

**Ionising Radiation
(Medical Exposure)
Regulations Inspection
(announced)**
Nuffield Health
Cardiff & Vale Hospitals

20th & 21st August 2015

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1. Introduction

Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of all health care in Wales.

HIW's primary focus is on:

- Making a 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 is responsible for monitoring compliance against the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000 (and its subsequent amendments 2006 and 2011). We achieve this through a programme of assessment and inspection of services in the NHS and independent sectors that use ionising radiation.

The regulations place responsibilities on practitioners, operators, those who refer patients for medical exposures and the employers of these three groups. The employer is required under the regulations to create a framework for the safe, efficient and effective delivery of ionising radiation by the provision of written procedures and protocols. A breach of the regulations can result in the issue of prohibition notices, improvement notices or criminal proceedings.

The regulations are designed to ensure that:

- Patients are protected from unintended, excessive or incorrect exposure to medical radiation and that, in each case, the risk from exposure is assessed against the clinical benefit (justification)
- Patients receive no more exposure than necessary to achieve the desired benefit within the limits of current technology (optimisation),
- Volunteers in medical research programmes are protected.

We publish our findings within our inspection reports under four themes:

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

2. Methodology

During the inspection we gather information from a number of sources including:

- Information held by HIW
- Interviews with staff (where appropriate) and senior management
- Conversations with patients and relatives (where appropriate)
- Examination of a sample of patient records
- Examination of policies and procedures
- Examination of Imaging rooms and the environment
- HIW patient questionnaires.

At the end of each inspection, we provide an overview of our main findings to representatives of the service to ensure that they receive appropriate feedback.

Inspections capture a snapshot on the day of the inspection of the extent to which services are meeting essential safety and quality standards and regulations.

3. Context

A compliance inspection against the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) for diagnostic imaging was undertaken on 20th & 21st August 2015 at the radiology departments at Cardiff Bay Hospital and The Vale Hospital, Hensol, which are part of Nuffield Health. Cardiff Bay Hospital and Vale Hospital, Hensol are both owned and operated by Nuffield Health which is a registered charity.

Cardiff Bay Hospital provides a range of private healthcare services which include outpatient consultations, physiotherapy, rehabilitation and diagnostic services whilst the Vale Hospital offers a full range of outpatient clinics, surgery and inpatient / overnight stays.

The hospital and clinic treatments include a range of surgical interventions as well as cosmetic surgery, weight loss surgery, sports injury treatments and orthopaedics including joint replacements.

The main diagnostic imaging department is located in Cardiff Bay Hospital where general radiology, fluoroscopy, mobile CT, mammography and ultrasound services are provided. At Vale Hospital imaging includes general radiology, theatre fluoroscopy, and ultrasound.

Services are supported by a total of 15 radiologists who work across both sites. Whilst most radiography staff are based on one site, half of staff rotate to work across both sites.

Radiation protection advice, support and routine monitoring for Cardiff Bay Hospital and Vale Hospital is provided by the Radiological Protection Centre, St George's Hospital, London

4. Summary

This was the first time HIW had undertaken an IR(ME)R inspection of the radiology departments at Cardiff Bay Hospital and The Vale Hospital. The inspection was extremely well received by management and staff and all required pre-inspection documentation was completed and received within timescales required.

The team within the departments approached the inspection in a very positive way and were keen to receive constructive feedback to support their approach to maintain high standards of care and continuous improvement. We also received a positive welcome from both staff and patients who provided feedback on their experiences.

The inspection team were content and reassured that there were no breaches in relation to the Regulations and that there were no concerns about practice in relation to IR(ME)R.

Whilst we were satisfied there were no safety issues, some key issues for action were identified during our visit. These were raised and discussed at the time of the inspection and focussed mainly on documentation. Details of these are highlighted and described in the body of the report.

At the end of the inspection we provided feedback on our main findings and key recommendations. The management team will be submitting an improvement plan in response to our findings.

5. Findings

Quality of the Patient Experience

Patients felt the quality of their experience at both of the hospitals we visited was very good. Positive feedback was received about the staff, the department, the information they received and everyone said they had not experienced any delays.

