

Cwm Taf Health Board

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

**Date of Inspection:
18 and 19 July 2012**

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Copies of all reports, when published, will be available on our website or by contacting us:

In writing:

**Communications and Facilities Manager
Healthcare Inspectorate Wales
Bevan House
Caerphilly Business Park
Van Road
CAERPHILLY
CF83 3ED**

Or via

Phone: 029 20 928850
Email: hiw@wales.gsi.gov.uk
Fax: 029 20 928877
Website: www.hiw.org.uk

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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 18 and 19 July at the Radiology Department at Prince Charles Hospital, Cwm Taf 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 first time an IR(ME)R review has been undertaken at this Local Health Board by HIW.

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

1.4 During the site visit the inspection team discussed the information detailed in the self-assessment in 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.

1.5 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 Cwm Taf Local Health Board in a management letter, two weeks following the inspection, so that immediate action could be taken to discharge the recommendations.

Background to Department

1.6 Prince Charles Hospital (PCH) is part of the Cwm Taf Local Health Board (LHB) and serves the north region of the LHB.

1.7 At the time of the inspection, the self assessment form stated that the number of examinations performed by the Radiology Department at Prince Charles Hospital over the year was; 80,615 general radiology, 11,033 Computed Tomography (CT) scans, 740 fluoroscopy, 812 symptomatic mammography, 4,328 dental and 15 interventional radiology procedures. This inspection predominantly focused on general radiology (X-ray) and CT scans carried out in the diagnostic imaging department.

1.8 Staffing comprise 4.94 whole time equivalent (WTE) consultant radiologists, seven advance practitioners, 18.8 radiographers, two radiation protection supervisors and three students. The Medical Physics Experts are not directly employed by PCH but contracted through an agreement with Velindre NHS Trust. We were informed by PCH that there has been a high staff vacancy rate in Cwm Taf radiology over the past few months although, recruitment was now underway and posts were due to be filled.

1.9 PCH staff also provide support for two satellite sites within the Cwm Taf LHB; Ysbyty Cwm Cynon, a new hospital that opened this year, and St Tydfil's Community and Mental Health Hospital.

1.10 During our visit we met with the Director of Therapies and Health Science, Radiology Clinical Director, Superintendent Radiographer, two Medical Physics Experts and Superintendent Radiographer from Royal Glamorgan Hospital (in the South Cwm Taf region) as well as interviewed a cross section of radiology staff.

2. Executive Summary

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

2.2 We received some evidence from PCH that a framework and suite of procedures were in place, however these were less than adequate and did not meet all the requirements of IR(ME)R. Some of the key areas in need of strengthening, identified by the inspection, include:

- the entitlement process to ensure that duty holders are appropriately entitled for the tasks they undertake;
- IR(ME)R training of practitioners and operators and documented training records including continuous professional development; and
- improving optimisation through establishing diagnostic reference levels and undertaking dose clinical audits.

2.3 Discussions with staff highlighted that there was a general compliance with IR(ME)R. However until the required IR(ME)R framework is established, there is the potential risk of non compliance, inconsistency of approach and ultimately patients may be exposed to unnecessary radiation.

2.4 However, we did identify areas of noteworthy practice; we were pleased to note that there has been a coordinated approach across the LHB in areas such as clinical audits, standardisation of protocols and a preceptorship programme.

2.5 Furthermore, there was representation from Royal Glamorgan Hospital (south Cwm Taf) at the inspection so that the lessons learned from the inspection could be shared and actioned across the LHB on a timely basis.

2.6 We would like to thank staff at the Radiology Department at Prince Charles Hospital for their cooperation and assistance during our review.

2.7 On publication this report has been made available on the HIW website
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 the 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) medical exposures at a given radiological installation. For Cwm Taf LHB the Chief Executive is the employer.

3.3 The Director of Therapies and Health Science (which includes the Radiology Department) reports directly to the Chief Executive and is also the Chair of the Radiation Safety Group. However, we would recommend that the delegation of duties from the employer is clearly outlined as part of the employer's written procedures to ensure that roles and responsibilities are clarified and undertaken in practice.

Procedures and Protocols

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

3.5 The LHB has established a '*Medical Use of Ionising Radiation*' policy and '*Employer's Policies and Procedures Radiology Directorate*' for all Cwm Taf sites, including PCH. However, these do not directly meet the IR(ME)R requirements to establish written procedures and protocols.

