

Inspection Report

9 June and 10 July 2026



Royal Belfast Hospital for Sick Children Nuclear Medicine Department

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Assurance, Challenge and Improvement in Health and Social Care

Information on legislation and standards underpinning inspections can be found on our website <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 (BHSC)	Department Inspected: Royal Belfast Hospital for Sick Children (RBHSC) – Nuclear Medicine Department
Name of Employer: Ms Jennifer Welsh Chief Executive for the BHSC	Interim Imaging Service Manager BHSC (ISM): Mr Gary Burke
Brief description of how the service operates: The RBHSC Nuclear Medicine department provides a paediatric service Monday to Friday between 9am and 5pm. There is no out of hours provision. The paediatric nuclear medicine service receives referrals from within the BHSC and regionally as required. Prior to the inspection Mr Burke, ISM and his team were requested to complete a self-assessment form (SAF). The submitted SAF confirmed that for the last year 417 Planar/dynamic nuclear medicine imaging procedures were carried out. This included DMSA, MAG3, thyroid, gastric (Meckels), whole body planar bone imaging and whole body planar MIBG. Nuclear medicine therapy is not provided by this department. The RBHSC Nuclear Medicine 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 RBHSC nuclear medicine department. However, it was noted that the employer's licence included a range of nuclear medicine services that are not currently provided in this department. It was advised to consider when applying for future licences, limiting the application to those nuclear medicine services that it currently provides in the department. Currently one consultant radiologist acts principally as the licenced practitioner for the nuclear medicine service, with cover provided when required by another licenced practitioner. The radioisotopes routinely used within the department for nuclear medicine services are unsealed radionuclides: Tc-99m and I-123. Within the department, there is one gamma camera, a dose calibrator and a laminar flow cabinet. The department is staffed by 0.3 whole time equivalent (WTE) consultant radiologists (includes practitioner licence holders), 0.4 WTE band 7 radiographer, one WTE band 6 radiographer and five rotational radiographers. The service is supported by Medical Physics Experts (MPEs) specialising in nuclear medicine from BHSC Medical Physics Service. The BHSC Head of Radioisotopes supports the service in relation to the Administration of Radioactive Substances Advisory Committee (ARSAC) licencing arrangements. The Royal Victoria Hospital Radiopharmacy dispenses the radioisotopes to the service.	

2.0 Inspection summary

On 10 June 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 on-site IR(ME)R inspection of RBHSC nuclear medicine department, as part of RQIA's IR(ME)R inspection programme. However, during the morning of the inspection on 10 June 2026 concerns were raised in relation to potential civil unrest in the vicinity of the Royal Group of Hospitals which was reportedly planned from 1pm onwards. Following consultation with senior management in the BHSC and RQIA it was agreed the inspection would be halted at 10 June 2026 at 12.30pm and be completed remotely at a later date. Subsequently, a remote inspection via Microsoft (MS) Teams was carried out on 9 July 2026.

The inspection focused on the key themes for the 2026/27 inspection year:

- 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 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 the 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 areas of 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 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 department, patients were awaiting or immediately recovering from diagnostic procedures, it was deemed inappropriate to seek to speak to these patients or their representatives 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 11 March 2021		
Action required to ensure compliance with The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018		Validation of compliance
Area for Improvement 1 Regulation 6 (5) (c) Stated: First time	The Employer shall ensure DRLs provide clarity and state +/- 10% of the scaled DRL	Met
	Action taken as confirmed during the inspection: Management had confirmed that the RBHSC 'Protocol for dispensing and intravenous administration of radioisotopes to paediatric patients by nuclear medicine radiographers' and Employer's Procedure G have been amended to include +/- 10 % of the scaled DRL to ensure clarity.	
Area for Improvement 2 Regulation: 8 (4) Stated: First time	The Employer shall amend the Employer's Procedure L to include the SAUE guidance for the reporting of incidents and the timeframes for reporting and providing information to the Regulatory Authority.	Met
	Action taken as confirmed during the inspection: Employers Procedure L has been amended to include the SAUE guidance for the reporting of incidents and the timeframes for reporting and providing information to the regulatory authority.	

