The Regulation and Quality Improvement Authority

Inspection Report

28 January 2026

Royal Victoria Hospital, Nuclear Medicine Cardiology Department

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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: Belfast Health and Social Care Trust (BHSCT)	**Department Inspected:** Royal Victoria Hospital (RVH) – Nuclear Medicine Cardiology Department
Name of Employer: Ms Jennifer Welsh	**Service Manager Cardiology (SMC)** Ms Emma Herron

Brief description of how the service operates:

The RVH Nuclear Medicine Cardiology department provides an adult service and a very limited paediatric service Monday to Friday between 8am and 5pm.

Before the inspection Ms Herron, SMC and her team were requested to complete a self-assessment form (SAF). The submitted SAF confirmed that for the period from1 September 2024 to 31 August 2025 the RVH Nuclear Medicine Cardiology department carried out approximately 359 Myocardial Perfusion SPECT (2 day stress and rest test) and 10 Myocardial Perfusion SPECT (rest viability test).

The Nuclear Medicine Cardiology department operates under an Employer's Licence and Practitioner's Licences that covers the radioisotopes in use and the range of nuclear medicine services provided in cardiology. Currently one consultant cardiologist acts principally as the licenced practitioner for the nuclear medicine cardiology service. The radioisotope routinely used within the department for nuclear medicine cardiology is unsealed radionuclide: Tc-99m Tetrofosmin.

Within the department, there is one gamma camera, a dose calibrator and a laminar flow cabinet.

The department is staffed by one consultant cardiologist (practitioner licence holder), one associate specialist, 3.3 whole time equivalent (WTE) cardiac clinical physiologists – senior team and 3.1 WTE cardiac clinical physiologists (rotational team). The service is supported by Medical Physics Experts (MPEs) specialising in nuclear medicine from BHSCT Medical Physics Service. The BHSCT Head of Radioisotopes supports the service in relation to the Administration of Radioactive Substances Advisory Committee (ARSAC) licencing arrangements.

The RVH Radiopharmacy dispenses the radioisotope to the service.

2.0 Inspection summary

On 28 January 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 the RVH Nuclear Cardiology department, as part of RQIA's IR(ME)R inspection programme.

For the 2025/26 inspection year, the inspections are focusing on the following key themes:

- IR(ME)R governance, including arrangements for compliance with IR(ME)R, services provided outside of the main department, communication with other departments, and commissioning of new services.
- Justification and authorisation process including use of authorisation guidelines where appropriate
- Management of equipment performance
- Patient identification including pause and check
- Nuclear medicine therapies and radiotherapy - the study of risk
- Radiotherapy – focus on the breast pathway
- Any other areas identified through the review of the submitted SAF and supporting documentation

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

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

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

- Discussion with management and staff
- Examination of relevant nuclear medicine 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 nuclear medicine 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 nuclear medicine cardiology department, patients were awaiting or immediately recovering from nuclear medicine cardiology diagnostic 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?

This is the first IR(ME)R inspection of the RVH nuclear medicine cardiology service.

5.2 Inspection findings

5.2.1 Are there appropriate IR(ME)R governance arrangements in place to ensure compliance with the legislation?

Organisational Structures and Governance Committees

The overall responsibility for ensuring compliance with IR(ME)R lies with the Employer. The role of IR(ME)R Employer in the BHSCT is held by the Chief Executive.

The BHSCT Radiation Safety Policy sets out the organisational structures, lines of accountability and governance structures. Management advised that the policy is currently under review and a draft copy was provided.

Management confirmed that the Trust Board is responsible for establishing the organisation's strategic direction and aims in conjunction with the Executive Management Team. The Chair of the Trust Board works closely with the Employer (Chief Executive) to ensure the effectiveness of the Assurance Framework.

The Assurance Committee provides oversight of governance and assurance through review of information from the steering groups to support the Trust Board of Directors. The Safety and Quality Improvement Steering Group acts on behalf and reports to the Assurance Committee. Facilitating the implementation of Ionising (Radiation) and Non-ionising Radiations regulations and overseeing the development, implementation and review of the Trust Radiation Safety Policy.

The Radiation Protection Committee (RPC) is the overarching strategic committee for all matters pertaining to ionising radiation and non-ionising radiation. The RPC is co-chaired by the deputy medical director and a consultant radiologist. The head of radioisotopes represents the nuclear medicine cardiology service at these meetings and the RPC reports its activities to the Safety and Quality Improvement Steering Group.

The Diagnostic Radiology and Nuclear Medicine (DRNM) Committee meets biannually. The consultant cardiologist/ licenced practitioner for the nuclear medicine cardiology department attends this committee and provides a written report for this committee on behalf of the service. The DRNM Committee has been constituted by the RPC to provide assurance to the Trust and Employer through providing oversight on meeting statutory duties in relation to ionising radiation use within Diagnostic Radiology and Nuclear Medicine. Imaging sub-groups report to the DRNM, which includes Image Optimisation teams (IOTs) and the Radiation Incident Governance Group (RIGG). Each governance committee have terms of reference which outlines roles and responsibilities.

