

# **Betsi Cadwaladr University Health Board**

**Announced Inspection Compliance  
with Ionising Radiation  
(Medical Exposure) Regulations 2000  
and Amendments 2006  
and 2011 (IR(ME)R)**

**Date of Inspection:  
15 and 16 November 2012**

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## Contents

<b>Chapter</b>	<b>Page Number</b>
1. Introduction	1
2. Executive Summary	3
3. Findings	5
Duties of Employer	5
Duties of Practitioner, Operator and Referrer	8
Justification of Individual Medical Exposures	10
Optimisation	11
Clinical Audits	14
Expert Advice	15
Equipment	15
Training	15
4. Recommendations	16
5. Next Steps	18
<b>Appendix A</b> The Role and Responsibility of Healthcare Inspectorate Wales	19
<b>Appendix B</b> IR(ME)R Context	21
<b>Appendix C</b> Terms of Reference	22
<b>Appendix D</b> Action Plan	24

# 1. Introduction

1.1 A compliance inspection against the Ionising Radiation (Medical Exposure) Regulations 2000 and regulation amendments 2006 and 2011 for diagnostic imaging was undertaken on 15 and 16 November of the Radiology Department at Wrexham Maelor Hospital (WMH), Betsi Cadwaladr University (BCU) Local Health Board. The review was lead by Healthcare Inspectorate Wales (HIW) and supported by the Health Protection Agency (HPA).

## Methodology for Inspection

1.2 The healthcare organisation was selected as part of the annual announced IR(ME)R Inspection Programme. This is the second time an IR(ME)R review has been undertaken by HIW.

1.3 The earlier inspection was to Ysbyty Glan Clwyd in October 2007, when it was part of the former Conwy and Denbighshire NHS Trust. We considered the findings from the earlier review as part of the inspection. WMH radiology staff were also involved in the Powys Diagnostic Imaging IR(ME)R inspection undertaken in January 2010, as Powys was under a service level agreement with BCU, which provided staff and support.

1.4 The organisation was provided with eight weeks notice of the inspection and asked to complete a self-assessment and collate supporting evidence. This completed self-assessment formed the basis of our diagnostic imaging inspection.

1.5 During the site visit, the inspection team discussed the information detailed in the self-assessment with key staff. We reviewed policies, procedures, protocols, patient records (reviewed as a patient journey approach) and staff records. We also undertook observations within the clinical settings and interviewed a cross-section of staff in order to establish whether the information declared in the self-assessment and employer's written procedures was reflected in practice.

1.6 Detailed findings and associated recommendations were provided through verbal feedback throughout the inspection and more formally at the feedback meeting held on the second day of the visit. The key issues emerging from the inspection were also notified to BCU in a management letter, three weeks following the inspection, so that immediate action could be taken to discharge the recommendations.

## **Background to the Department**

1.7 WMH is part of BCU Local Health Board and is located in Wrexham.

1.8 At the time of the inspection, WMH confirmed that the number of examinations performed by the Radiology Department at WMH over the year was on average; 58,800 general radiology, 10,500 Computed Tomography (CT) scans, 3,300 fluoroscopy, 2,000 symptomatic mammography, 1,500 dental and 1,100 interventional radiology procedures. This inspection predominantly focused on general radiology (X-ray) and CT scans carried out in the department.

1.9 Staffing comprised of 8.5 whole time equivalent (WTE) consultant radiologists, 2 specialist registrars, 3 reporting radiographers, 46.86 radiographers, 2 (plain film) assistant practitioners, 6 radiation protection supervisors and 2 (radiology) medical physics experts (MPE).

1.10 WMH also rotate a fixed group of staff to two satellite sites within the BCU LHB; Deeside Community Hospital and Mold Community Hospital.

1.11 During our visit, we met with the Assistant Director of Therapies and Health Science, Head of Quality and Governance Radiology, Consultant Radiologist (Governance Lead), Principal Radiographers and MPEs as well as interviewed a cross section of radiology staff.

## 2. Executive Summary

2.1 As a result of this inspection, HIW can provide assurance that the Radiology Department at WMH and, more generally, the Local Health Board is broadly compliant with IR(ME)R.

2.2 We received evidence from BCU that a framework and suite of procedures were in place and discussions with staff highlighted that there was compliance with the regulations.