In order to gather the views of patients and their families about the service they received, we issued a questionnaire to a number of individuals

- Of the 17 questionnaires issued, 15 completed questionnaires were returned. Of those returned, the responses we received were mainly positive. For example: the department was easy to find and well sign posted
- It was clean and uncluttered
- Information patients had received was good and appropriate and none of the individuals who responded said they had experienced any delays.

Feedback was particularly positive about staff, with comments including:

“Staff are very friendly and helpful”

“Staff are very caring and professional, they were a pleasure to meet and chat with”

“They are excellent”

One person also commented

“I would recommend the service”

The only slightly negative comment we received was that there could, on occasions, be delays with payments being processed. It was however unclear whether the individual was referring to the insurance provider or the hospital.

Compliance with IR(ME)R

Duties of Employer

The employer is defined in IR(ME)R as 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.

The Group Ionising Radiation Protection Policy explains the duties of the employer as required under IR(ME)R. It clearly describes both organisational and individual responsibilities. The document does however refer to the Nuffield Hospital Directors as Care Quality Commission registered managers. This is incorrect given that this service is based in Wales and regulated and inspected by HIW. Also, this document is not referenced or retained in the IR(ME)R file and there are a number of other relevant procedures and protocols 'dotted' around in various files and documents. For example, The Quality Assurance procedure - as required under IR(ME)R – was not readily available. This is potentially confusing for existing and especially new staff. Consideration should, therefore, be given to reviewing and reorganising this information so that it is kept in a more coherent and helpful manner.

Despite this, document and version control for this policy are demonstrated and it clearly states that it is approved by the Group Quality and Safety Committee.

Recommendation

The Group Ionising Radiation Protection Policy needs to be reviewed for accuracy and be given a stronger profile in the context of IR(ME)R

Procedures and Protocols

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

Specific concerns identified regarding the written procedures and protocols included:

- It was unclear how the document entitled Procedures and Protocols for Medical Exposures was being used. This is because it was fulfilling the role of being both an overarching policy as well as providing the individual procedures required under IR(ME)R.
- Documents were stored and presented such that there was the potential to create confusion amongst staff.
- The quality assurance procedure, which is a requirement under IR(ME)R was difficult to locate and is currently not a stand alone document.
- The document currently being used as the fluoroscopy protocol is not an actual protocol. There is a need to include information within it about how specific procedures are undertaken rather than merely including positive ideas for optimisation¹.
- In some cases references were made to other policies, for example patient identification, but these were retained elsewhere.
- From discussions with radiology staff, it was clear that the procedures and protocols for medical exposures provided by St George's had been adopted, without having been adapted or customised to reflect local practices at Cardiff and Vale Hospitals. As a result the procedures contained within it were generic and often lacked detail.

¹ Optimisation is the process by which individual doses are kept as low as reasonably practicable consistent with the intended outcome

Recommendation

Review the content of the document Procedures and Protocols for Medical Exposures to ensure it accurately reflects the requirements under IR(ME)R and that it contains sufficient detail that reflects local practices

Clarify how policy and procedure documents are stored and presented to ensure clarity for all staff and managers

To review the fluoroscopy protocol to include information about how specific procedures are undertaken

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).

A procedure is in place regarding accidental or unintended exposures however it contained out of date information in relation to reporting processes. The contact details for this purpose and the timescales for reporting need to be amended

At the time of the inspection the site hadn't had any reportable incidents.

Recommendation

The incident reporting procedure needs to be reviewed and amended to include up to date information

Diagnostic reference levels

The regulations require the employer to establish diagnostic reference levels (DRL)² 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.

A procedure was in place in relation to DRLs however it was brief and did not contain the wording specified by the Regulations. There is no information contained within the procedure that describes where DRLs are displayed nor what to do if they are consistently exceeded.

Work had been progressed to establish local DRLs for a number of examinations. This work was positive however both local and National DRLs were in place which made it confusing for staff.

Where local DRLs have been established these should be used as the basis for monitoring

As a result of discussions with staff, it was clear that there was confusion about how DRLs are to be used and what should be done if the DRLs were consistently exceeded.

Recommendation

The procedure for the use of DRLs needs to be reviewed to include local information to guide staff about their use and what to do if constantly exceeded.

² DRLs are dose levels for typical examinations on standard sized adults or children for broadly defined types of equipment. They are used as a guide to help promote improvements in radiation protection practice.

Duties of Practitioner, Operator and Referrer

Entitlement

The regulations require that duty holders must be entitled³, in accordance with the employer's procedures for the tasks they undertake.

