight of entitlement for radiographers. The system sends an email alert to the relevant parties when entitlement is nearing its expiry date. The ARSM has oversight of this process. It was advised to consider a similar oversight approach for the entitlement of consultant interventional cardiologists.

An examination of patient records to evidence IR(ME)R compliance was carried out. The records did not always provide evidence of the referral, and it was not clear who the referrer and operator were. This aligned with discussions in the department, where there was ambiguity around operator roles.
An area for improvement has been identified to ensure clarity around the IR(ME)R pathway in cardiology and to ensure there is evidence in the patient records of the referral and duty holders involved in cardiology interventional imaging.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced whilst there are good entitlement arrangements within the cardiology department, they do require further strengthening. Addressing the areas for improvement will assist on this matter. The inspection team acknowledge the commitment of staff in this regard.

5.2.2 Does the service adhere to legislation in relation to Clinical Audit and IR(ME)R audit?

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.

It was evident the cardiology service has an underpinned culture of quality improvement (QI). Management and staff demonstrated an inclusive, enthusiastic and proactive approach to patient centred service improvement.

Management and staff described the process of clinical audit. A consultant cardiologist acts as clinical audit lead. The clinical audit program for cardiology service involves in a number of QI projects and national audits. Consultants are fully involved in QI projects, and where possible resident doctors will also be involved to support their own training. The pathway is drawn up, data collected and reviewed, findings presented locally and then re-audit takes place where appropriate. The service use these to benchmark against national averages. All consultant interventional cardiologists keep individual logs of their procedures and the complexity of these procedures.

Management described a multidisciplinary (MDT) approach to clinical audit, in particular involving nurse specialists, heart failure nurses, PPCI nurses and clinical physiologists. In terms of identifying audit topics, typically an individual will bring a protocol or procedure to the team, which may trigger a QI project focusing on this area. The clinical lead cardiologist and the clinical audit lead have oversight of clinical audit in cardiology. It is included in the morbidity and mortality (M&M) meetings and/or weekly teaching meetings. Findings are shared during the teaching sessions, or at the M&M meeting where all cath lab staff are present.

A standard template for clinical audit is in place. On review it was noted that the template would benefit from some additional target compliance sections and clear timelines in terms of actions. An area for improvement has been identified on this matter.

The notable dose audit was discussed in relation to significant findings. The service described how the audit was presented at the M&M meeting. However, it was noted that the same audit was performed two years prior with similar findings. Management confirmed that all consultant cardiologists were emailed the audit results and that the audit was uploaded on to QPulse and shared with the radiology team. This opened discussion around meaningful scrutiny of the findings, and the actions that should follow it, as there appears to be a gap in this regard.

Upon further discussion, the radiology service provided separate database of all audits being undertaken which identifies actions to be completed and the responsible individuals for these actions. It was confirmed there is an audit group which has oversight of the action log along with the ARSM and governance lead radiographer. The audit group meets on a monthly basis and the ARSM will meet with team leads two weeks after the audit meeting to follow up on any actions identified. The cath lab lead radiographer attends the audit group for cardiology when appropriate. The service is developing a ‘how to’ guide to support staff with performing particular audits. The service has also commenced audit training for staff, with 10 to 15 staff completing the training last month. The Trust audit team are involved in this training, which focuses on supporting staff with conducting audits.

The action log and audit group are both still in the process of further development. It was highlighted to the service that where there are significant findings, there must be a clear escalation process, and individuals identified who are responsible to carry out any actions required. An area for improvement has been identified to strengthen scrutiny of clinical audit findings; and establish clear escalation and oversight arrangements for interventional cardiology imaging services.

IR(ME)R Audit

The IR(ME)R audit schedule is maintained and updated by the lead radiographer and the Quality Standard for Imaging (QSI) lead. The audit schedule is reviewed regularly to ensure compliance with current legislation, Employer's Procedures and identified risks. The cardiology interventional imaging service is included in the IR(ME)R audit schedule. Observational IR(ME)R and patient safety audits were carried out in cath lab two in June 2026. Audits include entitlements, DRL's and dose optimisation, analysis of accidental and unintended exposures, near misses and learning from these.

A radiology audit group is established which meets monthly to agree trust wide annual audit schedule. Individual modality groups meets on an agreed timeline to progress and review audits.