2.3 During the inspection we recognised areas of noteworthy practice, in particular these included;

- WMH undertake their own audits for compliance with IR(ME)R, including scheduled audits and a rolling risk-based audit programme.
- A detailed and comprehensive entitlement matrix which was supported by individual certificates of entitlement held in staff training records.

2.4 We noted a number of areas that were in need of development, which WMH has recognised and at the time of our visit had begun working towards progressing, these include;

- Reviewing key policies and procedures to update and strengthen them, including the Medico Legal and Research Procedures.
- Improving reject/ repeat image recording and analysis.

2.5 Some other key areas in need of strengthening, include:

- Processed for formally disseminating messages to staff, such as updates to procedures and protocols or sharing the lessons learnt from incidents with staff to mitigate similar incidents occurring in the future.

- The revision of procedures and protocols to ensure that they are up to date and reflect what take place in practice, this needs to be supported by more frequent review and comprehensive document control.

2.6 We were pleased to note that there was representation from other hospitals within the Health Board at the two-day inspection, to enable them to cascade learning within their own hospital. We would encourage BCU to ensure that the lessons learned from the inspection are shared across the Health Board.

2.7 We would like to thank staff at the Radiology Department at WMH for their cooperation and assistance during our review.

2.8 On publication this report has been made available on the HIW website; [www.hiw.org.uk](http://www.hiw.org.uk)

## 3. Findings

3.1 We have structured our findings from the inspection around the key areas of IR(ME)R and the patient journey. The recommendations arising from our findings are covered in Section 4 of this report.

### Duties of Employer

3.2 IR(ME)R states that the employer is any person that carries out (other than as an employee), or engages others to carry out, medical exposures or practical aspects, at a given radiological installation.

3.3 For BCU, the Chief Executive is the employer and there were appropriate reporting lines in place to evidence the employer's authority. The Health Board's Ionising Radiation Protection Policy stated that the Chief Executive has overall responsibility and the BCU Executive Board has endorsed the policy. The Radiation Protection Committee and Risk Management Sub-Committee are chaired by an Executive Director who reports to the Chief Executive.

### Procedures and Protocols

3.4 The Regulations require the employer to have written procedures and protocols in place.

3.5 The Health Board's Radiation Protection Advisory Committee had established an '*Ionising Radiation Protection Policy*' and a suite of Radiology procedures, relevant for all BCU sites. We found that these were generally well written, comprehensive and covered the appropriate areas of IR(ME)R.

3.6 However, we identified some areas where the policy and procedures could be improved, specifically:



- Discussions identified some procedures that could be strengthened to provide more detail for completeness and clarity;
- A number of the procedures remained in draft form or had exceeded their review date, which were set as three-year periods, such as 'Procedure for Establishing Patient Pregnancy Status. Version control was confusing and it was not always clear when the last revision had taken place, with the 'Referral Criteria – CT Investigations Authorised by Operators under Delegated Procedures' stating the last review was 2007;
- References were made, in the 'Medico-legal Procedures', to out of date terminology and staff who had left their particular post;
- Procedures did not always reflect the noteworthy systems that staff described as taking place in practice such as 'Procedure for Entitlement and Assuring Competency of IR(ME)R 2000/6/11 Referrers, Practitioners and Operators'; and
- The amendments made to the regulations in 2006 and 2011 were not reflected in the procedures.

3.7 The staff we met during the inspection had a good understanding of the procedures and were aware of where they could obtain a copy to read. However, there was no read and sign procedure in place. Instead, changes to procedures were communicated through team meetings, however staff we spoke to were not aware that this was the formal communication route by which to share updates of the procedures.

3.8 The Regulations state that written protocols should be established for every type of standard radiological practice and for each piece of equipment.

3.9 We reviewed a sample of written protocols, which were available both electronically and in each of the examination rooms and staff confirmed they were aware of where to obtain copies.

3.10 Protocols were generally clear and well written. The Nuclear Medicine CT protocols (also used for non-nuclear medicine scans) demonstrated noteworthy practice and should be used as the basis for other protocols across all modalities.

However, we noted the following issues for the diagnostic imaging protocols which needs to be addressed:

- Some protocols were out of date and had exceeded their review date.
- They did not clearly state whether the protocols were adult or paediatric.
- There did not appear to be protocols established for interventional radiography and fluoroscopy.

