



The Regulation and
Quality Improvement
Authority

THE REGULATION AND QUALITY IMPROVEMENT AUTHORITY

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**BELFAST HEALTH AND SOCIAL CARE TRUST
BELFAST CITY HOSPITAL – RADIOTHERAPY
DEPARTMENT**

TEL: 028 9032 9241

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

27 MAY 2015

1.0 GENERAL INFORMATION

Name of Establishment:	Belfast City Hospital
Address:	51 Lisburn Road Belfast BT9 7AB
Department Inspected:	Radiotherapy Department
Telephone Number:	028 9032 9241
Name of Employer	Mr Michael McBride – Chief Executive (BHSCT)
Date and Time of Inspection:	27 May 2015 10.00 – 16.30
Name of Inspectors:	Mr Hall Graham Ms Jo Browne
Name of PHE Advisor:	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. In its work 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 our findings from our inspection of the radiotherapy department at the Belfast City Hospital.

3.0 Methodology

On 27 May 2015, warranted IR(ME)R inspectors from RQIA, with advice being provided by staff from Public Health England (PHE) inspected the radiotherapy department of the Belfast City Hospital (BCH) as part of RQIA's routine IR(ME)R inspection programme.

Prior to the inspection the radiotherapy department was required to complete a self-assessment questionnaire and provide RQIA with all relevant policies and procedures. This information was shared with PHE staff prior to the inspection visit and was used to direct discussions with key staff in the department and provide guidance for the inspection process.

Belfast City Hospital staff in attendance for all or part of the inspection:

Gillian Traub – Acting Co-Director, Cancer and Specialist Medicine
Leslie Frew – Head of Radiotherapy Physics Service
Gerard Hanna – Consultant in Clinical Oncology
Debbie Wightman – Acting Service Manager Oncology/Haematology
Christiona Logan – Quality Radiographer
Joanne McCarthy – Radiotherapy Clinical Co-Ordinator
Gaile Smyth – Radiotherapy Services Manager
Roy Mooney – Radiation Protection Advisor

4.0 Profile of the Service

The self assessment form submitted prior to the inspection confirmed that each year, the Belfast City Hospital radiotherapy department carries out approximately:

1,379	Conventional simulation and Sim CT (Computed Tomography)
4,401	CT planning scans
1,902	Palliative courses
2,445	Radical courses
4,347	External beam courses
66,311	External beam fractions
89	Brachytherapy HDR (High Dose Rate) new courses
242	Brachytherapy HDR fractions
79	Brachytherapy LDR (Low Dose Rate)
125	Brachytherapy seed implants
88	New emergency patients treated out of hours
3,515	New emergency patient treated out of hours fractions

The Belfast City Hospital radiotherapy department employs:

20 wte	Consultant Clinical Oncologists
3	Associate Specialists
12	Clinical Oncology SpRs (Specialist Registrars)
9	Consultant/Advanced Practice Radiographers
83	Radiographers
9.8 wte	Medical Physics Experts
14.8	Registered Clinical Scientists
1	Trainee Clinical Scientist IPEM Scheme Part 2, Year 1
1	Trainee Clinical Scientist IPEM Scheme Part 1, Year 2
2	Trainee Clinical Scientists STP Scheme Year 1
1	Trainee Clinical Scientist STP Scheme Year 2
15.5 wte	Dosimetrists (TP)
2.7	Dosimetrists (MR)
8	Medical Technical Officers (MTO's)

5.0 Previous Requirements and Recommendations

There were two requirements and six recommendations made as a result of the last inspection undertaken on 27 and 28 September 2011. The following is a summary of the requirements and recommendations made along with the action taken to address them:

Requirements

1. The employer must ensure that clinical protocols are developed and implemented for head and neck exposures.

Compliant - Clinical protocols for head and neck exposures had been developed and were reviewed as part of the inspection.

2. The employer must ensure that arrangements are in place to entitle referrers, operators and practitioners for their individual scope of practice and that a written record is maintained.