The most recent nuclear medicine cardiology IOT meeting was held during September 2025 and the minutes were reviewed. The meeting was found to have been attended by only two cardiology staff with apologies from the MPE and another member of senior management. The importance of a quorum attendance at the IOT meeting was highlighted to allow robust scrutiny to be applied to the matters to be discussed.

Management confirmed that the nuclear cardiology service and radio pharmacy department regularly liaise however; there are no formal governance structures. An area for improvement has been identified to establish regular formal meetings with clear terms of reference between the nuclear medicine cardiology service and the radio pharmacy department and to ensure these meetings are fully minuted.

The head of radioisotopes receives a written report from the licensed practitioner in relation to the nuclear medicine component of the cardiology service which includes incidents, IR(ME)R audits and diagnostic reference level (DRLs) audits. Management confirmed there is close liaison with the head of radioisotopes for medical physics expert for advice and support.

Employer Licence and Practitioners' Licences

IR(ME)R requires employers and practitioners who administer radioactive substances to hold a valid licence. Each employer licence is specific to the site where the administrations will take place and lists the authorised procedures that will be carried out for diagnostic, therapeutic and research purposes. Each practitioner licence lists the authorised procedures that may be justified by the named licence holder for diagnostic, therapeutic and research purposes.

As stated previously, the head of radioisotopes confirmed that part of her role is to manage the Employer and Practitioner licensing for the nuclear medicine service in cardiology. It was confirmed that an Employer Licence and Practitioner Licences are in place and appropriate for the current scope of service. The Employer Licence and Practitioner Licences are held on Q-Pulse. An audit of the licences is undertaken every six months to ensure on-going validity. There is also a detailed spreadsheet with all of the practitioner licences with the various licenced procedures listed. There is a procedure and checklist for the introduction of new techniques and this includes checking that an appropriate licence is available.

Communication

Management and staff confirmed there was good communication within the nuclear cardiology department.

On a daily basis there is a morning huddle within the department and the licensed practitioner and the team lead cardiac clinical physiologist meet every Tuesday morning. As outlined previously there are also six monthly IOT meetings held. It was confirmed that MPE support includes:

- selection and commissioning of equipment
- MPE is the first point of call for Quality Control (QC) problems of calibrator and gamma camera
- attending the IOT meeting(if availability allows)
- involvement in service changes such as change of isotope
- investigation of incidents or suspected incidents
- training of operators for example on carers and comforters

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.

Evidence of induction, training, competency and continuing professional development for a MPE, a cardiac clinical physiologist, and a consultant cardiologist (licenced practitioner) was reviewed; and found to be in line with the duty holder roles.

Systems are in place to check the professional qualifications and registration of all employees with their appropriate professional bodies. Comprehensive systems were in place to provide annual appraisals for all grades of staff and individual development needs are identified as part of this process. The consultant cardiologists have their appraisals undertaken by an approved medical appraiser.

Entitlement is reviewed at the annual appraisal and adjusted accordingly if a staff member's scope of practice has changed. This process is reflected in the Employer's Procedure (EP) B entitlement.

Individual entitlement records for a clinical scientist (MPE), a non-invasive cardiac physiologist team lead; a cardiac clinical physiologist and consultant cardiologist (licenced practitioner) were reviewed. The group entitlement records for medical practitioners in BHSCT and a separate group entitlement record for medical staff from South Eastern Health and Social Care Trust (SEHSCT) were also reviewed. Whilst entitlement records were overall well completed, the following was noted:

- The document "Competencies for Entitlement as a Duty Holder under IR(ME)R at BSHCT" lists tasks that are not related to IR(ME)R, this should be reviewed and updated as appropriate.
- Operator functions on the MPE entitlement form references nuclear medicine and not specifically nuclear medicine cardiology.
- The lead consultant cardiologist for nuclear medicine (licensed practitioner) entitlement form did not include the duty holder role of referrer for nuclear medicine cardiology with a defined scope of practice.
- The entitlement forms did not have dedicated space for entitlement review and this was being recorded free hand.

Another consultant cardiologist acts as referrer and practitioner for nuclear medicine cardiology imaging in the absence of the lead consultant cardiologist for nuclear medicine. The management gave assurances that appropriate licensing arrangements were in place however, management acknowledged that the entitlement arrangements and records may not reflect this. This matter is discussed further in the justification and authorisation section 5.2.2 of this report. An area for improvement has been identified on the above matters.

Discussion on the oversight arrangements for entitlement found that there was an individual review of entitlement however, no centralised overarching mechanism for recording entitlement such as a spreadsheet or electronic matrix. This would allow for auditing and offer reassurance to the Employer on the robustness of the entitlement arrangements. An area for improvement has been made on this matter.

Management outlined the arrangements for referral and entitling referrers for nuclear medicine cardiology scans. Referrals are submitted via the electronic system EPIC. The Referrer BHSCT entitlement form states nuclear cardiology does not accept Fy1 and Fy2 grade medical practitioner referrals. Only referrals for rest viability and two-day stress and rest test are accepted.

It was positive to note that the consultant cardiologist and team lead cardiac clinical physiologist were involved in designing the referral pathway on EPIC. The SEHSCT medical cardiology staff referrer role for nuclear medicine cardiology scans was discussed. It was noted that the group entitlement form did not fully reflect the specialist cardiology referrer role for SEHSCT medical cardiology staff. Discussion found that there was some ambiguity in relation to referral guidelines for nuclear cardiology.

