Inspection Report
08 March 2023

Antrim Area Hospital 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: Northern Health and Social Care Trust (NHSCT)	**Department Inspected:** Antrim Area Hospital Nuclear Medicine Department
Name of Employer: Ms Jennifer Welsh Chief Executive Officer (CEO) NHSCT	**Clinical Services Manager Radiology (CSMR):** Mr Matt Mallon
Clinical Director for Radiology NHSCT and IR(ME)R Lead: Dr Eddie Gibson	**Medical Physics Expert:** Mr Conor Ferris

Brief description of how the service operates:

The Antrim Area Hospital Nuclear Medicine department provides an adult and paediatric diagnostic nuclear medicine service Monday to Friday 9am - 5pm. There is no scheduled out of hours' service, however, occasionally the service may remain open beyond 5pm to facilitate a delay in the delivery of radioisotopes and have previously facilitated nuclear medicine waiting list initiatives at the weekend.

Before the inspection Mr Matt Mallon, CSMR, and his team were asked to complete a self-assessment form. The submitted self-assessment confirmed that each year, the Antrim Area Hospital Nuclear Medicine department carried out approximately 2230 planar/dynamic nuclear medicine imaging, 51 parathyroid single photon emission computed tomography (SPECT) imaging, 921 cardiac stress/rest SPECT imaging and sentinel node (breast) probe studies without imaging were carried out.

The nuclear medicine department operates under an Employer's Licence and three Practitioner's Licences that covers the radioisotopes in use and the range of nuclear medicine service provided. The following radioisotopes are routinely used within the department for nuclear medicine: Unsealed radionuclides: Tc-99m and I-123.

There is a dual head gamma camera with SPECT which was noted to be 17 years old, a dose calibrator and four gamma probes. The age of the gamma camera has led to a risk assessed approach to its use and a reduced range of diagnostic nuclear medicine services being provided. However, it was good to note that a planned upgrade of the nuclear medicine department is to be undertaken in June 2023 including the installation of a new SPECT-CT gamma camera which will replace the existing gamma camera.

The department is staffed by 1.725 whole time equivalent (WTE) consultant radiologists and 4.4 WTE radiographers.

The team is supported by a Medical Physics Expert (MPE) contracted from Regional Medical Physics Service (RMPS) based in the Belfast Health and Social Care Trust (BHSCT). The RMPS radiopharmacists provides radiopharmaceuticals from the radiopharmacy department, Royal Victoria Hospital, BHSCT.

2.0 Inspection summary

On 08 March 2023, 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 Antrim Area Hospital nuclear medicine department, as part of RQIA's IR(ME)R inspection programme. Remote IR(ME)R inspections had been conducted for inspection years 2020/21 and 2021/22 in line with COVID -19 restrictions. A decision has been taken to resume site based IR(ME)R inspections for the 2022/23 IR(ME)R inspection programme.

For the 2022/23 inspection year the inspections will focus on four key themes:

- Incident management with a focus on audit/action plans and shared learning
- Optimisation including establishing local Diagnostic Reference Levels (LDRLs)
- Entitlement of staff to include training and competency with a focus on those duty holders outside of the radiology department
- Equipment quality assurance (QA) programmes
- Any other areas identified through the review of the submitted self-assessment form and supporting documentation

The purpose of our focus was to minimise risk to service users and staff, whilst being assured that ionising radiation services were 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 requested to complete and submit a self-assessment form (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
- To carers and comforters

- To asymptomatic individuals
- To 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 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 nuclear medicine 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?

Areas for improvement from the last inspection on 12 March 2020		
Action required to ensure compliance with The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018		**Validation of compliance**
Area for Improvement 1 **Regulation:** 6 (1) (a) Schedule 2 **Stated:** First time	The Employer shall review the Employer's Procedures to ensure that the nuclear medicine service is accurately reflected. **Action taken as confirmed during the inspection**: Employers procedures were noted to accurately reflect the nuclear medicine service. This area of improvement is assessed as met.	**Met**
Area for Improvement 2 **Regulation:** 15 (6) (a) **Stated:** First time	In order to expedite the replacement of the gamma camera the Employer shall ensure that the business case for the replacement of the gamma camera includes the following information: • the potential implication the age of the sole gamma camera might have on the granting of an Employer Licence; • the impact on service delivery, highlighting a number of recent breakdowns; and • the status of this piece of equipment on the risk register. **Action taken as confirmed during the inspection**: A replacement gamma camera has been procured for installation in June 2023. This area for improvement has been assessed as met, further detail is provided in section 5.2.4	**Met**

