

**Inspection of compliance with the Ionising Radiation (Medical Exposure) Regulations 2000 and the Ionising Radiation (Medical Exposure) Amendment Regulations 2006 (IR(ME)R):**

**Diagnostic Imaging Departments:**

Victoria Memorial Hospital

Brecon War Memorial

Ystradgynlais Community Hospital

**Part of Powys teaching Health Board**

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**Healthcare Inspectorate Wales**

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**Review of Progress against Ionising Radiation  
(Medical Exposure) Regulations 2000 and the Ionising  
Radiation (Medical Exposure) Amendment  
Regulations 2006 (IR(ME)R).**

<b>Organisation:</b>	Powys teaching Health Board
<b>Sites Inspected:</b>	Victoria Memorial Hospital Brecon War Memorial Hospital Ystradgynlais Community Hospital
<b>Date of Inspection:</b>	27-29 January 2010

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## **Chapter 1. Introduction-Enforcing the Regulations**

On behalf of Welsh Ministers, Healthcare Inspectorate Wales (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 and HIW carry out this function on their behalf.

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.

This report is a summary of our findings from our inspection of the diagnostic imaging departments at:

Victoria Memorial Hospital.

Brecon War Memorial Hospital.

Ystradgynlais Community Hospital.

Our inspection report is based on discussions with staff, observational visits to clinical settings, evidence provided by the organisation prior to the inspection, including the completion of a self-assessment return.





## **Chapter 2. The Inspection-Powys teaching Health Board**

On the 27-29 January 2010 an assessment of the diagnostic imaging departments at the following hospitals were carried out:

- The Victoria Memorial Hospital.
- Brecon War Memorial Hospital.
- Ystradgynlais Community Hospital.

All three hospitals form part of Powys teaching Health Board (tHB) and the inspection 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 and prior to the visit each 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 inspection and in particular, discussions with key members of staff working within the departments.



## **Chapter 3. Activity and Staffing Details**

### **Victoria Memorial Hospital**

The Victoria Memorial Hospital provides a diagnostic imaging service for a local population of approximately 6, 647. The hospital is located in Welshpool.

Each year, the diagnostic imaging department carries out approximately 6000 general 'plain film' radiography procedures. The department also carries out Fluoroscopy and Medical and Antenatal Ultra Sound Scanning procedures.

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

- 3.4 Whole Time Equivalent (WTE) Radiographers.
- 1.5 WTE Helpers (covering the North Powys service).
- 2 Part time Radiation Protection Supervisors (RPS).

The hospital has a Service Level Agreement (SLA) with Betsi Cadwaladr University Health Board (HB) for Physicists and Consultant Radiologists. Consultant Radiologists provide three sessions per month on site, however, offsite support is always available.

### **Brecon War Memorial Hospital**

Brecon War Memorial Hospital provides a diagnostic imaging service for a local population of approximately 8,036. The hospital is located in Brecon.

Each year, the diagnostic imaging department carries out approximately 5000 general 'plain film' radiography procedures. The department also carries out Fluoroscopy, Medical and Antenatal Ultra Sound Scanning, and Dental procedures.

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

2.1 Whole Time Equivalent (WTE) Radiographers.

0.8 WTE Radiation Protection Supervisors (RPS).

1 WTE CDS Dental Officer.

The hospital has a SLA with Aneurin Bevan Health Board (ABHB) for Consultant Radiologists who provide one session per week on site; however, offsite support is always available. ABHB also provides cover for sickness and a radiologist is included in the rota for weekend cover. The hospital also has a SLA with Velindre NHS Trust for Physicist support.

## **Ystradgynlais Community Hospital**

Ystradgynlais Community Hospital provides a diagnostic imaging service for a local population of approximately 8,128. The hospital is located in Ystradgynlais.

Each year, the diagnostic imaging department carries out approximately 5000 general 'plain film' radiography procedures. The department also carries out Medical and Antenatal Ultra Sound Scanning procedures.

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

1.0 Whole Time Equivalent (WTE) Advance Practitioner Radiographer.

0.6 WTE Radiographers.

1.0 WTE Radiation Protection Supervisor (RPS).

1.0 WTE Radiographer Helper.

The hospital has a SLA with Abertawe Bro Morgannwg University Health Board for Consultant Radiologists who provide one session per week on site; however, offsite support is always available. This arrangement also covers the Physicist support when required.