### **Incident Notifications**

3.11 IR(ME)R states that where an incident has or may have 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 (HIW).

3.12 WMH maintains a record of radiation incidents, including near misses on the incident database (Datix) and in a Radiation Incident Log. Staff are informed of incidents that occur and the lessons to be learnt through patient safety items on the Radiography Bulletin, staff meetings and incidents are a standard item on the agenda of the Quality and Safety Group.

3.13 Each examination room at WMH had a Radiation Incident Reporting Flowchart to inform staff the steps that should be taken should an incident occur. BCU also had detailed procedures in place for incident reporting, however they could be developed further to include:

- Near miss reporting.
- Communicating with staff.
- Action plans.
- Audits.
- Escalation.

3.14 Between the period April 2011 and the time of the inspection, BCU had reported incidents to HIW, and a trend had begun to emerge where patients were

having an X-Ray examination instead of the requested Ultrasound. We discussed this issue with staff at WMH and they explained that a new referral form was being designed to mitigate errors and prevent similar incidents occurring in the future.

## **Diagnostic Reference Levels**

3.15 The Regulations require the employer to establish diagnostic reference levels (DRL) for radiodiagnostic examinations stating that these are not expected to be exceeded for standard procedures, when good and normal practice regarding diagnostic and technical performance is applied.

3.16 WMH had both National and Local DRLs in place for common examinations which were displayed in the examination rooms. DRLs were accompanied by a detailed and comprehensive procedure, which explained the BCU DRL Review Programme, annual reviews for ongoing comparisons against the local demographic baseline data and three yearly reviews against National DRLs.

3.17 The review of DRLs undertaken by WMH have shown in the past that the local levels used tend to be significantly lower than the National average, and an analysis of trends identified one examination room where higher doses were delivered. This resulted in the subsequent closure of the examination room. We commend BCU for the regular DRL reviews and adjustments as appropriate.

## **Duties of Practitioner, Operator and Referrer**

### **Entitlement**

3.18 The Regulations require that duty holders must be entitled, in accordance with the employer's procedures for the tasks they undertake under IR(ME)R.

3.19 WMH had a detailed and comprehensive Entitlement Matrix which stated the individual duty holders and their entitlement for the tasks they undertake. Duty holders are issued with a certificate of entitlement for their own records and sign the matrix to agree their competence and understanding of their entitlement. Staff

explained that they had plans to develop an entitlement database which could be used across the health board.

3.20 We reviewed a sample of examination records, held discussions with staff and reconciled their entitlement to the matrix and found it to be up to date, accurate and reflective of the tasks that staff were undertaking in practice.

3.21 However, it was noted that non-radiology department duty holders were not formally entitled to undertake clinical evaluations on the Entitlement Matrix, despite these taking place in practice. Furthermore, our review of the Entitlement procedure identified that not all the procedures undertaken in practice are appropriately documented; for example details of who awards the entitlement were not included.

## Referral

3.22 IR(ME)R states that a referrer is a healthcare professional who is entitled in accordance with the employer's procedures to refer individuals to a practitioner for medical exposures.

3.23 HIW recognised noteworthy practice as WMH maintained a database that records all non-medical referrers, including their scope of practice, signature and when they became entitled. Non-medical staff complete a half-day training course within the department to develop and test their competence before they are awarded entitlement.

3.24 All staff had access to the database so they could check referrers entitlement. If the referrer is not on the database, staff clarify their position with the referrer and escalate within WMH to confirm entitlement before proceeding with the examination.

3.25 We noted that BCU referral forms captured the appropriate information, in respect of patients, examinations and authorisation. However as noted earlier as part of Incident Notifications, a number of incidents have occurred where patients

have undergone the incorrect examination due to radiology staff misinterpreting the information on the referral form.

## **Justification of Individual Medical Exposures**

3.27 The Regulations require that all medical exposures are 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 is demonstrated that appropriate justification has been made and may be undertaken by: either the practitioner or, where justification guidelines have been used, an operator.

3.28 At WMH examinations are justified and authorised by practitioners and, for some CT examinations, authorised by operators through justification guidelines written by a practitioner.

3.29 Our review of the '*Referral Criteria – CT Investigations Authorised by Operators Under Delegated Procedures*' highlighted that they were out of date, as they should have been reviewed in 2010 but weren't; furthermore a different scanner has been installed since these guidelines were written. The procedures should also clarify who the practitioner is, i.e. who is responsible for any medical exposure authorised using justification guidelines. However, discussions indicated that a very limited number of examinations were authorised using the guidelines and therefore the document, did not reflect the practice in place at the time of our visit.