If 100% compliance is not achieved with IR(ME)R audits, any learning identified will be shared with the relevant teams. Re-audit will also be performed within a shorter timeframe than the standard IR(ME)R audit schedule to measure if learning has carried into practice. The service described how significant findings would prompt a re-audit within three months. Before an audit is signed off and closed, the ARSM will review the audit for approval to be uploaded on to QPulse. If the ARSM feels the timeline is prolonged or actions are not appropriate, they will discuss this with the auditor. Through this electronic process, all relevant staff are informed of the audit and must acknowledge the audit electronically. In addition to this, team leads will add it as a standing item to the next team meeting.

IR(ME)R audits are a standing item at the Radiation Protection Working Group (RPWG). The IR(ME)R employer sits on this group, which meets every four months. If anything requires urgent escalation, the service contacts the IR(ME)R employer directly.

The audit arrangements for clinical evaluations for interventional cardiology services were reviewed. Management confirmed clinical evaluation is recorded on Epic and also recorded on Northern Ireland picture archiving and communication system (NIPACS). On a monthly basis the NIPACS team check the safety lists on NIPACS to ensure all exposures have a clinical evaluation.

The NIPACS team will highlight any examinations which do not have a clinical evaluation to the cath lab lead radiographer. An area for improvement was identified to formalise this approach to evidence this audit process is taking place.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that the clinical audit process and IR(ME)R audit process are well understood by staff and implemented in accordance with the Employer's Procedures. The areas for improvement will assist to strengthen the processes already in place. The inspection team acknowledge the commitment of staff in this regard.

5.2.3 Does the service adhere to legislation with regard to DRLs?

DRLs are used as a guide to help promote improvements in radiation protection practice and can help identify issues relating to equipment or practice by highlighting unusually high radiation doses. DRLs do not apply to individual patient exposures and any assessment against the DRL should be based on the results of patient dose surveys for groups of patients.

Examination of the DRLs in place for interventional cardiology imaging highlighted that two of the three national DRL figures submitted and displayed in the cath labs are 'archived' and thus no longer considered national DRLs. Management confirmed that work had commenced to review DRLs. The cath lab lead radiographer has recently sent a summary of dose audits to the MPE which focuses on average dose. However, management outlined they are also moving towards a change in this process, which will involve sending the raw data to the MPE for analysis. The timescales for this work to be completed were unclear. RQIA requested the submission of a detailed action plan with timescales on the proposed action to be taken in relation to DRLs within one week of the inspection. RQIA received a detailed action plan with timescales. To ensure implementation of the action plan an area for improvement has been identified in relation to this matter.

Employer's procedure K which describes the use of DRLS, outlines that the relevant image optimisation team (IOT) are responsible for establishing, reviewing and approving DRLs. The IOT does not have a representative from interventional cardiology. An area for improvement has been identified to ensure interventional cardiology has representation at the IOT meeting to support optimisation in this area.

It was confirmed staff receive training on the use of DRLs as part of induction. Management and staff were able to correctly outline how to identify and escalate where DRLs are consistently exceeded.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that DRLs for the interventional cardiology imaging service requires to be established, implemented and reviewed. The areas for improvement will assist on this matter. The inspection team acknowledge the commitment of staff in this regard.

5.2.4 Does the service adhere to legislation and best practice with regard to the management of SAUEs, radiology incidents and near misses?

Incident and near miss management
Management and staff described the process of incident identification, reporting and investigation. Where an incident is identified, the exposure is stopped and the incident is reported immediately via Datix (web base incident reporting system) and a formal investigation is commenced. For all incidents involving an unintended radiation exposure, advice is sought from the MPE and the incident is fully investigated by the ARSM.

As soon as practicable following the event, a radiation incident form is completed in accordance with Appendix 9 of the Employer's Procedures. Supporting statements are obtained from relevant staff at the earliest opportunity and should include details of the sequence of events, exposure factors, dose information and any other relevant observations to support the investigation.

The clinical lead/RSM will nominate a senior officer, such as an ARSM, to liaise with and report to RQIA on behalf of the WHSCT where required.

Where an accidental or unintended exposure is assessed as meeting the threshold for a Significant Accidental or Unintended Exposure (SAUE), notification will be made to RQIA in accordance with the guidance outlined in 'Significant Accidental and Unintended Exposures under IR(ME)R: Guidance for Employers and Duty Holders' and the requirements of the Employer's Procedures.

