The Regulation and Quality Improvement Authority

Inspection Report

19 July 2023

Ulster Hospital Nuclear Medicine Department

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

1.0 Service information

Organisation/Registered Provider: South Eastern Health and Social Care Trust (SEHSCT)	**Department Inspected:** Ulster Hospital (UH) Nuclear Medicine Department
Name of Employer: Roisin Coulter, Chief Executive Officer (CEO) SEHSCT	**Interim Radiology Services Manager (RSM):** Linda Hamilton

Brief description of how the service operates:

The UH nuclear medicine department opened in September 2022 and provides a service Monday to Friday between 9am and 5pm to adult patients. However, the department can facilitate the delivery of radioisotopes from 8am if required. There is no scheduled out of hours service.

The nuclear medicine department operates under an Employer's Licence and one Practitioner's Licence that covers the radioisotopes in use and the limited range of nuclear medicine services provided. There are only two nuclear medicine procedures presently carried out, sentinel lymph node biopsies (SLNB) breast studies without imaging and SLNB for malignant melanoma studies (with imaging). The only radiopharmaceutical that is used in the department currently is 99mTc-Nanocolloid.

Before the inspection Linda Hamilton, RSM, and her team were asked to complete a self-assessment form (SAF). The submitted self-assessment confirmed that during the last year, the UH nuclear medicine department carried out two SLNB melanoma planar /dynamic nuclear medicine imaging, two SLNB melanoma single photon emission computed tomography (SPECT) imaging and computed tomography (CT) imaging and 147 SLNB breast non-imaging studies. It was confirmed the number of SLNB melanoma procedures have increased in the last number of months. The development of the nuclear medicine service will be determined by the commissioning process based on ongoing assessment of need and resources. The RSM is aware that any expansion of the nuclear medicine service must be reflected in the IR(ME)R licensing arrangements.

The facility is a modern, purpose designed, spacious nuclear medicine department. The layout is "circular" with the original plan to have paediatric patients on the left side of the entrance and adult patients on the right side. There is a large "cold" waiting area with reception and separate "hot" waiting areas. There is a central dispensing room with hatches through to two separate administration rooms (only one is currently in use for patients). The second administration room is currently used for gamma probe quality assurance (QA). The dispensing room has laminar flow cabinets for drawing up individual patient doses. A radionuclide calibrator is installed within one of the cabinets. There is space for drawing up therapy doses however this is not in use. A SPECT/CT gamma camera was installed in 2021.

There are multiple collimators available for different imaging investigations e.g. high energy collimators for therapeutic imaging for potential future use. There is space for a second gamma camera linked to a central control room which would allow staff to supervise both systems. There is space for a PET/CT suite with uptake bays for patients and space for a PET/CT scanner. This area of the department is not in use. Equipment in use includes, a dose calibrator, a SPECT/CT scanner and three gamma probes.

The department is staffed by two whole time equivalent (WTE) permanent clinical technologists: 0.06 WTE radiographers (for SLNB breast only); 0.3 WTE consultant radiologist (nuclear medicine licensed practitioner). It was confirmed a radiologist with an interest in nuclear medicine has been recruited and it is hoped they will complete their specialist training by 2025.

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).

2.0 Inspection summary

On 19 July 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 the UH nuclear medicine department, as part of RQIA's IR(ME)R inspection programme.

For the 2023/24 inspection year the inspections will focus on four key themes:

- Entitlement of staff focusing particularly on those duty holders outside of the nuclear medicine department and inter Trust duty holders
- Clinical evaluation including arrangements for peer review
- Clinical audit including robust interpretation of findings and action plans
- Patient identification including pause and check
- Any other areas identified through the review of the submitted SAF and supporting documentation

The purpose of our focus is to minimise risk to service users and staff, whilst being assured that ionising radiation services are being provided in keeping with the Ionising Radiation (Medical Exposure) Regulations (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

The nuclear medicine department did not have any scheduled patients on the day of the inspection therefore it was not possible to speak to patients.

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 UH 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 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. The individual 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 clinical technologists and a consultant radiologist was reviewed and found to be in line with duty holder roles. Complete training and competence records were not available for other duty holders such as the breast surgeons. An area of improvement has been identified to ensure entitlement is underpinned by evidence of training and competency in line with individual scope of practice.

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 has changed.

Individual entitlement records for a consultant radiologist (nuclear medicine licenced practitioner), two clinical technologists, two breast surgeons and a radiographer were reviewed. Overall these individual records did not clearly detail the individual scope of practice for the clinical technologists; the consultant radiologist and the breast surgeons. There were dates and signatures absent on a number of the entitlement records. On discussion and review of the authorisation guidelines it was noted that each clinical technologist had different scopes of practice however, their entitlement records did not reflect this detail. An area of improvement has been identified to ensure entitlement records reflect the specific duty holder role or roles, the individual scope of practice and that dates and signatures are completed where necessary.

