Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

DRIVING IMPROVEMENT THROUGH INDEPENDENT AND OBJECTIVE REVIEW

IR(ME)R Inspection (Announced)
Abertawe Bro Morgannwg University Health Board
Princess of Wales Hospital
Radiology Department

18 and 19 August 2014

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Contents

1. Introduction

An inspection to assess compliance with the Ionising Radiation (Medical Exposure) Regulations 2000 and the 2006 and 2011 amendments for diagnostic imaging was undertaken on 18th and 19th August 2014 at the radiology department at Princess of Wales Hospital (POWH), Bridgend part of the Abertawe Bro Morgannwg University (ABMU) Health Board. The inspection was led by Healthcare Inspectorate Wales (HIW) and supported by Public Health England (PHE).

Methodology for Inspection

1.2 The healthcare organisation was selected as part of HIW's annual planned inspection programme. It is the first time the department has been subject to an IR(ME)R inspection.

1.3 Due to operational issues within HIW the organisation received a condensed period of notice of the inspection. This was however discussed with the department senior team and it was mutually agreed to proceed with the inspection rather than delay the visit till later in the year.

1.4 During the site visit the inspection team discussed the information detailed within the self assessment with key staff. We reviewed policies, procedures, protocols and staff training records. We also reviewed patient records (as part of a patient journey approach). We undertook observations within the clinical settings and interviewed a cross section of staff in order to determine whether the information provided in the self assessment and employers written procedures was reflected in practice.

1.5 Detailed findings and associated recommendations were provided through verbal feedback throughout the inspection and more formally at the feedback meeting held at the end of the visit to enable the Health Board to make progress in undertaking any action required.

Background to the Department

1.6 Princess of Wales Hospital (POWH) is a district general hospital located in Bridgend and is part of the Abertawe Bro Morgannwg University (ABMU) Health Board.

1.7 The radiology department at POWH also provide staff for Maesteg Hospital. Neath Port Talbot Hospital have their own complement of staff however staff from POWH rotate to work there to provide cover. Staff from Neath Port Talbot Hospital also work at POWH on an ad hoc basis to ensure competency across both sites. It is hoped that this rotation will become a more formalised arrangement in the future. Radiologists provide cover across all three sites.

1.8 At the time of the inspection the self assessment form stated that the number of examinations performed by the radiology department at POWH during the year was; 80,130 general radiology (plain film), 13,291 computed tomography (CT) scans,1,000 fluoroscopy, 2058 interventional procedures, 2133 symptomatic mammography and 890 cardiac catheterisations. This inspection predominantly focused on general radiology (XRay) and CT scans carried out in the diagnostic imaging department.

1.9 Staffing comprise 10.9 whole time equivalent (WTE) consultant radiologists who also provide sessional cover on site at Neath Port Talbot Hospital (NPTH), 1 Specialist Registrar, 0.6 reporting radiographers, 29.93 radiographers, 0.8 assistant practitioners, 3 radiation protection supervisors and access to 3 radiology medical physics experts (MPE). The department is not currently working at full complement with both radiologist and radiographer vacancies.

1.10 During our visit we met with the following:

- Director of Therapies and Health Science
- Clinical Director of Clinical Support Services
- Associate Medical Director
- Associate Clinical Director for Radiology

- Radiology Services Manager
- Associate Director of Clinical Support Services
- Site Superintendent
- Radiation Protection Adviser / Medical Physics Expert (MPE)
- Cross section of radiology staff

1.11 It was noted at the time of the visit that the physical layout of the department was challenging and there were some questions in terms of whether the available space was being used effectively, however the practical difficulties in relation to this were also acknowledged.

2. Executive Summary

2.1 As a result of this inspection HIW can provide assurance that the radiology department at POWH is broadly compliant with IR(ME)R.

2.2 We received evidence from POWH that a framework and a suite of procedures were in place and discussions with staff highlighted that there appeared to be compliance with the regulations.

2.3 During the inspection we recognised areas of noteworthy practice, in particular these included;

- The robust approach taken by radiology staff with regard to checking pregnancy for patients in theatre
- A comprehensive set of procedures in place with good evidence of version control and review

2.4 We also noted however a number of areas that required further development, which were acknowledged by the radiology team at the time of the inspection, these included;

- The need to consider which procedures should be corporate and which need to be local to the service
- The need for greater clarity regarding some of the roles and responsibilities of duty holders
- The need to give urgent consideration to putting local Diagnostic Reference Levels (DRLs) in place given that the National DRLs currently in use appear to be regularly exceeded, possibly due to patient demographics
- When reviewing the procedures there is a need for greater clarity around such things as clinical evaluation for non-radiology staff with regard to entitlement, replacing the use of Korner categories to describe the scope of practice for practitioners and providing information about action to be taken when a positive response to checking pregnancy in children is disclosed