## **Chapter 4. Findings and Key Recommendations**

We found all the three diagnostic imaging departments to comply with the IR(ME) Regulations 2000 and the subsequent amendments in 2006.

We were assured that key procedures were in place and that these were in line with regulatory requirements. However, some minor redrafting of the tHB's Standing Operating Procedures (SOPs) and Ionising Radiation Policy is required to ensure that their purpose is clear, the content is relevant and reflects practice in the tHB.

At the time of the visit the service reported having no long term vacancies; however, the previous post of 'Head of Radiography' services across Powys tHB no longer existed within the staffing structure. From a professional perspective, staff within the departments stated that this had caused some difficulties; however, from our experience at the time of the inspection it was clear that this did not have a negative effect on clinical practice. The Deputy Director of Nursing, who had responsibility for managing the departments at the time of the visit, worked with the teams and has developed a range of skills and expertise since being in post. This is further enhanced in the level and type of professional support received from neighbouring Health Boards.

Throughout the inspection senior staff working within Powys tHB, together with those from neighbouring Health Boards, were available to participate in discussions with the inspection team. This positive engagement demonstrated the strong working relationship between Powys tHB and the neighbouring Health Boards that supported these services. It was evident that all the departments had a real focus on the individual and on radiation protection. From an examination of training records and discussions with staff it was evident that staff were adequately trained and training records were comprehensive and maintained to a very high standard.

Staff were clear about their roles and responsibilities and were working in line with written procedures. In particular, we found good evidence of audit demonstrated in Welshpool including monthly audits of request cards.

The departments now need to move forward to further improve the quality of service they provide and more detail of these can be found at Annex B. The over arching recommendations for the tHB are set out below:

Regulation	Key Recommendations
	Employer responsibility and engagement needs to be clearly demonstrated within the Radiation Protection Policy with clear lines of delegation of duties to individuals expressed.
Schedule 1b	The process of 'Entitlement' for duty holders needs to be formalised. This needs to include a scope of practice for each duty holder supported by adequate training.
Schedule 1k	Procedure (k) in Schedule 1 of the regulations relating to reducing the probability and magnitude of accidental or unintended doses to patients needs to be developed.
Regulation 11(1)	At Brecon Hospital there is a need to ensure that radiographic operators are able to maintain their level of competence to undertake intra oral examinations due to small numbers being carried out.
	Also at Brecon Hospital work was needed to clarify how duty holders were identified on the request card which also needs to be in line with the employer's written procedure.
	At Ystradgynlais Hospital, action needs to be taken to address the issue of GP referrers submitting incomplete request cards.
	Individual comments need to be reflected within the written procedures (see Annex B).



## **Annex A. About Healthcare Inspectorate Wales**

Healthcare Inspectorate Wales<sup>1</sup> (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 Assembly 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 and is the Local Supervising Authority for the Statutory Supervision of Midwives.

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<sup>1</sup> On behalf of Welsh Ministers Healthcare Inspectorate Wales (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 and HIW carry out this function on their behalf.

HIW carries out its functions on behalf of Welsh Ministers and, although part of the Welsh Assembly 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.

Annex B	Regulation	Evidence	Compliance
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APPLICATION	3	<p>These Regulations shall apply to the following medical exposures -</p> <p>(a) the exposure of patients as part of their own medical diagnosis or treatment;</p> <p>(b) the exposure of individuals as part of occupational health surveillance;</p> <p>(c) the exposure of individuals as part of health screening programmes;</p> <p>(d) the exposure of patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes;</p> <p>(e) the exposure of individuals as part of medico-legal procedures.</p>	<p>Outlined in Ionising Radiation Policy 1.2</p>	<p>Yes</p>
PROCEDURES	4 (1) a	<p>The employer shall ensure that written procedures for medical exposures including the procedures set out in Schedule 1 are in place and - shall take steps to ensure that they are complied with by the practitioner and operator; or</p>	<p>Written procedures in place except for Schedule 1k It must be noted that some of the contents of this procedure could be found amongst the other procedures</p>	<p>Improvement needed</p>
ENTITLEMENT	Schedule 1b)	<p>procedures to identify individuals entitled to act as referrer or practitioner or operator;</p>	<p>Procedure C in place however a clear entitlement process needs to be documented, to include:</p> <ul style="list-style-type: none"> <li>• Who is entitling each duty holder including MPE and how is this duty delegated from the Employer</li> <li>• How entitlement is carried out</li> <li>• What documentation is used and where it can be accessed</li> <li>• Each duty holder also requires an associated scope of practice</li> <li>• What constitutes adequate training for practitioners and operators?</li> <li>• How is competence assessed in the first instance and competence and CPD assessed on going?</li> </ul>	<p>Improvement needed</p>

