Ionising Radiation (Medical Exposure) Regulations Inspection (Announced)

Nuclear Medicine Department, Withybush General Hospital - Hywel Dda University Health Board

Inspection date: 27 and 28 July 2021

Publication date: 29 October 2021

This publication and other HIW information can be provided in alternative formats or languages on request. There will be a short delay as alternative languages and formats are produced when requested to meet individual needs. Please contact us for assistance.

Copies of all reports, when published, will be available on our website or by contacting us:

In writing:

Communications Manager

Healthcare Inspectorate Wales
Welsh Government

Rhydycar Business Park

Merthyr Tydfil

CF48 1UZ

Or via

Phone: **0300 062 8163**

Email: **hiw@gov.wales**

Website: **www.hiw.org.uk**

Digital ISBN 978-1-80391-189-2

Contents

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 Withybush General Hospital's Nuclear Medicine Department on 27 and 28 July 2021.

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

HIW explored how the service:

- Complied with the Ionising Radiation (Medical Exposure) Regulations 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, staff had an adequate awareness of their duty holder roles and responsibilities in line with IR(ME)R 2017.

There was very positive feedback provided from patients about their experiences when attending the department. We saw that arrangements were in place to promote privacy and dignity of patients and found that staff treated patients in a kind, respectful and professional manner.

Discussions with staff throughout our inspection provided assurances that arrangements were in place to ensure that examinations were being undertaken safely. However, a number of areas were highlighted in regards to the associated documentation in place, including ensuring that written procedures accurately reflect clinical practice.

Overall, staff were happy with the level of support provided by the nuclear medicine department lead. However, concerns were highlighted in relation to the level of support and engagement provided by senior managers within the service.

Issues were highlighted by staff around the available capacity within the department to carry out the relevant tasks required as part of their duty holder roles.

This is what we found the service did well:

- Evidence of good clinical audits being undertaken
- Good working links between Medical Physics Experts and staff working within department
- Information provided indicated that appropriate arrangements had been implemented to allow for effective infection prevention and decontamination
- Evidence of adequate written information being provided to patients prior to their examinations.

This is what we recommend the service could improve:

- Arrangements should be implemented to routinely collate patient feedback on the services provided within the department
- Undertake a review of workforce capacity to ensure all staff working within the department have sufficient capacity to undertake their roles
- Employer's written procedures must be reviewed to ensure that they include accurate detail on the practices and procedures in place within the nuclear medicine department
- Ensure that evidence is available to demonstrate that all duty holders have undertaken the required level of training and have been entitled to carry out their relevant roles
- Ensure all staff are up to date with mandatory training requirements.

3. What we found

Background of the service

Hywel Dda University Health Board (HDUHB) was established on 1 October 2009 and provides primary, community, hospital and mental health services to the people of the counties of Ceredigion, Carmarthenshire and Pembrokeshire. The health board as a whole provides service to a population of around 387,000 people

The Nuclear Medicine Department at Withybush General Hospital in Haverfordwest consists of equipment including a gamma camera with a built in CT scanner, dose calibrators and gamma probes. The department employs a number of staff including Radiographers, Clinical Technologists, a Consultant Radiologist and Consultant Cardiologist.

The department also has advice and support provided by Medical Physics Experts[1] (MPE) and Clinical Scientists employed by Swansea Bay 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

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

There was very positive feedback provided by patients about their experiences when attending the department.

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

Information provided indicated that overall there were adequate 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.

The service needs to implement a process to routinely collate patient experience feedback and ensure that subsequent findings and actions are shared with patients and staff.

As part of the inspection process HIW issued both online and paper surveys to obtain patient views of the service provided within the department. In total, there were 18 patient responses received.

Patients were asked in the survey to rate their overall experience provided by the service. Responses were positive; every patient rated the service as either 'very good' or good. Patients told us that:

> *"The staff were all very friendly and helpful and made my experience a lot easier."*
>
> *"Service was excellent."*
>
> *"The service I received during my visit really put me at ease. The staff were all very friendly."*

"100 percent care and attention from all involved in my treatment."

Staying healthy

There was information displayed in the department's main waiting area detailing the benefits and risks of the various types of exposures carried out. There was also some information available in relation to how patients could improve their own health and wellbeing which included smoking cessation support, healthy lifestyles, advice on breast pain and cardiac risks.

Dignified care

During our time in the department we observed staff speaking to patients in a polite, sensitive and professional manner.

All of the patients who completed a survey said that they had been treated with dignity and respect by staff and all patients confirmed that they were able to maintain their own privacy, dignity and modesty during their appointments.

We did not overhear any sensitive conversations taking place within the department during our visit. We were informed that there were rooms available for staff to have private conversations with patients. All patients confirmed that they were able to speak to staff about their procedure or treatment without being overheard by other people.

Areas were available within the department to allow patients to change in private prior to any procedure if required. Whilst we did not observe patients having their procedures, we saw staff greeting patients in a friendly manner. We were informed that doors to examination rooms were locked when examinations were being undertaken.

The department main waiting area had been reorganised to allow for social distancing between waiting patients. Signs were displayed on the chairs not to be used. The number of seats available within the department appeared appropriate for the number of patients attending during our visit.

Patient information

As previously detailed, we saw some evidence of posters displayed within the department waiting area, which included information regarding benefits and risks of the exposure procedures undertaken.

The employer had a written procedure in place in relation to the 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 along with their appointment letter was provided as evidence. The information detailed within these documents included a brief outline of the procedure, post procedure requirements and information relating to pregnancy and breastfeeding status.

