

**Ionising Radiation
(Medical Exposure)
Regulations Inspection
(announced)**

Betsi Cadwaladr University
Health Board: Ysbyty
Gwynedd Bangor
Radiology Department

22 and 23 January 2015

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1. Introduction

A compliance inspection against the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000 and regulation amendments 2006 and 2011 for diagnostic imaging was undertaken on 22nd & 23rd January 2015 at the radiology department Ysbyty Gwynedd , part of the Betsi Cadwaladr University Health Board

Our inspection considers the following issues in the context of the regulations:

- Quality of the Patient Experience
- Compliance with IR(ME)R
- Staffing Management and Leadership
- Delivery of a Safe and Effective Service

2. Methodology

HIW's 'IR(ME)R Inspections', selects a healthcare organisation as part of the annual announced IR(ME)R Inspection Programme.

We review documentation and information from a number of sources including:

- Information held to date by HIW
- Conversations with patients, relatives and discussions with staff
- Discussions with senior management within the health board
- Examination of a sample of patient medical records
- Scrutiny of policies and procedures which are required by IR(ME)R
- General observation of the environment of care and clinical practice

These inspections capture a snapshot of the standards of care patients receive. These inspections may point to wider issues about the quality and safety of services provided.

3. Context

Betsi Cadwaladr University Health Board is responsible for providing healthcare services to the population of North Wales.

The health board provides the full range of hospital and community services from three district general hospitals and a number of community hospitals

Ysbyty Gwynedd is located in Bangor in the suburb of Penrhosgarnedd. It has 506 beds which makes it the smallest of the three district general hospitals with Ysbyty Maelor at Wrexham having 540 beds and Ysbyty Glan Clwyd near Rhyl having 569 beds. Ysbyty Gwynedd also houses the headquarters of the health board.

We were informed that over the last 5 years there have been significant changes both managerially and to the infrastructure of the radiology department. This approach resulted in a complete restructuring in respect of staffing. As a result there has been an increase and improvement in terms of skill mix as well as encouragement of cross site working.

Since the formation of the Betsi Cadwaladr University Health Board the radiology departments have worked as a single Clinical Programme Group (CPG) across North Wales which at the time of the visit was clearly working well for radiology services. CPG's are similarly known as divisions in other health boards. Each CPG has their own senior management team which in radiology consists of the Chief of Staff (a radiologist), Associate Chief of Staff, Operations (general manager), Associate Chief of Staff, Radiography, (professional lead for radiographers), Head of Quality and Governance (radiographer) and a Head of Performance and Information Systems (radiographer). The CPG has a 'Board' consisting of its senior management team, site clinical directors, lead radiology nurse, trade unions and corporate members. The CPG also has monthly meetings including Quality Assurance and Governance meeting, a member of which is a patient representative, and Workforce and Finance meetings.

There was however some uncertainty about how the department will operate in the future due to work currently being undertaken to restructure.

The radiology department at Ysbyty Gwynedd installed a new nuclear medicine suite including a SPECT/CT which provides some resilience for the general CT scanner. During 2013/14 replacement CT and fluoroscopy rooms were installed and the opportunity was taken at that time to create improved patient facilities.

Radiology services provided at Ysbyty Gwynedd include:

- General radiography
- Fluoroscopy
- Computed Tomography (CT)
- Interventional Radiology
- Mammography (symptomatic)
- Magnetic Resonance Imaging (MRI)
- Ultrasound

We were informed that the department is also responsible for ionising radiation at Llandudno General Hospital, Ysbyty Bryn Beryl, Ysbyty Alltwen, Ysbyty Penrhos Stanley, Dolgellau and Barmouth District Hospital, Twywn Memorial Hospital and Ysbyty Eryri.

4. Summary

The inspection was exceptionally well received by the departmental management team and the standard of documentation submitted to HIW prior to the inspection was very high. The whole experience was very positive for the inspection team and the department should be commended for their high standards of work and compliance with IR(ME)R.