Compliant - Review of entitlement records confirmed that robust systems are in place to entitle referrers, operators and practitioners for their individual scope of practice.

Recommendations

1. The employer should ensure that the clinical protocols are developed as outlined in the main body of the report.

Compliant - The clinical protocols had been reviewed and further developed following the previous inspection in relation to content and format. As the protocols are developed by different clinical teams full consistency of approach was not fully achievable.

2. The employer should ensure that the issues identified in relation to referrals are addressed as outlined in the main body of the report.

Compliant - The referral procedure was reviewed and clarified following the previous inspection.

3. The employer should make a positive decision regarding the use of in vivo dosimetry and when this is to be used so that the choice is not left as optional.

Compliant - Discussion confirmed that the position paper clearly states that the use of IVD is no longer optional.

4. The employer should ensure that the documentation currently used by the head and neck team for peer review is shared with and adapted by the other teams.

Compliant - Discussion confirmed that some of the teams have already adapted their documentation for routine peer review and the process of peer review across all sites is currently being reviewed.

5. The employer should ensure that Employer's Procedure B is further developed regarding justification and the role of the practitioner for all stages of treatment.

Compliant - Discussion and review of Employer's Procedure B confirmed that this recommendation has been fully addressed.

6. The employer should ensure that Employer's Procedure D is further developed to include arrangements for patients with communication difficulties.

Compliant - Discussion and review of Employer's Procedure D confirmed that this recommendation has been fully addressed.

6.0 Key Findings

6.1 Duties of the Employer

Employer's Procedures

The BHSCT had Employer's Procedures in place for external beam radiotherapy and sealed source brachytherapy. The inspectors were informed that the Employer's Procedures were reviewed in April 2014 and were due for review in April 2017 or more frequently if changes occur. The Employer's Procedures had clear document control on all pages.

The overall responsibility for IR(ME)R lies with the Chief Executive, Mr Michael McBride. Within the BHSCT Radiation Safety Policy the Chief Executive has nominated Dr Richard Wright to act as his representative and chair the Radiation Protection Committee. The radiation protection committee forms trust policy with regards to matters of radiation protection.

The committee reports its activities through clinical governance arrangements to the assurance group, executive team and trust board, as outlined within the policy.

The BHSCT Radiation Safety Policy was updated in March 2014 and is due for review in March 2017.

Compliance with the Employer's Procedures is monitored by the Radiation Protection Supervisor (RPS) and any identified issues are reported to the Radiotherapy Service Manager.

The Employer's Procedures are available to staff in electronic format. All staff are made aware of their responsibilities under the Employer's Procedures as part of their induction. Radiographers are required to read the Employer's Procedures every two years, or more frequently if changes occur, and a record is retained.

Clinical Protocols

Clinical protocols have been developed by each specialist clinical team. All clinicians are assigned to a 'consultant team' with expertise in certain site specialities. The clinical protocols reviewed were site specific, contained good background information and had a sound evidence base.

Clinical protocols had been developed for head and neck exposures following the last inspection.

Clinical protocols had been reviewed and further developed following the previous inspection in relation to content and format. As the protocols are developed by different clinical teams full consistency of approach was not fully achievable.

The radiotherapy department currently use the NICaN (Northern Ireland Cancer Network) metastatic spinal cord compression guidelines which were published by NICE (National Institute for Health and Clinical Excellence) in 2008. There is an agreed procedure in place for patients requiring treatment of spinal cord compression outside of normal working hours.

After a clinical protocol is written, it is presented at a quarterly radiotherapy development meeting. All consultant clinical oncologists sign off clinical protocols relevant to their specialised area of practice. Electronic copies are made available via the trust intranet.

The quality management team maintains a list of signatures of all medical practitioners who have received a copy of the clinical protocols and Employer's Procedures.