Annex B	Regulation	Evidence	Compliance
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REFERRAL	4 (3) a	(the employer shall establish) recommendations concerning referral criteria for medical exposures, including radiation doses, and shall ensure that these are available to the referrer;	Procedure D 4 Need to include dental referral criteria and how it is made available to these referrers	Yes
	5 (5)	The referrer shall supply the practitioner with sufficient medical data (such as previous diagnostic information or medical records) relevant to the medical exposure requested by the referrer to enable the practitioner to decide on whether there is a sufficient net benefit as required by regulation 6(1)(a)	Standard Operating Procedures in Radiography (page 7) Procedure D 4	Yes
ID	Schedule 1a)	procedures to identify correctly the individual to be exposed to ionising radiation;	Procedure A Consider including a statement that if ID cannot be confirmed that the exposure should not be carried out except in exceptional circumstances	Yes

Annex B	Regulation	Evidence	Compliance
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PREGNANCY	Schedule 1d)	procedures for making enquiries of females of childbearing age to establish whether the individual is or may be pregnant or breastfeeding;	Procedure B Needs to be updated to reflect current HPA guidance and include the action required if a child were to indicate they were pregnant	Yes
	6 (1) e	No person shall carry out a medical exposure unless - in the case of a female of childbearing age, he has enquired whether she is pregnant or breastfeeding, if relevant.	Procedure B 1 <sup>st</sup> section Would suggest that the word 'patients' in the last sentence of the 1 <sup>st</sup> paragraph is changed to 'females'	Yes
	6 (3) c i	the practitioner justifying an exposure pursuant to paragraph (1)(a) shall pay special attention to – the urgency of the exposure, where appropriate, in cases involving - a female where pregnancy cannot be excluded, in particular if abdominal and pelvic regions are involved, taking into account the exposure of both the expectant mother and the unborn child; and	Procedure B 5 <sup>th</sup> paragraph Procedure F 3	Yes
	6 (3) c ii	the practitioner justifying an exposure pursuant to paragraph (1)(a) shall pay special attention to – a female who is breastfeeding and who undergoes a nuclear medicine exposure, taking into account the exposure of both the female and the child.	N/A	
	7 (7) e	Optimisation - the practitioner and the operator shall pay special attention to - where appropriate, females in whom pregnancy cannot be excluded and who are undergoing a medical exposure, in particular if abdominal and pelvic regions are involved, taking into account the exposure of both the expectant mother and the unborn child; and	Procedure B <u>Pregnant patients</u> 1 <sup>st</sup> paragraph	Yes
	7 (7) f	Optimisation - the practitioner and the operator shall pay special attention to - where appropriate, females who are breastfeeding and who are undergoing exposures in nuclear medicine, taking into account the exposure of both the female and the child.	N/A	

Annex B	Regulation	Evidence	Compliance
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JUSTIFICATION AND AUTHORISATION	6 (1) a	No person shall carry out a medical exposure unless - 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	Procedure F	Yes
	6 (1) b	No person shall carry out a medical exposure unless - it has been authorised by the practitioner or, where paragraph (5) applies, the operator;	Procedure F 4	Yes
	6 (2) a	The matters referred to in paragraph 6 (1)(a) are – the specific objectives of the exposure and the characteristics of the individual involved;	Procedure F 2 Need to include characteristics of the individual	Yes
	6 (2) b	The matters referred to in paragraph 6 (1)(a) are – the total potential diagnostic or therapeutic benefits, including the direct health benefits to the individual and the benefits to society, of the exposure;	Procedure F 2 Need to include the benefits to society	Yes
	6 (2) c	The matters referred to in paragraph 6 (1)(a) are – the individual detriment that the exposure may cause; and	Procedure F 2	Yes
	6 (2) d	The matters referred to in paragraph 6 (1)(a) are – the efficacy, benefits and risk of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.	Procedure F 2	Yes
	6 (4)	In deciding whether to justify an exposure under paragraph (1)(a) the practitioner shall take account of any data supplied by the referrer pursuant to regulation 5(5) and shall consider such data in order to avoid unnecessary exposure.	Procedure F 1	Yes
	6 (5)	Where it is not practicable for the practitioner to authorise an exposure as required by paragraph (1)(b), the operator shall do so in accordance with guidelines issued by the practitioner.	We were informed that all requests are justified by a practitioner so justification guidelines are not required	Yes
	5 (2)	The practitioner shall be responsible for the justification of a medical exposure and such other aspects of a medical exposure as is provided for in these Regulations	Procedure F 1	Yes