Area for Improvement 3 Regulation: 8 (4) Schedule 2 (1) k Stated: First time	The Employer shall ensure that the reporting, investigating, shared learning and governance of incidents and near misses in nuclear medicine and wider radiology departments are in accordance with the relevant Employer's Procedures and legislation. Action taken as confirmed during the inspection: Employers Procedure L has been updated to include the SAUE guidance and timelines for reporting. The Radiation Incident Governance Group (RIGG) Terms of reference have been updated to include nuclear medicine services. The 'Procedure for reporting and investigating incidents' has been amended to include RBHSC nuclear medicine services.	Met
Area for improvement 4 Regulation: 17 Stated: First time	The Employer shall ensure training records for Consultant Radiologists are used to underpin entitlement; and ensure that they are made available for inspection. Action taken as confirmed during the inspection: Management and staff confirmed that training records for all duty holders are used to underpin entitlement; and are made available for inspection.	
Area for improvement 5 Regulation 6 (1) (a) Stated: First time	The Employer shall ratify and issue the draft Employer's Procedures. Action taken as confirmed during the inspection: The most recent version of the Employers procedures were in place which had been ratified and approved 17 June 2025.	Met

Area for improvement 6 Regulation: 11 (5) Stated: First time	The Employer shall amend the authorisation guidelines as outlined in section 7.5.1. (11 March 2021 inspection report)	Met
	Action taken as confirmed during the inspection: Authorisation guidelines were in place and have been updated in line with guidance outlined in the March 2021 inspection. This area of improvement has been met. Further discussion on authorisation guidelines can be found within section 5.2.1 of this report.	
Area for improvement 7 Regulation 15 (3) Stated: First time	The Employer shall review the frequency of the extrinsic uniformity QA testing to ensure it is in accordance with best practice and current guidance.	Met
	Action taken as confirmed during the inspection: Review of QA testing records and discussion with staff confirmed that extrinsic uniformity QA testing is in accordance with best practice and current guidance.	
Area for improvement 8 Regulation 15 (3) Stated: First time	The Employer shall ensure all radiology equipment is fully commissioned prior to use with patients.	Met
	Action taken as confirmed during the inspection: Management and staff confirmed all radiology equipment is fully commissioned prior to use with patients.	

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 BHSCT 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 Chief Executive, as IR(ME)R Employer, holds overall responsibility for entitlement. The task of entitlement is formally delegated by the Employer to named senior staff including, clinical directors, clinical leads, clinical service managers and senior managers.

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 and the entitling individual. This process is documented on individual entitlement forms or under group entitlement records.

Evidence of induction, training, competency and continuing professional development for radiographers and consultant radiologists 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 radiologists, radiographers, clinical scientists and non-medical referrers (NMRs) were reviewed. A group entitlement record for BHSCT medical practitioners was also reviewed. The entitlement records were overall well completed.

Radiographers

Radiographers have individual entitlement records with clear signed competency in accordance with the duty holder roles and a defined scope of practice within the nuclear medicine department. There was evidence of annual review of individual entitlement arrangements. Radiographers are entitled as operators for a range of operator functions by the site lead. They have undertaken specific training and assessment of competency for this role. Operators have been entitled to carry out the task of authorising nuclear medicine procedures under authorisation guidelines. Review of the authorisation guidelines noted that they require further development to provide clear instructions in relation to authorisation of nuclear medicine procedures. An area of improvement has been made on this matter

Staff demonstrated understanding of their duty roles and responsibilities. They confirmed they felt well supported to carry out their duty holder duties. Entitlement was found to be carried out as outlined in Employers Procedure B.

Consultant Radiologists

Consultant Radiologists are entitled through a process aligned with that used for radiographers. There are two entitled licensed practitioners for the paediatric nuclear medicine service. They had individual entitlement records outlining a clear scope of practice in line with their licensing arrangements and are entitled by the clinical director of radiology.

Clinical scientists/MPEs

One clinical scientist/MPE entitlement records were reviewed. They had been entitled by the Head of Radioisotopes. The entitlement records outlined evidence of competency assessment and a clear comprehensive scope of practice in line with the paediatric nuclear medicine service. They were subject to annual review and it was noted there was evidence of an updated scope of practice.