An area for Improvement has been identified to ensure:

- that written referral guidelines are in place for nuclear cardiology scans and that they are made available to referrers
- If medical/cardiology staff from SEHSCT are to be entitled to refer to nuclear cardiology scans, then "Medical Staff from South Eastern Health and Social Care Trust Group Entitlement Form" should be updated to specify nuclear medicine cardiology and include details to identify referrers.

Clinical Audit

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

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

A RVH nuclear cardiology audit calendar for 2025/early 2026 was in place. A review found it to be limited and there was confusion is relation to IR(ME)R compliance audits and clinical audit. Examination of a number of completed audits noted the following:

- A 'MPI audit' undertaken in April 2025 outlined brief details of the outcomes of the audit.
- A dose audit summary (not dated) related to patient scans that took place in 2023. It was good to note the dose audit resulted in a change in practice in relation to the method of checking body mass index (BMI) as part of the administration of the radioisotope process.
- The audits had limited information in relation to methodology, objectives, compliance targets, findings, interpretation of findings, clear outcomes and shared learning.

Management confirmed that the results of audits are shared at departmental meetings and at the IOT. The licensed practitioner provides audit updates to the cardiology team meetings, and all cardiology staff are invited to a half day every month audit update with attendance monitored. Audits are also included in the licensed practitioner's report to the DRNM Committee. Management confirmed that they did not have a clinical audit template, and they had no formal links to the Trust audit team for support.

To strengthen clinical audit an area for Improvement has been identified to ensure the following:

- ensure clarity on what is a clinical audit and an IR(ME)R audit
- establish a robust nuclear medicine cardiology clinical audit schedule
- implement and use standardised audit templates for recording objectives, methodology, outcomes of clinical audits and how outcomes and learning have been disseminated

As stated previously a limited IR(ME)R compliance audit schedule was in place. It was emphasised on the importance of establishing a robust IR(ME)R compliance audit programme as part of offering assurances to the Employer on IR(ME)R compliance. It was also outlined that IR(ME)R audits compliance rate must be set at 100%.

An area for improvement has been identified in relation to strengthening IR(ME)R audit as follows:

- to implement a rolling programme for IR(ME)R audit which would be a more robust approach to assess practice and ensure assurance can be provided to the Employer on IR(ME)R compliance
- involve the wider team in the audit process
- establish an IR(ME)R audit form/template to formalise the approach and track actions appropriately
- consider introducing observational IR(ME)R audits

Incident and near miss management

The process for the management and notification of significant accidental or unintended exposures is detailed in the Policy and Procedures for Reporting and Investigating IR(ME)R incidents. Employer's Procedures L and O also include detail of the management of incidents.

The staff member must report radiation exposure incidents and near miss radiation incidents to the team lead cardiac clinical physiologist. The staff member directly involved in the incident must complete a DATIX as soon as possible. The submitted SAF outlined that an incident log is also completed. Management and staff described this as a spreadsheet where "low level" incidents, clinical incidents of interest, IR(ME)R incidents and near misses that occurred in nuclear medicine cardiology department were logged. The incident log is used for trend analysis. It was discussed that by having two ways of recording incidents/near misses there is a risk of not all IR(ME)R incidents being recorded on DATIX. An area for improvement has been identified to re-evaluate and review use of the nuclear medicine cardiology internal incident log.

The team lead cardiac clinical physiologist immediately reports the radiation exposure event to a MPE, head of radioisotopes and the licensed practitioner. Sufficient information on the incident and radiation exposures must be provided to allow the MPE to undertake a dose assessment and advise whether the incident is notifiable to RQIA. In the case that the incident is determined to be notifiable, the team lead cardiac clinical physiologist will notify RQIA within 2 weeks of discovering the radiation incident. The MPE will also advise as to whether a diagnostic procedure incident needs to be considered as a 'clinically significant' exposure as a result of the risk-based assessment.

The head of radioisotopes or lead clinical scientist will inform the chair of the RPC. The team lead cardiac clinical physiologist will inform the cardiology service manager and cardiology clinical director. An internal investigation is undertaken according to the Radiation Incidents policy. This is recorded on the radiation incident investigation form (RIIF) and the radiation incident action plan (RIAP). The MPE will complete a radiation dose report. The notification coding, guidance and timescales within the Significant Accidental and Unintended Exposures (SAUE) guidance and Radiation Incidents policy is followed.

The incident will be recorded in the Trust DATIX system and in the Radiation Incidents spreadsheet. Incidents will be discussed at the weekly Radiation Incidents Governance Group (RIGG), and significant incidents are reported to the weekly divisional governance meeting, chaired by the co-director and chair of division. The lead MPE for nuclear medicine cardiology attends RIGG meetings on behalf of the nuclear medicine cardiology department.

Radiation incidents are discussed at departmental staff meetings to provide learning and a forum is held to discuss follow–up actions. An annual review of incidents and near misses is carried out and the findings, learning and actions are shared with the department. Incidents and near misses are included in the licensed practitioner's report to the DRNM committee.

