# Ionising Radiation (Medical Exposure) Regulations Inspection (Announced)

Cardiac department services,

University Hospital of Wales,

Cardiff and Vale University Health Board

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**Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of healthcare in Wales**

# Our purpose

**To check that people in Wales are receiving good care.**

# Our values

- **Patient-centred: we place patients, service users and public experience at the heart of what we do**
- **Integrity: we are open and honest in the way we operate**
- **Independent: we act and make objective judgements based on what we see**
- **Collaborative: we build effective partnerships internally and externally**
- **Professional: we act efficiently, effectively and proportionately in our approach.**

# Our priorities

**Through our work we aim to:**

| | |
|---|---|
| **Provide assurance:** | **Provide an independent view on the quality of care.** |
| **Promote improvement:** | **Encourage improvement through reporting and sharing of good practice.** |
| **Influence policy and standards:** | **Use what we find to influence policy, standards and practice.** |

# 1. What we did

Healthcare Inspectorate Wales (HIW) completed an announced Ionising Radiation (Medical Exposure) Regulations inspection of the diagnostic and interventional imaging cardiac department services at the University Hospital for Wales, part of Cardiff and Vale University Health Board on the 3 and 4 October 2017. The following areas were visited during this inspection:

- Cardiac Catheter Laboratories (A, B and C)
- Cardiac Pacing Room
- Cardiac Day Ward

Our team, for the inspection comprised of two HIW Inspectors and two Senior Clinical Officers from the Medical Exposures Group (Public Health England), who acted in an advisory capacity.

We met with senior managers, superintendent radiographers, cardiologists, radiographers and a medical physics expert.

We adopted a 'patient journey' approach to our inspection, seeking evidence from written procedures most of which had been provided in advance of the inspection, and from discussions with staff over a period of two days. We therefore examined how procedures, processes and practice from patient referral through to diagnosis, treatment and clinical evaluation, met the requirements of IR(ME)R. In particular, we explored the identity and responsibilities of the various duty holders, the nature of X-ray referral criteria and how X-ray diagnostic and interventional exposures were justified[1], authorised and optimised[2].

[1] Justification of radiographic (X-ray) examinations is the practice of evaluating requests for radiological examinations to assess for clinical merit and appropriateness based on clinical notes and patient information.

[2] An optimal image refers to a balance between a good quality X-ray image with diagnostic value, and minimal radiation dose to the patient.

HIW explored how the service:

- Complied with the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000 (and its subsequent amendments 2006 and 2011)
- Met the Health and Care Standards (2015).

Further details about how we conduct Ionising Radiation (Medical Exposure) Regulations inspections can be found in Section 5 and on our website.

# 2. Summary of our inspection

Overall, we found that the cardiac service delivered safe and effective care to patients. This was in accordance with the Ionising Radiation (Medical Exposure) Regulations and the Health and Care Standards.

However, we did identify the need for improvement to some administrative aspects of the service, none of which resulted in the issue of a non compliance notice.

This is what we found the service did well:

- patients told us they were happy with the care they had received
- staff demonstrated that they had a good awareness of the risks associated with ionising radiation and their responsibilities in this regard
- staff working within the service were 'dose aware' which meant that every effort was being made to expose patients to the lowest possible doses of radiation
- senior staff provided effective management and leadership

This is what we recommend the service could improve:

- the health board must ensure that all training undertaken by staff regarding the use of radiographic equipment, is recorded
- staff training records need to contain the full name of the employee, are to be signed and dated by the trainee, and include a countersignature of the trainer, for verification purposes. This was also a recommendation within the previous HIW inspection report (August 2010)
- aspects of the content of employers (IR(ME)R) procedures need to be updated and streamlined, whilst other procedures need to be

finalised and formally adopted. This is to ensure that staff are provided with clear and current information to guide them in their work

# 3. What we found

## Background of the service

Cardiff and Vale University Health Board is one of the largest National Health Service (NHS) organisations in the UK. It provides day to day health services to a population of around 472,400 people living in Cardiff and the Vale of Glamorgan who need emergency and scheduled hospital treatment and mental health care. It also delivers care in people's own homes and community clinics.

Cardiff and Vale University Health Board includes six in-patient hospitals and four out-patient hospitals (Dental, Cardiff Royal Infirmary, Whitchurch, and Lansdowne).

The delivery of NHS primary care services in Cardiff and the Vale of Glamorgan, including general practitioners, community pharmacists, dentists, and optometrists are also the responsibility of Cardiff and Vale University Health Board. Additionally, it serves the population across Wales for specialties such as paediatric intensive care, specialist children's services, renal services, cardiac services, neurology, bone marrow transplantation and medical genetics.

