Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

DRIVING IMPROVEMENT THROUGH INDEPENDENT AND OBJECTIVE REVIEW

Abertawe Bro Morgannwg University Health Board

Singleton Hospital Radiotherapy Services

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

Date of Inspection: September 2011

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About 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 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 - The Regulations

1.1 The Ionising Radiation (Medical Exposure) Regulations 2000, amended in 2006, are generally referred to as IR(ME)R. They place various duties and requirements on healthcare providers that expose patients to ionising radiation for medical purposes; such as X-rays, CT scans or courses of radiotherapy. The regulations were made with the intention of:

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

1.2 The Regulations have associated powers of inspection and enforcement, which are outlined in the Health and Safety at Work Act 1974. In Wales, these powers have sat with Welsh Ministers since 1 November 2006. HIW undertakes these inspection and enforcement roles on behalf of Welsh Ministers by undertaking a programme of routine inspections to services which undertake activities regulated by IR(ME)R.

1.3 The Regulations require services to notify Welsh Ministers, i.e. HIW, of incidents where patients have been exposed to ionising radiation, to an extent much greater than intended. HIW reviews the notifications it receives, seeks further information where required and decides on a course of action; this could be assessing the service's priority in our inspection programme, initiating an immediate inspection or taking enforcement action.

1.4 This report is the result of a routine inspection undertaken at Singleton Hospital, carried out by HIW staff, with clinical advice provided by staff from the Health Protection Agency (HPA).

1.5 Prior to the inspection the radiotherapy service completed a self-assessment return and submitted additional evidence. During the site visit the team discussed information in the self assessment and examined policies and procedures in discussion with key staff. They also reviewed case notes and staff records, made observations within the clinical settings and interviewed a cross section of staff in order to establish whether the information in the self-assessment was reflected in operational custom and practice.

Chapter 2: Profile of the Inspected Service

2.1 Singleton Hospital is located in Swansea and is one of the hospitals that form part of Abertawe Bro Morgannwg University Health Board (ABM UHB). It is one of three radiotherapy centres in Wales, providing a service to patients from ABM UHB, Hywel Dda Health Board and parts of Powys Teaching Health Board; i.e. from Bridgend in the east, across to Pembrokeshire and as far north as Aberystwyth. Patients may be seen for some consultations and reviews in satellite clinics across the region but travel to Swansea for all radiotherapy. Singleton does not administer radiotherapy to children.

2.2 Radiotherapy involves the delivery of a prescribed dose of radiation carefully designed to meet the needs of individual patients and often involves daily attendance for a series of exposures known as fractions, over a course of weeks. The most common forms are external beam therapy[1] and brachytherapy[2]. Radiotherapy can also require other exposures to ionising radiation, such as CT scans taken for the purposes of planning treatment and verifying it is being correctly delivered. These are known as concomitant exposures.

2.3 The majority of patients receive radiotherapy at the hospital to treat cancers, either as radical treatment, where the aim is to destroy the tumour, or as palliative treatment to shrink a cancer, slow down its growth, or control symptoms, but not to cure the cancer. Radiotherapy is often combined with other treatments including surgery or chemotherapy.

2.4 Radiotherapy services at Singleton are delivered by staff from two Directorates of ABM UHB. Cancer services, consisting of clinical oncologist, nursing staff and radiographers, are part of the Regional Services Directorate whilst Medical

[1] Exposure to an X-ray beam shaped to the size and shape of the area requiring treatment, to target the cancer cells whilst minimising damage to healthy cells and nearby organs.

[2] The placement of short-range radiation sources directly at the site requiring treatment. These are enclosed in a protective capsule or wire, which allows the ionising radiation to escape to treat and kill surrounding tissue, but prevents the charge of radioisotope from moving or dissolving in body fluids. The capsule may be removed later, or it may be allowed to remain in place, depending on the radioisotope used.

Physics and Clinical Engineering (MPCE), which provides radiotherapy physics services, is part of the Clinical Support Services Directorate.

2.5 Between June 2010 and June 2011 the department carried out*:*

Procedure	**Amount per year**
CT planning scans	1,956
Conventional simulation and SimCT	529
External beam	2010 new courses, made up of 28,343 fractions. Of these courses 1,255 were for radical treatment and 755 were palliative in nature.
Superficial[3]	51 new courses, 127 treatment fractions.
Orthovoltage[4]	22 new courses, 70 treatment fractions.

2.6 The department currently has four linear accelerators which deliver radiotherapy. A new machine was being installed during our visit and was due to be commissioned in October, after which the oldest linear accelerator would be taken out of service. The new machine has additional capabilities and the department was beginning to develop new work processes, on a staged basis, to take advantage of these facilities, learning from other radiotherapy centres' experiences.