Area for Improvement 3 **Regulation:** 6 (5) (c) 12 (3) (c) **Stated:** First time	The Employer shall ensure clarification is provided on the Diagnostic Reference Levels (DRLs) in use and share this information with duty holders.	**Met**
	Action taken as confirmed during the inspection: Following the previous inspection, the nuclear medicine DRLs were immediately reviewed and with the involvement of the MPE and the lead radiographer for nuclear medicine. The updated DRLS were ratified by the Image Optimisation Team (IOT) and Radiation Safety Committee. The amendments were circulated to all relevant duty holders and training was provided on their use. DRLs observed on display in the nuclear medicine department were clear and unambiguous. Staff demonstrated a very good understanding of their use. This area for improvement has been assessed as met, further detail on DRLs is provided in section 5.2.3.	
Area for improvement 4 **Regulation:** 7 **Stated:** First time	The Employer shall review how the dose is recorded, consideration should be given to auditing the administered patient dose against the Local DRLs.	**Met**
	Action taken as confirmed during the inspection: Immediately following the RQIA inspection the nuclear medicine lead radiographer reviewed how the patient dose was recorded on the radiology information system (RIS) for a variety of examinations. The nuclear medicine lead radiographer met with the nuclear medicine department staff, to ensure they understood how dose should be recorded on RIS, including the details of the two appropriately trained and entitled operators who check, verify and record the drawn up activity, and the details of the appropriately trained and entitled operator who checks and records the administered activity on RIS.	

	The details of this process have been clearly recorded within Employer's Procedure E: Procedure for the assessment of patient dose and administered activity. An audit is carried out of the administered patient activity against the Local DRLs. This area for improvement has been assessed as met, further detail on DRLs is provided in section 5.2.3.	
Area for improvement 5 **Regulation:** 7 **Stated:** First time	The Employer shall audit the level of residual activities in the syringes as a foundation to make any necessary changes to practice.	**Met**
	Action taken as confirmed during the inspection: A residual activity audit has been incorporated into the Nuclear Medicine Dose Audit. Corrective actions were agreed and implemented in accordance with results, with regards to the appropriateness of the residual activity. It was confirmed that a three-way tap has been introduced which has proven very benefical on the matter of residual activity. This area for improvement has been assessed as met.	
Area for improvement 6 **Regulation:** 8 (4) **Stated:** First time	The Employer shall include in 'Employer's Procedure Q' a quick reference guide such as a flowchart for staff in relation to incident notification.	**Met**
	Action taken as confirmed during the inspection: A reference flowchart has been included in Employer's Procedure Q: Procedure for the reporting of radiation incidents. Employer's Procedures have been ratified by the Radiation Safety Committee.	

	This area for improvement has been assessed as met.	
Area for improvement 7 **Regulation:** 6 (a), Schedule 2 (1) (b) **Stated:** First time	The Employer shall further develop the record of entitlement for radiologists in relation to the tasks associated with the Operator's role.	**Met**
	Action taken as confirmed during the inspection: Entitlement forms for radiologists were noted to reflect their scope of practice and tasks associated with their duty holder's role. This area for improvement has been assessed as met, further detail in relation to entitlement is provided in section 5.2.2.	
Area for improvement 8 **Regulation:** 6 Schedule 2 (1) (b) **Stated:** First time	The Employer shall ensure the evidence of the entitlement record for the Medical Physics Experts (MPEs) is completed and fully understood by the duty holder and the entitler.	**Met**
	Action taken as confirmed during the inspection: There was a group entitlement record for the MPEs which outlined individual MPE's scope of practice. The MPE demonstrated a sound understanding of his duty holder role. This area for improvement has been assessed as met. Further detail is provided in relation to entitlement in section 5.2.3.	
Area for improvement 9 **Regulation:** 6 (5) (a) **Stated:** First time	The Employer shall issue further information on referral guidelines to internal and external Referrers in relation to nuclear medicine.	**Met**
	Action taken as confirmed during the inspection: Referrers are made aware of iRefer and how to access it. General practitioners (GPs) received a formal letter in relation	