Referral Criteria

Referral criteria are outlined within the clinical protocol for each specialised area of practice. This includes who is entitled to make referrals in line with the clinical protocols.

Only internal referrals can be made within the radiotherapy department. Consultant clinical oncologists or trainees with FRCR, FFRRCSI or EU equivalent are entitled to act as referrer for all external beam radiotherapy treatments. This task may be delegated to a named trainee/associate or staff grade working under their supervision.

Radiographers, at Band 6 or above, may act as operator for further verification during a treatment course according to the appropriate protocol.

Referrals for brachytherapy treatment can only be made by a consultant clinical oncologist.

The department keeps a record of non-conformity if referrals are returned to a practitioner.

Audit of Standard Operating Procedures

There is a written Employer's Procedure E in place to ensure that quality assurance programmes are followed for standard operating procedures. The inspectors reviewed this procedure, found it to be satisfactory and relevant to the radiotherapy department.

Patient Dose

Employer's Procedure F outlines arrangements for the assessment and recording of patient dose in the following areas of treatment:

- External Beam Treatment Exposures
- External Beam Electronic and Film Portal Imaging
- Radiotherapy Simulator Fluoroscopy Imaging
- Radiotherapy and Brachytherapy CT Planning and Verification
- Brachytherapy Fluoroscopy Imaging
- Brachytherapy Treatment Exposures

In vivo dosimetry (IVD) using thermoluminescent dosimetric (TLD) methods is undertaken routinely for Total Body Photon or Electron Irradiation treatments and at the request of the practitioner where required for other techniques. The radiotherapy physics service within the department has reviewed their position paper on the use of IVD following the previous inspection and any statement which could be interpreted as indicating that the use of IVD is optional has been removed.

Staff Qualifications and training

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

Systems are in place to check the professional qualifications and registration of all employees with their appropriate professional bodies.

An induction programme and peer review is in place for locum consultants.

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. Training and development needs are identified for individual staff as part of the appraisal process. The consultant clinical oncologists have their appraisals undertaken by the clinical director.

All grades of staff are responsible for maintaining their own portfolio of evidence to maintain their individual professional accreditation.

Incidents

Following examination of policies and discussion with staff it was clear that there are good systems in place to identify, report, record, manage, investigate and learn from incidents. No incidents have been reported to RQIA within the past two years.

The radiotherapy services manager, deputy radiotherapy services manager, section managers and team leaders are responsible for the analysis and review of non-conformities, near misses and radiation incidents. The radiotherapy department uses an error classification system described in the document; 'Towards Safer Radiotherapy' by the Royal College of Radiologists which covers error terminology and definitions; an outcome based severity classification and a pathway coding system. Each radiotherapy error is classified (Level 1 – 5) and then pathway coded. These codes are used for analysis in the quality report.

The inspectors acknowledged the comprehensive information contained within the quality report and commended this as good practice. The report is used by senior management to inform decision making within the department.

6.2 Duties of the Practitioner, Operator and Referrer

There are systems in place for ensuring that duty holders comply with the Employer's Procedures as outlined in the Radiation Safety Policy. These include:

- Good communication systems in place
- Quality management systems
- Quarterly Radiation Development Meeting
- Staff training and induction
- Compliance monitored by RPS
- Accountability of individual duty holders

Entitlement

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

The following is recommended to further enhance Employer's Procedure B:

- Clarify the role of the assessor and entitler within the procedure
- Clarify the role where the referrer is an SpR and/or Associate Specialist

The senior team reported that all duty holders had been appropriately entitled according to their individual scope of practice which is held on an electronic database. Along with the database, a sample of completed entitlement forms were reviewed and discussed during the inspection.

Entitlement is reviewed at annual appraisal and adjusted accordingly if a staff member's scope of practice had changed.

A record of staff competency is displayed in the various areas of the radiotherapy department to outline the scope of practice of each staff member and ensure safe and effective care.

