

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 Department,
Withybush General Hospital,
Hywel Dda Health Board**

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Healthcare Inspectorate Wales

Bevan House
Caerphilly Business Park
Van Road
CAERPHILLY
CF83 3ED

Tel: 029 2092 8850

Fax: 029 2092 8877

www.hiw.org.uk

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

Organisation:	Hywel Dda Health Board
Site Inspected:	Withybush General Hospital
Date of Inspection:	9 October 2009

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Healthcare Inspectorate Wales
Bevan House
Caerphilly Business Park
Van Road
Caerphilly
CF83 3ED

Telephone Number: 029 2092 8850

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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 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, the Local Supervising Authority for the Statutory Supervision of Midwives and is responsible for monitoring approved nurse education programmes provided by higher education institutions in Wales.

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.

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 department, 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 Withybush General Hospital provides a diagnostic imaging service for a local population of approximately 112,900 which can increase significantly during the summer months when there are many visitors to the area. The hospital is located in Haverfordwest, Pembrokeshire and is one of the District General Hospitals that form part of Hywel Dda Health Board.

2.2 Each year, the diagnostic imaging department carries out approximately 40,776 general 'plain film' radiography procedures. The department also carries out Fluoroscopy, Computerised Tomography (CT) Scanning, Magnet Resonance (MR) Scanning, Symptomatic Mammography, Medical and Antenatal Ultra Sound Scanning, and Dental procedures.

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

4.8	Whole Time Equivalents (WTE) Consultant Radiologists,
6.51	WTE Reporting Sonographers
21.225	WTE general Radiographers
6	Students on placement per annum
1	Radiation Protection Supervisor (RPS)

and the departments Physicists are contracted from the Regional Medical Physics Service.

2.4 At the time of the visit, the department reported having one long term Sonographer vacancy and there was also a restriction on recruiting a trainee Sonographer.

2.5 Between January 2001 and the date of the inspection the Welsh Assembly Government (WAG) had received five notifications from the diagnostic imaging department of exposures 'much greater than intended'. The circumstances of each incident have been fully reviewed by the WAG's specialist advisor and appropriate actions taken.

Chapter 3 The Inspection

3.1 On the 9 October 2009 an assessment of the diagnostic imaging department at Wthybush General Hospital 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 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 and on radiation protection. 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; that said there is evidence of a good in-house Continued Professional Development (CPD) programme.

3.3 At the end of the inspection a few issues were raised and fed back to the team, which related to the following:

- Some of the Procedures needed to be amended to reflect current practice.
- Staff needed to be informed about the new Radiation Protection Policy and the already amended Patient Identification and Pregnancy procedures.
- The written Protocols in place within the department need to have a system of document control.

- The principles of IR(ME)R need to be re-visited with staff so that they clearly understood their role and responsibilities.
- Provisions for the carrying out of Clinical Audit need to be put into place

3.4 We identified no major areas of concern during this inspection visit.

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 the majority of their procedures were in place and were in line with regulatory requirements and that staff were adequately trained. There are, however, some further actions that are required in order to further improve the department and details of these may be found in Annex A.

Regulation	Recommendation
Regulation (1) Duties of the Employer	Further work on reviewing the procedures needs to be undertaken in order to reflect current practice
Regulation (3) b Duties of the Employer	A system of document control needs to be in place for all IR(ME)R documents
Regulation 8	Provisions for Clinical audit need to be in place
	There needs to be a clear plan developed to ensure staff are aware of the new Radiation Protection Policy and the revised procedures

IR(ME)R Feedback Following Inspection

WITHYBUSH GENERAL HOSPITAL, HYWEL DDA HEALTH BOARD

	Regulation	Evidence	Compliance
<p>Details of the required improvements are listed below</p> <p>If the texts background is blue it is deemed required by legislation</p> <p>If the texts background is white it is suggested or may be considered best practice</p> <p>All procedures must comply with legislation and match local practice</p>			
APPLICATION	3	<p>These Regulations shall apply to the following medical exposures -</p> <ul style="list-style-type: none"> (a) the exposure of patients as part of their own medical diagnosis or treatment; (b) the exposure of individuals as part of occupational health surveillance; (c) the exposure of individuals as part of health screening programmes; (d) the exposure of patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes; (e) the exposure of individuals as part of medico-legal procedures. 	<p>Hywel Dda Ionising Radiation Safety Policy 1.3</p> <p>Yes</p>