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 confirmed that referrals are made from four breast surgeons and three plastic surgeons for SLNB breast and SNLB malignant melanoma respectively.

However, the breast surgeons and plastic surgeons had not been entitled as referrers for these specific procedures. Following discussion, it was confirmed that the breast surgeons undertake clinical evaluation of breast sentinel node studies as do the plastic surgeons for SNLB melanoma. Clinical evaluation is an operator task under IR(ME)R and therefore these individuals should be entitled as an operator for this duty holder role. An area of improvement was identified to ensure the breast surgeons and plastic surgeons who refer for SLNB breast and SLNB melanoma respectively are entitled as a referrer for these procedures and staff undertaking clinical evaluation of medical exposures are subject to the entitlement process as an operator.

For nuclear medicine it was confirmed that there are no non-medical referrers. Group entitlement records were reviewed for MPEs; these were found to clearly evidence the entitlement of this group of staff.

It was confirmed that iRefer is made available to referrers. However, iRefer does not include referral guidelines for nuclear medicine procedures such as sentinel lymph node studies. It was good to note that referral guidelines for SLNB breast and SLNB malignant melanoma had been developed in June 2023 and made available to the relevant referrers.

Employers Procedure (EP) A, which details the entitlement procedure was reviewed. EP A should be updated to reflect the nuclear medicine service in more detail and reflect the changes made to the entitlement procedure as a result of this inspection. An area of improvement has been made in this regard.

Justification and Authorisation

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.

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

It was confirmed that within the UH nuclear medicine department the clinical technologists act as operators and authorise exposures using authorisation guidelines. Authorisation guidelines were reviewed, these stated that named duty holders may authorise a sentinel node procedure if the correctly completed form states that the patient is having a SLNB breast procedure and the patient must be over 18 and not pregnant. With regard to identifying the practitioner for exposures undertaken using these authorisation guidelines it stated “If the request is authorised by an operator under the above guidelines, then the request is justified and I will be the IRMER Practitioner for the procedure”, the guidelines are signed by the nuclear medicine licensed practitioner. This statement does not clearly identify the practitioner. The guidelines must name the practitioner and be signed by them.

Staff stated that the 'correctly completed form' outlined in the authorisation guidelines is the referral form. On review of the completed referral forms it was noted that there was very limited and insufficient clinical detail included on the referrals for breast SLNB e.g. Mx SNB. This did not match the information in the authorisation guidelines or the referral guidelines. There was also a variation in the examination requested by the referrer for breast SLNB procedures.

There was sufficient clinical information noted in the referrals for melanoma SLNB. However, melanoma referrals were submitted on referral forms from the BHSCT – and this has not been described in the EPs, authorisation guidelines or referral guidelines. An area of improvement was identified to ensure EP B referral, clearly states if referral forms from other Trusts or Independent Healthcare Providers are accepted as a referral for radiology procedures including nuclear medicine services.

One referral for breast SLNB was for a pregnant patient. There was an attached email trail of guidance from the MPE and from the practitioner confirming that the referral was justified. However, the referral form had been signed as authorised as an operator, in contravention of the authorisation guidelines, where it should have been signed by the practitioner.

A further referral had been sent from a referrer who was not a listed referrer or entitled (a specialist training doctor – not a consultant). This had not been queried by the staff who authorised the referral. The specialist training doctor is under the supervision of a consultant whose name had been handwritten on the referral. Staff suggested that this was probably what had been recorded on the Radiology Information System (RIS).

An area of improvement has been made to ensure that referral forms contain sufficient clinical information, are completed by an entitled referrer and are subject to regular audit.

The authorisation guidelines were overall found not to be robust or detailed enough to serve as authorisation guidelines. An area of improvement has been identified to ensure that authorisation guidelines are updated to provide clarity on what criteria should be included in the referral forms to allow operators to authorise the exposure, clearly identify the purpose of the guidelines and identify the practitioner.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that entitlement arrangement and in particular entitlement of some staff groups outside of the nuclear medicine department requires to be strengthened. Management and staff were receptive to advice on the entitlement process. The inspection team acknowledge the commitment of staff in this regard.

5.2.2 Does the service have appropriate arrangements for the clinical evaluation of medical exposures including peer review?

