Inspection Report of Compliance with the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018

21 January 2021

Ulster Independent Clinic
Nuclear Medicine

Address: Level 2, 245 Stranmillis Road, Belfast, BT9 5JH
Inspectors: Winifred Maguire and Carmel McKeegan
Public Health England (PHE) Advisor: Nasreen Parkar

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

2.0 How we inspect

In response to the COVID-19 pandemic we reviewed our inspection methodology and considered various options to undertake inspections. The purpose of this review was to minimise risk to service users and staff, including our staff, whilst being assured that ionsing radiation services are being provided in keeping with IR(ME)R legislation.

Having considered different inspection methodologies a decision was taken to undertake remote themed inspections to ionsing radiation services. This methodology means that providers completed and submitted a self-assessment with supporting documentation to be reviewed in advance of the inspection. A decision was also taken that the inspections would focus on four themes.

The providers were notified of the inspection date and time and participants from the radiology service were invited to join a zoom meeting with the IR(ME)R inspection team. The purpose of the inspection was to validate the information submitted through discussion and for key radiology staff to provide clarification on a range of matters. This approach did not allow for a tour and review of the radiology department, an examination of patient records or interviewing staff within the radiology department.

The inspection had a particular focus on four themes as outlined below:

- diagnostic reference levels (DRL's);
- audit, including clinical audit and compliance with IR(ME)R;
- accidental and unintended exposures; and entitlement.

In addition, on this occasion to reflect the nuclear medicine service, we reviewed the area of patient dose and administered activity.

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

- patients as part of their 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.

3.0 Service details

Name of Establishment: Ulster Independent Clinic, Nuclear Medicine	**Department Inspected:** Nuclear Medicine
Name of Employer: Ms Diane Graham (Chief Executive/Matron, Ulster Independent Clinic)	**Superintendent Radiographer:** Ms Joanne Craig
Clinical Director of Radiology: Dr Peter Ball	**Medical Physics Expert:** Ms Sandra Biggart (Nuclear Medicine)

4.0 Profile of services

We confirmed that the Ulster Independent Clinic Nuclear Medicine department only provides a breast sentinel node service using technetium -99m (radioisotope). Twenty-six patients had received this procedure in 2020. We confirmed that there is a valid Employer's Licence in place which covers the site and there is a licenced Practitioner for the provision of the service.

The nuclear medicine service in the Ulster Independent Clinic is provided by one Consultant Radiologist (one session per week), two radiographers and an appointed MPE for nuclear medicine (under contract from Regional Medical Physics Service).

5.0 Inspection summary

On 21 January 2021, warranted IR(ME)R inspectors from RQIA, with advice being provided by Public Health England (PHE) staff, carried out a remote themed inspection of the Ulster Independent Clinic 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 supporting information including policies and procedures. This information was shared with PHE prior to the inspection and was used to direct discussions with key members of staff working within the radiology department and guide the inspection process. We noted that the information provided demonstrated a clear understanding of the regulations with consistent use of regulatory terminology throughout.

We found that radiological practice in the Ulster Independent Clinic Nuclear Medicine department was safe, effective and largely in line with the requirements of IR(ME)R and good practice guidelines.

Staff who spoke with us were found to be knowledgeable and professional. We acknowledge the work undertaken and effort made by staff to comply with IR(ME)R 2018 during difficult times. We confirmed the Ulster Independent Clinic Nuclear Medicine department had in place a radiation safety policy; a full set of Employer's Procedures; robust clinical audit relating to the nuclear medicine service; the establishment of a clear written pathway for sentinel lymph node procedures; well written patient information leaflets; and the inclusion of nuclear medicine staff on the Radiation Safety Committee (RSC). We noted that the RSC involves all modalities, departments and specialities which strengthen robust scrutiny.

We found that the Ulster Independent Clinic 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. We also found that the service was well supported by the Medical Physics Expert with respect to the involvement required under IR(ME)R.

We noted that the radiation safety policy had been issued in October 2020. However, we found that it did not clearly identify the Employer in line with IR(ME)R legislation. We established that the Chief Executive, Ulster Independent Clinic, is the Employer under IR(ME)R and demonstrated an understanding of the responsibilities of the Employer's role. We were informed of the governance structures associated with ensuring IR(ME)R compliance. However, this was not fully reflected in the radiation safety policy or the written organisational structure and we identified an area of improvement to address this matter. The management and staff were receptive to the advice given throughout the inspection.

We identified areas for improvement in relation to amendments to the radiation safety policy, the organisational structure and four Employer's Procedures.