Annex B	Regulation	Evidence	Compliance
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PROTOCOLS	4 (2)	The employer shall ensure that written protocols are in place for every type of standard radiological practice for each equipment	Demonstrated in departments. The majority of the protocols are provided by the various supporting Health Boards e.g. Betsi Cadwaladr	Yes
PRACTICAL ASPECTS	5 (3)	Practical aspects of a medical exposure or part of it may be allocated in accordance with the employer's procedures by the employer or the practitioner, as appropriate, to one or more individuals entitled to act in this respect in a recognised field of specialisation.	Procedure C and corroborated through discussions with staff on site	Yes
	5 (4)	The operator shall be responsible for each and every practical aspect which he carries out as well as for any authorisation given pursuant to regulation 6(5) where such authorisation is not made in accordance with the guidelines referred to in regulation 6(5).	Procedure C and corroborated through discussions with staff on site	Yes
	5 (6)	The practitioner and the operator shall cooperate, regarding practical aspects, with other specialists and staff involved in a medical exposure, as appropriate.	Procedure C and corroborated through discussions with staff on site	Yes

Annex B	Regulation	Evidence	Compliance
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TRAINING	11 (1)	Subject to the following provisions of this regulation no practitioner or operator shall carry out a medical exposure or any practical aspect without having been adequately trained.	Procedure C and demonstrated on site by comprehensive training records Need to ensure that staff are adequately trained to undertake intra oral dental examinations within the Radiology Department of the Brecon War Memorial Hospital	Improvement needed
	11 (2)	A certificate issued by an institute or person competent to award degrees or diplomas or to provide other evidence of training shall, if such certificate so attests be sufficient proof that the person to whom it has been issued has been adequately trained.	Procedure C <u>Practitioners and Operators</u> Under duty of Director of HR	Yes
	11 (4)	The employer shall keep and have available for inspection by the appropriate authority an up-to-date record of <b>all training undertaken by (amendment 3(4))</b> all practitioners and operators engaged by him to carry out medical exposures or any practical aspect of such exposures or, where the employer is concurrently practitioner or operator, of his own training, showing the date or dates on which training qualifying as adequate training was completed and the nature of the training.	Procedure C <u>Practitioners and Operators</u> Only appears to relate to radiographers. Need to document provisions for all other staff groups (e.g. radiologists and dentists) within the procedures. Training records for radiographers and dentists were provided and these were comprehensive and well maintained	Yes
	11 (5)	Where the employer enters into a contract with another to engage a practitioner or operator otherwise employed by that other, the latter shall be responsible for keeping the records required by paragraph (4) and shall supply such records to the employer forthwith upon request.	Procedure C <u>Practitioners and Operators</u>	Yes
	4 (4) a	The employer shall take steps to ensure that every practitioner or operator engaged by the employer to carry out medical exposures or any practical aspect of such exposures - complies with the provisions of regulation 11(1); and	Procedure C and training documents provided at all sites	Yes
	4 (4) b	undertakes continuing education and training after qualification including, in the case of clinical use of new techniques, training related to these techniques and the relevant radiation protection requirements; or	Provided training documents	Yes
	11 (3)	Nothing in paragraph (1) above shall prevent a person from participating in practical aspects of the procedure as part of practical training if this is done under the supervision of a person who himself is adequately trained.	Not mentioned	Improvement needed



