The Regulation and Quality Improvement Authority

Inspection Report

3 July 2024

Altnagelvin Hospital Nuclear Medicine Department

Address: Glenshane Road, Londonderry, BT47 2SB
Telephone: 028 71611322

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

1.0 Service information

Organisation/Registered Provider: Western Health and Social Care Trust (WHSCT)	**Department Inspected:** Altnagelvin Hospital (AH) Nuclear Medicine Department
Name of Employer: Dr Brendan Lavery Medical Director WHSCT	**Radiology Services Manager (RSM):** Ms Tracey McIvor

Brief description of how the service operates:

The AH nuclear medicine department provides a service Monday to Friday between 9am and 5pm to adult and paediatric patients. There is no scheduled out of hours' service.

Before the inspection Ms Tracey McIvor, RSM and her team were asked to complete a self-assessment form (SAF). The submitted SAF confirmed that each year, the AH Nuclear Medicine department carried out approximately 1359 planar/dynamic nuclear medicine imaging, 621 single photon emission computed tomography (SPECT) imaging and 330 SPECT/ computed tomography (CT) imaging, and 235 sentinel node probe studies (breast and penile cancer).

The nuclear medicine department operates under an Employer's Licence and two 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: ^{99m}Tc, ^{123}I, and ^{75}Se. The management confirmed that no nuclear medicine therapies are carried out in AH nuclear medicine department.

Within the department there are two gamma cameras, one of which is a SPECT/CT scanner, radionuclide calibrators, a technegas generator; and gamma probes (held in theatre).

The department is staffed by ten whole time equivalent (WTE) permanent radiographers nine of whom are rotational staff with the general radiology service; two WTE consultant radiologists (licensed practitioners), and another consultant radiologist (reporting nuclear medicine scans), five radiology registrars who also rotate through the main radiology department. Consultant radiologists from a third party provider had been clinically evaluating nuclear medicine scans, however this service has been used less frequently in the last year.

There is a radiopharmacy onsite which is staffed by a lead radiopharmacist and a lead radiopharmacy technician. There are an additional three radiopharmacists and three radiopharmacy technicians involved in the radiopharmacy service. The radiopharmacy service is further discussed in section 5.2.4 of this report.

The team is supported by a Medical Physics Expert (MPE) contracted from Regional Medical Physics Service (RMPS) based in the Belfast HSCT.

2.0 Inspection summary

On 3 July 2024, 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 AH nuclear medicine department, as part of RQIA's IR(ME)R inspection programme.

For the 2024/25 inspection year the inspections will focus on the following key themes

- Referral process
- IR(ME)R governance, including arrangements for compliance with IR(ME)R, nuclear medicine services provided outside of the nuclear medicine department, communication with other departments, and commissioning of new services
- Equipment quality assurance including nuclear medicine equipment held outside the nuclear medicine department
- The study of risk (radiotherapy and nuclear medicine therapies only)
- Brachytherapy (radiotherapy only)
- Any other areas identified through the review of the submitted SAF and supporting documentation

As previously stated AH nuclear medicine department do not provide nuclear medicine therapies, therefore the study of risk theme was not applicable to this service.

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

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

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

- Discussion with management and staff
- Examination of relevant nuclear medicine documentation
- Review of the department and facilities
- Review of patient records to ensure compliance with IR(ME)R
- Discussion with patients/representatives (where appropriate)

IR(ME)R is intended to protect individuals undergoing exposure to ionising radiation as follows:

- Patients as part of their own medical diagnosis or treatment
- Individuals as part of health screening programmes
- Patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes
- Carers and comforters
- Asymptomatic individuals
- Individuals undergoing non-medical imaging using medical radiological equipment

3.0 How we inspect

RQIA is responsible for monitoring, inspecting and enforcement of IR(ME)R. The inspection process includes the gathering and review of information we hold about the service, examination of a variety of relevant written procedures, protocols and records, and discussion with relevant staff. RQIA inspection reports reflect on how a service was performing at the time of inspection, highlighting both good practice and any areas for improvement.

The information obtained is then considered before a decision is made on whether the service is operating in accordance with the relevant legislation and professional standards. Examples of good practice are acknowledged and any areas for improvement are discussed with the relevant staff in charge and detailed in the quality improvement plan (QIP).