The inspection team were content and reassured that there were no breaches in relation to the regulations. The inspection was an extremely positive experience and it was clear from our discussions, observations and scrutiny of the documentation that staff were committed to the service and safety of patients.

There has clearly been significant change for staff and managers over the last 5 years however this change appears to have been managed proactively and effectively with staff being supported throughout.

5. Findings

Quality of the Patient Experience

Overall we found that patients felt the quality of their experience whilst visiting the department was good. Positive feedback was received about the department and the information they received. In addition everyone commented about the staff and how friendly and helpful they were to them during their visit.

In order to gather the views of patients and their families about the service they received from the department at Ysbyty Gwynedd a brief questionnaire was completed by a number of patients who placed their responses in sealed individual envelopes which we took away at the end of the inspection.

Everyone who completed the questionnaire said that arranging their appointment was straight forward and one person commented:

“It was extremely straight forward and it came through very quickly.”

Everyone said that the department was easy to find and two people commented that the signage to the department was “very clear”. All patients said that they had been given enough information about their treatment and that they were clear about what was going to happen

When asked how they viewed the staff within the department, everyone without exception commented that they were very good or excellent. One person commented:

“They are very friendly and helpful and you are always greeted with a reassuring smile.”

No one who responded said they had experienced any delays in the department however one person did comment that they had problems parking at the hospital.

In terms of cleanliness within the department everyone commented that they felt it was very clean and tidy or that it was excellent. One person commented that whilst the X ray department was very clean he / she had seen a number of wards in the hospital which would benefit from a deep clean. Our observations as an inspection team also confirmed that the department was clean and well maintained.

Only one person made any additional comments however these did not relate to the radiology department and have been fed back to managers who oversee inpatient services.

It was clear from our visit that there are limitations in terms of design for the department in that there is a main hospital corridor running through it which is not ideal. It is clear however that wherever possible opportunities have been taken to maximise space and privacy such as creating separate waiting areas for in patients and out patients as an example

Compliance with IR(ME)R

Duties of Employer

The definition in IR(ME)R means any natural or legal person who, in the course of a trade, business or other undertaking, carries out (other than as an employee), or engages others to carry out, medical exposures or practical aspects, at a given radiological installation

Betsi Cadwaladr University Health Board has a policy document in place entitled 'Ionising Radiation Protection Policy' that clearly explains the duties of the employer.

The overarching policy is well written and clearly defines the duties and responsibilities of the employer as required under IR(ME)R. The policy clearly defines the Chief Executive of the health board as having the responsibility as the employer for ionising radiation across the region.

The Policy clearly describes both organisational and individual responsibilities. The employer's procedures are accurately referenced.

Document and version control for this policy are clearly noted and there is a clear committee structure in place and the procedures are reviewed by the Radiation Governance Group in radiology and then ratified by the Radiology CPG Quality and Safety Group. The Executive Chair of the overarching Radiation Protection Committee reports to the Board via the Clinical Effectiveness sub Committee and the Quality, Safety and Experience Sub Committee. There is also a direct link to the Chief Executive for escalation of urgent matters which was confirmed by the Assistant Director of Therapies and Healthcare Science during our discussions.

Procedures and Protocols

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

The health board have a suite of procedures in place as required under IR(ME)R that are clearly written and comprehensive

All the procedures required under IR(ME)R were in place and there was a clear process both across the health board and within radiology for document control in the context of review.

An annual cycle of business has been developed in radiology that includes a process for annual review of procedures by the Radiation Governance Group in

radiology which are then ratified by the Quality and Safety Group within the CPG. This approach was developed as a result of taking on board feedback from a previous IR(ME)R inspection at Wrexham Maelor Hospital which demonstrated that the radiology service is committed to continuous improvement and development.

From our discussions with staff within the department it was clear that they had a good understanding of their roles and responsibilities, as laid out within the procedures. This understanding was also observed in practice at the time of the visit.