Annex B	Regulation	Evidence	Compliance
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OPTIMISATION (excluding medico legal, pregnancy and breastfeeding)	7 (7) b	Optimisation - the practitioner and the operator shall pay special attention to - medical exposures of children;	Paediatric exposure charts provided by supporting Health Boards. We were informed that a paediatric radiologist was involved in the writing of these in Welshpool.	Yes
	7 (7) c	Optimisation - the practitioner and the operator shall pay special attention to - medical exposures as part of a health screening programme;	N/A	
	7 (7) d	Optimisation - the practitioner and the operator shall pay special attention to - medical exposures involving high doses to the patient;	N/A	
DOSE ASSESSMENT	Schedule 1f)	procedures for the assessment of patient dose and administered activity;	Procedure H Requires clarity about what is recorded for each type of examination Need to check that dentists can comply with this procedure	Yes
	7 (3) b	the operator shall select equipment and methods to ensure that for each medical exposure the dose of ionising radiation to the individual undergoing the exposure is as low as reasonably practicable and consistent with the intended diagnostic or therapeutic purpose and in doing so shall pay special attention to - assessment of patient dose or administered activity;	N/A as there is only one piece of equipment at each site to choose from	Yes

Annex B	Regulation	Evidence	Compliance
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RESEARCH	Schedule 1h)	procedures for determining whether the practitioner or operator is required to effect one or more of the matters set out in regulation 7(4) including criteria on how to effect those matters and in particular procedures for the use of dose constraints established by the employer for biomedical and medical research programmes falling within regulation 3(d) where no direct medical benefit for the individual is expected from the exposure;	Procedure K	Yes
	4 (3) d	(the employer shall establish) dose constraints for biomedical and medical research programmes falling within regulation 3(d) where no direct medical benefit for the individual is expected from the exposure.	Procedure K 2	Yes
	6 (1) c	No person shall carry out a medical exposure unless - in the case of a medical or biomedical exposure as referred to in regulation 3(d), it has been approved by an <a href="#">Local Research Ethics Committee</a> ; ; (amendment 3(3))	Procedure K 1	Yes
	6 (3) b	the practitioner justifying an exposure pursuant to paragraph (1)(a) shall pay special attention to – exposures that have no direct health benefit for the individuals undergoing the exposure	Procedure F 3	Yes
	7 (4) a	For each medical or biomedical research programme falling within regulation 3(d), the employer's procedures shall provide that - the individuals concerned participate voluntarily in the research programme;	Procedure K 5	Yes
	7 (4) b	the individuals concerned are informed in advance about the risks of the exposure;	Procedure K 5	Yes
	7 (4) c	the dose constraint set down in the employer's procedures for individuals for whom no direct medical benefit is expected from the exposure is adhered to; and	Procedure K 3	Yes
	7 (4) d	individual target levels of doses are planned by the practitioner for patients who voluntarily undergo an experimental diagnostic or therapeutic practice from which the patients are expected to receive a diagnostic or therapeutic benefit.	Procedure K 4	Yes

Annex B	Regulation	Evidence	Compliance
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MEDICO-LEGAL	Schedule 1c)	procedures to be observed in the case of medico-legal exposures;	Procedure E This procedure contains more than just medico-legal exposures.	Yes
	6 (1) d	No person shall carry out a medical exposure unless - in the case of an exposure falling within regulation 3(e), it complies with the employer's procedures for such exposures; and	Procedure E	Yes
	6 (3) a	the practitioner justifying an exposure pursuant to paragraph (1)(a) shall pay special attention to - exposures on medico-legal grounds;	Procedure E 2 <sup>nd</sup> and 4 <sup>th</sup> paragraph Procedure F 3	Yes
	7 (7) a	Optimisation - the practitioner and the operator shall pay special attention to - the need to keep doses arising from medico-legal exposures as low as reasonably practicable;	Not mentioned	Improvement needed

