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Healthcare Inspectorate Wales

DRIVING IMPROVEMENT THROUGH INDEPENDENT AND OBJECTIVE REVIEW

Ionising Radiation (Medical Exposure) Regulations Inspection (announced)

Radiotherapy Department, North Wales Cancer Treatment Centre, Glan Clwyd Hospital

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Contents

1. Introduction

A compliance inspection, against the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000 and regulation amendments 2006 and 2011, was undertaken on 24 and 25 August of the Radiotherapy Department, North Wales Cancer Treatment Centre at Glan Clwyd Hospital, part of Betsi Cadwaladr University Health Board.

The regulations place responsibilities on practitioners, operators, those who refer patients for medical exposures and the employers of these three groups. The employer is required under the regulations to create a framework for the safe, efficient and effective delivery of ionising radiation by the provision of written procedures and protocols. A breach of regulations can result in the issue of prohibition notices, improvement notices or criminal proceedings.

The regulations are designed to ensure that:

- Patients are protected from unintended, excessive or incorrect exposure to medical radiation and that, in each case, the risk from exposure is assessed against the clinical benefit (justification)
- Patients receive no more exposure than necessary to achieve the desired benefit within the limits of current technology (optimisation)
- Practitioners and operators do not undertake any medical exposure without being adequately trained. Employers ensure adequate training is provided and records of this training are maintained.

Our inspection considers the following issues in the context of the regulations:

- Quality of the Patient Experience
- Compliance with IR(ME)R
- Quality of Management and Leadership

2. Methodology

During the inspection we gather information from a number of sources including:

- Information held to date by HIW
- Conversations with patients, relatives and discussions with staff
- Discussions with senior management within the health board

- Examination of a sample of patient records
- Scrutiny of policies and procedures which are required by IR(ME)R
- General observation of the environment of care and care practice
- Responses within completed HIW patient questionnaires.

At the end of each inspection, we provide an overview of our main findings to representatives of the service.

These inspections capture a snapshot of the standards of care patients receive and the extent to which services are meeting the regulations and may point to wider issues about the quality and safety of services provided.

3. Context

Betsi Cadwaladr University Health Board provides primary, community, mental health and acute hospital services for a population of around 678,000 people across the six counties of North Wales (Anglesey, Gwynedd, Conwy, Denbighshire, Flintshire, and Wrexham).

The health board has three main hospitals (Ysbyty Gwynedd in Bangor, Ysbyty Glan Clwyd in Bodelwyddan and Wrexham Maelor Hospital) along with a network of community hospitals, health centres, clinics, mental health units and community team bases. The health board also coordinates the work of 114 GP practices and NHS services provided by dentists, opticians and pharmacists in North Wales.

The health board provides a radiotherapy service in the North Wales Cancer Treatment centre at Glan Clwyd Hospital. The Centre opened in June 2000.

Activity

The radiotherapy department treats approximately 1800 new patients per year and the number of treatments in a radiotherapy course can vary from 1 up to 37. Most patients attend daily for treatment.

Equipment

The radiotherapy department has capability to deliver external beam, orthovoltage and superficial treatments, all of which are planned and delivered on site. Computed Tomography (CT), Positron Emission Tomography (PET/CT) and Magnetic Resonance (MR) scanning are available as part of the radiotherapy treatment planning process. A dedicated CT scanner is available onsite and patients can be referred for PET/CT and MRI as required. On treatment imaging is available as 2D planar and cone beam CT (CBCT) imaging. Patients are referred to another site for brachytherapy as required.

Staffing

A total of eight consultant clinical oncologists and four specialist registrars support the radiotherapy department. This is complemented with 39 radiographers and 14 physics staff, of which there are four medical physics experts and four medical technical officers. No substantive long term vacancies were reported.

4. Summary

Patients told us they were happy with the service provided. Positive comments were made regarding the approach and attitude of the staff team. We saw that the environment was clean and tidy and this was confirmed by patients. Information on radiotherapy treatments was readily available to patients.

We found that the health board had identified an employer under IR(ME)R. This was a senior person within the health board who had ultimate responsibility for ensuring IR(ME)R was implemented within the radiotherapy service.

