



**THE REGULATION AND QUALITY IMPROVEMENT AUTHORITY**

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**ACTION CANCER**

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

**29 OCTOBER 2013**

## 1.0 GENERAL INFORMATION

|                               |   |
|-------------------------------|---|
| Name of Establishment:        | Action Cancer   |
| Address:                      | Action Cancer House<br>1 Marlborough Park<br>Belfast<br>BT9 6XS |
| Department Inspected:         | Breast Screening  |
| Telephone Number:             | 028 9080 3344   |
| Name of Employer:             | Gareth Kirk – Chief Executive Officer                           |
| Radiation Protection Advisor: | Phil Orr  |
| Date and Time of Inspection:  | 29 October 2013   |
| Name of Inspectors:           | Winnie Maguire<br>Jo Browne                                     |
| Name of PHE Advisors:         | Kathlyn Slack<br>Gail Woodhouse                                 |

## 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 Action Cancer House and does not include the mobile service.

### **3.0 METHODOLOGY**

On 29 October 2013, warranted IR(ME)R inspectors from RQIA, with advice being provided by Public Health England (PHE) staff, visited the breast screening department of Action Cancer, as part of RQIA's IR(ME)R inspection programme.

Prior to the inspection, the charity 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 department and provide guidance for the inspection process.

Action Cancer staff in attendance for part or all of the inspection:

Gareth Kirk – Chief Executive Officer

Geraldine Kerr – Head of Professional Services

Joanne Currie – Consultant Radiographer/Radiation Protection Supervisor (RPS)

Sharon McCollum – Advanced Practitioner

Phil Orr – Radiation Protection Advisor (RPA)

Adam Workman – Medical Physics Expert (MPE)

### **4.0 PROFILE OF SERVICE**

Action Cancer is a charitable organisation which provides free breast screening services for women aged 40 to 49 years and 70 years and over. The age group screened by Action Cancer falls outside of eligibility for the National Health Service Breast Screening Programme (NHSBSP) and where benefits from screening have been demonstrated.

Action Cancer provides services to women who do not have the symptoms of breast cancer. They operate an Early Detection Clinic for Breast Cancer and mammography is used as a screening tool. Women presenting with symptoms of breast cancer will not be screened and will be referred back to their general practitioner for ongoing care.

The self assessment form submitted prior to the inspection confirmed in 2012/2013, Action Cancer carried out approximately:

- 3,866 mammography at Action Cancer House
- 4,269 mammography at The Big Bus (Mobile Unit).

Action Cancer employs:

- 3 Consultant Radiologists
- 1 Consultant Radiographer
- 1 Advanced Practitioner
- 3 Part time Radiographers
- 1 Bank Radiographer

## **5.0 KEY FINDINGS**

### **5.1 DUTIES OF THE EMPLOYER**

#### **Employer's Procedures**

Action Cancer had the required Employer's Procedures in place which had been signed by the Head of Professional Services, the RPS and the RPA. It was recommended that the Employer's Procedures are signed by the Employer who in this instance is the Chief Executive Officer.

The Employer's Procedures were updated in September 2012 and are due to be reviewed every two years or more frequently if changes occur. A recommendation was made to review the Employer's Procedures to ensure that they are consistent with the policies and procedures in place for the mammography service.

The Employer's Procedures had evidence of document control in place.

The overall responsibility for IR(ME)R lies with the Chief Executive Officer, Mr Gareth Kirk, however the Radiation Safety Policy indicated the delegation of responsibility for IR(ME)R to the Head of Professional Services. It is recommended that the policy is reviewed to show that tasks can be delegated regarding IR(ME)R, however the responsibility remains with the Employer.

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

#### **Examination Protocols**

There were examination protocols in place for mammography. On review it was recommended that the examination protocols were linked to the equipment manual to provide a more robust and comprehensive protocol.

#### **Referral Criteria**

An Employer's Procedure was in place for the acceptance and prior justification of a referral for a screening mammogram.

A recommendation was made to further develop the referral criteria procedure within the Employer's Procedures to reflect the information provided on the self-assessment and during discussion.

The referral criteria for Action Cancer is based on breast screening guidelines developed by the Royal College of Radiologists. The charity currently screens women aged 40-49 and 70+ who are not eligible for the NHSBSP but for whom breast screening has a proven benefit.