The cardiac services department at the University Hospital of Wales performs a range of procedures using specialist X-ray equipment. These include diagnostic angiograms[3], angioplasties[4], trans-catheter aortic valve implantation[5] (TAVI), electrophysiology[6], percutaneous cardiac intervention[7] (PCI), cardiac ablations[8]

[3] An angiogram is a type of X-ray to check blood vessels.

[4] An angioplasty is a non-surgical procedure used to treat narrowed blood vessels of the heart.

[5] A trans-catheter aortic valve implantation is a procedure that uses a catheter (hollow tube) to guide and fix a replacement valve over the damaged aortic valve.

[6] Electrophysiology is a test which looks at the heart's electrical activity.

[7] Percutaneous coronary intervention (PCI) is a procedure used to open blocked coronary arteries (caused by coronary artery disease). It restores blood flow to the heart muscle without open-heart surgery.

and pacing[9] procedures for adults only. Cardiac paediatric services are provided through arrangements with hospitals in England who specialise in that area of healthcare.

At the time of our inspection 22 consultant cardiologists (4 of who were visiting consultants from the Gwent area and four from the Cwm Taf area), 14 specialist registrars, 16 radiographers and two medical physics experts (MPEs)[10] supported the cardiac department. No substantive long term vacancies were reported within cardiac services.

[8] Cardiac ablation is a treatment that helps to control or correct an abnormal heart rhythm.

[9] Cardiac pacing is used to treat some abnormal heart rhythms.

[10] An MPE is a suitably experienced medical physicist having the knowledge and training to give advice on all aspects of radiation protection of patients involving ionising radiation when used for medical exposures.

## Quality of patient experience

*We spoke with patients, their relatives, representatives and/or advocates (where appropriate) to ensure that the patients' perspective is at the centre of our approach to inspection.*

We saw staff treating patients with dignity, respect, compassion and kindness.

Patients told us they were happy with the care they had received. In addition, they told us that they felt they had been given enough information about their care.

Patients were also complimentary about the cleanliness of the environment.

Prior to the inspection, we asked senior staff to distribute HIW questionnaires to patients to obtain their views on the services provided. A total of 23 were completed and returned. We also spoke to six patients during the inspection. Patients who completed questionnaires, and those we spoke to, had either previously attended, or were present, at the Cardiac Day Ward. Patient comments regarding staff working in that area included the following:

> *"All the staff from the cardiac day unit along with all operation theatre staff were warm, welcoming and kept me informed of all going on. The atmosphere was relaxed and easy going."*
>
> *"The nursing staff of this department were all very good. Very attentive, very polite and all very nice people."*
>
> *"Knowledgeable, efficient, warm, empathetic, caring."*
>
> *"Excellent service on arrival and throughout the day. Can't fault anyone."*

### Staying healthy

There was a range of hospital and British Heart Foundation information leaflets available to patients and their families within the cardiac day unit. These

provided information about conditions which affect the heart and the nature of a variety of cardiac procedures. This meant that patients had information on how to care for themselves following their procedures and who to contact for further advice.

The employer had a written procedure for the management and follow up of patients who have received a (managed) high dose of radiation. This set out the verbal information that needed to be given to patients before and after the procedure which included the need to inform their GP. This meant that if the patient experienced any after effects following the procedure (usually skin reddening) they would know who to contact.

Whilst we were informed that the department had not received any notification of incidents where patients had experienced such problems, we advised senior managers of the need to provide patients and their respective GPs with written information following the delivery of planned high radiation doses. This was, in order to ensure that any post procedure patient concerns could be addressed promptly.

## Dignified care

We saw staff treating patients with respect dignity, respect, compassion and kindness.

Arrangements were in place to promote patients' privacy and dignity within the cardiac catheter laboratories. Patients were wearing dignity gowns and were not overly exposed during procedures. In addition, the general information leaflet provided prior to admission, advised patients to bring a dressing gown with them to enhance their dignity further. Curtains were in use within the cardiac catheter laboratories to create a private area for patients on their arrival.

We were told that the cardiac day ward was used to provide an environment for patients for relatively short periods of time both before and after their procedures (on a booked admission basis). Patients confirmed that this was the case. In instances where patients were not considered to be well enough to be discharged home on the day of their procedure, accommodation would be found elsewhere within the hospital, as stated by staff. The ward had two separate toilet facilities and patient bed areas were not located directly opposite one another which assisted with the promotion of patients' privacy and dignity.

### Patient information

As described above, we saw that information leaflets were available to patients and their families. Patients, who returned a completed questionnaire and those

who spoke with us, also told us that they had been given sufficient information about pre-admission arrangements and their planned cardiac procedure.