Non-Medical Referrers

A clear process of entitlement of non-medical referrers (NMRs) was demonstrated. There are two entitled NMRs with a defined scope of practice for the paediatric nuclear medicine. They receive formal written confirmation of their entitled scope of practice. The entitlement process requires completion of an application supported by evidence of IR(ME)R training, which is delivered via an online regional training platform. The application is submitted to the modality lead consultant radiologist for review and approval. Following this, the application is sent to the chair of the radiation protection committee for formal entitlement. Once entitled, the individual's name is added to a central database, which is accessible to all staff. 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.

Team leads are responsible for ensuring all staff within their teams have appropriate entitlement and this is reviewed annually during appraisal. Entitlement was found to be carried out as outlined in Employer's Procedure B.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced there are robust entitlement arrangements within the nuclear medicine department. It is hoped the area of improvement identified, will assist in relation to clear authorisation guidance to entitled operators. 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 is 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 nuclear medicine service has an underpinned culture of quality improvement. Management and staff demonstrated an inclusive, enthusiastic and proactive approach to patient-centred service improvement.

Management and staff described the process of clinical audit. One of the licensed practitioners for the paediatric nuclear medicine service leads on the clinical audit programme. The RBHSC Nuclear Medicine Clinical Audit Schedule 2026 was in place.

The clinical audit schedule is planned from initial suggestions through departmental, medical physics or radiology meetings. Specific departmental clinical audits are then discussed and planned at the Image Optimisation Team meeting.

Depending on the type of clinical audit, duty holders involved may include operators (radiographers), practitioners (radiologists) and referrers who will be involved at different stages.

A range of clinical audits were reviewed. A robust clinical audit template was in place to ensure consistency of approach in carrying out and recording clinical audits. A clear action plan was implemented. The results of the audits are shared with the relevant teams via huddles and through education sessions as required. Clinical audit outcomes are discussed and any actions agreed at the IOT meeting. Learning from audit is cascaded at departmental meetings. Audit results are also available to RBHSC staff on the RBHSC departmental Microsoft Teams channel. Audit results & corrective measures (where applicable) are also shared with relevant stakeholders other than the radiography team. A radiology audit meeting is held monthly where a variety of clinical audits are presented. Management confirmed all modality consultant radiologists are involved with this. Overall there is a well-developed clinical audit programme. However, there is no written procedure in relation to clinical audit and it was suggested to establish a clinical audit procedure to provide a robust framework for management and staff to follow for this important component of service improvement.

IR(ME)R Audit

There is a nuclear medicine IR(ME)R audit schedule which occurs over a 12-month period. This schedule outlines the range of audits which must be completed biannually and annually by nuclear medicine radiographers (operators). The Governance and QSI team maintain a dedicated audit record channel on MS Teams, where completed audits are shared. A gap analysis tool is also available on the same Microsoft Teams which allows the area service managers and the lead QSI radiographer to overview compliance of audits, the audit schedule and outcomes.

The audit schedule is reviewed annually to identify if the schedule remains appropriate or amendments are required. The frequency of each audit depends on the audit topic. The audit schedule is a 12-month rolling schedule. Where variation in compliance is noted, re-audit occurs within 1-3 months. Completion of the audit action plan is overseen by the audit co-ordinator designated for the department and Nuclear Medicine Lead Radiographer.

Audit outcomes are shared via email with the relevant stakeholders. Outcome findings are cascaded at departmental huddles and team meetings/IOTS/bimonthly modality meetings and includes all modalities in radiology. Staff confirmed they are aware of IR(ME)R audits and that the findings are shared with them including any resultant changes to practice.

A review of a number of IR(ME)R audits noted that overall they were well completed. However, there was some ambiguity and inconsistency in exactly what benchmarks and methodology were being used within the audits. An area of improvement has been identified to ensure clear and consistent benchmarks and methodology are fully outlined in the IR(ME)R audits.

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

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

Diagnostic reference levels (DRLs) are defined as radiation dose levels, or for Nuclear Medicine the administered activity, for typical diagnostic examinations for groups of standard size adults and paediatrics for broadly defined types of equipment.

They are not expected to be exceeded when good and normal practice regarding diagnostic and technical performance is applied. DRLs should be used with professional judgement, and all operators must be familiar with and be trained in their appropriate use.

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.

The BHSCT have established local DRLs which are based on the DRLs quoted in the ARSAC Notes for Guidance (March 2025).