The employer had comprehensive written procedures and protocols in place as required by IR(ME)R with the aim of delivering a safe and effective radiotherapy service to patients. Some of these would benefit from being revised to avoid unnecessary duplication and promote further clarity.

We saw clear evidence of duty holders' scope of entitlement. Training records had been maintained and were available for inspection. Consideration should be given to the development of a service level agreement in respect of brachytherapy to clearly define responsibilities under IR(ME)R.

Up to date lists were available of named individuals setting out their scope of entitlement to act as referrers, practitioners or operators.

Arrangements were in place to ensure medical exposure doses were kept as low as reasonably practicable. We have, however recommended that improvement is made in this regard in relation to CBCT exposures.

An up to date schedule for clinical audit was available. Examples of clinical audits carried out and their findings were demonstrated.

Medical physics experts were involved in medical exposures. Their role, however, could be better defined within supporting documentation.

An up to date inventory of radiological equipment used at the radiotherapy service was available.

We found effective leadership and management being provided by senior staff. Clear lines of reporting and accountability under IR(ME)R were described and demonstrated.

5. Findings

Quality of the Patient Experience

Patients told us they were happy with the service provided. Positive comments were made regarding the approach and attitude of the staff team. We saw that the environment was clean and tidy and this was confirmed by patients. Information on radiotherapy treatments was readily available to patients.

Prior to the inspection, we asked the radiotherapy service to distribute HIW questionnaires to patients to obtain their views on the service provided. We also sought their views by speaking to a number of patients attending the service during our inspection. In total, 28 questionnaires were completed and returned.

All patients/carers who provided comments told us they were happy with the service they had received and praised the approach and attitude of the staff team. Comments included,

> *'Staff very helpful. Good care. Any queries sorted during appointments.'*
>
> *'Relaxed atmosphere. Staff lovely.'*
>
> *'Treatment has been perfect.'*
>
> *'Everybody so helpful and friendly.'*
>
> *'The hospital is clean. The staff are polite and helpful.'*

We saw patients being treated with respect and kindness by the staff team and this was reflected in the comments from patients we received. During our discussions with the radiotherapy services manager, it was clear that the team placed a strong emphasis on promoting patients' privacy and dignity. We saw that a number of sub waiting areas were available with privacy screens where patients could wait, prior to and following their treatments, if they felt unwell. Changing cubicles were also available, which offered patients privacy when needing to change in to/out of dignity (hospital) gowns.

During a tour of the radiotherapy service, we saw that all areas were clean and tidy. Patients who provided comments also told us that they were satisfied with the cleanliness.

Information leaflets were readily available within the waiting areas and we were told by staff that these were also available to patients and their carers on the

health board’s website. Patients who provided comments told us they felt they had been provided with enough information about their treatments.

Senior radiotherapy staff explained that they worked closely with other members of the multi-disciplinary team, for example, dieticians, speech and language therapists, physiotherapists and counsellors. This meant that patients were supported along their care pathway by staff who could provide specialist help and advice as appropriate according to their care needs. Members of the multi-disciplinary team held clinics within the department with a view to making these more convenient for patients to attend.

Overall, patients told us that they had not experienced any delays when attending for their treatments. Those patients who did report delays described different reasons, including delays with pharmacy and transport. Whilst these are not under the direct control of the radiotherapy service, the management team may wish to explore this further to determine what improvements could be made in this regard.

Compliance with IR(ME)R

We found that the health board had identified an employer under IR(ME)R. This was a senior person within the health board who had ultimate responsibility for ensuring IR(ME)R was implemented within the radiotherapy service.

The employer had comprehensive written procedures and protocols in place as required by IR(ME)R with the aim of delivering a safe and effective radiotherapy service to patients. Some of these would benefit from being revised to avoid unnecessary duplication and promote further clarity.

We saw clear evidence of duty holders' scope of entitlement. Training records had been maintained and were available for inspection. Consideration should be given to the development of a service level agreement in respect of brachytherapy to clearly define responsibilities under IR(ME)R.