There are clear arrangements in place to report, record, investigate and learn from radiation incidents or near misses in the nuclear medicine cardiology department. The management and staff clearly outlined action to be taken if it suspected significant accidental or unintended exposure (SAUE) had occurred, and this was fully reflected in the Policy and Procedures for Reporting and Investigating IR(ME)R incidents. Employers Procedures L and O also include detail of the management of incidents.

The decision making process for clinically significant accidental or unintended exposures (CSAUE) and informing relevant stakeholders was clearly outlined by management, and reflected in the Employer Procedure O - CSAUE.

Risk register

The arrangements for ensuring the Trust risk register reflects risks associated with non-compliance with IR(ME)R was reviewed. The management outlined clear information to ensure that the Trusts risk registers are examined and updated, to ensure all identified risks associated with IR(ME)R compliance are appropriately captured and that specific actions to mitigate the risks are identified and appropriate systems of assurance are put in place. The lead cardiac physiologist is responsible for the management and oversight of the risk register in relation to nuclear medicine cardiology services.

The ratification process for Employers Procedures (EPs) and other IR(ME)R documentation

It was good to note that the Employer's procedures for Diagnostic and Therapeutic Uses of Unsealed Radioactive Materials approved on 17 June 2025 is in place. It was confirmed that the DRNM Committee reviews draft EPs and protocols. They are then reviewed by the Policy and External Guidance Assurance Committee and then to the Executive Team Meeting for final ratification.

All written procedures and protocols are stored and accessed electronically on a Trust limited access shared account. All documents are reviewed at least every two years or more frequently if required. All procedures have a formal review and approval process with the involvement of the licensed practitioner, the team lead cardiac clinical physiologist and the MPE where relevant. Changes are communicated to staff by email and team briefings.

The nuclear medicine cardiology service does not have a quality management system (QMS) in place for all electronic documents held. This presents a risk in terms of document control. There are a number of hard copy procedures which are subject to an informal tracking system to ensure that the most up to date version is in place. On discussion, senior management agreed that a Quality Management System (QMS) should be considered for the nuclear medicine cardiology service.

Standard operating procedures (SOPs) for the provision of the nuclear medicine cardiology service were reviewed.

Overall, they were well written however the following was noted:

- SOPs included reference to radiopharmaceuticals not in use by service.
- SOP should have sufficient detail included for stress protocol especially where administration of a prescription only medicine (POM) for example, Regadenoson, is used. This can be within or as a separate protocol but should be suitably referenced in the SOP and include detailed administration instructions.
- SOP included the incorrect use of IR(ME)R terminology regarding justification and authorisation.

An area for improvement has been identified on the matters above.

The introduction of a new nuclear medicine service

Management outlined the process to be followed when a new nuclear medicine cardiology procedure or piece of equipment was intended to be introduced. This would involve, seeking funding, reviewing licensing arrangements, involving the MPE in commissioning and performing the relevant tests as well as setting up protocols and signing off the equipment for clinical use. The equipment is then added to the equipment inventory and assigned a unique ID. Application training is provided by the manufacturer, and the manufacturer may have remote access for additional support.

The governance arrangements for the new service will be fully reviewed including ensuring compliance with IR(ME)R. Once a new service is introduced, it will be subject to audit. There is a procedure in relation to the introduction of a new service, which is available to the main nuclear medicine department. It was advised to share the procedure with the nuclear medicine cardiology service and management gave assurances on this matter.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that there are good governance arrangements with respect to the nuclear medicine cardiology service and these arrangements are regularly reviewed and, if necessary, improvements are made. It is hoped that addressing the areas for improvement made will enhance the governance systems in place. The inspection team acknowledged the commitment of staff in this regard.

5.2.2 Does the service adhere to legislation in relation to the justification and authorisation of ionising radiation procedures?

Justification is the intellectual activity of weighing up the expected benefits of an exposure against the possible detriment of the associated radiation dose and is the primary role of the practitioner. Authorisation is a separate process to justification and is the documentation confirming that the intellectual activity of justification has taken place.

The duty holder roles of operator and practitioner were examined in relation to the justification and authorisation of exposures. It is not always possible for a practitioner to review every imaging referral, so regulations allow an appropriately entitled operator to authorise an exposure following written authorisation guidelines issued by a named practitioner.

Authorisation guidelines must be clearly written using precise statements that are unambiguous in order to allow the operator to confirm whether the referral can be authorised.

The practitioner is responsible for the justification of any exposure that is authorised by an operator following the authorisation guidelines. The operator is responsible for the authorisation and following the authorisation guidelines accurately.

Justification is either recorded (authorised) by a licensed practitioner or authorisation by an entitled operator who authorises against authorisation guidelines provided by the licensed practitioner. For nuclear medicine cardiology procedures the act of authorisation is recorded under the section "Protocolling" on EPIC under the field name "comment". Records sampled did have the relevant field completed however, there was not a clear easily identifiable section to record authorisation which could make compliance auditing challenging. The team lead cardiac clinical physiologist stated that they have requested an update on EPIC to improve this.