Additional areas of improvement were made in relation to ensuring compliance with the Employer's Procedures, the establishment of referral criteria, the entitlement of Referrers, ensuring entitlements were reflective of practice and updating the otherwise comprehensive 'Procedure for Isotope Injections' to include the +/-10% activity range and next day procedure.

During the inspection, we spoke with Ms Diane Graham, Chief Executive, Ulster Independent Clinic; the Superintendent Radiographer; the Consultant Radiologist (Practitioner licence holder); a Senior Radiographer and the MPE for nuclear medicine.

The findings of the inspection were provided to Ms Diane Graham; the MPE; members of radiology and nuclear medicine team in attendance at the conclusion of the inspection.

6.0 Inspection outcome

	Regulations
Total number of areas for improvement	10

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.

7.0 The inspection - key findings

7.1 Review of area of improvements from previous inspection.

No previous IR(ME)R inspection has been carried out to the Ulster Independent Clinic Nuclear Medicine department.

7.2 Diagnostic Reference Levels (DRLs)

7.2.1 DRLs

We found that the process for establishing, reviewing, and checking compliance with DRLs has been developed in the collaboration with the MPE and is set out in 'Employer's Procedure 11'. We noted that local DRLs were in place which have been based on DRLs quoted in the current ARSAC notes for guidance, with activities reduced as low as reasonably practicable.

We were informed that local DRLs are displayed in the radioisotope administration room. We confirmed DRLs are regularly reviewed with the close involvement of the MPE and that updated DRLs are distributed to relevant staff.

We found an audit of patient administered activities is carried out regularly and compared to the local DRLs. We established that the completed audit is reviewed by the MPE for comment or identification of any further action. We suggested that this important component of audit should be recorded as part of the audit report.

We confirmed that the findings are shared and action taken as appropriate. We established that should the audit show a DRL is consistently exceeded then this will be investigated and reported to the Chair of the RSC.

Staff spoken with demonstrated an understanding of the use of DRLs and what action to take in the event of DRLs being consistently exceeded.

Areas of good practice: DRLs

There were examples of good practice found in relation to the local DRLs that are in place, the understanding of staff on the use of the DRLs, the robust audit of patient administered activities and the close involvement of the MPE in the review of DRLs.

Areas for improvement: DRLs

We identified no areas for improvement regarding DRLs

	Regulations
Areas for improvement	0

7.3 Clinical audit

7.3.1 Clinical audit

We reviewed the arrangements for clinical audit and found that the Ulster Independent Nuclear Medicine service has an underpinning culture of quality improvement. Management and staff demonstrated an inclusive, enthusiastic and proactive approach to client centred service improvement.

We confirmed that the Superintendent Radiographer is responsible for ensuring that audits of radiation safety arrangements including compliance with IR(ME)R are carried out, reviewed and acted upon. We found that there was a nuclear medicine audit schedule in place.

Evidence of audits was provided and we found them to be completed by the radiographers and included areas of compliance under IR(ME)R. We established that the inclusion of radiologists and surgeons in clinical audit for the nuclear medicine service is under development.

We reviewed the following audits:

- Outcomes for patients who have had sentinel node biopsy - February 2019
- Injection Audit 2019
- Injection Audit 2020
- Sentinel Node Report Audit February 2020
- Sentinel Node request form audit 2018-2019
- Dose audit of sentinel node biopsy 2019

We established the findings and learning from audits are shared with the MPE in the team brief; presented at the relevant audit meetings; discussed at the site and/or modality meetings; and at RSC meetings. We found that audit is used to drive improvement within the nuclear medicine department.

We provided advice on further developing the audit programme, particularly where changes or updates to procedures are introduced.

Areas of good practice: Clinical audit

There were examples of good practice found in relation to an inclusive, enthusiastic and proactive approach to patient centred service improvement, evidence of a robust approach to audit for nuclear medicine and a well-established rolling audit programme with regards to IR(ME)R compliance.

Areas for improvement: Clinical audit

We identified no areas for improvement regarding clinical audit.

	Regulations
Areas for improvement	0

7.4 Accidental and unintended exposures

7.4.1 Accidental and unintended exposures

Management and staff described to us the process for reporting accidental or unintended exposures internally and then to the appropriate enforcing authority including to RQIA in accordance with the Significant Accidental or Unintended Exposures (SAUE) guidance, August 2020.

We were informed that no accidental or unintended exposures or near misses had occurred in the Ulster Independent Clinic Nuclear Medicine department in the previous two years. We confirmed there were clear processes in place to report, investigate, share findings and take any necessary action to prevent reoccurrence.