As already stated, prior to the inspection, the service was requested to complete a SAF and provide RQIA with all relevant supporting information including written policies and procedures. This information was shared with UKHSA prior to the inspection and was used to direct discussions with key members of staff working within the nuclear medicine 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?

A previous inspection had not been undertaken of the AH nuclear medicine department under the current IR(ME)R legislation.

5.2 Inspection findings

5.2.1 Does the service adhere to legislation in relation to the referral process?

A referral is a request for an exposure to be performed, not a direction to undertake an exposure. A referral must be made by an appropriately entitled registered health care professional as defined by IR(ME)R. The referrer must supply sufficient medical data for the practitioner to enable justification. The referrer must also supply accurate up to date information to enable the operator to correctly identify the individual to be exposed.

It was confirmed that all referrals made to the AH nuclear medicine department are managed through the Northern Ireland Picture Archiving and Communications System (NIPACS) and electronic care record (ECR). The majority of referrals are electronic with hard copy referrals being scanned on to NIPACS.

Clear entitlement arrangements for referrers were described by management and largely reflected in the Employers Procedure (EP) C. It was noted that there are entitled referrers from the Republic of Ireland (ROI) with a limited scope of practice for nuclear medicine procedures. A list of ROI referrers is maintained, and management confirmed that staff would check the Irish Medical Council register if the referrer is not on the list to ensure that the individual is a registered medical professional. Reports and images resulting from referrals from ROI are sent on encrypted Compact Disc (CD) and through a secure portal system.

There are two Non-Medical Referrers (NMR) entitled for a limited scope of practice in nuclear medicine. It was good to note there is a robust application process and training on the role and responsibilities of a referrer in accordance with IR(ME)R. However, it was noted that one NMR entitlement record reflected the previous IR(ME)R regulations and the other NMR scope of practice was outlined in a fragmented way. An area for improvement was identified to ensure NMR entitlement is under the current IR(ME)R regulations and there is a clear well defined scope of practice outlined. Entitlement is further discussed in section 5.2.2 of this report.

It was confirmed that referrals made by General Practitioners (GPs) are assessed on a case by case basis by a licensed practitioner and who will justify and authorise them. The justification and authorisation process is further outlined in section 5.2.4 of this report.

The Employer has responsibility for putting referral guidelines in place and making sure these are available to referrers. Referral guidelines set out the conditions in which an individual would typically be referred for a specific type of exposure and must include an estimate or indication of the radiation dose associated with the exposure.

It was confirmed iRefer is made available to referrers, however it does not include referral guidelines for nuclear medicine procedures such as sentinel lymph node studies. It was good to note that referral guidelines for breast and penile sentinel lymph node biopsy (SLNB) had recently been developed. However, there were no clear arrangements for making these referral guidelines available to appropriate referrers nor was information on radiation dose stated within the guidelines. An area for improvement has been identified to ensure that referral guidelines for breast and penile SLNB procedures are made available to referrers and information of radiation dose is added to the referral guidelines.

The management and staff clearly outlined arrangements for nuclear medicine referrals in relation to prioritising, timing future examinations and the referral cancellation process. The measures in place to minimise the possibility of receiving duplicate referrals were reviewed. Staff confirmed they check the radiology information system (RIS) for any prior approval or request and to check for pending appointments or previous scans. If a duplicate is found, radiographers contact the referrer to inform them. The matter was also well described in the submitted SAF, however this detail was not reflected in EP C - referral process. An area of improvement has been identified to further develop EP C - referral process, to include measures to minimise the possibility of receiving duplicate referrals.

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

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that the AH nuclear medicine department have good arrangements with respect to the referral process 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 Are there appropriate IR(ME)R governance arrangements in place to ensure compliance with the legislation?

Organisational Structures and Governance Committees.

The overall responsibility for ensuring compliance with IR(ME)R lies with the Employer. The role of IR(ME)R Employer in the WHSCT is held by the Medical Director. The WHSCT Radiation Protection Policy and Radiation Quality Manual sets out the organisational structures, lines of accountability and governance structures.