The entitlement procedure currently in place is not fit for purpose and only provides an overview of the general criteria for being a referrer / operator / practitioner. In addition the procedure needs to reflect the need for referrers and practitioners to be registered healthcare professionals. This needs to be developed further to reflect current practice and provide detail as to how duty holders are entitled.

The procedure needs to clearly explain what actually happens and make reference to their scope of practice in terms of entitlement as well as referring to the importance of ensuring documented training records are in place.

Recommendation

The entitlement procedure needs to be reviewed and amended to explain how duty holders are entitled and make reference to their scope of practice

Referral Criteria

IR(ME)R states that the employer shall establish recommendations concerning referral criteria for medical exposures, including radiation doses and shall ensure that these are available to the referrer

³ Entitlement is the process of defining the roles and tasks that individuals are allowed to undertake

The Royal College of Radiologists referral guidelines 'iRefer, Making the Best Use of Clinical Radiology Services' are the referral criteria in use at Cardiff and Vale Hospitals. Copies of these guidelines are available in the consulting rooms and electronically by those consultants who also work in the NHS.

There was, however, no formal mechanism in place to inform referrers external to the organisation about the referral criteria. Managers were unclear how external referrers would be aware of iRefer. It was assumed, for example, that they would work in the same way as they do for NHS patients. It was stressed by the radiology team that they would query any unusual requests with the radiologist on site

There was also no formal mechanism in place for reminding referrers of their responsibilities and requirements under IR(ME)R.

The Procedures and Protocols for Medical Exposures document, it refers to 'Self Requests'. This terminology is misleading as in the situations referenced in the document; the individuals are actually still referred for the examination by an appropriately entitled healthcare professional.

Recommendation

External referrers to be informed of the referral criteria in use at Cardiff and Vale Hospitals and reminded of their responsibilities as described in the employer's procedures

Review the use of the term 'Self Request' as used in the procedure document

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.

Radiographers are entitled as practitioners for general radiography. As all exposures are justified and authorised by practitioners justification guidelines

are not required. It is important that the procedures are amended to reflect this issue.

Identification

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

The IR(ME)R procedure refers to a different document for patient identification which is retained in a different place. For ease of use and understanding for staff it would be easier to keep all IR(ME)R procedures in the same place

The procedure was well written and fit for purpose. The good practice which had been implemented in the department in the use of the 'Pause and Check' initiative was not however reflected in the procedure. This initiative is aimed at reducing the likelihood of identification errors as part of the procedure and it's implementation by the service is positive and could be reflected in the procedure

The WHO checklist is used in theatre for ensuring they have the correct patient

Recommendations

See recommendation under the 'Procedures and Protocols section regarding the storing and presentation of documents

To review the patient identification procedure to include the notable practice around 'Pause and Check'.

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 procedure in place for checking the pregnancy status of females of child bearing age. It does not, however, include reference to the process for checking pregnancy in theatres

The text of the procedure is also different to the information contained on the flowchart which is attached to it. The flowchart is comprehensive and explains what staff should do, however the text needs to be reviewed and amended to reflect the same information. In discussions with staff at the time of the visit they were all able to demonstrate what they do in practice which was in line with the flowchart

The use of the 28 day rule is applied for all examinations other than those with high fetal dose, but this is explained at the end of the current procedure and hidden in the high dose examination section. The department may wish to include this information earlier in the procedure to ensure staff awareness of the process

The procedure should also include reference to the child protection procedure for situations where a child provides a positive response to the pregnancy question

Recommendation

Work needs to be undertaken to consolidate this procedure to provide staff with consistent information regarding checking the pregnancy status for females of child bearing age.

In the revised procedure it would be good practice to include reference to the child protection procedure should a minor provide a positive response to the pregnancy question

Optimisation

The regulations state that procedures to ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced as low as reasonably practicable (ALARP) for the intended purpose

The procedure for minimising the probability and magnitude of accidental and unintended doses to patients as required in Schedule 1 of the regulations is in

place however it fails to recognise or highlight the positive work being undertaken in the department. Such work includes such things as the establishment of local DRLs, audit work undertaken, near miss reporting and the Nuffield Health newsletter highlighting feedback from incidents.

