THE REGULATION AND QUALITY IMPROVEMENT AUTHORITY
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WESTERN HEALTH AND SOCIAL CARE TRUST

ALTNAGELVIN AREA HOSPITAL
NUCLEAR MEDICINE DEPARTMENT

TEL: 028 71345171

INSPECTION OF COMPLIANCE WITH THE IONISING RADIATION (MEDICAL EXPOSURE) REGULATIONS (NORTHERN IRELAND) 2000 AND THE IONISING RADIATION (MEDICAL EXPOSURE) (AMENDMENT) REGULATIONS (NORTHERN IRELAND) 2010

14 APRIL 2016

1.0 GENERAL INFORMATION

Name of Establishment:	Altnagelvin Area Hospital
Address:	Glenshane Road Londonderry Co Londonderry BT47 6SB
Department Inspected:	Nuclear Medicine
Telephone Number:	028 71345171
Name of Employer:	Ms Elaine Way Chief Executive Western Health and Social Care Trust
Divisional Clinical Director	Dr Charles Mullan
Radiology Service Manager	Mr Dan McLaughlin
Medical Physicist	Dr Ian Gillan
Date of Inspection	14 April 2016
Name of Inspectors	Mrs Winnie Maguire Mr Hall Graham
Name of PHE Advisor	Mrs Louise Fraser

2.0 INTRODUCTION

The Regulation and Quality Improvement Authority (RQIA) is the independent health and social care regulatory body for Northern Ireland. RQIA encourages continuous improvement in the quality of services, through a planned programme of inspections and reviews.

In 2005, RQIA was established as a non departmental public body (NDPB) under The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003. The vision of RQIA is to be a driving force for positive change in health and social care in Northern Ireland through four core activities:

- Improving Care: we encourage and promote improvements in the safety and quality of services through the regulation and review of health and social care.
- Informing the Population: we publicly report on the safety, quality and availability of health and social care.
- Safeguarding Rights: we act to protect the rights of all people using health and social care services.
- Influencing Policy: we influence policy and standards in health and social care.

The responsibility for assessing compliance with and enforcing The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000 known as IR(ME)R transferred from the DHSSPS to RQIA on 15 March 2010 under The Ionising Radiation (Medical Exposure) (Amendment) Regulations (Northern Ireland) 2010.

The regulations are intended to:

- Protect patients from unintended, excessive or incorrect exposure to ionising radiation and ensure that, in each case, the risk from exposure is assessed against the clinical benefit.
- To ensure that patients receive no more exposure than is necessary to achieve the desired benefit within the limits of current technology.
- To protect volunteers in medical or biomedical, diagnostic or therapeutic research programmes and those undergoing medico-legal exposures.

This report is a summary of the findings from the inspection of the nuclear medicine services provided at Altnagelvin Area Hospital, part of the Western Health and Social Care Trust (WHSCT).

3.0 METHODOLOGY

On 14 April 2016, warranted IR(ME)R inspectors from RQIA, with advice being provided by Public Health England (PHE) staff, visited the nuclear medicine department of Altnagelvin Area Hospital, as part of RQIA's IR(ME)R inspection programme.

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

WHSCT staff in attendance for part or all of the inspection:

Dr Charles Mullan	Consultant Radiologist (ARSAC Certificate Holder)
Mr Dan McLaughlin	Radiology Services Manager
Dr Ian Gillan	Medical Physicist
Ms Tracey McIvor	Radiology Department Manager
Ms Mary Moran	Acting Clinical Specialist
Ms Tina Doran	Radiographer in Nuclear Medicine
Ms Kim Martin	Radiographer in Nuclear Medicine
Mr Sam Stevenson	Radiopharmacist

4.0 PROFILE OF SERVICE

The self assessment form submitted prior to the inspection confirmed that each year, the Altnagelvin Area Hospital nuclear medicine department carries out approximately:

- 2500 Nuclear medicine imaging procedures (annually)
- 0 Non imaging
- 0 In-patient therapies
- 0 Out-patient therapies
- 0 PET/CT

Altnagelvin Area Hospital nuclear medicine department has available:

- 3 Consultant Radiologist
- 6 wte Radiographers
- 3 ARSAC (Administration of Radioactive Substances Advisory Committee) certificate holders

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

- Technetium-99m
- Iodine-123

5.0 KEY FINDINGS

5.1 DUTIES OF THE EMPLOYER

Employer's Procedures

Altnagelvin Area Hospital had the Employer's Procedures required by IR(ME)R in place. The inspection team was informed that these had been re-issued in February 2016, and were due to be reviewed in February 2017. The Chair of the trust Radiation Protection Committee through the Radiation Protection Committee is responsible for reviewing the Employer's Procedures annually, or in the event of any change in practice.

The overall responsibility for IR(ME)R lies with the Chief Executive, Ms Elaine Way. Within the WHSCT Radiation Safety Policy, the Chief Executive is clearly identified as the Employer and has overall responsibility for ensuring compliance with IR(ME)R. The Chair of the Radiation Protection Committee is the identified person for radiation safety within the trust and is responsible for the implementation of the policy. The Chief Executive has nominated the Chair of the Radiation Protection Committee to have responsibility for management of non-compliance with the policy and also to ensure that it is updated in line with legislation.

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

All new members of medical staff are required to read the Employer's Procedures as part of their induction process and are directed to the trust intranet where the Radiation Safety Policy and Employer's Procedures can be found.

Regular directorate staff meetings are held at which any proposed changes to procedures would be discussed. Information is passed upwards through the Radiation Protection Committee to the Chief Executive and also to all members of staff through regular staff meetings.

Document and version control are clearly noted on the Employer's Procedures and all relevant policies and procedures can be found on the trust intranet.

Examination Protocols

Nuclear medicine examination standard operating procedures and guidelines have been developed which were examined during the inspection. The documentation was found to be extensive but on closer examination there was duplication of information and in a number of cases there was conflict with Employer's Procedures.

It was recommended that these should be reviewed to remove unnecessary duplication and ensure that they are in line with the latest version of the trust Employer's Procedures.

Consideration should be given to combining the acquisition protocols and the examination guidelines. A standard format could be used including various sections: e.g. Background, Injection information, Preparations, ARSAC practitioners, Image acquisition parameters and Image processing. Consistent subheadings should be included in each section e.g. Preparations: clinical indications, contraindications, drug interactions, breast feeding, adverse reactions, patient preparation. Document control should be included, consistent with Trust policies.

The activity to be administered should be clear and unambiguous. The local DRL and acceptable tolerance should be listed within the department protocols.

Referral Criteria

The referral criteria currently being used are the Royal College of Radiologists i-refer Guidelines- Making the Best Use of Clinical Radiology Services 7th Edition and referrers are made aware of these through the trust intranet.

Procedure (F) outlines the process for acceptance of a referral for a medical exposure. In the nuclear medicine department all internal referrals are electronic. At the moment hard copy referrals are accepted from a number of external referrers.

Management outlined a robust process for dealing with incomplete referrals which are logged onto the RIS.

Procedure (H) – A procedure for the authorisation of non-medical referrers was found to be detailed and robust. An example of a completed application was examined and found to reflect the procedure.

Audit of Compliance with Employer's Procedures

Procedure (I) outlines quality assurance mechanisms and review of protocols and procedures to be undertaken. Audits of compliance with Employer's Procedures are included in a comprehensive audit calendar.

Examples are

- 3 Point ID
- Pregnancy check
- Breast feeding status
- Dose check

Regular meetings take place to pass on the learning from audits.

Diagnostic Reference Levels (DRLs)

Procedure (K) outlines the procedure for the use of DRLs. It is clear from the procedure the process to be followed if DRLs are discovered to be consistently exceeded.

For most nuclear medicine procedures, local DRLs have been adopted. The local DRLs are either the same or lower than those outlined in the Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and use of Sealed Radioactive Sources (ARSAC 2016).

Staff were aware of national DRLs but reported that activity administered in the nuclear medicine department was consistently lower than national values. It was recommended that local DRLs are developed and used.