	to referrals to the nuclear medicine department. Referrals are audited as part of the nuclear medicine audit programme. This area for improvement has been assessed as met. Further detail on referral guidelines is provided in section 5.2.3.	
Area for improvement 10 **Regulation:** 6 (5) (a) **Stated:** First time	The Employer shall further develop 'Employer's Procedure O' to include more specific detail relating to Nuclear Medicine referral process.	**Met**
	Action taken as confirmed during the inspection: Employer's Procedure O: Procedure for Referral, Justification and Authorisation, has been updated to reflect all appropriate detail regarding nuclear medicine referrals, and access to the nuclear medicine service. This area for improvement has been assessed as met.	
Area for improvement 11 **Regulation:** 11 (5) Schedule 2 (1) (b) Schedule 2 (1) (n) **Stated:** First time	The Employer shall accurately reflect the arrangements for the justification and authorisation of exposures to carers and comforters and ensure that references to multiple Practitioners are removed from the authorisation guidelines.	**Met**
	Action taken as confirmed during the inspection: The authorisation guidelines have been reviewed and updated to reflect the arrangements for the justification and authorisation of exposures to carers and comforters and references to multiple practitioners has been removed. The authorisation guidelines were noted to clearly identify one named practitioner who takes responsibility for the justification of exposures undertaken using the guidelines. Operators have received training on the use of the authorisation guidelines. This area for improvement has been assessed as met.	

Area for improvement 12 **Regulation:** 6 (4) **Stated:** First time	The Employer shall ensure that the written protocols include a specific range of activity that can be administered and are consistent in relation to dosages of concomitant medication.	**Met**
	Action taken as confirmed during the inspection: The imaging protocols include a specific range of activity that can be administered and are consistent in relation to dosages of concomitant medication. This area for improvement has been assessed as met.	
Area for improvement 13 **Regulation:** 14 **Stated:** First time	The Employer shall enhance the role of the MPE within the nuclear medicine department is in accordance to legislation and 'Employer's Procedure P'.	**Met**
	Action taken as confirmed during the inspection: It was confirmed the MPE carries out their role in accordance to legislation and Employer's Procedure P. This includes: attendance at the departmental IOT meetings. • involvement with the procurement of the new nuclear medicine equipment. • involvement with the implementation of new and developing techniques within nuclear medicine. • involvement with the application of the IR(ME)R Employer License. • manufacturer reports and equipment maintenance reports will be sent to the nuclear medicine lead MPE, by the nuclear medicine lead radiographer. • provides advice and guidance as requested as part of the on-going nuclear medicine dose audit.	

	• collates Radiation Risk Assessments to assist in the risk/benefit process with regards to patient exposures, including carers and comforters, in nuclear medicine. • provides training to nuclear medicine staff members with regards to DRL's. • The MPE meets regularly with the lead nuclear medicine radiographer and formally meets at least twice yearly with the lead radiographer, IR(ME)R practitioner and service manager to review the nuclear medicine service. This area for improvement has been assessed as met.	

5.2 Inspection findings

5.2.1 Does the service manage ionising radiation incidents in accordance with the legislation, professional standards and guidance?

Management and clinical staff described the internal process for reporting accidental or unintended exposures and how notifiable incidents are reported to the appropriate enforcing authority.

A review of nuclear medicine incidents evidenced that they had been reported and investigated, with the findings shared, and any necessary action taken to prevent reoccurrence. Discussion on previous reportable significant accidental and unintended exposures noted a robust approach to their management including follow up with all stake holders outside of the nuclear medicine department. This has highlighted the benefit in having formal avenues of communication with such stakeholders to have a joint approach to investigating and learning from nuclear medicine errors. However, it was noted that there was no such formal regular communication with the radiopharmacy department to discuss such matters as errors and ongoing governance arrangements. An area of improvement was identified to establish regular formal communication with the radiopharmacy department for example through planned meetings.

There is a very good culture of incident reporting across all types of incidents: notifiable, non-notifiable and near misses. The investigation of incidents by the Trust showed the identification of learning outcomes and the implementation of safety barriers, as well as providing support for those duty holders involved in the incident.

There is a robust incident reporting procedure which is outlined in Employer's Procedure (EP) Q 'reporting, investigation and learning from radiology errors'.

Through discussion it was clear as to who makes the clinical decision as to when an incident should be classified as clinically significant. It was confirmed that the clinical lead for radiology is responsible for classifying an incident as clinically significant, taking into consideration the medical physics report generated by the MPE. However, EP L, clinically significant accidental and unintended exposures (CSAUE), did not clearly outline the decision making process, who has the responsibility for the decision for confirming a CSAUE and where the details of the CSAUE should be recorded including the patients notes. An area of improvement has been identified to review EP L to ensure it reflects the decision making process, who is responsible for identifying a CSAUE and where the details of the CSAUE should be recorded including in the patients notes.