There was a clear process in place for ensuring that staff were made aware of any changes made to policies. Some of the approaches include daily department 'huddles' which supported the process of effective communication within the department along with local and divisional Quality and Safety meetings and newsletters.

Examination protocols

General radiographic protocols were present and a review date was clearly noted. There were both adult and paediatric protocols and exposure charts available and the staff when questioned were able to describe where and when they are used. During the inspection of the CT scanning unit CT protocols were reviewed and appeared comprehensive, included version control and review date. Discussions with staff were conducted as to how they ensure paediatric CT protocols were used for children.

Incident notifications

IR(ME)R states that where an incident has 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).

There is a clear process in place for the reporting of incidents which was clearly understood by staff.

When an incident occurs staff complete a DATIX reporting form and a radiation incident reporting sheet. There is a flowchart attached to the back of the form which clearly outlines the procedure to be followed in deciding whether it requires external notification.

The team explained that there had been some under reporting of incidents in a part of the health board which had now been addressed

There was clearly an open reporting culture in place which was reflected by the notifications received by HIW. It was encouraging to see that any learning from these events is taken very seriously with robust processes in place for sharing and disseminating learning as a result.

Safety bulletins were prepared to assist the process of learning as a result of incidents which is to be commended. In CT a workshop had been organised to consider what was good and not so good as a result of incidents having occurred. This we were told proved to be very successful and a second workshop is in the process of being arranged. In addition an annual report is also prepared by medical physics based on incidents that have occurred during the year.

Diagnostic reference levels

The regulations require the employer to establish diagnostic reference levels (DRL) for radio diagnostic 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.

Diagnostic reference levels had been established and there was a robust procedure in place

Employers Procedure RAD 09 Procedure for Diagnostic Reference Levels outlines the procedure for the use of DRLs and clearly explains the process to follow if DRLs are consistently exceeded. The Radiology Department utilises local DRLs taking a set of the more common examinations reflecting the cohort of the population.

It was also discussed that whilst the hospital does not perform enough examinations on babies and small children to produce a set of local DRLs for common examinations the doses are monitored and reviewed regularly by medical physics. Graphic records were provided for the inspector to see.

The procedure describes how the local DRLs are compiled and there are clear flow charts describing the annual and three yearly appraisal and re measurement There was evidence in each area inspected of up to date LDRLs and staff ,when questioned, demonstrated their understanding of how and when the DRL should be used.

Duties of Practitioner, Operator and Referrer

Entitlement

The regulations require that duty holders must be entitled, in accordance with the employer's procedures for the tasks they undertake.

There is a clear and detailed procedure in place that identifies staff entitled to act in the roles with reference to the examinations using ionising radiation being performed by the radiology CPG. It also identifies the level of training required to act in each capacity.

The overarching health board Ionising Radiation Protection Policy gives general guidance on entitlement whilst the Employers Entitlement Procedure RAD4 clearly outlines the individuals entitled to act as referrer, practitioner and operator for medical exposures.

The referral criteria are published on the health board intranet site and HOWIS. GPs are also informed of their duties as a referrer by letter.

The employer's procedure and the Ionising Radiation Policy (Appendix 2 general guidance on entitlement) clearly outline who is responsible for entitling the staff groups and individuals performing the duties of referrer practitioner and operator.

The procedure clarifies further who, when trained and competent are entitled to be referrers practitioners and operators and includes the latter's training requirements. A matrix is used to help clarification and this appeared to work well.

The procedure also included examples of the sign off forms for entitlement.

It was evident from the discussion with staff in the department that all who were asked were aware of their roles duties and entitlement and could describe where they would go for information if they had a query with regard to any entitlement queries.

Non medical referrers and practitioners were found to be comprehensively included in the procedure and policy.

Referrer

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.

A compliant, clear and effective process is in place for referrer entitlement.

The Entitlement procedure RAD 4 clearly lists those professional groups of staff that can refer and what they are entitled to refer for. All groups, including non-medical referrers, are clearly documented and a description of where the lists of named individuals can be accessed is included.