3.6 The policy and procedures were not considered to be fit for purpose as they did not:

- always reflect accurate requirements of the Regulations including the 2006 and 2011 amendments;
- always reflect local practice;
- contain sufficient detail in respect of different scenarios that could occur, when procedures would be most needed;
- satisfy the requirement for document quality assurance, i.e. have version control, appropriate review dates or state the document's author;
- reflect the difference in practice that takes place across Cwm Taf sites;
- include Cwm Taf satellite sites which also use ionising radiation; and
- remain consistent in approach between the policy and procedures.

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

3.8 PCH, in conjunction with Royal Glamorgan, have recently established '*Standard View*' guidelines; these could be considered to be a basis for protocols, although they currently do not contain sufficient detail for standard radiological practices.

Incident Notifications

3.9 IR(ME)R 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 (HIW).

3.10 Cwm Taf maintains a record of all incidents at its Radiology departments, not just those reportable under IR(ME)R, including near misses. These incidents are categorised by site and nature of incident.

3.11 Between the period April 2011 and the time of the inspection, PCH had reported one incident to HIW, which was in August 2011. The incident related to an identification error of an inpatient. At the time of the inspection the investigation report had not been provided to HIW and therefore was not included in the scope of this review.

Diagnostic Reference Levels

3.12 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.

3.13 At the time of inspection, PCH only had DRLs for Computed Tomography (CT). Neither national nor local DRLs had been established for other modalities.

Duties of Practitioner, Operator and Referrer

Entitlement

3.14 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.

3.15 Cwm Taf has an Entitlement Matrix which records the duty holders, who have been entitled to carry out medical exposure functions; however this was not an effective formal mechanism for entitlement.

3.16 We did not consider the matrix to be fit for purpose because:

- it was not clear who awarded the entitlement and whether they had been authorised to do so on behalf of the employer;
- there was no clear procedures to accompany the matrix to clarify the process and to provide guidance for staff;

- entitlement was awarded by modality and did not include specific functions such as patient identification, checking pregnancy status and clinical evaluation;
- it only covered the Radiology Department, other duty holders such as GPs as referrers or ward doctors as operators for clinical evaluation, did not appear to be entitled,
- unrelated modalities were grouped together such as Nuclear Medicine and MRI;
- the use of Korner categories to define scopes of practice is considered to be inappropriate;
- the matrix was not dated and there was no evidence of version control/review; and
- a second entitlement document did not reconcile to the staff outlined by the matrix.

3.17 There was no evidence to demonstrate a formal competence assessment of practitioners and operators prior to entitlement, and thereafter periodic review of duty holder scope of practice. Discussions with staff over the course of the inspection identified that some staff are undertaking tasks for which they are not entitled.

Referrer

3.18 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.

3.19 PCH uses the Radiology Information System (RadIS), which has an integrated list of entitled referrers. If the referrer is not on the list, staff will clarify with the healthcare organisation and escalate within PCH to confirm that the referrer is entitled. PCH has an on call system where staff are able to contact Consultant Radiologists or Superintendent Radiographers when required.

3.20 Cwm Taf has also recently developed its communications with GP referrers. Radiologists at PCH have met with referrers to provide guidance and clarify

procedures; a *'Top Tips for Referrers to Radiology'* guidance note has been designed. We also reviewed template letters, to inform and advise referrers when examinations do not take place due to incomplete or inappropriate referrals.

3.21 Cwm Taf has established well-designed referral forms, which cover the appropriate information in respect patient, examination and authorisation. However, we became aware that referral forms were not completed for radiology procedures in theatre, even for elective surgical cases; instead the theatre schedule was used as evidence of referral.

3.22 Referral procedures have been developed for the LHB which describe the procedure for vetting radiological requests and also include the scope of practice of referrers. However, we found that these procedures do not contain sufficient detail in respect of the different types of referral i.e. theatre, A&E, medico-legal, research etc.

3.23 Under IR(ME)R, the employer is obliged to establish recommendations concerning referral criteria and make these available to referrers. The referral criteria used by Cwm Taf Health Board is the Royal College of Radiologists (RCR) Guidelines *'Making the Best Use of Clinical Radiology'* 6th Edition. Whilst we recognise RCR guidelines to be noteworthy practice, these have now been superseded with iRefer (7th edition). We were informed that negotiations are ongoing at a NHS Wales basis to purchase the revised guidelines.