Where a SAUE is confirmed, the process described within Employer's Procedures Q and R is followed. This includes informing the patient, notifying RQIA and, where appropriate, notifying the Strategic Planning and Performance Group (SPPG) if the incident meets the criteria for a Serious Adverse Incident (SAI). If the investigation identifies an equipment related fault or failure, the Medicines and Healthcare products Regulatory Agency (MHRA) will also be notified as required.

Once investigation is complete, any learning is shared with the radiology team and cardiology team if relevant via Qpulse or wider MDT by methods such as: e-mail, memos and posters.

Governance of incidents
The radiology department have recently established the 'radiation incident governance group' (RIGG). The first RIGG meeting was held the week prior to this inspection and focused on reviewing incidents, near misses and trends from the previous year. The service intend to run these meetings on a fortnightly basis. Membership of the RIGG includes the governance radiographer (chair), MPE, RSM, radiation protection advisor (RPA) and modality leads. The cath lab lead radiographer will attend if there are cardiology radiation incidents. It was positive to note that the radiology department is developing a systems based approach to investigation and learning from incidents and near misses. This includes the development of radiation incident investigation forms and a table of prompts for the investigator to consider such as environment, people and other potential contributory factors.

Management described that certain trends had been identified at the most recent RIGG meeting.
This forum was used to explore the actions taken, explore any further actions that could be taken, and any audits that should be triggered following the identification of these trends.

On a six monthly basis incidents are reviewed by classification and graphical visualisation enabling a trend analysis to be performed which is shared with staff on QPulse. Analysis of incidents, trends and near misses, causes and potential risks are identified and reviewed at bi - monthly clinical governance meeting and the quarterly by the radiation protection sub group (RPSG).

Follow up and review of any identified actions is monitored at clinical governance, this then feeds back to risk management sub-committee which is chaired by the medical director (Employer). An annual report of all incidents is devised which includes analysing all radiation incidents recorded on Datix for the Trust.

Clinically significant accidental and unintended exposures (CSAUE)
Employer's procedure R in regards to CSAUE was in place and examined. It was noted the Employer's procedure was unclear as to who is responsible for determining if an unintended exposure reaches the threshold to be classed as a CSAUE. The Employer's procedure notes 'the assessment of these risks is the responsibility of the MPE'.

However, management indicated it would most likely be the clinical lead radiologist who would determine a CSAUE. In addition the Employer's procedure does not detail how the practitioner is informed in the event of a CSAUE. An area for improvement has been identified to further develop Employer's Procedure R to include clear information on the CSAUE decision making process and informing the practitioner of a CSAUE.

Overall the Trust has a structured and compliant process for the management of radiology incidents, near misses and significant accidental or unintended exposures (SAUE) in line with IR(ME)R.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced clear and robust incident and near misses management processes are in place. We acknowledge and commend the ongoing development of a more system based approach to investigation of incidents. The area for improvement outlined will assist on ensuring further clarity regarding the management of a CSAUE. 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

Equipment Quality Assurance
The Employer must keep an up-to date inventory of all medical radiological equipment including ancillary devices that can directly control or influence the exposure.

It was noted that the equipment inventory reflected all information required under IR(ME)R. Management and staff confirmed there is an appropriate amount of equipment available for the workload of the cardiology department.

There is a formal, written equipment quality assurance (QA) programme in place. It was confirmed that the MPE had been involved in devising the equipment QA procedures. It was confirmed that daily and monthly quality checks (QC) of the radiology equipment in the cardiology department are carried out by appropriately trained and entitled operators.

A review of equipment QC records evidenced that they are paper based. The QC record folder included a description of how to perform the tests. It was noted that there were aspects of these records that were struck through and additional written information added. Equipment QA was up to date at the time of inspection, however there were some tests which had a six month gap prior to April 2026 in the testing schedule for both cath lab one and cath lab two. There was no recorded explanation for this gap and it could not be determined if this matter had been formally escalated.

Management and staff confirmed that QA is uploaded to QPulse which contains in built alerts to highlight due dates. However, there had been equipment QA challenges during this period due to an equipment replacement programme in one of the cath labs.