Less common referrals such as tertiary referrals and those from external healthcare organisations are described and a process to follow is included.

Those acting as referrer practitioner and operator also have a process described in the procedure.

The process for reminding referrers in primary and secondary care of their responsibilities is issued on an annual basis by the Radiology CPG. This noteworthy practice demonstrates the Radiology CPG's commitment to leading and encouraging safe and compliant practice.

There is also an entitlement matrix of entitlement which was found to be up to date.

Justification of Individual Medical Exposures

The regulations require that all medical exposures should be 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 can be demonstrated that justification has been carried out and may be undertaken by the practitioner or, where justification guidelines are used, an operator.

There is an electronic matrix of entitlement in place along with written confirmation and additional training where required. Each request is signed by the practitioner who is responsible for justifying each exposure.

The process for justification across modalities was described by the management team. Radiographers on completion and sign off of their induction and competencies are practitioners for general radiography.

CT currently has one radiographer practitioner trained and entitled to justify for CT scans and this individual is at Ysbyty Gwynedd. There are however guidelines for radiographers to authorise for CT being produced and these were presented to the inspection team in their draft form.

The process of justification for general radiography examinations was witnessed during discussions with staff and a number of both CT general and fluoroscopic examinations were retrospectively reviewed via RadIS to demonstrate staff were following the process robustly.

Identification

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

There is a clear and comprehensive procedure in place surrounding patient identification which staff understand and comply with

There is a clear procedure in place and we observed staff carrying out the patient identification process during the visit to the department which was in line with the written procedure.

The procedure clearly identifies the person who is responsible for identification and also explains what happens when a person is unable to identify themselves. It also includes the use of patient identification bands, checking with clinical staff escorting the patient as well as with relatives and or carers.

The procedure also addresses situations where more than one operator is directly involved in the medical exposure and explains that it is the operator who initiates the exposure who has overall responsibility for identification

Patient identification errors constitute a significant number of notifications across the UK and there is a campaign to promote and introduce 'Pause and Check' factors into the procedure of identification. Noteworthy practice was seen with the Good Practice Points (3.2.9) included in the Identification Procedure.

It was noted whilst observing staff that this process alerted the radiographer to the fact that a patient about to be examined had undergone an x-ray at another hospital recently. This demonstrates the process is being followed and safeguards are in place to minimise the possibility of unnecessary exposure to radiation.

Females of child bearing age

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.

There is a clear procedure in place for establishing the pregnancy status of an individual prior to the radiological examination taking place.

The procedure in place is clear and relates to all diagnostic exposures within the health board and includes all radiological investigations involving ionising radiation.

It includes details of the age range for whom an enquiry must be made and also states which person has the responsibility for making the enquiry. The procedure includes a reference to the link for child protection should a child under the age of 16 be found to be pregnant. In discussion with staff this had recently been used and the system worked.

Flow charts are attached to the procedure and clearly illustrate the process for establishing pregnancy status for both adults and patients under the age of 18.

The inspection team discussed with staff how pregnancy testing was used in the department for those patients where pregnancy cannot be excluded. It was confirmed that the pregnancy testing was not completed by the radiology department but either by the ward or the Emergency Department.

Optimisation

The regulations state that the operator and practitioner should ensure that the dose arising from the exposure is kept as low as reasonably practicable for the intended purpose.

There appeared to be good arrangements in place to ensure medical exposures are kept as low as reasonably practicable

Examples that were seen include but may not be limited to:

- Staff training –comprehensive training records(including equipment) and evidence of staff development. Specific in-house study days provided by Medical Physics Department
- Comprehensive current examination protocols for adults and paediatrics
- DRLs- in place, local, monitored and staff aware of process if consistently exceeded
- Incident management-clear process in place with evidence of learning from errors and practice change
- Recording and review of patient dose

- Comprehensive audit programme

Paediatrics

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

Evidence was seen that the radiology department had in place measures for optimising the exposures to children

There is limited paediatric imaging carried out at Ysbyty Gwynedd- indeed there is not enough data to calculate local paediatric DRLs. However as mentioned previously the exposure factors for paediatric patients are monitored by medical physics.