Additionally, there was an employer procedure in place in relation to the provision of adequate verbal information to patients regarding the benefits and risks of an exposure. This procedure set out the steps to be taken by staff to ensuring patients are provided with the required level of information and also provided a qualitative statement for staff to use in conversations with patients prior to their exposure.

Staff we spoke with confirmed that verbal discussions with the patient routinely took place prior to procedures, regarding the benefit and risk of the exposure. Every patient who completed a survey confirmed that they had received clear information to help them understand the benefits and risks of their procedure.

All patients who completed our questionnaire said that they felt that they had been as involved as much as they wanted to be in relation to decisions about their treatment.

Additionally, all patients confirmed that they had been given information on how to care for themselves following their procedure, as well as information on who they should contact for advice about any after effects from the exposures they had received.

Communicating effectively

All patients who responded to our survey said that they felt that they were listened to by staff during their appointment.

We were informed that there was a hearing loop available in the department's main reception area, to assist people wearing hearing aids to communicate with staff. However, not all staff we spoke with during our visit were aware that this system was available. We were informed that arrangements were made to assist patients with hearing impairments which have included writing information down and also wearing clear visors instead of masks, to allow patients to lip read when communicating with staff.

Staff confirmed that they have access to communication support services to assist should a patient attend the unit unable to communicate in English. We

were informed that this support has previously been used; which included arranging for a member of the support service to attend to unit for a patient appointment and translation support via telephone.

The majority of information displayed within the department was available in English and Welsh. We were informed that there were some Welsh speaking radiographers working within the Radiology Department. However, it was not immediately obvious within the public areas of the department that patients could speak to staff in Welsh if they wished to do so. The availability of Welsh speakers working within the department or via communication support services could be better promoted to help deliver an 'Active Offer'[2].

One patient who responded to our survey stated that their first language was Welsh and they felt that they had not been able to converse in their preferred language nor was information provided to them in their preferred language.

Improvement needed

The health board is required to ensure that action is taken to promote the availability of Welsh speaking staff / support within the department to help deliver the 'Active Offer'.

The health board must ensure that arrangements are in place to provide written information to patients in Welsh when required.

Timely care

Of the 15 patients who responded to this question on our survey, all except one told us that it was "very easy" or "fairly easy" to get an appointment within the department.

We were informed that arrangements were in place to ensure that patients are routinely notified on arrival to the department if there is likely to be a significant delay to their scheduled appointment time. On these occasions patients are asked if they would like to return at a later time. The majority of patients who responded to our survey, confirmed that they waited less than 15 minutes to have their procedure.

[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

Individual Care

Listening and learning from feedback

Staff we spoke with described the arrangements in place to respond to any verbal concerns raised by patients. We were informed that attempts were made, where possible, to try to resolve the issues with the patient quickly and efficiently. Where this was not possible, we were told that patients were signposted to department managers and/or the health board concerns process.

Information leaflets and a poster were available within the department in regards to the all Wales NHS complaints procedure, known as Putting Things Right (PTR)[3]. Information leaflets were also available in regards to the Patient Advice and Liaison Service (PALS)[4], should patients require advice about NHS services.

There were health board and department specific patient feedback slips available within the leaflet rack, within the reception area. These slips were not easily noticeable nor were they advertised.

We were informed by senior staff that questionnaires have previously been made available to collate patient experience feedback, but there was no standardised approach to collating feedback within the department. Additionally, we were informed that no results or information relating to subsequent actions taken following previous questionnaires has been displayed.

More than half of the staff members who completed our staff survey as part of the inspection process, said that they did not receive regular updates relating to patient feedback collated. Additionally, 75 percent of staff responded to say that they did not know if patient feedback was used to make informed decisions within the department.

---

[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.

[4] https://www.nhs.uk/nhs-services/hospitals/what-is-pals-patient-advice-and-liaison-service/

Improvement needed

The health board should ensure that arrangements are in place to routinely collate patient feedback on the services provided within the department.

The health board should ensure that arrangements are in place to provide staff and patients with regular updates on the patient experience feedback received by the service, as well as any subsequent actions taken.

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 had an adequate awareness of their duty holder roles and responsibilities in line with IR(ME)R 2017.

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

Discussions with staff throughout our inspection provided assurance that arrangements were in place to ensure that examinations were being undertaken safely. However, a number of areas were highlighted including the need to ensure that written procedures accurately reflect clinical practice and that relevant documentation was being completed to evidence that checks required had taken place prior to procedures.

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 is aimed to ensure that the correct patient has 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, date of birth and home address. This approach is in keeping with current UK guidance[5].

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

The procedure also described the steps staff should take if they encounter different types of patients including individuals who may lack capacity, paediatric patients and patients unable to communicate in English.

Staff we spoke with were able to describe the correct procedure to identify patients prior to any examinations. Additionally, all patients who responded to our survey said that they were asked to confirm their personal details prior to the procedure. However, evidence provided as part of our inspection included an audit of referral forms submitted to the department. The audit set out to assess the completeness of a sample of department request forms. The audit reviewed 83 referral forms and highlighted that the patient identification checks on 10 percent of the forms reviewed had not been properly recorded.

Improvement needed

The employer must ensure that staff are reminded of the importance of routinely updating relevant documentation to demonstrate that patient identification checks have been undertaken prior to exposures.

Individuals of childbearing potential (pregnancy enquiries)

The employer had a written procedure in place in relation to the process for establishing whether an individual of childbearing age maybe pregnant or breastfeeding, prior to undergoing a nuclear medicine examination. This procedure aimed to ensure that such enquiries were made in a standard and consistent manner.

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 or breastfeeding, which was between the ages of 12 and 55. In addition to the employer's procedure, there was a pregnancy enquiry flow chart available for staff to follow.