We found that there is a good culture of incident reporting across all types: notifiable, non-notifiable and near misses.

Staff who spoke with us demonstrated a good understanding of the action to take in the event of an incident occurring and confirmed learning from incidents across the organisation is shared at staff meetings.

We found ‘Employer’s Procedure 15 ’; the reporting of radiation incidents was in place and overall provided a sound framework for the management of radiology errors. However, we noted it did not fully reflect SAUE guidance and an area of improvement was identified to amend the procedure to include the SAUE guidance for the reporting of incidents and reference to reporting timeframes.

We found ‘Employer’s Procedure 16’ outlined arrangements to inform the Referrer; the Practitioner; and the individual exposed or their representative of any Clinically Significant Accidental or Unintended Exposures (CSAUE) and the outcome of the analysis of this exposure.

We noted it did not reflect the following:

- the involvement of the Practitioner in determining if it is a CSAUE; and
- the professional guidance 'IR(ME)R: Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine' June 2020 which outlines a definition of a CSAUE.

We identified an area of improvement on this matter.

We confirmed there were systems in place for the analysis of the errors and near misses across modalities. We found that whilst the nuclear medicine department did not have any SAUEs or near misses learning from other modalities had been shared with the nuclear medicine department. We noted the MPE shares learning with the nuclear medicine team in Ulster Independent Clinic from other sentinel node services in Northern Ireland.

We found that all radiation incidents are collated and sent to the RSC and through the Ulster Independent Clinic's governance framework.

Areas of good practice: Accidental and unintended exposures

We found examples of good practice in relation to having systems in place for reporting, investigating and learning from radiology incidents. Staff demonstrated a good understanding of the action to take in the event of an incident occurring and confirmed learning from incidents across the organisation is shared.

Areas for improvement: Accidental and unintended exposures

We identified two areas for improvement in relation to reviewing and updating 'Employer's Procedures 15 and 16'.

	Regulations
Areas for improvement	2

7.5 Entitlement

7.5.1 Entitlement

Entitlement is the term used to describe the process of endorsement by an appropriate and specified individual within the organisation. They must have the knowledge and experience to authorise on behalf of the IR(ME)R Employer, that the duty holder or a group of duty holders have been adequately trained and deemed competent in their specific IR(ME)R duty holder roles. The Employer has the responsibility to ensure that all Practitioners and Operators are adequately trained to perform the tasks defined within their scope of practice.

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

We confirmed comprehensive systems were 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.

We noted that all grades of staff are responsible for maintaining their own portfolio of evidence to maintain their individual professional accreditation.

We reviewed the training records which underpin the entitlement process. We found them to be in line with the individual duty holder's scope of practice. We reviewed entitlement records which included competency sign off forms for duty holder tasks. We noted that the sign off box confirming that the duty holder had read the Employer's Procedures had not always been completed. We discussed the importance of ensuring compliance with the Employer's Procedures and providing evidence that duty holders have read and understood these legal frameworks. An area of improvement was identified on this matter.

We discussed the Ulster Independent Clinic's written referral criteria for sentinel node biopsy. We noted the self-assessment outlined iRefer as their referral criteria however sentinel node biopsy is not covered by iRefer. The Consultant Radiologist outlined very clearly the criteria used to make a sentinel node biopsy referral. However, we confirmed there are no formal written referral criteria for sentinel node biopsy. We identified an area of improvement to establish referral criteria for sentinel node biopsy and ensure that they are made available to Referrers.

We examined the entitlement of Referrers and were informed of the process for granting practising privileges to medical Consultants in the Ulster independent Clinic. We were informed that breast surgeons with practising privileges in the Ulster Independent Clinic are viewed by the duty holders as Referrers for sentinel node biopsy. Whilst we acknowledged the importance of granting practising privileges, it does not fulfil the entitlement process for Referrers. We identified an area of improvement to establish the formal written entitlement of Referrers and ensure this is fully reflected in the 'Employer's Procedure 2'.

We found that 'Employer's Procedure 2' clearly sets out the arrangements for the entitlement of Operators and Practitioners. Management and staff demonstrated a good understanding of the entitlement process both as duty holders and individuals who entitled duty holders.

We reviewed the entitlement records for Operators and the Practitioner. We found two radiographers were entitled as Operators for the nuclear medicine service. Their scope of practice includes authorising the administration of radioisotopes in accordance with authorisation guidelines devised by the Practitioner. We found the authorisation guidelines provided a sound framework, however, we noted that details of individuals entitled to inject radioisotopes were also included. We noted this was unusual and it was agreed to consider an alternative place for this information.