Provided for review with the completed SAF was "Appendix 3 RBHSC NM DRL Table", which is also present in the document "RBHSC Protocol for dispensing and intravenous administration of Radioisotopes to Paediatric patients by nuclear medicine Radiographers" as the local DRLs. However, also included in the document "RBHSC Protocol for dispensing and intravenous administration of Radioisotopes to Paediatric patients by nuclear medicine Radiographers" and on display in the injection room were the tables "Appendix 1-RBHSC NM Paediatric Isotope Activity" and "Appendix 2 "RBHSC NM Paediatric Isotope Activity". Clarity was sought on the use of all the tables in the appendices provided. Staff outlined that "Appendix 1-RBHSC NM Paediatric Isotope Activity" was devised to enable staff dispensing to find the correct activity without needing to do a manual calculation and that they find this better to use than "Appendix 3- RBHSC NM DRL Table".

For paediatric patients, the adult radiopharmaceutical DRL is scaled according to the table of weight based child scaling factors given in the ARSAC Notes for Guidance, this table has been reproduced locally as Appendix 2 "RBHSC NM Paediatric Isotope Activity".

Staff were asked how they interpolate between weight ranges provided in "Appendix 1- RBHSC NM Paediatric Isotope Activity" for example a paediatric patient weighing 9 kg. It was confirmed that they would usually round down i.e. use the lower weight category, and, on some occasions, they have calculated a value in the middle. It was advised that the approach is documented in Appendix 1 to ensure a consistent approach is used by all staff.

An Area of Improvement has been identified in relation to DRLs:

- to clarify the use of appendix 1, 2 and 3 in document “RBHSC Protocol for dispensing and intravenous administration of Radioisotopes to Paediatric patients by nuclear medicine Radiographers” in order to make clear, which document is considered and is used by operators as the local DRLs.
- to include a statement in Appendix 1 on how operators should interpolate between weight categories, so there is consistent approach between operators.

If the Licensed Practitioner and MPE decide that there is adequate scientific and clinical justification for setting the local radiopharmaceutical DRL at a higher level than that in the ARSAC Notes for Guidance, then this decision must be discussed and approved through the Trust Diagnostic Radiology and Nuclear Medicine Committee. These decisions must be documented in a local procedure.

Staff confirmed that if it was noted DRLs are routinely exceeded a Datix would be raised and medical physics would be contacted. The investigation would include whether there were drawing up errors or if route cause was from procedure. Lead NM radiographer would check with the MPE that the DRL table is correct. The dispensing and administration log is used for audit to ensure DRLs are not exceeded. Dose audits are scheduled periodically in line with the IR(ME)R dose audit schedule. Data is collected retrospectively from Northern Ireland Picture Archiving and Communication System (NIPACS). Key parameters recorded include patient age, weight, clinical indication, radiopharmaceutical administered activity and protocol (including scaling method). It was advised to ensure the DRLs audits set out clear benchmarks in particular whether compliance is measured against LDRLs or ARSAC guidance. Management provided assurances on this matter.

Dose constraints for Carers and Comforters (C&Cs)

A C&C form is completed for individual C&Cs, this is scanned onto the patient record. A dose constraint for C&Cs is outlined in Employer’s Procedure M. Staff confirmed that if a paediatric patient requires support over multiple appointments/exposures they try to share the C&C role between two caregivers (i.e. both parents/guardians).

The MPE also outlined measures they have proposed for those C&Cs who return on multiple occasions. This included recording the dose received by the C&C from each appointment using for example an electric personal dosimeter (epd). The MPE also stated that they can be contacted by the local department for advice. However, this valuable approach was not within any written procedures. An area of Improvement has been identified to update local written procedures to include measures taken/required to ensure C&C exposure are within annual dose constraint.

There is an annual audit to ensure that C&C forms have been scanned onto SETRA.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced there are well developed processes in place for the establishing, implementing and reviewing of DRLs. The area of improvement identified 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. This is supported with service documentation, a radiation incident investigation form (RIIF), near miss form and the radiation incident action plan (RIAP). The individual involved will complete the Datix form and inform the modality lead. The local manager/modality lead immediately reports the radiation exposure event to the service area manager and MPE via DATIX and email. Where appropriate the Assistant Service Manager immediately notifies RQIA following advice from the MPE. For incidents which are not clearly identified as notifiable incidents the service area manager will be advised by the MPE by email as to whether the incident is notifiable to RQIA. In the case that the incident is determined to be notifiable the service area manager will notify RQIA within one week of receiving advice from the MPE. The MPE will also advise to whether it needs to be considered as a 'clinically significant' exposure.