On discussion with radiopharmacy staff, it was apparent that they dispense individual syringes with an activity of the local DRL (range +/- 5%). However, just prior to injection, the Radiography staff within the nuclear medicine department re-measure the syringe activity and compare this against the ARSAC DRL (range -10%).

It was recommended that both staff groups use consistent local DRLs with the same agreed range of measurements.

For paediatric examinations, paediatric weight charts are used and staff check activity against these prior to injection, to ensure appropriate optimisation in these cases.

Staff Qualifications

Before employment, a radiographer's HCP registration is checked online and this is subsequently checked on a regular basis, to ensure that registration has continued.

Records of GMC and CCST registration for radiologists are checked and held by the HR department.

Appraisals

As part of the Knowledge and Skills Framework (KSF), there are comprehensive systems in place to provide annual appraisals for all radiographers. Training needs are identified for individual staff as part of the appraisal process.

As part of their appraisal, radiographers present their CPD folder for examination. An example was examined by the inspection team, which was found to be well structured and comprehensive.

All radiologists are appraised annually and now participate in revalidation.

Incidents

No incidents reportable under IR(ME)R, as an exposure much greater than intended, had occurred in the Nuclear Medicine Department..

Employer's procedure (P) contains details of the process to be followed in the event that a patient receives an exposure that is much greater than intended.

The local Radiation Protection Supervisor supported by risk management staff as required investigates any incident where a patient has or may have had received a radiation dose much greater than intended.

A summary report is provided to the Clinical Incident Group to formally approve the actions suggested by the Risk Management Coordinator. All incidents and near misses are recorded on the DATIX system.

Trust staff were advised during the inspection to reference the Medical Physics Expert (MPE) in the procedure.

5.2 DUTIES OF THE PRACTITIONER, OPERATOR AND REFERRER

. **Entitlement**

Employer's Procedure (B) outlines the procedure to identify individuals entitled to act as referrer, practitioner or operator for medical exposures. The inspection team acknowledged the large amount of work that the trust had carried out in relation to entitlement.

The procedure was found to be effective and examination of a number of entitlement documents by the inspection team found that the documentation was compliant with the procedure.

While the entitlement documentation clearly outlined the person responsible for entitling the various staff groups, it was not clear in the actual procedure that the appropriate person was identified for all staff groups. It was recommended that Procedure B is reviewed to ensure that the appropriate person responsible for entitling staff groups is identified.

5.3 JUSTIFICATION OF INDIVIDUAL MEDICAL EXPOSURES

As the ARSAC certificate holder, the lead consultant in nuclear medicine acts as practitioner and has developed a set of authorisation guidelines.

The guidelines were reviewed and it was felt that they required some further detail to enable them to be used appropriately as authorisation guidelines. Authorisation guidelines need to enable the operator to select the appropriate imaging protocol for the patient, based on their individual characteristics. Some further detail should be added to this document to include information on previous imaging and the timing of scans, criteria for the selection of hybrid imaging, details of specific referrers where relevant, special attention for paediatrics and pregnant patients, age limits if applicable and alternative examinations involving less or no radiation.

Authorisation guidelines are a living document and a process should be developed to keep them under regular review. This process should ensure that they are detailed enough from the point of view of both the practitioner and the operator.

It was recommended that guidelines are re-titled as Authorisation guidelines and reviewed to ensure that they contain sufficient detail to allow operators to use them correctly.

Medico- Legal

Employer's Procedure (N) outlines the arrangements in place for medico-legal and occupational health surveillance exposures.

No medico-legal procedures are carried out in the nuclear medicine department.

Females of Child Bearing Age

Employer's Procedure (D) outlines the process for making enquiries of females of childbearing age. A flowchart was also used by staff and after some discussion the inspection team agreed that the flowchart reflected what was actually happening in practice. A pregnancy status form which is scanned onto the RIS was reviewed and found to be comprehensive.

5.4 OPTIMISATION

There appear to be good arrangements in place to ensure that medical exposures are kept as low as reasonably practicable. These include:

- equipment QA
- training of staff
- entitlement
- use of ARSAC guidance notes
- competency assessments
- use of local DRLs
- audit including dose audits

Paediatrics

It was noted that special attention is paid to optimisation when undertaking medical exposures of children, which includes calculation of children's doses using the children's activity scaling chart from the ARSAC Notes for Guidance.

Clinical Evaluation

An Employer's Procedure (G) is in place for the carrying out and recording of an evaluation for each medical exposure and all clinical evaluations are recorded on the RIS.

The management confirmed Sentinel node biopsies were reported by a specific surgeon and it was advised he should be added to the list of those entitled to carry out a clinical evaluation in Appendix 5

5.5 RESEARCH

An Employer's Procedure (O) was in place for biomedical and medical research programmes which was satisfactory.

The management team confirmed that no research is currently taking place in the nuclear medicine department.

5.6 CLINICAL AUDIT

Procedure (I) outlines the process for carrying out clinical audits. A detailed audit calendar has been developed.

The inspection team reviewed a sample of clinical audits and found them to be comprehensive, leading to service improvement. Learning from audits is shared at regular departmental meetings.

5.7 EXPERT ADVICE

The WHSCT retains the services of a MPE/RPA on a contractual basis. The MPE/RPA was present for the duration of the inspection.

The MPE/RPA provides ongoing advice and support to the management team on a range of issues and will visit the site on request.

5.8 EQUIPMENT

There is an appropriate amount of equipment available for the workload and throughput of the nuclear medicine department.

5.9 TRAINING

There is evidence of induction, competency based assessments and continuing professional development for radiographers.

Comprehensive training records and CPD files for radiographers were reviewed as part of the inspection process and found to be of a high standard.

Radiologists including the ARSAC certificate holder retain their own training records. These were not reviewed during the inspection.

There is a formal induction programme for new members of staff entering the nuclear medicine department, which was examined and found to be comprehensive.

A competency file is completed for all staff when a new piece of equipment is introduced and following an internal equipment audit, this system has been updated.

5.10 PATIENT IDENTIFICATION

An Employer's Procedure (A) is in place to correctly identify individuals to be exposed to ionising radiation. The procedure clearly outlines that it is the responsibility of the operator making the exposure to carry out the ID check and ensure that the correct patient receives the correct medical exposure.

The procedure clearly references the three point patient identification process. It outlines the procedure to be followed in cases where it is difficult to obtain patient identification details.

Some minor amendments were suggested during the course of the inspection.

5.11 RISK MANAGEMENT

An Employers' Procedure (P) is in place to ensure that the probability and magnitude of accidental or unintended doses from radiological practices are reduced so far as reasonably practicable. This was found to be detailed and comprehensive.

5.12 RADIOPHARMACEUTICALS

Procedures (J), (L) and (M) outline

- the procedure for the assessment of patient dose and administered activity
- the procedure for the giving of information and written instructions as referred to in the case of patients undergoing treatment or diagnosis with radioactive medicinal products
- the procedure for ordering of radioisotopes from radiopharmacy

Procedure (L) outlines the information that is provided for nuclear medicine patients. The nuclear medicine department also had a standard operating procedure outlining this information but it did not reflect procedure L in the same level of detail. The label on the 'green form' matched the Nuclear Medicine standard operating procedure and it was advised it is amended to match procedure L.

On visiting the radiopharmacy and in discussion with the radiopharmacist it was noted that syringes are labelled with the local DRL rather than measured activity.

A recommendation was made that syringes should be labelled with measured activity levels.

5.12 REVIEW OF ENVIRONMENT

The inspection team reviewed the facilities available in relation to nuclear medicine. The department was found to be clean, tidy and well organised.

5.13 STAFF DISCUSSION/REVIEW OF PATIENT RECORDS

The inspection team met with radiographers and discussed: the application of the Employer's Procedures; the role and function of duty holders; patient identification; pregnancy enquiries; the use of justification guidelines; induction; continued professional development; the use of DRLs as a reference tool; and the action to be taken if they thought a patient had received a dose that was much greater than intended. Staff demonstrated a good working knowledge of Employer's Procedures and the other areas discussed. Review of patient records indicated that the correct procedures are being followed.

5.14 CONCLUSION

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

A lot of work has gone into development of written procedures and protocols that are generally comprehensive and fit for purpose.

Inspectors concluded that there were no identified serious concerns regarding the actual delivery of the service.

There were six recommendations made as a result of this inspection. These are fully outlined in the appended Quality Improvement Plan.

The management team is to be commended for their commitment and enthusiasm to ensuring that the department is operating 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.

QUALITY IMPROVEMENT PLAN

The details of the Quality Improvement Plan appended to this report were discussed with the senior team as part of the inspection process.

The timescales commence from the date of inspection.

Requirements are based on The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000 and The Ionising Radiation (Medical Exposure) (Amendment) Regulations (Northern Ireland) 2010.

Recommendations are based on other published standards which promote current good practice and should be considered by the WHSCT to improve the quality of service experienced by patients.

The employer is required to record comments on the quality improvement plan.

Enquiries relating to this report should be addressed to:

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

_____ _____

Mrs Winnie Maguire **Mr Hall Graham**
Inspector **Head of Programme**

_____
DATE

QUALITY IMPROVEMENT PLAN
ALTNAGELVIN AREA HOSPITAL
NUCLEAR MEDICINE DEPARTMENT

INSPECTION OF COMPLIANCE WITH THE IONISING RADIATION (MEDICAL EXPOSURE) REGULATIONS (NORTHERN IRELAND) 2000 AND THE IONISING RADIATION (MEDICAL EXPOSURE) (AMENDMENT) REGULATIONS (NORTHERN IRELAND) 2010

14 APRIL 2016

NOTES:

Issues identified during inspection were discussed with the senior team and timescales given for addressing any requirements and recommendations made as part of the inspection process. Details are appended to this report.

The timescales commence from the date of inspection.

Requirements are based on The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000 and The Ionising Radiation (Medical Exposure) (Amendment) Regulations (Northern Ireland) 2010 and must be met.

Recommendations are based on published standards which promote current good practice and should be considered by the management of the WHSCT to improve the quality of service experienced by patients.

It should be noted that failure to comply with any of the requirements or recommendations may resort in further action being taken.

The Employer is required to detail the action taken in response to the issues raised on the form attached.

The quality improvement plan is to be signed below by the employer and returned to:

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

SIGNED: _____

NAME: _____
(Print) EMPLOYER

DATE: _____

No.	RECOMMENDATIONS	TIMESCALE	DETAILS OF ACTION TAKEN
1	Standard operating procedures should be reviewed to remove unnecessary duplication and ensure that they are in line with the latest version of the trust Employer's Procedures **Ref Duties of the Employer**	Within six months	The Clinical Specialist for Nuclear Medicine retired in Apr 2016. The post is being replaced and the Nuclear Medicine team has already commenced work on condensing the documents and confirming they match the Employer's Procedures. A process for document control has been agreed
2	Local DRLs should be developed and used. **Ref Duties of the Employer**	Within six months	Local DRLs are equal to or less than the National DRL.
3	Staff working in the radiopharmacy and nuclear medicine departments should use consistent local DRLs with the same agreed range of measurements. **Ref Duties of the Employer**	One month	range +/5 %.New list of max activity produced for each exam inline with DRLs. Not doable within the timeframe
4	Employers Procedure B should be reviewed to ensure that the appropriate person responsible for entitling staff groups is identified. **Ref Duties of the Practitioner, Operator and Referrer**	Within three months	Need to review. Radiology SS Clin Lead NS Clin Lead Radiopharmacy Aseptic Services Manager Radiography Site Managers Medical Referrers entitle by CE but professional group
5	Justification guidelines should be re -titled as Authorisation guidelines and reviewed to ensure that they contain sufficient detail to allow operators to use them correctly. **Ref: Justification of Individual Medical Exposures**	Within three months	Nuclear Medicine lead (ARSAC certificate holder) identified to review documents with Nuc Med team

6	Radiopharmaceutical syringes should be labelled with measured activity levels. **Ref Radiopharmaceuticals**	One month	Change process required in pharmacy to remove the standard predicted activity. All labels to have hand written actual activity Not doable within the timeframe