Justification of Individual Medical Exposures

3.24 The Regulations 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 either the practitioner or, where justification guidelines have been used, an operator.

3.25 The approach to justification adopted by PCH is for all examinations to be justified by a practitioner, and not an operator authorising exposures using guidelines issued by a practitioner, therefore removing the need for justification guidelines. However, this differed to the information provided on the self-assessment form.

3.26 Scheduled medical exposures are allocated to operators through a work log, which is managed by the on-site practitioner on a daily basis; referral forms are also signed by the practitioner to evidence the justification. However, we became aware of early morning examinations taking place before the practitioner arrived for the day, which are therefore not formally justified.

3.27 We reviewed a selection of examinations where the duty holder who undertook the clinical evaluation of the images had questioned the justification. In the three examinations reviewed, we found that the referrer had requested that an area of the body outside the immediate region of interest and this had been imaged unnecessarily.

Identification

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

3.29 A review of the written procedures identified that they didn't include sufficient information relating to those situations where it may be more difficult to obtain confirmation of correct patient identity. These would include scenarios such as patients for whom English/Welsh is not a first language, unconscious patients or those with learning disabilities. It also appears that the current procedures may not apply to areas outside of the Radiology Department such as dentistry, theatre and the wards.

3.30 Discussions with staff confirmed that they understood the identification procedure and were aware of additional processes that were not covered as part of the written procedures, such as the availability of interpreters.

Females of Child Bearing Age

3.31 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.

3.32 A review of the written procedures for '*Checking for Pregnancy in Female Patients*' found them to make reference to out of date guidance, not include different scenarios and at times appeared inappropriate. Discussions with staff also found that there seemed to be variation in practice to the written procedures.

3.33 Discussions with staff, during the inspection, found that they had an appropriate understanding for checking for pregnancy prior to relevant examinations. However, there was ambiguity as to how enquiries should be evidenced and this was not made clear by the written procedures.

Optimisation

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

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

- periodic checks of equipment by MPEs;
- image intensifiers close to patients;
- local DRL for CT;
- patient lead protection; and
- adapting exposure factors from manufacturer guidelines.

3.36 We understand that staff at PCH are currently deleting undiagnostic images. Furthermore, there was an inconsistent approach to recording rejected images on

the request form and it would appear that this was not monitored. As a consequence of not recording all images, there is no reject analysis to monitor and explore trends and patterns as to why exposures may be repeated, which could help mitigate the number of rejects and potential excess radiation to the patient.

Paediatrics

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

3.38 PCH had noteworthy procedures in place for neonatal imaging on the Special Care Baby Unit (SCBU). Special attention had been given to the dose levels and the images were audited on a regular basis.

3.39 However, as there are no DRLs established across PCH, there are also no paediatric specific DRLs for the Radiology Department.

Clinical Evaluation

3.40 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.

3.41 The written procedures only referred to clinical evaluations performed at the Radiology Department and not those undertaken elsewhere.

Clinical Audits

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

3.43 We reviewed evidence of a Cwm Taf Clinical Audit Programme which included audits of barium enema bowel cancer cases, use of CT Pulmonary Angiography (CTPA) for suspected Pulmonary Embolism (PE), imaging of head injuries and radiographic technique for ankle x-rays. There was also accompanying management pathways to support changes to clinical practice following the reviews.

3.44 In recent years, a mammography dose audit has been undertaken by Breast Test Wales and two CT dose audits have been undertaken by MSc students as part of their final year. There have not been any general film dose audits in recent years. Without undertaking dose audits, PCH are unable to establish Local DRLs and to analyse when examinations are consistently exceeding agreed levels.

3.45 We found that factors relevant to patient dose were not recorded in a standardised format e.g. either DAP or kV/ mAs. One referral form used the term '*standard dose*', but it was not clear what the standard dose was. Furthermore, doses were not inputted directly into the database, RadIS, but were instead written on referral forms and scanned onto the database. This approach does not allow PCH to undertake effective audits of dose levels.