Management described these arrangements which were set out in the above documents. It was confirmed that the Employer chairs the Risk Management Subcommittee which meets quarterly. The chair of the Radiation Protection Working group (RPWG), which meets twice a year, is the Associate Medical Director who reports issues raised at RPWG to the Risk Management Subcommittee. The Chair of the Radiation Protection Subgroup (RPSG), which meets quarterly, is the RSM who reports any issues raised at RPSG to the chair of RPWG. There are representatives from nuclear medicine, medical physics and radiopharmacy on this committee. At RPWG meetings, each department where IR(ME)R is applicable provides a report on incidents, updates on procedures, training, audits, inspections, equipment and documentation.

RPWG also reports to the Clinical and Social Care Governance Working Group. This group is chaired by the Medical Director (Employer). There are also clinical governance meetings set up to review incidents. This meeting feeds into Higher Management Team (HMT) clinical governance meetings and radiology /nuclear medicine is represented at this meeting by the RSM.

It was good to note that the nuclear medicine service has established an image optimisation team (IOT) which is a multi-disciplinary group that meets twice a year. It has representatives from nuclear medicine, medical physics and radiopharmacy. There are clear terms of reference for this group which focuses on optimisation strategies.

Minutes from all the above meetings were reviewed. The meetings were to be found to be well attended with robust scrutiny being applied to the matters discussed.

Employer Licence and Practitioners' licences

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

As stated previously it was confirmed that an Employers Licence and two Practitioner licences are in place and appropriate for the current scope of service. The Employers Licence and Practitioner Licences are held on Q-Pulse. The Employers Licence review date is set six months prior to the licence expiry date. However, the practitioner licences review date is set one month prior to the licence expiry date. This should be reviewed to allow sufficient time for a renewal application to be completed, submitted and processed by Administration of Radioactive Substances Advisory Committee (ARSAC). An area of improvement has been identified on this matter.

It was noted that various documents reviewed referred to out of date terminology in relation to employer and practitioner licencing. An area of improvement has been identified to update all relevant documents to ensure that accurate terminology is used that reflects the licencing requirements as outlined under current IR(ME)R regulations.

Communication

Management and staff confirmed there was good communication within the nuclear medicine department**.** Q-Pulse is often used for communication, all documents to be signed as read and understood are included on Q-Pulse. Memos are also shared through Q-Pulse. It was confirmed all staff have access to Q-Pulse. Nuclear Medicine aim to hold monthly team meetings where items or updates can be shared. Staff commented positively on the initiative known as "Lunchtime bites" which are short meetings held on an ad-hoc basis to provide feedback on such areas as the British Nuclear Medicine Society (BNMS) courses undertaken and conferences attended.

The communication with line management outside of the nuclear medicine department was reviewed. The ARSMs confirmed open lines of communication with the RSM. The RSM holds formal weekly meetings with the assistant directors for operations and performance and assistant director of nursing who report to the director of unscheduled care, specialist medicine, cancer and clinical services. The RSM attends the HMT meetings. If required there are clear escalation procedures in place. The clinical lead radiologist has regular meetings with the divisional clinical director who is managed by the medical director. The radiopharmacy lead holds formal meetings with the assistant director for radiopharmacy, who reports to director of unscheduled care, specialist medicine, cancer and clinical services.

It was confirmed that the radiopharmacy department hold ad-hoc Microsoft Teams meetings with the nuclear medicine department and wider radiology staff. They confirmed they also have regular communication via telephone and email. However, whilst there is a good working relationship between the departments, there are no formal meetings held between radiopharmacy and the nuclear medicine department. An area of improvement was identified to establish formal meetings between the radiopharmacy and the nuclear medicine department which should have an agenda, be minuted and action plan generated as necessary.

Communication between the wards and the nuclear medicine department was discussed and staff confirmed that inpatient referrals will include details of the ward, infection information and mobility needs and appointments prioritised for the next day if possible. Inpatients are brought to the nuclear medicine department to receive their radioisotope injection, with the exception of a specific group of paediatric patients, where the nuclear medicine staff go to paediatric day-case unit to inject the patients. It was confirmed that nuclear medicine staff verbally outline precautions to be followed after the scan to the staff at ward level. In addition, written aftercare instructions and precautions are provided and situated at the end of each relevant patient's bed. There are also clear written information leaflets provided to patients and ward staff which includes nuclear medicine contact details for queries.

