

Ionising Radiation (Medical Exposure) Regulations Inspection (Announced)

Radiology Department / Royal
Glamorgan Hospital / Cwm Taf
Morgannwg 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 receive good quality healthcare

Our values

We place patients at the heart of what we do. We are:

- Independent
- Objective
- Caring
- Collaborative
- Authoritative

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 Royal Glamorgan Hospital within Cwm Taf Morganwwg University Health Board on the 11 & 12 December 2019. The following areas were visited during this inspection:

- Radiology Department

Our team, for the inspection comprised of two HIW Inspectors and a Senior Clinical Diagnostic Officer from the Medical Exposures Group of Public Health England, who was acting in an advisory capacity.

HIW explored how the service:

- Complied with the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R 2017)
- 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, from the evidence we examined, we found that compliance with IR(ME)R 2017 was good. Discussions with staff demonstrated that awareness of responsibilities in line with IR(ME)R was also generally good.

Policies and written procedures required under IR(ME)R 2017 were available and up to date. These helped the department to comply with the requirements of the regulations as they apply to radiology.

The department was being well managed and comments from staff indicated that they felt supported by senior staff.

We identified that further efforts could be made to fully meet some of the Health and Care Standards (2015) and Ionising Radiation (Medical Exposures) Regulations 2017.

This is what we found the service did well:

- Feedback received from patients indicated that they were highly satisfied with the services provided within the department.
- Senior staff were very receptive to our inspection and demonstrated a willingness to make improvements as a result
- Arrangements were in place to promote the privacy and dignity of patients.

This is what we recommend the service could improve:

- Promote the availability of Welsh speaking staff working within the department to help deliver an 'Active Offer'
- Ensure patients are routinely being provided with information in regard to the risks and benefits of undergoing their examinations, and also details on who to contact should they experience any issues following an exposure.
- Ensure staff consistently undertake patient identification checks and pregnancy status enquiries prior to exposure to ionising radiation.

3. What we found

Background of the service

Cwm Taf Health Board was established in October 2009 and achieved University Status in July 2013. On 1 April 2019, Cwm Taf University Health Board changed its name to Cwm Taf Morgannwg University Health Board (UHB), as it took responsibility for providing healthcare services for the people in the Bridgend County Borough area.

The UHB now provides primary, community, hospital and mental health services to the people of Merthyr Tydfil, Rhondda Cynon Taf, Bridgend and the surrounding areas.

The radiology department at Royal Glamorgan Hospital consists of four general radiography x-ray units (one digital radiography and three computed radiography) and three c-arm fluoroscopy mobile units.

Examinations are also provided using a range of other equipment, including:

- Computed Tomography (CT) scanners
- Ultrasound, mammography and dental units
- Magnetic Resonance (MR) scanners

The department employs a number of staff including Consultant Radiologists, Radiographers, Advanced Practice Radiographers, and Specialist Registrars.

The department also has support and advice from a Medical Physics Expert¹ (MPE) provided through a Service Level Agreement (SLA) between the UHB and the Radiation Protection Service based in Cardiff.

¹ The functions of Medical Physics Experts (MPEs) are different to that of the radiation protection adviser, or radioactive waste adviser. Specifically, an MPE is a person who holds a science degree or its equivalent and who is experienced in the application of physics to the diagnostic and therapeutic uses of ionising radiation.

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.

Feedback from patients indicated that they were highly satisfied with the service provided by staff within the radiology department.

We saw that arrangements were in place to promote the privacy and dignity of patients and found that staff treated patients in a kind and respectful manner.

Whilst the communication needs of patients were being met, we identified that improvements could be made to provide additional information to patients in regard to their care and treatment. Also, more could be done to promote the availability of Welsh speaking staff within the department.

Before our inspection we invited the department to hand out HIW questionnaires to patients. This was to obtain their views on the service provided. Questionnaires were also made available to patients visiting the department during our inspection. In total, we received 22 completed questionnaires from patients.

Patients were asked in the questionnaire to rate their overall experience provided by the service. Responses were very positive, nearly all of the respondents rated the service as either 'excellent' or 'very good'. Patients told us:

"Have been treated with utmost courtesy and respect. All staff are very helpful, friendly and professional. Excellent service."

"Staff are always fab!"

"Excellent. No improvement".

Staying healthy

Information was displayed in the department's main reception and patient waiting area on how patients could look after and care for their own health. The

information available included advice on smoking cessation, alcohol awareness and smear testing.

Posters displayed throughout the department also included basic information on radiology, as well as information in relation the other procedures and treatment linked to Nuclear Medicine and Radiotherapy.

Dignified care

Staff were observed treating patients in a polite, sensitive and professional manner.

All patients who completed a questionnaire agreed that they had been treated with dignity and respect by the staff at department. Patients also agreed that they were always able to maintain their own privacy, dignity and modesty during their appointments.

We did not observe any sensitive conversations taking place within the department during our visit but the questionnaire responses indicated that patients felt that they were able to speak to staff about their procedure or treatment without being overheard by other people.

The main patient waiting area, as well as the sub waiting areas, within the department were clean and in a good state of repair.

Individual changing cubicles for patients were available near to the examination rooms. These provide privacy when patients need to change out of their clothes into dignity gowns before and after their examination.

Whilst we did not observe patients having their procedures, we saw staff greeting patients in a friendly manner and asking about their welfare. X-ray room doors were being closed when patient consultation / treatment was taking place.

Patient information

We saw that a range of patient information was available and displayed within the department which related to a variety of topics, including what patients should expect with regards to their treatment / procedure. The majority of patients who completed a questionnaire felt that they had been given clear information to help them understand the risks and benefits of their examination or treatment. However, a few patients told us that they did not feel that they had been given clear information.

The majority of patients who completed our questionnaires said that they felt that they had been as involved as they wanted to be in relation to decisions about their treatment.

Most of patients who completed a questionnaire said that they had been given information on how to care for themselves following their treatment. However, a third of the patients told us that they had not been provided with information on who to contact for advice about any after effects they may experience following any treatments they had received. One patient commented:

"It is information that would assist should any queries arise".

Improvement needed

The UHB must ensure that patients are routinely provided with information outlining the risks and benefits related to their procedure / treatment.

The UHB must ensure that patients are routinely provided with information advising them who to contact should they have any issues following their procedure / treatment.

Communicating effectively

The majority of patients who completed our questionnaire said that it was 'very easy' or 'fairly easy' to find their way to the department once in the hospital.

Reception staff confirmed that a hearing loop was installed and working to assist people wearing hearing aids when communicating with staff. We were told that any requested for information in Braille or large print would be made available on request, to assist those patients with sight impairments.

All patients who completed our questionnaire confirmed that their preferred language was English. Also, all patients told us that they felt that they were listened to during their appointments.

We saw that posters and other leaflet information was available in English and Welsh. Also, senior staff confirmed that a number of staff within the department, including some radiographers and consultants, could speak Welsh. However, it was not immediately obvious within public areas of the department that patients could speak to staff in Welsh if they wished to do so.

Senior staff were receptive to our comments and agreed that the availability of Welsh speakers working within the department could be better promoted to help deliver an 'Active Offer'².

Improvement needed

The UHB is required to provide HIW with details of the action taken to promote the availability of Welsh speaking staff working in the department to help deliver the 'Active Offer'.

Timely care

The majority of patients who completed our questionnaire told us that they felt it was 'very easy' or 'fairly easy' to get appointments. However, a few disagreed. One patient commented:

“Only negative thing is it took from August until December to get the appointment.”

Most patients told us that they had waited less than 15 minutes to undergo their procedure when they'd arrived at the department. Others told us that they had waited for more than 30 minutes.

There was no method in place to inform patients of the current waiting time to be seen and the majority of patients' questionnaire responses stated that they were not informed on arrival how long they would likely have to wait for their procedure or treatment. This issue was discussed with senior managers, who told us that given the reactive nature of the department it can be difficult to provide patients with an approximate waiting time when they arrive. We were told that on the occasions where patients could be faced with a substantial wait to be seen, they

² An 'Active Offer' means providing a service in Welsh without someone having to ask for it. The Welsh language should be as visible as the English.

It is a key principle of 'More than just words', the Welsh Government initiative for strengthening Welsh language provision in health and social services. <https://gov.wales/welsh-language-healthcare-more-just-words-action-plan-2019-2020>

would be informed. However, given the comments we received, the UHB should consider further ways to communicate any delays to patients.

Improvement needed

The UHB is required to provide HIW with details of the action taken to better inform patients visiting the department of current waiting times.

Individual Care

Listening and learning from feedback

The UHB had a procedure in place for responding to any concerns that are received from patients in regard to the services they receive. The procedure was in line with the All Wales NHS Complaints procedure, known as Putting Things Right³.

Senior managers told us that they are notified of concerns via the PTR Team when they are received. We were informed that the Radiology element of concerns received, usually forms part of the individual patient's overall concern.

There was some information displayed within the main waiting room area in the department in relation to 'Putting Things Right'. However, half of the patients who completed our questionnaire told us that they would not know how to raise a concern or complaint about the services they had received. Given this feedback, efforts should be made to better inform patients of the UHB complaints procedure.

Staff told us that on the occasions where verbal concerns were raised by patients, where possible, attempts were made to deal with the patients' issues immediately (i.e. 'on the spot') to help resolve any issues quickly and efficiently.

³ 'Putting Things Right' (PTR), is the integrated process for the raising, investigation of and learning from concerns. Concerns are issues identified from patient safety incidents, complaints and, in respect of Welsh NHS bodies, claims about services provided by a Responsible body in Wales.

There was no information displayed in relation the Community Health Council⁴ (CHC). The CHC is able to offer support and advice to any individuals who wish to raise concerns about their NHS treatment.

Arrangements were in place for patients to provide feedback about their experiences of using the radiology department. There was a 'Have your say' notice board clearly displayed next to the main reception desk within the department. In front of the board was a box and feedback cards to allow visitors to the department to provide feedback on their experiences.

A patient satisfaction audit was completed in 2019 for the whole of the Cwm Taf Morgannwg UHB Radiology Department. The audit included collating views from patients who had visited each of the five Radiology Department hospitals within the UHB. These are the Royal Glamorgan, Prince Charles, Ysbyty Cwm Rhondda, Ysbyty Cwm Cynon and Dewi Sant. The purpose of the audit was to gain a better understanding of the performance of the overall department from a patient perspective.

The audit covered four areas which were appointment bookings, examinations, cleanliness and overall experience. The overall results from this survey were positive. However, there were also a number of recommendations highlighted from the patient feedback received which included the need to keep patients informed of any delays to their appointments when they arrive.

Improvement needed

The UHB is required to provide HIW with details of the action to be taken, to ensure that patients are fully aware of their right to raise concerns about their NHS care or treatment.

The UHB should ensure that information is available advising patients of the role of Community Health Council (CHC)

⁴ <http://www.wales.nhs.uk/sitesplus/899/page/71619>

Delivery of safe and effective care

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

Overall, we found that compliance with IR(ME)R 2017 was good from the evidence available and discussions undertaken with staff.

Staff awareness of their IR(ME)R 2017 responsibilities was generally very good.

Policies and written procedures required under IR(ME)R 2017 were available and up to date. These helped the department to comply with the requirements of the regulations as they apply to radiology.

A few areas for improvement were highlighted in regard to consistency with recording patient identification checks and pregnancy status enquiries prior to exposure.

Compliance with Ionising Radiation (Medical Exposure) Regulations

Duties of employer

Patient identification

The employer had an up to date written procedure for staff to follow to correctly identify patients prior to their exposure. This aimed to ensure that the correct patient had the correct exposure and is one of the employer's procedures required under IR(ME)R 2017.

The procedure clearly identified those staff responsible for correctly identifying patients. Staff were expected to ask patients to confirm their name, date of birth and address. This approach is in keeping with current UK guidance⁵.

The procedure also described alternative approaches that staff must use should patients be unable to verbally confirm their identity themselves, further promoting patient safety.

It was highlighted during our review of the procedure that there may be additional information required, setting out the process that staff should follow when undertaking identification checks for paediatric patients. The procedure should also outline that a record of this check should be documented by staff. This issue was discussed with senior staff as part of our inspection, who were receptive to our suggestion.

Staff we spoke to as part of our inspection, were able to describe the correct procedure to identify patients.

Nearly all of the patients who completed a questionnaire confirmed that they were asked to confirm their personal details before starting their procedure or treatment. However, one patient told us that they had not been asked to confirm their details prior to their procedure or treatment. The employer must ensure that all staff are reminded of the importance of following the process outlined in the UHB's patient identification procedure, to mitigate the risk of an incorrect exposure being undertaken.

Improvement needed

The employer must provide HIW with details of the action taken to ensure that all staff are undertaking patient ID checks prior to all exposures, in line with the UHB procedure.

⁵ Department of Health and Social Care (2018); Guidance to the Ionising Radiation (Medical Exposure) Regulations 2017

Individuals of childbearing potential (pregnancy enquiries)

The employer had two separate procedures in place in relation to the process for carrying out pregnancy enquiries for individuals of childbearing age prior to any exposures. The procedures set out the processes to follow for high and low dose exposures.

This aimed to ensure that such enquires were made in a standard and consistent manner. The procedures clearly identified those staff responsible for making relevant enquires and set out the actions they must follow depending on the individual's responses.

The written procedures included the age range of patients who should be asked about pregnancy in accordance with UK guidance⁶.

As part of our review of these procedures a few suggestions were highlighted that the employer should consider incorporating into the documents. These suggestions were discussed with senior managers during our inspection and included incorporating additional guidance for staff within the procedures in relation to transgender patients and unresponsive patients.

Posters were displayed within the department advising individuals to speak with staff if they either are or think they may be pregnant. This is important to minimise potential harm to an unborn child from the exposure to ionising radiation.

Staff we spoke with as part of our inspection were able describe their responsibilities in regard to the pregnancy enquiries, which were in line with the procedures described above. We were also informed that pregnancy status would be verbally checked with carers and comforters prior to any exposure. However, we were told that this enquiry was not recorded. It was discussed that the department might consider, for completeness, that these pregnancy enquiries for carers and comforters be recorded.

As part our inspection, we reviewed a random sample of patient records. One of the sets of records reviewed, which related to an individual of child bearing age, did not evidence that a pregnancy status check had been carried out by staff. The employer must ensure that staff are reminded of the importance of routinely

⁶ Guidance to the Ionising Radiation (Medical Exposure) Regulations 2017.

completing pregnancy status checks when appropriate and also that evidence of these checks is being recorded.

Improvement needed

The employer must provide HIW with the action taken to ensure that required pregnancy status checks are routinely being undertaken by staff and that patient records are updated to evidence when a check has taken place.

Non-medical imaging exposures

The employer had a written procedure in place which set out the criteria for carrying out non-medical imaging exposures⁷.

We were informed that non-medical imaging was not a common referral and only performed occasionally within the UHB for medico-legal cases and health insurance purposes.

Referral guidelines

The employer had established referral guidelines in place. Arrangements were described for making these available to those entitled to act as referrer under IR(ME)R 2017.

Staff we spoke to as part of our inspection were clear on the referral guidelines and process in place.

Currently all referrals submitted to the department for imaging are paper based using the radiology referral form. Once received all referrals are registered onto the electronic system RadIS⁸.

⁷ Non-medical imaging exposures include those for health assessment for employment purposes, immigration purposes and insurance purposes. These may also be performed to identify concealed objects within the body.

⁸ An All Wales Radiology Information System (WRIS), RadIS, which allows the sharing of information in order to support seamless patient care across the NHS Wales organisations is available to all health boards in Wales.

We reviewed a random sample of patient referral documentation as part of our inspection. The layout of the referral forms reviewed was clear and clinical information provided was in line with referral guidelines.

The majority of referrals included sufficient clinical details and were signed by an appropriately entitled practitioner confirming justification⁹. However, one of the records we reviewed did not have a signature to confirm whether the justification process had been completed and who the practitioner was that performed the exposure. This issue has also been noted under the sub heading of justification later on in this section.

Another record we reviewed had no evidence that clinical evaluation for the patient had been undertaken following completion of the examination which was carried out on 11 November 2019.

Duties of referrer, practitioner and operator

The employer had a system in place to identify the different types and roles of the professionals involved in referring and performing radiology examinations for patients. The employer's procedure on how IR(ME)R 2017 is implemented within the department identified, by staff group, who were entitled to be referrers¹⁰ practitioners¹¹ and operators¹² (known as duty holders).

Information is included within the employers Ionising Radiation Protection Policy in relation to the minimum competency / training requirements for each duty holder role.

⁹ Justification is the process of weighing up the expected benefits of an exposure against the possible detriment of the associated radiation dose.

¹⁰ Under IR(ME)R a referrer is a registered healthcare professional who is entitled, in accordance with the employer's procedures, to refer individuals for medical exposures

¹¹ Under IR(ME)R a practitioner is registered healthcare professional who is entitled, in accordance with the employer's procedures, to take responsibility for an individual medical exposure. The primary role of the practitioner is to justify medical exposures.

¹² Under IR(ME)R an operator is any person who is entitled, in accordance with the employer's procedures, to carry out the practical aspects of a medical exposure.

Entitlement is linked to successful completion of the relevant training and competency checks for specific equipment and examinations. At this hospital there is also discussion with senior staff to ensure understanding of procedures and protocols before entitlement is signed off.

Practitioners and Operators are entitled by the Radiology Clinical Director. All staff have copies of their individual entitlement certificates and entitlements are also displayed on a staff matrix.

Staff we spoke to had a clear understanding of their relevant duty holder roles and scope of entitlement under IR(ME)R.

Staff confirmed that they were able to access up to date electronic versions of policies and employer's procedures via the department's online shared drive. We were told that all staff had computer access within the department.

Senior staff described the system for notifying department staff of any changes to policies and procedures within the department. This involved individual staff members being provided with details of any reviewed and updated documents. Staff were then asked to confirm that they had reviewed and understood the relevant changes, a record of which was subsequently made and retained. Staff we spoke to confirmed they were aware of the system in place.

There is a contract in place between all health boards in Wales for Everlight Radiology¹³ to provide a radiology reporting service which includes, in some instances, out of hours justification of specified examinations and associated clinical evaluation. This arrangement was detailed within the employer's procedural documentation. However, there were inconsistencies highlighted with how the Everlight Radiologist's entitlement was defined within the documentation provided. This issue was discussed with senior managers during our inspection and it was agreed that the defined entitlement for Everlight needed to be amended to ensure consistency within all the documentation.

¹³ Everlight Radiology is a substantial provider of teleradiology services based in London and Australia.

Improvement needed

The employer must provide HIW with the action taken to ensure that documentation is clear and consistent in relation to the entitlement of Everlight Radiology for the radiology services provided on behalf of the UHB.

Justification of Individual Medical Exposures

The employer had a written procedure for the justification and authorisation of medical exposures.

The justification process was discussed with a number of different staff within the department and a clear understanding of the process was evident.

Justification of individual medical exposures was recorded on the radiology requests forms, with the date and signature of the practitioner. As outlined previously, as part of our inspection we reviewed a sample of radiology referrals. One of the records reviewed provided no evidence that the exposure had been justified, as there was no signature from an appropriately entitled practitioner.

Given the IR(ME)R 2017 definition of carers and comforters, we held discussions with senior managers about this aspect of service delivery. We were told that radiographers have been entitled to act as practitioners to enable them to justify the exposures to carers and comforters. We were informed that the type of examination would determine which duty holder would justify. However, it would more commonly be the duty holder carrying out the procedure who would justify the exposure to carers and comforters.

During discussions with staff it was highlighted that on the occasions where justification for an individual medical exposure was being provided by Everlight Radiology, in line with the out of hours contract agreement in place, the name of the individual practitioner justifying the exposure was not being recorded on the relevant documentation. For any medical or non-medical exposure, the individual practitioner justifying the exposure, needs to be identified.

This matter was discussed further with senior managers from the department and we were told that some staff do follow up receipt of the documentation justifying the exposure with a phone call, to request the name of the practitioner. However, it was acknowledged that this information was not being recorded. It was agreed that this practice needed to be updated.

As the out of hours contract with Everlight is in place with all of the health boards in Wales, it is likely that this could be an issue in other Radiology Departments.

Healthcare Inspectorate Wales will seek further clarification and assurance from the Welsh Government on this matter.

Improvement needed

The employer must provide HIW with details of the action taken to ensure that all medical and non-medical exposures are justified and that the individual practitioner justifying each exposure can be identified.

Optimisation

The employer had arrangements in place for the optimisation¹⁴ of exposures. For example, the Image Optimisation Team (IOT) meets regularly within the radiology department. Staff are requested to identify and action where optimisation of equipment is likely to be possible. Also, the IOT will review other processes in place to identify any possible improvements or changes in practice which should be made.

It is clear from our inspection that the IOT is working well and radiology staff are clearly engaged. We would encourage that the work being carried out by the team continues and includes the involvement of the MPE (Regulation 14(2)(c)).

Senior staff confirmed that paediatric protocols and exposure settings were used to ensure that exposures to children were being optimised and paediatric exposure settings were evidenced in a number of the areas visited

Diagnostic reference levels

There were processes in place for determining, implementing and reviewing Diagnostic Reference Levels (DRLs). During our tour of the department, we noted that local and national DRLs were clearly displayed in each area visited.

All of local DRLs examined were either below or in line with the National DRL for the specified examination.

¹⁴ Optimisation refers to the process by which individual doses are kept as low as reasonably practicable.

In discussion with senior managers we were informed that the local DRLs are continually being reviewed by a programme of protocol optimisation in collaboration with the MPE. Evidence was seen in the minutes of the IOT meetings that demonstrated that the topic of protocol optimisation and the oversight of local DRLs was a focus for the team. Regulation 14(2)(c) requires the MPE to be involved for consultation on optimisation and it is hoped that the IOT will have appropriate support from the MPE for protocol optimisation.

We saw that regular audits of dose input onto RadIS by staff following treatment had been undertaken within the department. The most recent audit results available at the time of our inspection indicated that 96% of doses had been recorded electronically for all Radiology examinations completed. As part of our review of patient documentation, all records reviewed had evidence that the doses had been recorded on RadIS.

Clinical evaluation

There was an employer's procedure in place (EP10), which described the process regarding clinical evaluation.

We were told that all examinations and exposures involving ionising radiation have a clinical evaluation performed by an appropriately entitled member of staff.

As outlined previously, as part of our review of a random sample of patient records, one of the patient records we reviewed had no evidence to indicate that a clinical evaluation had been undertaken four weeks after the examination had been completed. In discussion with senior staff it was clear there are time delays for some examinations to be evaluated. During the visit to the department staff described some of the processes being implemented, such as a reporting dashboard, which are being used to prioritise clinical evaluation in an effort to address the wait times.

Improvement needed

The employer must provide HIW with details of the action taken to ensure that patient clinical evaluation reports are routinely completely within a reasonable timeframe.

Equipment: general duties of the employer

The employer had an up-to-date inventory (list) of the equipment used within the radiology department. The inventory contained the information required under (IR(ME)2017).

We were told by senior staff that all equipment within the department was fully maintained under service contracts. Also, evidence was available to demonstrate that quality assurance testing was being performed regularly on imaging equipment.

A procedure for quality assurance (QA) of equipment by the radiographic staff was provided to the inspection team and a number of examination room records of the QA were seen. The MPE explained that the annual equipment QA carried out by the radiation protection service was in the process of being undertaken.

Safe care

Managing risk and promoting health and safety

The environment was well maintained and arrangements were in place to promote the safety of staff, patients and visitors to the department.

The department was located on the ground floor and there was level access throughout. This allowed patients with mobility difficulties to enter and leave the department safely.

The department was clean and generally free from clutter and obvious trip hazards. Appropriate signage and restricted access arrangements were in place to deter and prevent unauthorised persons entering areas where radiology equipment was being used. This helped promote the safety of patients and visitors to the department.

Infection prevention and control

Arrangements were in place for effective infection prevention and control and decontamination.

The environment was well maintained and arrangements were in place to promote the safety of staff, patients and visitors to the department. At the time of our inspection, all areas of the department were visibly clean and generally tidy.

We were told by senior staff that there was a good rapport with the infection control team, who were able to provide the department with advice as and when required. The team were also consulted during the planning stages on the development of the new areas to the department to ensure that infection control matters were fully considered in the process.

There are handwashing champions within the department who undertake regular audits on hand hygiene compliance. We were told that findings from audits was collated and fed back to the department staff.

There were cleaning regime checklists available in each of the treatment rooms we visited. Cleaning labels were put onto equipment to indicate when it was last cleaned to ensure regular cleaning of equipment was being carried out.

We saw that personal protective equipment (PPE) was readily available. Staff we spoke to confirmed that they always had access to PPE such as disposable gloves. The use of PPE together with effective handwashing is important to reduce the spread of infection.

Concerns were raised by senior staff in regard to the infection control training required to be undertaken by radiology staff. Senior staff felt the current training is very nursing specific and that it would be beneficial for bespoke radiology infection control training to be offered, that would be more relevant to the department staff.

Current staffing pressures at the department has meant that it has been difficult for staff to complete the level two infection control training. However, discussions with staff revealed that, with the exception of one staff member, they had completed the required eLearning (online) level one training on infection control. The member of staff we spoke with yet to complete the training was currently going through the induction process and the training was scheduled.

All of the staff we spoke to had good knowledge of their responsibilities in regard to infection and control.

Nearly all of the questionnaire responses said the department was 'very clean' or 'fairly clean'.

Safeguarding children and adults at risk

Discussions with staff within the department demonstrated that there was an awareness of current safeguarding procedures in place. We also informed that staff had completed online training to help them keep up to date with relevant safeguarding issues.

Effective care

Quality improvement, research and innovation

Clinical audit

Information was provided to demonstrate compliance with IR(ME)R 2017 in regard to clinical audit. Evidence was provided of the audits already completed this year, as well as the audit schedule for the remainder of the year.

We were informed that clinical audits within the radiology department are led by a Consultant Radiologist.

Evidence to demonstrate that learning was being shared following audits completed was available. Audit meetings are organised on a quarterly basis and involve all staff groups. Predominantly practitioners and operators attend the meetings, however there are occasionally some referrers from outside the radiology department that attend, depending on the audit topics being discussed.

Within the UHB's radiation protection policy, it was recommended that audits should be completed to assess the appropriateness and quality of referrals, and the recording of the clinical outcomes within patient notes. However, during discussions with senior staff it was highlighted that neither of these audits were currently taking place. We were told that that consideration was being given to incorporating each of these audits into the overall radiology programme.

Expert advice

There was one MPE working with the UHB under the service level agreement with the Radiation Protection Service based in Cardiff. The MPE was listed on the approved list for RPA 2000, the certification body for MPEs.

We were informed by senior staff that the MPE was involved in the work within the radiology department including the ongoing protocol optimisation to attempt to bring local DRLs in line with national levels and routine audits of dosage levels to enable to ongoing review exposure factors. Focused work optimising protocols to bring local DRLs, currently higher than the National DRL for that examination, should continue, with support from the MPE. If these higher values cannot be brought in line with the National DRL then the MPE should provide a statement providing a suitable explanation.

Senior staff also told us that they were able to contact an MPE for advice when necessary on an ad hoc basis.

Medical research

The employer had an established procedure in place with regard to Medical Research exposures (EP7). A discussion was held with senior staff in regard to this procedure and it was suggested that more operational detail could be included within the document. We were informed by staff that additional detail will be considered.

Information governance and communications technology

Information management systems within the department were described and demonstrated by staff. The systems in place allowed for relevant patient details and information about diagnostic and interventional procedures performed, to be recorded and easily accessed by staff.

Record keeping

We reviewed a sample of patient care records. The majority of records we saw had been completed with appropriate details by those staff involved in the exposure. However, as previously detailed we did identify an issue in regards the recording of the relevant entitled practitioner details to demonstrate that exposures were being justified.

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

A management structure with clear lines of reporting and accountability was described and demonstrated.

The department was well being well managed and comments from staff indicated that they felt supported by senior staff within the department. It was clear from our inspection that there was a good rapport between department staff and senior managers.

Senior staff confirmed that there were ongoing recruitment issues, however this was being actively managed by the UHB to minimise the impact on the delivery of services.

Governance, leadership and accountability

A management structure with clear lines of reporting was described and demonstrated. We found that governance arrangements were in place to support the effective operation of the radiology department.

Staff we spoke to confirmed that they felt supported by their line manager. Staff also told us that they felt that the senior managers were very visible and approachable should they have any issues or queries they wish to discuss.

Senior management staff made themselves available on the days of the inspection and facilitated the inspection process. They were receptive to our feedback and demonstrated a willingness to make improvements as a result of the inspection.

Ahead of the inspection, HIW required senior staff within the department to complete and submit a self-assessment questionnaire. This was to provide HIW with detailed information about the department and the employer's key policies and procedures in respect of IR(ME)R. This document was used to inform the inspection approach.

The self-assessment form was returned to HIW within the agreed timescale and was comprehensive. Where we required additional information or clarification in respect of the responses within the self-assessment, senior staff provided this promptly.

Duties of the employer

Entitlement

As previously described, the employer had a suitable system in place to identify the different types and roles of the professionals involved in referring and providing radiology examinations for patients, as required under IR(ME)R 2017. The employer's policy on how IR(ME)R 2017 is implemented within the department identified personnel, by staff group (duty holders).

Overall, the staff entitlement records we saw as part of our inspection were complete and up to date. However, we did identify a few areas where more detail was required in setting out arrangements for entitlement. This included conflicting information within the entitlement procedure and the radiation protection policy around who entitles the Everlight radiologists providing third party clinical evaluation and justification services. The detail around the entitlement of maintenance engineers also requires amending. The issues highlighted were discussed and agreed with senior managers during our inspection and recommendations for improvements needed are made earlier in this report where applicable.

Procedures and protocols

The Chief Executive of the UHB was designated as the employer. This arrangement was detailed within the UHB's Ionising Radiation Protection Policy. At the time of our inspection we were informed that this policy was being updated and was scheduled for final approval at the health board, Quality, Safety and Risk Committee. A number of suggestions were provided during our conversations with senior managers in regard to the current detail included within the document to assist the ongoing revision of the document.

We saw that clear written procedures and protocols had been developed and implemented in accordance with IR(ME)R 2017.

As previously detailed, staff we spoke to as part of our inspection confirmed that they had access to up to date versions of the policies and procedures in place. Also, senior staff confirmed that when any changes to documents occur, notifications are circulated to department staff, who are subsequently ask to confirm that they have read and understand the relevant changes.

Significant accidental or unintended exposures

The employer had a written procedure for reporting and investigating significant accidental or unintended exposures (SAUE) within the department (Regulation 8(3)).

The employer's procedure clearly sets out the process staff should follow if they suspect that a SAUE has occurred. The procedure guided staff of the process to follow and subsequently resulted in Healthcare Inspectorate Wales (HIW) being informed of such incidents in a timely manner.

We were informed that any incidents or near misses are recording via Datix, the incident management system used in CTMUHB. Radiation incidents are brought to the attention of the specific modality lead Radiographer for the analysis to be disseminated and discussed. All incidents were being reviewed and during our inspection analysis information was made available to demonstrate this. During our review of this information we identified that the analysis being carried out currently was only numeric, there was no detail in the information reviewed in regard to the specifics of the incidents or a detailed analysis of radiation incidents and near misses which would highlight trends, enable shared learning and identify changes in practice to improve patient safety.

Staff we spoke to were able to describe the process to follow in regard to reporting incidents involving ionising radiation.

There is a requirement under IR(ME)R 2017, (Schedule 2(l)), to have an employer's procedure detailing the process for ensuring that the referrer, the practitioner and the individual exposed (or their representative) are informed of the occurrence of any relevant clinically significant accidental or unintended exposures and the outcome of the analysis of these events.

It was highlighted following review of this employer's procedure, that detail was required around clinically significant accidental or unintended exposures as this was not explicitly described in the current procedure. Suggested information has been shared with the UHB to assist in updating the procedure with relevant additional details.

Improvement needed

The employer must provide HIW with details of the action taken to ensure detailed analysis (including themes and trend analysis) of SAUE is undertaken to ensure any learning is shared and changes implemented.

The employer's procedure should include specific detail around clinically significant accidental or unintended exposures.

Staff and resources

Workforce

Senior staff told us that more department staff were required, but felt that the department was managing to maintain an appropriate level of service at the moment. This was in part due to the use of agency / locum staff who work within the department to cover staff shortages.

We were told that recruitment for the department is a challenge and is one of the key risks to the service. Discussions are ongoing in regard to how this risk can be addressed for the service moving forward.

The staff vacancies included four band five radiographer posts within the department. Interviews have taken place and individuals have been appointed, however, as the individuals appointed are students, the service must wait until July 2020 for them to qualify, before they are able to start working within the department.

There are also four band six radiographer vacancies, two of which are part of the interventional team which does leave the service vulnerable. Interviews for two of these posts were scheduled to take place the week following our inspection.

Senior staff described arrangements to minimise the impact of vacancies on the delivery of the service. It was clear that there was very effective and flexible use of the current workforce to meet the demands on the service.

Department staff we spoke with felt that the staffing levels were safe. Also, as previously mentioned staff felt that they were supported by their manager and also told us that senior managers were very approachable, if they had any queries that needed advice on.

As described previously, the employer had arrangements in place for the entitlement of 'practitioners', 'operators' and 'referrers'.

We looked at a sample of training records for 'practitioners' and 'operators' working within the department. These demonstrated that staff had received relevant training and had their competency assessed in relation to carrying out exposures and examinations. These records also clearly identified each individual's scope of practice.

Radiology staff confirmed they had access to training and were supported by senior staff to meet their continuing professional development needs.

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, measurable, 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 services that use ionising radiation

HIW are responsible for monitoring compliance against the [Ionising Radiation \(Medical Exposure\) Regulations 2017](#) and its subsequent amendment ([2018](#)).

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 summarizes 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 highlighted during inspection.			

Appendix B – Immediate improvement plan

Hospital: Royal Glamorgan Hospital

Ward/department: Radiology Department

Date of inspection: 11 and 12 December 2019

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 / Regulation	Service action	Responsible officer	Timescale
No immediate improvements highlighted during inspection.	N/A			

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: Royal Glamorgan Hospital

Ward/department: Radiology Department

Date of inspection: 11 and 12 December 2019

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 / Regulation	Service action	Responsible officer	Timescale
Quality of the patient experience				
The UHB must ensure that patients are routinely provided with information outlining the risks and benefits related to their procedure / treatment.	4.2 Patient Information	This task is included within the employers' procedures in the Health Board. Staff have been reminded of the necessity to ensure all patients are informed of risk and benefit prior to undertaking their examination. We have also placed further information in all examination rooms alongside the 'Pause & Check' information asking Radiographers if they have informed the patient of the risk and benefit.	Paul Johnston	24 th January 2020

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		<p>Additionally we will include a question asking patients if they were informed in our patient satisfaction questionnaire.</p> <p>We will also be including checks as part of our future observational audits.</p>	<p>Andrew Thomas</p> <p>Sarah Rees</p>	<p>For next patient satisfaction survey – likely to be in 2021 (surveys conducted biannually).</p> <p>Observational audits to commence in March 2020.</p>
<p>The UHB must ensure that patients are routinely provided with information advising them who to contact should they have any issues following their procedure / treatment.</p>	<p>4.2 Patient Information</p>	<p>A reminder has been sent to all staff reminding them of their responsibility to ensure patients are fully aware of who to contact.</p> <p>We have also produced a poster which has been placed in all waiting areas</p>	<p>Paul Johnston</p>	<p>24th January 2020</p>

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		<p>indicating that results will be sent back to the person who referred them for their examination.</p> <p>It tells the patient to check with the Radiographer performing the examination or the receptionist if they are not sure who referred them.</p>		
<p>The UHB is required to provide HIW with details of the action taken to promote the availability of Welsh speaking staff working in the department to help deliver the 'Active Offer'.</p>	<p>3.2 Communicating effectively</p>	<p>Posters inviting patients to ask if they wish to have their examination conducted in Welsh are now on display in all of the Radiology Directorate reception areas.</p>	<p>Collette Jones / Marc Phillips</p>	<p>Completed 10th January 2020</p>
<p>The UHB is required to provide HIW with details of the action taken to better inform patients visiting the department of current waiting times.</p>	<p>5.1 Timely access</p>	<p>As discussed at the feedback session this can sometimes be difficult as we have many patients arriving without set appointment times. However, staff have all been informed to ensure they keep patients informed of any delays and we have also produced information to be displayed in our waiting areas encouraging patients to speak to staff if they have waited for some time.</p>	<p>Paul Johnston</p>	<p>24th January 2020</p>

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
The UHB is required to provide HIW with details of the action to be taken, to ensure that patients are fully aware of their right to raise concerns about their NHS care or treatment.	6.3 Listening and Learning from feedback	We have discussed with the concerns team in the Health Board. We have reviewed the provision of the information for patients in all of our Radiology Departments and have displayed additional information more prominently for patients.	Paul Johnston / Ruth Friel	24 th January 2020
The UHB should ensure that information is available advising patients of the role of Community Health Council (CHC)	6.3 Listening and Learning from feedback	We have contacted the Community Health Council and they have sent us posters which are now displayed prominently in our Departmental waiting areas	Collette Jones / Marc Phillips	Completed 10 th January 2020
Delivery of safe and effective care				
The employer must provide HIW with details of the action taken to ensure that all staff are undertaking patient ID checks prior to all exposures, in line with the UHB procedure.	Schedule 2 (a) Regulation 10 (4)	All staff have been informed of their duty to undertake appropriate identification checks prior to exposing patients to radiation. Supplemented with the 'STOP' poster embedded above which has been placed in all Radiology examination rooms.	Paul Johnston	24 th January 2020

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
The employer must provide HIW with the action taken to ensure that required pregnancy status checks are routinely being undertaken by staff and that patient records are updated to evidence when a check has taken place.	Schedule 2 (c) Regulation 11 (1) (f)	All staff have been informed of their duty to undertake appropriate pregnancy status checks prior to exposing patients to radiation. Supplemented with the 'STOP' poster embedded above which has been placed in all Radiology examination rooms	Paul Johnston	24 th January 2020
The employer must provide HIW with the action taken to ensure that documentation is clear and consistent in relation to the entitlement of Everlight Radiology for the radiology services provided on behalf of the UHB.	Schedule 2 (b)	The Ionising Radiation Protection Policy has been amended to identify external providers (such as Everlight) as Practitioners with an up to date list of entitled practitioners working for the company held in the Radiology Department.	Paul Johnston	24 th January 2020
The employer must provide HIW with details of the action taken to ensure that all medical and non-medical exposures are justified and that the individual practitioner justifying each exposure can be identified.	Regulation 11 (1) (b) Regulation 11 (2) (a-d)	The procedure for performing imaging that has been justified by Everlight has also been amended so that the Radiographer will now ask for, and record on the Radiology request form, the individual who has justified the examination.	Sarah Rees / Paul Johnston	24 th January 2020

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
<p>The employer must provide HIW with details of the action taken to ensure that patient clinical evaluation reports are routinely completely within a reasonable timeframe.</p>	<p>Regulation 12 (9)</p>	<p>The following actions have been undertaken or are underway:</p> <p>We have employed a locum Consultant Radiologist to report CT and MRI studies.</p> <p>We are offering additional sessions to Consultant Radiologists for reporting.</p> <p>We have incorporated dedicated sessions in to Consultant timetables to sign off Radiographer CT colon studies.</p> <p>We are instigating 'quiet' reporting sessions to minimise disturbances to staff and to hopefully increase reporting productivity.</p> <p>We are reviewing our 'Duty Radiologist' sessions to try and steer more work towards secretarial staff where appropriate.</p>	<p>Dr Sally Bolt</p>	<p>Ongoing</p>

Quality of management and leadership

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
<p>The employer must provide HIW with details of the action taken to ensure detailed analysis (including themes and trend analysis) of SAUE is undertaken to ensure any learning is shared and changes implemented.</p>	<p>Regulation 8 (3)</p>	<p>All radiation incidents will now be collated on a quarterly basis and feature as a standing agenda item on the Radiology Clinical Governance Meeting Agenda.</p> <p>Incidents will be categorised by themes as will any actions taken.</p> <p>Only incidents from the previous quarter will be discussed at each meeting but the themes will be reviewed cumulatively to try and ensure any patterns are identified.</p>	<p>Paul Johnston / Dr Phillip Wardle</p>	<p>Ongoing at all Radiology Clinical Governance Meetings</p>
<p>The employer's procedure should include specific detail around clinically significant accidental or unintended exposures.</p>	<p>Regulation 8 (1) Schedule 2 (1) (l)</p>	<p>A revised Employers Procedure has been drafted following advice kindly received from the Senior Clinical Diagnostic Officer, Public Health England, who attended the inspection and acted in an advisory capacity.</p> <p>The Senior Clinical Diagnostic Officer has offered to provide further comment and the Radiology Directorate is awaiting those comments. If the Inspector is unable to provide further comments then</p>	<p>Paul Johnston with support and advice from the Senior Clinical Diagnostic Officer</p>	<p>29th February 2020</p>

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		the revised procedure will be implemented no later than 29 th February 2020.		

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): Paul Johnston

Job role: Superintendent Radiographer

Date: 22nd January 2020