On review of the information available it was identified that guidance in relation to pregnancy testing was unclear and there also were some inconsistencies identified between the procedure and the flow chart. The flow chart indicated that pregnancy testing is used as part of the checking process, but the written procedure states that pregnancy testing should only be considered in discussion with the referrer and practitioner. The written procedure did not describe the process shown in the flow chart for using the results on the pregnancy test.

As previously detailed, staff confirmed information relating to pregnancy and breastfeeding enquiries was sent to patients along with the appointment letter.

Additionally, we saw evidence of posters displayed within the department advising patients to speak with staff if they either are or think they may be pregnant.

Staff we spoke with were able to describe their responsibilities in regards to enquires required, which were in line with the employer's procedure described above. As part of our inspection, we reviewed a random sample of patient referral records which all provided evidence to demonstrate that pregnancy status checks had been carried out and recorded by staff. However, we identified that breastfeeding status enquiries had not been recorded for two relevant patients.

Improvement needed

The employer should ensure that a review of the employer's written procedure relating to pregnancy and breastfeeding enquires is undertaken to ensure that there is sufficient detail on the process to be followed by staff.

The employer should ensure a review of the pregnancy enquiry flow chart is undertaken to ensure that it accurately reflects the agreed procedure in place.

Non-medical imaging exposures

The employer had an up to date written procedure in place in relation to non-medical exposures[6] undertaken within the health board. We were informed that non-medical exposures are not undertaken within the nuclear medicine department.

Referral guidelines

The referral guidelines in place use the Royal College of Radiologist (RCR) iRefer publication, which sets out the referral guidelines and provides an indication of the radiation dose for individuals wanting to refer a patient for imaging. We were informed that this guidance is readily available to all healthcare professionals employed by NHS Wales and also available on the health board intranet site.

There was a written employer's procedure in place in relation to referrals and referral guidelines for individuals to follow. Information included within the document set out that referrals are accepted from entitled referrers on condition

[6] 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.

that it is in accordance with the set guidance for referral to the department. The information required included the relevant patient details, the referrer identity and signature, the examination required and significant medical data to justify the exposure.

The procedure detailed that if the referral form received is lacking in sufficient detail to meet the set criteria, it should be returned to the referrer.

Following review of the procedure it was highlighted that there was reference to the European Commission referral guidelines for imaging. However, this document may not be appropriate for use as referral guidelines as more recent, UK specific, guidance is available reflecting modern clinical practice (iRefer).

The employer's procedure described the process for making a referral to the department; a paper referral form is completed by the referrer and then sent to the nuclear medicine department via hand, post or electronically. The referrals are then scanned/uploaded onto Radiology Information System (RadIS)[7]. Referral letters may also be sent to the department, however, the procedure set out that department staff are then responsible for transcribing the relevant details within the letter onto a referral form and scanning the letter onto RadIS.

As part of our inspection, we reviewed a random sample of current and retrospective patient referral documentation received by the department. Overall, the referral forms were completed to an adequate standard. However, issues were highlighted in regards to one retrospective referral received via letter. Following receipt of this letter, the information was not transcribed onto a paper referral form and the letter was not scanned onto RadIS, as described within the employer's procedure. This issue was discussed with staff and we were informed that the employer's procedure does not reflect current practice within the department. The employer should review the 'Procedure for referral and referral criteria' and consider the best approach to standardising the referral process. This review should consider the potential risk of error in transcribing information from referral letters against the loss of detailed information contained within these letters.

Further issues were highlighted with regards to the letter referral reviewed, as it was unclear which entitled individual had signed the referral to confirm

[7] 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.

justification[8] and which entitled individual had authorised[9] the procedure prior to the exposure. This issue has also been noted further under the sub heading 'Justification of Medical Exposures'.

Improvement needed

The employer should update the procedure in relation to referrals and referral guidelines to remove reference to the European Commission referral guidelines for imaging.

The employer must undertake a review of the all procedures in relation to referrals and referral guidelines to ensure that they accurately reflect the agreed referral processes in place within the department.

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 holder roles and responsibilities in line with IR(ME)R, which are referrer[10], practitioner[11] and operator[12]. Overall, staff we spoke with demonstrated a good awareness and understanding of duty holder role requirements.

Information provided indicated that the health board Medical Exposures Group, which is chaired by the clinical lead for radiology, was established to oversee compliance with this policy and to consider patient safety matters arising from medical exposures within the health board. The policy sets out that the Medical

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

[9] Authorisation is the evidence that justification has taken place.

[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..

Exposures Group is responsible for authorising individual department managers to entitle staff within their area of responsibility to be practitioners and operators for specified scopes of practice, as well as providing advice on duty holder training requirements.

The policy also included details around the training, experience and competency requirements before an individual can be formally entitled to become a duty holder.

As part of our inspection, we reviewed a sample of duty holder training, competency and entitlement records. Overall, the training records provided were adequate. However, there were a few issues highlighted in relation to the information reviewed; one of the records reviewed did not provide clear evidence that the staff member had completed suitable training relating to radiation protection and statutory obligations relating to ionising radiations as set out in Schedule 3, Table 1[13] within the IR(ME)R 2017 Regulations, and within another training record reviewed it was identified that there was no evidence available to demonstrate that the individual's competence had been assessed.

Additionally, it was identified that the operator training and assessment record for the nuclear medicine superintendent had been assessed and signed by two radiographers working within the department, who report to the superintendent. We do not feel that this is appropriate and would suggest that the lead superintendent for the radiology department would have been a more suitable assessor/signatory.

Whilst evidence of practitioner licenses were provided, there was no information provided to evidence practitioner training or entitlement. This issue is detailed further within the 'Entitlement' section.