Expert Advice

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

3.47 A Service Level Agreement (SLA) Contract has been established for radiation protection advice and support from two Velindre NHS Trust colleagues, which includes the role of MPE. At the time of the inspection, the latest SLA expired in April 2012 and was under consultation.

Equipment

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

3.49 PCH provided an up to date inventory of equipment at the hospital, which included the details of manufacturer, model, serial number, year of manufacture and year of installation.

3.50 However, we noted that the inventory did not include all equipment that could affect the medical exposure such as pressure injectors in CT, but just those which were delivering the ionising radiation.

Training

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

3.52 No training records for staff at PCH, as required under IR(ME)R, were available for inspection. We were able to review the application forms for external associated training courses; however, there was no evidence of a comprehensive and structured approach to staff training. In particular, there was no equipment-specific training for operators, especially when PCH staff provide cover for satellite sites using different equipment.

3.53 At the time of inspection, there were a number of new starters to the department and PCH were introducing the recently revised preceptorship programme, currently in use at the Royal Glamorgan Hospital. However, there was no reference to providing newcomers with the written procedures and protocols as guidance.

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
Regulation 4(1) Schedule 1 Regulation 4(2)	3.3 - 3.8	<p>Procedures and Protocols</p> <p>We recommend that Cwm Taf review its policy, procedures and protocols to ensure that they comply with IR(ME)R, contain the required information, are fit for purpose, have appropriate version control and review dates.</p> <p>Staff should be engaged in the development of the working documents, embed procedures into their working practice, be made aware and understand any changes to procedures and protocols.</p>
Regulation 4(3) c and 4(6) Regulation 7(3)c Schedule 1g	3.12 - 3.13 and 3.39	<p>Diagnostic Reference Levels</p> <p>We recommend that Cwm Taf establish appropriate DRLs immediately for all typical examinations, including paediatrics, carried out at PCH and across the LHB.</p> <p>Once in place, the employer's written procedures should describe the process of investigation for consistently exceeding DRLs.</p>
Schedule 1b	3.14 - 3.17	<p>Entitlement</p> <p>We recommend that the process of entitlement is clarified within the employer's written procedures to ensure that duty holders are appropriately entitled for tasks that they undertake.</p> <p>There should also be clear demonstration of the link back to the employer.</p> <p>Staff should be aware of their entitlement and scope of practice, and this should be embedded into their training and appraisal.</p>

IR(ME)R Regulation	Finding (Paragraph Reference)	Recommendation
<p>Regulation 4(3)a</p> <p>Regulation 5(5)</p> <p>Regulation 6(4)</p>	<p>3.19 - 3.23</p>	<p>Referral</p> <p>We recommend that the PCH referral procedures for theatre are formally evidenced and this process is reflected as part of the written procedures.</p> <p>We recommend that NHS Wales purchases iRefer as soon as possible so that the latest noteworthy practice is available to all radiology staff.</p>
<p>Regulation 6(b)</p>	<p>3.25 - 3.27</p>	<p>Justification Guidelines</p> <p>We recommend that PCH reviews its current procedures regarding justification and authorisation.</p> <p>PCH should either reconsider whether some staff currently entitled as operators should be entitled as practitioners with a clearly defined scope of practice or establish justification guidelines for their examinations.</p> <p>Staff should be made aware of when they are entitled to undertake justification as a practitioner or should refer to justification guidelines when authorising examinations.</p>
<p>Schedule 1a</p>	<p>3.29</p>	<p>Identification</p> <p>We recommend that Cwm Taf LHB develop the written procedures for identification of patients to include the various scenarios where straight forward identification can not be used.</p> <p>Relevant staff should be made aware of these procedures.</p>
<p>Regulation 6(e)</p> <p>Schedule 1d</p>	<p>3.32 - 3.33</p>	<p>Females of Child Bearing Age</p> <p>We recommend that Cwm Taf LHB revise the written procedures for 'checking pregnancy' to ensure that they are comprehensive, appropriate and clearly describe how pregnancy enquiries should be recorded.</p> <p>Staff should be made aware of these procedures.</p>