PROCEDURE S	4 (1) a	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;	Hywel Dda Ionising Radiation Safety Policy 6.16 and 6.17	Yes
ENTITLEMENT	Schedule 1b)	procedures to identify individuals entitled to act as referrer or practitioner or operator;	New entitlement procedure - needs to reflect use of Medica as discussed during inspection and entitle the MPE	Improvement required
	Entitlement	<u>Authorisation to carry out entitlement</u> The task of entitlement can be delegated but not the responsibility. This always lies with the employer. This should be reflected throughout this document as it is repeated within other sections		
	Entitlement	<u>1.1 Medical Referrers – Who can refer – General Practitioners</u> All GP's within the Trusts catchment area are entitled but what provisions are in place for a GP outside the catchment area or if a referral comes in for a GP not currently entitled?		
	Entitlement	<u>1.2 Dental Referrers – Who can refer</u> The use of the term 'Trust catchment area' suggests that the Medical director is also responsible for entitling the community dentists however they appear to be covered in Section B		
	Entitlement	<u>2.1 Medical Practitioners</u> It may be worth mentioning that the primary function of the practitioner is to undertake the justification of the medical exposure Regulation 5(2) for Medical practitioners as it is clearly stated in 2.2 for non medical practitioners.		
	Entitlement	<u>2.1 Medical Practitioners – Who can act as a Practitioner</u> Who is responsible for ensuring that the Practitioner list is kept up to date?		

	Entitlement	Are Dentists within the hospital acting as practitioners? Do they issue guidelines or justify exposures?	
	Entitlement	<u>3.1 Medical Operators – Who can act as an operator</u> A list of medical staff is kept by HR; does this include the scope of practice for each doctor and is every doctor entitled as an operator? Who is responsible for keeping this list up to date and ensuring that it is available to radiology staff	
	Entitlement	<u>3.1 Medical Operators – Who can act as an operator - outside the radiology department</u> Do the Dentists that work in the hospital clinically evaluate images? Also this section could mention the need to record the evaluation in line with local procedures	
	Entitlement	<u>3.2 Non-Medical Operators – Scope of Practice</u> Does this mean that an HCA's and nurses do not check ID or pregnancy within Hywel Dda? You need to operate equipment to be entitled as an operator for ID and Pregnancy according to this document	
	Entitlement	<u>3.2 Medical Physics Personnel</u> QA of equipment is required under IRR99. What functions are these physicists undertaking under IR(ME)R? This needs some further explanation	
	Entitlement	<u>3.2 Medical Physics Personnel</u> Who undertakes an assessment of training for these individuals so that the RSM may entitle them as operators? Where is an up to date list of names including scope of practice kept and who is responsible for ensuring that it is up to date? Where are the training records kept?	
	Entitlement	<u>3.2 Medical Physics Expert</u> Even after they have been appointed they still need to be entitled as an operator with a scope of practice and the training records need to be furnished on request	
	Entitlement	<u>Figure 1</u> The duty holder role is displayed in most of the boxes except for non community dentists, GP's and consultants.	

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;	Entitlement - mentioned in Section 1.1 & 1.3 but missing from 1.2	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)	Revised Hywel Dda Ionising Radiation Safety Policy 6.15	Yes
	Entitlement	<u>1.2 Dental Referrers – Scope of Practice</u> There is no mention of providing these dentists with the referral criteria as required in Reg 4 (3)a, except by the medical director in Policy 6.8. Is it correct that the Medical director makes all dentists aware of their referral criteria?		
	Entitlement	<u>Community Dental Service</u> Who is providing these dentists with the referral criteria as required in Reg 4 (3) a? Is it correct that the Medical director in the Policy 6.8 makes all dentists aware of their referral criteria?		
ID	Schedule 1a)	procedures to identify correctly the individual to be exposed to ionising radiation;	EP 005 needs date and signature	Yes
PREGNANCY	Schedule 1d)	procedures for making enquiries of females of childbearing age to establish whether the individual is or may be pregnant or breastfeeding;	EP 004 needs date and signature	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.	EP 004 Responsibility	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	EP 004 Procedure 3.2, 4.2, 4.3 & 5 discussed during inspection	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.	EP 004 Procedure 5	Yes
	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	discussed during inspection	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.	EP 004 Procedure 5 discussed during inspection and with staff	Yes
	EP 004	Procedure 4 Ensure that local practice is reflected within this procedure, would you proceed if the LMP was within dates?		
AND AUTHO RISATION	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	EP 008 needs date and signature Procedure 8 and 9	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;	EP 008 Procedure 9	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;	EP 008 Procedure 8	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;	EP 008 Responsibility and Procedure 8	Yes
6 (2) c	The matters referred to in paragraph 6 (1)(a) are – the individual detriment that the exposure may cause; and	EP 008 Purpose and Procedure 8	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.	EP 008 Responsibility and Procedure 8	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.	EP 008 Procedure 4	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.	EP 008 Procedure 12	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	EP 006 2	Yes

	EP 008	<u>Procedure 9</u> This could be strengthened by adding the phrase 'No person shall carry out a medical exposure unless it has been justified and authorised'	
	Guidelines	Justification guidelines need to be clearly identified and be approved for use by an appropriate and entitled practitioner	
PROTOCOLS	4 (2)	The employer shall ensure that written protocols are in place for every type of standard radiological practice for each equipment	Some protocols provided and protocols for each type of standard practice demonstrated during inspection 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.	Procedures in place 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).	Hywel Dda Ionising Radiation Safety Policy 6.16 and 6.17 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.	Hywel Dda Ionising Radiation Safety Policy 6.16 and 6.17 Yes
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.	EP 006 4 Training Yes