Annex B	Regulation	Evidence	Compliance
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WRITTEN INSTRUCTIONS FOR NUCLEAR MEDICINE	Schedule 1i)	procedures for the giving of information and written instructions as referred to in regulation 7(5);	N/A	
	7 (5) a	In the case of patients undergoing treatment or diagnosis with radioactive medicinal products, the employer's procedures shall provide that, where appropriate, written instructions and information are provided to - the patient, where he has capacity to consent to the treatment or diagnostic procedure; or	N/A	
	7 (5) b	where the patient is a child who lacks capacity so to consent, the person with parental responsibility for the child; or	N/A	
	7 (5) c	where the patient is an adult who lacks capacity so to consent, the person who appears to the practitioner to be the most appropriate person.	N/A	
	7 (6) a	The instructions and information referred to in 7 (5) shall - specify how doses resulting from the patient's exposure can be restricted as far as reasonably possible so as to protect persons in contact with the patient;	N/A	
	7 (6) b	The instructions and information referred to in 7 (5) shall - set out the risks associated with ionising radiation; and	N/A	
	7 (6) c	The instructions and information referred to in 7 (5) shall - be provided to the patient or other person specified in paragraph (5) as appropriate prior to the patient leaving the hospital or other place where the medical exposure was carried out.	N/A	

Annex B	Regulation	Evidence	Compliance
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DIAGNOSTIC REFERENCE LEVELS	Schedule 1g)	procedures for the use of diagnostic reference levels established by the employer for radiodiagnostic examinations falling within regulation 3(a), (b), (c) and (e), specifying that these are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied;	Procedure I 1 <sup>st</sup> paragraph	Yes
	4 (3) c	(the employer shall establish) diagnostic reference levels for radiodiagnostic examinations falling within regulation 3(a), (b), (c) and (e) having regard to European diagnostic reference levels where available;	Procedure I 1 <sup>st</sup> paragraph	Yes
	4 (6)	The employer shall undertake appropriate reviews whenever diagnostic reference levels are consistently exceeded and ensure that corrective action is taken where appropriate.	Procedure I 2	Yes
	7 (3) c	the operator shall select equipment and methods to ensure that for each medical exposure the dose of ionising radiation to the individual undergoing the exposure is as low as reasonably practicable and consistent with the intended diagnostic or therapeutic purpose and in doing so shall pay special attention to - adherence to diagnostic reference levels for radiodiagnostic examinations falling within regulation 3(a), (b), (c) and (e) as set out in the employer's procedures.	N/A as there is only one piece of equipment at each site to choose from	Yes
INCIDENT REPORTING	4 (5)	Where the employer knows or has reason to believe that an incident has or may have occurred in which a person, while undergoing a medical exposure was, otherwise than as a result of a malfunction or defect in equipment, exposed to ionising radiation to an extent much greater than intended, he shall make an immediate preliminary investigation of the incident and, unless that investigation shows beyond a reasonable doubt that no such overexposure has occurred, he shall forthwith notify the appropriate authority and make or arrange for a detailed investigation of the circumstances of the exposure and an assessment of the dose received.	Procedure J Consideration needs to be given to the title of this procedure to ensure that it reflects the content. It also needs to reflect the duties of the MPE as well as the RPA. 7. needs to reflect the different multiplication factors for reporting exposures MGTI to HSE or HIW	Yes

Annex B	Regulation	Evidence	Compliance
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CLINICAL EVALUATION	Schedule 1j)	procedures for the carrying out and recording of an evaluation for each medical exposure including, where appropriate, factors relevant to patient dose;	Procedure G This procedure needs to reflect all practice within the Health Board e.g. radiographer reporting Entitlement of staff as operators for the purpose of clinical evaluations needs to be clear as it is implied that in some situations it may be the responsibility of the referrer	Yes
	7 (8)	The employer shall take steps to ensure that a clinical evaluation of the outcome of each medical exposure, is recorded in accordance with the employer's procedures or, where the employer is concurrently practitioner or operator, shall so record a clinical evaluation, including, where appropriate, factors relevant to patient dose.	Procedure G 1 and 5	Yes
MEDICAL PHYSICS EXPERT	9 (1)	The employer shall ensure that a medical physics expert shall be involved in every medical exposure to which these Regulations apply in accordance with paragraph (2).	Standard Operating Procedures in Radiography – Responsibilities of the Chief Executive Medical Physics support was evident during the inspection by 3 <sup>rd</sup> party providers. They confirmed their role as MPE	Yes
	9 (2) a	A medical physics expert shall be - closely involved in every radiotherapeutic practice other than standardised therapeutic nuclear medicine practices;	N/A	
	9 (2) b	A medical physics expert shall be - available in standardised therapeutic nuclear medicine practices and in diagnostic nuclear medicine practices;	N/A	
	9 (2) c	A medical physics expert shall be - involved as appropriate for consultation on optimisation, including patient dosimetry and quality assurance, and to give advice on matters relating to radiation protection concerning medical exposure, as required, in all other radiological practices.	Discussed support with radiographers and medical physicists on site	Yes
PROB & MAG	Schedule 1k)	procedures to ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced so far as reasonably practicable.	Although there are elements throughout the other procedures there was not a single procedure	Improvement needed