IR(ME)R Regulation	Finding (Paragraph Reference)	Recommendation
Regulation 7 Schedule 1f	3.36	<p>Reject Analysis</p> <p>We recommend that PCH does not delete undiagnostic images but instead record, monitor, analyse and evaluate reject images as part of a quality control programme.</p> <p>This update in practice should also be reflected in the written procedures and communicated to staff, not just those within the Radiology Department.</p>
Regulation 7(8) Regulation 8 Schedule 1j Schedule 1f	3.44 – 3.45	<p>Dose Recording</p> <p>We recommend that a standard approach to recording doses is outlined in the written procedures and a system is put into place to ensure that this practice is adopted by staff.</p> <p>We recommend that RadIS is interrogated for trends and patterns in dose levels for all radiological examinations over a rolling programme.</p>
Regulation 9	3.47	<p>Expert Advice</p> <p>We recommend that the Service Level Agreement with Velindre NHS Trust for the role of Medical Physics Expert is renewed on a timely basis.</p>
Regulation 10(1)	3.50	<p>Equipment</p> <p>We recommend that the equipment inventory is updated to include:</p> <ul style="list-style-type: none"> - all equipment which delivers and controls the extent to which ionising radiation is exposed to a patient; and - equipment at all Cwm Taf satellite sites, as it is an employer responsibility.
Regulation 11 Schedule 2	3.52 - 3.53	<p>Training</p> <p>We recommend that Cwm Taf establish an appropriate IR(ME)R training programme for all practitioners and operators. This should include as appropriate:</p> <ul style="list-style-type: none"> - continuous professional development undertaken post qualification; - training on new equipment and infrequently used equipment; and - new techniques/modalities.

IR(ME)R Regulation	Finding (Paragraph Reference)	Recommendation
		Cwm Taf should maintain up to date training records, which demonstrate that staff are adequately trained for the tasks they are entitled to carry out.

5. Next Steps

5.1 The Local 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 The LHB has confirmed that all actions will be completed by March 2013, within eight months of the inspection. HIW has reviewed the action plan and is satisfied that the concerns raised by the inspection will be appropriately addressed.

5.3 HIW will monitor the progress of Cwm Taf LHB implementing the actions agreed and review policies and procedures where applicable. Based on the level of assurance we receive, Cwm Taf LHB may also 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 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 Compliance Inspection against Ionising Radiation (Medical Exposure) Regulations

In accordance with the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000 and subsequent amendments (2006 and 2011), Healthcare Inspectorate Wales (HIW) will conduct an announced inspection of Prince Charles Hospital, Merthyr Tydfil in Cwm Taf Local Health Board.

The inspection of diagnostic imaging will take place between Wednesday 18 and Thursday 19 July 2012. Nicola Bresner, Inspection Manager and Sarah Lewis, Assistant Inspection Manager will lead on the review, accompanied by experts from the Health Protection Agency, Kathlyn Slack and Sarah Peters.

Objective

The objective of the inspection is to provide assurance that the principles of IR(ME)R are achieved for diagnostic imaging at Prince Charles Hospital.

Scope

The scope of the inspection will include the review of:

- policies, standard operating procedures and protocols, to ensure that they are compliant, communicated and periodically reviewed;
- roles, responsibilities to ensure that they are clearly defined and provide for the appropriate segregation of duties amongst the practitioners, operators, referrers and employers;

- IR(ME)R training and continuous professional development to ensure that it is appropriate, completed, documented and readily available;
- incidents to ensure that they are notified to HIW in an appropriate and timely manner, internally investigated and actioned upon;
- the environment to ensure it is clean, professional and appropriate.
- research programmes, where they take place, to ensure that the appropriate approval and implementation procedures have been followed;
- exceptional circumstances, where policies and protocols have not been followed, to ensure that there has been appropriate authorisation and documentation of decisions; and
- any other matters which are considered under the scope of IR(ME)R.

Approach

We will initially ask that Management complete a self-assessment and submit to HIW ten 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 visit, the inspection team will give initial feedback, this will provide an opportunity to discuss the accuracy and any issues raised as part of the review's findings.

A written report will be developed and shared with you for comments to the points raised and the overall factual accuracy. We would expect to receive your formal response within ten working days. On publication, we will then place the final report on the HIW website.

Once the report has been agreed, you will have 20 working days to develop an action plan, which addresses and implements the recommendations made within the report. This provides an opportunity to publish your written response to the recommendations. The action plan will then be placed on the HIW website alongside the final report.