There was a clear pathway described in relation to the management of incidents. A staff member must report a radiation exposure incident or near misses to the local departmental manager. A DATIX must be completed immediately by the witness directly involved in the incident. The local manager immediately reports the radiation exposure event to the service manager and MPE and updates the DATIX report. Sufficient information on the exposure must be provided to allow the MPE to undertake a dose assessment (for example radiopharmaceutical and activity). The incident review group and invited attendees chaired by the governance lead for radiology have oversight of the management of the incident and ensure all necessary action is taken. They meet weekly to review incidents. The CSMR or assistant CSMR are informed of any potentially reportable incidents. The MPE undertakes a dose and risk assessment and advises the clinical lead and departmental manager of any requirement to notify RQIA of the incident using the "Significant accidental and unintended exposures under IR(ME)R, guidance for employers and duty-holders" (SAUE) guidance.

Where appropriate the local responsible manager begins a local preliminary investigation to include any actions to address issues identified as applicable and documents this on the radiation incident investigation form and the radiation action plan form.

If the cause of the incident is due to an equipment defect or failure, the Northern Ireland Adverse Incident Centre (NIAIC) may also be informed.

It was confirmed there are robust arrangements for the governance and oversight of nuclear medicine incidents. Feedback to staff and management is through the radiology governance systems including quarterly reports to image optimisation teams (IOTs), radiation safety committee, departmental governance meetings and the safety and care quality steering group. Learning from incidents may be shared regionally where appropriate. It was good to note that the quarterly radiology error report includes Clinical Imaging Board (CIB) coding which allows for a more robust trend analysis.

Staff demonstrated a clear understanding of the action to take in the event of an incident occurring and confirmed the arrangements for shared learning.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection, evidenced that the Antrim Area Hospital Nuclear Medicine department have robust arrangements with respect to the management of ionising radiation incidents/near misses and are enthusiastic to ensure these arrangements are regularly reviewed and if necessary improvements are made. The inspection team acknowledge the commitment of staff in this regard.

5.2.2 Does the service have appropriate arrangements in relation to optimisation including establishing local Diagnostic Reference Levels (DRLs)?

Optimisation is a key principle of the radiation protection framework within IR(ME)R. The optimisation process is the joint responsibility of the practitioner, operator and MPE. The aim of optimisation is to achieve the image quality required to answer the clinical question using the lowest dose possible.

Staff and management outlined a range of measures in place to ensure that medical exposures are kept as low as reasonably practicable (ALARP).EP K reflected the arrangements in place, these include:

- Applications training
- Modality specific training
- Radiographic protocols
- Standard operating protocols
- Employer's procedures
- IR(ME)R documents are subject of review and amendment
- Routine equipment maintenance
- Equipment quality assurance
- Develop and implement Local DRLs (LDRLs) which are displayed in the relevant department
- Appropriate exposure charts
- Incident management
- Management of near misses
- Dose audits
- A multi-disciplinary audit programme
- Identification of the correct radiopharmaceutical and any corresponding calculations are checked by two operators

It was confirmed that optimisation of exposures is co-ordinated through IOT.

The optimisation of paediatric exposures was discussed and staff outlined clearly the measures taken to optimise these exposures including the use of paediatric protocols and administration of Radioactive Substances Advisory Committee (UK) (ARSAC) guidance weight scaling factors which are available to radiographers and are clearly displayed in the clinical area. It was noted that that ARSAC guidance used for scaling paediatric doses is not subject to audit of how staff apply these scaling factors. An area of improvement has been identified to audit how staff apply ARSAC guidance used for scaling paediatric doses. It was confirmed that the facilities will be reviewed with new gamma camera installation to further enhance opportunities for optimisation of paediatric exposures.

Staff described clear arrangements in accordance to employer procedures (EPs) for the optimisation of exposures where pregnancy cannot be ruled out and for carers and comforters. It was confirmed patient information leaflets are issued to all patients prior to a nuclear medicine study clearly requesting patients who are breast feeding to contact the nuclear medicine department for advice. The lead radiographer for nuclear medicine confirmed a breast feeding patient is spoken to directly and given clear verbal and written instructions on the breast feeding protocol. However, review of the patient information on breastfeeding noted it was due to be reviewed in 2019. Other documents displayed in the department such as decay sheets and paediatric weight scaling charts were confirmed as not part of the quality management system (QMS) and therefore not formally subject to the usual review mechanisms. An area of improvement was identified to ensure this patient information on breast feeding is reviewed and other documentation such as decay sheets and paediatric weight scaling information are included in the QMS and subject to review.

It was confirmed operators make breast feeding enquires as outlined on the EPs.

A range of patient information leaflets were available including preparation for a nuclear medicine investigation and post investigation instructions. It was noted that the information provided within the post investigation instructions was not fully in line with current best practice. An area of improvement was identified that the Employer with the involvement of the MPE should review the post nuclear medicine investigation written instruction leaflets to ensure they are in accordance to current best practice.