Peer Review

There are currently systems in place for peer review for the following specialised teams according to the volume of treatments within each speciality:

- Head and Neck
- Lung
- Genitourinary

Following the last inspection the inspectors were informed that the Lung team has reviewed their peer review documentation. The senior management team informed the inspectors that the process of peer review was being reviewed across all sites.

The inspectors were informed that a team peer review meeting was being undertaken at the time of inspection.

6.3 Justification of Individual Medical Exposures

Employer's Procedure B identifies the individuals entitled to justify exposures and treatment. This procedure was updated following the previous inspection.

A list of practitioners is held in the booking office, the simulator suite, the quality assurance office, radiotherapy database and the checking room. This was confirmed by the inspectors during a review of the facilities.

Pre-Treatment

The signature of the practitioner on the radiotherapy request form indicates justification for the planning exposures for the intended treatment plan.

Verification

The signature of the practitioner on the treatment chart and plan indicates approval of the treatment plan and justification of the verification images.

Electronic Portal Imaging (EPI)

The practitioner's signature on the treatment chart and plan is the written justification for the additional dose from EPI as per the appropriate EPI protocol. If the number of images acquired reaches or is likely to reach twice the minimum standard the practitioner is requested to give a further written justification of the subsequent images.

Treatment

The signature of the practitioner on the treatment chart justifies all treatment and concomitant exposures.

Re-Planning

Justification for re-planning is confirmed by the practitioner's signature on the treatment chart.

Females of Child Bearing Age

Employer's Procedure D for making enquiries of females of childbearing age was reviewed and found to be satisfactory. It was updated following the previous inspection to include arrangements for patients with communication difficulties.

There are clear lines of responsibility for the checking of pregnancy status from the initial consultation to end of treatment. Records reviewed during the inspection confirmed that pregnancy enquiries were made and documented at the various stages.

If pregnancy cannot be excluded it is the responsibility of the operator who is about to carry out the procedure to refer the patient back to the practitioner for guidance on how to proceed.

6.4 Optimisation

There are good arrangements in place to ensure that non target volume doses are kept as low as reasonably practicable. The management outlined the following as examples:

- Induction programme
- Externally accredited quality management system
- Equipment competency training
- Applications training
- Clinical protocols
- EPI Protocols
- Dose assessments calculated by medical physics
- Tolerance level included in each site specific imaging protocol
- Planning suite training manual
- Regular quality assurance checks by radiographers and MPE
- Equipment maintenance programme
- Communication
- Right of appeal by TP staff if target volume is considered inappropriate
- Shielding for non target tissues
- Peer review
- Individually planned exposures of target volumes
- Awareness of overall dose distribution

Discussion took place around the optimisation of 2-D KV imaging. The PHE advisor suggested that the manufacturer supplied default settings should be reviewed as part of an optimisation programme.

There are very robust systems in place to undertake checks at all stage of planning and treatment to ensure safe and effective care to the patients, some examples of these include:

- Medical staff ensuring that parameters are recorded on the treatment chart during simulation or clinical mark-up.
- Radiographers undertaking manual calculation and independent checking of treatment monitor units within a set of fixed parameters for simple photon treatments
- Radiographers writing up the treatment chart and checking the consistency of the transcription of documented machine parameters and prescription on the treatment chart/RT physics data and ARIA as appropriate
- Radiographers ensure that the chart and plan are prescribed and signed off by the appropriate practitioner prior to commencing radiotherapy
- Treatment delivery must not proceed unless the two operators, irrespective of grade, are independently satisfied that all parameters have been checked and are correct
- Medical Physics have written procedures to specify the checking process which must be undertaken.

Paediatrics

The department uses the national protocols for treating children. There are currently no local clinical protocols in place.

The department has three clinical oncologists who specialise in treating children with cancer. Information regarding specific imaging doses and protocols for children is held in the planning suite training manual.

6.4 Clinical Evaluation

An Employer's Procedure I is in place for the carrying out and recording of a clinical evaluation. The procedure was reviewed and the arrangements were discussed as part of the inspection process and found to be satisfactory.