2.7 The orthovoltage unit was not in service, following a major failure. The costs of simply examining it to establish whether and how it could be repaired meant it was unlikely to be repaired. The department's superficial radiotherapy unit has the capability to undertake its work, given sufficient financial and staff resources to update the equipment and associated software. The department was intending to

[3] Superficial treatment is used to treat lesions that do not require a dose of radiation to a great depth, such as skin and bone cancers or scars.

[4] Lower energy radiation used for treatments on the skin or very close to the skin.

analyse whether there was a case for this investment given the limited demand for such a facility.

2.8 Cancer Services is funded for the following whole time equivalent (WTE) posts:

7.6	Consultant Clinical Oncologists With 2 additional posts to be advertised
6	Clinical Oncology Registrars (SpRs)
0.8	Advanced practice radiographer
30	Radiographers
9	Radiography students
3	Radiotherapy helpers

The department reported that it had 1.6 WTE radiographer and 0.64 WTE Band 2 staff vacancies of over three months

2.9 The MPCE department is funded for the following WTE staff who work in both radiotherapy and other services across ABM UHB:

6.3	Registered clinical scientists who can act as Medical Physics Experts in certain areas of practice
1	Trainee clinical scientist on rotation
6.4	Dosimetrists
3.5	Engineers

MPCE reported that they had one clinical technologist and two clinical scientist long term vacancies. One clinical scientist post had been vacant for nearly four years, despite numerous advertisements with a variety of terms and conditions.

Chapter 3 Summary of Findings

3.1 In general the team found the service provided at Singleton to be of good quality and based on sound clinical practices. There was a clear focus on the individual patient and on radiation protection practices. The service has expanded significantly over the last eight years and it was clear that improvements had been made since HIW's last inspection in 2008.

3.2 We identified no major areas of concern during the inspection visit. In general custom and practice was good but there was some evidence that in some cases this needed to be formalised within written procedures and protocols. At the end of the inspection the inspection team provided verbal feedback to staff from cancer services and MPCE as well as an Executive Director of ABM UHB. This chapter contains a summary of the team's findings, including areas they felt to be in need of some attention: Entitlement of '*Referrers*[5]*, Practitioners*[6] *and Operators*[7].'

3.3 The Regulations require the Employer to have procedures in place to assess the competence of staff and subsequently entitle them to undertake the specified functions of the Referrer, Practitioner and Operator roles as defined within the legislation. While there was no evidence that tasks and functions were being undertaken by staff who were not competent to do so, it was not clear that the formalisation of their entitlement was in place before the staff performed these tasks and functions. This applied to radiographers and medical staff.

3.4 The team also found that the procedures at Singleton did not always make it clear as to what type of entitlement or what IR(ME)R role was being undertaken when performing a particular action, such as signing a form.

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[5] *'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.

[6] *'Practitioner'* means a registered healthcare professional who is entitled in accordance with the employer's procedures to take responsibility for an individual medical exposure to ionising radiation.

[7] *'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).

3.5 The entitlement processes were not understood by some staff and were insufficient to provide assurance to the Employer that individuals had demonstrated the appropriate skills and training to enable them to be entitled. These issues were noted particularly for oncology and radiography staff.

3.6 These are some examples we identified that demonstrate the issues outlined above:

- Processes had been developed to entitle newly appointed radiographers, which involved the need for them to demonstrate competency in specific activities whilst working under supervision and for them to be signed off as being competent by their supervisor. Once signed off this information was passed to the individual delegated with the power of entitlement, who formally authorised individuals and recorded this on a matrix. However, systems in place for the recording and assessment of skills varied significantly; for example while some skills were evidenced by a supporting log of practice, others were not. In addition some staff did not understand the importance and relevance of this process, and hence had not forwarded on their documents to obtain entitlement in a way that was timely. There is therefore the possibility that for a period of time they were performing functions they believed they were entitled to do, when in fact they were not.

- There were no clear processes or matrices setting out the entitlement of radiographers who had worked at Singleton for some time.

- The entitlement matrix for oncologists did not describe their entitlement sufficiently, thus leaving a number of grey areas. In general, consultant clinical oncologists practice in specific anatomical sites and to agreed treatment protocols. Further, a number of consultants are entitled by the Health Board to prescribe a course of treatment that diverts from the agreed protocol for a specific condition, where it is clinically appropriate to meet an individual's needs. On occasion, in order to ensure timely treatment and care, other staff may be asked to review cases or images

for patients in the absence of the lead clinician. However, it was unclear from the local protocols and records as to what these other staff were entitled to do for those patients whose treatment did not follow agreed protocols.