Management described that a QA audit is performed every six months which examines equipment across the sites. This audit involves ensuring records are uploaded on to QPulse. However, QA challenges for the radiology equipment in cardiology department was not highlighted by this audit. An area for improvement has been identified to ensure that good oversight and mechanisms are in place to escalate and record challenges around carrying out equipment QA in the cardiology department.

Employer's Procedures
It was good to note that Employer's Procedures were in place which had been approved in July 2026. They largely reflected the cardiology service and were overall well written.
However, an area for improvement has been identified to amend the following Employer's procedures:

- Employer's Procedure F - referral: To include more detail about the referral process to cardiology, including how referrals are managed in the cardiology department.
- Employer's Procedure I - QA procedures: To update the frequency of review and how updated documents are shared
- Employer's Procedure D - pregnancy enquiries: To include further clarification around pregnancy enquiry in cardiology and to define high dose procedures.

Discussion also took place in relation to the use of referral guidelines for cardiology in which there was some ambiguity on this matter. An area for improvement has been identified to review the referral guidelines in place and to ensure dose indicators are included and that they are made available to referrers.

'X-ray at home' pilot service
The SAF made reference to an "X-ray at home" service. Management provided a brief outline of this pilot service and reported that it will hopefully be commenced soon. The Trust have identified five appropriate Trust owned care facilities for this pilot which have been assessed by senior radiology and MPE staff to ensure suitability. An appropriate room has been identified in each establishment to perform X-rays. It was confirmed that chest X-rays will be the only exposures carried out. Suitably trained and competent staff will be entitled as operators to perform the examinations.

The equipment must first go to medical physics for testing prior to commencing the pilot. The Trust are reviewing their Employer's Procedures and other organisation's Employer's Procedures to identify any gaps to consider in relation to IR(ME)R. The MPE is involved in the review of the Employers Procedures. Management were advised to ensure the IR(ME)R pathway is fully considered and that compliance is in place for this proposed service. RQIA have requested to be kept updated on the pilots development.

6.0 Conclusion

There were 12 areas of improvement identified as a result of this inspection. These are fully outlined in the appended QIP.

The management team and staff are to be commended for their ongoing commitment and enthusiasm to ensuring that the cardiology department is well managed and operating within the legislative framework; and maintaining optimal standards of practice for patients.

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

7.0 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.

Total number of areas for improvement	12

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 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	
Area for improvement 1 **Ref: Regulation 6 Schedule 2.1.(b)** **Stated: First time** **To be completed by:** **22 October 2026**	The Employer must consider formally reviewing entitlement arrangements on at least an annual basis. Management are encouraged to integrate the entitlement review into structures already in place (such as the staff annual review) and to evidence this review. Ref 5.2.1
	Response by Employer detailing the actions taken: Appraisal format has been reviewed by management team and Entitlement will be reviewed annually with all staff groups in Radiology and Cardiology.
Area for improvement 2 **Ref: Regulation 6 Schedule 2.1 (b)** **Stated: First time** **To be completed by:** **22 October 2026**	The Employer must provide a more comprehensive record of entitlement for consultant interventional cardiologists which fully reflects the individuals scope of practice. Ref 5.2.1
	Response by Employer detailing the actions taken: The Cardiology Entitlement document has been updated to mirror the Radiology Entitlement form, providing a standardised format across both specialties and clearly outlining the approved scope of practice for individual Cardiologists.