The arrangements for notifying staff of any changes to policies and procedures within the department were described to us. The relevant changes are discussed amongst team members and then followed up in an email. We were informed that staff have to confirm that they have read and understood the new or updated procedure in place.

[13] http://www.legislation.gov.uk/uksi/2017/1322/schedule/3/made

Improvement needed

The employer must ensure that clear evidence is available to demonstrate that duty holders have undertaken the required level of training, as well as clear evidence of competency assessment.

The employer must ensure that duty holder training and assessment records are reviewed and signed by a more senior manager.

The employer must ensure that training and competency records are maintained for all duty holders working within the department, including practitioners, non-medical referrers and those staff providing medical physics support.

Justification of Individual Medical Exposures

The employer had a written procedure in place for the justification and authorisation of medical exposures within the department. Information provided detailed that justification of individual medical exposures was being recorded on the paper referral forms submitted, via signature from a practitioner. Staff we spoke with had a clear understanding of the justification and authorisation process.

Additional evidence provided detailed that delegated authorisation guidelines (DAG's) have been issued by a named practitioner. Some of the operators have been entitled to authorise exposures in accordance with the DAG on the occasions it is not practicable for a practitioner to do so. Operators working under DAG guidelines are able to authorise the exposure by signing the appropriate section on the referral form.

As previously outlined, issues were highlighted in regards to one letter referral received within the department. Following review, it was unclear which entitled practitioners had justified and authorised the procedure prior to the exposure. The employer must ensure that staff are reminded of the importance of clearly signing referral documents to ensure that there is an identifiable name recorded.

Any carer and comforter medical exposure must also be justified. There was an employer's written procedure in place in relation to dose constraints and guidance for nuclear medicine exposures of carers and comforters. The procedure set out the steps to be followed by staff to justify and authorise these exposures, and to ensure that the individual is provided with adequate information, including the benefits and risk. Entitled operators may authorise

exposures to carers and comforters in accordance with the two separate DAGs issued by the practitioners.

The written procedure stated that if the operator cannot authorise an exposure to a carer and comforter, a practitioner must review and justify (where appropriate) the exposure. Individuals must read and sign a consent form to confirm their understanding of the risk and their agreement to follow the instructions given. The signed consent form is then scanned onto the relevant patient record on RADIS. In discussions with the MPE, we suggested that the employer's procedure should be revised to remove the exceptions for low dose exposures to carers and comforters and that these exposures should be included within the relevant DAG.

Improvement needed

The employer must ensure that all medical exposures are justified and that the individual practitioner (or operator under DAG) justifying and authorising each exposure can be identified.

The employer's written procedure for carer and comforter exposures in nuclear medicine should be reviewed to remove the exception relating to low dose exposures of carers and comforters.

Optimisation

The employer had arrangements in place for the optimisation[14] of patient exposures. For example, we were informed that administered activity or image acquisition settings are adjusted in accordance with the specific patients' size and mobility. Additionally, MPEs provide advice and contribute to the optimisation, by completing routine checks of department equipment, patient doses and undertake routine audits, which may result in recommendations to optimise specific procedures. This is to help ensure that exposure doses are kept as low as reasonably practicable.

We were informed that arrangements were in place to ensure that paediatric patient exposures were optimised. Paediatric doses are calculated using the weight of the patient to determine the appropriate dose required. Scaling factors

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

were displayed in the dispensing room within the department to provide guidance to staff.

The employer's procedure for establishing whether individuals of childbearing age are pregnant or breastfeeding set out that staff must seek advice from a nuclear medicine practitioner or MPE if the patient is breastfeeding. The employer should consider including further detail for staff within the procedure in relation to optimising exposures for breastfeeding patients and providing standard guidance for more common examinations in this type of patient.

Improvement needed

The employer should consider including additional guidance within the employer's procedure in regards to optimisation of exposures for breastfeeding patients.

Diagnostic reference levels

There was an employer's written procedure in place relating to the use and review of diagnostic reference levels (DRLs). The procedure detailed that nuclear medicine DRLs are established and reviewed by an MPE and issued to the department lead. We were informed that staff are notified of any changes to DRLs as and when required. We also saw that the standard operating procedures (SOP) and established local DRLs, for each type of nuclear medicine examination undertaken, were displayed within the department for staff to refer to.

The local DRLs in place are based on Administration of Radioactive Substances Advisory Committee (ARSAC)[15] guidance and the national DRLs. The local DRLs are reviewed as part of the MPE audits undertaken. It was highlighted that the employer's procedure does not provide sufficient detail in relation to the review process and frequency of nuclear medicine DRLs. The employer should consider updating this information within the procedure.

Information provided detailed that the health board Radiation Protection Group will now be responsible for signing off any new DRLs. However, it was highlighted that this change was not reflected in the employer's procedure.

[15] 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.

We were informed that the agreed tolerance range for administered activity was within 10 percent above or below the set DRL. The administered activity for every patient must be recorded in three places; on the referral form, on RADIS and on the administered activity record within the dispensing room. However, following discussions with staff and review of documentation, it was highlighted that some staff were recording the exact measured activity if it was below the set DRL, but were only recording the set local DRL if the measured activity was within 10 percent above.

Staff must accurately record the activity that has been dispensed and administered to patients. This issue was discussed with senior staff and it was agreed that staff should be reminded that the exact activities dispensed and administered to patients need to be recorded. Additionally, the relevant documentation should be updated to clear set out the agreed tolerance levels.

There was a process in place to ensure that any administered activities which exceed the agreed DRL tolerance levels are routinely recorded.