The Assistant Service Manager will inform the Chair of the RPC, Chair of Division, Divisional Co-Director and the Clinical Director of the service area, of the notifiable incident. Where appropriate the local manager responsible or service area manager begins local preliminary investigations and actions as applicable. This is recorded on the radiation incident investigation form (RIIF) and the radiation incident action plan (RIAP).

The local manager/modality lead ensures the radiation incident has been added to the radiation incident tracker log on MS Teams. This log is on MS Teams only and has controlled access (modality leads, divisional and governance leads), consultants can access but cannot edit entries. There are quarterly audits to ensure the log matches records that are on Datix. The incident tracker log was found to be an excellent tool to scrutinise, monitor and provide robust oversight of radiology incidents and near misses. However, this key valuable element of managing incidents and near misses is not reflected in the written Employer's Procedures and an area of improvement has been identified to update written Employers Procedures to reflect use of the incident log tracker.

The Radiation Incident Governance Group (RIGG) meets weekly. As part of the agenda, all new radiation incidents which occurred in the 7 days prior are reviewed, as well as review on ongoing incidents. The minutes from RIGG are shared at the weekly divisional governance huddle, which is chaired by the Co-Director and Chair of Division.

Radiation incidents are discussed at departmental staff meetings to provide learning and a forum to discuss follow up actions. Wider learning with other departments may be shared via a learning letter, after discussion at the weekly divisional governance meeting in accordance with the BHSCT policy for shared learning.

Review of the incidents and trend analysis found that some work has been undertaken on the system based approach of investigations. However, there remains a 'duty-holder blame' approach in place, with operator error or referrer error routinely outlined as the reason for the occurrence of the incident. Management acknowledged that they were aware of the limitations of this process. Discussions took place on moving away from this process to a more systems-based approach to incident and near miss investigation and analysis. To support the work already in place, an area of improvement has been identified to develop a robust systems-based approach including the development of templates to support the management of incidents, to ensure meaningful findings and shared learning.

A policy and procedure for the reporting and investigating of IR(ME)R incidents is in place. The objective of this procedure is to ensure that the Trust investigates all accidental or unintended medical exposures to ionising radiation and where the BHSCT IR(ME)R employer knows or thinks that it is significant, the incident is investigated and reported to RQIA.

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 the ongoing development of a more system-based approach to investigation of incidents and hope the area of improvement will assist on this matter. The inspection team acknowledge the commitment of staff in this regard.

5.2.5 Does the service adhere to legislation and best practice for the administration of radioisotopes?

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.

Once received the vials are removed from the secured case and checked for any signs of damage. The amount and type of radiopharmaceutical in each vial is checked then recorded in the 'RBHSC Nuclear Medicine record of material received and dispensed'. Each dose is then stored in the department's lead lined cupboard until it is required. When it is required, it is transferred from the blue container it was transported in, into the silver lead lined dispensing pot. If there is more than one radiopharmaceutical present on that day, then the one that is no longer needed is either stored in the lead lined cupboard or disposed of.

Where possible a variety of examinations is avoided on a scheduled list to reduce the risk of administering the incorrect radiopharmaceutical. Occasionally an urgent study is required, which would vary from the scheduled examination list. On this occasion, the urgent study would be scheduled at the point of a significant gap on the worklist to minimise the risk of confusion amongst operators.

Dispensing and administration is performed in accordance with the 'RBHSC protocol for dispensing and IV administration of Radioisotopes to Paediatric patients'.

It was confirmed that all radiopharmaceuticals must be checked by a second operator after dispensing to include a check for both radiopharmaceutical type and activity dispensed. This is evidenced in the 'Patient Dispensing and Acquisition Form', where both operators must sign to confirm they have checked the radiopharmaceutical and dispensed activity. Review of these forms found them to be well completed. However, it was noted that Employer's Procedure G, for the assessment patient dose and administered activity and the 'RBHSC protocol for dispensing and IV administration of radioisotopes to paediatric patients' did not reflect the second operator check. An area of improvement has been made in this regard.