## **Identification**

3.30 The Regulations state that written procedures for medical exposures should include procedures to correctly identify the individual to be exposed to ionising radiation.

3.31 A review of the Patient Identification procedures found them to be comprehensive and detailed, especially in relation to those situations where it may be more difficult to obtain confirmation of correct patient identity. Discussions with

staff confirmed that they understood the identification procedure and followed them in practice.

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

3.32 IR(ME)R 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.

3.33 BCU have a detailed procedure for establishing patient pregnancy status prior to radiological examinations. Our review of the procedure found a few areas of noteworthy practice, that were outside of IR(ME)R, such as reference to the Child Protection Service should an under 16 year old inform Radiology that they are pregnant. However, we also noted that the procedures required updating in terms of the advice they provided to staff when speaking with an under 16 year old, to ensure that staff were suitably sensitive and provided the correct factual information in relation to ionising radiation.

3.34 Discussions with staff, during the inspection, found that they had a good understanding of the need to check for pregnancy prior to relevant examinations. Referral forms and the Radiology Information System (RadIS) were updated to reflect the outcome of pregnancy enquiries, and compliance with this procedure was evidenced in the sample of examinations that we reviewed.

3.35 Theatre pre-operative checklists included a pregnancy check by the nursing staff prior to the patient leaving the ward. If the patient is pregnant, a radiologist or radiographer is contacted to assess whether the procedure should go ahead.

### **Optimisation**

3.36 The Regulations state that the operator and practitioner should ensure that the dose arising from the exposure is kept as low as reasonably practicable and is consistent with the intended purpose.

3.37 Discussions with staff highlighted that WMH has a number of practical controls in place to support optimisation during the examination, these include:

- Periodic checks of equipment by Medical Physics Experts (MPE).
- Image intensifiers close to patients.
- National and local DRLs.
- Audit reviews.
- Patient lead protection.
- Adapting exposure factors from manufacturer settings (to adapt for local needs and optimisation).

3.38 At the time of the inspection, WMH were not undertaking formal reject analysis, to assess trends in deleted images, as it was not a function easily supported by their database system. However, students had undertaken reject analysis projects as part of their learning and development. Staff are also encouraged to note on RadIS the number of images taken.

3.39 BCU has recently purchased a new database system which has a reject analysis function. BCU are now planning to undertake a more formal approach to reject analysis of images.

## Paediatrics

3.40 IR(ME)R states that the practitioner and operator shall pay special attention to the optimisation of medical exposures of children.

3.41 DRLs were not established for paediatrics, although the equipment at WMH had pre-programmed paediatric settings, which resulted in lower doses than adult settings. The department had a specialist paediatric radiologist write the technique file for paediatrics.

3.42 Paediatric protocols were in place, however these were not clearly titled and could be confused with the adult protocols.

## **Medico Legal Procedures**

3.43 The Regulations state that a medico-legal examination is performed for insurance or legal intentions without a medical indication. The practitioner and operator are required to pay special attention to the justification and optimisation of these exposures.

3.44 WMH undertake medico-legal procedures and have a procedure in place. However this was drafted in 2002 and appeared not to have been updated since 2003, references were made to out of date terminology and staff who had left particular posts. Furthermore, the procedure did not contain sufficient detail regarding the identification of a medico-legal exposure or the justification process.

3.45 WMH were aware that this procedure required attention and were in the process of revising the procedure at the time of our visit.

## **Medical Research Programmes**

3.46 IR(ME)R states that for each medical or biomedical research programme, individuals must participate voluntarily, and be informed in advance of the risks of exposure, dose constraint must be set down in the employer's procedures, for individuals where no benefit is expected, or target levels of doses are planned by the practitioner, where patients are expected to receive a benefit.

3.47 WMH undertake medical research programmes and have a policy in place, which was recently reviewed. However, BCU are still in the process of developing the accompanying procedure which will comply with the requirements of IR(ME)R.

## **Clinical Evaluation**

3.48 The Regulations state that the employer shall ensure a clinical evaluation of the outcome of each medical exposure is recorded in accordance with written procedures.



3.49 WMH recorded and monitored the turnaround time for clinical evaluation and summarised the results in regular performance reports, using Welsh Government set standards. BCU explained that they had improved on their performance targets since the introduction of the new Picture Archiving and Communication System (PACS) in the autumn.