For CT(computed tomography) imaging used as part of SPECT-CT[16] imaging, we were told that staff must record the dose factors within the DRL exceeded logbook and that information is reviewed on a regular basis as part of the routine MPE audit programme, to ensure corrective actions are implemented.

Improvement needed

The employer should review and update the written procedure in relation to the use and review of diagnostic reference levels to ensure there is sufficient detail regarding the review process and frequency of nuclear medicine DRLs.

The employer should ensure that the written procedure in relation to the use and review of diagnostic reference level is updated to reflect the role of the Radiation Protection Group.

The employer must ensure that relevant documents are updated to clearly set out the agreed administered activity tolerance levels and ensure that staff are

[16] Imaging used to measure some body functions. Patients are injected with a small amount of radioactive material and then have to lie in the machine that captures gamma ray emissions from the material.

reminded of the importance of recording the exact measured value of patient administered activity.

Clinical evaluation

There was an employer's procedure in place which detailed the process regarding the clinical evaluation of medical exposures. 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.

Equipment: general duties of the employer

The employer had an inventory (list) of the equipment used within the department. However, this document did not include all of the equipment information required under IR(ME)R 2017. Additionally, we highlighted that nine out of the twelve pieces of equipment were overdue an electrical safety test.

We were informed that there was an employer's procedure in place in relation to quality assurance (QA) of employer's procedures and equipment. However, following review of this document it was highlighted that there was very limited information available to describe that arrangements for equipment QA.

There was an equipment quality assurance handbook available which set out relevant information including the test frequency of equipment within the department. We were informed that the MPE coordinates and undertakes the equipment quality assurance programme. Additionally, periodic equipment quality control is performed by the clinical scientist.

Improvement needed

The employer must ensure that the inventory of equipment used within the department is updated to include the information required under IR(ME)R 2017.

The health board must ensure that electrical safety tests are completed for all equipment listed on the inventory as being overdue.

The employer must ensure that there is a written procedure in place which clearly sets out the equipment quality assurance arrangements.

Safe care

Managing risk and promoting health and safety

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

Arrangements were in place to promote the safety of staff, patients and visitors. For example, appropriate signage and restricted access arrangements were in place to deter and prevent unauthorised persons entering areas where radiology equipment was being used.

Overall, the environment was well maintained, however, we found that there was damage to the plaster board above a plug socket within the department waiting room area. Also, there was seat fabric damage found on the front of one of the chairs within the waiting room.

Responses received via our staff survey detailed that all staff would know how to report concerns about unsafe clinical practice and would feel secure in doing so.

Improvement needed

The health board must ensure that remedial actions are taken to address the issues highlighted in the department waiting room area.

Infection prevention and control

Overall, at the time of our inspection the environment was visibly clean and free from clutter. Arrangements were in place for effective infection prevention and decontamination within the department. We were informed that these arrangements have been strengthened as a result of COVID-19.

Senior staff confirmed that cleaning regimes had improved and described some of the arrangements in place, including ensuring that relevant areas are routinely cleaned after every patient. Feedback from staff indicated that they agreed that decontamination arrangements were in place for equipment and relevant areas within the department.

We were informed that information is sent out to patients with their appointment letter, outlining that they should not attend their appointment if they have any

COVID-19 symptoms. We were also informed that any hospital inpatient scheduled to be seen within the department are routinely tested for COVID-19.

As outlined previously, the chairs within the department waiting area had been reorganised to allow for social distancing, with signs displayed on the chairs not to be used. We were informed that the chairs were wiped clean every hour. However, as previously detailed, we found damage to the fabric of one of the chairs which would prevent effective cleaning.

All patients who responded to our survey confirmed that they felt the department was 'very clean' or 'fairly clean', with all patients confirming that they felt that COVID-19 compliant procedures were evident during their time on the department. However, responses received via our staff survey indicated that three members of staff working within the department did not feel that necessary adaptations had been made to the department environment or in regards to practice undertaken.

We were informed that all staff are required to complete mandatory infection prevention and control (IPC) eLearning training. As part of our inspection, we reviewed a sample of staff training records and it was highlighted that IPC training for two members of staff had expired.

Feedback from staff indicated that there was a sufficient supply of personal protective equipment (PPE) available. Senior staff confirmed that PPE was stored within the department and staff were able to collect additional equipment as and when required. Additionally, we were informed that all staff have been fit tested for PPE and have received training in regards to donning and doffing[17].

Improvement needed

The health board should ensure that the views of department staff are collated to ensure that, where possible, the necessary adaptations have been made to the environment and practice undertaken, in regards to COVID-19.

[17] Donning – putting on personal protective equipment (PPE); Doffing – taking off personal protective equipment (PPE)

Safeguarding children and adults at risk

Staff we spoke with described the action they would take should they have any safeguarding concerns. We were informed that safeguarding guidance and support was available on the health board intranet page. We were also informed that all staff are required to complete mandatory online training. The sample of staff training records reviewed indicated that all staff were up to date with safeguarding training at the time of our inspection.

Effective care

Quality improvement, research and innovation

Clinical audit

The employer had a written procedure in place entitled 'Procedure for clinical audit of radiological procedures relating to IR(ME)R'. However, on review of this document it was highlighted that the content related to IR(ME)R audits and not clinical audits. Staff we spoke with were able to describe the arrangements in place in relation to the clinical audits performed within the department. The employer should update the employer's procedure to ensure that it accurately reflects the arrangements in place.

Evidence was provided of good nuclear medicine audits undertaken within the department. Evidence also showed the relevant department staff were involved in the process and information was being shared within the department, locally and at a national level. Examples of the changes implemented as a result of the audits undertaken were provided, however, we highlighted that the subsequent outcomes or changes to practice were not always clear on the audit documentation reviewed.