The activity of the prepared radiopharmaceutical is measured using a calibrated ionisation chamber prior to administration to a patient. Measured activities for diagnostic nuclear medicine procedures are recorded in the patient encounter in Encompass and on the examination administration form and dispensing log. Staff confirmed that 'transcription errors' audits were regularly conducted i.e. when conducting audits of dispensing and administration log if any values looked unusual, they would check paper records for transcription errors.

The arrangements for the administration of radioisotopes outside of the nuclear medicine department such as at ward level were reviewed. The nuclear medicine arrangements are made with the ward prior to the examination to ensure they are aware of the nature of the examination, possible precautions that are needed and that the patient has patent intravenous (IV) access available. Once confirmation of patient IV access is confirmed, a nuclear medicine radiographer confirms the patient's weight with the ward. The radiopharmaceutical is drawn up in line with the 'RBHSC protocol for dispensing and IV administration of Radioisotopes of Paediatric patients'. The radiopharmaceutical is placed into a lead lined syringe shield and is then placed into the lead lined carrier. It was confirmed a minimum of two entitled operators who have drawn up the radioisotope then go to the ward with the lead lined carrier to administer the dose.

Patients' location is confirmed and confirmation is sought from allocated nurse to ensure understanding of what the examination entails. Patient ID is checked with the patient via the patient's armband and verbally with parents or nurse depending on who is present. All relevant documentation is filled out, (C&C form, patient acquisition form, LMP if required). The radiopharmaceutical is administered in accordance with the relevant protocol. All radioactive waste at this time is transported back in the lead lined carrier and disposed of within the nuclear medicine department.

The ward is provided with an inpatient aftercare advice sheet. The sheet provides a warning sign which must be visible on the patient's clipboard to ensure staff are informed.

Contact details of the nuclear medicine department are provided, if there are any additional queries. The ward staff are then given a time to take the patient to the nuclear medicine department for the scan.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced there are clear well understood procedures in place for the safe administration of radioisotopes. The area of improvement identified will assist in this matter. The inspection team acknowledge the commitment of staff in this regard

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

Patient identification (ID)

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 and provides a clear comprehensive framework for staff to follow. Correct identification (ID) of the patient or individual to be exposed is an operator task and must be undertaken prior to any exposure.

Management and staff confirmed that it is the responsibility of the operator to ensure the correct patient is being examined against the referral. Whilst multiple staff may be involved with the patient, the responsibility for correct ID lies with the operator who administers the radioisotope to the patient.

Staff confirmed that the operator must always check the patient's name, address and date of birth on the referral on RIS. 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 as stated in Employer's Procedure A are also carried out such as:

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

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

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

However, it was not clear where supplementary safety checks are recorded and Employer's Procedure A did not include this information. An area of improvement has been identified to amend section 4 of Employer's Procedure A- patient identification, to include where supplementary safety checks are documented.

Clinical Evaluation

Clinical evaluation involves the assessment of an image and the documentation by a suitably trained and entitled operator. Entitled consultant radiologists undertake clinical evaluations with appropriate training and experience. All clinical reports are stored with the patient record in PACS. Management and staff confirmed a written radiology report is provided for all nuclear medicine studies.

All patient records reviewed had clinical evaluation on PACS and consultants conduct clinical evaluation in a timely fashion after scans. The process of clinical evaluation and adherence to the employer's procedures should be assessed by audit. It was noted that clinical evaluation for the paediatric nuclear medicine service is not included in the IR(ME)R compliance audit programme. An area of improvement has been identified to include an audit of clinical evaluation completion by appropriate entitled operator within IR(ME)R compliance audit programme.

6.0 Conclusion

There were nine 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 nuclear medicine 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	9
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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 11 (5) Stated: First time To be completed by: 9 October 2026	The Employer must ensure authorisation guidelines are further developed to provide clear instructions in relation to authorisation of nuclear medicine procedures. Ref 5.2.1
	Response by Employer detailing the actions taken: Authorisation Guidelines no longer reference incorrect appendices, and the clarity has been improved by updating all headings to ensure each one reflects the correct section throughout the document.
Area for improvement 2 Ref: Regulation 6 (2) Stated: First time To be completed by: 9 October 2026	The Employer must ensure clear and consistent benchmarks and methodology are fully outlined in the IR(ME)R audits. Ref 5.2.2
	Response by Employer detailing the actions taken: Documentation containing information pertaining to incorrect review period has been archived and is no longer in circulation. Lead Radiographer has undertaken a local review of audit results following inspection and ensured all benchmarks are now upheld.