3.50 At the time of our visit, BCU adopted a system that requires clinical evaluation duty holders to dictate the evaluation, which secretaries typed up onto PACS. The radiologist who undertook the clinical evaluation would then confirm the evaluation before it was relayed to the referrer.

3.51 As highlighted under Entitlement, non-radiography staff were not formally entitled to undertake clinical evaluation, despite undertaking this task in practice.

## Clinical Audits

3.52 IR(ME)R states that employer's procedures shall include provision for carrying out clinical audits as appropriate.

3.53 WMH undertakes a number of its own clinical audits. The Quality and Safety group determine the audits to be undertaken and disseminate the lessons learned. BCU explained that they are currently introducing a rolling programme of audits across the Health Board.

3.54 WMH undertook an annual IR(ME)R audit, to check compliance with the regulations. This review identified recommendations for action, which were allocated to staff within the Radiology Department. The hospital also undertakes four other regular audits of employer's procedures, these are:

- Procedures to Identify Individuals to be Exposed to Ionising Radiation;
- Procedures to check pregnancy status.
- The recording justification of exposure to ionising radiation; and
- The recording of patient doses.

## Expert Advice

3.55 IR(ME)R states that the employer shall ensure a MPE is involved as appropriate in every radiological medical exposure.

3.56 WMH directly employs MPEs who provide consultation on optimisation, including patient dosimetry and quality assurance, as well as advice on matters relating to radiation protection concerning medical exposure.

## Equipment

3.57 The Regulations state that the employer shall keep an up to date inventory of equipment for each radiological installation.

3.58 WMH maintain an up to date inventory of all radiology equipment at the hospital which is organised by each examination room; this included the details of manufacturer, model, serial number, year of manufacture and year of installation.

## Training

3.59 The Regulations require that all practitioners and operators are adequately trained for the tasks they undertake and the employer keeps up to date records of this training.

3.60 We reviewed a sample of staff training records, for staff within various roles, spanning different grades and who had joined the department at different times. We found that their records were complete, comprehensive and authorised by Management.

3.61 Training records contained information regarding induction training, equipment and examination room training and were signed by the member of staff, competence assessor and the department training lead. Training records also included a certificate of entitlement, which corresponded to the entitlement matrix.

## 4. Recommendations

4.1 The recommendations set out below address any non-compliance with the Ionising Radiation (Medical Exposure) Regulations 2000 and amendments 2006 and 2011 that we identified as a result of the inspection;

IR(ME)R Regulation	Finding (Paragraph Reference)	Recommendation
IR(ME)R 4 (1), 4 (2) Duties of Employer  Schedule 1	3.6	<p><b>Procedures and Protocols</b></p> <p>We recommend that Betsi Cadwaladr introduce more frequent version control dates to update their policy and procedures, to ensure procedures are complete, comprehensive and reflect what takes place in practice and is required by the regulations.</p> <p>The areas of improvement for the protocols included;</p> <ul style="list-style-type: none"> <li>• Review protocols, as some were out of date/ not used and had exceeded their review date.</li> <li>• Clearly state whether protocols are adult or paediatric, and</li> <li>• Establish and share protocols for interventional radiography and fluoroscopy, as there did not appear to be any in place.</li> </ul>
IR(ME)R 5 (1) – Duties of Practitioner, Operator and Referrer  IR(ME)R 4 (1)(a) – Duties of the Employer	3.7	<p><b>Communication Channels</b></p> <p>Any amendments made to the policy, procedures or protocols and the lessons learnt from EMGTI should be clearly and effectively highlighted to staff through a clear communication channel, such as team meetings, read and sign, posters in order that staff are appropriately updated.</p> <p>Methods of communication should be clearly understood by staff, and documented as part of the policy and procedures.</p>
Schedule 1(b)	3.21	<p><b>Entitlement</b></p> <p>We recommend that BCU ensure that all staff outside of the Radiology Department are formally entitled to undertake clinical evaluation of images where appropriate.</p>