Up to date lists were available of named individuals setting out their scope of entitlement to act as referrers, practitioners or operators.

Arrangements were in place to ensure medical exposure doses are kept as low as reasonably practicable. We have, however recommended that improvement is made in this regard in relation to CBCT exposures.

An up to date schedule for clinical audit was available. Examples of clinical audits carried out and their findings were demonstrated.

Medical physics experts were involved in medical exposures. Their role, however, could be better defined within supporting documentation.

An up to date inventory of radiological equipment used at the radiotherapy service was available.

<u>Duties of Employer</u>

The employer is defined in Regulation 2(1) as any natural or legal person, who, in the course of a trade, business or other undertaking, carries out (other than as an employee), or engages others to carry out, medical exposures or practical aspects, at a given radiological installation.

The Chief Executive of the health board was designated as the employer. This is in keeping with the national guidance[1] on implementing IR(ME)R legislation as it applies to radiotherapy.

The health board's *Ionising Radiation Protection Policy* document identified the Chief Executive as the employer under IR(ME)R. This written policy clearly set out that the Chief Executive was responsible for the safe delivery of ionising radiation used within the health board's premises.

Senior staff described and demonstrated clear lines of reporting and accountability between the radiotherapy service and the health board. We saw that comprehensive written procedures and protocols had been developed and implemented in accordance with IR(ME)R legislation. We also saw that the employer had arrangements in place for quality assurance activity, ensuring practitioners and operators were adequately trained and for investigating and reporting incidents. These are all duties of the employer as required by IR(ME)R.

Procedures and Protocols

Regulation 4(1) and 4(2) requires the employer to have written procedures and protocols in place.

Prior to our inspection visit the health board submitted copies of relevant written policies, procedures and protocols. These were comprehensive and included those employer's procedures required under IR(ME)R. Senior staff described the process for reviewing written procedures and protocols and the system for informing staff of any changes made. Departmental staff we spoke to also confirmed they were made aware of changes by the system described.

We did identify some written procedures and protocols that would benefit from being revised to avoid unnecessary duplication and promote further clarity. These related to:

- revising some of the terminology used to ensure that terms used are consistent with those used within IR(ME)R

[1] A Guide to Understanding the Implications of Ionising Radiation (Medical Exposure) Regulations in Radiotherapy - https://www.rcr.ac.uk/sites/default/files/publication/BFCO083_IRMER.pdf

- the employer's *Medical Exposures Manual for Radiotherapy*, which referred readers to other written procedures used within the radiotherapy service. We saw some duplication between this and the other written procedures referred to

- headings within the manual that referred to procedures required by IR(ME)R but that did not apply to the radiotherapy service. We saw 'N/A' used for *not applicable* rather than a clear statement to reflect that those types of exposures were not performed in the radiotherapy department

- describing clearly how medical physics experts (MPE) are involved in planning, techniques for optimising medical exposures and quality assurance activities

- some minor inconsistences between the information within the manual and that within the other procedures.

We highlighted the above to senior staff who agreed to give thought to how the written policies, procedures and protocols could be improved and take action as appropriate.

Improvement needed

Consideration should be given to streamline IR(ME)R procedures at time of review to reduce duplication of information and offer further clarification.

Incident notifications

Regulation 4(5) states that where an incident has occurred in which a person, whilst undergoing a medical exposure, has been exposed to ionising radiation much greater than intended, this should be investigated by the healthcare organisation and reported to the appropriate authority.

The employer's *Reporting of Radiation Incidents* and *Non-Conformance and Corrective Action* documents, set out the procedures for recording, reporting and investigating incidents. Senior staff were aware of and were able to describe these. We were told incidents were reported via the health board's electronic incident reporting system. Relevant radiation incidents had also been

reported to HIW in accordance with the incident reporting process[2] for NHS Wales services.

We saw examples of the analysis of incidents. Senior staff described that learning from incidents was shared within the department, other hospitals within the health board and other radiotherapy departments in Wales and across the UK. Senior staff also demonstrated a willingness to seek advice from other radiotherapy centres across Wales. This was with a view to making improvements to patient safety within the health board and the wider radiotherapy community.

