

Cardiff and Vale University Health Board

University Hospital of Wales Diagnostic Imaging Services

Inspection of compliance
with the Ionising Radiation
(Medical Exposure) Regulations

Date of Inspection: August 2010

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About 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 of 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 systemic failures in delivering healthcare services to ensure that rapid improvement and learning takes place. In addition, HIW is the regulator of independent healthcare providers in Wales, the Local Supervising Authority for the Statutory Supervision of Midwives and undertakes the monitoring of the use of the Mental Health Act in Wales.

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 and Amendment Regulations 2006.

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.

Chapter 1: Introduction- Enforcing the Regulations

1.1 On behalf of Welsh Ministers HIW assesses compliance with the Ionising Radiation (Medical Exposure) Regulations 2000, known as IR(ME)R as amended in 2006. The responsibility for enforcing the regulations transferred from the Department of Health to Welsh Ministers on 1 November 2006.

The regulations are intended to:

- Protect patients from unintended excessive or incorrect exposure to radiation and ensure that, in each case, the risk from exposure is assessed against the clinical benefit.
- To ensure that patients receive no more exposure than is necessary to achieve the desired benefit within the limits of current technology.
- To protect volunteers in medical or biomedical, diagnostic or therapeutic research programmes and those undergoing medico-legal exposures.

1.2 Our inspection sought information from discussions with staff and observations within the clinical settings, which was supplemented by additional evidence provided by the organisation prior to the inspection, including the completion of a self-assessment return.

1.3 This is a summary report of the findings from our inspection of the diagnostic imaging services, using information from the observations, discussions, completed self-assessment return and documents collected. During the inspection, we recorded a summary of the evidence relating to the regulations. The inspection was carried out by Healthcare Inspectorate Wales, supported by staff from the Health Protection Agency.

Chapter 2: Background to the Inspection

2.1 University Hospital Wales (UHW) is located in the Heath area of Cardiff and is one of the hospitals that form part of Cardiff and Vale University Health Board (UHB). UHW provides a diagnostic imaging service.

2.2 Within UHW, Diagnostic Imaging investigations are carried out in the Radiology and Medical Physics and Clinical Engineering (MPCE) departments. The two departments have recently merged into the same directorate and the management structures have changed.

2.3 Each year, the Radiology & MPCE departments perform approximately:

Procedure	Amount per year
General ' <i>plain film</i> ' radiography	154,328
Fluoroscopy	3546
Computed Tomography (CT) scanning	20,044
Magnet Resonance (MR) scanning	11,326
Interventional radiology	1924
Cardiology	4816
Symptomatic Mammography	4180
Medical and Antenatal Ultra Sound scanning	21,880 (medical) 13,432 (antenatal)
Dental Procedures	1124
CT Scanning (MPCE) Department	100
Vascular Ultra Sound scanning (MPCE Department)	9000
Dual Energy X-ray Absorptiometry DEXA (MPCE Department)	6900

2.4 In terms of staffing, the Radiology department is funded for the following:

20.8	Whole Time Equivalent (WTE) Consultant Radiologists.
35	WTE Radiology Specialist Registrar (SpRs.)
15	WTE Consultant/Advanced Practice Radiographers.
83	WTE Radiographers.
3	WTE Assistant Practitioners.
3	Other.

The MPCE department is funded for the following staff:

13	Clinical Technologists.
13.8	Physicists working across all disciplines.
7.6	Other (2 trainees, 2 nursing staff and 3.6 A/C).

Chapter 3 The Inspection

3.1 On the 4 August 2010 an assessment of the Diagnostic Imaging Department at University Hospital Wales (UHW) was undertaken by Healthcare Inspectorate Wales (HIW) with advice being provided by staff from the Health Protection Agency (HPA). The visit was part of HIW's routine inspection programme. Prior to the visit the department was required to complete a self-assessment questionnaire and provide HIW with copies of all policies and procedures in place. This information was used to inform the focus of the visit and in particular, discussions with key members of staff working within the department.

Summary of Findings and Concerns Raised

3.2 Throughout the visit senior staff from within the organisation were available to participate in discussions with the team. It was evident that there was some notable practice taking place within the department with a real focus on the individual patient and on radiation protection.

3.3 We identified no major areas of concern during this inspection visit. At the end of the inspection a number of issues identified were fed back to Health Board staff. The inspection team felt that some attention needs to be given to the following areas:

Documentation

3.4 The Radiology department and MPCE had their own IR(ME)R procedures in place prior to their merger. At the time of the inspection, a different document control system existed in the Radiology and MPCE departments; therefore there was no system in place to ensure consistency between Radiology and MPCE's versions of procedures. In addition the document control systems in place appeared to have varying degrees of effectiveness, as the team found inaccuracies, inconsistencies and a lack of cross referencing in some documents. There is also duplication in many documents. We found a number of versions of documents covering the same

procedures, for example patient identification or checking whether a patient may be pregnant. In addition, some staff reported that practice did not always match the written procedures.