DRLs are radiation dose levels or for nuclear medicine the administered activity for typical diagnostic examinations on standard size adults and children for broadly defined types of equipment for example CT, fluoroscopy or general radiography. DRLs are benchmarks of patient radiation dose, based on dose indices and where certain variables such as equipment type, examination and patient size are standardised to minimise uncertainty. DRLs are often considered the first step in the optimisation process. DRLs should not be consistently exceeded when good and normal practice is applied.

DRLs are available and displayed within the nuclear medicine –dispensing room. They are regularly reviewed and authorised in accordance with EP F. National DRLS (set by ARSAC) are available and LDRLs have been established for a number of examinations. It was confirmed when the new SPECT CT system is installed, the IOT will review the DRLs. It was good to note that it is intended to involve their CT colleagues in optimisation of these hybrid exposures.

Staff outlined that if the DRL is to be exceeded in exceptional circumstances for example a bariatric patient or a patient who is unable to tolerate standard acquisition times and where the administered activity is increased based on an individual clinical needs, this must be justified and recorded by the licensed practitioner. Staff demonstrated a very good understanding of the use of DRLs and what action to take in the event of them being consistently exceeded.

Management confirmed that following the previous RQIA inspection improvement had been made to optimisation measures including administered activity audits.

As previously stated it was good to confirm that the MPE involvement in optimisation includes the following;

- Involved with and attends IOT meetings
- Provides guidance on dose audits and DRLs, ensuring a consistent approach
- Advice on protocols and on equipment
- Involved with procurement of equipment and commissioning. MPEs have been present for manufacturer presentations when procuring new equipment and have provided technical advice

Staff outlined how a review of optimisation is carried out on a regular basis via a rolling schedule of radiology audit, including nuclear medicine, and the departmental equipment QA programme.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that the department have robust arrangements with respect to optimisation of nuclear medicine studies and are enthusiastic to ensure these arrangements are regularly reviewed and if necessary improvements are made. The inspection team acknowledge the commitment of staff in this regard.

5.2.3 Does the service adhere to legislation in relation to the entitlement of duty holders including assessing training and competency?

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.

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

It was confirmed there are comprehensive systems in place to provide annual appraisals for all grades of staff. It was further confirmed that training and development needs are identified for individual staff as part of the appraisal process. All grades of staff are responsible for maintaining their own portfolio of evidence to maintain their individual professional accreditation.

EP B on entitlement, sets out the arrangements for entitlement and provides a sound framework for the entitlement process.

The inspection team reviewed a number of completed induction programmes, competency and entitlement records for operators and practitioners including consultant radiologists, radiographers and a MPE. Training records for a non-medical referrer were also reviewed. Staff undertake an induction programme which includes IR(ME)R and radiation safety awareness and are required to read the EPs. Training and competency records were found to support entitlement and were in accordance with individual scope of practice. However, it was noted that previous versions of training and entitlement records referred to a “system of work (SOW)” for authorising referrals. This process has now been replaced with authorisation guidelines but the individual records have not been updated.

An area of improvement was identified to update radiographer's entitlement records to accurately reflect use of authorisation guidelines.

The arrangements for entitlement of non-medical referrers (NMR) were very robust and it was good to evidence that they are subject to regular review. Group entitlement records were reviewed for MPEs; these were found to clearly evidence the entitlement of this group of staff.

The entitlement of staff outside the nuclear medicine department such as those who may act as a duty holder in theatres was discussed. It was noted that breast surgeons undertake clinical evaluation of sentinel node studies. Clinical evaluation is an operator task under IR(ME)R and therefore these individuals should be entitled as an operator duty holder role. An area of improvement was identified to ensure staff undertaking clinical evaluation of medical exposures are subject to the entitlement process as an operator.

It was confirmed iRefer is made available to referrers however it does not include referral guidelines for sentinel lymph node studies. Local clinical guidelines are in place, but these do not include dose information as required under Regulation 6 (5) (a). It was not clear that the clinical guidelines were used as referral guidelines. An area of improvement has been identified to devise sentinel lymph node studies referral guidelines, include dose, and make these available to referrers.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced clear and robust entitlement arrangements are in place. Management and staff were receptive to advice on the entitlement process. The inspection team acknowledge the commitment of staff in this regard.

5.2.4 Does the service adhere to legislation with regard to equipment quality assurance (QA)?

An inventory of radiological equipment was supplied which contained all of the information as specified within the legislation. This list of equipment will be kept under constant review and will be updated when there is a change.

The inspection team sought to ensure that all QA equipment tests are undertaken and to schedule, that the results of the tests are recorded and interpreted in a suitable manner and that any actions necessary as a result of the tests are followed through appropriately. In addition, Trust staff liaise with external providers of QA who advise on performance and optimisation e.g. Regional Medical Physics Service (RMPS).