We confirmed that the Consultant Radiologist is entitled as a Practitioner and an Operator. We established that one of the Operator tasks he carries out is administering radioisotope injections. We noted this had not been reflected in his entitlement record. We identified an area of improvement to ensure entitlement records are fully reflective of all the duty holder's scope of practice and associated tasks.

We reviewed the entitlement arrangements for MPEs and noted that the entitlement records fully reflect the entitlement of MPEs as set out in the 'Employer's Procedure 2'.

We established that they had been entitled by the Clinical Director of Radiology. We provided advice on ensuring any MPE providing cover for an entitled MPE is also entitled to do so.

We confirmed that the Consultant Radiologist for nuclear medicine who is entitled as an Operator carries out written clinical evaluation for each sentinel node biopsy undertaken in the Ulster Independent Clinic. We reviewed 'Employer's Procedure 13' relating to clinical evaluation and found that it did not fully reflect that clinical evaluation is carried out by the Consultant Radiologist for nuclear medicine as part of his scope of practice. We identified an area of improvement on this matter.

We discussed 'Employer's Procedure 8', carers and comforters, which was found to be limited in relation to nuclear medicine. We identified an area of improvement with regards to amending 'Employer's Procedure 8' to reflect the nuclear medicine service.

Areas of good practice: Entitlement

We found aspects of good practice in relation to the implementation of the entitlement process for duty holders. Systems were in place to check the professional qualifications and registration of all employees with their appropriate professional bodies, all of which is used to underpin entitlement arrangements.

Areas for improvement: Entitlement

We identified six areas for improvement in relation to ensuring duty holders read the Employer's Procedures; referral criteria for sentinel node biopsy; entitlement of Referrers; updating the relevant Employer's Procedures; and scope of practice.

	Regulations
Areas for improvement	6

7.6 Patient dose and administered activity

7.6.1 Patient dose and administered activity

We confirmed that radiopharmaceuticals are delivered in multi-dose vials from the Regional Radiopharmacy based on the Royal Victoria Hospital site, Belfast Health and Social Care Trust. Staff informed us that the individual radiopharmaceutical dose for diagnostic procedures is measured using a calibrated ionisation chamber prior to administration to a patient. We were told the measured activities are recorded by an Operator on the notification sheet and the label to be attached to the referral/request form and this is scanned onto the patient record in RIS.

We noted 'Employer's Procedure 10' outlines the procedure for assessment of patient dose and administered activity.

We found that there was a detailed Procedure for Isotope Injection and a Pathway for Sentinel Lymph Node Procedures in place. Staff demonstrated they were very familiar with the content of these documents and they served as good operating frameworks. We noted that the pathway document included the activity to be administered and the allowance for +/-10 of the activity, however, this was not included in the Procedure for Isotope Injection.

We confirmed that on rare occasions the activity is administered the day before the sentinel node biopsy procedure. This next day procedure was not included in either the procedure or the pathway. We identified an area of improvement to include the allowance of +/- 10% activity in the Procedure for Isotope Injection and reflect 'the next day procedure' in the Procedure for Isotope Injection and the Pathway document.

We confirmed that an information sheet is given to all sentinel node biopsy patients during their breast-care consultation. Staff informed us the Operator undertaking the procedure explains the procedure to the patient to ensure that the patient has understood the information before administrating the radiopharmaceutical. We found this is outlined in 'Employer's Procedure 17'. We advised that a record is made of providing this information to the patient which could be subsequently audited to ensure compliance with IR(ME)R.

Areas of good practice: Patient dose and Administered Activity

We found examples of good practice in relation to the provision of a Procedure for Isotope Injection and a Pathway for Sentinel Lymph Node Procedures; the knowledge of staff on administering isotope injections and the provision of information sheets to patients undergoing a sentinel node procedure.

Areas for improvement: Patient dose and Administered Activity

An area for improvement was made in relation to updating the Procedure for Isotope Injection, Procedure for Isotope Injection and the Pathway document.

	Regulations
Areas for improvement	1

7.7 Total number of areas for improvement

Total number of areas for improvement	10

There were 10 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 ongoing commitment and enthusiasm for 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 contribution to the inspection process.

8.0 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.

8.1 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.

8.2 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.

Quality Improvement Plan	
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 clients.	
Area for improvement 1 **Regulation:** 6 **Stated:** First time **To be completed by:** 21 April 2021	The Employer shall amend the radiation safety policy and the written organisational structures to clearly outline the Employer and the associated governance arrangements to ensure compliance with IR(ME)R. Ref: 5.0
	Response by the Employer detailing the actions taken: The Radiation Safety Policy has been amended to clearly outline the the Employer and associated governance arrangements to comply with IR(ME)R Complete
Area for improvement 2 **Regulation:** 8 (4) **Stated:** First time **To be completed by:** 21 April 2021	The Employer shall ensure that 'Employer's Procedure 15' reflects the SAUE guidance for the reporting of incidents and references to timeframes Ref: 7.4.1
	Response by the Employer detailing the actions taken: Employer's Procedure 15 and the Radiation Safety Policy have been revised and reflect SAUE guidance, including timeframes, for the reporting of incidents. Complete
Area for improvement 3 **Regulation:** 8 (1) and 6 Schedule 2 (l)	The Employer shall ensure that 'Employer's Procedure 16' is amended to include the involvement of the Practitioner in nuclear medicine in determining if it is a CSAUE and the 'IR(ME)R-Implications for clinical practice guidance June 2020 which outlines

Stated: First time **To be completed by:** 21 April 2021	a definition of a CSAUE. Ref: 7.4.1
	Response by Employer detailing the actions taken: Employer's Procedure 16 has been revised to include the involvement of the Practitioner in nuclear medicine in determining a CSAUE. Complete
Area for improvement 4 **Regulation:** 6 (2) **Stated:** First time **To be completed by:** 21 March 2021	The Employer shall ensure that there is evidence that duty holders have read and understood the Employer's Procedures Ref: 7.5.1
	Response by the Employer detailing the actions taken: The revised Employer's Procedures have been circulated and a signed record detailing that each duty holder has read and understands the Employer's Procedures is held by the Superintendent Radiographer. Complete
Area for improvement 5 **Regulation:** 6 (5) **Stated:** First time **To be completed by:** 21 March 2021	The Employer shall establish referral criteria for a sentinel node biopsy procedure and ensure that they are made available to Referrers. Ref: 7.5.1
	Response by the Employer detailing the actions taken: Referral criteria for a sentinel node biopsy procedure have been detailed, signed by the Consultant Radiologist for nuclear medicine and these have been circulated to the Referrers. Complete
Area for improvement 6 **Regulation:** 6 Schedule 2 (b) **Stated:** First time **To be completed by:** 21 March 2021	The Employer shall establish the formal written entitlement of Referrers and ensure this is fully reflected in the 'Employer's Procedure 2'. Ref: 7.5.1
	Response by the Employer detailing the actions taken: Employer's Procedure 2 has been revised to detail the procedure for obtaining and retaining written entitlement for Referrers. Written entitlement documentation is being obtained for each of the Referrers. In progress
Area for improvement 7 **Regulation:** 6 Schedule 2 (b) **Stated:** First time **To be completed by:** 21 March 2021	The Employer shall ensure entitlement records are fully reflective of all the duty holder's scope of practice and associated tasks. Ref: 7.5.1
	Response by the Employer detailing the actions taken: Entitlement records have been revised to reflect the duty holder's scope of practice and associated tasks. Complete

Area for improvement 8 **Regulation:** 6 Schedule 2 (j) and 12 (9) **Stated:** First time **To be completed by:** 21 March 2021	The Employer shall ensure that 'Employer's Procedure 13' fully reflects that clinical evaluation is carried out by the Consultant Radiologist for nuclear medicine as part of his Operator's scope of practice. Ref: 7.5.1
	Response by the Employer detailing the actions taken: Employer's Procedure 13 has been revised to include clinical evaluation by the Consultant Radiologist for nuclear medicine as part of his scope of practice. Complete
Area for improvement 9 **Regulation**: 6 Schedule 2 (n) **Stated:** First time **To be completed by:** 21 April 2021	The Employer shall amend 'Employer's Procedure 8', carers and comforters, to reflect the arrangements within the nuclear medicine service. Ref: 7.5.1
	Response by the Employer detailing the actions taken: Employer's Procedure 8 has been revised to reflect the arrangements for carers and comforters within the nuclear medicine service. Complete
Area for improvement 10 **Regulation:** 6 (4) **Stated:** First time **To be completed by:** 21 March 2021	The Employer shall include the allowance of +/- 10% activity in the Procedure for Isotope Injection and reflect 'the next day procedure' in the Procedure for Isotope Injection and the Pathway document. Ref: 7.6.1
	Response by the Employer detailing the actions taken: The Procedure for Isotope Injection and Pathway document has been revised to include the +/-10% activity. Complete

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

The Regulation and Quality Improvement Authority

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