As stated previously SLNBs are carried out which involves the patient receiving a radioisotope injection within the nuclear department and then they have a SLNB procedure carried out in theatre. Nuclear medicine staff don't routinely go into theatres and only attend in order to deal with radioactive waste which is not regulated under IR(ME)R.

It was confirmed ad-hoc communication takes place regularly with theatre staff but there are no formal meetings. However, following a recent non-IR(ME)R incident involving management of radioactive waste in theatre, an area of improvement has been identified to establish formal meetings between the nuclear medicine department and the theatre service to enhance communication and understanding of the legal frameworks which apply to nuclear medicine. These meetings should have an agenda, be minuted and action plan generated as necessary.

Entitlement

Entitlement is the term used to describe the process of endorsement by an appropriate and specified individual within an organisation. They must have the knowledge and experience to authorise on behalf of the Employer, that a duty holder or group of duty holders, have been adequately trained and deemed competent in their specific IR(ME)R duty holder roles.

Evidence of induction, training, competency and continuing professional development for radiographers, consultant radiologists and radiopharmacists 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. It was confirmed comprehensive systems were in place to provide annual appraisals for all grades of staff and individual development needs are identified as part of this process. The consultant radiologist and surgeons have their appraisals undertaken by an approved medical appraiser. It was confirmed that entitlement is reviewed at annual appraisal and adjusted accordingly if a staff member's scope of practice had changed.

There are clear oversight arrangements for entitlement of radiology staff and staff outside of radiology such as NMRs and surgeons.

Individual entitlement records for two consultant radiologists (licenced practitioners), radiographers, radiopharmacists, one surgeon and two NMRs were reviewed. The group entitlement record for MPEs was also reviewed. It was noted that individual entitlement records referenced clinical referral protocols which, it was confirmed, are not used in the nuclear medicine department. Overall, the entitlement records were found to require to be updated in relation to clarity on scope of practice, ensuring the correct legislation is cited and accurate references to other documents to support entitlement is outlined. An area of improvement has been made on this matter.

Clinical Audit

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

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

A range of clinical audits had been undertaken over the last year. In addition, a recurrent IR(ME)R audit programme is carried out. The audit template includes a section for actions, responsible staff, and target date for completion. The ARSMs are responsible for ensuring actions and review dates reflect the audit outcome. A multi - disciplinary team (MDT) approach to audit is in place. All radiologists are required to complete an audit within their appraisal year. Radiographers confirmed that they could be involved in data collection for audits. The findings of audits are shared with staff through staff meetings, Q-Pulse and 'Lunchtime bites' sessions.

Urgent findings from audits are shared with the RSM and escalated as required. Any issues arising from audit, which require the Employer to be aware of, are either taken via RPSG to RPWG to the risk Management subcommittee or directly to the Employer, if deemed high risk.

A Trust wide radiology audit group has been established. The first meeting of the Trust wide radiology audit group convened in April 2024, led by the new Trust wide lead Consultant for Radiology Audit. The work of the group included:

- Reviewed the current schedule for audit and the template and agreed to trial a new method of recording the overall schedule
- Review of appropriateness of current audits, considering value added and agreed which audits could be ceased
- Lead radiologist to review RCR audit examples and agree new additional audits with Consultants and Radiology managers
- Managers to review any audits which are overdue for completion and allocate time for staff to complete
- Radiographers audit topics to be discussed at appraisals in May/June and agreement to increase volume of Trust wide audit topics

This was noted to be a very positive and proactive inaugural meeting. The RSM and other radiology lead staff are represented on this audit group. However, it was confirmed that no nuclear medicine lead staff are directly involved. An area of improvement has been identified to ensure a representative from the nuclear medicine staff is directly involved in the Trust wide audit group.

It was confirmed that the process for audit is currently under review to remove duplication and incorporate the Trust wide approach to audit as endorsed by the Trust wide radiology audit group. The ARSMs are working on developing the audit programme for the next year.

There is a separate audit schedule for the radiopharmacy department which was outlined by the lead radiopharmacist. It was confirmed that results of radiopharmacy audits are not shared formally with the nuclear medicine department and vice versa.