6.5 Research

The radiotherapy department participates in research projects and provides data accordingly. All research goes through the required ethics committee and approval process.

Employer's Procedure H relates to the procedure for the exposure of patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic research programmes.

6.6 Clinical Audit

There is a robust multidisciplinary approach to clinical audit with an ongoing audit cycle in place. Audits are reviewed and discussed at monthly clinical audit meetings.

The inspectors reviewed some of the completed clinical audits as part of the inspection process, along with the planned audit schedule.

6.7 Expert Advice

The BHSCT retains the services of a MPE on a contractual basis. The MPE was 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. Development of non-standard radiotherapeutic techniques will involve MPE input from initial investigations through to development of routine practice.

6.8 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 the radiotherapy department.

Since the previous inspection, the department has purchased two CT replacements, and two linear accelerators which has increased their capacity.

There is a multidisciplinary approach to developing the specification for new equipment with input from consultant medical staff, radiographers, MPE and health estates when appropriate.

Medical physics will perform appropriate radiation protection checks and the acceptance checks indicated by the manufacturer or additional checks as necessary.

6.9 Patient Identification

Employer's Procedure A is in place to correctly identify individuals to be exposed to ionising radiation. 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. The procedure was noted to be robust and specific to the radiotherapy department.

The department has considered the introduction of photo identification and a trial was conducted. Following this, a decision was taken not to pursue this process at this stage. The decision may be reviewed again in the future.

6.10 Risk Management

An Employers' Procedure J 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.

6.11 Review of the Environment

The inspection team reviewed the facilities available within the various areas of the radiotherapy department including:

- Booking office
- Pre-Treatment area
- Patient waiting/reception area
- Simulator suite
- Treatment area

The department was found to be clean, tidy and well organised.

6.12 Staff Discussion/Review of Patient Records

The inspection team met with staff of various grades and discussed: the application of the Employer's Procedures; the role and function of duty holders; patient identification; pregnancy enquiry; induction; continued professional development; treatment plans; clinical protocols; planning; simulation; concomitant exposures; out of hours protocols; and the action to be taken if they thought a patient had received a dose that was much greater than intended.

Staff demonstrated an excellent working knowledge of the Employer's Procedures and the other areas discussed. Review of patient records indicated that the correct procedures are being followed.

6.13 Conclusion

Prior to the inspection the radiotherapy department was asked to submit a self assessment form regarding the services provided. The inspectors would like to acknowledge the amount of comprehensive information contained within this assessment and the supporting documentation provided.

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

While some further development is needed in relation to an Employer's Procedure, it was clear through discussions with the management team and staff that practice is in keeping with the principles of IR(ME)R and work is ongoing to achieve full compliance. It was good to note that the Employer's Procedures had been specifically written for the radiotherapy department.

Inspectors concluded that there were no identified serious concerns regarding the actual delivery of the service and felt the department should be commended for their multidisciplinary team and patient centred approach to care.

There was one recommendation made as a result of this inspection. This is outlined in the appended Quality Improvement Plan.

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

7.0 Quality Improvement Plan

The details of the Quality Improvement plan appended to this report were discussed with the employer's representative 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.

Recommendations are based on other published standards which promote current good Trust 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



Mr Hail Graham
INSPECTOR

24-08-15

DATE



Ms Jo Browne
INSPECTOR

24/08/15.

DATE



The Regulation and
Quality Improvement
Authority

QUALITY IMPROVEMENT PLAN

**BELFAST HEALTH AND SOCIAL CARE TRUST
BELFAST CITY HOSPITAL – RADIOTHERAPY DEPARTMENT**

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NOTES:

The 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 must be met.

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

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.	The employer should ensure that Employer's Procedure B is updated as outlined in the main body of the report. Ref: 6.2	Within three months	

Date Received/Approved	Signature of Inspector