Annex B	Regulation	Evidence	Compliance
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QUALITY ASSURANCE & AUDIT	Schedule 1e)	procedures to ensure that quality assurance programmes are followed;	<p>Procedure M 3</p> <p>These call for one audit of an SOP each year. Thought should be given as to the frequency of these. There was good evidence of audits on completion of request cards, LMP enquiries and recorded doses on site but needs to be documented</p>	I Improvement needed
	4 (3) b	(the employer shall establish) quality assurance programmes for standard operating procedures;	Procedure M 3	Yes
	8	The employer's procedures shall include provision for the carrying out of clinical audit as appropriate.	<p>Procedure G 6</p> <p>Procedure H 4</p> <p>Procedure I 2 &amp; 3</p> <p>These need to reflect the frequency of the audit, who is responsible for carrying these out and where the results are reported to.</p>	Yes
	7 (3) a	the operator shall select equipment and methods to ensure that for each medical exposure the dose of ionising radiation to the individual undergoing the exposure is as low as reasonably practicable and consistent with the intended diagnostic or therapeutic purpose and in doing so shall pay special attention to -quality assurance	N/A as there is only one piece of equipment at each site to choose from	Yes

Annex B	Regulation	Evidence	Compliance
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EQUIPMENT	10 (1)	The employer shall draw up, keep up-to-date and preserve at each radiological installation an inventory of equipment at that installation and, when so requested, shall furnish it to the appropriate authority.	Provided by Health Board on site	Yes
	10 (2)	The inventory referred to in paragraph (1) shall contain the following information (a) name of manufacturer (b) model number (c) serial number or other unique identifier (d) year of manufacture and (e) year of installation	Procedure K and Equipment Inventory provided on site	Yes
	10 (3)	The employer shall ensure that equipment at each radiological installation is limited to the amount necessary for the proper carrying out of medical exposures at that installation.	A dental unit within the radiology department at Brecon War Memorial Hospital is rarely being used. It is not clear how the operators are able to remaining competent and adequately trained on this unit. We have been informed that At Brecon War Memorial Hospital there are digital dental units which are in use by operators who undertake these exams regularly. Thought needs to be given to the continued use of this machine.	Improvement needed
	4 (1) b	The employer shall ensure that written procedures for medical exposures including the procedures set out in Schedule 1 are in place and - where the employer is concurrently practitioner or operator, he shall comply with these procedures himself.	N/A	
	4 (4) c	The employer shall ensure that written procedures for medical exposures including the procedures set out in Schedule 1 are in place and - where the employer is concurrently practitioner or operator, he shall himself ensure that he undertakes such continuing education and training as may be appropriate.	N/A	
	5 (1)	The practitioner and the operator shall comply with the employer's procedures	Standard Operating Procedures in Radiography (page 7)	Yes



Annex B	Regulation	Evidence	Compliance
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	5 (7)	For the avoidance of doubt, where a person acts as employer, referrer, practitioner and operator concurrently (or in any combination of these roles) he shall comply with all the duties placed on employers, referrers, practitioners or operators under these Regulations accordingly.	N/A	
	7 (1)	In relation to all medical exposures to which these Regulations apply except radiotherapeutic procedures, the practitioner and the operator, to the extent of their respective involvement in a medical exposure, shall ensure that doses arising from the exposure are kept as low as reasonably practicable consistent with the intended purpose.	Demonstrated on site and through staff discussions	Yes
	7 (2)	In relation to all medical exposures for radiotherapeutic purposes the practitioner shall ensure that exposures of target volumes are individually planned, taking into account that doses of non-target volumes and tissues shall be as low as reasonably practicable and consistent with the intended radiotherapeutic purpose of the exposure.	N/A	
	7 (9)	In the case of fluoroscopy - (a) the operator shall ensure that examinations without devices to control the dose rate are limited to justified circumstances; and (b) no person shall carry out an examination without an image intensification or equivalent technique.	Equipment list and corroborated on site	Yes