INSPECTION REPORT OF COMPLIANCE WITH THE IONISING RADIATION (MEDICAL EXPOSURE) REGULATIONS (NORTHERN IRELAND) 2018

12 March 2020

NHSCT Antrim Area Hospital
Nuclear Medicine Department

Address: Bush Road, Antrim, BT41 2RL
Inspectors: Winifred Maguire & Stephen O'Connor
Public Health England (PHE) Advisor: Nasreen Parkar

www.rqia.org.uk

Assurance, Challenge and Improvement in Health and Social Care

It should be noted that this inspection report should not be regarded as a comprehensive review of all strengths and areas for improvement that exist in the service. The findings reported on are those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not exempt the service from their responsibility for maintaining compliance with legislation, standards and best practice.

1.0 What we look for

RQIA has employed refreshed inspection methodology in relation to compliance of radiology services with The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018, known as the IR(ME)R regulations. The regulations came into force on 6 February 2018.

This inspection had a particular focus on the key changes to the regulations including:

- communication of benefits and risks;
- diagnostic reference levels (DRL's);
- accidental and unintended exposures;
- equipment;
- carers and comforters;
- study of risk for accidental and unintended exposures in nuclear medicine for therapeutic purposes (not provided on this site); and
- the role of the medical physics expert.

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

- 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; and
- non-medical exposures using medical radiological equipment.

2.0 Service details

Name of Establishment: Antrim Area Hospital Northern Health and Social Care Trust (NHSCT)	**Department Inspected:** Nuclear Medicine Department
Name of Employer: Dr Tony Stevens, Chief Executive of NHSCT	**Radiology Services Manager:** Mr Matt Mallon
Director of Surgical and Clinical Services: Ms Margaret O'Hagan	**Medical Physics Expert:** Mr Conor Ferris

3.0 Profile of services

The self-assessment form submitted prior to the inspection confirmed that each year, Antrim Area Hospital (AAH) Nuclear Medicine department carries out approximately:

2338 Planar/dynamic nuclear medicine imaging
51 SPECT Imaging – Parathyroid
921 SPECT Imaging – Cardiac Stress/Rest

The following radioisotopes are routinely used within the department for nuclear medicine imaging:

Unsealed radionuclides: Tc-99m, I- 123.

AAH Nuclear Medicine department employs:

1.725 Consultant Radiologists
4.4 Radiographers
1 Lead Medical Physics Expert (MPE) Nuclear medicine (under contract from Regional Medical Physics Service (RMPS)
1 Clinical Scientist (under contract from RMPS)

RMPS radiopharmacists provides radiopharmaceuticals from the Radiopharmacy department, Royal Victoria Hospital, Belfast Health and Social Care Trust (BHSCT) under contract.
The nuclear medicine service is provided Monday to Friday.

4.0 Methodology

On 12 March 2020, warranted IR(ME)R inspectors from RQIA, with advice being provided by Public Health England (PHE) staff, carried out an announced inspection to AAH, Nuclear Medicine Department, as part of RQIA's IR(ME)R inspection programme.

Prior to the inspection, the service was requested to complete a self-assessment form and provide RQIA with all relevant policies and procedures. This information was shared with PHE prior to the inspection visit and was used to direct discussions with key members of staff working within the nuclear medicine department and provide guidance for the inspection process.

NHSCT staff and MPE staff were in attendance for part or all of the inspection:

Ms Margaret O'Hagan	Director of Surgical and Clinical Services
Dr Myles Nelson	Clinical Director of Radiology
Dr Barry Patterson	IR(ME)R Lead/Chair of Radiation Protection Committee
Mr Matt Mallon	Radiology Services Manager
Ms Cora Regan	Assistant Clinical Service Manager, Radiology
Ms Marie Harvey	Trust Lead Radiographer
Ms Cristiona Logan	Governance Lead Radiographer
Ms Dorota Ferguson	Clinical Scientist

Mr Conor Ferris	MPE Nuclear Medicine
Ms Karen Johnston	Radiographer Nuclear Medicine

The inspection team reviewed relevant documentation and patient records. A tour of some areas of the nuclear medicine department was undertaken and the inspectors took the opportunity to speak with two radiographers.

5.0 Inspection outcome

	Regulations
Total number of areas for improvement	13

Details of the Quality Improvement Plan (QIP) were discussed with senior management as part of the inspection process. The timescales for completion commence from the date of inspection.

6.0 The inspection - key findings

6.1 Review of area of improvements from a previous inspection.

This is the first inspection of this service against IR(ME)R 2018 legislation.

6.2 Duties of the employer

Employer's Procedures

AAH, NHSCT had the required Employer's Procedures in place, which had been reviewed and updated in accordance with The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018. The Employer's Procedures were issued in February 2020 and are reviewed every two years or more frequently if change is necessary. There is one set of Employer's Procedures which cover all modalities including nuclear medicine. We found that specific information and processes relating nuclear medicine as outlined in the self-assessment was not always reflected in the Employer's Procedures. An area of improvement was identified to review the Employer's Procedures to ensure that the nuclear medicine service is accurately reflected.