Diagnostic reference levels

Regulation 4(3)(c) requires the employer to establish diagnostic reference levels (DRL) for radio diagnostic examinations. These are not expected to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied.

Establishing diagnostic reference levels is not relevant to radiotherapy treatments.

Entitlement

Regulation 2(1) requires that duty holders must be entitled, in accordance with the employer's procedures for the tasks they undertake. Regulations 11(1) and 11(4) states that practitioners and operators must also be adequately trained and the employer must keep up to date training records of this training.

IR(ME)R defines four duty holders, namely the employer, referrer, practitioner and operator.

The employer's *Identification of Referrers/Practitioners and Operators for Radiotherapy Treatment* document defined who may act as referrers, practitioners or operators. Up to date lists were available of named individuals setting out their scope of entitlement to act as referrers, practitioners or operators

[2] Putting Things Right: Guidance on dealing with concerns about the NHS from 1 April 2011 http://www.wales.nhs.uk/sites3/docopen.cfm?orgid=932&id=170588

We saw a sample of training records for practitioners and operators. In the main these were comprehensive and demonstrated the dates on which these staff groups had attended training and when they had been deemed competent. Opportunities for the improvement of training records for clinical oncologists entitled as operators were discussed during the visit.

It was noted that one individual was entitled as a duty holder in the delivery of brachytherapy at another centre. This arrangement was agreed as part of a working agreement with the remote centre and the individual was clear about their responsibilities across both radiotherapy departments. Consideration should be given to the development of a service level agreement to strengthen this relationship and clearly define responsibilities under IR(ME)R.

Improvement needed

Training records for clinical oncologists entitled as operators should be improved.

Consideration should be given to the development of a formal service level agreement to outline arrangements and IR(ME)R responsibilities for patients referred on for brachytherapy

Referral Criteria

Regulation 4(3)(a) states that the employer shall establish recommendations concerning referral criteria for medical exposures, including radiation doses and shall ensure that these are available to the referrer.

Decisions to refer each individual patient for radiotherapy were made as part of a multidisciplinary team meeting. This practice is to be commended. However, written referral criteria should be improved.

As part of this there is a requirement that an estimate of the associated doses is made available to the referrers. This includes the doses associated with CBCT imaging. Estimates of doses associated with treatment were included in clinical protocols and CT planning dose estimates were included in imaging protocol and procedures. This should be better reflected in the IR(ME)R documentation.

Improvement needed

Improve written referral criteria for radiotherapy.

Establish dose estimates for radiotherapy CBCT imaging.

Justification of Individual Medical Exposures

Regulations 6(1)(a) and 6(1)(b) require that all medical exposures should be justified and authorised prior to the exposure. The practitioner is responsible for the justification of the medical exposure. Authorisation is the means by which it can be demonstrated that justification has been carried out and may be undertaken by the practitioner or, where justification guidelines are used, an operator.

The employer's *Identification of Referrers/Practitioners and Operators for Radiotherapy Treatment* and *Verification Imaging* documents set out the arrangements for justification and authorisation of medical exposures. It was clear that clinical oncologists acting as practitioners were responsible for the justification and authorisation of medical exposures and that they had to be entitled and deemed competent to do so.

We saw examples of completed *Referral for Radiotherapy* forms. These had been signed by referrers and practitioners to show operators that medical exposures had been authorised and justified by appropriately entitled healthcare professionals. Staff we spoke to were aware of the need for referral forms to be signed prior to carrying out medical exposures on patients.

There were occasions where referrers and practitioners were the same person. Whilst referral forms had been signed, only one signature was present. We recommended that the forms be completed as intended, with two signatures to clearly show that the person signing the form was acting as both the entitled referrer and practitioner. Senior staff agreed to remind staff to do this.

Identification

Schedule 1(a) states that written procedures for medical exposures should include procedures to correctly identify the individual to be exposed to ionising radiation.