As part of the service level agreement (SLA) between the NHSCT and the RMPS a programme for external QA is undertaken using recommended QC test methods and at a frequency advised by The Institute of Physics and Engineering in Medicine (IPEM). The IPEM set the standards for 'Quality Control of Gamma Cameras and Nuclear Medicine Computer Systems' in their IPEM Report 111.

There is a clear equipment QA programme in place and this is reflected in the EPs. Staff involved in performing QA testing had evidence of training and a competency assessment to undertake this role and had been entitled to do so. Daily QC checks on the gamma camera and the calibrator are carried out by entitled radiographers according to departmental work instructions and are reviewed monthly by an entitled clinical scientist from RMPS.

Additional monthly QC checks are carried out by entitled RMPS staff. Quarterly and annual checks carried out in tandem with monthly QA visits. RMPS staff carries out an annual audit of equipment QA.

Review of QC test records found they were up to date, well completed and comprehensive. However, these records were paper records. It was advised to consider establishing electronic equipment QA records to make accessibility of results easier to RMPS staff. Staff outlined clearly what action to take if issues with test results outside of baselines including informing the superintendent radiographer, the test repeated and seeking advice from the MPE and manufacturer and if necessary removing the equipment from service on the advice of MPE. It was noted that a clear process for taking faulty equipment out of use was in place.

As stated previously the gamma camera is scheduled for replacement in June 2023. A Siemens system has been procured as this is consistent with other nuclear medicine equipment across the region. Diagnostic CT will be enabled but it is not planned to be used as stand-alone CT. The lead MPE for nuclear medicine has been involved in the procurement of gamma camera. There has been no involvement of a MPE for CT at the procurement stage however previous experience from another procurement exercise within CT was availed of.

It was good to note that a Project Group has been set up to manage the installation project with the involvement of MPEs for nuclear medicine and CT. The nuclear medicine service will require to be stood down during installation. It was confirmed arrangements had been made that other Trusts across the region will undertake red flag referrals. Risk assessments will be reviewed and updated accordingly.

It was noted there is a clear governance and oversight of the equipment QA programme and including monthly QA meetings with support from the MPE if necessary, IOT meetings, radiation safety committee with lines of accountability to the safety and care quality steering group, safety group and to Trust board level and the Employer.

Staff and management demonstrated understanding of their roles and responsibilities in relation to equipment QA. The governance structures have been strengthened which serves to ensure a safe and effective approach 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.

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

Administered Activity

It was confirmed that radiopharmaceuticals are delivered in multi-dose vials from the Regional Radiopharmacy based on the Royal Victoria Hospital 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 diagnostic 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 and paediatric nuclear medicine examination, scan time, Trust DRLs, appropriate pre and post exam patient care and details of other medication required.

Staff demonstrated how the 'day diary record for drawn up activity' is recorded on paper and then transposed to RIS. On review of this day diary, it was found to include a list of: hand written patient names (no other identifiers), the vial activity, volume to be dispensed, activity dispensed, residual activity and actual administered activity. This record was quite informal e.g. there were no headings to the columns and no clear description of what information goes in each column. However, it was found to be filled in consistently in accordance with local custom and practice. The entries from this diary are retrospectively entered onto RIS. An area of improvement was identified to consider the introduction of a handheld electronic system to formally record details of 'drawn up' and administered activity contemporaneously.

EP E, assessment of patient dose and administered activity, outlined in a table where the RIS record shows dispensed activity, checked activity, administered activity and administered drugs as part of the examination however it did not reflect the order data was entered for each task. An area of improvement was identified to amend EP E to accurately reflect the order administered activity data is entered for on the RIS record.

6.0 Conclusion

There were 10 areas of improvements identified as a result of this inspection. This is fully outlined in the appended quality improvement plan (QIP).

The management team and staff are to be commended for their ongoing commitment and enthusiasm to ensuring that the Antrim Area Hospital 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	10