Recommendation

To review the procedure for minimising the probability and magnitude of accidental and unintended doses to patients to include references to the positive work being undertaken in the department

Paediatrics

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

At the time of the visit we were informed that very few paediatric examinations are undertaken. There are however paediatric exposure charts in place which is good practice.

Clinical audits

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

There was evidence of a great deal of audit activity having taken place along with evidence of audits being followed up which was very positive. Some examples of the audits undertaken were:

- Reject analysis⁴
- Clinical evaluation of theatre imaging
- Referrals to ensure correct completion

⁴ Reject analysis is a regular audit looking at the reasons why images need to be repeated e.g. inadequate patient positioning or missing a bit of the required anatomy off the image

- Regular dose audits

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.

Medical physics expertise is provided to the service by the St George's Radiation Protection Advisors who also act as MPEs. The MPE undertakes annual audits and equipment testing at each site and is also available for advice in the event of an unintended or accidental exposure.

The MPE is also available to the service for consultation and advice at any time

The RPA / MPE was present at the visit which was extremely helpful and enabled discussions surrounding the employer's procedures

Equipment

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

An equipment inventory was in place however the information regarding the date of manufacture was missing

Recommendation

The equipment inventory needs to be updated to include the information about the date of manufacture for all pieces of equipment.

Management and Leadership

It was clear from the inspection that both the management team and the radiology managers and staff are committed to providing a high standard of service that is safe and in line with IR(ME)R.

The team recognised and accepted the work that needs to be undertaken to achieve this based on the feedback provided at the time of the visit.

All managers and staff that met with the inspection team engaged positively in the process as a whole and in particular in the visit itself. The management team demonstrated they were keen to receive feedback with a view to improving the service they provide

It was evident from both the paperwork received and the discussions with staff that the impact of a number of influences on radiology services has resulted in some complexities which can be potentially confusing for staff. Whilst our discussions with staff at the time of the visit confirmed they were all clear about their roles and responsibilities under IR(ME)R, what was described to us by staff did not always reflect what was stated in the policies and procedures.

The importance of simplifying the documentation to ensure that what happens in practice is clearly described in the documents is fundamentally important and was reinforced at the time of the visit.

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.

Training records and documented induction training were in place for all staff working in the department apart from equipment training records for radiologists. Our discussions with the team at the time of the visit highlighted the importance of putting these in place.

It was suggested that references to this could be included in the documentation either as part of entitlement or alternatively could be included in the 'notes' section under training in the procedure document.

Recommendation

To review the policies and procedures in place to clarify and simplify their use

To review the content of some of the procedures to ensure they reflect what happens in practice

To develop equipment training records for radiologists

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.

From our discussions with the team during the visit which included representation from the Radiological Protection Centre at St George's Hospital London, the health and safety of its employees, contractors and members of the public is clearly prioritised

From what the inspection team observed and discussed during the course of the inspection we are satisfied that the above statement is upheld.

6. Next Steps

This inspection has resulted in the need for the service to complete an improvement plan to address the recommendations identified during this visit. The details of this can be seen within Appendix A of this report.

The improvement plan should clearly state how the improvement identified at Nuffield Health, Cardiff and Vale Hospitals will be addressed, including timescales.

The improvement plan, once agreed, will be published on HIW's website and will be evaluated as part of the ongoing inspection process.

Appendix A

IR(ME)R: Improvement Plan

Registered service: Nuffield Health, Cardiff and Vale Hospitals

Date of Inspection: 20 & 21 August 2015

Page Number	Recommendation	Action	Responsible Officer	Timescale
	Quality of the Patient Experience			
	None			
	Compliance with IR(ME)R			
8	<i>The Group Ionising Radiation Protection Policy needs to be reviewed for accuracy and be given a stronger profile in the context of IR(ME)R</i>	The group policy is being updated to make it clearer how Nuffield senior management is involved in IRMER.	Teresa Lack/ Ishmail Badr	Dec 2015
10	<i>Review the content of the document Procedures and Protocols for Medical Exposures to ensure it accurately reflects the requirements under IR(ME)R and that it contains sufficient detail that reflects</i>	New corporate IRMER procedures are being launched in November 2015 and the template provided by the Quality Manager will be customised for local rules when it is received.	Teresa Lack/ Ishmail Badr/ Anita Cox	Dec 2015