A Radiation Safety Policy had been issued in February 2020 and confirmed that the Employer has been clearly identified in line with IR(ME)R legislation. It was established that the overall responsibility for IR(ME)R lies with Dr Tony Steven, Chief Executive, NHSCT and his subsequent responsibilities are clearly set out. Flow charts included in the Radiation Safety Policy outlined the governance and reporting structures in relation to the use of ionising radiation through the NHSCT assurance framework.

The structures outlined in the Radiation Safety Policy were discussed with senior management together with roles and responsibilities. The Chief Executive Officer (CEO), through the executive team nominates the Chair of the Radiation Safety Committee (RSC) with the tasks associated to ensure compliance with the requirements set out in the Ionising Radiation Safety Policy and the IR(ME)R regulations.

Review of the submitted documentation and discussion with the senior management team outlined that systems are in place to ensure that Employer's Procedures are complied with by Practitioners and Operators, through audit, induction and training.

Senior management and staff demonstrated a good understanding of the roles and responsibilities as set out in the Radiation Safety Policy. Document and version control are clearly noted on the Employer's Procedures and all relevant policies and procedures can be found on NHSCT intranet.

Employer and Practitioner Licences

The NHSCT has not yet applied for an Employer's Licence for the AAH nuclear medicine service. Until the Employer Licence is granted authorisation using the Administration of Radioactive Substances Advisory Committee (ARSAC) certificate of Dr Myles Nelson is still being made. We were advised that the CEO for NHSCT is to change in the coming weeks and an application for an Employer's Licence will be made when the new CEO is in place.

We noted that the sole gamma camera is 15 years old. A replacement plan including a business case is in place and awaiting approval for funding from Department of Health with a target date for replacement is April 2021. We highlighted concerns ARSAC has with older gamma cameras which may result in a limited licence being granted. In addition this gamma camera had been involved in a number of breakdowns leading to incidents and is currently included on the risk register. An area of improvement was identified to ensure that the business case for replacement includes the implication of age of the sole gamma camera on the granting of an Employer's Licence; the impact on service delivery, highlighting relevant incidents relating to breakdown; the current status of this piece of equipment on the risk register; and that in light of these matters the replacement of this gamma camera should be expedited.

There are two Practitioners entitled for the service with valid ARSAC certificates or a Practitioner Licence under IR(ME)R. Copies of ARSAC certificates and IR(ME)R Practitioner Licences are retained in Radiology Quality Management System. The renewal or application for Practitioner or Employer licence will include liaison with the nuclear medicine modality lead radiographer and MPE and review of the application to identify new requirements or radiopharmaceuticals required. The scope of current licences will be reviewed as part of the procedure for new practice developments. Nuclear Medicine Safety meetings are held twice yearly prior to the RSC. The review of IR(ME)R licences and ARSAC certificates is a standing agenda item for these meetings. The Chair of the RSC is delegated with the tasks associated with ensuring the licensing process is in accordance with legislation.

Quality Assurance programme for written policies and procedures

Review of the documentation provided to the inspection team confirmed that a quality assurance system of documentation is in place. Radiology documentation is available on The Radiology Shared Drive – Radiology Protocols.

'Employer's Procedure D', outlines the quality assurance programmes in respect of written procedures, written protocols, and equipment. Equipment Quality Assurance (QA) is further discussed in section 6.6 of this report.

Diagnostic Reference Levels (DRLs)

The process for establishing, reviewing, and checking compliance with DRLs has been developed in collaboration with the MPEs and is set out in 'Employer's Procedure F'. DRL's for nuclear medicine procedures are available on the shared drive and available electronically to Operators.

We found that Local DRL's (LDRLs) have been established for eight nuclear medicine procedures and staff confirmed that they use them when they draw up the activity. We found that the National DRLs, as quoted in the ARSAC Notes for Guidance, are displayed alongside the LDRLs in the nuclear medicine injection room. This may lead to confusion in the application of the DRLs. An area of improvement was identified to ensure clarification is provided on the DRLs in use and sharing this information with duty holders.

Paediatric doses are scaled according to weight using the ARSAC Guidance. The modality lead radiographer is responsible for ensuring DRLs are available, reviewed and updated when necessary. The LDRLs are reviewed by the Licensed Practitioners and submitted to RSC for approval. The DRLs are reviewed at least annually as part of the Image Optimisation Team (IOT) dose optimisation agenda. We noted that the Lead MPE for Nuclear Medicine had not been previously involved in the IOT and has only recently been invited to join the IOT.

Dose audits are carried out; a comparison of mean doses for each type of examination with the relevant DRL is undertaken and a report written on the dose survey results that will identify whether any of the dose levels measured either approach or exceed DRLs. We found that dose audits were conducted in relation to the drawn up dose not the administered dose. Operators explained that there may be significant variations due to residual activity in the syringe. Both values (residual activity and the drawn up dose) are logged on Radiology Information System (RIS). We found that the dose is audited in accordance to National DRLs not LDRLs. This audit is conducted to ascertain if DRLs have been consistently exceeded. The use of the drawn up dose and National DRLs as the fundamental components of the audit may lead to less than an accurate picture and confusion on the use of the LDRLs. An area of improvement was identified to review how dose is recorded, consideration should be given to auditing the administered patient dose against LDRLs.