It may be an area of interest to be discussed when formal meetings between the two departments are established as previous identified through an area of improvement.

Incident and near miss management

There are clear arrangements in place to report, record, investigate and learn from nuclear medicine incidents or near misses in the nuclear medicine department. The management and staff clearly outlined action to be taken if it suspected significant accidental or unintended exposure (SAUE) has occurred which was fully reflected in relevant employer's procedures.

The decision making process for clinical SAUE (CSAUE) was clearly outlined by management, however this was not reflected in the EP R- CSAUE. An area of improvement has been identified to amend EP R to clearly outline the decision making process; and roles and the responsibilities for CSAUEs.

It was confirmed that radiology incidents are reviewed by classification and graphical visualisation enables a trend analysis to be performed. Analysis of all radiation incidents, trends and near misses, causes and potential risks identified are reviewed at bi-monthly clinical governance meetings and quarterly RPSG meetings. Follow up and review of action plans is monitored at bi-monthly clinical governance and closure of incidents confirmed there. Follow up and review of action plans is monitored at clinical governance meetings. This then feeds back to the Risk Management Subcommittee which is Chaired by Employer (Medical Director). On review, the analysis of incidents was found to be detailed however, it was people focused for example: referrer error or operator error rather than a process error focus. An area of improvement has been identified to focus on the process rather than people when analysing radiology or nuclear medicine incidents.

An annual report of all incidents is devised and this is shared with staff via Q-Pulse.

Risk register

The arrangements for ensuring the Trust risk register reflects risks associated with non-compliance with IR(ME)R was reviewed. The RSM is responsible for adding risks to the risk register after discussion at RPSG, RPWG and HMT. Proformas are completed and sent to HMT, approved at directorate level and then uploaded to the risk register by the business manager. The Employer would be made aware of any additions to the risk register through the previously described governance structures. The RSM reviews the risk register three-monthly.

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

It was confirmed that RPSG review draft EPs and protocols. They then go to RPWG for ratification and the assistant medical director ratifies EPs and protocols. Diagnostic Reference Levels (DRLs) are set and reviewed by the IOT. They will be ratified by the RPWG. There is a quality management system (QSM) in place for all electronic documents which are held on Q-Pulse. Newly ratified documents will be uploaded to Q-Pulse with the older versions archived. Staff will be informed of the new documents on Q-Pulse. There are a limited number of hard copy procedures which are subject to a clear tracking system to ensure the most up to date version is in place.

The introduction of a new nuclear medicine service

Management described the process for introducing a new nuclear medicine service which was outlined in a document shared from Q-Pulse. The clinical governance group will be made aware of initial approval. The proposal then goes to HMT who will review what new governance is required e.g. entitlement. It was confirmed that for nuclear medicine there will also be checks of the IR(ME)R employer and practitioner licences and the involvement of radiopharmacy in the process. Once a new service is introduced it will be audited. The management confirmed that no third party provider would be providing a nuclear medicine service in the WHSCT.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that the AH nuclear medicine department have robust governance arrangements with respect to the nuclear medicine service 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 with regard to equipment QA?

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

It was noted that the equipment inventory on Q-Pulse did not include radionuclide calibrators in radiopharmacy, nor the gamma probes in theatre. Not all information required under IR(ME)R was contained in the equipment inventory, e.g. the serial number for one gamma camera was missing. An area of improvement has been identified to ensure all nuclear medicine equipment and its location is outlined in the equipment inventory and all legislative information is listed.

Management and staff confirmed there is an appropriate amount of equipment available for the workload of the nuclear medicine department.

There is a formal, written equipment quality assurance (QA) programme in place. It was confirmed that the MPE had been involved in devising the equipment QA procedures. It was confirmed that daily checks of the radionuclide calibrators are carried out by appropriately trained and entitled operators. The MPE carries out annual accuracy checks, traceable to National Standards. Nuclear medicine staff carry out QA checks on the gamma probes owned and held in theatres. However, it was reported that there had been communication difficulties with theatres on this matter and it is suggested to include equipment QA in the formal meetings with theatre once established.