## **Audit of Standard Operating Procedures**

There is a written Employer's Procedure 5 in place to ensure that quality assurance programmes are followed for standard operating procedures. Systems are in place to ensure that all duty holders are notified of any changes to the Employer's Procedures.

## **Diagnostic Reference Level (DRL)**

Action Cancer has undertaken dose audits and adopted a local DRL for mammograms. The DRL is clearly displayed in the examination room. The DRL is not expected to be exceeded for standard mammograms when good and normal practice regarding diagnostic and technical performance is applied. Employer's Procedure 7 outlines the action taken if dose audits indicate that the DRL is being consistently exceeded.

Dose audits are also undertaken to establish compliance with the locally adopted DRL.

## **Staff Qualifications**

Action Cancer ensures that all staff are appropriately qualified and registered with their relevant professional bodies.

All Action Cancer radiographers have a diagnostic radiography qualification and certificate of competency in mammography. Reporting radiographers must have completed a diploma in Mammography Image Interpretation and Reporting and participate in six monthly performance reviews.

The charity has a procedure in place for the validation and monitoring of professional registration for allied health professionals.

There are systems in place to check the registration of radiographers and radiologists annually.

## **Appraisals**

There were comprehensive systems in place to provide annual appraisals for all grades of staff. Review of the appraisal documentation confirmed that all staff had received their annual appraisal.

## **Incidents**

No incidents had been reported under IR(ME)R since April 2010. Action Cancer has systems in place to report and investigate incidents and near misses.

All staff have been trained in incident reporting and there is an incident reporting procedure in place.

## **5.2 DUTIES OF THE PRACTITIONER, OPERATOR AND REFERRER**

There are systems in place for ensuring that duty holders comply with the Employer's Procedures.

### **Entitlement**

Action Cancer has developed their entitlement arrangements and supporting documentation for individual duty holders.

Employer's Procedure 3 outlines the entitlement arrangements within Action Cancer. It is recommended that the procedure should reflect the arrangements for entitlement as outlined during the inspection.

It is also recommended that arrangements are in place to entitle MPE's as operators.

## **5.3 JUSTIFICATION OF INDIVIDUAL MEDICAL EXPOSURES**

The radiographers within Action Cancer are entitled as practitioners and can therefore justify mammograms as outlined within their individual scope of practice.

Action Cancer undertakes justification audits to ensure compliance.

### **Medico Legal**

Action Cancer does not undertake any medico legal exposures.

### **Females of Child Bearing Age**

Employer's Procedure 4 for making enquiries of females of childbearing age was reviewed. It was recommended that the procedure was further developed to reflect the information provided on the self-assessment and discussions during inspection.

## **5.4 OPTIMISATION**

There are good arrangements in place to ensure that medical exposures (mammograms) are kept as low as reasonably practicable. The management outlined the following as examples:

- Liaising with the manufacturer regarding optimal settings at installation
- Servicing of equipment
- Robust quality assurance programme
- Monthly reporting figures and recall rates
- Reject analysis
- Standard operating procedures
- Audits
- Competency assessments
- Use of a local DRL

- Training and CPD (Continuous Professional Development)
- Dose Audits
- Image Quality
- Application specialists involved in training for all new equipment
- Service level agreement with Medical Physics
- QA programme

### **Clinical Evaluation**

Employer's Procedure 8 outlines arrangements in place for the carrying out and recording of an evaluation for each medical exposure. The procedure was reviewed and no issues were identified.

Good systems are in place to ensure all medical exposures have an appropriate clinical evaluation undertaken and recorded.

### **5.5 RESEARCH**

Action Cancer is not involved in any research programmes.

### **5.6 CLINICAL AUDIT**

There is an Employer's Procedure 10 in relation to clinical audits. It is recommended that the procedure is updated to reflect all ongoing audits or makes reference to an audit plan or audit file.

### **5.7 EXPERT ADVICE**

Action Cancer retains the services of a MPE on service level agreement. The MPE and RPA were present for the duration of the inspection.

The MPE 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 legislative information. There is an appropriate amount of equipment available for the workload and throughput of Action Cancer.

### **5.9 TRAINING**

There is evidence of induction, competency based assessments and continuing professional development for staff. The comprehensive training records for radiographers were reviewed as part of the inspection process and found to be of an excellent standard.