We found that there may be potentially high residual activities in the syringes and some consideration had already being given to using different syringes or a three-way tap to address this issue. However no formal auditing of this matter had taken place. An area of improvement was identified to audit the level of residual activities in the syringes as a foundation to make any necessary changes to practice.

Staff spoken with demonstrated a clear understanding of what action to take in the event of DRL's being consistently exceeded.

Patient doses and administered activity

'Employer's Procedure F' outlines the procedure for assessment of patient dose and administered activity. We found that radiopharmaceuticals are delivered in multi-dose vials from

the Regional Radiopharmacy based on the Royal Victoria Hospital site, BHSCT. The multi-dose vials are ordered the day before and delivered on the morning of administration. The activity of individual radiopharmaceutical doses for diagnostic procedures is measured using a calibrated ionisation chamber prior to administration to a patient.

As previously stated the measured activities are recorded by an Operator into the patient record in RIS. In addition, there is a nuclear medicine diary where the Operator logs vial details at the start of the day and records individual patient administrations against this.

Clinical audit

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

A planned audit programme is in place and evidence of audits was provided. The inspection team reviewed radiology audits carried out in the nuclear medicine service and it was good to note that where there were areas of non-compliance identified, there was evidence of a re-audit being carried out within a specified timeframe. This resulted in increased compliance rates. Audits are used to improve and change practice with results being shared at the radiological team briefs, departmental audit meetings, site meetings and IOT meetings. The Chair of the RSC attends the IOT meetings and is made aware of the audit findings and any action taken.

Accidental and unintended exposures

Following examination of policies and discussion with staff it was clear that there are good systems in place to identify, report, record, manage, and learn from incidents and near misses. We found that there had been strengthening of reporting and managing accidental and unintended exposures following previous IR(ME)R inspections to other modalities in the Trust.

Management and staff explained the process for reporting internally and then to the appropriate enforcing authority. This was set out in 'Employer's Procedure Q' in a detailed narrative form. An area of improvement was identified to include a quick reference guide such as a flowchart for staff in relation to incident notification.

All radiation incidents are recorded on DATIX either as a near miss or radiation incident with an action plan included. A radiation incident investigation form is also completed which is in accordance with the Significant Accident and Unintended Exposures (SAUE) guidance. Staff clearly understood their roles involving incidents and that the service manager is responsible for reporting to RQIA. 'Employer's Procedure L', clinically significant incidents, was in place and included specific information on deterministic tissue injuries and informing the patient.

We reviewed two Radiology Errors Quarterly reports, which included a trend analysis on accidental or unintended medical exposures. We found there was meaningful analysis of the data and evidence of trends. This has led to changes in practice in the provision of sentinel node injection procedures.

All radiation incidents are collated and sent to the RSC and through the governance framework as previously described. Incidents have been appropriately reported to RQIA under IR(ME)R that have occurred within the last few months.

Training, competence and entitlement

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

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

The inspection team reviewed a number of completed induction programmes, competency and entitlement records for Operators and Practitioners including radiologists, radiographers, a clinical scientist and a MPE. Staff undertake an induction programme which includes IR(ME)R and radiation safety awareness and are required to read the Employer's Procedures. Training and competency records for radiographers were found to support entitlement and were in accordance with individual scope of practice. We noted that the entitlement records for radiologists did not fully reflect the Operator role. An area of improvement was identified to further develop the record of entitlement for radiologists in relation to the tasks associated with the Operator role.

The entitlement of MPEs was discussed and senior management outlined that they favoured the individual entitlement of MPEs. It is presently group entitlement with an outline of individual scope of practice and a letter from Head of RMPS confirming competence of MPEs. The entitlement documentation provided did not have the signature of the MPE to evidence that they are aware of what they are entitled to do. An area of improvement was identified to ensure the entitlement record for MPEs is completed and fully understood by the duty holder and the entitler. 'Employer's Procedure B' in relation to entitlement process was in place.

Referrals

The referral guidelines currently being used are the Royal College of Radiologists iRefer Guidelines Making the Best Use of Clinical Radiology 8th edition. There were no additional specific referral guidelines for nuclear medicine. iRefer guidelines are available via the Radiology Service Business page.

We found iRefer guidelines and further information relating to referrals are not routinely shared with Referrers such as General Practitioners. An area of improvement was identified to issue further information on referral guidelines to internal and external Referrers in relation to nuclear medicine.

The Clinical Services Manager, radiology, attended a regional radiology forum where an issue with sending referrals between Trusts was highlighted which may result in the original Referrer potentially not being entitled by the receiving Trust. The forum created an awareness of the matter and the Clinical Services Manager then ensured appropriate measures were put in place to ensure inter-trust referrals were in accordance with the regulations.

Staff described how referrals are made to the department, including prioritising referrals and specifically timed future examinations. A clear process was evidenced for returning/rejecting referrals which are incomplete, inappropriate or unjustified. Cancelling referrals was discussed including how Referrers are made aware of the process to cancel a referral they have made.

'Employer's Procedure O', referral, justification and authorisation was in place. It provided some information relating to the referral process. Discussion with staff and the information provided in the self-assessment form (submitted to RQIA prior to the inspection) and within the authorisation guidelines gave a much clearer picture of the referral process. An area of improvement was identified to further develop 'Employer's Procedure O' to include more specific detail relating to Nuclear Medicine referral process.