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

It was noted there is clear governance and oversight of the equipment QA programme and this includes monthly QA meetings with support from the MPE if necessary, IOT meetings, RPSG and from there on to RPWG and then to clinical safety and governance group which is chaired by IR(ME)R Employer.

Staff and management demonstrated understanding of their roles and responsibilities in relation to equipment QA.

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

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

Radiopharmacy and Administered Activity

It was confirmed an order form is completed by nuclear medicine staff the day before the nuclear medicine procedure which includes patient details, activity required, injection time and other relevant information. Administration staff in nuclear medicine prepare the order with patient details and this is then checked by two radiographers. The original is photocopied and the hard copy sent to radiopharmacy. For any last minute referrals nuclear medicine would phone radiopharmacy to check if it is possible to include it in the next day production. A separate order form is completed which is emailed to radiopharmacy. With the introduction of a new regional health service IT platform Encompass in the coming months all nuclear medicine orders will be electronic.

When the order is received by radiopharmacy, it is checked by a radiopharmacist against the RIS. Worksheets are set up and materials are prepared for the next day. There is a 7am start daily in radiopharmacy. All radiopharmaceuticals are prepared and drawn up in an aseptic suite.

Radiopharmacy prepare individual syringes and measure activity to within +/-5% of local DRLs. The syringes and lead shields are individually labelled and delivered to nuclear medicine each morning. A multi-dose vial is sent to nuclear medicine for lung perfusion imaging. A vial of pertechnetate is sent each day for use in the technegas generator (used for lung ventilation imaging).

As stated, deliveries are made daily from radiopharmacy to the nuclear medicine department. There are two deliveries of $^{99}Mo/^{99m}Tc$ generators to the radiopharmacy each week, Tuesday and Friday. Orders for SeHCAT and DaTscan are delivered to radiopharmacy as required via individual capsule (SeHCAT) or vial (DaTscan) for each patient.

Staff demonstrated how they check and record administered activity within the nuclear medicine department. The following were reviewed: record of dispensed activity, record of double check of dispensed activity, record of administered activity (residual activity measured and subtracted from dispensed activity) and the record of other drugs administered as part of exposure. All records were found to be well completed. It was confirmed that there are always two operators involved in the dispensing and administering activity for witnessing and verifying purposes.

Justification and Authorisation

The duty holder roles of operator and practitioner was examined in relation to the justification and authorisation of exposures. Justification is the intellectual activity of weighing up the expected benefits of an exposure against the possible detriment of the associated radiation dose and is the primary role of the practitioner. Authorisation is a process separate to justification and is the documentation confirming that the intellectual activity of justification has taken place.

It is not always possible for a practitioner to review every nuclear medicine referral, so regulations allow for an appropriately entitled operator to authorise an exposure following written authorisation guidelines issued by a named practitioner. The practitioner is responsible for the justification of any exposure that is authorised by an operator following the authorisation guidelines. The operator is responsible for the authorisation and following the authorisation guidelines accurately. Authorisation guidelines must be clearly written using precise statements that are unambiguous in order to allow the operator to confirm whether the referral can be authorised.

It was confirmed that authorisation guidelines are in place and used to authorise exposures by entitled operators. Review of the authorisation guidelines noted, whilst they contained relevant information, there were a number of areas that were unclear or absent from the guidelines. This included:

- It was not clear who the practitioner was for exposures carried out using these guidelines as there were two licenced practitioners named. Staff did clarify that the authorisation guidelines were written by a specific licenced practitioner. A single practitioner should be identified within the authorisation guidelines.
- The authorisation guidelines referred to ARSAC certificates and this should be updated to reflect the licensing arrangements in the current IR(ME)R regulations.
- Entitlement records referred to “clinical referral protocols” but this should state authorisation guidelines.
- Staff were clear that if the referral did not meet the guidelines in any way, they would consult the practitioner. However, this was not explicitly clear in the guidelines.
- In practice, referrals from GPs cannot be authorised under the guidelines and all GP referrals are reviewed by the practitioner. Again this was not clear in the guidelines.
- Further details could be added to the authorisation guidelines to include contraindications, clarity on “elevated” or “abnormal” results, information on thyroid blocking etc.
- Links should be included in the authorisation guidelines for breast and penile SLNB, directing referrers to referral guidelines instead of authorisation guidelines.