## **5.10 PATIENT IDENTIFICATION**

Employer's Procedure 2 is in place for the identification of patients. The procedure references the three point patient identification process and clearly outlines that it is the responsibility of the operator who carries out the medical exposure to ensure that the correct patient receives the correct medical exposure, according to the request made.

## **5.11 RISK MANAGEMENT**

Employers' Procedure 9 outlines the arrangements 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.

## **5.12 REVIEW OF ENVIRONMENT**

The inspection team reviewed the facilities available in relation to breast screening. 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 enquires; referral criteria including the age range; audits; induction; continued professional development; the use of the DRL 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 the Employer's Procedures and the other areas discussed. Review of patient records indicated that the correct procedures are being followed.

## 5.14 CONCLUSION

While some further development of documentation is recommended, it was clear through discussions with the management team and staff that practice is in keeping with the principles of IR(ME)R and the Employer's Procedures.

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

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

The management team and staff are to be commended for their commitment and enthusiasm to ensuring that Action Cancer is operating a breast screening programme within the legislative framework and maintaining optimal standards of practice for patients.

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 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 Action Cancer 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**

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Mrs Winnie Maguire  
**INSPECTOR**

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Ms Jo Browne  
**INSPECTOR**

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**DATE**



The Regulation and  
Quality Improvement  
Authority



## **QUALITY IMPROVEMENT PLAN**

### **ACTION CANCER**

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

**29 OCTOBER 2013**

**NOTES:**

Issues identified during inspection were discussed with 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 Action Cancer 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  
9<sup>th</sup> Floor Riverside Tower  
5 Lanyon Place  
BELFAST  
BT1 3BT

SIGNED:

Geena Kirk - Chief Executive

NAME:  
(Print)

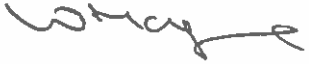
Action Cancer  
EMPLOYER

DATE:

13<sup>th</sup> February 2014

| No. | RECOMMENDATIONS   | TIMESCALE         | DETAILS OF ACTION TAKEN   |
|-----|---|-------------------|---|
| 1.  | The employer should sign the Employer's Procedures.<br><br><b>Ref: Employer's Procedures</b>  | Immediately       | Done;   |
| 2.  | The employer should review and update the Employer's Procedures as outlined in the main body of the report.<br><br><b>Ref: Employer's Procedures</b>                                  | Within six months | Employer's Procedures have been reviewed and updated. They are currently under the RPA for review.  |
| 3.  | The employer should amend the Radiation Safety Policy as outlined in the main body of the report.<br><br><b>Ref: Employers Procedures</b>   | Within six months | Dicto   |
| 3.  | The employer should ensure that the examination protocols are linked with the equipment manual as outlined in the main body of the report.<br><br><b>Ref: Examination Protocols</b>   | Within six months | Dicto   |
| 4.  | The employer should further develop the referral criteria procedure within the Employer's Procedures as outlined in the main body of the report.<br><br><b>Ref: Referral Criteria</b> | Within six months | Dicto   |
| 5.  | The employer should ensure that Employer's Procedure 3 is updated as outlined in the main body of the report.<br><br><b>Ref: Entitlement</b>  | Within six months | Dicto   |
| 6.  | The employer should ensure that arrangements are in place to entitle MPEs as operators.<br><br><b>Ref: Entitlement</b>  | Within six months | M.P.E entitlement has been addressed within the revised draft Employer's Procedures RPA for review. |
| 7.  | The employer should ensure that Employer's Procedure 4 is updated as outlined in the main body of the report.<br><br><b>Ref: Females of Child Bearing Age</b>                         | Within six months | Employer's Procedures have been reviewed and updated. They are currently under the RPA for review.  |

| No. | RECOMMENDATIONS   | TIMESCALE         | DETAILS OF ACTION TAKEN |
|-----|---|-------------------|-------------------------|
| 8.  | <p>The employer should ensure that Employer's Procedure 10 is further developed as outlined in the main body of the report.</p> <p><b>Ref: Clinical Audit</b></p> | Within six months | Ditto.                  |

| Date Received/Approved | Signature of Inspectors   |
|------------------------|---|
| 5/3/14 Yes ✓           |  |