We found that the Trust issues a Radiation Referral Safety Newsletter to Referrers.

6.3 Justification and authorisation of individual medical exposures

Justification and authorisation was discussed with staff, who demonstrated understanding of the process and described how justification and authorisation is recorded electronically on the radiology information system (RIS). This was evidenced in a randomly selected number of patient records.

There are two Practitioners within the nuclear medicine department who justify and authorise exposures. One of whom, has developed a set of authorisation guidelines, which entitles Operators to authorise a specific range of exposures.

The justification and authorisation of exposures to carers and comforters was discussed at length. Authorisation guidelines outline the arrangements for the justification and authorisation of carers and comforters exposures. Entitled Operators authorise carers and comforters exposures in accordance to the authorisation guidelines and the author of the authorisation guidelines acts as the Practitioner. Carers and comforters who are or may be pregnant must be discussed with the Practitioner who must justify the exposure, preferably prior to the patient arriving in the department.

We found that the authorisation guidelines named four Practitioners with regards to justification of the exposures to carers and comforters. However we confirmed only the two licenced Practitioners within the nuclear medicine department act as Practitioners for exposures to carers and comforters. An area of improvement was identified to remove reference to the other Practitioners within the authorisation guidelines and to accurately reflect the arrangements for justification and authorisation of exposures to carers and comforters. A Carers and Comforters Record Form-Nuclear Medicine is completed, scanned, verified and attached to the appropriate patient details on RIS. 'Employer's Procedure N', carers and comforters, is in place and there is a section relating to nuclear medicine and dose constraints.

6.4 Optimisation

There are good arrangements in place to ensure that medical exposures are kept as low as reasonably practicable. 'Employer's Procedure K' outlines the arrangements in place, these include

- applications training;
- radiographic protocols;
- standard operating protocols;
- routine equipment maintenance;

- appropriate exposure charts;
- daily quality assurance of equipment; and
- core safety audits.

The specific arrangements for Nuclear Medicine were also reflected in the Employer's Procedures which included:

- only one vial being used in the Laminar flow cabinet at one time;
- each drawn up dose is individually labelled;
- two radiographers check multi-dose vials before drawing up a single dose; and
- identification of the correct radiopharmaceutical and any corresponding calculations are independently checked and verified by two appropriately trained and entitled radiographers.

Communication of benefits and risks of having an exposure to ionising radiation

Staff displayed clear understanding in relation to the process of providing the individual (or their representative) to be exposed with adequate information on the benefits of having the exposure and the risks associated with the radiation dose. It was confirmed that staff had training in relation to providing benefits and risks information.

It was good to note information posters prominently displayed in the waiting areas, injection rooms and treatment rooms of the nuclear medicine department. We found written patient information and preparation leaflets had been developed and were well written. Patients are sent a statement on benefits and risks with their appointment letter. New devised information leaflets were reviewed and we confirmed they are to be implemented when the ratification process has been completed. 'Employer's Procedure H', giving written instructions as referred to in regulation 12(6), was in place and outlined clearly the arrangements within nuclear medicine department.

'Employer's Procedure I', benefits and risks associated with the radiation dose from the exposure, was in place and included reference to the nuclear medicine department.

Paediatrics

Paediatric imaging is provided by the nuclear medicine department. It was noted that special attention is paid to optimisation when undertaking exposures of children. This includes:

- the administered activity is reduced for children according to body weight in accordance to the ARSAC Notes for Guidance;
- additional time is allocated for paediatric procedures; and
- use of paediatric protocols

Written protocols

A range of written nuclear medicine adult and paediatric protocols were in place which had been issued February 2020. The protocols objective is to ensure that the appropriate nuclear medicine examination is performed consistently to answer the clinical question, ensuring optimization of the administered radiopharmaceutical and associated imaging. Staff demonstrated an understanding of the protocols and confirmed they are readily available to them.

We found that the range of activity that can be administered was not fully reflected in the written protocols. Discussion with management and staff in the department highlighted a discrepancy, with +/- 5% of the indicated activity mentioned and +/- 10% of the indicated activity also mentioned as the range of activity that can be administered.

We noted that there was some information relating to concomitant medications dosage on page 47 of the paediatric protocols which was not consistent.

An area of improvement was identified to ensure that the written protocols include a specific range of activity that can be administered and are consistent in relation to concomitant medication.

Clinical evaluation

'Employer's Procedure J' is in place for the clinical evaluation for medical exposures and it outlines that a documented clinical evaluation is produced for all medical exposures.

Consultant Radiologists undertake clinical evaluation with the appropriate training and experience and in line with their entitlement and scope of practice. All reports are stored with the patient record in RIS. Radiographers who have successfully completed post graduate training in Nuclear Medicine reporting may provide a technical report on Scaphoid Bone scans and VQ Lung scans, following appropriate training and assessment, and as entitled by the Clinical Services Manager, Radiology. These examinations are double reported and a clinical report is provided by an appropriately entitled Radiologist.