A range of authorisation guidelines was reviewed including a 'justification flowchart.' The authorisation guidelines were found to be limited and will require further development to ensure that they are fit for purpose. The flow chart was not in accordance with IR(ME)R requirements of who can justify and authorise an exposure and the purpose of this flow chart was unclear.

In the licensed practitioner absence another consultant cardiologist would act as the licensed practitioner. The service needs to ensure that this practitioner is entitled to justify procedures for nuclear medicine cardiology scans and it should be clear that when operators are authorising whose authorisation guidelines they are acting under in these circumstances.

From review of documentation relating to justification and authorisation, and discussion with staff on the matter, it was demonstrated that there was some confusion with regards the duty holder roles and process of justification and authorisation.

As a result a number of areas for improvement have been identified:

- Ensure all practitioners who justify nuclear medicine cardiology procedures are entitled to do so and have appropriate authorisation guidelines to follow.
- Establish and implement clear authorisation guidelines (issued by a licensed practitioner) so that the authorisation can be carried out by an appropriately entitled IR(ME)R operator. Consider referencing entitlement rather than named individuals in authorisation guidelines.
- Review and update the "justification flowchart" to ensure it is in accordance with IR(ME)R requirements of who can justify and authorise exposure, and the service should consider whether this flow chart is required.
- Ensure staff receive bespoke IR(ME)R training regarding duty holder roles and responsibilities and how this relates to the process of justification and authorisation.

Exposures to carers and comforters (C&Cs) require individual justification and authorisation. Justification of the exposure of C&Cs who knowingly and willingly provide help and support should consider both the direct benefit to the health of the individual undergoing the medical exposure as well as the indirect benefit to the carer or comforter. The exposure of a carer or comforter should only be permitted when this net benefit can be clearly identified. There are authorisation guidelines in place for C&Cs. They apply to individuals who will be accompanying the patient in the injection room or scan room; and are over 18 years old and not pregnant. Entitled operators authorise nuclear medicine cardiology exposures to C&Cs using these guidelines.

There were three C&C exposures in the last year. The C&C form has sufficient radiation information and fields for operators to complete in order to associate with patient record and signatories.

The authorisation guidelines for C&Cs outlined the incorrect use of IR(ME)R terminology and was found to require further development. Specifically, it was advised to review and update the terminology in last sentence regarding justifying and authorisation of exposure. An area for improvement has been identified to review and update document “Delegation of authorisation or medical exposures to carers and comforters” to ensure correct IR(ME)R terminology.

The justification and authorisation of breast feeding patients was discussed. Management and staff confirmed that they would be referred to the licensed practitioner for justification however, this was not outlined in the authorisation guidelines.

An area for improvement has been identified to ensure breastfeeding patients are included in authorisation guidelines as requiring referral for justification to the licensed practitioner.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that the justification and authorisation process requires strengthening and addressing the areas for improvement will assist on this matter. The inspection team acknowledge the commitment of staff in this regard.

5.2.3 Does the service adhere to legislation with regard to 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. The equipment inventory reviewed 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 nuclear medicine cardiology department.

There is a formal, written equipment quality assurance (QA) programme in place. This is detailed in the QPulse management system. Records of quality checks (QC) undertaken are also kept within QPulse. Suitably trained and competent entitled operators undertake daily QC before use for the gamma camera and the dose calibrator. Clinical scientists who are entitled operators undertake more extensive testing as specified in the QC schedule.

On discussion in relation to the QC testing carried out by MPE. The MPE explained that tomographic resolution and uniformity checks had not been conducted since 2022 due to a leaking phantom. The MPE has asked the workshop to design a new phantom however, timescales for delivery on this is unknown therefore, MPE implemented bi-annual testing with a cardiac phantom. The Nuclear Medicine Cardiology Quality Control schedule was updated to include cardiac phantom testing. The MPE stated that the result of the in-house tomographic resolution / uniformity phantom would not be deemed as a necessary test by the manufacturer. It was advised that the MPE should review if tests performed are satisfactory to assure performance of gamma camera, if tomographic resolution and uniformity testing is required, and to escalate the equipment required via the risk register. Management gave assurances on this matter.

The team lead clinical cardiac physiologist monitors that the daily QC of the gamma camera and dose calibrator have been performed in accordance to the QC schedule. However, this good practice of monitoring is not currently documented. It was advised that this monitoring arrangement is formally documented and management were receptive to this advice. The MPE stated that on visits to the nuclear medicine cardiology department to conduct QC testing they also check the daily QC records.

The daily QC results are not entered electronically due to a computer not being present in the dispensing room. The MPE does not envisage a need for retrospectively electronically recording daily QC values and a visual check of the paper records were deemed by the MPE as sufficient. The MPE has confidence that nuclear cardiology staff would escalate any issue with equipment as appropriate.

Employers Procedure F - equipment QA, is in place which was found to be a comprehensive and a clear framework for staff to follow.

It was noted there is clear governance and oversight of the equipment QA programme. Staff and management demonstrated understanding of their roles and responsibilities in relation to equipment QA.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced a clear and robust equipment QA programme is in place. The inspection team acknowledge the commitment of staff in this regard.