IR(ME)R Regulation	Finding (Paragraph Reference)	Recommendation
		Furthermore they could strengthen their procedures by introducing an audit of non radiology clinical evaluation.
IR(ME)R 4 (5) IR(ME)R 5(5)	3.14	<p><b>Referral Form</b></p> <p>BCU to introduce revised referral form which clearly identifies the modality required as identified by the BCU Quality and Safety Group .</p>
IR(ME)R 6 justification of individual medical exposure	3.29	<p><b>Justification Guidelines</b></p> <p>We recommend that the BCU '<i>Referral Criteria – CT Investigations Authorised by Operators Under Delegated Procedures</i>' are reviewed and amended to reflect what takes place in practice.</p> <p>They should also clarify the practitioner of the procedure.</p>
IR(ME)R 7 Optimisation IR(ME)R 4(3)(c)	3.41-3.42	<p><b>Paediatrics</b></p> <p>We recommend that BCU introduce DRLs and protocols for paediatric patients.</p>
IR(ME)R 7 Optimisation  IR(ME)R 8 Clinical Audit  Schedule 1(c), (e), (h),	3.38 3.44-3.45 3.47	<p><b>Quality Assurance Programmes</b></p> <p>There were a number of IR(ME)R areas where BCU were aware that their systems required updating and improving, where they had begun to make progress. This included;</p> <ul style="list-style-type: none"> <li>• Research Procedure,</li> <li>• Medico Legal, and</li> <li>• Reject Analysis</li> </ul> <p>We reviewed the current drafts of the procedures and some of the work that had already taken place, providing advice where applicable.</p> <p>We recommend that BCU continue to undertake the work that is already underway to ensure that the above systems are updated and implemented into their IR(ME)R working practices.</p>

## 5. Next Steps

5.1 The Health Board has accepted all of the findings detailed in the report and developed an action plan to address the issues raised (attached to this report at Appendix D).

5.2 HIW has reviewed the action plan and is satisfied that the concerns raised by the inspection will be appropriately addressed. The Health Board has confirmed that all actions will be completed by September 2013, within 10 months of the inspection.

5.3 HIW will monitor the progress of BCU Health Board implementing the actions agreed and review policies and procedures where applicable. Based on the level of assurance we receive, BCU may be included as part of an IR(ME)R follow up review in the future.

# The Role and Responsibility of Healthcare Inspectorate Wales

Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of all healthcare in Wales. HIW's primary focus is on:

- Making a significant contribution to improving the safety and quality of healthcare services in Wales.
- Improving citizens' experience of healthcare in Wales whether as a patient, service user, carer, relative or employee.
- Strengthening the voice of patients and the public in the way health services are reviewed.
- Ensuring that timely, useful, accessible and relevant information about the safety and quality of healthcare in Wales is made available to all.

HIW's core role is to review and inspect NHS and independent healthcare organisations in Wales to provide independent assurance for patients, the public, the Welsh Government and healthcare providers that services are safe and good quality. Services are reviewed against a range of published standards, policies, guidance and regulations. As part of this work HIW will seek to identify and support improvements in services and the actions required to achieve this. If necessary, HIW will undertake special reviews and investigations where there appears to be systematic failures in delivering healthcare services to ensure that rapid improvement and learning takes place. We also protect the interests of people whose rights are restricted under the Mental Health Act. In addition, HIW is the regulator of independent healthcare providers in Wales and is the Local Supervising Authority for the statutory supervision of midwives.

HIW carries out its functions on behalf of Welsh Ministers and, although part of the Welsh Government, protocols have been established to safeguard its operational

autonomy. HIW's main functions and responsibilities are drawn from the following legislation:

- Health and Social Care (Community Health and Standards) Act 2003
- Care Standards Act 2000 and associated regulations
- Mental Health Act 1983 and the Mental Health Act 2007
- Statutory Supervision of Midwives as set out in Articles 42 and 43 of the Nursing and Midwifery Order 2001
- Ionising Radiation (Medical Exposure) Regulations 2000 (amendments 2006 and 2011).

HIW works closely with other inspectorates and regulators in carrying out cross sector reviews in social care, education and criminal justice and in developing more proportionate and co-ordinated approaches to the review and regulation of healthcare in Wales.

### IR(ME)R Context

The Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) came into force in 2000. The 2000 regulations and amended regulations 2006 and 2011 lay down measures for the health protection of individuals against the dangers of ionising radiation in relation to medical exposure for diagnostic, therapeutic, occupational health, health screening, research or medico-legal purposes.

IR(ME)R places responsibilities on practitioners, operators, those who refer patients for medical exposure and the employers of these three groups. The employer is obliged 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. The employer is also responsible in law for ensuring that these procedures are in place and are complied with.