The employer's procedure, *Patient Identification*, set out that an active three point check was to be used by operators, practitioners, receptionists and nurses to identify patients prior to performing treatment related procedures. The written procedure clearly stated that it was the shared responsibility of both operators involved in the patient set-up and exposure initiation to check a patient's identification prior to any exposure to ionising radiation.

The procedure also described the procedure to follow for patients unable to confirm their identity.

Staff we spoke to were aware of the correct procedure to follow.

Females of child bearing age

Schedule 1 (d) states that written procedures for medical exposures should include procedures for making enquiries of females of child bearing age to establish whether the individual is or maybe pregnant.

The employer's *Pregnancy Procedure* document described the procedure to be followed by referrers, practitioners and operators to identify potentially pregnant women prior to medical exposures. This provided detailed instructions for staff to follow depending on the outcome of enquiries. It also referred to the need for referrers to advise women of child bearing age not to become pregnant immediately prior to, or during a course of radiotherapy due to associated risks.

We saw information for female patients was displayed, advising them to inform operators if they are or may be pregnant.

Staff we spoke to were aware of the correct procedure to follow.

Optimisation

Regulation 7(1) requires that doses for all diagnostic medical exposures are kept as low as reasonably practicable (ALARP) consistent with the intended purpose.

The employer's *Medical Exposures Manual for Radiotherapy* document set out the overall arrangements for ensuring that medical exposure to critical body organs and surrounding tissues is kept as low as reasonably practicable (often referred to as ALARP). Additional written procedures and checklists were available to assist operators and practitioners to ensure exposures were ALARP.

Whilst written procedures and checklists had been implemented, opportunities to optimise CBCT exposures were not demonstrated during the inspection. This is an area that should be improved.

Improvement needed

The employer must make suitable arrangements to demonstrate that where CBCT is used, opportunities have been taken to optimise exposures.

Paediatrics

Regulation 7 (7) (b) states that the practitioner and operator shall pay special attention to medical exposures of children.

The radiotherapy service did not provide treatments for children.

Clinical evaluation

Regulation 7(8) states that the employer shall ensure a clinical evaluation of the outcome of each medical exposure is recorded in accordance with the employer's procedures.

The employer's *Follow-up and Clinical Evaluation* document set out the arrangements for the clinical evaluation of radiotherapy treatment and associated medical exposures. This clearly described that operators were responsible for evaluating CT planning scans to ensure their image quality was satisfactory.

The document also set out the arrangements for the follow up of patients following a course of radiotherapy treatment.

The arrangements for clinical evaluation could be better reflected within the employer's *Medical Exposures Manual for Radiotherapy* document.

Clinical audits

Regulation 8 states that employer's procedures shall include provision for carrying out clinical audits as appropriate.

Senior staff described the arrangements for clinical audit. We were told that a multi-disciplinary audit committee meet regularly to monitor progress of existing audits and prioritise new ones. We saw two examples of audits carried out within the radiotherapy service in the last year. Senior staff were able to describe how these had influenced local practice.

The radiotherapy service also had a schedule of ISO certified audit activity as part of its quality management system. This included an internal audit of IR(ME)R compliance. Arrangements were in place to address areas of improvement identified.

Expert advice

Regulation 9(1) and 9(2) states that the employer shall ensure a Medical Physics Expert (MPE) is available in standardised therapeutic nuclear medicine practices, in diagnostic nuclear medicine practices and involved as appropriate in every other radiological medical exposure.

A list of MPEs was available and reference was made to this within the employer's *Medical Exposures Manual for Radiotherapy* document. The

document should, however, better define the role of MPEs within the radiotherapy service.

Whilst their role could be better defined in the above document, discussions with senior staff demonstrated that MPEs were involved as appropriate in medical exposures.

Improvement needed

The role of the MPE should be better reflected in the supporting documentation.

Equipment

Regulation 10 requires that the employer has an up to date inventory of equipment that contains the name of manufacturer, model number, serial number, year of manufacture and the year of installation.

The employer had an up to date inventory of radiological equipment. This met the requirements of IR(ME)R. For completeness, the employer should give consideration to including all ancillary equipment which can influence the medical exposure, for example, quality assurance equipment/software packages. This data, however, was seen to be included on the asset register.