Discussions with management and staff confirmed a clear understanding of the clinical evaluation for medical exposures. There is an audit trail on the RIS which identifies which exposures have not been reported on. The Clinical Services Manager, Radiology, monitors compliance on a monthly basis.

6.5 Expert advice

The NHSCT involves the MPE in accordance with the requirements of IR(ME)R legislation. The MPE was present for the duration of the inspection. It was confirmed the appointed MPE for Nuclear Medicine is currently recognised by Department of Health (DOH) and is entitled as an Operator who is competent and appropriately trained for their scope of practice. As stated previously an area of improvement has been made in relation to the entitlement of MPEs.

We found that the MPE involvement within the nuclear medicine department had not been as fulsome as the legislation had intended. The role of the MPE currently within the department is as follows:

- the quality control (QC) of equipment is carried out by another clinical scientist monthly in accordance with the MPE's guidelines. The MPE has an overview of this if there are any problems;
- biannual attendance on site for review and oversight of service to include reviewing audits performed;
- review of incidents including dose assessment; and
- optimising protocols.

The MPE had not been involved in the work carried out so far on the procurement of a new gamma camera; in the IOT work; in the licencing arrangements; and the engineer reports on equipment maintenance and repair had not been shared with the MPE.

Senior management and the MPE acknowledged that greater involvement and utilisation of the MPE's expertise must be developed. The MPE has been invited to participate in the next IOT meeting. We advised that they consult the European Commission guidelines on appropriate levels of MPE support referenced in the ARSAC Notes for Guidance in relation to the role of the MPE locally.

'Employer's Procedure P' was in place which outlined clear arrangements for the involvement of the MPE, however MPE involvement in the nuclear medicine had not been fully in accordance with the procedure.

An area of improvement has been identified to enhance the role of the MPE within the nuclear medicine department in accordance to legislation and Employer's Procedure P.

6.6 Equipment

An inventory of radiological equipment was submitted to RQIA which contained all of the legislative information. Management and staff confirmed there is an appropriate amount of equipment available for the workload of the nuclear medicine department.

As stated previously 'Employer's Procedure D' includes information on QA of equipment. A comprehensive NHSCT equipment QA programme is available on all equipment which is maintained by the site/Modality Lead radiographer in each respective area. We found records of QC were comprehensive and well completed and included information on limits of performance. QC testing is carried out daily before use of the gamma cameras. The Clinical Scientist undertakes more extensive testing on monthly and on annual basis as outlined in the QC schedule.

There was a clear understanding from staff as to how to communicate in relation to defective equipment within the department. The process for flagging potential and unplanned equipment issues which may impact on the service delivery or may require capital replacement sooner than expected was clearly communicated verbally to the inspection team. This included discussions on the 15 year old gamma camera. Equipment issues are reported through the governance structures and may be reported to the Radiation Safety Committee. The replacement of the gamma camera had been escalated within the governance structures.

6.7 Patient identification

'Employer's Procedure A' is in place to correctly identify individuals to be exposed to ionising radiation. The procedure references the three-point patient identification process, and it clearly outlines that it is the responsibility of the Operator who carries out the medical exposure, to ensure that the correct patient receives the correct medical exposure, according to the request made.

Staff outlined the patient identification procedure and that the Operator responsible must sign their name beside the identity (ID) check on the request form or sign electronically in RIS as appropriate. Review of a sample of patient records confirmed an ID check had been recorded.

6.8 Pregnancy and breast feeding enquiries

'Employer's Procedure C' for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breast feeding was in place and found to be adequate.

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.

Patients are asked in their appointment letter and patient information sheet to contact the nuclear medicine department if they are or could be pregnant or breast feeding. "Inform the staff if you are pregnant/breast feeding" posters were displayed in the waiting areas in the department instructing patients to inform staff before they are administered radiopharmaceuticals. If relevant, patients are given written information on breast feeding interruption times in accordance to ARSAC Notes of Guidance.

6.9 Research

We confirmed that no research is carried out in AAH, nuclear medicine department. NHSCT 'Employer's Procedure I' was in place for research exposures.

6.10 Review of environment

The inspection team reviewed the facilities available in relation to the nuclear medicine department. The department was found to be clean, tidy and well organised. There were posters to provide patients with information regarding the benefit and risk of the exposure and pregnancy posters were displayed. There was a well-appointed waiting area and changing cubicles for patients.

6.11 Staff discussion and review of patient records

The inspection team met with two radiographers and discussed: the application of the Employer's Procedures; the role and function of duty holders; patient identification; pregnancy and breast feeding enquiries; the use of authorisation guidelines; induction; continued professional development; the use of DRLs as a reference tool; carers and comforters; and the action to be taken if they thought a patient had received an accidental or unintended exposure. Staff demonstrated a good working knowledge of the Employer's Procedures and the other areas discussed. Review of patient records indicated that the correct procedures are being followed.

6.12 Conclusion

Radiological practice in AAH nuclear medicine department was found to be safe, effective and largely in line with the principles of IR(ME)R and good practice guidelines.

The staff were found to be knowledgeable and professional. It is acknowledged the work that has been undertaken to ensure compliance with the IR(ME)R regulations 2018 including updating the Radiation Safety Policy and the Employer's Procedures; developing posters and information leaflets for the communication of the benefits and risks of medical exposures to patients (and/or their representative); and devising a robust audit programme.

