



THE REGULATION AND QUALITY IMPROVEMENT AUTHORITY

9th Floor Riverside Tower 5 Lanyon Place Belfast BT1 3BT

Tel: (028) 9051 7500 Fax: (028) 9051 7501

**SOUTHERN HEALTH AND SOCIAL CARE TRUST
CRAIGAVON AREA HOSPITAL
BREAST SCREENING UNIT**

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**

9 DECEMBER 2015

1.0 General Information

Name of Establishment:	Southern Health and Social Care Trust Craigavon Area Hospital
Address:	68 Lurgan Road Portadown Craigavon County Armagh BT63 5QQ
Department Inspected:	Breast Screening Unit
Telephone Number:	028 38 334444
Name of Employer:	Ms Paula Clarke – Acting Chief Executive
Radiology Clinical Director:	Dr David Gracey
Medical Physics Expert:	Dr Ian Gillan
Date and Time of Inspection:	09 December 2015 10.00 – 13.30
Names of Inspectors:	Winnie Maguire and Jo Browne
Name of PHE Advisor:	Sarah Peters

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 the Regulation and Quality Improvement Authority (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 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 breast screening services provided at SHSCT Craigavon Area Hospital.

3.0 Methodology

On 9 December 2015, warranted IR(ME)R inspectors from RQIA, with advice being provided by Public Health England (PHE) staff, visited SHSCT Craigavon Area Hospital Breast Screening Unit, as part of RQIA's IR(ME)R inspection programme.

Prior to the inspection, the trust 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. It was also used to direct discussions with key members of staff working within the breast screening unit and provide guidance for the inspection process.

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

Dr Stephen Hall - Assistant Medical Director
Jeanette Robinson - Head of Diagnostics
Andrene Graham - Site Lead Radiographer
Margaret Holland - Site Lead
Fiona Kearney - QMS Lead Radiographer
Adam Workman - Medical Physics Expert (BHSCT)
Philip Orr - Clinical Scientist (BHSCT)

4.0 Focus of Inspection

The focus of the inspection was to review compliance with the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000 and the Ionising Radiation (Medical Exposure) (Amendment) Regulations (Northern Ireland) 2010 in relation to the following areas:

- procedures for making pregnancy enquiries of females of child bearing age;
- procedures for ensuring correct patient identification;
- procedures for managing and reporting incidents;
- procedures to ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced so far as are reasonably practicable;
- clinical audit; and
- quality assurance programmes for standard operating procedures.

5.0 Profile of the Service

SHSCT Craigavon Area Hospital Breast Screening Unit provides breast screening for women aged 50 -70, every three years, in line with the National Health Service Breast Screening Programme (NHSBSP).

The Breast Screening Unit contacts each GP practice in turn, and all eligible women are sent an invitation to attend the mobile units. This report only refers to the medical

exposures undertaken for breast screening and does not include symptomatic medical exposures.

The self assessment form submitted prior to the inspection confirmed that SHSCT Craigavon Area Hospital Breast Screening Unit carried out:

- 6,475 screening mammography in 2014/2015 (including intervention)
- 11,402 symptomatic mammography in 2014/2015

SHSCT Craigavon Area Hospital Breast Screening Unit for screening and symptomatic medical exposures employs:

- 3 WTE Consultant Radiologists
- 3.15 Consultant/advanced practice radiographers (including reporting radiographers)
- 6.73 WTE Radiographers
- 1.54 WTE Assistant Practitioners
- 1 Radiation Protection Supervisor and 2 in training

6.0 Key Findings

6.1 Employer's Procedures

Craigavon Area Hospital Breast Screening Unit had the required Employer's Procedures in place. The Employer's Procedures had recently been developed in November 2015 and were found to be comprehensive and service specific to the breast screening unit.

Prior to the development of the service specific Employer's Procedures for breast screening, the unit had developed local breast screening procedures to assist staff while using the generic SHSCT Employer's Procedures for diagnostic imaging. To avoid confusion it is recommended that the unit only retains the newly developed service specific Employer's Procedures for Breast Screening and removes the previous set of local procedures from use.

The inspection team would like to acknowledge the work undertaken by the management team within the breast screening unit in producing the Employer's Procedures.

On this occasion the inspectors only reviewed the Employer's Procedures and documentation relating to the focus of the inspection as outlined in section 4.0 of this report.

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 practitioners and operators, through audit, staff meetings, emails and training.

Document and version control are clearly noted on the Employer's Procedures.

6.2 Females of Child Bearing Age

Employer's Procedure D for making enquiries of females of child bearing age to establish whether the individual is or may be pregnant or breast feeding was reviewed. The procedure clearly indicates that there is no significant radiation dose to the foetus from mammography and therefore the breast screening unit does not make pregnancy enquiries.

6.3 Patient Identification

Employer's Procedure A is in place to correctly identify individuals to be exposed to ionising radiation. Some minor suggestions were made during the inspection to enhance Employer's Procedure A.