Healthcare Inspectorate Wales (HIW) are the appropriate authority with associate powers for the inspection and enforcement of IR(ME)R. This role has been transferred to HIW from the Welsh Ministers under the Health and Safety at Work Act.

HIW undertakes a programme of routine inspections to services which undertake activities regulated by IR(ME)R. A breach of the regulations can result in the issue of improvement notices, prohibition notices or criminal proceedings.



### TERMS OF REFERENCE

#### **HEALTHCARE INSPECTORATE WALES ANNOUNCED INSPECTION: COMPLIANCE AGAINST IONISING RADIATION (MEDICAL EXPOSURE) REGULATIONS**

In accordance with the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000 and regulation amendments 2006 and 2011, Healthcare Inspectorate Wales (HIW) will conduct an announced inspection of Wrexham Maelor Hospital in Betsi Cadwaladr Local Health Board.

The inspection will take place on Thursday 15 and Friday 16 November 2012. Nicola Bresner, Inspection Manager will lead on the review, accompanied by Sarah Peters from the Health Protection Agency.

#### **OBJECTIVE**

The objective of the inspection is to provide assurance that Wrexham Maelor Hospital and Betsi Cadwaladr Local Health Board are compliant with IR(ME)R for diagnostic imaging.

#### **SCOPE**

The scope of the inspection will include compliance with IR(ME)R in respect of:

- The Duties of the Employer,
- The Duties of the Referrer, Operator and Practitioner,
- Justification of Individual Medical Exposures,
- Optimisation,
- Clinical Audit,
- Expert Advice,
- Equipment,
- Training, and
- Any other matters which are considered to be under the scope of IR(ME)R.

## **APPROACH**

We will initially ask that Management submit a self-assessment tool 10 working days prior to the inspection. This will enable us to pre-assess the framework of policies and protocols to undertake appropriate tests at inspection.

On inspection we will interview staff and speak with patients where appropriate, review relevant documentation and assess the environment.

We will then form our conclusions on the adequacy of the systems and practices in place and to frame recommendations for improvement, as appropriate.

## **REPORTING**

At the end of the two-day inspection, the team will hold a meeting to provide initial feedback and the opportunity to discuss the issues raised at inspection.

A management letter will be issued to the Local Health Board shortly after the inspection, which outlines the key findings arising from the review. The purpose of this letter is to provide you with the opportunity to address some of these matters in advance of the publication of the report.

A draft report will be issued to the Local Health Board, which will enable you to comment on the overall factual accuracy and points raised. We would expect to receive your formal response to the report and a corresponding action plan, which addresses and implements the recommendations made within the report, within 10 working days.

On publication, we will then place the final report and your action plan in response to the recommendations on the HIW website.

## Action Plan

IR(ME)R Reference	Recommendation	LHB Action	Responsible Officer	Target Date
IR(ME)R 4 (1), 4 (2) Duties of Employer Schedule 1  <b>Para            reference            3.6</b>	<b>Procedures and Protocols</b>  We recommend that Betsi Cadwaladr introduce more frequent version control dates to update their policy and procedures, to ensure procedures are complete, comprehensive and reflect what takes place in practice and is required by the regulations. The areas of improvement for the protocols included; <ul style="list-style-type: none"> <li>• Review protocols, as some were out of date/ not used and had exceeded their review date.</li> <li>• Clearly state whether protocols are adult or paediatric, and</li> <li>• Establish and share protocols for interventional radiography and fluoroscopy, as there did not appear to be any in place</li> </ul>	Radiology Clinical Programme Group will review it's IR(ME)R procedures annually with a programme of rolling review overseen by the radiation governance group  Review and update all IR(ME)R protocols  Separate adult and paediatric protocols  Develop protocols for interventional radiography and Fluoroscopy	Head of Quality & Governance Radiology	Annual  Completed  Completed
IR(ME)R 5 (1) – Duties of Practitioner, Operator and	<b>Communication Channels</b>  Any amendments made to the policy, procedures or protocols and the lessons learnt from EMGTI should be clearly and effectively highlighted to staff through a clear communication channel, such as team meetings,	Strategy for the sharing of information and lessons learnt from incidents be developed for the Radiology CPG to include:-	Head of Quality & Governance Radiology	Rolling review