Clinical Evaluation

The employer must ensure that a clinical evaluation of the outcome is recorded for each exposure. Clinical evaluation involves the assessment of an image and the documentation by the suitably trained and entitled operators. Clinical evaluation is most commonly considered to be a documented radiology report, which is usually recorded on the RIS. Other methods of clinical evaluation include written records in patient notes.

It is considered that evaluation is the final step in the justification process. A clinical evaluation is not required for individuals who are exposed while being a carer or comforter.

The SLNB studies for malignant melanoma are clinically evaluated by a consultant radiologist (a licensed practitioner). The imaging reports on to the picture archiving and communication system (PACS), is copied to the electronic care record (ECR) system and surgeons can access this report. As outlined in section 5.2.1 of this report the operating plastic surgeons continue to clinically evaluate the exposure to direct the surgical procedure and as stated are carrying out an operator task and require to be entitled as an operator. This type of clinical evaluation should be recorded in the patient notes.

The SLNB breast studies are completed without imaging and as stated previously the clinical evaluation of the SLNB breast studies is being carried out by the breast surgeons during surgery. The surgeons may be based locally within the Trust or patients may go to another Trust. As with the plastic surgeons as outlined in section 5.2.1 an area of improvement was identified that breast surgeons are entitled as operators for clinical evaluation where the surgery is performed locally.

It was noted that the reporting turnaround is assessed on a weekly basis for radiology services. The PACS team monitor this continually to identify examinations that are awaiting clinical evaluation. The weekly report goes to radiology senior management team and site leads. The monthly directorate meeting discusses all reporting, any backlogs and identify plans to address these. It was confirmed that arrangements for nuclear medicine clinical evaluation reporting will be included in this monitoring process going forward and in line with the small volumes.

The EP P clinical evaluation was reviewed and evidenced that it did not fully reflect the clinical evaluation arrangements for all nuclear medicine studies. An area of improvement has been identified to amend this procedure to fully reflect clinical evaluation arrangements for nuclear medicine studies.

Peer Review

Peer review in radiology and nuclear medicine means an assessment of the accuracy of a written report (clinical evaluation) issued by another radiologist/radiographer/surgeon (entitled operator). The implementation of the recently issued regional guidance on peer review was discussed. The Clinical Director of Radiology and Quality Standard for Imaging (QSI) lead consultant radiologist are responsible for peer review within the department.

It was confirmed that the peer review programme is a PACS based system and will be incorporated in NIPACS worklist of 100 examinations will be incorporated into each consultant radiologist's workload. It was confirmed that there is a regional approach to the grading of clinical evaluation reports for consistency. In addition, monthly Radiology Education and Learning Meetings (REALM) meetings take place, where learning and discrepancies are discussed. Nuclear medicine will hold similar monthly meetings which will feed into the REALM group.

The nuclear medicine licensed practitioner confirmed that regional multi-disciplinary meetings for the malignant melanoma patients are held which included a peer review component and also outlined a detailed external peer review exercise which was undertaken when unusual findings were noted on a number of SLNB malignant melanoma studies. This exercise proved very valuable in promoting reflective practice and assuring best practice.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced that the UH nuclear medicine department have good arrangements with respect to clinical evaluation 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 clinical audit including robust interpretation of findings and action plans?

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.

As the nuclear medicine service has only been operational since late 2022 there has been limited patient numbers to undertake meaningful clinical audit, therefore no formal clinical audits have been completed. However, it was confirmed that clinical audits had been discussed with the nuclear medicine licensed practitioner and lead surgeons and an agreement reached to undertake clinical audits by the end of 2023. Engagement has taken place with the Trust clinical audit team who will provide support on this once a clinical audit topic is identified. It was noted that radiology governance colleagues were not involved as yet in the development of the clinical audit programme. The topics for this clinical audit programme under consideration include review of melanoma technique and surgical outcomes, and review of breast SLNB surgical outcomes.

A nuclear medicine departmental audit programme was in place which included compliance with IR(ME)R audits. The audit schedule for 2023 was provided. It is held on the nuclear medicine SharePoint site which is separate from the radiology services quality management system. It was confirmed that results and learning are shared at staff meetings (this is the small nuclear medicine team) and via email to all radiographers who are involved in the nuclear medicine service. Audit findings will be discussed at the nuclear medicine image optimisation team meetings. The radiology management and governance lead have read only access to the nuclear medicine SharePoint site.