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

IR(ME)R requires the Employer to establish a procedure to identify correctly the individual to be exposed to ionising radiation. The procedure should specify how and when an individual is to be identified. Employers Procedure A - patient identification is in place. Management and staff described the patient identification process to be followed in the nuclear medicine cardiology department and where this is recorded. Employer's Procedure A although comprehensive did not fully reflect the patient identification process in the nuclear cardiology department therefore an area for improvement has been made on this matter.

Correct identification (ID) of the patient or individual to be exposed is an operator task and must be undertaken prior to any exposure. Management and staff confirmed that it is the responsibility of the operator to ensure the correct patient is being examined against the referral. The operator who is administering the radiopharmaceutical or carrying out the medical exposure has the overall responsibility for identifying each patient prior to making the exposure. They must complete the appropriate ID check on EPIC and sign the administration form.

A three point ID check must be carried out by the operator undertaking the exposure. Staff confirmed that the patient must be asked to state their name, address and date of birth rather than confirm these details. They outlined the following questions:

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

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

- Why are you here?
- Have you been scanned recently?

When the patient is incapable of confirming their ID, the operator must confirm ID by other means. This may include checking the patient ID armband or checking with a relative, nurse or interpreter. It was confirmed that there is a subsequent ID check undertaken prior to the scan for those procedures which require delayed imaging. Staff confirmed that the ID check can be repeated multiple times by different operators as the patient goes through the imaging pathway.

Staff confirmed that the professional guidance on Pause and Check is used and promoted in the nuclear medicine cardiology department. It was good to note that Pause and Check notices were displayed in the department.

For other scenarios, for example such as patients who lack capacity and children, a clear patient ID process was outlined for each situation.

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

A patient ID audit is carried out as part of the annual of IR(ME)R audit and there was a very high compliance level noted.

Staff explained the process followed for discrepancies in the patient ID and it was very clear from responses that the exposure would not be undertaken if the patient ID could not be confirmed.

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

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that clear and robust patient identification processes are in place. Addressing the area for improvement identified will consolidate this approach. 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 SAF and supporting documentation

Administration of radioisotopes

Radiopharmaceuticals are delivered in multi-dose vials from the Regional Radio Pharmacy based on the RVH site, BHSCT. The multi-dose vials are ordered the day before and delivered on the morning of administration.

The activity of individual radiopharmaceutical doses for nuclear medicine cardiology procedures is measured using a calibrated ionisation chamber prior to administration to a patient.

Examination protocols provided outlined the radiopharmaceutical detail and appropriate range of required 'drawn up' activity for each adult nuclear medicine cardiology examination, scan time, Trust Diagnostic Reference Levels (DRLs), appropriate pre and post exam patient care and details of other medication required.

Staff demonstrated how they check and record administered activity within the nuclear medicine cardiology department. A record of dispensed activity in a logbook was examined and whilst it was well completed, it was noted that a staff signature was repeatedly illegible and one column was untitled. An area for improvement has been identified to ensure clear and accurate completion of the Dispensing of Radioisotopes log and consider the inclusion of a signature list of operators who administer/dispense radiopharmaceuticals so that it is clearly identifiable who the entitled operator is that has carried out that operator function.

In addition to the above log, an electronic record is completed on EPIC. It was confirmed that there are always two operators involved in dispensing and administering activity for witnessing and verifying purposes. It was also confirmed that administered activity is within the diagnostic DRLs and staff were aware of the use of DRLs. The DRLs were displayed on the wall in the dispensing room and it was positive to note that local DRLs had been established considerably below the national DRLs. The DRLs are calculated using a body mass index (BMI). Management and staff described how the BMI is calculated. The patient's weight and height is measured when they arrive for appointment and a BMI calculation is performed using an online calculator.

It was positive to note that current local DRLs are based on optimisation conducted as part of gamma camera commissioning. This included a visual assessment of image quality and the number of counts per pixel achieved. Furthermore, cross comparisons of phantom data from the previous gamma camera to the current gamma camera were conducted as well as the assessment of patient scan data. Local DRLs are reviewed at the IOT meeting.

Management and staff confirmed that where there is an overlap of BMI values in the local DRLs the lower activity range is selected. The licensed practitioner and the team lead cardiac clinical physiologist stated that the range of activities was easier to interpret and worked locally for staff better than having a fixed activity value and +/-10 % range. However, clear use of the local DRL table was not outlined on the DRL document and an area for improvement has been identified to update the local DRL document to ensure sufficient detail is included on how to use BMI ranges and include a review date on the local DRL form.

Research

The nuclear medicine cardiology department have not been involved in research. On discussion management outlined that there is currently no option to flag a referral for a research study on EPIC. The employer (site) and practitioner licences include ARSAC approval for research. It was advised to incorporate a mechanism on EPIC for identifying research approval and ensure staff are familiar with requirements and employer's procedure for research referral arrangements in the event of receiving one.