Quality of Management and Leadership

We found effective leadership and management being provided by senior staff. Clear lines of reporting and accountability under IR(ME)R were described and demonstrated.

A radiotherapy service manager was responsible for the day to day management of the service supported by a multidisciplinary team of health care professionals and support staff. Close and effective working relationships were demonstrated between clinical staff, scientists and technical engineering staff working within the radiotherapy service.

Clear lines of accountability and reporting in respect of IR(ME)R were described and demonstrated.

During our inspection, we met with a number of staff working within the radiotherapy service. We found the staff team to be friendly, yet professional and it was clear that they were committed to providing a safe and high quality service to patients.

During our feedback meeting at the end of the inspection, senior health board managers and radiotherapy staff were receptive to our comments. They clearly demonstrated a commitment to learn from the inspection and to make improvements as appropriate.

6. Next Steps

The health board is required to complete an improvement plan (Appendix A) to address the key findings from the inspection and submit their improvement plan to HIW within two weeks of the publication of this report.

The health board improvement plan should clearly state when and how the findings identified within the North Wales Cancer Treatment Centre at Glan Clwyd Hospital will be addressed, including timescales. The health board should ensure that the findings from this inspection are not systemic across other departments/ units of the health board.

The health board's improvement plan, once agreed, will be published on HIW's website and will be evaluated as part of the ongoing IR(ME)R inspection process.

Appendix A

IR(ME)R: Improvement Plan

Hospital: Glan Clwyd Hospital

Department: North Wales Cancer Treatment Centre

Date of Inspection: 24 and 25 August 2016

Page	Improvement needed	Service Action	Responsible Officer	Timescale
	Quality of the Patient Experience			
-	No improvement plan required.			
	Compliance with IR(ME)R			
10	Consideration should be given to streamline IR(ME)R procedures at time of review to reduce duplication of information and offer further clarification.	Review and amendment of relevant documentation.	Head of Quality Assurance in Radiotherapy/ Head of Radiotherapy Services	March 2017
12	Training records for clinical oncologists entitled as operators	In future, training relating to operator tasks following software and equipment upgrades will extended to include Oncologists	Clinical Director/Head of	Ongoing

Page	Improvement needed	Service Action	Responsible Officer	Timescale
	should be improved.	and will be documented and held electronically within the radiotherapy department.	Radiotherapy Physics/ Head of Radiotherapy Services	
12	Consideration should be given to the development of a formal service level agreement to outline arrangements and IR(ME)R responsibilities for patients referred on for brachytherapy	Develop a service level agreement with Clatterbridge Centre for Oncology for patients referred for brachytherapy	Head of Quality Assurance in Radiotherapy/ Head of Radiotherapy Services/ Cancer General Manager	December 2016
13	Improve written referral criteria for radiotherapy. Establish dose estimates for radiotherapy CBCT imaging.	Include referral criteria in clinical protocols as and when reviewed The service will ensure dose estimates for CBCT measured at equipment/technique commissioning to be readily available at clinical risk- benefit decision making	Head of Quality Assurance in Radiotherapy/ Head of Radiotherapy Services Head of Radiotherapy Physics	As reviewed - June 2017 Jan 2017
14	The employer must make suitable arrangements to demonstrate that where CBCT is used, opportunities	For the optimisation of CBCT exposures currently no UK guidelines exist. The service will closely monitor this position and in the mean time benchmark its practice against	Head of Radiotherapy Physics	Jan2017 then ongoing

Page	Improvement needed	Service Action	Responsible Officer	Timescale
	have been taken to optimise exposures.	evidence in the public domain and act on the recommendations expected from the recently established Working Party by the professional body.		
17	The role of the MPE should be better reflected in the supporting documentation.	At time of documentation review, supporting documentation will be clarified; at the next review specifically the role of the MPE will be better reflected	Head of Radiotherapy Physics	March 2017 then Ongoing
	Management and leadership			
-	No improvement plan required.			

Service Representative:

Name (print): **Carmel Barnett.....**

Title: **Radiotherapy Services Manager.....**

Date: **27th September 2016.....**