Evidence of audits were provided which included:

- Post-administration residual activity audit
- Compliance with IR(ME)R employer's procedure (C) patient identification audit

The patient identification audit was a Trust wide audit and demonstrated a high level of compliance within the nuclear medicine department. A review of the residual activity audit carried out by the nuclear medicine staff identified residual activity outside of the usual -/+ 10% value. The significance of this audit finding was discussed at length. It was noted that this finding had not been meaningfully analysed and there was limited information on the action taken as a result of the finding. The timing for re-audit had not altered from the original timescale and was due to be conducted a year later. Advice was provided on additional factors that could be included in the re-audit, such as vial concentration, time injection dispensed and who dispensed the injection.

Additionally, consideration should be given to including an assessment on the success of the surgical procedure in relation to any effect that may have been experienced as a result of the variation in residual activity. The nuclear medicine staff were receptive to advice.

An Employer and a Practitioner licence audit had also been completed, which highlighted when the licenses are due to expire and that they are in accordance with nuclear medicine procedures provided. A flowchart has been devised by the nuclear medicine department in relation to a proposed new nuclear medicine procedure and outlines due diligence on licensing, and such matters as environmental permits. In light of the potential evolvement of the nuclear medicine service this was noted to be a positive and proactive approach.

To further enhance and strengthen clinical audit and the departmental audit, an area of improvement was identified to undertake a robust approach to analysing the findings of audits. The template for recording audits should be reviewed and include more detail on the findings, an action plan, a named person responsible for addressing the audit findings and the date by which a re-audit should be completed.

It was noted that meaningful oversight and external scrutiny of the nuclear medicine audits and new written procedures by the radiology management and governance lead was very limited and is further discussed in section 5.2.5 of this report.

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced clinical audit arrangements are under development and departmental audit requires to be strengthened. Management and staff were receptive to advice on the clinical audit process. The inspection team acknowledge the commitment of staff in this regard.

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

IR(ME)R requires the Employer to establish a procedure to identify correctly the individual to be exposed to ionising radiation. The procedure should specify how and when an individual is to be identified. EP C patient identification, is in place and provides a clear comprehensive framework for staff to follow. Correct identification (ID) of the patient or individual to be exposed is an operator task and must be undertaken prior to any exposure.

Management and staff confirmed that it is the responsibility of the operator to ensure the correct patient is being examined against the referral. Whilst many people may be involved with the patient, the responsibility for correct ID lies with the operator who carries out the medical exposure. Staff described the patient ID process, the patient arrives in the department (all patients at present are inpatients) and is called through to the injection room for the administration of the radioisotope, prior to administration a three-point ID check is carried out using the patient hospital wristband and compared with the referral which is a hardcopy referral form which has been scanned onto RIS. Patients may leave the department after their injection. If imaging is to be performed upon return to the department post injection, a second patient three-point ID check is carried out by the operator.

The operator must always check the patient's name, address and date of birth against the referral on RIS. The patient must be asked to state their name, address and date of birth rather than confirm these details.

Staff outlined the following questions:

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

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

- Why are you here?
- Have you been x-rayed or scanned recently?

Staff confirmed that the professional guidance on Pause and Check is used and promoted in the nuclear medicine department. Pause and Check notices were noted to be displayed in the dispensing room, the injection room and the scanning room.

For other scenarios such as patients who lack capacity or non-English speaking patients a clear patient ID process was outlined for each situation.

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

As stated previously a patient ID audit is carried out as part of the rolling programme of audits and there was a high compliance level noted.

Staff explained the process for any discrepancies in the patient ID, this included; checking if the individual is known as any other name, checking with carers/relatives, checking the PACS, making a record of the changes required, and sending a request to the PACS team to change the demographics. There is also a field in RIS for incorrect demographics. However, it was very clear from responses that the exposure would not be undertaken if the patient ID could not be confirmed.

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

Review of the submitted SAF, supporting documentation and discussion with key staff during the inspection evidenced clear and robust patient identification processes are 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 Radio Pharmacy based at on the Royal Victoria Hospital site, BHSCT.

The multi-dose vials are ordered the day before and delivered on the morning of administration. It was confirmed that there had been some ongoing delays with the deliveries of radioisotopes as further drivers were required to undertake specialist training in the delivery of radioisotopes and the radio pharmacy department is undergoing a major renovation. It was good to note that a number of additional drivers have undertaken the necessary training and competency assessment to transport radioisotopes. A development plan has been put in place for the radio pharmacy department, however, it will take some time for this to be completed and difficulties may continue in the meantime.

It was confirmed there is informal ad hoc communication with the radio pharmacy department with the Nuclear Medicine Lead telephoning and emailing the radio pharmacy department on a daily basis. However, it was noted that there was no formal regular communication with the radio pharmacy department to discuss such matters as errors and ongoing governance arrangements. An area of improvement was identified to establish regular formal communication with the radio pharmacy department for example through planned meetings.