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 area 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 8 (3) **Stated:** First time **To be completed by:** 8 June 2023	The Employer must establish regular formal communication with the radiopharmacy department for example through planned meetings. Ref 5.2.1
	Response by Employer detailing the actions taken: Formal meetings have been established with Radiopharmacy. The first meeting occurred on the 11/05/2023. Twice yearly meetings will occur going forward.
Area for improvement 2 **Ref:** Regulation 8 (1) **Stated:** First time **To be completed by:** 8 June 2023	The Employer must review employers procedure (EP) L to ensure it reflects the decision making process of who is responsible for identifying a clinically significant accidental or unintended exposure (CSAUE) and where the details of the CSAUE should be recorded including in the patients notes. Ref 5.2.1
	Response by Employer detailing the actions taken: The Senior Management Team have reviewed and updated Procedure L of the Radiology Employer's Procedures. Detail has been added in relation to the Clinical Director's responsibility in regards to the decision making process for CSAUE's and the location of the record of a CSAUE within the patient's corresponding notes and Radiology Record System. All necessary changes to the Employer's Procedures will be made and circulated to the Radiation Safety Committee (RSC) for review, prior to ratification at the RSC meeting. The Employer's Procedures will subsequently be issued and communicated Trust wide.
Area for improvement 3 **Ref:** Regulation 12 (8) **Stated:** First time **To be completed by:** 8 March 2023	The Employer must audit how staff apply the administration of Radioactive Substances Advisory Committee (UK) (ARSAC) guidance used for scaling paediatric doses. Ref 5.2.2
	Response by Employer detailing the actions taken:

	In liaison with the Trust appointed MPE, a paediatric dose audit has been undertaken by the department. The audit considered: 1. Was the patient weighed, or was the estimated weight taken from a generic table (World Health Organisation) based on age/sex? 2. Was the correct scaling factor used to modify the dose, and was this double checked? 3. Was the dose calculated correctly? What action was taken if the dose was below the minimum for adequate patient quality? 4. Was the administered dose within 10% of the calculated dose from point 3 above? 5. Were there any comments in the report about the image quality? The audit has been completed departmentally and shared with the NHSCT Nuclear Medicine MPE for consideration and discussion. Initial compliance results have been positive. The sample primarily included paediatric DMSA examinations from January 2023 until May 2023, including a sample of 20 patients. Results will be presented and discussed at the Nuclear Medicine Image Optimisation Team (IOT) Sub-Committee and departmental IOT meeting.
Area for improvement 4 **Ref:** Regulation 6 Schedule 2 (d) **Stated:** First time **To be completed by:** 8 June 2023	The Employer must ensure written patient information on breast feeding is reviewed and other documentation such as decay sheets and paediatric weight scaling information are included in the quality management system (QMS) and subject to regular review. Ref 5.2.2
	Response by Employer detailing the actions taken: Form 73.1 ("Nuclear Medicine Instructions for Breast Feeding Mothers") has been reviewed and updated by the Lead Nuclear Medicine Radiographer. The updated form has been shared with the Trust appointed MPE for review and feedback. When feedback has been received and considered the updated form will be re-issued via the QMS and communicated to all relevant staff members. The Radiology Employer's Procedure, "Procedure H: Procedure for the giving of written instructions and information" as referred to in regulation 12(6), is under review by the Trust Lead Nuclear Medicine Radiographer in collaboration with the Trust appointed MPE. All necessary changes to the Employer's Procedures will be made and circulated to the Radiation Safety Committee (RSC) for review, prior to

	ratification at the RSC meeting. The Employer's Procedures will subsequently be issued and communicated Trust wide. The Decay information for 99mTc has been recorded upon a Quality Record and shall be formally issued via the Radiology Quality Management System (QMS) and communicated to all relevant staff. The paediatric weight scaling information has been recorded upon a Quality Record. Advice has been sought from the Trust appointed MPE in regards to the action required when the patient's weight falls outside the ARSAC stipulated weight ranges. The action required will be considered in liaison with the results of the paediatric dose audit. When appropriate action has been confirmed this will be added to the Quality Record, and the paediatric weight scaling information shall be issued via the Radiology QMS, and communicated to all relevant staff. All documentation within the Radiology QMS is subject to regular review in accordance with QAP 3.1 Procedure for Document Control.
Area for improvement 5 **Ref:** Regulation 12 (6) **Stated:** First time **To be completed by:** 8 June 2023	The Employer must with the involvement of the Medical Physics Expert (MPE) review the post nuclear medicine investigation written instruction leaflets to ensure they are in accordance to current best practice. Ref 5.2.2
	Response by Employer detailing the actions taken: Nuclear Medicine Patient Information Leaflets have been reviewed and updated by the Lead Nuclear Medicine Radiographer. The updated leaflets have been shared with the Trust appointed MPE for review and feedback. When feedback has been received and considered in accordance with current best practice, the updated leaflets will be re-issued via the QMS and communicated to all relevant staff members.
Area for improvement 6 **Ref:** Regulation 10 (4) **Stated:** First time **To be completed by:** 8 June 2023	The Employer must update radiographers entitlement records to accurately reflect use of authorisation guidelines. Ref 5.2.3
	Response by Employer detailing the actions taken: Senior Management Team (SMT) have reviewed and confirmed that all Nuclear Medicine Radiographer entitlement records accurately reflect use of Authorisation Guidelines within Nuclear Medicine. Nuclear Medicine Radiographers current IR(ME)R Non-Medical Referrer entitlement records reflect historic processes. Actions shall be taken in accordance with "PPP 0.4 Protocol for