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Referrer IR(ME)R 4 (1)(a) – Duties of the Employer  <b>Para 3.7</b>	read and sign, posters in order that staff are appropriately updated. Methods of communication should be clearly understood by staff, and	Review and monitoring of lessons learnt at both Divisional and CPG wide levels  Formal structure for up dating staff on changes to procedures and documenting that information  Sharing information via the Radiology CPG Newsletter  Radiology Radiation Governance Group to monitor and audit communication of lessons learnt and changes to procedures is disseminated and acted upon		For ratification May 2013  Completed  Rolling review
Schedule 1(b) <b>Para 3.21</b>	<b>Entitlement</b>  We recommend that BCU ensure that all staff outside of the Radiology Department are formally entitled to undertake clinical evaluation of images where appropriate. Furthermore they could strengthen their procedures by introducing an audit of non-radiology clinical evaluation.	Structures to be implemented across all Clinical Programme Groups to ensure staff undertaking clinical evaluation are formally entitled by BCU. BCU will work with other Health Boards in Wales via the All Wales Imaging Quality forum and the inspector to produce a Wales wide procedure.	Head of Quality & Governance Radiology	September 2013

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		<p>Non Medical referrers who undertake clinical evaluation will have this documented as part of the entitlement for referral. Procedure T&amp;SH01 to be amended to reflect this change as part of the current review ready for ratification at the next overarching radiation protection committee ( approvals for NMR status now include an assessment of the clinical evaluation requirements)</p> <p>Audit tool to be developed for CPG's outside radiology to audit clinical evaluation</p>	<p>Head of Quality &amp; Governance Radiology/ Associate Chief of Staff Radiography</p> <p>Clinical Audit &amp; Effectiveness Manager</p>	
<p>IR(ME)R 4 (5) IR(ME)R 5(5) <b>Para 3.14</b></p>	<p><b>Referral Form</b> BCU to introduce revised referral form which clearly identifies the modality required as identified by the BCU Quality and Safety Group</p>	<p>New request form to be finally approved and implemented across BCU</p>	<p>Associate Chief of Staff Radiography/ Head of Quality &amp; Governance Radiology</p>	<p>September 2013</p>
<p>IR(ME)R 6 justification of individual medical</p>	<p><b>Justification Guidelines</b> We recommend that the BCU '<i>Referral Criteria – CT Investigations Authorised by Operators Under</i></p>	<p>Full review of this procedure to be undertaken across BCU and a single procedure developed.</p>	<p>Principal Radiographer CT</p>	<p>June 2013</p>

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exposure  <b>Para 3.29</b>	<i>Delegated Procedures'</i> are reviewed and amended to reflect what takes place in practice. They should also clarify the practitioner of the procedure.	Review current East Procedure	Service Lead Radiographer CT - East	Completed
IR(ME)R 7 Optimisation IR(ME)R 4(3)(c)  <b>Para 3.41-3.42</b>	<b>Paediatrics</b>  We recommend that BCU introduce DRLs and protocols for paediatric patients.	We regularly review paediatric doses and the low workload does not allow a great deal of meaningful dose evaluation to be carried out.  We have collated and reviewed the annual paediatric workload (2009-2012) to monitor CT head, X-ray Chest, XR Chest and Abdomen and XR Pelvis examinations. We have identified DRLs for XR Chest and we monitor trends for the other examinations.  Paediatric protocols in place and separate from adult protocols	MPE/RPA	Completed
IR(ME)R 7 Optimisation IR(ME)R 8 Clinical Audit Schedule	<b>Quality Assurance Programmes</b>  There were a number of IR(ME)R areas where BCU were aware that their systems required updating and improving, where they had begun to make progress. This included;	Complete the work that is already underway taking on board advice received from the inspecting team	Head of Quality and Governance Radiology	To be ratified 2 May 2013

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1(c), (e), (h),  <b>Para 3.38</b> <b>3.44-</b> <b>3.45</b> <b>3.47</b>	<ul style="list-style-type: none"> <li>• Research Procedure,</li> <li>• Medico Legal, and</li> <li>• Reject Analysis</li> </ul> We reviewed the current drafts of the procedures and some of the work that had already taken place, providing advice where applicable. We recommend that BCU continue to undertake the work that is already underway to ensure that the above systems are updated and implemented into their IR(ME)R working practices.	Research procedure and Medico legal procedure to be ratified by the Radiology CPG  As part of the PACs installation a reject analysis procedure is to be developed for plain film radiology	Research Radiographers  Head of Performance and IT	September 2013