The activity of individual radiopharmaceutical doses for diagnostic procedures is measured using a calibrated ionisation chamber prior to administration to a patient. The dispensing room has a hatch which is used to transfer patient doses with only one dose transferred at a time to minimise errors.

A review of the submitted examination protocols evidenced that they included the details of the radiopharmaceutical to include the appropriate range of required ‘drawn up’ activity for each adult nuclear medicine examination, scan time, Trust diagnostic reference levels (DRLs), appropriate pre and post exam patient care and details of other medication required.

Staff demonstrated how they check and record administered activity within the nuclear medicine department. The following were reviewed: - a 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.

It was confirmed that administered activity is within -10% of the DRLs and staff were aware of the use of DRLs. However, it was noted that the local DRLs on display in the dispensing room was a table copied from the Administration of Radioactive Substances Advisory Committee (ARSAC) Notes for Guidance, including the footnotes. This table had not been adapted for local practice. 20MBq and 40MBq were both listed in separate rows of the table for breast SLNB, but no information was included to indicate that 20MBq would be administered where surgery is performed on the same day or that 40MBq would be used for “next-day” surgical procedures. This should be clarified as currently only same-day surgical procedures are performed at this site. No information was included on the -10% tolerance for administered activity, this should be displayed on the local DRL chart so that staff can clearly see the acceptable range of activity to dispense, particularly in light of the residual audit findings detailed in section 5.2.3. An area of improvement was identified to amend the local DRLs to clarify the administration of 20MBq and 40MBq activity for Breast SLNB and ensure -10% tolerance administered activity is clearly outlined in the DRLs.

Two documents were on display in the dispensing room giving 'authorisation' to inject from a named consultant radiologist (nuclear medicine practitioner licence holder). These documents were not part of the QA system and are not required as the entitlement process and records cover administration of radioactive substances. These documents may have been used under previous regulations but are no longer required under IR(ME)R 2018. An area of improvement was identified to remove the two documents displayed in the dispensing room outlining authorisation by a named consultant radiologist, to avoid confusion and the undermining of the entitlement process.

Pregnancy and Breast Feeding

Staff confirmed that pregnancy status enquiries are carried out for patients aged 11-55. A pregnancy enquiry form is completed and scanned on to the PACS. Staff outlined that breast SLNB patients have a urine pregnancy test prior to coming to the nuclear medicine department.

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

EP D pregnancy enquiries and breast feeding was in place and it was found to be overall well written, however it did not reflect the full pregnancy enquiries and breast feeding protocol in relation to a nuclear medicine service as described by staff. An area of improvement was identified to update EP D and outline the procedure for making pregnancy enquiries and breast feeding protocols for the nuclear medicine service.

EP D also referred to EP R, giving written instructions and information for patients undergoing treatment or diagnosis with radioactive substances, in relation to further information on breast feeding, however EP R did not reflect any such information. An area of improvement was identified to amend EP R to include information on breast feeding and ensure references within EPs to other EPs are correct and accurately reflect the content referenced.

Review of a sample of scanned pregnancy forms found them to be appropriately completed.

Employers Procedures (EPs)

There were comprehensive detailed EPs in place with version 9 having been approved in July 2023 by the Radiation Safety Sub-committee. As the EPs had been ratified and approved just days before the inspection, it was not possible to review all of the EPs however, a focused review found them to be overall well written and a much improved framework to support staff in complying with IR(ME)R. It was evident that considerable work and consideration had gone into their development. However, as previous areas of improvement on the EPs outlined in this report would highlight, the process would have benefitted from the full engagement of the nuclear medicine department in their development.

In additional to those EPs already referred to in this report the following was noted:

- EP S document QA, should include further information in relation to how document control is implemented.
- EP I equipment QA, should include further information to reflect the requirements for nuclear medicine equipment as this is missing from the current procedure.
- EP O providing information on benefits and risks, this procedure is referred to in EP A where it states that details about the entitled referrers for nuclear medicine are included in EP O. However, this information is not included in EP O, but is included in EP B. These procedures should be reviewed to ensure that the relevant information is available in the correct place and any cross references are up to date.

An area of improvement was identified to update:

- EP S to fully reflect how document control is implemented
- EP I equipment QA, should include nuclear medicine equipment QA
- EP 0 and EP B should be reviewed to ensure that the relevant information is available in the correct place and any cross references are up to date.

There have been significant changes in version 9 of the EPs and management team confirmed that staff have been informed of the updated version via email and requested to review. However, this is a 101 page document which would be difficult for staff to fully review and ascertain the relevant changes to practice. An area of improvement was identified to devise a summary of the significant changes to the EPs which should be made available to staff to ensure staff can be aware of the impact and/or changes to their practice.