Page Number	Recommendation	Action	Responsible Officer	Timescale
	<p><i>local practices</i></p> <p><i>Clarify how policy and procedure documents are stored and presented to ensure clarity for all staff and managers</i></p> <p><i>To review the fluoroscopy protocol to include information about how specific procedures are undertaken</i></p>	<p>Continue to maintain a paper copy in the office on each site which is accessible to all radiology staff. New staff are guided through the IRMER file as part of the induction process and it is endorsed by local management annually.</p> <p>Details added that are specific to our fluoroscopy equipment e.g. the pulse rate that would normally be used (continuous, fast or slow) and the fluoroscopy mode (normal, low dose or high quality).</p>		
10	<p><i>The incident reporting procedure needs to be reviewed and amended to include up to date information</i></p>	<p>The incident reporting procedure reviewed and up dated.</p>	Anita Cox	Complete
11	<p>The procedure for the use of DRLs needs to be reviewed to include local information to guide staff about their use and what to do if constantly exceeded.</p>	<p>New DRL procedure is clear that staff would investigate where a dose audit shows mean doses 20% or more over the local DRL.</p>	Teresa Lack/ Ishmail Badr/ Anita Cox	January 2016

Page Number	Recommendation	Action	Responsible Officer	Timescale
12	<i>The entitlement procedure needs to be reviewed and amended to explain how duty holders are entitled and make reference to their scope of practice</i>	New IRMER procedures for entitlement of referrers, practitioner and operators which clarifies the process.	Teresa Lack	Jan 2016
13	<i>External referrers to be informed of the referral criteria in use at Cardiff and Vale Hospitals and reminded of their responsibilities as described in the employer's procedures</i> <i>Review the use of the term 'Self Request' as used in the procedure document</i>	Identification of Referrers document produced. The procedures have been made clearer that in the patient cannot be a referrer and in that case a suitably-qualified healthcare professional would take on the role of IRMER referrer if a patient presents for breast screening.	Teresa Lack/ Anita Cox	Jan 2016
14	<i>See recommendation under the 'Procedures and Protocols section regarding the storing and presentation of documents</i> <i>To review the patient identification procedure to include the notable practice around 'Pause and Check'.</i>	Paper copy in the radiology manager's office on each site for all staff to access and ensure local management sign off annually. Electronic copy also kept on a shared drive for departmental access. Signage in each room to remain & the 'Pause &	Teresa Lack/ Anita Cox	Jan 2016

Page Number	Recommendation	Action	Responsible Officer	Timescale
		Check' criteria to appear in the patient ID policy.		
15	<p><i>Work needs to be undertaken to consolidate this procedure to provide staff with consistent information regarding checking the pregnancy status for females of child bearing age.</i></p> <p><i>In the revised procedure it would be good practice to include reference to the child protection procedure should a minor provide a positive response to the pregnancy question</i></p>	New pregnancy procedure to be produced which will be amended to include the child protection & Nuffield safeguarding procedure as recommended.	Teresa Lack/ Anita Cox	Dec 2015
16	<i>To review the procedure for minimising the probability and magnitude of accidental and unintended doses to patients to include references to the positive work being undertaken in the department</i>	The RPA, incident reporting, DRL's, Theatre notes, Reject Analysis, Internal QA, Equipment QA, Referral Form, WHO form, Patient ID, Double read audits, Nuffield News Letter & near miss reporting added to the procedure list.	Anita Cox	Dec 2015
17	<i>The equipment inventory needs to be updated to include the information about</i>	Manufacture Date added	Anita Cox	Complete

Page Number	Recommendation	Action	Responsible Officer	Timescale
	<i>the date of manufacture for all pieces of equipment</i>			
Management and leadership				
19	<p><i>To review the policies and procedures in place to clarify and simplify their use</i></p> <p><i>To review the content of some of the procedures to ensure they reflect what happens in practice</i></p> <p><i>To develop equipment training records for radiologists</i></p>	<p>This will be achieved via local customisation of the new IRMER procedures when they are launched next month.</p> <p>Nuffield proforma equipment-specific checklists introduced.</p>	Anita Cox	Feb 2016
Delivery of a Safe and Effective Service				
	None			

Service Representative:

Name (print): **Simon Rogers**

Title: **Hospital Director**

Signature: 

Date: **20th October 2015**