6.0 Conclusion

There were 17 areas improvement identified as a result of this inspection. This is 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 nuclear medicine 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	17

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 **Stated:** First time **To be completed by:** 28 April 2026	The Employer must establish regular formal meetings with clear terms of reference between the nuclear medicine cardiology service and the radio pharmacy department and ensure these meetings are fully minuted. Ref 5.2.1
	Response by Employer detailing the actions taken: Contacted Radiopharmacy head of service and biannual meeting schedule will be arranged with clear terms of reference and fully minuted. First meeting proposed for May 2026.
Area for improvement 2 **Ref:** Regulation 6 Schedule 2(1)(b) **Stated:** First time **To be completed by:** 28 April 2026	The Employer must ensure the following: • the document "Competencies for Entitlement as a Duty Holder under IR(ME)R at BSHCT" lists IR(ME)R functions only • Operator functions on the MPE entitlement form should specify nuclear medicine cardiology as part of their scope of practice • the lead consultant cardiologist for nuclear medicine (licensed practitioner) entitlement form should include the duty holder role of referrer for nuclear medicine cardiology with a defined scope of practice • the entitlement forms should have a dedicated space for entitlement review Ref 5.2.1
	Response by Employer detailing the actions taken: (i) Operator entitlement form amended to reflect IR (ME) R functions only. New document attached. (ii) Operator functions carried out within the cardiology department will be added to the IRMER entitlement form for the MPE (iii) The entitlement form for the Practitioner includes the 'referrer' duties. (iv) An additional table for formal documentation of entitlement review has been added (document attached)
Area for improvement 3 **Ref:** Regulation 6 Schedule 2(1)(b)	The Employer must establish a centralised overarching mechanism for recording entitlement such as a spreadsheet or electronic matrix. This would allow for auditing and offer reassurance to the Employer on the robustness of the entitlement arrangements.

Stated: First time **To be completed by:** 28 April 2026	Ref 5.2.1
	Response by Employer detailing the actions taken: Excel spreadsheet has been created, detailing all entitled staff,with review date identified every 12months. This will be reviewed by the Nuclear Cardiology Service Cardiac Physiologist Lead annually and is included within Nuclear Cardiology annual IR (ME) R audit schedule.
Area for improvement 4 **Ref:** Regulation 6(5)(a) and Schedule 2(1)(b) **Stated:** First time **To be completed by:** 28 April 2026	The Employer must ensure: • that written referral guidelines are in place for nuclear medicine cardiology scans and that they are made available to referrers • If medical/cardiology staff from the SEHSCT are to be entitled to refer to nuclear medicine cardiology scans, then update "Medical Staff from South Eastern Health and Social Care Trust Group Entitlement Form" to specify nuclear medicine cardiology and include details to identify referrers. Ref 5.2.1
	Response by Employer detailing the actions taken: (i) Formal referral guidelines are attached to this reponse. These have been disseminated to referrers, and are reflected in the categories listed on the electronic request form on EPIC. The guidelines have also been sent to the cardiology lead in SEHSCT for dissemination to referrers there. (ii) This requirement has been discussed with the cardiology Lead/Clinical Director in SEHSCT. Appropriate grades of staff who can act as referrers have been clarified. The required documentation is being prepared in SEHSCT and will be taken through the appropriate committees for approval.It is likely to be a little time before this has been finally signed off.
Area for improvement 5 **Ref:** Regulation 7 **Stated:** First time **To be completed by:** 28 April 2026	The Employer must: • ensure clarity on what is a clinical audit and an IR(ME)R audit • establish a robust nuclear medicine cardiology clinical audit schedule • implement standardised audit template for recording objectives, methodology, outcomes of clinical audits and how outcomes and learning have been disseminated Ref 5.2.1
	Response by Employer detailing the actions taken: (i) and (ii) A clinical audit schedule form has been agreed and the first 3 planned audits for 2026 listed. This is appended. (ii) An audit template has been agreed and implemented. The first clinical audit for 2026 has been carried out and reported using the template. This is appended.

Area for improvement 6 **Ref:** Regulation 6(2) **Stated:** First time **To be completed by:** 28 April 2026	The Employer must strengthen IR(ME)R audit as follows: • implement a rolling programme for IR(ME)R audit to ensure a more robust approach to assess practice and ensure assurance can be provided to the Employer on IR(ME)R compliance • involve the wider team in the audit process • establish an IR(ME)R audit form/template to formalise the approach and track actions appropriately • consider introducing observational audit Ref 5.2.1
	Response by Employer detailing the actions taken: A more detailed IR (ME) R annual audit schedule has been created, clearly defining the audit title and the audit target date (2026 schedule appended). This schedule also clearly identifies staff who will complete the audit to ensure wider team involvement. An audit template has been agreed and implemented (sample QTR 4 2025 DRL compliance audit appended).
Area for improvement 7 **Ref:** Regulation 8 **Stated:** First time **To be completed by:** 28 April 2026	The Employer must re-evaluate and review the use of the nuclear medicine cardiology internal incident log. Ref 5.2.1
	Response by Employer detailing the actions taken: The incident log has been reviewed. There is now a separate log where all IR (ME) R related incidents will be listed. This includes for each incident whether a Datix was generated, whether the incident was reportable to RQIA, and whether the findings/learning from the incident have been discussed at the Image Optimisation Team meeting and disseminated to staff. All incidents related to cardiology issues have been removed and are recorded separately. The log gives oversight of all IR (ME) R related incidents. A blank copy is appended.
Area for improvement 8 **Ref:** Regulation 6(4) **Stated:** First time **To be completed by:** 28 April 2026	The Employer must review and amend the standard operating procedures (SOP) as follows: • references to radiopharmaceuticals not in use by the service should be removed from the SOPs • SOP should have sufficient details included for stress protocol especially where administration of a prescription only medicine (POM) for example, Regadenoson, is used. This can be within or as a separate protocol but should be suitably referenced in the SOP and include detailed administration instructions • ensure IR(ME)R terminology is accurately used in the SOP Ref 5.2.1