However, four patients who completed a HIW questionnaire indicated that they had found it difficult to find the cardiac day ward. We therefore advised senior managers that it may help patients to have a map of its location ahead of their appointment, in the future.

### Communicating effectively

Discussions with staff within the cardiac day ward highlighted the emphasis placed on open and honest communication between the staff team. Staff also described the efforts made to tailor the care to be provided to individual patients, the nature of which was established during the pre-assessment stage and recorded on various forms of care pathway documentation (in accordance with the planned procedure).

We saw reference to daily staff safety briefings on a noticeboard within the cardiac day unit (in respect of catheter laboratory C). We were also informed that safety briefings took place each day within catheter laboratories A & B. We were further made aware of the use of patient safety checklists that had been adapted for use within the cardiac catheter laboratories. This was considered to be good practice.

## Timely care

When asked whether they had experienced any delay in having their procedure, patients provided us with a mixed response. Thirteen patients who completed a HIW questionnaire indicated they had not experienced any delay; ten describing delays with having their procedure performed. We were unable to fully establish whether this was due to clinical reasons or service pressures. However, six patients who spoke with us said that they had not needed to wait very long for their appointment/treatment. Comments received within completed HIW questionnaires in relation to whether patients had experienced any delays in getting an appointment or receiving treatment, included the following:

> *"Cancelled appointment due to emergency. That was absolutely fine with me."*
>
> *"It took quite a long time to get the first appointment-I can't recall exactly, maybe a couple of months"*
>
> *"Yes. Not due to department*

*"It was a long time waiting for the appointment. Eventually rang the hospital to prompt and within days, received an appointment"*

## Listening and learning from feedback

The health board's annual quality statement stated that patient feedback was regarded as very important. People are able to provide such feedback in terms of how they are treated and whether their surroundings are considered to be safe and clean in a number of ways, (for example, by completing paper surveys, via the health board website or by completing 'how are we doing' feedback cards which were available in clinical areas during this inspection).

## Delivery of safe and effective care

*We considered the extent to which services provide high quality, safe and reliable care centred on individual patients.*

It was evident that the service placed an emphasis on the health, safety and welfare of patients and its staff. This was with a view to providing a safe and effective service.

We did however; identify the need for greater protection of patient confidentiality within the cardiac day unit.

### Compliance with Ionising Radiation (Medical Exposure) Regulations

#### Duties of employer

*Patient identification*

The employer[11] had a written procedure to correctly identify individuals who were about to be exposed to ionising radiation. This set out that operators were responsible for ensuring the correct identification of individuals undergoing medical exposures.

The procedure required operators to conduct a three point identification check (to confirm the individual's name, date of birth and address) to positively identify the individual prior to the medical exposure. It also described the alternative procedure operators must follow, should individuals be unable to confirm their identity verbally or in writing, (for example, unconscious patients).

[11] The employer refers to the Chief Executive of the local Health Board or Trust in the NHS environment.

Conversations with staff also resulted in clear and consistent descriptions of the procedure to follow. It was therefore evident that staff placed a strong emphasis on correctly identifying patients to promote their safety and wellbeing.

*Females of child bearing age*

The employer had a written procedure for making enquires with regard to pregnancy. This aimed to ensure that enquiries were made in an appropriate and consistent manner.

The procedure required operators to make relevant enquires and set out the actions they must follow depending on the individual's responses. The written procedure applied to all women of childbearing age (12 - 55 years) which is in accordance with UK guidance[12].

*Medico-legal exposures*

We were informed that medico-legal exposures were not performed within diagnostic and interventional cardiac services.

*Medical research*

There was an employer's procedure in place with regard to research. However, we found that this needed to be revised to provide greater clarity as to how individuals with identified cognitive impairment/dementia, would be recruited to any approved research programme.

The 'referrer' role in research programmes also needed to be made clearer within the procedure. Specifically, the current procedure indicated that only one referral per volunteer would be accepted. This was at odds with the need for some patients to return for further imaging within the defined period of research.

The need for improvement to procedures in place within diagnostic imaging-cardiac services is referred to in more detail in the section of this report entitled 'Quality of Management and Leadership'.

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[12] British Institute of Radiology, Society and College of Radiographers and the Royal College of Radiologists. 'A guide to understanding the implications of the Ionising Radiation (Medical Exposure) Regulations in diagnostic and interventional radiology'. London: The Royal College of Radiologists, 2015. https://www.rcr.ac.uk/sites/default/files/bfcr152_irmer.pdf

*Referral criteria*

The information provided by the service was considered to be satisfactory.