- Review of training records in terms of accuracy of completion as well as the need for equipment training records to be in place for radiologists and surgeons operating the mini c-arm

2.5 Furthermore there was representation from the Swansea hospitals at the feedback session so that lessons learned from the inspection could be shared and actioned across the Health Board on a timely basis

2.6 We would like to thank all the staff at the Radiology Department POWH for their cooperation, openness and honesty during the inspection

2.7 On publication this report has been made available on www.hiw.org.uk

3. Findings

3.1 We have structured our findings from the inspection around the key areas of IR(ME)R and the patient journey. The recommendations arising from our findings are covered in Section 4 of this report

Duties of Employer

3.2 IR(ME)R states that the employer is any person that carries out (other than as an employee), or engages others to carry out, medical exposures or practical aspects, at a given radiological installation.

3.3 For ABMU Health Board, the Chief Executive is the employer and there are appropriate lines in place to evidence the employer's authority. The Health Board's Ionising Radiation Safety Policy states that the Chief Executive has overall responsibility and this has been endorsed by the ABMU Executive Board. The Radiation Protection Committee (RPC), which oversees the implementation of the Health Board's radiation protection arrangements on behalf of the Chief Executive is chaired by the Director of Therapies and Health Sciences. This committee reports to the Quality and Safety Committee and onwards to the Executive Board.

3.4 There is also a Medical Exposures Committee (MEC) which is chaired by the Medical Director and is set up as a sub-committee of the RPC. This committee oversees the implementation of IR(ME)R.

Procedures and Protocols

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

3.6 The Health Board's RPC established their 'Policy for Ionising Radiation Safety' and a suite of radiology procedures. We found that these were generally well written and covered the appropriate areas of IR(ME)R.

3.7 We did, however, find some areas where the procedures and / or protocols could be strengthened to provide more detail for completeness and clarity and in some cases amendments for accuracy.

- There is a need to review which procedures are corporate and which are local
- Two of the examples listed in the medico-legal procedure are not medico-legal exposures
- More clarity is needed in the guidelines used to authorise CT head scans for a suspected stroke care pathway. Staff are unclear who is the practitioner for these exposures authorised against the document

3.8 The staff we met during the inspection had a good understanding of the procedures and were aware of where the copies where retained in the department when they needed to refer to them.

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

3.10 A sample of the written protocols for CT were reviewed at the time which were generally clear and well written and staff in the department did demonstrate an understanding of them. These were available in CT and staff confirmed they were aware of where to obtain copies.

Incident Notification

3.11 IR(ME)R states that where an incident has or may have occurred in which a person, whilst undergoing a medical exposure, has been exposed to ionising radiation much greater than intended, this should be investigated by the healthcare organisation and reported to the appropriate authority (HIW)

3.12 POWH maintains a record of all radiation incidents, not just those reportable under IR(ME)R, including near misses, on the incident database (Datix).

3.13 During the two years prior to the date of the inspection POWH reported 11 incidents to HIW under IR(ME)R. Since May 2014 there had been three incidents reported involving laterality errors. This was discussed with the team at the inspection and we were satisfied that full investigations of each of the incidents had been carried out with no common factors identified.

Diagnostic Reference Levels

3.14 The Regulations require the employer to establish diagnostic reference levels (DRLs) for radiographic examinations stating that these are not expected to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied

3.15 POWH use National DRLs which are displayed in the examination rooms. We were informed however that DRLs are frequently exceeded due to patient size. The POWH team were strongly advised at the time of the inspection that local DRLs should be established as the National levels were clearly not appropriate for their patient population.

Duties of Practitioner, Operator and Referrer

Entitlement

3.16 The Regulations require that duty holders must be entitled, in accordance with the employer's procedures for the tasks they undertake under IR(ME)R

3.17 The process for entitlement is described in Standard Operating Procedure (SOP) 1 and the Corporate IR(ME)R procedure A which describes the Chief Executive as delegating the task of entitlement to the Clinical Director who, in turn entitles various staff groups as referrers, practitioners and operators. Within radiology the Radiology Services Manager entitles radiographers as operators. There is a clear process in place for competence assessments for radiographers and assistant practitioners.

3.18 We suggested that the corporate IR(ME)R procedure should be reviewed to better reflect the differing roles of the Medical Director and the Clinical Director in the process of duty holder entitlement.