	Response by Employer detailing the actions taken: Standard Operating Procedure has been reviewed and updated in line with the recommendations. It is included within Appendix.
Area for improvement 9 **Ref:** Regulation 11, 11(5) **Stated:** First time **To be completed by:** 28 April 2026	The Employer must ensure all practitioners who justify nuclear medicine cardiology procedures are entitled to do so and have issued appropriate authorisation guidelines. Ref 5.2.2
	Response by Employer detailing the actions taken: Guidelines have been issued (see point 10 below) and all staff have been made aware of appropriate roles under IRMER. Of note, this inspection report (on page 12) indicates that in the absence of the usual practitioner, another cardiologist acts in this role. In fact, it is a Nuclear Medicine Radiologist who carries out this role, and not a cardiologist. A meeting has been arranged to ensure that this is clearly reflected in the entitlements and authorisation guidelines.
Area for improvement 10 **Ref:** Regulation 11(5) **Stated:** First time **To be completed by:** 28 April 2026	The Employer must establish and implement clear authorisation guidelines (issued by practitioner) to facilitate authorisation to be carried out by an appropriately entitled IR(ME)R operator. Consider referencing entitlement rather than named individuals in the authorisation guidelines. Ref 5.2.2
	Response by Employer detailing the actions taken: The authorisation guidelines have been rewritten and discussed with staff, including the correct operation of the authorisation process. The authorisation guidelines are appended.
Area for improvement 11 **Ref:** Regulation 11 **Stated:** First time **To be completed by:** 28 April 2026	The Employer must review and update the “justification flowchart” to ensure that it is in accordance with IR(ME)R requirements of who can justify and authorise exposures. The service should consider whether this flow chart is required. Ref 5.2.2
	Response by Employer detailing the actions taken: Following discussion it has been decided that the flowchart is not required and has been withdrawn.
Area for improvement 12 **Ref:** Regulation 17 **Stated:** First time	The Employer must ensure staff receive bespoke IR(ME)R training regarding duty holder roles and responsibilities and how this relates to the process of justification and authorisation. Ref 5.2.2

To be completed by: 28 April 2026	**Response by Employer detailing the actions taken**: Training has been provided by the medical physics team and a Q+A session was also provided. The training specifically linked the IR (ME) R regulations to the processes within the department. A sample of training certificates is appended.
Area for improvement 13 **Ref:** Regulation 11(5) **Stated:** First time **To be completed by:** 28 April 2026	The Employer must review and update the document "Delegation of authorisation for medical exposures to carers and comforters" to ensure correct IR(ME)R terminology is used. Ref 5.2.2
	Response by Employer detailing the actions taken: This document has been reviewed and edited appropriately. The updated version is appended.
Area for improvement 14 **Ref:** Regulation 11 **Stated:** First time **To be completed by:** 28 April 2026	The Employer must ensure breastfeeding patients are included in the authorisation guidelines as requiring justification by the licensed practitioner. Ref 5.2.2
	Response by Employer detailing the actions taken: This has been included in the latest version which is appended.
Area for improvement 15 **Ref:** Regulation 6 Schedule 2(1)(a) **Stated:** First time **To be completed by:** 28 April 2026	The Employer must amend Employer's Procedure A to ensure it fully reflects the patient identification process in the nuclear medicine cardiology department. Ref 5.2.4
	Response by Employer detailing the actions taken: Employer's Procedure A refers to patient identification process. An amendment to this procedure has been requested to reflect Nuclear Cardiology process and how it is documented on the electronic patient record system. This will take time to be amended and approved through the appropriate Trust committees.
Area for improvement 16 **Ref:** Regulation 10(4) **Stated:** First time **To be completed by:** 28 April 2026	The Employer must ensure clear and accurate completion of the Dispensing of Radioisotopes log and consider the inclusion of a signature list of operators who administer/dispense radiopharmaceuticals so that it is clearly identifiable who the entitled operator is that has carried out these operator functions. Ref 5.2.5

	Response by Employer detailing the actions taken: A new dispensing radioisotope log has been implemented. This also includes a list of entitled operators signatures. A copy of dispensing log is appended.
Area for improvement 17 **Ref:** Regulation 6(5)(a) **Stated:** First time **To be completed by:** 28 April 2026	The Employer must update the local DRL document to ensure sufficient detail is included on how to use BMI ranges and include a review date on the local DRL form. Ref 5.2.5
	Response by Employer detailing the actions taken: The DRL document has been updated. The BMI range has been slightly altered to ensure there is no overlap between categories which has led to improved clarity for operators. Further instruction about matching the activity on days 1 and 2 has been added. A review table has been added. The document has been appended

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