Governance arrangements for the nuclear medicine department.

As a new department and a new modality for the Trust the nuclear medicine department is evolving and it is important that there are clear lines of accountability from the department to the Employer. As with the general radiology department there must be systems established to assure the Employer of IR(ME)R compliance, these systems were not evident for the nuclear medicine department. There was a disconnect between the nuclear medicine department and the general radiology service and radiology management oversight and governance was found to be inadequate to ensure IR(ME)R compliance.

This was evidenced through the following: -

- the nuclear medicine department had established a separate SharePoint site with limited access by radiology management
- the nuclear medicine department were not fully part of the radiology service management system SharePoint site
- nuclear medicine procedures had been devised within the nuclear medicine department which had not been subject to the radiology service and the Trust ratification processes
- document control on nuclear medicine documents was not in accordance with Trust standards
- audits carried out within the nuclear medicine department were largely without the support and external scrutiny of the radiology management and governance lead
- communication between the nuclear medicine department and the wider radiology service and management was noted to require strengthening

The matter was highlighted as part of overall feedback on the day of the inspection. Following the inspection to provide further context to the matter the RSM was contacted by RQIA and a lengthy positive discussion took place. The RSM was requested to submit, in writing, an action plan by 27 July 2023 to address the identified governance matters. A robust action plan was received on 26 July 2023 that outlined the following:

- the general radiology service and nuclear medicine service are to be rebranded under the new title of The Imaging Service to reflect a more inclusive service
- Nuclear Medicine Lead is to attend fortnightly senior management team meetings
- weekly one to one meetings are to be established between the RSM and the Nuclear Medicine Lead, with the agenda provided by the Nuclear Medicine Lead
- the Nuclear Medicine Lead to take the lead in the next image optimisation team IOT meeting
- nuclear medicine SharePoint site is to be integrated into the radiology SharePoint site, with full access by radiology and nuclear medicine
- Nuclear medicine documents are to be re-formatted in line with other modalities and Trust standards
- Nuclear medicine lead and MPE for nuclear medicine are to be involved in actioning the QIP outlined in this report including review of the EPs
- Nuclear medicine audits going forward will be fully integrated into the radiology plans.

To ensure the full implementation of the action plan an area of improvement has been identified to strengthen communication, establish robust formal governance and oversight systems and promote good working relationships between the nuclear medicine department and radiology service management to offer assurance to the Employer on the compliance of IR(ME)R.

6.0 Conclusion

There were 17 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 UH 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	17

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

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

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

Quality Improvement Plan	
Action required to ensure compliance with The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018	
Area for improvement 1 **Ref:** Regulation 17 (4) **Stated:** First time **To be completed by:** 19 October 2023	The Employer must ensure entitlement is underpinned by evidence of training and competency in line with individual scope of practice. Ref 5.2.1
	Response by Employer detailing the actions taken: The Imaging Service will adopt the same approach to gathereing evidence of training and competency for the Breast and Plastic Surgeons as that being used for the Urology team 1. Formal reassurance from the Lead Breast and Plasctic Surgeons that both gropus of Surgeons are trained in the procedures they perform and remain up to date in terms of CPD and compliance with governance requirements. 2. A certificate from each Surgeon showing that they have completed the IRMER training associated with being considered a referrer an doperator under the IRMER regulations. This would require 3 yearly renewal. 3. On receipt of confirmation that training and competency is satisfactory and IR(ME)R Awareness Training certificates received an entitlement form will be issued outlining the individual Surgeons scope of practice and requiring a signature that IR(ME)R documentation such as Employers Procedures, Radiation Safety Policy and Local Rules have been read and understood. Table 5 in EP A will be updated to identify who holds referrer and operator duty roles in the Nuclear Medicine Service
Area for improvement 2	The Employer must ensure entitlement records reflect the specific duty holder role or roles, the individual scope of