Area for improvement 3 Ref: Regulations 6 (5) (c), 6 (7) Stated: First time To be completed by: 9 October 2026	The Employer must :- - to clarify the use of appendix 1, 2 and 3 in document “RBHSC Protocol for dispensing and intravenous administration of Radioisotopes to Paediatric patients by nuclear medicine Radiographers” in order to make clear which document is considered and is used by operators as the local DRL. - include a statement in Appendix 1 on how operators should interpolate between weight categories, so there is consistent approach between operators. Ref 5.2.3 Response by Employer detailing the actions taken: Appendix 1 title has been updated along with instruction stating how operators should interpolate between weight categories to ensure a consistent approach. Lead Radiographer has added clearer instruction on how to use each appendix. Medical Physics to review prior to republication to ensure ongoing compliance with IR(ME)R.
Area for improvement 4 Ref: Regulation 6 (3) (ii) Stated: First time To be completed by: 9 October 2026	The Employer must update local written procedures to include measures taken to ensure C&C exposures are within annual dose constraint. Ref 5.2.3 Response by Employer detailing the actions taken: Instruction has been added to local written procedures describing appropriate process for ensuring carer and comforter's cumulative dose remain within annual dose constraints: Prior to proceeding with examination it must be confirmed by operator that the cumulative radiation dose received by the individual acting as comforter and carer remains within the annual dose constraint. If individual acting as comforter and carer is identified as routinely having performed this task, medical physics advice will be sought.
Area for improvement 5 Ref: Regulation 8 Stated: First time To be completed by: 9 October 2026	The Employer must update written Employers Procedures and other relevant written procedures to reflect use of incident log tracker. Ref 5.2.4 Response by Employer detailing the actions taken: Additional information reflecting the use and regular review of the radiation incident log tracker through RIGG meetings will be added to EP L and local policies and procedures. Medical Physics to approve prior to republication to ensure ongoing compliance with IR(ME)R.

Area for improvement 6 Ref: Regulation 8 Stated: First time To be completed by: 9 October 2026	The Employer must develop a robust systems-based approach including the development of templates to support the management of incidents, to ensure meaningful findings and shared learning. Ref 5.2.4 Response by Employer detailing the actions taken: The service has created a new "Learning from Radiation Incidents in Imaging" form. The template includes titled sections as below for highlighting: - Key messages - "Good catches" (near miss) - Summary of themes - "Beyond the numbers" - Changes made - "Looking forward"
Area for improvement 7 Ref: Regulation 6 Schedule 2.1 (j) Stated: First time To be completed by: 9 October 2026	The Employer must ensure that Employers Procedure G, assessment patient dose and administered activity and the 'RBHSC protocol for dispensing and IV administration of radioisotopes to paediatric patients' are updated to reflect the second operator check. Ref 5.2.5 Response by Employer detailing the actions taken: "RBHSC protocol for dispensing and IV administration of radioisotopes to paediatric patients" has been updated to reflect the 2nd operator checks currently performed and recorded. EP G will be reviewed by Medical Physics and updated accordingly to ensure ongoing compliance with IR(ME)R.
Area for improvement 8 Ref: Regulation 6 Schedule 2.1 (a) Stated: First time To be completed by: 9 October 2026	The Employer must amend section 4 of Employers Procedure A- patient identification, to include where supplementary safety checks are documented. Ref 5.2.6 Response by Employer detailing the actions taken: Employer's Procedure A will be reviewed and updated regarding how supplementary safety checks are recorded in conjunction with Medical Physics and Imaging Leads to ensure ongoing compliance with IR(ME)R.

Area for improvement 9 Ref: Regulation 12 (9) Stated: First time To be completed by: 9 October 2026	The Employer must include an audit of clinical evaluation completion by appropriate entitled operator within IR(ME)R compliance audit programme. Ref 5.2.6
	Response by Employer detailing the actions taken: An audit for clinical evaluation completion by an appropriate entitled operator within IR(ME)R has now been added to the IR(ME)R compliance audit schedule for Nuclear Medicine



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