Appraisal

3.7 Whilst continuing professional development and training was being undertaken by staff, formal processes of appraisal or review of competency appeared under-developed, with some staff reporting that they had not had an appraisal for some time. Staff attributed this shortfall to problems that had arisen following the introduction of the Knowledge and Skills Framework. Given the shortfalls in the entitlement processes highlighted above, there is a risk that staff returning to work in a particular area after a break could retain their entitlement and hence theoretically be able to take up duties again without any assurance that they have retained the necessary skills and knowledge, although in practice this seems unlikely.

Referral

3.8 The difference between *'clinical referral'* into the service for a course of treatment and the point at which a *'Referral,'* as defined in the Regulations, is made for an exposure or exposures to radiation, by someone entitled to be a Referrer, was not always clear from documentation and discussion with staff. For example the team could not clearly identify the point of *'Referral'* in circumstances when an individual is seen in an outlying clinic by someone who does not specialise in their particular condition; it was unclear as to whether this did or did not happen in practice.

Documentation

3.9 There was a clear document control system with cross-referencing between policies and protocols to ensure consistency, for example, there is one patient

identification protocol, which is referred to by all other protocols, rather than each protocol outlining the identification process. The service has identified a problem with the timely review of documents and a number of the documents we reviewed did not have a review interval specified.

3.10 Documents need to reflect both clinical and operational custom and practice and how these interface with the requirements of IR(ME)R. Some of the issues described earlier around entitlement and referral reflect this lack of clarity in documentation.

Patient identification

3.11 The team spoke to a number of staff, all of whom could clearly describe the correct process for identifying a patient and seemed aware of their individual responsibilities in this regard. However, some were less clear that their signatures on documents indicated that they had undertaken this check as well as delivered treatment.

Pregnancy

3.12 The was a clear process for ensuring staff asked questions to establish whether a female patient is pregnant or may be pregnant, at set points in their course of treatment. Stickers were used on the covers of patient notes to remind staff of the need to undertake these checks and in addition reminders were entered against the relevant days on treatment charts.

Learning from mistakes

3.13 Since June 2010 HIW has been notified of three incidents by the radiotherapy service. Each incident involved errors in the calculation or targeting of dosages whilst planning therapy or when setting up equipment. None of the incidents resulted in serious harm to the patient and all errors were able to be corrected by adjustments being made to future treatments so that patient received no more than

the required total dose. All types of incident, whether or not reportable to HIW, are recorded and reviewed through the Health Board's incident recording system.

3.14 The inspection team took the opportunity to discuss these incidents with staff and examine whether actions identified at the time had led to improvements. They found evidence to demonstrate that improvements to practice had been made, and staff were open to considering further developments in light of the team's comments.

3.15 The MPCE have also developed a planning errors database to enable them to identify and address trends.

Integration of IR(ME)R into operational practice and culture

3.16 We have already referred to an apparent lack of interface between, or understanding of, the requirements of IR(ME)R in the context of clinical and operational practices. The team felt that the department relied heavily on one or two individuals being the *'torch bearers'* for IR(ME)R and holding a lot of knowledge of staff skills in their head. Whilst the team recognised the significant contribution of these individuals, this has allowed other staff across grades to become disengaged with IR(ME)R and overlook their personal and professional responsibilities to ensure compliance with its requirements. This is unfortunate, and leaves ABM UHB at risk should these individuals not be available for any reason. We understand there are plans to establish a multi-disciplinary IR(ME)R committee in the department and that this will involve a wider group of staff in considering IR(ME)R compliance. We welcome this step.

Environment of care

3.17 The department appeared clean, calm and generally well maintained. Staff noted that parking could be difficult for some patients, with the main car park some distance away from the radiotherapy department. The department has two waiting areas; one for patients attending for consultations, reviews and treatment planning and the other for those undergoing treatment. There were originally reception desks

in each area, but the one in the treatment area is currently unmanned. The control areas for some of the treatment rooms are adjacent to this waiting area, only screened off by glass partitions. Some staff reported that as a consequence patients would approach them with queries rather than go back to the front desk, particularly if there were time constraints on their treatment. These staff members felt this distracted them when they were operating the machinery delivering treatments.

Chapter 4: Conclusions and Recommendations

4.1 During the visit, the department provided evidence which showed that it largely 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 in line with regulatory requirements. However there is a need for some improvement and the following recommendations are made:

Regulation	Recommendation
Regulation 11 Training **Regulation 4(4)** Duties of the Employer **Schedule 1(b)**	The process of entitlement should be reviewed to ensure that there is a clear and consistent process of assessing and demonstrating fitness for entitlement. Written processes, protocols and matrices should be reviewed to ensure they clearly identify when entitlement is required for a particular task and what IR(ME)R role is involved. The Health Board should ensure this is an integral part of developing and reviewing such documents in the future. The records of staff operating as referrers, practitioners and operators should be reviewed to ensure they have the entitlement to undertake all their current duties.
Regulation 11 Training	The Health Board should ensure that staff understand their roles and responsibilities under IR(ME)R.