Area for improvement 3 **Ref: Regulation 6** **Stated: First time** **To be completed by:** **22 October 2026**	The Employer must ensure clarity around the IR(ME)R pathway in cardiology and ensure there is evidence in the patient records of the referral and the duty holders involved in cardiology interventional imaging. Ref 5.2.1
	Response by Employer detailing the actions taken: EPIC workflows reviewed by Cardiology Team to ensure duty holders aware of responsibilities and this is now reflected in patient referrals as standard.
Area for improvement 4 **Ref: Regulation 7** **Stated: First time** **To be completed by:** **22 October 2026**	The Employer must review the clinical audit template to include some additional target compliance sections and clear timelines in terms of actions. Ref 5.2.2
	Response by Employer detailing the actions taken: Radiology audit template has been reviewed and amended. Clinical Audit group formalised within Cardiology, Lead Radiographer is a member of this group for any shared learning or actions.
Area for improvement 5 **Ref: Regulation 7** **Stated: First time** **To be completed by:** **22 October 2026**	The Employer must strengthen scrutiny of clinical audit findings; and establish clear escalation and oversight arrangements for interventional cardiology imaging services. Ref 5.2.2
	Response by Employer detailing the actions taken: Audit actions are recorded within an overarching action log with a designated lead to implement actions and disseminate learning within agreed timescales.
Area for improvement 6 **Ref: Regulation 12(9)** **Stated: First time** **To be completed by:** **22 October 2026**	The Employer must formalise the audit process of clinical evaluation in cardiology to evidence this audit process is occurring. Ref 5.2.2
	Response by Employer detailing the actions taken: NIPACS+ Manager has formalised this audit: ‘ Cath Lab Exams with completed Report on NIPACS’ . This involves a review of NIPACS worklists to identify any examintions that do not have a report/clinical evaluations available. This audit has been added to the IRMER Audit schedule to be completed monthly.

Area for improvement 7 **Ref: Regulation 6(5)(c),(7)** **Stated: First time** **To be completed by: 22 October 2026**	The Employer must ensure the full implementation of the diagnostic reference levels action plan. Ref 5.2.3
	Response by Employer detailing the actions taken: Action Plan devised in association with Medical Physics Team, data collection is currently ongoing and progress will be discussed at the next IOT.

Area for improvement 8 **Ref: Regulation 12** **Stated: First time** **To be completed by:** **22 October 2026**	The Employer must ensure interventional cardiology has representation at the IOT meeting to support optimisation in this area. Ref 5.2.3
	Response by Employer detailing the actions taken: Terms of Reference of IOT has been reviewed to ensure Interventional Cardiology representation at all meetings.
Area for improvement 9 **Ref: Regulation 6, 8(1) Schedule 2.1.l** **Stated: First time** **To be completed by:** **22 October 2026**	The Employer must further develop Employer's Procedure R to include clear information on the CSAUE decision making process and informing the practitioner of a CSAUE. Ref 5.2.4
	Response by Employer detailing the actions taken: EP Procedure R has been reviewed and revised as per recommendations. Will be circulated for comments and ratified outside next RPSG (December 2026).
Area for improvement 10 **Ref: Regulation 15(1)** **Stated: First time** **To be completed by:** **22 October 2026**	The Employer ensure good oversight and mechanisms are in place to escalate and record challenges around carrying out equipment QA in the cardiology department. Ref 5.2.5
	Response by Employer detailing the actions taken: Cardiology Interventional Equipment QA documentation is available on the Radiology QMS and will be monitored as part of the Radiology equipment quarterly (3-monthly) audit programme. An escalation process will be implemented to ensure that any QA concerns, equipment failures, or downtime issues are promptly communicated to the Radiology Service Manager.
Area for improvement 11 **Ref: Regulation 6 Schedule 2.1** **Stated: First time** **To be completed by:** **22 October 2026**	The Employer must amend the following Employer's Procedures: • Employer's Procedure F- referral: To add more detail about the referral process to cardiology including how referrals are managed in the cardiology department. • Employer's Procedure I – QA procedures: To update the frequency of review and how updated documents are shared • Employer's Procedure D –pregnancy enquiries: To include further clarification around pregnancy enquiry in cardiology and to define high dose procedures. Ref 5.2.5

	Response by Employer detailing the actions taken: Procedure F, Procedure I and Procedure D have been revised and updated. Will be circulated for comments and ratified outside next RPSG (December 2026).

Area for improvement 12 **Ref: Regulation 6(5)(a)** **Stated: First time**	The Employer must review the referral guidelines in place and to ensure dose indicators are included; and that they are made available to referrers. Ref 5.2.5
To be completed by: **22 October 2026**	**Response by Employer detailing the actions taken**: Cardiology referral guidelines are currently being developed collaboratively by the Radiology and Cardiology teams and will be incorporated into the induction programme for all newly appointed Consultant Cardiologists and the wider team.



The Regulation and Quality Improvement Authority
James House
2-4 Cromac Avenue
Gasworks
Belfast
BT7 2JA

Tel 028 9536 1111
Email info@rqia.org.uk
Web www.rqia.org.uk
@RQIANews