*Diagnostic reference levels (DRLs)*

The employer had a written procedure for the use of DRLs[13]. This set out arrangements to establish DRLs for procedures performed in the cardiac department. The procedure (which had been produced by relevant clinical staff) also set out the arrangements for recording and monitoring doses (of ionising radiation) delivered to patients. However, further detail was needed to advise staff of the action to be taken should DRLs be exceeded.

We saw national and local DRLs were available to staff working in the laboratories to follow, in accordance with the above procedure. Staff generally demonstrated a good understanding of the procedure to follow for checking and recording the doses delivered. The cardiac radiology team also provided us with practical examples of how they placed an emphasis on reducing levels of radiation to a level as low as reasonably possible (ALARP). This was particularly evident within two of the three catheter laboratories who had agreed local DRLs with associated lower doses of radiation, with work currently underway to agree local DRLs in the third laboratory.

## Duties of practitioner, operator and referrer

The employer had written procedures for the entitlement and identification of practitioners[14], operators[15] and referrers[16] (known as duty holders). These

[13] Diagnostic Reference Levels refer to dose levels of radiation used during medical radio-diagnostic procedures. It is expected that these levels are not to be exceeded for standard procedures when good and normal practice is applied.

[14] An IR(ME)R practitioner, is a registered health care professional who is entitled in accordance with the employer's procedures and whose primary responsibility is justification of individual medical exposures (X-rays)

[15] The IR(ME)R operator is a person who is entitled in accordance with the employer's procedures to undertake the practical aspects of the medical exposure.

[16] A referrer is a registered health care professional who is entitled in accordance with the employer's procedures to refer patients for medical exposures.

clearly described the arrangements for entitlement and identified duty holders by staff group. The procedures set out the expected level of training for each entitled staff group together with their scope of practice.

### Justification of Individual Medical Exposures

The employer had a written procedure for the justification and authorisation of medical exposures. This stated that consultant cardiologists and locum consultant cardiologists were entitled to justify medical exposures. We saw examples of patients' records that demonstrated authorisation (i.e. evidence of justification) of medical exposures.

### Optimisation

The employer had arrangements in place concerning the optimisation of medical exposures. These included written procedures, evidence of relevant staff training and maintenance programmes for equipment used in cardiac services. These arrangements aimed to ensure that doses delivered to patients as a result of medical exposures are kept as low as reasonably practicable (also referred to as ALARP).

Discussions with radiology staff also led to assurance about their awareness and understanding of the range of different radiation dose levels and frame rates[17] although the specific employer's procedure did not reflect the good practice adopted by the department. We further heard about the efforts made to reduce the dose of radiation to patients in collaboration with medical physics experts and saw written guidance for staff in that regard.

*Paediatrics*

Senior staff confirmed that the diagnostic and interventional imaging (cardiac) department at the hospital did not perform diagnostic or treatment procedures with regard to children.

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[17] The term frame rate refers directly to the frequency at which an X-ray image is displayed/captured. The radiation dose relates directly to the frame rate. For example, a frame rate, such as 7.5 frames per second, produces less radiation than 15 frames per second.

*Clinical evaluation*

The employer had written procedures concerning the clinical evaluation of all medical exposures. These clearly stated that consultant cardiologists were responsible for recording their clinical evaluation (of patients' medical exposure to radiation) and radiographers were responsible for recording an indication of the dose to patients (for each medical exposure). Senior managers also described how the outcome of medical exposures could be accessed by relevant staff.

We were therefore satisfied that the service was compliant with this aspect of the IR(ME)R regulations.

## Clinical audit

Senior managers described aspects of the 'in-house' audits which took place as part of a rolling programme of agreed audit activity. These related to the patient identification process and peer review of the quality of X-ray imaging; action being taken to improve services as necessary. However, we found that the written clinical audit procedure did not reflect the nature and frequency of activity taking place/happening within interventional cardiac services.

In addition, we requested sight of the written, agreed, radiology audit programme but this was not provided during the inspection. We were therefore unclear as to what audits should have been completed, and with what frequency.

We were provided with notes from the previous two clinical audit meetings to which all relevant staff are invited. These demonstrated that a variety of presentations took place (involving a range of professionals) with a view to increasing awareness among staff about key issues and making improvements to patient services.

## Expert advice

Senior staff confirmed that medical physics experts (MPEs) and radiation protection advisers (RPAs) were involved as appropriate in relation to medical exposures. The responsibilities of MPEs and RPAs were also described in the employer's overarching policy on the implementation of IR(ME)R.

## Equipment

The employer provided us with an up to date inventory of radiological equipment used within diagnostic imaging cardiac services. This contained all (IR(ME)R information required.