3.19 We also identified that the entitlement for some non-clinical staff requires clarification as in some cases non-clinical staff would be reviewing images and deciding patient treatment on the basis of the review. The radiology team were informed that in such cases the staff members need to be entitled as operators

3.20 In the procedures it states that radiographers are entitled as practitioners for Korner categories A&B however there is no list in the department describing what examinations are included in these categories. General discussion at the time of the inspection confirmed that radiographers only justify general radiography however there are examinations contained within the Korner categories that would normally only be justified by a radiologist. It was suggested that consideration be given to amending the heading on the entitlement matrix column to reflect this.

3.21 In Table 2 of the entitlement procedure, it suggests that surgeons are entitled as practitioners for cases in theatre involving the use of mobile fluoroscopy. Discussions with staff during the inspection highlighted that in reality radiographers undertake this duty

3.22 There is a group matrix in place identifying the individuals entitled as practitioners and operators. Clarification is required to demonstrate that radiologists are entitled as operators for clinical evaluation and radiographers for undertaking the exposure. Reporting radiographers are not included on the matrix and should reflect those radiographers performing clinical evaluation.

Referral

3.21 IR(ME)R states that a referrer is a healthcare professional who is entitled in accordance with the employer's procedures to refer individuals to a practitioner for medical exposures

3.22 A list of the staff groups entitled to refer for medical exposures has been produced identifying GPs, hospital doctors, dentists and non-medical referrers eg physiotherapists, nurse practitioners, radiographers.

3.23 Non-medical referrers have to complete an ABMU Health Board authorisation pack before they can be entitled which includes background evidence and identifies a mentor who has to endorse their application to be a referrer and confirm their competence. There must also be evidence to demonstrate that there is a benefit to the service by entitling the individual to be a non-medical referrer. Most non-medical referrers can only refer for general radiography

Justification of Individual Medical Exposures

3.24 The Regulations require that all medical exposures are justified and authorised prior to the exposure. The practitioner is responsible for the justification of the medical exposure. Authorisation is the means by which it is demonstrated that appropriate justification has been made and may be undertaken by the practitioner or, where authorisation guidelines have been used, an operator.

3.25 Generally the approach taken by POWH is for all examinations to be justified by a practitioner. However there are exceptions for example CT head scans on a stroke care pathway are authorised by a number of trained and competent CT radiographers.

Identification

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

3.27 Discussion took place with the team on the day of the inspection about the fact this should be a corporate procedure rather than a local one as the approach should be consistent across all sites in the Health Board.

3.28 The team informed us that they are planning to introduce a ‘pause and check’ into the identification process. This will include confirmation of clinical details with the patient in an effort to reduce the risk of laterality errors

3.29 The inspection team felt that the procedure could be laid out more clearly and could include information relating to helpful tools such as translation services. It was also discussed that an unconscious patient in theatre presents different identification issues to the emergency department patient and these could be described more explicitly in the procedure.

Females of Child Bearing Age

3.30 IR(ME)R states that written procedures for medical exposures should include procedures for making enquiries of females of child bearing age to establish whether the individual is or maybe pregnant.

3.31POWH have a clear procedure in place for establishing patient pregnancy status prior to radiological examinations. Our review found an area of noteworthy practice in respect of the robust approach taken by the radiology department in checking to see if pregnancy has been checked by theatre staff. It was reported that operations have been paused in the past by radiographers until pregnancy status has been ascertained.

3.32 From discussions with the team it was confirmed that there were some additional procedures that should be reflected in the procedure under high dose examinations.

3.33 Whilst not a regulatory requirement under IR(ME)R we noted that the procedure needed to be reviewed to reflect what should happen in the event of a positive response to an enquiry of a child under the age of 16. The inspection team suggested it would be helpful to include references to the Boards safeguarding policies and contact details of the Boards safeguarding team

Optimisation

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

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

- Equipment quality assurance checks
- Audit reviews
- Patient lead protection
- Log books for consistently exceeded DRLs

3.36 The process for documenting patient dose is that the DAP is written on the referral form which is then re-scanned onto RADIS. This process makes it very difficult to undertake dose surveys however dose information is more readily available for mammography and cardiac examinations. The CTDI is also recorded for CT in the CT log book and on PACs as part of the image file

Paediatrics

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

3.38 Paediatric specific protocols were available in each of the examination rooms

Medico Legal Procedures

3.39 The Regulations state that a medico-legal examination is performed for insurance or legal intentions without a medical indication. The practitioner and operator are required to pay special attention to the justification and optimisation of these exposures.

3.40 POWH has a procedure in place covering medico-legal procedures. The team was advised by the inspection team however that two of the examples listed in the procedure are not medico-legal exposures and as such need to be removed from the procedure or that the title of this procedure is altered to reflect the fact that occupational exposures are also included in it.