Action Plan

IR(ME)R Reference	Recommendation	LHB Action	Responsible Officer	Target Date
Regulation 4(1) Schedule 1 Regulation 4(2)	<p>Procedures and Protocols</p> <p>We recommend that Cwm Taf review its policy, procedures and protocols to ensure that they comply with IR(ME)R, contain the required information, are fit for purpose, have appropriate version control and review dates.</p> <p>Staff should be engaged in the development of the working documents, embed procedures into their working practice, be made aware and understand any changes to procedures and protocols.</p>	<p>Cwm Taf to review its policy, procedures and protocols with advice from the RPA to ensure that they comply with IR(ME)R.</p> <p>Version control and review dates to be included.</p> <p>Staff to be engaged in development of documents.</p>	<p>Paul Johnston, Superintendent Radiographer.</p> <p>Chris Kalinka, Directorate Manager.</p>	<p>Work commenced.</p> <p>EP Docs – Nov 2012.</p> <p>Policy – Dec 2012.</p>
Regulation 4(3) c and 4(6) Regulation 7(3)c Schedule 1g	<p>Diagnostic Reference Levels</p> <p>We recommend that Cwm Taf establish appropriate DRLS immediately for all typical examinations, including paediatrics, carried out at PCH and across the LHB.</p> <p>Once in place, the employer's written procedures should describe the process of investigation for consistently exceeding DRLs.</p>	<p>National DRLs now in place.</p> <p>Local DRLs under development – dose recording underway for typical examinations.</p> <p>Written procedures to reflect action / investigation of exceeding DRL.</p>	<p>Andrew Thomas, RPS.</p> <p>Stephen Davies, RPS.</p> <p>Paul Johnston, Superintendent Radiographer.</p>	<p>National DRLs - completed.</p> <p>Local DRLs: Dec 2012.</p> <p>EP Docs – Nov 2012.</p>

IR(ME)R Reference	Recommendation	LHB Action	Responsible Officer	Target Date
Schedule 1b	<p>Entitlement</p> <p>We recommend that the process of entitlement is clarified within the employer's written procedures to ensure that duty holders are appropriately entitled for tasks that they undertake.</p> <p>There should also be clear demonstration of the link back to the employer.</p> <p>Staff should be aware of their entitlement and scope of practice, and this should be embedded into their training and appraisal.</p>	<p>New written procedure under development.</p> <p>Link back to Employer / Chief exec being included for different entitlements.</p> <p>Appraisal ongoing – IRMER entitlements to be addressed where appropriate.</p>	Paul Johnston, Superintendent Radiographer.	EP Docs – Nov 2012.
<p>Regulation 4(3)a</p> <p>Regulation 5(5)</p> <p>Regulation 6(4)</p>	<p>Referral</p> <p>We recommend that the PCH referral procedures for theatre are formally evidenced and this process is reflected as part of the written procedures.</p> <p>We recommend that NHS Wales purchases iRefer as soon as possible so that the latest noteworthy practice is available to all radiology staff.</p>	<p>Theatre procedures / referral to be revised at PCH – including referral forms etc.</p> <p>iRefer has been purchased and is available via web links.</p>	Paul Johnston, Superintendent Radiographer, Stephen Montoto, Superintendent Radiographer.	Nov 2012. Completed.

IR(ME)R Reference	Recommendation	LHB Action	Responsible Officer	Target Date
Regulation 6(b)	<p>Justification Guidelines</p> <p>We recommend that PCH review its current procedures regarding justification and authorisation.</p> <p>PCH should either reconsider whether some staff currently entitled as operators should be entitled as practitioners with a clearly defined scope of practice or establish justification guidelines for their examinations.</p> <p>Staff should be made aware of when they are entitled to undertake justification as a practitioner or should refer to justification guidelines when authorising examinations.</p>	<p>Justification / authorisation procedures under review.</p> <p>PCH staff – justification guidelines established, authorised by Clinical Director (particularly for CT scanning @ 8.30am).</p>	Paul Johnston, Superintendent Radiographer, Stephen Montoto, Superintendent Radiographer	Nov 2012
Schedule 1a	<p>Identification</p> <p>We recommend that Cwm Taf LHB develop the written procedures for identification of patients to include the various scenarios where straight forward identification can not be used.</p> <p>Relevant staff should be made aware of these procedures.</p>	<p>Identification EP (revised and currently with RPA for review) includes scenarios where straight forward identification can not be used.</p> <p>Staff will be trained in new procedures.</p>	Paul Johnston, Superintendent Radiographer.	Nov 2012.