Ref: Regulation 6 Schedule 2, 1. (b) **Stated:** First time **To be completed by:** 19 October 2023	practice and that dates and signatures are completed where necessary. Ref 5.2.1
	Response by Employer detailing the actions taken: Entitlement forms will be reviewed and amened so that the forms clearly state an individuals scope of practice and duty holder roles for each the Consultant Radiologists, Clinical Technologists, the Radiographers and Breast and Plastic Surgeons Forms will be checked to ensure dates and signatures are completed where necessary
Area for improvement 3 **Ref:** Regulation 6 Schedule 2, 1. (b) **Stated:** First time **To be completed by:** 19 October 2023	The Employer must ensure breast surgeons and plastic surgeons who refer for sentinel lymph node biopsies (SLNB) breast and SLNB melanoma respectively are entitled as a referrer for these procedures and staff undertaking clinical evaluation of medical exposures are subject to the entitlement process as an operator. Ref 5.2.1
	Response by Employer detailing the actions taken: Steps as per Recommendation 1 will be followed The Medical Consultant Entitlement form will be adopted for the Nuclear Medicine Service
Area for improvement 4 **Ref:** Regulation 6 Schedule 2, 1. (b) **Stated:** First time **To be completed by:** 19 October 2023	The Employer must ensure Employers Procedure (EP) A is updated to reflect the nuclear medicine service in more detail and reflect the changes made to the entitlement procedure as a result of this inspection. Ref 5.2.1
	Response by Employer detailing the actions taken: EP A will be reviewed and updated by the Imaging Services Team to reflect the areas for improvment in the QIP and also by referring the recommendations discussed on the day of inspection
Area for improvement 5 **Ref:** Regulation 6 Schedule 2, 1. (b) **Stated:** First time **To be completed by:** 19 October 2023	The Employer must ensure EP B referral, clearly states if referral forms from other Trusts or Independent Healthcare Providers are accepted as a referral for radiology procedures including nuclear medicine services. Ref 5.2.1
	Response by Employer detailing the actions taken: EP B will be updated to state clearly that referral forms from other Trusts or Independent Healthcare Providers are accepted as a referral for radiology procedures in the Nuclear Medicine Service

	This will be described in the authorisation and referral guidelines Changes will be minuted at SLNB Steering Group 25/09/23 Staff will be informed of the changes and will be minuted at staff meeting
Area for improvement 6 **Ref:** Regulation 10 (5) **Stated:** First time **To be completed by:** 19 August 2023	The Employer must ensure that referral forms contain sufficient clinical information, are completed by an entitled referrer and are subject to regular audit. Ref 5.2.1
	Response by Employer detailing the actions taken: The Nuclear Medicine Service will ensure recommendtions in Improvement 6 are fulfilled and are subjected to regular audits Audits will be listed on the Imaging Service audit schedule Nuclear Medicine audits will be suppoterd and undergo external scrunity by the Imaging Mangment team and the Governance Lead The Nuclear Medicine Service have communicated with their referrers highlighting the importance of sufficient clinical information being documented on all referrals Referral guidelines will be reviewed and enhanced Following update and review, the guidelines will be circulated amongst the Surgical teams who refer into the service Imaging Services template and document control will be adopted in accordance with Trust standards Nuclear Medicine Share point will be update Following QSI assessment further changes to the share point may be required
Area for improvement 7 **Ref:** Regulation 11 (5) **Stated:** First time **To be completed by:** 19 September 2023	The Employer must ensure that authorisation guidelines are updated to provide clarity on what criteria should be included in the referral forms to allow operators to authorise the exposure; clearly identify the purpose of the guidelines and identify the practitioner. Ref 5.2.1
	Response by Employer detailing the actions taken: The authorisation guidelines will be reviewed and updated to provide more clarity on what criteria should be included in the referral forms to allow the operators to authorise the exposure The purpose of the guidelines will be stated and the named practitioner will be identified New guidelines will be shared with all relevant staff and will be minuted at staff meeting Share point will be updated Imaging Services template and document control will be adopted

Area for improvement 8 **Ref:** Regulation 6 Schedule 2, 1. (j) **Stated:** First time **To be completed by:** 2023	The Employer must amend EP P to outline the arrangements for the clinical evaluation of nuclear medicine studies. Ref 5.2.2
	Response by Employer detailing the actions taken: This is SET EP H EP H needs to state Breast and Plastic Surgeons will document their clinical evaluation in the patient's notes Breast and Plastic Surgeons will be reminded of this role as stated under IRMER regulations by the Departmental Lead. Breast and Plastic Surgeons will be entitiled to clinically evaluate under the duty holder role of operator EP P will be reviewed and reflect the clinical evaluation arrangements for all Nuclear Medicine studies
Area for improvement 9 **Ref:** Regulation 7 **Stated:** First time **To be completed by:** 19 September 2023	The Employer must undertake a robust approach to analysing the findings of audits. The template for recording audits should be reviewed and include more detail on the findings, an action plan, a named person responsible for addressing the audit findings and the date by which a re-audit should be completed. Ref 5.2.3
	Response by Employer detailing the actions taken: Nuclear Medicine have adopted the Imaging Service audit template The re audti date and named person responsible are stated on each audit witin the template Communication between Nuclear Medicine and the other parts of the Imaging Service are being enhanced and developed Nuclear Medicine will be part of future audit planinning
Area for improvement 10 **Ref:** Regulation 6 **Stated:** First time **To be completed by:** 19 October 2023	The Employer must establish regular formal communication with the Regional Radio Pharmacy Department for example through planned meetings. Ref 5.2.5
	Response by Employer detailing the actions taken: First meeting between the Radio Pharmacy Department and the Imaging Services Department is scheduled for 19/09/23 Following this first meeting a meeting schedule will be decided Any errors or discrepanies identified between meetings will be addressed using the pathway in the Local Rules which have been signed by the Radiation Protection Advisor The Local Rules were ratified at the last Radiology Safety Sub Committee Meeting and discussed at the bi weekly senior management team meeting