Improvement needed

The employer should ensure that there is a written procedure in place that accurately reflects and formalises the clinical audit arrangements in place within the nuclear medicine department.

The employer should ensure that outcomes and changes to practice following clinical audits are clearly documented.

Expert advice

Information provided detailed that the overall radiology department had access to advice and support from three MPEs, two of which had an expertise in nuclear

medicine. As previously mentioned the MPEs were employed by Swansea Bay University Health board (UHB), with an agreement in place for support to be provided to the department. All three of the MPEs assigned to provide support were listed on the approved list from RPA2000, the certified body for MPE recognition.

We were informed that an MPE attends the department once a month to provide advice and support, as well as to undertake tasks including equipment QA and testing, staff training and patient dose assessments. Additionally, evidence was provided of the annual audit undertaken by the MPE in relation to equipment performance, optimisation and quality compliance. This document was comprehensive and set out the required actions identified as a result of the audit.

Discussions with department staff demonstrated that there was a good working relationship with the MPEs. We were also informed that staff were able to contact an MPE for advice and support where necessary, on an ad hoc basis.

We saw evidence of an appointment letter for an MPE, however, queries were raised by staff around the formal arrangements in place in regards to the agreed capacity requirements and scope of practice for MPEs. These queries were subsequently discussed with senior managers and we were informed that a Service Level Agreement (SLA) was in place with Swansea Bay UHB which set out the details of the arrangements in place. However, no evidence of this agreement was made available during our inspection. Given the queries raised, the employer should ensure that information in regards to capacity requirements and scope of practice is made available to relevant staff.

There was no evidence available to demonstrate that MPEs had been entitled as operators to undertake the required tasks within the department. We were informed by senior managers that as they were not employed by Hywel Dda UHB, it was thought that they could not be entitled and that they’re entitlement would be covered by Swansea Bay UHB. However, this is not the case and there must be evidence available to demonstrate that all duty holders working within the department have been entitled to do so. This issue is detailed further in the ‘Entitlement’ section.

Improvement needed

The employer should ensure that information is available setting out the capacity requirements and scope of practice for MPEs that provide advice and support to the department.

Medical research

The department does participate in research involving medical exposures and a written employer's procedure was in place. Information provided detailed that the department participates in the ARAMIS research trial, which relates to a multi-national prostate cancer drug trial. The trial involves the radiology team within Prince Philip Hospital undertaking CT scans and bone scans being undertaken at Withybush General Hospital at three month intervals.

Evidence was available to demonstrate that the required employer and practitioner licences were in place to allow the research medical exposures to be undertaken within the department.

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

An organisational structure was in place for the overall radiology department, with clear lines of reporting.

There was evidence of an experienced and committed workforce within the department, with a good team working ethos. Overall, staff were happy with the level of communication and support provided by the department lead. However, concerns were highlighted in relation to the level of support and engagement provided by senior managers within the service.

Issues were highlighted by staff around the available capacity within the department to carry out the relevant tasks required as part of their duty holder roles.

Governance, leadership and accountability

There was a hospital radiology organisation chart in place, which set out the clear lines of reporting within the overall service, including the nuclear medicine department.

The nuclear medicine department lead indicated that as the department consisted of a small team working in a small area, it allowed for regular discussions to be held in relation to current workload, any issues and any required changes to existing processes. It was clear from our feedback from staff that the department consisted of committed staff and a good team working ethos was evident.

Feedback received from department staff indicated that they felt that there was good communication and support from the department lead. However, concerns were highlighted following feedback from staff in regards to support, visibility and engagement from senior managers within the service. For example, staff

indicated that they felt that they were not always involved in decisions which impacted on their roles.

Prior to our inspection, HIW require staff at a senior and department level to complete a self-assessment questionnaire. This is 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. Whilst we did highlight a number of discrepancies in the responses provided, in the majority of areas highlighted, staff were able to provide the additional information or clarification promptly.

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

Improvement needed

The health board should consider methods to improve the visibility, engagement and support being provided to the nuclear medicine department by senior managers.

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. Evidence was available to demonstrate that valid employer and practitioner licences were in place. Additionally, arrangements were in place to monitor the status of required licences; we were informed that the MPE maintains a matrix of all ARSAC licences and licences are also covered as part of the MPE annual audit.

Duties of the employer

Entitlement

Evidence of good entitlement records for operator staff working within the department was provided as part of our inspection. However, there were a few discrepancies highlighted within the sample of duty holder training, competency and entitlement records reviewed, as detailed within the 'Duties of practitioner, operator and referrer' section earlier in this report.

As previously detailed, whilst evidence of practitioner licences was available, there was no information provided to evidence practitioner training or entitlement. Additionally, there was no evidence to demonstrate that MPEs or clinical scientists undertaking tasks within the service had been entitled to do so. The employer must ensure that evidence is available to demonstrate that all duty holders have been entitled.

On review of the documentation provided in relation to entitlement of duty holders, it was highlighted that there were inconsistencies and some duplication in the information available. Within the nuclear medicine training matrix, some tasks had been grouped together to cover a very broad range of tasks and the level of detail was not consistent with the training and competency records. The level of detail within the documentation should describe each task or function separately, for example, evaluating images and referring for additional images should be two separate tasks.

This issue was discussed with staff and it was agreed that the relevant documentation would benefit from further review to ensure that the documentation in place accurately reflects the agreed entitlement process, as well as to reduce the amount of duplicated content, as this presents a risk of inconsistent and/or out of date information being available to staff.

Improvement needed

The employer must ensure that evidence is available to demonstrate that all duty holders have been entitled, in line with the agreed written procedure in place.