IR(ME)R Reference	Recommendation	LHB Action	Responsible Officer	Target Date
Regulation 6(e) Schedule 1d	<p>Females of Child Bearing Age</p> <p>We recommend that Cwm Taf LHB revise the written procedures for 'checking pregnancy' to ensure that they are comprehensive, appropriate and clearly describe how pregnancy enquiries should be recorded.</p> <p>Staff should be made aware of these procedures.</p>	<p>Cwm Taf LHB will revise the written procedures for '<i>checking pregnancy</i>' to ensure that they are comprehensive, appropriate and clearly describe how pregnancy enquiries should be recorded.</p> <p>Staff will be made aware of new procedures.</p>	Paul Johnston, Superintendent Radiographer.	Nov 2012.
Regulation 7 Schedule 1f	<p>Reject Analysis</p> <p>We recommend that Cwm Taf LHB do not delete undiagnostic images but instead record, monitor, analyse and evaluate reject images as part of a quality control programme.</p> <p>This update in practice should also be reflected in the written procedures and communicated to Radiology staff.</p>	<p>Investigation and system options to be explored with current PACS provider at PCH.</p> <p>Reject analysis programme to be introduced at PCH and YCC.</p>	Andrew Thomas, RPS.	Jan 2013.

IR(ME)R Reference	Recommendation	LHB Action	Responsible Officer	Target Date
Regulation 7(8) Regulation 8 Schedule 1j Schedule 1f	<p>Dose Recording</p> <p>We recommend that a standard approach to recording doses is outlined in the written procedures and a system is put into place to ensure that this practice is adopted by staff.</p> <p>We recommend that RadIS is interrogated for trends and patterns in dose levels for all radiological examinations over a rolling programme.</p>	<p>Dose Recording – doses for CT and Fluoroscopy / Nuclear Medicine being recorded in RADIS.</p> <p>RADIS recording to be investigated for general imaging – including hardware and software provision.</p>	Phil Jones, PACS Manager.	Completed for high dose examinations at RGH – implement in PCH (Nov 2012). Jan 2013.
Regulation 9	<p>Expert Advice</p> <p>We recommend that the Service Level Agreement with Velindre NHS Trust for the role of Medical Physics Expert is renewed on a timely basis, to ensure that the MPE is available as appropriate.</p>	<p>The Service Level Agreement is renewed on an annual basis - 1st April.</p> <p>MPE is continuously available to Cwm Taf, both for Radiation Protection advice and new equipment / tube monitoring.</p>	Chris Kalinka, Directorate Manager.	Completed.
Regulation 10(1)	<p>Equipment</p> <p>We recommend that the equipment inventory is updated to include:</p> <ul style="list-style-type: none"> - all equipment which delivers and controls the extent to which ionising radiation is exposed to a patient, and - equipment at all Cwm Taf satellite sites, as it is an employer responsibility. 	<p>Radiology Equipment inventory to be updated to include all radiology satellite sites (and pressure injectors).</p>	Paul Johnston.	Nov 2012.

IR(ME)R Reference	Recommendation	LHB Action	Responsible Officer	Target Date
<p>Regulation 11</p> <p>Schedule 2</p>	<p>Training</p> <p>We recommend that Cwm Taf establish an appropriate IR(ME)R training programme for all practitioners and operators. This should include as appropriate:</p> <ul style="list-style-type: none"> - continuous professional development undertaken post qualification, - training on new equipment and infrequently used equipment, - new techniques/ modalities. <p>Cwm Taf should maintain up to date training records, which demonstrate that staff are adequately trained for the tasks they are entitled to carry out.</p>	<p>Cwm Taf will establish an appropriate IR(ME)R programme for all practitioners and operators.</p> <p>Cwm Taf will compile and maintain up to date training records, which demonstrate that staff are adequately trained for the tasks they are entitled to carry out.</p>	<p>Collette Jones, Superintendent Radiographer, RGH.</p> <p>Stephen Montoto, Superintendent Radiographer PCH.</p>	<p>March 2013.</p>