Area for improvement 11 **Ref:** Regulation 6 (5) (c) **Stated:** First time **To be completed by:** 19 August 2023	The Employer must amend the local DRLs to clarify the administration of 20MBq and 40MBq activity for Breast SLNB and ensure -10% tolerance administered activity is clearly outlined in the DRLs. Ref 5.2.5 **Response by Employer detailing the actions taken**: Updated and completed
Area for improvement 12 **Ref:** Regulation 6 **Stated:** First time **To be completed by:** 19 August 2023	The Employer must remove the two documents displayed in the dispensing room outlining authorisation by a named consultant radiologist, to avoid confusion and the undermining of the entitlement process. Ref 5.2.5 **Response by Employer detailing the actions taken**: Documents have been removed
Area for improvement 13 **Ref:** Regulation 6 Schedule 2, 1 (c) **Stated:** First time **To be completed by:** 19 October 2023	The Employer must update EP D and outline the procedure for making pregnancy enquiries and breast feeding protocols for the nuclear medicine service. Ref 5.2.5 **Response by Employer detailing the actions taken**: EP D will be updated to reflect the procedure for pregnancy checking and breast feeding Lead Clinical technologist will consult with MPE A LMP protocol will be developed and any changes or impact on staff practice will be disseminated with the team, this will be evidenced in the EP D With each change of an employers proceedure all relevant cross references will be checked to ensure they are accurate and up to date

Area for improvement 14 **Ref:** Regulation 6 Schedule 2, 1 (h) **Stated:** First time **To be completed by:** 19 October 2023	The Employer must amend EP R to include information on breast feeding and ensure references within an EP to other EPs are correct and accurately reflect the content referenced. Ref 5.2.5
	Response by Employer detailing the actions taken: The EP R will be updated as per Improvement 13 Full review of the EP's will be undertaken to ensure references within an EP to other EP's are correct and are accuratley reflected
Area for improvement 15 **Ref:** Regulation 6 Schedule 2 **Stated:** First time **To be completed by:** 19 October 2023	The Employer must update: • EP S to fully reflect how document control is implemented • EP I equipment quality assurance (QA), to include nuclear medicine equipment QA • EP O and EP B should be reviewed to ensure that the relevant information is available in the correct place and any cross references within are up to date. Ref 5.2.5
	Response by Employer detailing the actions taken: The EP's listed above will be updated to reflect the actions required by RQIA
Area for improvement 16 **Ref:** Regulation 6 Schedule 2 **Stated:** First time **To be completed by:** 19 August 2023	The Employer must devise a summary of the significant changes to the EPs which should be made available to staff to ensure staff are aware of the impact and or changes to their practice. Ref 5.2.5
	Response by Employer detailing the actions taken: A summary sheet will be devised following the update and review of the employers proceedures Summary sheet will be disseminated to all staff across sites in an all user email and will be minuted at all staff meetings
Area for improvement 17 **Ref:** Regulation 6 **Stated:** First time **To be completed by:** 19 September 2023	The Employer must strengthen communication, establish robust formal governance and oversight systems and promote good working relationships between the nuclear medicine department and radiology service management to offer assurance to the Employer on the compliance of IR(ME)R. Ref 5.2.5
	Response by Employer detailing the actions taken: The name of the service will change following rebranding to the Imaging Service Deparment following the QSI assessment in early October Nuclear Medicine Lead or deputy will attend in person at bi weekly Senior Management Team 1:1's will be attended on a regular basis

	The Nuclear Medicine Lead has not been included in actioning the QIP to date as currently on sick leave Band 7 has deputised in her place for completion and review of this QIP A meeting will be scheduled with the Nuclear Medicine Lead on her return to discuss any changes, feedback from QSI relevant to her service and action points that require implementation from the QIP

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