Medical Research Programmes

3.41 IR(ME)R states that for each medical or biomedical research programme, individuals must participate voluntarily and be informed in advance of the risks of exposure, dose constraint must be set down in the employer's procedures for individuals where no benefit is expected or target levels of doses are planned by the practitioner, where patients are expected to receive a benefit.

3.42 POWH undertake medical research programmes and reference to this is made in the Health Boards corporate procedure. This issue was not however discussed during the inspection visit

Clinical Evaluation

3.43 The Regulations state that the employer shall ensure a clinical evaluation of the outcome of each medical exposure is recorded in accordance with written procedures

3.44 It was reported that audits have been undertaken of documented clinical evaluations in patient notes. We were told that they were not meeting the Welsh Government radiology reporting times. We were told that there is sometimes a backlog of up to 3,000 unreported studies, with GP and emergency referrals given priority. Reporting radiographers are currently being trained to assist in clearing the backlog. In addition a locum radiologist has been recruited to commence at the end of August which will also help in tackling the problem.

3.45 A ‘red star’ unexpected findings system has been in place since February 2014. This approach means that when a secretary types a ‘red star’ report it is emailed directly to the referrer, who then acknowledges receipt of the report. A system of ‘back up’ email addresses has also been put in place to deal with occasions when referrers are on leave etc.

3.46 Clinical evaluation by non-medical referrers and the extent to which the referrers have been entitled as operators was highlighted earlier in the section relating to entitlement. We were informed that this issue is to be discussed with the MEC in relation to training and competence.

Clinical Audits

3.47 IR(ME)R states that employers procedures shall include provision for carrying out clinical audits as appropriate

3.48 Most audits are undertaken by the radiologists. A few audits have taken place but they relate many to clinical practice issues. A proforma for IR(ME)R audits is about to be introduced which will assist in for example picking a random sample of referrals and checking the form has been completed correctly

Expert Advice

3.49 IR(ME)R states that the employer shall ensure a MPE is involved as appropriate in every radiological medical exposure

3.50 There is access to three MPE's across ABMU Health Board who provide consultation on optimisation, including patient dosimetry and quality assurance, as well as on matters relating to radiation protection concerning medical exposure

Equipment

3.51The Regulations state that the employer shall keep an up to date inventory of equipment for each radiological installation

3.52 POWH maintain an up to date inventory of all radiological equipment at the hospital which is organised by examination room; this includes the details of manufacturer, model, serial number, date of installation, date of manufacture

Training

3.53 The Regulations require that all practitioners and operators are adequately trained for the tasks they undertake and the employer keeps up to date records of this training

3.54 We reviewed a sample of staff training records working in various roles spanning different grades and whose length of service varied. We found that there were a number of the records that were incomplete or that had been filled in incorrectly

3.55 There were also no documented equipment training records in place for radiologists or mini C arm users. We were assured this training is carried out however there were no documents to evidence it.

4. Recommendations

4.1 The recommendations set out below address any non-compliance with the Ionising Radiation (Medical Exposure) Regulations 2000 and amendments 2006 and 2011 that we identified as a result of the inspection

IR(ME)R Regulation	Finding (Paragraph Reference)	Recommendation
Schedule 1b Entitlement	3.18 3.19 3.20, 3.21, 3.22	**Entitlement** We recommend that the corporate IR(ME)R procedure should be reviewed to better reflect the differing roles of the Medical Director and the Clinical Director in the process of duty holder entitlement. Entitlement for some non-radiology staff as operators for clinical evaluation requires clarification We recommend the need to amend the entitlement matrix to ensure accuracy in relation to the examinations that practitioners are entitled for
Regulation 4(1)	3.7 3.40	We recommend the need to review which procedures are corporate and which are local The examples listed in the medico-legal procedure need to be reviewed as two are not medico-legal procedures The procedure for patient identification needs to be reviewed and the lay out improved

	3.29	
Regulation 4(6) Regulation 7(3)c	3.15	We recommend the need to review the usage of National DRLs as we were informed that these are frequently exceeded due to patient size and are clearly not appropriate for the patient population. Local DRLs need to be established
Regulation 11 Schedule 2	 3.54 3.55	**Training** We recommend the need to review training records in terms of accuracy of completion Equipment training records need to be in place for radiologists and surgeons operating the mini c-arm
	3.33	Whilst not a regulatory requirement under IR(ME)R we would recommend that the procedure for checking pregnancy be reviewed to reflect what should happen in the event of a positive response to an enquiry of a child under the age of 16.
	3.7	More clarity is needed in the protocol for justifying / authorising CT heads for suspected stroke patients as to who is the practitioner for the examinations authorised within the document