An area of improvement has been identified to update the authorisation guidelines as outlined above.

DRLs

A review of the DRLs noted local optimisation for some procedures where the local DRL (LDRL) is lower than the National DRL (NDRL). In other cases, the NDRL is used.

A written table relating to DRLs outlined a +5% tolerance for measured activity prior to injection. It was confirmed that radiographers working in nuclear medicine apply this tolerance. Staff drawing up individual patient syringes in radiopharmacy use +/- 5% however, the EP K - DRLS, specifies a tolerance of +/- 10%. An area of improvement was identified to review EP K- DRLs to ensure it reflects practice.

Pregnancy and Breast Feeding

Staff interviewed demonstrated a very good understanding of making pregnancy and breast feeding enquiries, including the 10 - day rule, describing clearly what they would do in a range situations and where to record details of these enquiries.

Staff confirmed a breast feeding patient is spoken to directly, a specific instruction leaflet is available for breastfeeding patients, the MPE would carry out an individual risk assessment, this would be sent to the department by email and recorded in patient record in RIS.

An updated breast feeding protocol in relation to a nuclear medicine service was described by staff. However, the above clear procedures were not fully outlined in the EP D - pregnancy /breast feeding enquiries. In general, the nuclear medicine department was not outlined in the EP or the appendix flow chart. An area of improvement was identified to update EP D and EP L to reflect full details of pregnancy enquiries and breast feeding protocol for the nuclear medicine service. A review of a sample of scanned pregnancy forms found them to be appropriately completed.

Carers and comforters.

EP V- carers and comforters (C&C) was in place and found to be well written. There was an additional procedure on C&C which did not fully reflect the definition of a C&C under IR(ME)R. It was suggested to review this procedure and be clear about its use. Management and the MPE were responsive to this advice and gave assurances to review.

6.0 Conclusion

There were 15 areas of improvement identified as a result of this inspection. This is fully outlined in the appended QIP.

The management team and staff are to be commended for their ongoing commitment and enthusiasm to ensuring that the AH nuclear medicine department grows from strength to strength, 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	15

Areas for improvement identified during this inspection are detailed in the QIP. Details of the QIP were discussed with senior management as part of the inspection process. The timescales commence from the date of inspection.

It is the responsibility of the Employer to ensure that all areas for improvement identified within the QIP are addressed within the specified timescales.

The QIP should be completed and detail the actions taken to address the areas for improvement identified. The Employer should confirm that these actions have been completed and return the completed QIP via BSU.Admin@rqia.org.uk for assessment by the inspector.

Quality Improvement Plan	
Action required to ensure compliance with The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018	
Area for improvement 1 **Ref:** Regulation 6. (1) Schedule 2.1 (b) **Stated:** First time **To be completed by:** 3 September 2024	The Employer must ensure non-medical referrer (NMR) entitlement is under the current IR(ME)R regulations and there is a clear well defined scope of practice outlined. Ref 5.2.1
	Response by Employer detailing the actions taken: Complete: Documentation changed, table added to define scope
Area for improvement 2 **Ref:** Regulation 6 (5) (a) **Stated:** First time **To be completed by:** 3 September 2024	The Employer must ensure that referral guidelines for breast and penile sentinel lymph node biopsy (SLNB) procedures are made available to referrers and information of radiation dose is added to the referral guidelines. Ref 5.2.1
	Response by Employer detailing the actions taken: Complete: Guidelines amended and shared with referrers.
Area for improvement 3 **Ref:** Regulation 6 (1) (a) Schedule 2 **Stated:** First time **To be completed by:** 3 September 2024	The Employer must further develop employer's procedure (EP) C referral process to include measures to minimise the possibility of receiving duplicate referrals. Ref 5.2.1
	Response by Employer detailing the actions taken: Complete: Employers Procedure C amended
Area for improvement 4 **Ref:** Regulation 5 (1) (a) **Stated:** First time **To be completed by:** 3 September 2024	The Employer must ensure the practitioner licences review date increases to allow sufficient time for a renewal application to be completed, submitted and processed by Administration of Radioactive Substances Advisory Committee (ARSAC). Ref 5.2.2
	Response by Employer detailing the actions taken: Complete: Review dates ammended on QMS

