Ionising Radiation (Medical Exposure) Regulations Inspection (Announced)

Nuclear Medicine Department –
Royal Gwent Hospital / Aneurin Bevan 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 remote Ionising Radiation (Medical Exposure) Regulations inspection of Royal Gwent Hospital's Nuclear Medicine Department on 2 and 3 February 2021.

Our team, for the inspection comprised of two HIW Inspectors and a Senior Clinical Nuclear Medicine 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)
- 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 staff we spoke with had a clear understanding of their duty holder roles and responsibilities in line with IR(ME)R 2017.

There was evidence of an experienced and committed workforce, with a good team working ethos. Overall, staff were happy with the level of support provided by senior managers.

Discussions with managers and department staff throughout our inspection provided assurance that arrangements were in place to ensure that examinations were being undertaken safely. However, we highlighted additional detail was required in the majority of written procedures reviewed, to ensure the procedures accurately reflected the practises in operation.

This is what we found the service did well:

- Evidence was provided of advanced practices in place and staff confirmed there was support for continued training and professional development
- Information provided indicated that adequate arrangements had been implemented to allow for effective infection prevention and decontamination within the department. Arrangements which had been strengthened as a result of COVID-19
- Arrangements were in place to allow patients to submit their experiences of using the department.

This is what we recommend the service could improve:

- Employer's written procedures must be reviewed to ensure that they accurately reflect the practices and procedures in place, reflect the requirements of IR(ME)R 2017 and provide the required level of information to guide staff in performing their roles
- Ensure routine staff appraisals are being carried out, to allow for training and development needs to be identified and monitored

- Update the clinical audit plan to include audit frequency, and ensure that relevant staff have sufficient capacity to complete audits, in line with the agreed frequency

- Ensure arrangements are in place to allow for relevant documents to be routinely reviewed in line with the agreed frequency, in accordance with the employer's procedure for the QA of documentation.

3. What we found

Background of the service

Aneurin Bevan University Health Board was established on 1 October 2009 and provides primary, community, hospital and mental health services to the people of Blaenau Gwent, Caerphilly, Monmouthshire, Newport, Torfaen and South Powys.

The health board as a whole serves a population of more than 600,000 people and many of the inpatient and specialist services at the Royal Gwent Hospital support the entire catchment area.

The Nuclear Medicine Department at the Royal Gwent Hospital consists of equipment including a hybrid gamma camera with a built in CT scanner, a dose calibrator and gamma probes. The department employs a number of staff including Consultant Radiologists, a consultant Cardiologist, Clinical Technologists and Radiographers.

The department also has advice and support provided by a Medical Physics Expert[1] (MPE) and Clinical Scientist provided through a Service Level Agreement (SLA) with the Cardiff and Vale University Health Board.

[1] An MPE is a person having knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure in diagnostic radiology, nuclear medicine and radiotherapy, whose competence in this respect is recognised by a competent authority. All employers who carry out medical exposures are required in IR(ME)R to appoint a suitable medical physics expert.

Quality of patient experience

As part of our remote inspection, we reviewed some of the arrangements in place to communicate with and obtain feedback from patients regarding the services provide.

Information provided indicated that there were sufficient arrangements in place to meet the communication needs of patients attending the department.

Evidence was available of adequate written information being provided to patients prior to their examinations within the department.

Arrangements were in place to allow patients to submit feedback on their experiences of using the department, which included patient surveys, as well as a clear process for dealing with and responding to formal concerns received by the service.

As part of our remote IR(ME)R inspection methodology, we developed an online patient survey, to allow patients to provide their views and experiences on the services provided within the department. This survey was publicised via a poster displayed within the department in the lead up to our inspection, as well as on the HIW social media pages.

Unfortunately, for this inspection we did not receive any responses from patients to our survey. Therefore, the findings set out below are based on staff discussions and evidence provided by the service.

Patient information

The employer had a written procedure in place in relation to written instructions and information that should be provided to patients prior to them undergoing diagnosis with radioactive substances. An example of the written documents sent to patients prior to their appointment was provided as evidence. The information detailed within the documents included a brief outline of the procedure, the required preparation, pregnancy and breastfeeding status information and the restrictions following the procedure.

Following review of the employer's procedure it was highlighted that additional clarity was required to clearly detail who is responsible for providing this written information to patients and how staff should verify that the information has been received and understood by the patient.

The employer's procedure also detailed that the information included within the written guidance should be reinforced verbally by staff with the patient, prior to procedures. Staff confirmed that these discussions routinely took place with patients.

Staff also confirmed that verbal discussions with the patient took place prior to procedures, regarding the benefit and risk of the exposure. We were informed that staff led tailored discussions for each patient. However, following review of the employer's procedure, it was highlighted that this requirement was not fully reflected. The employer should ensure that the employer's procedure is updated to include further details regarding the process of discussing benefits and risk with the patient, which should include the process to follow if the patient requires further support and reference to relevant professional guidance available.

Improvement needed

The employer should ensure that the employer's procedure in relation to the provision of written information to patients is updated to include detail around the arrangements for sending the information to patients and the process for confirming receipt.

The employer should ensure that the employer's written procedure is updated to include further details regarding the process of discussing benefits and risk with the patient.

Communicating effectively

We were informed that there was a hearing loop system available in the department's main reception area, to assist patients wearing hearing aids when communicating with staff. Staff we spoke with told us that additional arrangements could be made, where required, if patients have any communication impairments. For example, we were told that that sign language interpreters can be booked to attend the unit if required.

Staff confirmed that they have access to translation services to assist should a patient attend the unit unable to communicate in English. We were informed that staff are able to book a member of the translation service team to attend the unit for the patient's appointment or support can be provided over the phone.

Additionally, we were informed that there are radiographers working within the department able to converse with patients in a number of languages if required, including Welsh.

Individual Care

Listening and learning from feedback

Staff confirmed that arrangements were in place to allow patients to provide feedback on their experiences using the department. We were informed that there were feedback cards available within the department to allow patients to provide their views. Staff we spoke with confirmed that feedback received from patients was routinely shared with them. However, responses received via our staff survey highlighted that the majority of staff respondents indicated that regular updates on patient experience feedback were not provided to them.

Additionally, we were informed that patient surveys are completed annually for the whole of the radiology service within the health board. As part of our inspection, we reviewed the results from most recent survey completed in September 2020, which detailed that overall feedback from patients was extremely positive.

Staff explained that on the occasions where verbal concerns were raised by patients, attempts were initially made, where possible, to try to resolve the issues immediately. However, if the patient still wanted to raise a formal complaint, they would be signposted to the Putting Things Right[2] (PTR) NHS Wales complaints procedure. We were informed that there were posters displayed within the department advising patients of this procedure.

Senior managers confirmed that following receipt of any formal concerns, the PTR Team notify the department lead, who is then involved in ensuring that the concern is investigated and a response provided to the complainant. We were informed that any learning identified as result of concerns received is shared with relevant staff.

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[2] '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.

Improvement needed

The UHB must ensure that arrangements are in place to provide staff with regular updates on the patient experience feedback received by the service.

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 staff we spoke with had a clear understanding of their duty holder roles and responsibilities in line with IR(ME)R 2017.

Information provided indicated that adequate arrangements had been implemented by the service to allow for effective infection prevention and decontamination within the department.

Discussions with managers and department staff throughout our inspection provided assurance that arrangements were in place to ensure that examinations were being undertaken safely. However, we highlighted additional detail was required in the majority of written procedures reviewed, to ensure the procedures accurately reflect the practises in operation. Our findings within this section details some of the areas where the requirement for additional detail was highlighted.

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 in accordance with the requirements of IR(ME)R 2017. The procedure set out that staff were expected to confirm the patient's full name, home address and date of birth. This approach is in keeping with current UK guidance[3].

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

Information detailed within the employer's procedure also set out the steps staff should take if they were to encounter different types of patients including individuals who may lack capacity, paediatric patients, individuals with hearing impairments and individuals unable to communicate in English.

Staff we spoke with were able to clearly set out the steps they routinely take to correctly identify patients prior to examinations within the department.

Individuals of childbearing potential (pregnancy enquiries)

The employer had a written procedure in place in relation to the process for establishing if a female patient is or may be pregnant, prior to undergoing a nuclear medicine examination. This procedure aimed to ensure that such enquiries were made in a standard and consistent manner. The employer's written procedure included references to terminology from IR(ME)R 2000 and consideration should be given to updating with reference to professional bodies' guidance. The employer must ensure the procedure is updated to refer to the terminology from IRMER 2017 i.e. individuals of childbearing potential.

The procedure set out the process staff should follow depending on the individual's responses. Details included the age range of patients who should be asked about pregnancy, which was between the ages of 12 and 55 years. The written procedure also included guidance in relation to patients who are breastfeeding, to ensure that the necessary steps are taken where required.

In addition to the employer's procedure, evidence was also provided of a pregnancy flow chart and a contraception flow chart available to staff working within the department. These documents set out the required steps following the responses provided by the patient. Staff we spoke with were able to describe their responsibilities in regards to pregnancy enquiries, which were in line with the procedure in place.

As previously detailed, staff confirmed that prior to any examination within the department a written appointment letter is sent to patients. The information included within this letter includes pregnancy status and breastfeeding enquiries. Additionally, we were informed that there were posters displayed within the department advising individuals to speak with staff if they either are or think they may be pregnant.

Improvement needed

The employer must ensure the procedure for identifying if individuals may be pregnant is updated to refer to the terminology from IRMER 2017, with reference to the professional bodies' guidance, i.e. individuals of childbearing potential.

Non-medical imaging exposures

There was an up to date employer's procedure in place which detailed that there were currently no non-medical exposures[4] undertaken within the health board.

Referral guidelines

The referral guidelines in place use the Royal College of Radiologists (RCR) iRefer publication, which sets out the referral criteria and provides an indication of the radiation dose for individuals wanting to refer a patient for imaging.

Additionally, the employer had a written procedure in place setting out the referral process for individuals to follow. Information included within this document set out that referrals are accepted from entitled referrers, on condition that it is in accordance with the set guidance for referral. The information required includes relevant patient details, name and signature of referring clinician, the examination required and sufficient clinical information to justify the exposure.

The information required was set out in the department's electronic referral request form provided as evidence. A copy of the paper referral request form was also provided as evidence, which also included the information required. However, we did identify that the form referenced IR(ME)R 2000, instead of IR(ME)R 2017. The employer must ensure this detail is corrected on the form.

Senior managers confirmed that the health board has purchased relevant licences to ensure iRefer is accessible to all relevant staff. Medical staff are informed of the referral guidelines and process as part of their induction and via their entitlement letters. We were also informed that the service clinical director writes out to practice managers of all GPs within the health board, to notify them of the referral guidelines and process.

[4] 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.

Improvement needed

The employer must ensure that the paper version of the referral request form is updated to refer to IR(ME)R 2017.

Duties of practitioner, operator and referrer

The employer had a system in place to identify the different IR(ME)R roles of the professionals involved in referring, justifying and undertaking nuclear medicine administrations. The Ionising Radiation Safety Policy detailed the specific duty roles and responsibilities in line with IR(ME)R, which are referrer[5], practitioner[6] and operator[7].

The policy included some detail around the requirements that must be met before an individual can be formally entitled to become a duty holder, as well as training requirements for newly appointed duty holder roles. However, following review of this document and discussions with senior staff, it was highlighted that the policy needed further in relation to the specific training requirements for each of the duty holder roles pre and post entitlement.

For example, additional evidence submitted by the service detailed that newly entitled staff must complete a three month training induction and training for specific equipment. However, this requirement was not detailed within the Radiation Safety Policy.

Senior managers described the arrangements for notifying staff of any changes to the policies and procedures in place. Prior to any amendments, the proposed changes are discussed with service leads. Subsequently, the service lead will discuss the updates with department staff and the new procedure is also displayed within the department for staff to view. We were informed that all relevant staff are required to sign to confirm that they have read and understood

[5] 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

[6] 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.

[7] 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..

the new policy or procedure in place. Staff also confirmed that they were able to access the relevant policies and procedures when required.

Improvement needed

The employer must ensure that the Radiation Safety Policy, as well as other relevant employer's procedures, are updated to include specific training requirements for each duty holder role.

Justification of Individual Medical Exposures

The employer had a written procedure in place for the justification and authorisation[8] of medical exposures within the department. Following review of this document, we highlighted a number of outdated references, including reference to IR(ME)R 2000, as well as other inconsistencies in regards to the processes in place. We also highlighted that the procedure was not clear on the distinction between the roles of the operators authorising under guidelines and of the practitioner justifying the exposure. The practice described during discussions with senior managers was not accurately reflected in available documentation.

We were informed that justification of individual medical exposures was being recorded on the radiology request forms submitted, via signature from the practitioner. Additional evidence provided detailed that delegated authorisation guidelines (DAG's) have been issued for a number of procedures to allow operators, who have been entitled to act under the DAG, to authorise exposures on the occasions it is not practicable for the practitioner to do so. The procedure indicated that operators authorising under guidelines would be recorded by adding "(DAG)" to the signature on the request form.

Overall, evidence provided suggested that the use of DAGs appeared to be working well in practice within the service. However, on review of the relevant DAG documentation available, it was again highlighted that the relevant information in written procedures needs to be reviewed and updated to ensure that the detail included accurately reflects the processes and practises in place.

Any carer and comforter medical exposures must also be justified. There was an employer's written procedure in place and senior managers confirmed that this

[8] Justification is the process of weighing up the expected benefits of an exposure against the possible detriment for that individual from the exposure. Authorisation is the evidence that justification has taken place.

justification should be recorded using the same process used for justification of the associated patient's medical exposure. We were informed that staff will discuss the relevant information with the carer and comforter prior to the exposure, following which the individual is required to sign the comforter and carer's form, to confirm they have understood the implications of the exposure. This information is then scanned onto the patient's record on the electronic radiology information system.

On review of the carer and comforter's employer's procedure, it was highlighted that additional detail was required to ensure that the written procedure accurately reflects the process in place, which was described by senior managers. The procedure should also set out the staff responsible for completing the relevant tasks in regards to performing and recording the justification of these exposures. An additional carer and comforters procedure specific to nuclear medicine was provided, though it was not clear how this fit in with the employer's procedure. Consideration should be given to rationalising these documents to ensure that it is clear who the practitioner for these exposures is and what the dose constraint is for exposures to carers and comforters from nuclear medicine procedures.

Additionally, on review of the comforter and carer's form, we highlighted that the form currently indicated that the staff member who signed the document would be the 'witness'. However, it is our understanding that the staff member signing the form would be the practitioner, justifying the exposure to the individual. The document needs to be reviewed and updated to ensure it clearly details who the practitioner is.

Overall staff we spoke with had a clear understanding of their duty holder roles and responsibilities. However, during discussions with staff we identified that there was some uncertainty around their specific duty holder roles in relation to justifying carer and comforter exposures and where exposures are authorised using a DAG.

The employer must ensure that the relevant employer's procedures, as well as any other relevant documentation, are reviewed and updated to ensure that all information is up to date, consistent and accurately reflects the justification and authorisation arrangements in place.

Improvement needed

The employer must ensure that all employer's procedures relating to justification and authorisation of medical exposures are reviewed and updated to ensure information is up to date, accurately reflects the arrangements in place and the role of each duty holder under the regulations.

The employer must ensure that the documentation for comforters and carers is reviewed and updated to ensure information is up to date and accurately reflects the arrangements in place for the identification of practitioner and the dose constraint.

Optimisation

The employer had arrangements in place for the optimisation[9] of exposures. For example, employer's procedures were available in relation to the recording and assessment of every medical exposure delivered within the department. Senior Managers confirmed that staff were trained in methods of dose reduction for specific procedures. However, it was not clear where this information was made available to staff. The employer must ensure that dose optimisation methods are documented in standard operating procedures.

The nuclear medicine MPE provides advice and contributes to the optimisation of exposures, by completing routine checks including equipment performance quality assurance tests and patient dose audits, which may result in recommendations to optimise specific procedures. This is to help further ensure that exposure doses are kept as low as reasonably practicable.

Senior managers confirmed that arrangements were in place to ensure that paediatric patient exposures were optimised. We were informed that scaling of the administered activities was set by the radiopharmaceutical provider, based on the age of the child. Senior managers confirmed that the scaling had been approved by the licenced practitioner, however the local protocols should be updated to clearly detail the scaling factors approved in line with appropriate good practice guidance.

Evidence provided also confirmed that measures were in place to minimise any exposures to breastfed children. However, during review of the relevant documentation, we highlighted that guidance in relation to breastfeeding patients was repeated in a few areas. This presents a potential risk of inconsistent and out of date information being available to staff. This issue is detailed further in the 'Procedures and Protocols' section.

[9] Optimisation refers to the process by which individual doses are kept as low as reasonably practicable

Improvement needed

The employer must ensure that standard operating procedures are updated to reflect current practice with respect to dose optimisation and paediatric dose scaling

Diagnostic reference levels

There was an employer's written procedure in place for establishing and reviewing diagnostic reference levels (DRLs). Evidence provided detailed that the local DRLs used within the department were set by the MPE, which senior managers confirmed were lower than the national DRLs.

We were informed that all DRLs are reviewed annually by the Lead Practitioner and Superintendent for Nuclear Medicine. Senior managers confirmed that the latest review undertaken considered the most recent guidance published by the Administration of Radioactive Substances Advisory Committee[10] (ARSAC).

Additionally, as previously mentioned, the MPE undertakes annual patient dose audits and subsequently, where required, provides recommendations for new modified local DRLs. Senior managers confirmed that DRLs are displayed within the department for staff and that staff are notified of any modifications to any DRLs to be used, as and when required.

Following review of the information included within the employer's procedure, it was highlighted that it did not accurately reflect the process described by staff in relation to the establishment and review arrangements for DRLs, and also the process when DRL's were consistently exceeded in Nuclear Medicine. The employer must ensure that the procedure is reviewed and updated to confirm that information included accurately reflects the operational arrangements in place.

[10] The Administration of Radioactive Substances Advisory Committee (ARSAC) is an expert committee for the United Kingdom, sponsored by the Department of Health and Social Care. The committee advises government on the use of radioactive substances on people and on licenses for employers and practitioners.

Improvement needed

The employer must ensure that the employer's written procedure relating to DRLs, is reviewed and updated to ensure that information accurately reflects the operational arrangements in place.

Clinical evaluation

There was an employer's procedure in place which detailed the process regarding the clinical evaluation of medical exposures. Senior managers confirmed that all medical exposures are evaluated with the resulting findings recorded, apart from sentinel node biopsy procedures. It is a requirement under IR(ME)R 2017, that all medical exposures are clinically evaluated by an entitled operator and that a record of the evaluation is recorded. Therefore, the employer must ensure that adequate clinical evaluation arrangements are in place.

Improvement needed

The employer must provide assurance that arrangements are in place to ensure all medical exposures undertaken are being clinically evaluated by entitled operators.

Equipment: general duties of the employer

The employer had an inventory (list) of the equipment used within the department. The inventory contained the information required under IR(ME)R 2017, however, on review of the document it was highlighted that the review date had passed (April 2020).

Senior managers confirmed that a quality assurance (QA) programme was in place for all equipment within the department. We were informed that the QA programme was implemented following advice and sign off from the MPE.

We were informed that the ongoing equipment QA programme does have routine MPE involvement, for example the MPE reviews the results following completed tests on a six monthly basis, develops protocols for each QA test and provides training and support to staff where required.

Following review of the equipment QA programme in place, we identified that the information detailed within the document did not accurately reflect the arrangements within the department that were described to us during discussions with staff.

Evidence was provided of some of the individual QA tests in place for relevant equipment. We identified that two of the QA protocols provided included handwritten amendments. The employer must ensure that these amendments are incorporated into the electronic versions of the relevant documents. We identified that only one of the QA results sheets provided as evidence included detail around the permitted performance tolerances. The employer should consider including this information on all QA results sheets and protocols. Information should be available outlining the required steps staff should take, if results are not within the acceptable values.

Additionally, on review of the QA protocols, it was highlighted that they did not appear to follow the QA processes in place for written procedures. For example, there was no scheduled review date included on the protocols and it was therefore unclear when the last review of the protocol took place, as well as the next review scheduled.

Overall, following review of all of the equipment QA documents provided as evidence, we highlighted that the information detailed did not accurately reflect the arrangements described during discussions with staff. The employer must ensure that all equipment QA programmes, protocols and results sheets are reviewed and where required updated, to ensure they accurately detail the agreed processes in place, including frequency for each test and performance criteria.

Improvement needed

The employer must ensure that all QA protocols are routinely reviewed and relevant review information is included on the document, in line with the employer's procedure for QA of documentation.

The employer must ensure that the employer's written procedures and protocols relating to QA of equipment, are reviewed and updated to ensure that they accurately reflect the arrangements in place.

Safe care

Managing risk and promoting health and safety

Staff we spoke with were able to describe the risk management arrangements and assessments in place within the department. Additionally, responses received via our staff survey detailed that all staff respondents felt that they would feel secure raising concerns about any unsafe clinical practice within the department, and that they felt that their concerns would be appropriately dealt

with. However, one respondent to our survey stated that they would not know how to report concerns about unsafe clinical practice.

Improvement needed

The UHB must ensure all staff are provided with information outlining the required steps to report any concerns in relation to unsafe clinical practice within the department.

Infection prevention and control

Information provided by staff indicated that adequate arrangements were in place for effective infection prevention and decontamination within the department. We were informed that these arrangements had been strengthened as a result of Covid-19.

Senior staff confirmed that there were good links with the IPC team within the health board. We were informed the team had regularly engaged with the service from the outset of the pandemic, to provide updates on the guidance and requirements, as well as to provide suggestions as to how the service could improve the IPC arrangements in place. Staff confirmed members of the IPC team routinely visit the department to assess the arrangements in place.

We were informed that prior to any appointment within the department, patients are contacted to complete a questionnaire over the phone, to check for any infectious symptoms. Patients scheduled to attend the department are allocated a risk level relating to their infection risk. On arrival, the patients' temperature is taken and they are asked additional questions to again check for any relevant symptoms. There is a one way system for patients within the department, to allow for adequate social distancing.

Staff informed us that cleaning schedules were in place, which set out the frequency of required cleaning for relevant rooms and equipment throughout the department. Staff confirmed that relevant areas are cleaned after every patient and that the level of cleaning will depend on the risk level of the patient. In response to Covid-19, additional time was allocated to complete procedures, to also ensure sufficient time was available for the required cleaning and decontamination.

Staff we spoke with confirmed that they had received IPC training and demonstrated a good awareness of their responsibilities in regards to infection control within the department.

Senior managers confirmed that the lead nurse in the department is responsible for providing updates on the personal protective equipment (PPE) requirements, as well as relevant training to staff. Staff also confirmed that PPE guidance is displayed within the department.

We were informed that there are PPE stores at each hospital site, to ensure that there is a sufficient supply available. In addition, we were informed that weekly PPE stock checks are completed for the department. Staff we spoke with confirmed that they have sufficient access to PPE and that adequate training and guidance has been provided.

Safeguarding children and adults at risk

Staff we spoke with demonstrated an awareness of the required action should they have any safeguarding concerns. We were informed that there was a process flow chart available within the department outlining the required steps and that there was a safeguarding lead within the department available to provide advice and guidance to staff. We were also informed that all 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

Evidence was provided of the clinical audit plan in place within the department. This document detailed the types of audit to be completed, the clinical question to be covered by each audit, as well as the operator responsible for undertaking the audit and the completion date. However, the document did not detail the required frequency or re-audit dates for the audits listed. The employer should consider updating the document to ensure that this information is included.

Senior managers confirmed that staff do not get protected time to complete audits and the required tasks have to be completed when possible. We were informed this has been a challenge over the past year, due to the pressures on the service. The employer must ensure that relevant staff are supported to undertake clinical and IRMER audits in line with the agreed frequency, to ensure that services are being provided in line with the required standards and regulations.

Examples of clinical audit reports completed for the department were provided as evidence. One of the reports, relating to cardiac imaging, was well structured and clearly set out the relevant information including the scope, methodology and findings. Additionally, a clinical audit action plan was included which set out the

actions required, timescales and responsible individual. However, an additional audit report was submitted to us in relation to radiology request card audit results, which did not include the same level of detail, with no action plan included. The employer should consider implementing a standardised audit report format, to ensure that information is consistently being recorded and that relevant actions are being undertaken to address any issues identified.

Senior managers confirmed that arrangements were in place to share audit findings with the relevant staff including the MPE and staff working within the department.

Improvement needed

The employer should consider updating the clinical audit plan to include the frequency/re-audit dates for each of the audits listed.

The employer must ensure that arrangements are in place to enable staff to undertake clinical and IRMER audits in accordance with the agreed frequency.

The employer should consider implementing a standardised clinical audit report format, to ensure that this type of information is being recorded consistently.

Expert advice

The service had a service level agreement (SLA) with Cardiff and Vale University Health Board for the provision of MPEs, under IR(ME)R 2017. The MPE list provided by the service indicated that there were four MPEs available to the whole of the Radiology department, one of which had an expertise in Nuclear Medicine. All four of the MPEs allocated to provide support to the radiology department, were listed on the approved list for RPA 2000, the certification body for MPEs.

We were informed that all MPEs were entitled as operators to enable them to perform the required tasks and that this was included as part of their appointment letter. Evidence provided detailed that MPEs were appointed by the Radiology Service Manager. A copy of the appointment letter for the Nuclear Medicine MPE was provided. Following review of this document, it was highlighted that additional detail was required to reflect the MPEs entitlement as an operator under IR(ME)R 2017 and their scope of practice.

As previously detailed, we were informed that MPE support and advice is provided in a number of areas within the department. Areas of support included providing training to staff, equipment QA, dose assessments, reviewing clinical protocols, investigation of accidental or unintended exposures and clinical audit. Staff we spoke with confirmed that they were able to contact the MPE for advice and support where necessary, on an ad hoc basis.

The MPE confirmed that they have a good working relationship with the radiation protection advisor and radioactive waste advisor who are provided under SLA by Velindre University NHS Trust.

Improvement needed

The employer must update the MPE appointment letters to include specific details of the entitlement of the MPEs as an operator under IR(ME)R 2017 and their scope of practice.

Medical research

Senior managers confirmed that the nuclear medicine department does not participate in any research involving medical exposures and does not have an employer licence to do so.

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

Overall there was an organisational management structure in place that provided clear lines of reporting and accountability.

There was evidence of an experienced and committed workforce, with a good team working ethos. Staff were happy with the level of support provided by senior managers.

As outlined in the previous section, our inspection highlighted the requirement for the employer to ensure that all employer's written policies and procedures are reviewed to ensure they accurately reflect the practises in place and provide the level of information required for staff to follow.

Governance, leadership and accountability

There was a radiology directorate management structure in place, which set out the clear lines of reporting for the service for the overall service. There was also a radiology governance structure in place which set out the governance arrangements from the relevant radiology departments up to the executive board within the health board.

We were informed that whilst team meetings have decreased as a result of Covid-19, efforts have been made by senior managers to utilise Microsoft Teams to undertake meetings with department staff. Additionally, senior managers confirmed that efforts were made to attend every site regularly to ensure that staff had the opportunity to speak with them to raise any concerns or queries with them. Overall, feedback received from staff indicated that they were happy with the level of support provided by senior managers within the service.

Prior to our inspection, HIW require 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 place, in respect of IR(ME)R 2017. This document was used to inform the inspection approach.

The self-assessment form was returned to HIW within the agreed timescale and overall was comprehensive. Whilst we did highlight a number of discrepancies in the responses provided, senior staff provided additional information or clarification promptly.

On the days of our inspection, senior management staff made themselves available and facilitated the inspection process. They were receptive to our feedback and demonstrated a willingness to make improvements as a result of the issues highlighted.

Requirement to hold a licence

Under IR(ME)R, no exposure involving the administration of a radioactive substance can take place unless the employer holds a valid licence at the installation. There was a valid employer's licence in place covering all of the services provided on site, however this was scheduled to expire on 13 February 2021. Senior managers confirmed that a revised application had been submitted for renewal of the licence.

We were informed that a project group had been established to improve the internal arrangements for managing the employer's licence in a timely manner and discussed the requirement for applications to be submitted at least 8 weeks prior to expiry. The group is chaired by the Radiology Services Manager and other members include the Superintendent for Nuclear Medicine, the lead radionuclide Radiologist and the Chief Pharmacist.

Duties of the employer

Entitlement

Overall department staff we spoke with had an understanding of their duty holder role and their scope of entitlement under IR(ME)R. Evidence provided demonstrated that there was an adequate framework in place to entitle staff using letters and to ensure that entitled staff were routinely informed of their entitlement and scope of practice. Evidence was also provided of 'training records of entitlement', however from discussion with staff these appeared to be records of training and competence and were not used to record entitlement.

Additionally, there was an entitlement flow chart in place, which set out the staff members responsible for entitling staff at each level within the service. Senior

managers confirmed there was an entitlement matrix available to all staff detailing the scope of practice for all duty holders.

As previously detailed, we highlighted that the employer's procedure did not adequately reflect the current practice and did not provide sufficient detail of the process for entitlement.

The employer must update the written procedures and related documentation to provide further details on the current process for entitlement of individuals. Consideration should be given to providing further details on all aspects of entitlement including the training requirements, the process by which entitlement is carried out and how the scope of practice is defined for duty holders.

Improvement needed

The employer must update the written procedures and related documentation to reflect current practice regarding entitlement of all duty holders.

Procedures and protocols

Senior managers confirmed that the health board Chief Executive was designated as the IR(ME)R employer. However, we were informed that whilst the CEO retains the responsibility associated with being the employer, the CEO had delegated the associated tasks relating to IR(ME)R, to the health board's Executive Director of Therapies and Healthcare Science. This arrangement is acceptable, however, it was not clearly detailed within the written documentation provided as evidence. The employer must ensure that relevant documents are reviewed and updated so that they clearly set out the employer arrangements in place, including the employer tasks which have been delegated within the service.

As previously detailed, staff we spoke with as part of our inspection confirmed that they were able to access to relevant policies and procedures where required. Also, senior managers confirmed that arrangements were in place to notify relevant staff on the occasions where updates were made to written procedures or protocols, as well as to confirm that staff have read and understood these documents.

There was an employer's procedure in place in relation to the quality assurance programme for the employer's written procedures and protocols. This document set out the required frequency of reviews, the staff responsible for reviewing

documents and the review process. The document also detailed that any updates must be authorised by the service Radiation Protection Committee.

On review of the written procedures and protocols provided as evidence, we highlighted that the review dates for a number of the documents had passed. Senior managers confirmed that the service was currently reviewing the QA process for written procedures and there were plans to implement a new electronic storage system. We were informed that this system will standardise the QA process in place to mitigate against any missed reviews, as well as make it easier for staff to access relevant documents as and when required.

The employer must ensure that arrangements are in place to allow for relevant documents to be routinely reviewed, in line with their agreed review dates and the employer's procedure for the QA of documentation. Additionally, the service should ensure that review dates set for the relevant procedure are appropriate and achievable.

As highlighted previously, following review of the employer's procedures in place, we highlighted that many of the procedures were lacking the required level of detail and clarity for staff to follow. During discussions with staff as part of our inspection, we were provided with assurances on the practice being carried out. However, the practice described exceeded the level of detail within the written procedures.

The employer must ensure that a review is undertaken to confirm that the detail included within employer's procedures accurately reflects the agreed practise in operation, as well as to address any issues highlighted within our report. The service should consider involving the MPE more in the review and development of the employer's procedure documents, to advise on compliance with IR(ME)R and ensure that sufficient detail is included to reflect the arrangements in place.

Additionally, following review of the written procedures, we identified that there was duplicate information included in a number of areas, including content relating to breastfeeding and carers and comforters. As previously mentioned, this presents a risk of inconsistent and/or out of date information being available to staff. As part of the review of the written procedures, the employer should consider reducing the repeated information within the relevant documentation to mitigate the risk of any inconsistencies.

Improvement needed

The employer must ensure that relevant documents are reviewed and updated, to confirm that information clearly sets out the employer arrangements under IR(ME)R in place, including the employer tasks which have been delegated within the service.

The employer must ensure that arrangements are in place to allow for relevant documents to be routinely reviewed in line with the employer's procedure for the QA of documentation.

The employer must ensure all written employer's procedures are reviewed and updated to ensure they accurately reflect practices and arrangements in place, as well as address the issues highlighted throughout this report.

Significant accidental or unintended exposures

Senior Managers described the process in place should an incident occur or is suspected to have occurred, which may have caused an accidental or unintended exposure to patients. We were informed that following a suspected incident, staff are required to notify the department manager or radiation protection supervisor. They will discuss the incident with the individuals involved, ensure that the relevant information in regards to the exposure is collated and then contact the MPE. The MPE will advise whether the incident is a significant accidental and unintended exposure (SAUE) which needs to be reported to HIW and provide a report of the doses involved.

Additionally, we were informed that all incidents and near misses are record via Datix, the electronic incident report system. If required, an investigation is completed which will subsequently result in a summary report, including any actions and learning identified. Senior managers confirmed that any learning outcomes following incidents are shared with relevant staff. We were also informed that the relevant patients are always informed following any accidental or unintended exposures which occur.

Staff we spoke with were able to describe the process to follow in regards to reporting incidents and near misses. Staff also confirmed that feedback was provided to the department following reported incidents.

An 'errors and near misses' log is maintained by the service, which detailed all incidents which occurred in 2020 and set out the specific learning and actions for

the relevant incident. Following discussion with senior managers it was highlighted that some of the information relating to previous incidents logged on the document was not up to date. For example, we were informed an investigation had been completed for an incident, however this did not reflect the detail within the log.

There was an employer's procedure in place relating to the process for informing relevant individuals of clinically significant accidental and unintended exposures (CSAUE). This included the details of the process for all accidental and unintended exposures. Following review of this document we again highlighted that the information included did not reflect the description of the process described to us by staff.

Additional information is required within this procedure, around the investigation process for accidental and unintended exposures, significant accidental and unintended exposures (SAUE) and clinically significant accidental and unintended exposures (CSAUE). This should include who is responsible for determining if an incident is clinically significant, actions required if the incident is determined to be clinically significant, where relevant information should be recorded, timescales for tasks and the specific staff responsible for completing the tasks at each stage of the process. Consideration should be given to referring to published professional guidance on the definition of clinically significant.

We also highlighted that some of the information included within the procedure was outdated, for example the procedure detailed that patient exposures following equipment malfunctions should be reported to the Health and Safety Executive (HSE). However, as these notifications are now covered under IR(ME)R, notifications must be submitted to HIW. References were also made to the SAUE guidance from June 2019 and terminology from IRMER 2000 which is no longer used.

The procedure also included a link to the outdated HIW 'Notification of IR(ME)R Incident' form, which included previous HIW email and postal address. The employer must ensure that this information is updated within the procedure.

Improvement needed

The employer must ensure that the incident log maintained by the service is routinely reviewed to ensure information is up to date and accurate.

The employer must ensure that the relevant employer's written procedures, relating to clinically significant accidental or unintended exposures, are reviewed and updated to ensure they accurately reflect the required process,

are consistent with terminology within IR(ME)R 2017, and address the issues highlighted within this section.

The employer must ensure that the relevant written procedures relating to accidental or unintended exposures are updated to accurately reflect current practice, to include, up to date SAUE guidance, appropriate incident reporting process requirements and contact details for HIW.

Staff and resources

Workforce

As part of our inspection, discussions were held with senior managers for the service, as well as a selection of staff working within the department. Additionally, a staff survey was made available to provide all staff working within the department with the opportunity to provide their views.

Overall, staff reported that they felt the staffing levels within the department were adequate and that they have enough time to perform their roles. It was clear from our discussions that the department consists of experienced and committed staff, with a good team working ethos. As previously outlined, overall, staff were happy with the level of support provided to them.

Senior managers confirmed that whilst the whole radiology service had been under increased pressures over the past year, as a result of the pandemic, additional pressure was experienced as a result of the opening of the new Grange University Hospital in Cwmbran, in November 2020. We were informed that efforts were made to ensure that adequate staffing levels for the service were in place across all hospital sites within the health board. This has subsequently meant that a large number of staff have been recruited to the radiology service.

Senior managers confirmed that they felt the staffing numbers across the service were safe and we were informed that rolling staffing rotas were in place to ensure that routine monitoring of staffing levels takes place and that appropriate action is taken when any shortfalls are identified. Additionally, we were informed that there was a workforce review planned, scheduled to be completed in March 2021, to assess the current service staffing levels against the demand across all sites, to identify any deficits.

We were informed that there was a process in place to ensure that all staff receive annual personal appraisal development reviews (PADRs). During these discussions staff are able to discuss any issues, as well as their own development and training requirements. We were informed that training compliance was also monitored as part of the PADR process.

Feedback from the majority of staff indicated they had received their annual PADR discussion which covered their training, learning and development needs. During discussions we were provided with examples of the training and development opportunities that were made available to staff as part of the process. However, one staff respondent to our survey indicated that they had not had a PADR discussion with their line manager within the last 12 months.

Senior managers confirmed that arrangements were in place to allow staff to access additional wellbeing support if required. However, feedback received from staff indicated that not all staff were aware of the wellbeing support available to them or how to access it.

Improvement needed

The UHB must ensure that all staff receive routine PADRs, to allow for training, learning and development needs to be identified and monitored.

The UHB must ensure that all staff are provided with information on the additional wellbeing support available to them.

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 seven 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.

Prior to the inspection, the service is required to complete a self-assessment form and provide supporting documentation as evidence. The two day remote inspection consists of discussions with senior managers and operational staff working within the department, in relation to the policies and procedures in place.

To allow us to collate additional views, relevant patient and staff surveys are conducted in the weeks leading up to our inspection.

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 on this inspection.			

Appendix B – Immediate improvement plan

Hospital: Royal Gwent Hospital

Ward/department: Nuclear Medicine Department

Date of inspection: 2 and 3 February 2021

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 were identified on 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: Royal Gwent Hospital

Ward/department: Nuclear Medicine Department

Date of inspection: 2 and 3 February 2021

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 employer should ensure that the employer's procedure in relation to the provision of written information to patients is updated to include detail around the arrangements for sending the information to patients and the process for confirming receipt.	4.2 Patient Information Reg 12 (6) Reg 12(7) Schedule 2(h)	Review Reg 12 (6) & (7) and update procedure document 2(h) to include the different patient groups and what information will be sent to the patient. The information is sent to the patient as part of the appointment letter so the information is available in advance of the appointment. When attending for the appointment the patient will be asked to verify that they have read and understood the	Mark Wilkes Radiology Services Manager	30.4.21

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		information provided. Any restrictions post injection are reinforced by staff before the patient leaves the department. The Appointment letters to be amended to include details of radiation risks.		
The employer should ensure that the written procedure is updated to include further details regarding the process of discussing benefits and risk with the patient	Schedule 2(i)	An All Wales approach to Schedule 2(i) has been discussed at the Quality Forum meetings. Clarity will be sought regarding the unified approach and the procedure document 2(i) will be updated to provide comprehensive guidance to staff. The current documentation will be reviewed to ensure more guidance is given for staff relating to the discussion they have with the patient prior to the examination and the individual patient's capability to understand the terminology used. We will also include where the patient can access additional information, should they require it and any relevant guidance from the relevant professional bodies This document will remain as our	Mark Wilkes Radiology Services Manager	31.5.21

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		reference until an All Wales agreement is reached.		
The UHB must ensure that arrangements are in place to provide staff with regular updates on the patient experience feedback received by the service.	6.3 Listening and Learning from feedback	We will adopt various methodologies for staff feedback and adopt a range of effective processes including displaying results on notice boards in staff rooms, team meetings to feedback outcomes and emails to staff, to ensure effective communication across all sites.	Andrew Carter Radiology Services Manager	30.4.21
Delivery of safe and effective care				
The employer must ensure the procedure for identifying if individuals may be pregnant is updated to refer to the terminology from IRMER 2017, with reference to the professional bodies' guidance, i.e. individuals of childbearing potential.	Schedule 2(c)	The procedure document 2(c) has been updated to reflect the appropriate terminology from IRMER 2017. The terminology "Female patient" has been replaced with "individuals of childbearing potential." This change will be ratified at the Clinical Governance committee and communicated across the Directorate.	Mark Wilkes Radiology Services Manager	31.5.21

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
The employer must ensure that the paper version of the referral request form is updated to refer to IR(ME)R 2017.	Reg 6(1)	Communication has been made with the print team who produce our paper request forms to make the necessary adjustment. Future printing will have the correct reference to IR(ME)R 2017. There will be a time period where there are request forms with IR(ME)R 2000 due to the sheer number of referral sources in the Health Board. When checking the electronic request formats it was noticed that the requests from the A&E Symphony system had the same error. An action has been requested with the team to make the alterations.	Andrew Carter Radiology Services Manager	12.4.21
The employer must ensure that the Radiation Safety Policy, as well as other relevant employer's procedures, are updated to include specific training requirements for each duty holder role.	Reg 6(3)	The Radiation safety policy and all associated employer's procedures will be reviewed, the Operator and Practitioner roles will then be updated. For the Operator we will reflect the use of the induction pack training and the subsequent additional training related to new procedures/examinations, to include any Radiation dose impact. For the Practitioners there is the requirement for	Andrew Carter Radiology Services Manager	30.04.21

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		the award of an ARSAC license and the subsequent maintenance and renewal of their license.		
The employer must ensure that all employers' procedures relating to justification and authorisation of medical exposures are reviewed and updated to ensure information is up to date, accurately reflects the arrangements in place and the role of each duty holder under the regulations.	Reg 11	The documents relating to justification will be reviewed to ensure there is no duplication of information which can lead to misinterpretation. There is a separate document for NM justification and authorisation so this will be referenced in the x-ray justification document and any NM references removed. The roles of the duty holders will be clarified in the documents.	Mark Wilkes Radiology Services Manager	30.04.21
The employer must ensure that the documentation for comforters and carers is reviewed and updated to ensure information is up to date and accurately reflects the arrangements in place for the identification of practitioner and the dose constraint.	Reg 11, Schedule 2(n)	An All Wales approach to Schedule 2(n) has been discussed at the Quality Forum meetings. Clarity will be sought regarding the unified approach and the procedure document 2(n) will be updated to provide comprehensive guidance to staff. The current documentation will be reviewed to ensure inclusion of the identification of the practitioner and clarity of dose constraints. There is a separate	Andrew Carter Radiology Services Manager	30.05.21

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		document for NM Carers and comforters so this will be referenced in the x-ray justification document and any NM references removed. This document will remain as our reference until an All Wales agreement is reached.		
The employer must ensure that standard operating procedures are updated to reflect current practice with respect to dose optimisation and paediatric dose scaling.	Reg 6(4) Reg 12	The Standard Operating procedures will be reviewed to ensure that dose optimisation methods are detailed in the procedure. We will have the procedures reviewed by the MPE. The local protocols will be updated to include the scaling for paediatric doses, which will be supplied by the dose supplier.	Alison Lee Nuclear Medicine lead	30.04.21
The employer must ensure that the employer's written procedure relating to DRLs, is reviewed and updated to ensure that information accurately reflects the operational arrangements in place.	Schedule 2 (f)	The employer's procedure Schedule 2 (f) will be updated to include a more accurate reflection of the establishing and review of DRL's specifically for Nuclear Medicine.	Andrew Carter Radiology Services Manager	30.04.21
The employer must provide assurance that arrangements are in place to ensure all medical	Reg 12 (9)	There is a letter documenting agreement with the Clinical director for Surgery for the clinical evaluation of Sentinel node		

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
exposures undertaken are being clinically evaluated by entitled operators.		identification and the recording of this evaluation in the patient's notes. A standard operating procedure will be developed for all departments with non-reporting agreements. The SOP will detail the procedure and frequency of required audit. We will then conduct a random audit of the Breast surgery patient's notes to check compliance with the agreement. We will then share the outcome of this audit with HIW to provide assurance.	Alison Lee Nuclear Medicine lead	31.05.21
The employer must ensure that all QA protocols are routinely reviewed, and relevant review information is included on the document, in line with the employer's procedure for the QA of documentation.	Reg 6(5)b Schedule 2(d)	The QA protocols will be reviewed to ensure they reflect current practice, that they are written in the appropriate format and they have an achievable review date. The documents will be reviewed every two years unless there is a change in regulations or practice.	Alison Lee Nuclear Medicine lead	31.05.21
The employer must ensure that the employer's written procedures and protocols relating to QA of equipment, are reviewed and updated to	Reg 15	The whole QA programme for Nuclear Medicine will be reviewed to and appropriate electronic documentation will be created to ensure that staff have a	Alison Lee	31.05.21

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
ensure that they accurately reflect the arrangements in place		standard format to record and interpret results. The documentation will also include guidance to staff on the relevant remedial actions required if results are not within acceptable values.	Nuclear Medicine lead	
The UHB must ensure all staff are provided with information outlining the required steps to report any concerns in relation to unsafe clinical practice within the department.	6.3 Listening and Learning from Feedback 7.1 Workforce	All staff, including Nuclear Medicine staff, will be reminded of the process in place to report any concerns in relation to unsafe clinical practice. Communication will be via, letters and staff briefings.	Andrew Carter Radiology Services Manager	30.04.21
The employer should consider updating the clinical audit plan to include the frequency/re-audit dates for each of the audits listed.	Reg 7	The current audit plan will be updated to include the frequency and re-audit dates for the planned audits	Rebecca Wallace Radiology Research lead	30.04.21
The employer must ensure that arrangements are in place to enable staff to undertake clinical and IRMER audits in accordance with the agreed frequency.	Reg 7	The Radiology Directorate encourage staff to participate in audit and Senior management are actively recruiting radiographers which will allow for the provision of appropriate audit time for the individual staff whilst still maintaining the Clinical service.	Andrew Carter Radiology Services Manager	31.10.21

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
The employer should consider implementing a standardised clinical audit report format, to ensure that this type of information is being recorded consistently.	Reg 7	A standardised audit plan has been developed and will be used for all audits in the future	Rebecca Wallace Radiology Research lead	30.04.21
The employer must update the MPE appointment letters to include specific details of the entitlement of the MPEs as an operator under IR(ME)R 2017 and their scope of practice.	Schedule 2(b)	All MPE appointment letters will be reviewed to include confirmation of their entitlement as an Operator and will detail their scope of practice under this entitlement.	Mark Wilkes Radiology Services Manager	30.04.21
Quality of management and leadership				
The employer must update the written procedures and related documentation to reflect current practice regarding entitlement of all duty holders.	Schedule 2(b)	The employer will review procedure document 2(b) and the associated, entitlement flowchart and letters of entitlement to clearly demonstrate pathway of entitlement from Chief Executive through to duty holders.	Mark Wilkes Radiology Services Manager	30.04.21

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
The employer must ensure that relevant documents are reviewed and updated, to confirm that information clearly sets out the employer arrangements under IR(ME)R in place, including the employer tasks which have been delegated within the service.	Reg 6	The documentation will be updated to clearly define the role of the Executive Director Of Therapies in relation to the employer's arrangements in the delegation of associated tasks in relation to IRMER.	Andrew Carter Radiology Services Manager	30.04.21
The employer must ensure that arrangements are in place to allow for relevant documents to be routinely reviewed in line with the employer's written procedure for the QA of documentation.	Reg 6(5)b Schedule 2(d)	The Senior management team will continue with the review of the QA process for written procedures and the re-development of Q pulse. On completion of this review all documents will contain review dates that will be realistic and achievable. In the meantime Senior management will ensure that all documents are reviewed in line with their current review dates.	Mark Wilkes Radiology Services Manager	30.09.21
The employer must ensure all written employer's procedures are reviewed and updated to ensure they accurately reflect practices and arrangements in place, as well as address the issues highlighted throughout this report.	Reg 6	Al Employers procedures are currently being reviewed to ensure that they accurately reflect current working practices and will be amended to eradicate any duplication across	Mark Wilkes Radiology Services Manager	30.09.21

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		documents. The advice and guidance of the MPE will be included in the review.		
The employer must ensure that the incident log maintained by the service is routinely reviewed to ensure information is up to date and accurate.	Reg 8(3)	Senior management have implemented a monthly meeting with all leads who manage Datix incidents to ensure they are routinely reviewed, contain accurate information, are closed where investigations are complete or progress is recorded where incidents are still under investigation. A new all Wales Datix system covering the reporting/coding of incidents is to go live in April. The first meeting review meetings took place on the 11th March 2021.	Mark Wilkes Radiology Services Manager	11.03.21
The employer must ensure that the relevant employer's written procedures, relating to clinically significant accidental or unintended exposures, are reviewed and updated to ensure they accurately reflect the required process, are consistent with terminology within IR(ME)R	Reg 8(4) Schedule 2 (l)	With the support of the MPE we will review the documentation in line with the processes for accidental and unintended exposures. We will have a recordable, task assigned processes for who will make the decision for determining if an incident is clinically significant and any actions required relating to this.	Andrew Carter Radiology Services Manager	30.05.21

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
2017, and address the issues highlighted within this section.				
The employer must ensure that the relevant written procedures relating to accidental or unintended exposures are updated to accurately reflect current practice, to include, up to date SAUE guidance, appropriate incident reporting process requirements and contact details for HIW	Reg 8(4)	All written procedures will be updated to reflect the current working practices in the departments. The reporting of patient exposures following equipment faults will be changed to HIW. The terminology will be updated to reflect the SAUE update from August 2020 and IRMER 2017	Mark Wilkes Radiology Services Manager	30.05.21
The UHB must ensure that all staff receive routine PADRs, to allow for training, learning and development needs to be identified and monitored.	7.1 Workforce	The compliance of PADR completion is monitored at the Radiology Operational group meeting, against established Health Board targets. We will continue to ensure staff, reviewers and reviewees are given the opportunity to undertake their PADR'S in a timely manner to ensure compliance.	Mark Wilkes Radiology Services Manager	30.04.21
The UHB must ensure that all staff are provided with information on the additional wellbeing support available to them.	1.1 Health Promotion, Protection and Improvement 7.1 Workforce	There are posters in all departments informing staff of the well-being service and how to access it. There is also a link on the intranet, which all staff have access too. If any member of staff has an	Andrew Carter	06.04.21

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		issue where a Manger thinks they will benefit from accessing the wellbeing service then they are given the access details. We regularly discuss with staff who require it the benefits of an occupational Health referral and if in agreement a referral is made. The PADR document has a section dedicated to well-being where the reviewer and reviewee discuss the six pillars of the ABUHB employee experience framework, the reviewer also explains the role of the well-being service and how it can be accessed to the reviewee.	Radiology Services Manager	

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): Andrew Carter

Job role: Radiology Services Manager

Date: 06.04.21