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.	Entitlement Some Training records seen during inspection	Yes
11 (4)	The employer shall keep and have available for inspection by the appropriate authority an up-to-date record of all training undertaken by (amendment 3(4)) 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.	EP 006 4 Entitlement	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.	EP 006 4	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	Hywel Dda Ionising Radiation Safety Policy 6.16 and 6.17	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	EP 006 4 Excellent in house CPD programme	Yes

	EP 006	1 Referrer Does not mention referral criteria for dentists		
	EP 006	3 Operator Could be clearer by listing some of the practical aspects and other critical roles and responsibilities		
	EP 006	4 Training Staff are not 'acting as' they are 'entitled'.		
	EP 006	5.4 New radiographer should be entitled not 'allowed' to take on the practitioner role		
	records	Training records seen at site could be improved as discussed		
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 and protocols in place written by a paediatric consultant radiologist	Yes
	7 (7) c	Optimisation - the practitioner and the operator shall pay special attention to - medical exposures as part of a health screening programme;	No breast screening only symptomatic - self assessment form	
	7 (7) d	Optimisation - the practitioner and the operator shall pay special attention to - medical exposures involving high doses to the patient;	Discussions with CT staff demonstrated good practice and communication between radiologist and radiographers	Yes
DOSE ASSESSMENT	Schedule 1f)	procedures for the assessment of patient dose and administered activity;	EP 017 needs date and signature	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;	Discussed with staff on site during inspection	Yes

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;	EP 011 needs date and signature	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.	EP 011 Procedure 7	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 Ethics Committee; (amendment 3(3))	EP 011 Procedure 1 & 2	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	EP 011 Procedure 4 & 7	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;	EP 011 Procedure 10	Yes
	7 (4) b	the individuals concerned are informed in advance about the risks of the exposure;	EP 011 Procedure 10	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	EP 011 Procedure 18	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.	EP 011 Procedure 9	Yes
	EP 011	Procedure 4 Could be strengthened by adding that special attention will be given to exposures that have no direct health benefit for the individuals undergoing the exposure		
MEDICO-LEGAL	Schedule 1c)	procedures to be observed in the case of medico-legal exposures;	EP 007 out of date	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	EP 007	Yes
	6 (3) a	the practitioner justifying an exposure pursuant to paragraph (1)(a) shall pay special attention to - exposures on medico-legal grounds;	EP 007 Background and Procedure	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;	EP 007 Procedure 8	Yes
FOR	Schedule 1i)	procedures for the giving of information and written instructions as referred to in regulation 7(5);	Not inspected	

	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	Not inspected	
	7 (5) b	where the patient is a child who lacks capacity so to consent, the person with parental responsibility for the child; or	Not inspected	
	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.	Not inspected	
	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;	Not inspected	
	7 (6) b	The instructions and information referred to in 7 (5) shall - set out the risks associated with ionising radiation; and	Not inspected	
	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.	Not inspected	
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;	EP 010 needs date and signature	Improvement required

	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;	Not mentioned	
	4 (6)	The employer shall undertake appropriate reviews whenever diagnostic reference levels are consistently exceeded and ensure that corrective action is taken where appropriate.	EP 010 – Procedure 6	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.	Discussed with staff on site during inspection	Yes
	EP 010	This procedure should include that regard is given to national reference levels and that these are not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied		

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.	EP 012 needs date and signature	Improvement required
	EP 012	Needs to recognise MPE as well as RPA		
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;	EP 009 out of date EP 017 RAD 016	Improvement required
	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.	Entitlement 3.1 RAD 016	Yes
	EP 009	Needs to reflect that the task of clinical evaluation is an operator task not a practitioner one		
	EP 009	Needs to be updated to reflect current working practices and there needs to be audit to ensure that the evaluation is being recorded within patients notes		

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).	Hywel Dda Ionising Radiation Safety Policy 6.1 and 6.11 Entitlement	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.	Hywel Dda Ionising Radiation Safety Policy 6.11	Yes
	Entitlement	MPE must be entitled as previously mentioned		
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.	EP 020 needs date and signature	Improvement required
QUALITY ASSURANCE & AUDIT	Schedule 1e)	procedures to ensure that quality assurance programmes are followed;	EP 018 needs date and signature - Document QA only	Improvement required
	4 (3) b	(the employer shall establish) quality assurance programmes for standard operating procedures;	Only RAD 016 mentions audit of process	Improvement required
	8	The employer's procedures shall include provision for the carrying out of clinical audit as appropriate.	Audit mentioned in RAD16 but not on others needs improving	Improvement required

	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	Discussed with staff on site during inspection	Yes
		Need to demonstrate clinical audit programme for procedures		
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.	Equipment Inventory	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	Equipment Inventory	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.	Policy 4 (g)	Yes
	Equipment Inventory	Layout could be improved		

	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	Policy 6.14 , 6.16 and 6.17	Yes
	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.	Policy 4(d)	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 Inventory The fluoroscopy equipment installed and used at Withybush Hospital has controls for dose rates and an II	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.	Discussed with staff on site during inspection – students directly supervised	Yes