## Safe care

### Managing risk and promoting health and safety

We visited the catheter pacing room and were able to see (from a distance) that the layout and equipment in use, was appropriate. However, in order to access the laboratory, patients needed to be transported through the coronary care unit which wasn't ideal. This was because this arrangement increased the throughput of people and noise levels at times when patients were in receipt of care in this area. It was evident however, that there was no easy environmental remedy for this situation.

In contrast, access to the three catheter laboratories was not compromised in any way. We also saw that the laboratories were well equipped, and visibly clean and tidy. The control rooms were notably quiet and calm. Storage in each of these areas and the cardiac day ward was, however, limited; with no opportunity to increase such facilities. This led to cluttered areas within the cardiac day ward as well as the receiving bay linked to catheter laboratories A and B.

On examination of the fridge temperature records within the cardiac day unit, there were numerous gaps seen. Given that patients' food was kept in the fridge, we advised staff of the need to ensure that such records were kept up to date to ensure that food was kept at optimum conditions.

We saw that the housekeeping storage room was left open whilst unattended on day two of our inspection. We therefore highlighted this matter so that staff could be reminded that the room is kept locked to prevent unauthorised access to caustic substances.

### Infection prevention and control

Arrangements were in place to protect patients and staff from preventable healthcare associated infections.

For example, we saw that the cardiac day ward, cardiac catheter laboratories and pacing room were clean and designed to promote effective cleaning. In addition to the personal protective equipment (PPE) to protect staff from ionising radiation, suitable PPE was also available to protect staff and patients

from infection (such as aprons and gloves). Staff we spoke with were also aware of their responsibilities in relation to infection control procedures.

We also saw that alcohol gel was widely available and used by staff entering and leaving the coronary care unit and infection prevention and control advice was clearly displayed for staff and members of the public to see. In addition, disposable curtains were in use in all areas visited, each containing the date they were put in place to assist staff to determine when they should be replaced.

On day one of our inspection, the commode within the cardiac day ward was not labelled to indicate that it had been cleaned and was ready for use (although it appeared to be visibly clean). We therefore brought this to the attention of staff who addressed the matter. We were able to confirm that the commode was correctly labelled and was clean for use, on day two.

Patients who completed a HIW questionnaire praised the cleanliness of the cardiac day unit.

### Safeguarding children and adults at risk

Conversations with staff within the cardiac day ward demonstrated an awareness of current safeguarding procedures.

## Effective care

### Information governance and communications technology

Information management systems were described and demonstrated by various members of staff. This allowed for relevant patient details and information about diagnostic and interventional cardiac procedures performed, to be recorded, and easily accessed by staff.

### Record keeping

We found that patient's records were placed on the very top of the reception desk within the cardiac day unit on both days of our inspection. Whilst certain members of staff worked at the reception desk for part of the day, there were frequent periods when the desk was unattended which meant that patient records could have been accessed by unauthorised persons. In addition, we saw that patient's first initials and second name (in full), were displayed on a white board behind the reception desk together with some details of their admission, and one unattended computer terminal had not been switched off, permitting easy viewing of patient data.

This was brought to the attention of senior managers as such practise is not in-keeping with the Health and Care Standards or Data Protection legislation.

Improvement needed

The health board is required to provide details of the action to be taken to ensure that people's personal information and records are held securely at all times within the cardiac day ward.

## Quality of management and leadership

*We considered how services are managed and led and whether the workplace and organisational culture supports the provision of safe and effective care. We also considered how the service review and monitor their own performance against the Health and Care Standards / National Minimum Standards.*

We found that senior managers provided staff with effective leadership. We also found that staff understood their responsibilities and were supported to complete training relevant to their roles.

### Governance, leadership and accountability

#### Duties of the employer

*Entitlement*

The employer had a written procedure for the entitlement[18] of referrers, operators and practitioners (known as duty holders). This clearly described the arrangements for entitlement and set out the expected level of training for each entitled staff group, together with their scope of practice. Discussions with radiographers and assistant practitioners confirmed their understanding of the duty holder role.

There were key elements of the entitlement process included in the justification procedure, the IR(ME)R referrer's procedure and operator's procedure. To provide clarity, we therefore advised that references to entitlement within those procedures be removed; including any relevant content into the one entitlement

[18] Being entitled by the Employer, means that permission has been given to act, in compliance with the Regulations, according to the specific responsibilities of a duty holder role. There must be a documented entitlement process within the Employer's procedures.

procedure. The need for improvement in relation to these matters was also highlighted within the previous HIW inspection report (2010).

Additionally, the entitlement procedure made reference to third party engineers being entitled as operators. However, the inspection team advised senior managers that this was not in-keeping with current guidelines (as referenced at the foot of this page).

We were shown the 'electronically held' staff entitlement matrix. Whilst we acknowledged the extent of the work undertaken by the department in this regard, we provided further advice in terms of setting out, updating and managing this information in a clearer way.

We were provided with examples of letters sent to staff formally confirming their entitlement as duty holders. This appropriate form of action had been taken by the health board following the HIW IR(ME)R inspection of nuclear medicine services during 2016.

*Procedures and protocols*

The chief executive of the health board was designated as the employer. This is in keeping with the national guidance[19] on implementing IR(ME)R as they apply to diagnostic and interventional imaging within cardiac services.

Prior to the inspection, we had been provided with a list of IR(ME)R procedures. These contained a variety of dates, some of which had passed the time point when they should have been formally reviewed. In addition, some procedures were in draft form awaiting final approval from the health board executive team. However, discussions with senior managers revealed that procedure review work was underway, and would be further influenced by the findings of this inspection. In addition, were told that document control and information

[19] British Institute of Radiology, Society and College of Radiographers and the Royal College of Radiologists. 'A guide to understanding the implications of the Ionising Radiation (Medical Exposure) Regulations in diagnostic and interventional radiology'. London: The Royal College of Radiologists, 2015. https://www.rcr.ac.uk/sites/default/files/bfcr152_irmer.pdf

management in this area of service, would be supported through the use of Q Pulse[20] software by the end of 2107.

Whilst issue or approval dates were present on employer's procedures and the overarching IR(ME)R policy, the employer may wish to use the same format for consistency in the future. In addition, we were informed that staff were expected to read all relevant policies and provide their signature afterwards. Whilst we were not provided with written evidence of this at inspection, discussions with staff made it clear that they understood their responsibilities regarding IR(ME)R legislation.

Senior staff were receptive to our comments about the need to revise some of the wording within the employer's overarching policy and procedures. This largely related to the need to ensure that procedures made reference to cardiac interventions/laboratory work (where appropriate), avoid duplication and address the lack of clarity regarding the actions staff needed to take when reporting incidents. More specifically, staff appeared a little unclear as to the 'flow' of actions that needed to be taken following the identification of a reportable IR(ME)R incident, although the approach required, was clearly described by a senior manager.

Additionally, we found that aspects of current IR(ME)R practice (as described by staff) was not accurately reflected in a small number of written procedures. This could lead to error in service delivery. We were also unable to confirm whether all relevant clinical staff were actively involved in the ongoing development of IR(ME)R procedures.

The radiation protection service's review of all procedures was completed during 2015. Senior managers told us that they were in the process of pursuing a further date for the next required two year review.

Whilst the above has not resulted in the issue of a non compliance notice, the employer is required to take meaningful action in the form of revised, clear and ratified procedures for staff to follow.

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[20] Q Pulse is an electronic quality management system which assists organisations to automate and streamline business processes for standards and regulatory compliance, safety management and risk management.

*Incident notifications*

We held discussions with senior staff concerning risk management and clinical audit, including what arrangements were in place for the review of incidents and near misses. As a result, we were provided with written examples of how lessons had been achieved in addition to written reflective pieces of work completed by staff. We were also informed that individuals who generated a datix[21] report would receive acknowledgement and feedback following completion of investigations. This meant that there was an open culture within the department and a willingness to learn from clinical incidents.

Improvement needed

The health board is required to inform HIW of the action taken/to be taken to ensure that staff are provided with a set of revised, clear and ratified procedures to follow in their day to day work.

## Staff and resources

### Workforce

*Training*

We found a lack of written evidence in respect of the necessary practical training on equipment for cardiologists. However, separate discussions with cardiologists and radiographers demonstrated that such training had been provided on an informal basis to ensure the safety of patients and staff. We therefore advised the need for written records to support this in the future.

[21]The Datix Incident Reporting System and Adverse Event Reporting software includes an incident reporting form and template that enables reports to be submitted from anywhere in a hospital or other care setting, greatly improving rates of reporting and promoting ownership of safety issues.

We were informed of how checks were undertaken on the registration status of radiographic staff. However, we were unable to confirm the HCPC[22] registration of one member of one employee. Senior managers subsequently described how diagnostic radiology staff were expected to keep their own portfolio of continuing education and training because of the large number of people employed in the area. The inspection team however, reminded senior managers of the requirement to have all such records available at future inspections in accordance with IR(ME)R regulation (11 (4)).

We were provided with a copy of a comprehensive blank staff induction document. Discussions with a relatively new member of radiology staff however, revealed that they were not aware of the existence of an induction document. Unfortunately, we were not able to access any completed induction paperwork during our inspection as staff tended to retain such information at home as outlined above.

We took the opportunity to explore the content of a sample of staff training records and found that there was clear and detailed evidence of specific training undertaken by staff working within the cardiac catheter laboratories and in relation to one of the MPEs. We also found evidence of some appropriate training associated with staff working in other relevant areas of diagnostic (cardiac) imaging. However, we were not provided with convincing evidence that the department as a whole were compliant in respect of required training. Nor were we provided with a copy of the training manual mentioned within the health board's completed self assessment documentation. Additionally, there was no evidence of wider staff continuing education and training. The training records seen at this inspection though, were better than those considered during the 2010 inspection.

We further found there was a need for senior managers to ensure that all training records contained the full name of the employee and were signed and dated by staff on completion of training; with a counter signature by trainers for verification purposes. Senior managers were very receptive to our suggestions in this regard, together with our advice about the need to provide senior

[22] The Health and Care Professions Council (HCPC) is a statutory regulator of over 344,000 professionals from 16 health and care professions in the United Kingdom. Its main stated purpose is to protect the public.

managers (with responsibilities for the oversight of training) with protected time, to fulfil this aspect of their role.

Whilst the above has not resulted in the issue of a non compliance notice, the employer is required to take meaningful action to address the staff training matters highlighted by the inspection team through the completion of an improvement plan.

*Staffing*

Discussions with senior managers revealed that some radiographers were permanently assigned to work within the cardiac catheter laboratories in support of cardiologists, other radiographers working in this area on an agreed rota basis. Similarly, the cardiac pacing service was supported by radiographers and assistant practitioners on a rota basis; a small team of cardiac service trained nurses assisting with non-IR(ME)R related elements of patient procedures.

We considered staff levels to be adequate for the level and complexity of services provided.

Improvement needed

The health board is required to provide HIW with a description of the action taken/to be taken in relation to aspects of staff training as follows:

- There must be written evidence of any informal training undertaken by staff concerning the use of radiographic equipment
- All staff records are to be available at future inspections in accordance with IR(ME)R regulations
- Staff training records must provide evidence of wider continuing education and training (over and above that required by IR(ME)R
- Staff training records must contain the full name of the employee and be signed and dated by staff trainees; with a counter signature of the trainer for verification purposes

During the inspection, we received descriptions of how well staff worked collaboratively which provided us with assurance that there was cooperation between duty holders across the various professional disciplines (for example- in particular when patients presented with a cardiac emergency).

# 4. What next?

Where we have identified improvements and immediate concerns during our inspection which require the service to take action, these are detailed in the following ways within the appendices of this report (where these apply):

- Appendix A: Includes a summary of any concerns regarding patient safety which were escalated and resolved during the inspection
- Appendix B: Includes any immediate concerns regarding patient safety where we require the service to complete an immediate improvement plan telling us about the urgent actions they are taking
- Appendix C: Includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas

Where we identify any serious regulatory breaches and concerns about the safety and wellbeing of patients using the service, the registered provider of the service will be notified via a non-compliance notice. The issuing of a non compliance notice is a serious matter and is the first step in a process which may lead to civil or criminal proceedings.

The improvement plans should:

- Clearly state when and how the findings identified will be addressed, including timescales
- Ensure actions taken in response to the issues identified are specific, measureable, achievable, realistic and timed
- Include enough detail to provide HIW and the public with assurance that the findings identified will be sufficiently addressed.

As a result of the findings from this inspection the service should:

- Ensure that findings are not systemic across other areas within the wider organisation
- Provide HIW with updates where actions remain outstanding and/or in progress, to confirm when these have been addressed.

The improvement plan, once agreed, will be published on HIW's website.

# 5. How we inspect Ionising Radiation (Medical Exposure) Regulations

HIW are responsible for monitoring compliance against the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000 (and its subsequent amendments 2006 and 2011).

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
- Patients receive no more exposure than necessary to achieve the desired benefit within the limits of current technology
- Volunteers in medical research programmes are protected

We look at how services:

- Comply with the Ionising Radiation (Medical Exposure) Regulations
- Meet the Health and Care Standards 2015
- Meet any other relevant professional standards and guidance where applicable

Our inspections of healthcare services using ionising radiation are usually announced. Services receive up to twelve weeks notice of an inspection.

The inspections are conducted by at least one HIW inspector and are supported by a Senior Clinical Officer from Public Health England (PHE), acting in an advisory capacity.

Feedback is made available to service representatives at the end of the inspection, in a way which supports learning, development and improvement at both operational and strategic levels.

These inspections capture a snapshot of the standards of care relating to ionising radiation.

Further detail about how HIW inspects the NHS can be found on our website.

## Appendix A – Summary of concerns resolved during the inspection

The table below summaries the concerns identified and escalated during our inspection. Due to the impact/potential impact on patient care and treatment these concerns needed to be addressed straight away, during the inspection.

| Immediate concerns identified | Impact/potential impact on patient care and treatment | How HIW escalated the concern | How the concern was resolved |
|---|---|---|---|
| No immediate concerns were identified during this inspection. | | | |

## Appendix B – Immediate improvement plan

**Hospital:** University Hospital of Wales

**Ward/department:** Diagnostic Imaging-Cardiac Services

**Date of inspection:** 3 and 4 October 2017

The table below includes any immediate concerns about patient safety identified during the inspection where we require the service to complete an immediate improvement plan telling us about the urgent actions they are taking.

| Immediate improvement needed | Standard | Service action | Responsible officer | Timescale |
|---|---|---|---|---|
| We did not identify any immediate assurance issues during this inspection. | | | | |

The following section must be completed by a representative of the service who has overall responsibility and accountability for ensuring the improvement plan is actioned.

**Service representative:**

**Name (print):**

**Job role:**

**Date:**

## Appendix C – Improvement plan

**Hospital:** University Hospital of Wales

**Ward/department:** Diagnostic Imaging-Cardiac Services

**Date of inspection:** 3 and 4 October 2017

The table below includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

| Improvement needed | Standard | Service action | Responsible officer | Timescale |
|---|---|---|---|---|
| **Quality of the patient experience** | | | | |
| **Delivery of safe and effective care** | | | | |
| The health board is required to provide details of the action to be taken to ensure that people's personal information and records are held securely at all times within the cardiac day ward. | 3.5 Record keeping | • Review of current process in day case with storage/ availability of patients notes<br>• To ensure notes are not left unattended at the desk<br>• Reiterate the importance of safely storing of notes and to monitor compliance<br>• To ensure all staff are up to date with information governance | Deputy Sister/ Clinical Lead Cardiac day case | January 2018 |

| Improvement needed | Standard | Service action | Responsible officer | Timescale |
|---|---|---|---|---|
| | | training | | |
| **Quality of management and leadership** | | | | |
| The health board is required to inform HIW of the action taken/to be taken to ensure that staff are provided with a set of revised, clear and ratified procedures to follow in their day to day work. | Governance, Leadership and Accountability | • Review of current procedures and ratification by the Radiation Protection Group prior to roll out to staff.<br>• Arrange access to all relevant staff of 'read only' documentation on UHB, Radiology shared ('S' Drive).<br>• 'Go Live' with Q-Pulse (Quality and Document Management System | Professional Heads of Radiography & QSE Lead | February 2018<br>December 2017<br>December 2017 |
| The health board is required to provide HIW with a description of the action taken/to be taken in relation to aspects of staff training as follows:<br>There must be written evidence of any informal training undertaken by staff | 7.1 Workforce | • There is a programme in place to review ,revise and update training which reflects and evidences a pathway for training for each piece of new and existing equipment; both ionising radiation producing and ancillary. This will | Professional Heads of Radiography & QSE Lead | February 2018 |

| Improvement needed | Standard | Service action | Responsible officer | Timescale |
|---|---|---|---|---|
| concerning the use of radiographic equipment | | include the signature (full name) of both trainee and counter signature of the trainer. All signatures will be dated. | | |
| All staff records are to be available at future inspections in accordance with IR(ME)R regulation (11 (4)) | | • Staff training records; including cardiology duty holders under IR(ME)R, will be collated in each area of specialty and this information will be migrated onto Q-Pulse as implementation of this programme progresses. | Professional Heads of Radiography, Superintendent Radiographer Cardiology & QSE Lead | February 2018 |
| Staff training records must provide evidence of wider continuing education and training (over and above that required by IR(ME)R. | | • Training records will continue to document advanced learning in specialist areas beyond core operator requirements under IR(ME)R. These will be active records to reflect continued learning. Registered staff are required to hold and make available their individual CPD portfolios as a requirement of | Professional Heads of Radiography, Superintendent Radiographer Cardiology & QSE Lead | February 2018 |

| Improvement needed | Standard | Service action | Responsible officer | Timescale |
|---|---|---|---|---|
| Staff training records must contain the full name of the employee and be signed and dated by staff trainees; with a counter signature of the trainer for verification purposes | | their professional registration. Staff will be requested to make these available for future inspections.<br><br>• Staff training records will include the full name and signature of the trainee and full name and counter signature of the trainer. All records will be dated. | Professional Heads of Radiography, Superintendent Radiographer Cardiology & QSE Lead | February 2018 |

The following section must be completed by a representative of the service who has overall responsibility and accountability for ensuring the improvement plan is actioned.

## Service representative

**Name (print):** Sue Bailey

**Job role:** Clinical Board Lead for Quality, Safety and Patient Experience, CD&T

**Date:** 8-11-17 (updated 23-11-17)