The employer must ensure that a review of the entitlement documentation is undertaken to confirm that detail accurately reflects the agreed procedure, and to reduce the level of duplication within relevant documents.

Procedures and protocols

Senior managers confirmed that the health board Chief Executive (CEO) 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 Health Science. The Ionising Radiation Safety Policy set out that responsibilities for the management of radiation safety within the health board.

Feedback from department staff highlighted some concerns around the accessibility of up to date employer's procedures and also staff ability to contribute to the development of procedures which related to their area of work. As a result we were notified of a number of areas within the employer's procedures provided, which did not accurately reflect the arrangements in place within the nuclear medicine department. Given the issues highlighted, an exercise should be undertaken, involving relevant staff from the nuclear medicine department, to review and update the employer's procedures, to ensure that they are accurate and reflective of actual practices in operation within the nuclear medicine department.

There was an employer's procedure in place in relation to document control, which set out the methods for document control, including the revision and issue of employer's procedures and protocols, to ensure safe working practice. The procedure also set out the information that needed to be detailed in relation to version control, author and approval for each document. However, it was highlighted that several of the nuclear medicine protocols and standard operating procedures provided as evidence did not include the required information set out within the procedure.

As highlighted previously, following review of some of the employer's procedures in place, we did highlight several which were lacking the required level of detail and clarity for staff to follow. During discussions with staff, we were provided with assurances on the practice being carried out. However, on a number of occasions the practice described did not reflect the detailed included within the associated written procedure.

Improvement needed

The employer must ensure that up to date employer's procedures are readily available to all department staff.

The employer must ensure that written procedures in place are reviewed to ensure that they are accurate and reflective of actual practices in operation within the nuclear medicine department.

The employer should ensure that all written protocols in place include the required level of detail as set out within the employer's procedure for document control.

Significant accidental or unintended exposures

There was a written employer's procedure in place in relation to reporting and investigating accidental or unintended exposures. The procedure set out the

process to be followed if it is suspected that an accidental or unintended exposure has occurred within the department.

Evidence provided set out that staff are required to notify the site lead radiographer or service manager, who will then ensure that a detailed investigation is undertaken. Relevant information, which was set out within the procedure, must be collated and provided to the MPE, who will then complete a dose and risk assessment. The MPE will advise whether the incident is a significant accidental or unintended exposure (SAUE), which needs to be reported to HIW. The radiology clinical director will then establish if the SAUE is 'clinically significant' to determine whether the referrer, practitioner and patient need to be notified.

Detail in relation to the HIW incident notification requirements were available within the procedure, this included a link to the HIW IR(ME)R incident form. However, it was highlighted that the link included was out of date. The employer should ensure that the procedure is updated to include a functional link to allow staff to access the required information on the HIW website[18].

The procedure set out that the investigation report must include an action plan setting out the mitigations to minimise the risk of similar incidents occurring in the future. Also, detail set out that incident update reports must be presented for review by the health board Medical Exposures Group.

Senior managers confirmed that all incidents and near misses are reported via Datix, the electronic incident reporting system. We were informed that there have been no SAUEs that have occurred within the nuclear medicine department within the past two years.

Staff we spoke with were able to describe the process in regards to reporting and investigating suspected accidental or unintended exposures.

Improvement needed

The employer must ensure that the written procedure in relation to reporting and investigating accidental or unintended exposures is updated to include a functional link to the relevant section on the HIW website.

[18] https://hiw.org.uk/notifying-irmer-incidents

Staff and resources

Workforce

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

Feedback received highlighted concerns around staffing levels within the department. Staff felt that the levels within the department were not always adequate to meet the demand. Additionally, concerns were highlighted in particular around radiologist capacity. We were informed that the service does not have enough consultant radiologists available to meet the reporting demand. Therefore, there is a heavy reliance on the department lead as the only nuclear medicine reporting radiographer.

These concerns were discussed with senior managers and we were informed that they were aware of the issues in regards to consultant radiologist availability and that it was listed as a health board risk. We were informed that the health board was looking to build further links with Swansea Bay UHB to try to address the capacity issues. Additionally, we were informed that a workforce capacity review was underway for radiology within the whole health board. Given the concerns highlighted by department staff, we recommend that a review to determine the capacity requirements within the nuclear medicine department is undertaken, to ensure that staff have manageable workloads and that there is sufficient capacity to meet the service demands.

Further concerns were highlighted by the department lead in regards to adequate space to allow for reporting. Whilst we appreciate the limitations regarding the available space within the department, efforts should be made to ensure that relevant staff are able to access designated areas, when required, to enable them to undertake the required reporting tasks.

We were informed that there was a process in place to ensure that all staff received annual appraisals. All department staff, with the exception of the department lead, confirmed that they had received an appraisal within the last 12 months. However, two staff members stated that they did not feel that their training and development needs were discussed as part of their appraisal.

As previously detailed, as part of our inspection we reviewed a sample of department staff training records and we were informed that arrangements were in place to monitor compliance. Overall, compliance levels with mandatory training was good. However, following review of evidence provided it was

highlighted that some staff members training certificates had expired for health and safety, Mental Capacity Act and infection prevention and control.

We were informed that arrangements were in place to allow staff to access additional wellbeing supporting if required, via the health board occupational health service. However, concerns were raised around the length of time staff have had to wait to be contacted by the service following referral. Additionally, feedback received from staff indicated that not all staff working within the department were aware how to access the wellbeing support available.

Improvement needed

The health board must undertake a workforce capacity review to ensure that all staff working within the nuclear medicine department have sufficient capacity to undertake their relevant roles.

The health board should ensure that adequate space is available to enable relevant staff to undertake reporting tasks as part of their roles.