Area for improvement 5 **Ref:** Regulation 5 **Stated:** First time **To be completed by:** 3 September 2024	The Employer must update all relevant documents to ensure that accurate terminology is in place that reflects the licencing requirements as outlined under current IR(ME)R regulations. Ref 5.2.2
	Response by Employer detailing the actions taken: Complete: Review dates ammended to 6 months prior to expiry
Area for improvement 6 **Ref:** Regulation 10 (6) **Stated:** First time **To be completed by:** 3 October 2024	The Employer must establish formal meetings between the radiopharmacy and the nuclear medicine department which should have an agenda, be minuted and action plan generated as necessary. Ref 5.2.2
	Response by Employer detailing the actions taken: Annual schedule will be arranged prior to 3/10/24
Area for improvement 7 **Ref:** Regulation 10 (6) **Stated:** First time **To be completed by:** 3 October 2024	The Employer must establish formal meetings between the nuclear medicine department and the theatre service to enhance communication and understanding of the legal frameworks which apply to nuclear medicine. Meetings should have an agenda, be minuted and action plan generated as necessary. Ref 5.2.2
	Response by Employer detailing the actions taken: First meeting arranged for 12/09/24, annual meeting schedule will be arranged.
Area for improvement 8 **Ref:** Regulation 6 (1) (a) **Stated:** First time **To be completed by:** 3 September 2024	The Employer must update the entitlement records in relation to clarity on scope of practice, ensuring the correct legislation is cited and accurate references to other documents to support entitlement is outlined. Ref 5.2.2
	Response by Employer detailing the actions taken: Completed: Entitlements documents updated
Area for improvement 9 **Ref:** Regulation 7 **Stated:** First time **To be completed by:** 3 September 2024	The Employer must ensure a representative from the nuclear medicine staff is directly involved in the Trust wide audit group. Ref 5.2.2
	Response by Employer detailing the actions taken: Completed: TOR WHSCT Radiology Group attached, NM Radiographer noted in membership

Area for improvement 10 **Ref:** Regulation 8 (1) Schedule 2.1. (I) **Stated:** First time **To be completed by:** 3 October 2024	The Employer must amend EP R to clearly outline the decision making process in relation to clinically significant accidental or unintended exposures (CSAUEs) and the roles and responsibilities for CSAUEs. Ref 5.2.2
	Response by Employer detailing the actions taken: Review under way Managers will meet to discuss in advance of 3/10/24
Area for improvement 11 **Ref:** Regulation 6 **Stated:** First time **To be completed by:** 3 October 2024	The Employer must focus on the process rather than people when analysing radiology or nuclear medicine incidents. Ref 5.2.2
	Response by Employer detailing the actions taken: Area for improvement has been shared with all managers involved in incident review and requsted that this advice in implemented in future investigation.
Area for improvement 12 **Ref:** Regulation 15 (2) **Stated:** First time **To be completed by:** 3 September 2024	The Employer must ensure all nuclear medicine equipment and its location is outlined in the equipment inventory and all legislative information is listed. Ref 5.2.3
	Response by Employer detailing the actions taken: Complete: Inventory updated.
Area for improvement 13 **Ref:** Regulation 11 (5) **Stated:** First time **To be completed by:** 3 September 2024	The Employer must update the authorisation guidelines as outlined in section 5.2.4 of this report. Ref 5.2.4
	Response by Employer detailing the actions taken: Complete: Authorisation Guidelines updated.
Area for improvement 14 **Ref:** Regulation 6 (5) (c) **Stated:** First time **To be completed by:** 3 September 2024	The Employer must review EP K, DRLs to ensure it reflects practice. Ref 5.2.4
	Response by Employer detailing the actions taken: Complete: DRL table has been updated, approved by MPE and to be discussed at IOT and RPSG

Area for improvement 15 **Ref:** Regulation 6 (1) (a) Schedule 2.1. (c) **Stated:** First time **To be completed by:** 3 September 2024	The Employer must update EP D and EP L to reflect full details of pregnancy enquiries and the breast feeding protocol for the nuclear medicine service. Ref 5.2.4
	Response by Employer detailing the actions taken: Complete

The **Regulation** and
Quality Improvement
Authority

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

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