In general radiography areas paediatric exposure charts are clearly available and are equipment specific. Some specific paediatric imaging protocols have been developed and staff when questioned were aware of the NAI procedure

It was demonstrated there are CT paediatric protocols which have been optimised and are used. These are automatically selected when the age of the patient is programmed into the scanner however consideration was also given to the patient's weight for CT paediatric protocols.

Clinical evaluation

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.

There is a comprehensive procedure for ensuring medical exposures are clinically evaluated.

The process for evaluating images is described within the procedure and the role is clearly defined as an operator role.

Where the evaluation is not expected to be completed by Radiology Department staff the procedure contains a list of examinations and the individual /group responsible for evaluating and recording the findings. The procedure also describes who is responsible for ensuring the evaluation is completed by a suitably trained and competent individual.

Clinical audits

IR(ME)R states that employer's procedures shall include provision for carrying out clinical audits as appropriate.

The radiology department has a robust process in place for planning and undertaking clinical audit

Audit is actively encouraged by the department and is undertaken by all staff groups. All audits are registered by the audit leads with the radiology CPG and health board audit team. When completed they are presented at the radiology audit meetings which are held both locally and jointly across North Wales.

Audit is coordinated jointly by a lead radiologist and a lead radiographer who link with their colleagues in the other divisions. All radiology staff irrespective of role are encouraged to attend audit meetings.

There is a comprehensive list of audits performed. Learning opportunities for from the audit process were discussed and all staff groups are encouraged to perform and present their audit.

Expert advice

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

The Radiology CPG is actively supported by four MPE's.

The MPE's participate in the Radiation Protection Committee at both local and service wide level. The MPE also sits on the Radiology CPG Board and the Quality and Safety Committee and also chairs the Radiation Governance Group.

The MPE's are proactive in working with the service which was clearly evident at the time of the inspection.

The RPA produces an annual report summary. This overarching report looks at externally reportable radiation incidents broken down into each HB area, Central, East and West. The data is analysed further to assist learning from errors and includes audits of dose optimisation and staff radiation monitoring. This along with the Radiation Protection Newsletter is noteworthy documentation which demonstrates the HB commitment to optimisation of examinations, radiation protection and safe clinical practice.

Equipment

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

There was a clear and up to date inventory in place.

The equipment inventory was provided prior to the inspection and contains all required information including installation dates, planned replacement dates, year of manufacture, maintenance expiry dates and serial numbers.

Management and Leadership

It was clear from the inspection visit that radiology services at Betsi Cadwaladr University Health Board benefit from motivated and committed managers and leaders. The inspection was fully supported by the senior management team and this was evident from the documents received and the extent to which these were 'owned' and applied by all involved.

The experience was incredibly open and positive and managers demonstrated that they were eager to receive feedback with a view to improving what they do. The Clinical Programme Group approach clearly works well for this specialty and facilitates the sharing of information and expertise across the organisation in the context of radiology.

Over the past 5 years there have been significant changes both managerially and to the infrastructure of the radiology department. Since the formation of the health board radiology services have worked as a Clinical Programme Group across the whole of North Wales. This new approach to the structure of the service has resulted in significant change for staff with the introduction of new and different roles and increased cross site working.

The managers involved in these changes, however recognised the potential impact on staff and a comprehensive and in depth leadership programme was provided for staff working in all radiology services at a number of levels. The programme was evidently time consuming and challenging however it was clear that the service and the individuals involved have gained a great deal from it which has resulted in a cohesive team of leaders. This was clearly evident at the time of our visit.

It was interesting to note that the inclusion of a service wide post in radiology of Head of Quality and Governance appeared to have a significant impact on the extent to which there was a clear discipline, structure and coordination to the work within and across the departments.