The procedure clearly outlines:

- the three point patient identification process;
- 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;
- where confirmation of identification is to be recorded;
- the arrangements in place to identify a patient who is unable to identify themselves under various circumstances; and
- the arrangements in place when two duty holders are working together.

Staff were able to clearly describe how they would ensure that the correct patient was identified and action they would take if they could not clearly identify the patient. Staff reported that they had access to an interpreter service. Staff also reported that most non-English speaking patients were accompanied by someone who could translate for them.

Review of 20 patient care records found that all records had the three point check undertaken and the name of the operator who identified the patient was recorded on screening form.

6.4 Incidents

Employer's procedure J contains details of the SHSCT incident reporting mechanisms which operates in conjunction with the trust Incident Management Procedure.

The inspection team were informed that all incidents and near misses are recorded on the DATIX system by the person reporting the incident. The incident is reported to the RPS who will inform the Radiology Site Lead. The RPS will also inform the MPE/RPA who, if appropriate, will carry out an assessment of the dose received by the patient. The RPS provides information as requested to the MPE/RPA to assist in the assessment of dose. A query was raised by the management team regarding reporting incidents to RQIA that involve patients who attend for screening early and receive a medical

exposure. It was agreed that this will be discussed within RQIA and the trust informed of the outcome.

A review of incidents and near misses recorded over the past two years found that they have been documented, investigated and managed in line with the legislation. Learning from the incidents had been disseminated to staff within the department and action taken to minimise the risk of similar incidents occurring.

The management team discussed in detail the clinical governance arrangements for the trust in relation to radiation protection. All incidents and near misses are discussed at team meetings, senior management meetings, radiation protection committee meetings and trust board through the trust's clinical governance systems.

Incident management was discussed with staff during the inspection who were able to clearly describe the action they would take if an incident occurred within the department. Staff confirmed that learning from previous incidents had been shared with them.

6.5 Procedures to ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced so far as are reasonably practicable

Employers Procedure H outlines the arrangements in place to ensure that the probability and magnitude of accidental or unintended doses to patients are reduced so far as are reasonably practicable. Some minor suggestions were made during the inspection to enhance Employer's Procedure H. Discussion with the senior management team on how this is achieved and examples discussed included:

- staff training and induction;
- entitlement arrangements;
- Employer's Procedures;
- quality management system;
- authorisation guidelines;
- audit programme;
- ensuring patient ID procedure is followed;
- equipment maintenance; and
- learning from incidents and near misses.

6.6 Clinical Audit

There are a variety of clinical audits undertaken within a rolling audit calendar in SHSCT Craigavon Area Hospital Breast Screening Unit and the inspection team reviewed completed audits during the inspection. Employer's Procedures C outlines the arrangements for clinical audit.

6.7 Quality assurance programmes for standard operating procedures

Employer's Procedure C also outlines the quality assurance mechanisms and review of protocols and procedures to be undertaken.

6.8 Staff Discussion/Review of Patient Records

The inspection team met with two band 7 and two band 6 radiographers and discussed: the application of the Employer's Procedures; the role and function of duty holders; patient identification; pregnancy enquires; audits 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 the Employer's Procedures and the other areas discussed. Review of patient records indicated that the correct procedures are being followed in relation to patient identification.

7.0 Conclusion

It was clear through discussions with the management team and staff that practice within SHSCT Craigavon Area Hospital Breast Screening Unit is in keeping with the principles of IR(ME)R and the Employer's Procedures.

The inspectors concluded that there were no identified serious concerns regarding the actual delivery of the service. The radiological practice within breast screening was therefore found to be safe and effective.

There was one recommendation made as a result of this inspection.

The management team and staff are to be commended for their commitment and enthusiasm to ensuring that SHSCT Craigavon Area Hospital Breast Screening Unit is operating a breast screening programme within the legislative framework and maintaining optimal standards of practice for patients. The inspection team would also like to acknowledge the standard of Employer's Procedures and supporting documentation that had been developed.

The inspectors would like to thank 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 management team on behalf of the employer 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 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

Ms Winnie Maguire
INSPECTOR

DATE

DATE



The completed quality improvement plan for this service is not currently available. However, it is anticipated that it will be available soon. If you have any further enquiries regarding this report please contact RQIA through the e-mail address info@rqia.org.uk



The Regulation and
Quality Improvement
Authority

QUALITY IMPROVEMENT PLAN

CRAIGAVON AREA HOSPITAL

BREAST SCREENING UNIT

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

9 December 2015

NOTES:

Issues identified during inspection were discussed with the senior management team on behalf of the employer 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: _____

NAME: _____
(Print) EMPLOYER

DATE: _____

No.	RECOMMENDATION	TIMESCALE	DETAILS OF ACTION TAKEN
1.	<p>The employer should ensure that the breast screening unit only retains the newly developed service specific Employer's Procedures for Breast Screening and removes the previous set of local procedures from use.</p> <p>Ref: 6.1 Employer's Procedures</p>	Within 3 months	

Date Received/Approved	Signature of Inspector