3.5 The policy for reporting incidents needs to reflect the change to reporting them to Healthcare Inspectorate Wales rather than the Welsh Government.

3.6 The quality control of the exposure charts needs to be addressed. These charts should include version control, dates of issue and review and indicate who is responsible for them.

3.7 There needs to be an improved staff awareness of some policies and procedures.

Entitlement of Referrers¹, Practitioners² and Operators³

3.8 There needs to be clarity about who is responsible for justification (i.e. the practitioner) when new staff are in their induction period.

3.9 The employer has delegated the task of entitlement to the Medical Director for medical staff and the Clinical Director for non-medical staff. This needs to be made clear within the policy and written procedures.

¹ *'Referrer'* means a registered healthcare professional who is entitled in accordance with the employer's procedures to refer individuals for medical exposure to a practitioner.

² *'Practitioner'* means a registered healthcare professional who is entitled in accordance with the employer's procedures to take responsibility for an individual medical exposure;

³ *'Operator'* means any person who is entitled, in accordance with the employer's procedures, to carry out practical aspects including those to whom practical aspects have been allocated pursuant to regulation 5(3), medical physics experts as referred to in regulation 9 and, except where they do so under the direct supervision of a person who is adequately trained, persons participating in practical aspects as part of practical training as referred to in regulation 11(3).

3.10 The practitioner matrix needs updating and more detailed information regarding the scope of practice should be available.

3.11 The operator matrix needs updating – HIW suggests that a single matrix would make it easier for staff to know what they are entitled to do.

3.12 Some procedures need to more clearly identify responsibility, for example when junior doctors refer through a consultant, the responsibility of the consultant should be explicit in the documents and policies.

3.13 It needs to be ensured that agency staff are made aware of the written procedures and their responsibilities. This includes the scope of practice associated with their entitlement. The written procedures should describe this and how it is done.

Justification⁴:

3.14 The procedures used currently state that justification must take place but there was little information about how this should take place.

Patient Identification

3.15 Further clarity is required about who is responsible for ensuring a patient is identified correctly.

⁴ Justification of Individual Medical Exposures: 6. - (1) No person shall carry out a medical exposure unless - (a) it has been justified by the practitioner as showing a sufficient net benefit giving appropriate weight to the matters set out in paragraph (2); and (b) it has been authorised by the practitioner or, where paragraph (5) applies, the operator; and (c) in the case of a medical or biomedical exposure as referred to in regulation 3(d), it has been approved by an ethics committee; and (d) in the case of an exposure falling within regulation 3(e), it complies with the employer's procedures for such exposures; and (e) in the case of a female of childbearing age, he has enquired whether she is pregnant or breastfeeding, if relevant.

Pregnancy

3.16 There appears to be a differing approach to establishing whether a female patient is pregnant or may be pregnant, depending on whether she is seen during or outside of normal working hours. This needs to be addressed.

Training

3.17 From an examination of records and discussions with staff it was evident that staff were adequately trained. However, some of the training records require improvement; this is in terms of inclusion of dates and sign-off by a person competent to do so. That said there is evidence of a good in-house Continued Professional Development (CPD) programme.

Chapter 4: Conclusions and Recommendations

4.1 On the day of the inspection visit, the department provided evidence which showed that they complied with IR(ME)R. The department provided assurance that staff were adequately trained and that the majority of their procedures were in place and were in line with regulatory requirements. However there is a need for some improvement and the following recommendations are made:

Regulation	Recommendation
Regulation 4(1) Duties of the Employer	A single system of document control needs to be in place for all IR(ME)R documents in the Radiology and Medical Physics and Clinical Engineering Departments to ensure consistency.
Regulation 4(3) b Duties of the Employer	All written procedures under IR(ME)R should be reviewed to ensure: <ul style="list-style-type: none"> • They reflect changes to management structure following the recent merger of the Radiology and Medical Physics and Clinical Engineering Departments. • They reflect current practice. • Consistency between documents, elimination of inaccuracies and inclusion of appropriate cross-referencing.
Regulation 4(5) Duties of the Employer	Incident reporting procedures need clarification to reflect that incidents falling under this Regulation are now reported to Healthcare Inspectorate Wales rather than the Welsh Government.
Regulation 11 (4) Training	All training records are kept up to date.
Schedule 1(a)	A single procedure addressing the correct identification of patients should be developed.
Schedule 1(b)	The process of entitlement should be made clear in the written procedures. In addition, the records of entitlement for practitioners and operators should be reviewed.
Regulation 6(3)(c); Schedule 1(d)	The process of making enquires of females of childbearing age to establish whether the individual is or may be pregnant should be reviewed to ensure a consistent approach in and out of normal working hours. This should be reflected in the written procedures.