There was clear evidence of the importance placed on effective communication and we saw a number of examples of notable practice in the form of 'Over Exposure' the quarterly radiology newsletter, the radiation protection newsletter, flyers including, 'top tips for referrers to imaging', the radiation bulletin focusing on patient safety issues and more generally lots of good news and updates.

Training

The regulations require that all practitioners and operators are adequately trained for the tasks undertaken and the employer keeps up to date records of this training.

There was clear evidence that radiologists, radiographers and others providing the diagnostic imaging service are appropriately trained and competent to carry out their roles.

All new staff attend the Betsi Cadwaladr University Health Board orientation programme in the first week of employment. The radiology induction is tailored to meet the needs of the individual for example if they are newly qualified or an experienced member. Everyone receives an induction book about radiology which is clear and comprehensive and includes details on useful information on such things as where to find policies and procedures and equipment specific training.

Individual comprehensive training records were available and up to date for all staff for the equipment they use. There were also up to date records of all induction training, mandatory training, extended role training and authorisation and the interventional training programme. Individual staff maintain their own continuous professional development (CPD) records

Some of the training is competency based and as such they have sign off sections to indicate that the competency has been achieved. The radiology CPG has developed a format for recording competency for role or skill development. The CPG is currently introducing annual competency check sheets for review at PDR for role extension

There was clear evidence that annual appraisals take place with compliance being monitored on a regular basis. 100% of all staff had an appraisal in 2013/14 and the current rate for 2014/15 is 53%.

Any member of staff on maternity leave or long term sick will receive update training that is defined locally by the radiology site manager depending on need.

Whilst not a requirement under IR(ME)R it was suggested that it might be helpful to establish a training matrix to include an at a glance view of training completed and required. The department stated they would consider this as they felt it might be something that could assist them.

Delivery of a Safe and Effective Service

People's health, safety and welfare must be actively promoted and protected. Risks must be identified, monitored and where possible, reduced or prevented.

The inspection team were content and reassured that there were no breaches in relation to the regulations. The inspection was an extremely positive experience and it was clear that safety was of the essence for the service to patients and the commitment to staff

The radiology CPG state in its terms of reference that it is accountable to the health board via the Executive Director of Therapies and Health Science. It also states that the CPG ensures a consistent and efficient approach to the safe and effective provision and use of radiology services within the health board. The CPG board and its sub groups act as a focal point for information exchange between the CPG's identifying, escalating and communicating issues of relevance and significance across the organisation and the CPG.

During our inspection we believe that the CPG provides a high quality and safe service which is effectively monitored. Clinical governance and standards including IR(ME)R appear to be well managed and effective in the operation of the services provided.

6. Next Steps

As stated in the summary, this inspection was exceptionally well received by the departmental management team and the standard of documentation submitted to HIW prior to the inspection was very high. The conduct of the inspection was very positive and the high standards of work and compliance with IR(ME)R by the department are commendable.

As there were no areas for improvement identified during this inspection, the health board is not required to complete an improvement plan (Appendix A)

Appendix A

IR(ME)R: Improvement Plan

Hospital: Ysbyty Gwynedd Bangor

Ward/ Department: Radiology Department

Date of Inspection: 22 and 23 January 2015

Page Number	Recommendation	Health Board Action	Responsible Officer	Timescale
	Quality of the Patient Experience			
	No areas for improvement identified			
	Duties of Employer			
	No areas for improvement identified			
	Justification of individual medical exposures			
	No areas for improvement identified			
	Optimisation			
	No areas for improvement identified			

Page Number	Recommendation	Health Board Action	Responsible Officer	Timescale
	Clinical audits			
	No areas for improvement identified			
	Equipment			
	No areas for improvement identified			
	Management and leadership			
	No areas for improvement identified			
	Delivery of a Safe and Effective Service			
	No areas for improvement identified			

Health Board Representative:

Name (print):

Title:

Signature:

Date: