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

CRAIGAVON AREA HOSPITAL NUCLEAR MEDICINE DEPARTMENT

TEL: 028 38 334444

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

28 FEBRUARY 2013

1.0 GENERAL INFORMATION

Name of Establishment:	Craigavon Area Hospital
Address:	68 Lurgan Road Portadown Craigavon County Armagh BT63 5QQ
Department Inspected:	Nuclear Medicine
Telephone Number:	028 38 4444
Name of Employer:	Mrs Mairead McAlinden Chief Executive Southern Health and Social Care Trust
Clinical Lead Radiology:	Dr Fawzy
Head of Diagnostics	Mrs Alexis Davidson
Radiation Protection Advisor:	Mr Ian Gillan
Date of Inspection:	28 February 2013
Name of Inspectors:	Ms Jo Browne Mrs Winnie Maguire Mr Hall Graham
Name of HPA Advisor(s)	Mrs Louise Fraser Mr Steve Ebdon-Jackson

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 Craigavon Area Hospital, part of the Southern Health and Social Care Trust (SHSCT).

3.0 METHODOLOGY

On 28 February 2013, warranted IR(ME)R inspectors from RQIA, with advice being provided by Health Protection Agency (HPA) staff, visited the nuclear medicine department of Craigavon 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 HPA 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.

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

Mrs Mairead McAlinden	Chief Executive
Mrs Alexis Davidson	Head of Diagnostics
Mr Ian Gillen	Radiation Protection Advisor
Dr M Fawzy	Radiology Clinical Lead
Dr S Hall	Consultant Radiologist
Dr Gillian Rankin	Director of Acute Services
Ms Maria Calder	Lead radiographer in Nuclear Medicine

4.0 PROFILE OF SERVICE

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

- 2274 Nuclear medicine imaging procedures (Jan-Dec 2012)
- 0 Non imaging
- 0 In-patient therapies
- 0 Out-patient therapies
- 0 PET/CT

Craigavon Area Hospital nuclear medicine department has available:

- 1 Consultant Radiologist
- 5.2 wte Radiographers
- 1 ARSAC (Administration of Radioactive Substances Advisory Committee) certificate holder

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

- Technetium 99 m
- Iodine 123
- Indium 111
- Krypton 81 m

5.0 KEY FINDINGS

5.1 DUTIES OF THE EMPLOYER

Employer's Procedures

Craigavon 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 January 2013, and were due to be reviewed in June 2013. The Clinical Director of Radiology through the Radiation Protection Committee is responsible for reviewing the Employer's Procedures every two years, or in the event of any change in practice.

The overall responsibility for IR(ME)R lies with the Chief Executive, Mrs Mairead McAlinden. Within the SHSCT Radiation Safety Policy, the Chief Executive is clearly identified as the Employer and has overall responsibility for ensuring compliance with IR(ME)R. The Director of Cancer and Clinical Services 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. Procedure (M) outlines the procedure for induction of medical staff. 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.

New doctors are directed to the trust intranet where the Radiation Safety Policy and Employer's Procedures can be found.

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 protocols have been developed. These were examined briefly during the inspection and found to be detailed and well set out and were readily available in the department.

Care should be taken to relate the protocols to authorisation guidelines as a change in one will necessitate change in the other.

When reviewing the protocols, consideration should be given to ensuring consistency of information in each protocol.

Referral Criteria

The referral criteria currently being used are the Royal College of Radiologists Guidelines- Making the Best Use of Clinical Radiology Services 6th Edition.

It was discussed that the i -Refer 7th edition will be used when it is made available throughout the region.

It is anticipated that information on accessing the 7th Edition will be made available to GPs through the radiology managed clinical network and also through SALT (Southern Area Learning Together).

Internal referrers will be made aware of referral criteria through the Radiology User Group and also by way of the trust intranet which contains a guide to making the best use of clinical radiology services.

Procedure (A) 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 GPs but the trust is moving towards the introduction of e-referrals.

There seems to be a robust process in place for dealing with incomplete referrals which are logged onto the RIS.

Audit of Compliance with Employer's Procedures

Procedure (F) 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

- LMP audit
- Clinical evaluation audit
- Audits of DRLs
- Audits of pregnancy forms and breast feeding status

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

Diagnostic Reference Levels (DRLs)

Procedure (H) 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, DRLs outlined in the notes for Guidance on the Clinical Administration of Radiopharmaceuticals and use of Radioactive Sources (ARSAC 2006) have been adopted.

For certain examinations the trust has adopted DRLs that are lower than the ARSAC figures and these examinations are outlined in Procedure (H).

DRLs for paediatric examinations use the scaling factors published in the ARSAC Notes for Guidance.

Local DRLs (based on dose audits) have been developed for the CT component of SPECT/CT examinations.

Staff Qualifications

Before employment a radiographer's HPC 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.

All radiographers working in the nuclear medicine department have a BSc or equivalent.

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.

Incidents

Two incidents reportable under IR(ME)R as an exposure much greater than intended had occurred since April 2010.

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

Any potential incident is reported to the Radiology Services Manager who if necessary informs the Clinical Director of Radiology. Unless the initial investigation shows beyond reasonable doubt that no such overexposure has occurred, the RPA/MPE will be contacted for advice.

All incidents and near misses are reported via the DATIX system. All incidents are discussed at monthly meetings between the Radiology Services Manager and the Clinical Director of Radiology. If appropriate, incidents are also discussed at monthly governance meetings.

Learning from incidents is cascaded to all relevant staff and the person who has completed the initial IR1 form must be informed of the outcome.

5.2 DUTIES OF THE PRACTITIONER, OPERATOR AND REFERRER

Entitlement

Employer's Procedure (C) 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.

Following discussion it was recommended that

- All entitlement documents should be properly completed and signed off by the medical director
- The two consultants who act in the absence of the ARSAC certificate holder should be entitled as operators for clinical evaluation of certain procedures. It is also recommended that their scope of practice should be limited
- The ARSAC certificate holder needs to be entitled as a Practitioner
- Medica as an organisation should be entitled as Operator as they carry out clinical evaluations
- The duties of the operator outlined in the procedure should also include checking ID, pregnancy enquiry and carrying out the scan
- Entitlement could be tied in with appraisal

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 take individual patient characteristics into account, alternative examinations involving less or no radiation and the special attention required for justification.

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.

Medico- Legal

Employer's Procedure (D) 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 (E) outlines the process for making enquiries of females of childbearing age. The procedure was detailed and clear but the following recommendations were made

- SPECT/CT should be added to the list of high dose procedures
- The pregnancy enquiry form includes the possibility of a pregnancy test being carried out but this is not included in the procedure. The procedure should adequately reflect the process to be followed if a patient is pregnant.

The procedure follows trust policy in that pregnancy enquiry in young people aged 13-16 should be conducted in the presence of a parent or guardian.

Some further discussion could take place with the trust as to the appropriateness of following this policy in the case of radiology.

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 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 dose chart from the ARSAC guidance notes.

There was some discussion around the fact that ARSAC will not issue hard copies of updated guidance in this area with future revisions being published online. Some thought should be given to how the nuclear medicine department will accurately reflect the current guidance for paediatric patients in their procedures and protocols.

Clinical Evaluation

An Employer's Procedure (K) 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 referrer must also ensure that a written report is placed in the patient's notes.

Adequate arrangements are in place for evaluation of nuclear medicine examinations if the ARSAC certificate holder is not present in the department. These arrangements should be formalised through the entitlement process.

5.5 RESEARCH

An Employer's Procedure (I) 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 (N) 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 SHSCT 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

An inventory of radiological equipment was supplied which contained all of the necessary legislative information. 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. Only radiographers who are already experienced start work in the nuclear medicine department.

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 (B) 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.

5.11 RISK MANAGEMENT

An Employers' Procedure (L) 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.

The procedure outlined a range of methods utilised to achieve the above and it was felt that the procedure could be reviewed to include all the good practice that takes place in the nuclear medicine department.

5.12 RADIOPHARMACEUTICALS

Procedures (O), (P) and (Q) outline

- the procedure for preparation and administration of individual pharmaceutical doses
- the procedure for preparation and transport of blood samples to regional radiopharmacy for cell labelling
- the procedure for receipt, labelling and transport of blood for cell labelling

These procedures were found to be comprehensive and detailed and containing several areas of good practice such as only working on one pot at a time which reduces considerably the possibility of incorrect labelling and the measurement of residual activity and recording the dose that was actually administered.

Procedure (J) outlines the information that is provided for nuclear medicine patients. The information provided was found to be comprehensive and reviewed and updated regularly.

The nuclear medicine department currently has one practitioner who holds an ARSAC certificate and adequate processes are in place to provide cover on those occasions when the certificate holder is not present in the department.

Inspectors discussed the range of isotopes listed on the ARSAC certificate and in particular the use of Krypton 81m and its continuing use in the future.

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. It was recommended however that minimum activities for paediatric examinations to be administered should be displayed.

5.14 CONCLUSION

Radiological practice within the diagnostic imaging 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 three 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.

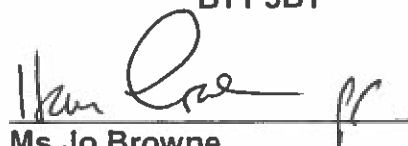
Requirements are based on The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000 and The Ionising Radiation (Medical Exposure) (Amendment) Regulations (Northern Ireland) 2010.

Recommendations are based on other published standards which promote current good practice and should be considered by the SHSCT 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



Ms Jo Browne
INSPECTOR

Mr H Graham
INSPECTOR

03.06.13

DATE

The Regulation and Quality Improvement Authority

QUALITY IMPROVEMENT PLAN
CRAIGAVON 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

28 FEBRUARY 2013

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 SHSCT 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: Angela McVeigh

NAME: ANGELA MCVEIGH
(Print) EMPLOYER

DATE: 3/7/13

07.07.13

No.	RECOMMENDATIONS	TIMESCALE	DETAILS OF ACTION TAKEN
1	Employer's Procedure (C) should be amended as outlined in the main body of the report. **Ref Duties of the Practitioner, Operator and Referrer**	Within three months	All recommendations outlined in the main body of the report with regards to Procedure (C) have been implemented.
2	A system should be developed for regular review of authorisation guidelines **Ref Justification of Individual Medical Exposures**	Within three months	The authorisation guidelines have been amended to include this recommendation.
3	The Employer should ensure that the Employer's Procedure (E) in relation to females of child bearing age is amended as outlined in the main body of the report. **Ref: Justification of Individual Medical Exposures**	Within three months	All recommendations outlined in the main body of the report with regards to Procedure (E) have been implemented.
4	Display minimum activities to be administered for paediatric examinations **Ref Staff Discussion/Review of Patient Records**	Within three months	This recommendation has been fulfilled – minimum activities to be administered for paediatric examinations have been displayed within the clinical area and discussion with staff have taken place.