As stated previously, it was evident the radiology department has an underpinning culture of quality improvement. Management and staff demonstrated an inclusive, enthusiastic and proactive approach to patient centred service improvement. The staff feedback provided on the day of inspection confirmed this approach.

Inspectors concluded that whilst there were no identified serious concerns regarding the actual delivery of the service, attention needs to be given to maintaining processes set out in IR(ME)R to protect patients as highlighted in the areas of improvement.

There were 13 areas of improvement identified as a result of this inspection. These are fully outlined in the appended Quality Improvement Plan (QIP).

The management team and staff are to be commended for their commitment and enthusiasm to ensuring that the department is striving to operate within the legislative framework and maintaining optimal standards of practice for patients.

The inspectors would like to extend their gratitude to the management team and staff for their hospitality and contribution to the inspection process.

7.0 Quality improvement plan

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.

7.1 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.

7.2 Actions to be taken by the service

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.

<table>
<tr><th colspan="2">Quality Improvement Plan</th></tr>
<tr><td colspan="2">Action required to ensure compliance with The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 and other published standards which promote current best practice to improve the quality of service experienced by patients.</td></tr>
<tr><td rowspan="2">Area for improvement 1

Regulation: 6 (1) (a), Schedule 2

Stated: First time

To be completed by:
12 July 2020</td><td>The Employer shall review the Employer’s Procedures to ensure that the nuclear medicine service is accurately reflected.

Ref: 6.2</td></tr>
<tr><td>Response by the Employer detailing the actions taken:
Changes have been made to:
Procedure B: Entitlement of IR(ME) Duty holders within a specified scope of practice
Procedure E: Procedure for the assessment of patient dose and administered activity
Procedure O: Procedure for referral, justification ad authorisation
Procedure Q: Procedure for the reporting of radiation incidents
In accordance with Quality Improvement Plan.

Procedure P: Procedure to identify the involvement of the MPE, has been reviewed by the Nuclear Medicine Lead MPE to ensure the detail accurately reflects Nuclear Medicine processes. It was not identified that any changes were required.

The Nuclear Medicine Lead Radiographer and MPE will review the remaining Employer’s Procedures to ensure they accurately reflect the Nuclear Medicine service (action to be completed by 22/05/2020).

Change requests will be raised and circulated to the Working Party where necessary, for review. All necessary changes to the Employer's Procedures will be made and circulated to the Radiation Safety Committee (RSC) for review, prior to ratification at the June RSC meeting. The Employer’s Procedures will subsequently be issued Trust wide.</td></tr>
</table>

<table>
<tr><td rowspan="2">Area for improvement 2

Regulation: 15 (6) (a)

Stated: First time

To be completed by:
12 June 2020</td><td>In order to expedite the replacement of the gamma camera the Employer shall ensure that the business case for the replacement of the gamma camera includes the following information:

• the potential implication the age of the sole gamma camera might have on the granting of an Employer Licence;
• the impact on service delivery, highlighting a number of recent breakdowns; and
• the status of this piece of equipment on the risk register.

Ref: 6.2</td></tr>
<tr><td>Response by the Employer detailing the actions taken:
The Nuclear Medicine Lead Radiographer will collate a summary report of equipment faults and the corresponding impact, to be included within the current business case (22/05/20).

The Nuclear Medicine equipment Business Case will be updated by Nuclear Medicine Lead Radiographer to include the following details:
• the potential implication the age of the sole gamma camera might have on the granting of an Employer Licence;
• the impact on service delivery, highlighting a number of recent breakdowns; and
• the status of this piece of equipment on the risk register

Although the aging Nuclear Medicine equipment is recorded upon the Risk Register, a formal Risk Assessment will be initiated by the Nuclear Medicine Lead Radiographer and reviewed by the Working Party (22/05/20).</td></tr>
<tr><td rowspan="2">Area for improvement 3

Regulation: 6 (5) (c)
12 (3) (c)

Stated: First time

To be completed by:
12 June 2020</td><td>The Employer shall ensure clarification is provided on the Diagnostic Reference Levels (DRLs) in use and share this information with duty holders.

Ref: 6.2</td></tr>
<tr><td>Response by the Employer detailing the actions taken:
The Nuclear Medicine Departmental DRL's were reviewed by the Working Party (08/05/2020). Following discussion the Nuclear Medicine MPE DRL’s were updated by the Nuclear Medicine Lead Radiographer to ensure DRL's are clear and unambiguous, i.e. removal of National DRL's, where Local DRL's are in place (12/05/20), and circulated to the Nuclear Medicine Lead MPE for review. When the DRL’s have been reviewed and approved by the Nuclear Medicine Lead, they shall be updated in accordance with his advice, authorised and displayed within the Nuclear Medicine</td></tr>
</table>

	Department (15/05/20). CPD will be given to the Nuclear Medicine staff regarding the updated DRL's and the subsequent use of DRL's (May 2020) The Nuclear Medicine Lead MPE will review the detail of Procedure F: Procedure for the use and review of DRL's, to ensure it reflects the requirements of the Nuclear Medicine service (20/05/20).
Area for improvement 4 **Regulation**: 7 **Stated:** First time **To be completed by:** 23 March 2020	The Employer shall review how the dose is recorded, consideration should be given to auditing the administered patient dose against the Local DRLs. Ref: 6.2
	Response by the Employer detailing the actions taken: Immediately following the RQIA inspection (13/03/20) the Nuclear Medicine Lead Radiographer reviewed how dose was recorded on RIS for a variety of examinations. The Nuclear Medicine Lead Radiographer met with the Nuclear Medicine staff, to ensure they understood how dose should be recorded upon RIS, including the details of the two appropriately trained and entitled Operators who check, verify and record the drawn up activity on RIS, and the details of the appropriately trained and entitled Operator who checks and records the administered activity on RIS. The details of this process have been clearly recorded within Procedure E: Procedure for the assessment of patient dose and administered activity. Subsequently Areas for Improvement 3, 4 and 5 will be addressed together, and will include a robust dose audit. The dose audit template will be drafted by the Nuclear Medicine Lead Radiographer and MPE and will include: 1. A review of dose record data quality (drawn up dose checked and verified, and administered dose to be recorded on RIS) 2. Retrospective audit of administered dose will be completed including all Nuclear Medicine examinations 3. The audit will review appropriateness of current locally developed DRL's against the administered dose 4. The audit will compare administered dose to National DRLs, where these have been adopted by the department. 5. The audit will also record and review the residual activity, in order to assess its appropriateness and whether further operational action must be taken to reduce this. DRL's to be reviewed again following dose audit, and action will be taken where required. Progress report to be communicated at the next Image Optimisation Team meeting (June 2020)

	Audit to be completed by Nuclear Medicine Lead Radiographer by the 22/05/20 Working Party to meet and review results 29/05/20. Corrective actions to be agreed and implemented in accordance with results. Departmental DRL's to be reviewed in accordance with audit results. Any changes to DRL's as a result of the dose audit to be ratified at the Image Optimisation Team Meeting/Radiation Safety Committee (June 2020)
Area for improvement 5 **Regulation:** 7 **Stated:** First time **To be completed by:** 12 August 2020	The Employer shall audit the level of residual activities in the syringes as a foundation to make any necessary changes to practice. Ref: 6.2
	Response by Employer detailing the actions taken: Please refer to Area for improvement 4. Residual activity shall be incorporated into the Nuclear Medicine Dose Audit, which shall be completed by the 22/05/2020. The Working Party will meet and review the audit results 29/05/20. Corrective actions will be agreed and implemented in accordance with results, with regards to the appropriateness of the residual activity and whether further operational action must be taken to reduce this.
Area for improvement 6 **Regulation:** 8 (4) **Stated:** First time **To be completed by:** 12 June 2020	The Employer shall include in 'Employer's Procedure Q' a quick reference guide such as a flowchart for staff in relation to incident notification. Ref: 6.2
	Response by the Employer detailing the actions taken: The Governance Lead Radiographer has drafted a quick reference flowchart, to be included in Procedure Q: Procedure for the reporting of radiation incidents. The flowchart has been circulated to the Working Party and the Incident Review Group on the 07/05/20. When feedback is returned from the Incident Review Group, the flowchart will be reviewed and updated accordingly. The flowchart will then be added to Procedure Q, prior to the Employer's Procedures review and ratification at the Radiation Safety Committee June 2020

Area for improvement 7 **Regulation:** 6 (a), Schedule 2 (1) (b) **Stated:** First time **To be completed by:** 12 July 2020	The Employer shall further develop the record of entitlement for radiologists in relation to the tasks associated with the Operator's role. Ref: 6.2
	Response by the Employer detailing the actions taken: The Governance Lead Radiographer reviewed and updated Form 0.3 Consultant Radiologist Entitlement Form, in accordance with the feedback provided by RQIA (07/05/20). The updated form was circulated to the Senior Management Team for review and feedback. The updated form will be discussed at the Radiology Directorate meeting (19/05/20). Upon agreement of the recommended changes, the form will be updated, issued and implemented Trust wide (June 2020).
Area for improvement 8 **Regulation:** 6 Schedule 2 (1) (b) **Stated:** First time **To be completed by:** 12 July 2020	The Employer shall ensure the evidence of the entitlement record for the Medical Physics Experts (MPEs) is completed and fully understood by the duty holder and the entitler. Ref: 6.2
	Response by the Employer detailing the actions taken: Area for Improvement 8 was shared with Senior Managers within RMPS, with a request for feedback and the agreement of an appropriate Entitlement process, in line with NHSCT Employer's Procedures. The Head of Radioisotopes Service at Regional Medical Physics Service has advised the following: *I can confirm that NHSCT MPE is aware of his entitlement and responsibilities as MPE for Nuclear Medicine, as outlined in his letter of appointment to this role and his letter of acceptance of this (copies of letters attached).* NHSCT continues to engage with RMPS to put a more robust system of Entitlement in place, in line with NHSCT Employer's Procedures, by 12th July 2020.
Area for improvement 9 **Regulation:** 6 (5) (a) **Stated:** First time **To be completed by:** 12 July 2020	The Employer shall issue further information on referral guidelines to internal and external Referrers in relation to nuclear medicine. Ref: 6.2
	Response by the Employer detailing the actions taken: Access to Nuclear Medicine was discussed with the Clinical Director for Radiology/Nuclear Medicine Lead Radiologist. GP access was clarified, and a subsequent formal letter was communicated on the 04/05/20. The Authorisation Guidelines were subsequently reviewed and updated in accordance with the agreed access.

	Procedure O: Procedure for Referral, Justification and Authorisation, has been updated to reflect all appropriate detail regarding Nuclear Medicine Referrers, and access to the Nuclear Medicine service. The appropriateness of Referrals within Nuclear Medicine shall be re-audited in August 2020, to re-assess compliance.
Area for improvement 10 **Regulation:** 6 (5) (a) **Stated:** First time **To be completed by:** 23 March 2020	The Employer shall further develop 'Employer's Procedure O' to include more specific detail relating to Nuclear Medicine referral process. Ref: 6.2
	Response by the Employer detailing the actions taken: Please refer to Area for Improvement 9 above. Procedure O: Procedure for Referral, Justification and Authorisation, has been updated to reflect all appropriate detail regarding Nuclear Medicine Referrers, and access to the Nuclear Medicine service.
Area for improvement 11 **Regulation:** 11 (5) Schedule 2 (1) (b) Schedule 2 (1) (n) **Stated:** First time **To be completed by:** 12 June 2020	The Employer shall accurately reflect the arrangements for the justification and authorisation of exposures to carers and comforters and ensure that references to multiple Practitioners are removed from the authorisation guidelines. Ref:6.3
	Response by the Employer detailing the actions taken: The Authorisation Guidelines have been reviewed and updated to reflect the arrangements for the justification and authorisation of exposures to carers and comforters and ensure that references to multiple Practitioners are removed (07/05/20). The Authorisation Guidelines have been circulated for review. The authorisation criteria for Nuclear Medicine is to be reviewed by Nuclear Medicine Operators, currently undergoing authorisation training, to ensure the criteria is clear and unambiguous. Feedback will be collated by the Nuclear Medicine Lead Radiographer and circulated to the Working Party by 22/05/20. The Working Party will meet and review changes by the 29/05/20. The Authorisation Guidelines will be updated, authorised and issued by the 05/06/20.
Area for improvement 12 **Regulation:** 6 (4) **Stated:** First time **To be completed by:** 12 June 2020	The Employer shall ensure that the written protocols include a specific range of activity that can be administered and are consistent in relation to dosages of concomitant medication. Ref: 6.4
	Response by the Employer detailing the actions taken: The Nuclear Medicine Lead Radiographer and MPE will review the Nuclear Medicine Imaging Protocols, to ensure the protocols include a specific range of activity that can be administered and are consistent in relation to dosages of concomitant medication. Review to be completed by the 22/05/20 and circulated to the Working Party.

	Working Party will meet and review changes on the 29/05/20. Imaging Protocols will be updated, authorised and issued by the 05/06/20.
Area for improvement 13 **Regulation:** 14 **Stated:** First time **To be completed by:** 12 June 2020	The Employer shall enhance the role of the MPE within the nuclear medicine department is in accordance to legislation and 'Employer's Procedure P'. Ref: 6.5
	Response by the Employer detailing the actions taken: The Nuclear Medicine Lead MPE has reviewed the detail in Procedure P, in liaison with Regional Medical Physics Service, and with reference to the EU report: "Radiation Protection No 174 European Guideline on Medical Physics Expert". The Procedure did not require any updates. The Nuclear Medicine Lead MPE has been invited to attend the departmental Image Optimisation Team meetings (June 2020). The Nuclear Medicine Lead MPE is a member of the Working Party tasked with the procurement of the new Nuclear Medicine equipment. The Nuclear Medicine Lead MPE will be invited to the Working Party tasked with the implementation of new and developing techniques within Nuclear Medicine. The Nuclear Medicine Lead MPE will be invited to the Working Party tasked with the application of the IR(ME)R Employer License. Manufacturer reports and equipment maintenance reports will be sent to the Nuclear Medicine Lead MPE, by the Nuclear Medicine Lead Radiographer. The Nuclear Medicine Lead MPE is a member of the Working Party tasked with addressing the Nuclear Medicine RQIA Quality Improvement Plan. The Nuclear Medicine Lead MPE advice and guidance has been requested as part of the on-going Nuclear Medicine dose audit. The Nuclear Medicine Lead MPE has been asked to collate Radiation Risk Assessments to assist in the risk/benefit process with regards to patient exposures, including carers and comforters, in Nuclear Medicine. The Nuclear Medicine Lead MPE has been asked to provide training to Nuclear Medicine staff members with regards to DRL's.

	The MPE will be meet regularly with the Lead Nuclear Medicine Radiographer and formally meet at least twice yearly with the Lead Radiographer, IR(ME)R practitioner and Service Manager to review the nuclear medicine service.

Please ensure this document is completed in full and returned via bsu.admin@rqia.org.uk

The Regulation and Quality Improvement Authority

The Regulation and Quality Improvement Authority
9th Floor
Riverside Tower
5 Lanyon Place
BELFAST
BT1 3BT

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