	Non-Medical IR(ME)R Duty Holders", to update current entitlement processes. This shall include: 1. Attendance at the IR(ME)R Non-Medical Referrer Training by appropriate staff - action completed 16/05/2023. 2. Clinical Guidelines currently under development. 3. Group entitlement document will be developed to reflect Clinical Guidelines, and appropriately authorised by NHSCT IR(ME)R Lead. 4. Currently entitled staff will be transferred across onto the updated process. 5. New staff members will undertake the required training and assessment of competency, prior to entitlement by the IR(ME)R Lead 6. Entitlement records will be updated and retained by each individual staff member. 7. Staff shall participate in regular audit of practice, in accordance with the Radiology Employer's Procedures.
Area for improvement 7 **Ref:** Regulation 12 (9) **Stated:** First time **To be completed by:** 8 June 2023	The Employer must ensure staff undertaking clinical evaluation of nuclear medicine studies are subject to the entitlement process as an operator. Ref 5.2.3 **Response by Employer detailing the actions taken**: NHSCT Breast Surgeons shall be formally entitled by the NHSCT IR(ME)R Lead, in accordance with Radiology Employer's Procedure, Procedure B. Entitlement documentation shall include the relevant Referral Guidelines. Documentation has been drafted, awaiting the relevant dose information from the Trust appointed MPE. When the documentation has been finalised, entitlement shall be authorised by the NHSCT IR(ME)R Lead, and communicated to the relevant staff, for retention within their corresponding training record.
Area for improvement 8 **Ref:** Regulation 6 5 (a) **Stated:** First time **To be completed by:** 8 June 2023	The Employer must devise for sentinel lymph node studies referral criteria to include dose, and make these available to referrers. Ref 5.2.3 **Response by Employer detailing the actions taken**: Referral criteria has been drafted and shared with the Breast service for review and feedback. Upon confirmation of dose data from the Trust appointed MPE, the agreed Referral criteria shall be recorded upon the corresponding entitlement documentation (Breast Surgeons and Breast Care Nurses) and shared with the relevant staff members.

Area for improvement 9 **Ref:** Regulation 6 Schedule 2 (e) **Stated:** First time **To be completed by:** 8 June 2023	The Employer must consider the introduction of a handheld electronic system to formally record details of 'drawn up' and administered activity contemporaneously. Ref 5.2.5
	Response by Employer detailing the actions taken: The Antrim Area Hospital Site Lead Radiographer has investigated and identified a suitable hand held device, compatible with current patient information systems. The device has been ordered in accordance with the NHSCT Procurement Policy. Upon receipt of the hand held device, the required software will subsequently be uploaded onto the device, and the Nuclear Medicine Radiographers will utilise the device to facilitate formal contemporaneous records of drawn up and administered activity. Procedure E of the NHSCT Employer's Procedures will subsequently be updated to reflect this change in practice. All necessary changes to the Employer's Procedures will be made and circulated to the Radiation Safety Committee (RSC) for review, prior to ratification at the RSC meeting. The Employer's Procedures will subsequently be issued and communicated Trust wide.
Area for improvement 10 **Ref:** Regulation 6 Schedule 2 (e) **Stated:** First time **To be completed by:** 8 June 2023	The Employer must amend EP E to accurately reflect the order administered activity data is entered on the RIS record. Ref 5.2.5
	Response by Employer detailing the actions taken: Following the RQIA inspection (08/03/2023) the Nuclear Medicine Lead Radiographer reviewed how dose was recorded on RIS for a variety of examinations. The Nuclear Medicine Lead Radiographer met with the Nuclear Medicine staff, to ensure they understood how dose should be recorded upon RIS, including the order in which checks should be contemporaneously recorded: 1.Details of the trained and entitled Operator who checks and records the drawn up activity; 2.Details of the trained and entitled Operator who verifies the drawn up activity; 3.Details of the appropriately trained and entitled Operator who checks and records the administered activity on RIS. Radiology Employer's Procedures, "Procedure E: Procedure for the assessment of patient dose and administered activity", shall be reviewed and updated, to ensure the detail and correct order of this process is clearly illustrated. All necessary changes to the Employer's Procedures will be made and circulated to the Radiation Safety Committee (RSC) for review, prior to ratification at the RSC meeting. The Employer's Procedures will subsequently be issued and communicated Trust wide.

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