The health board must ensure that all staff working within the department receive regular appraisal discussions with their line manager, which cover their training and development requirements.

The health board must ensure that all department staff are up to date with mandatory training requirements.

The health board must review the current arrangements in place relating to access to occupational health support.

The health board must ensure that all staff are provided with information on the additional wellbeing support available to them and how to access it.

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 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: Withybush General Hospital

Ward/department: Nuclear Medicine Department

Date of inspection: 27 and 28 July 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: Withybush General Hospital

Ward/department: Nuclear Medicine Department

Date of inspection: 27 and 28 July 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 health board is required to ensure that action is taken to promote the availability of Welsh speaking staff / support within the department to help deliver the 'Active Offer'.	3.2 Communicating effectively	To utilise Welsh speaking staff for patients who request to speak Welsh, and deliver 'Active Offer' whenever possible. Promote the wearing of badges to display Welsh speakers and those learning Welsh. Continue to follow HB guidelines regarding the employment of Welsh Speakers. To better promote the learning of Welsh within the department amongst	Site lead	December 2021

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		staff and engage with Health Board Welsh Language team		
The health board must ensure that arrangements are in place to provide written information to patients in Welsh when required.	3.2 Communicating effectively	Review of written patient information and translate into Welsh. Engagement with the HB Welsh Services Manager to develop culture where Welsh is seen equally to English within the department	Site Lead	March 2022
The health board should ensure that arrangements are in place to routinely collate patient feedback on the services provided within the department.	6.3 Listening and Learning from feedback	Engage with the Health Board patient experience team. Ensure staff are aware of how to report patient feedback through the HB service via the Radiology staff forum, which is held monthly. Modality leads will also be e-mailed to inform staff of this requirement. Ask for regular feedback from patients and act where necessary,	Site lead	December 2021
The health board should ensure that arrangements are in place to provide staff and patients with regular updates on the patient experience feedback received by the service, as well as any subsequent actions taken.	6.3 Listening and Learning from feedback	Arrange and display information of the patient feedback service on the waiting room notice board. 'you said, we did' section in response to comments/feedback. To communicate with staff at regular staff meetings	Site lead	December 2021

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
Delivery of safe and effective care				
The employer must ensure that staff are reminded of the importance of routinely updating relevant documentation to demonstrate that patient identification checks have been undertaken prior to exposures.	Sch 2(a)	Make staff aware of their responsibility regarding I.D. checks via Radiology Forum, and poster campaigns which will be displayed in prominent areas. Conduct regular audits via Picture Archiving Communication System (PACS) of the recording of request information and act where necessary	Site lead	December 2021
The employer should ensure that a review of the employer's written procedure relating to pregnancy and breastfeeding enquires is undertaken to ensure that there is sufficient detail on the process to be followed by staff.	Sch 2(c)	Review employers' procedures and ensure that the departmental SOP for breast feeding patients is referenced within the employers procedures. This will be ratified at the HB Exposures Meeting in November 2021.	Radiology services manager	November 2021
The employer should ensure a review of the pregnancy enquiry flow chart is undertaken to ensure that it accurately reflects the agreed procedure in place.	Sch 2(c)	Adjust the title of EP8 flow chart and reference to departmental SOP within this section of employers' procedures. This will be ratified at the HB Exposures Meeting in November 2021.	Radiology Services manager	November 2021

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
The employer should update the procedure in relation to referrals and referral guidelines to remove reference to the European Commission referral guidelines for imaging.	Reg 6(5)(a)	Amend employers procedures referral guidelines to i refer. This will be ratified at the HB Exposures Meeting in November 2021.	Radiology services manager	November 2021
The employer must undertake a review of the all procedures in relation to referrals and referral guidelines to ensure that they accurately reflect the agreed referral processes in place within the department.	Reg 10(5)	Amend and review EP4, 5 and 6 so that they are in accordance with RCR guidelines. Ensure that these more concisely reflect current practice. This will be ratified at the HB Exposures Meeting in November 2021.	Radiology services manager	November 2021
The employer must ensure that clear evidence is available to demonstrate that duty holders have undertaken the required level of training, as well as clear evidence of competency assessment.	Reg 17(4)	Training and competency assessment evidence is available in paper copy in the Nuclear Medicine Department,	Radiology services manager	Completed
The employer must ensure that duty holder training and assessment records are reviewed and signed by a more senior manager.	Reg 17(4)	Duty holder training and assessment records have been reviewed and signed by the previous site lead. This will be completed on an annual basis.	Radiology services manager	Completed

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
The employer must ensure that training and competency records are maintained for all duty holders working within the department, including practitioners, non-medical referrers and those staff providing medical physics support.	Reg 17(4)	Ensure that practitioner and non-medical referrer and medical physics training records meet competency requirements and undergo regular review. Work to develop an electronic version which can be both read, updated and signed by users	Radiology services manager	October 2022
The employer must ensure that all medical exposures are justified and that the individual practitioner (or operator under DAG) justifying and authorising each exposure can be identified.	Reg 11(1)(c)	Review current written procedure and reflect any changes made within the employers procedures.	Radiology services manager	November 2021
The employer's written procedure for carer and comforter exposures in nuclear medicine should be reviewed to remove the exception relating to low dose exposures of carers and comforters.	Sch 2(n)	Currently under review by MPE and will be amended within employers procedures.	Radiology services manager	November 2021
The employer should consider including additional guidance within the employers procedure in regards to optimisation of exposures for breastfeeding patients.	Sch 2(c)	Ensure employers procedures cross reference departmental SOP with consideration for lower dose/non ionising examinations	Radiology services manager	November 2021

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
The employer should review and update the written procedure in relation to the use and review of diagnostic reference levels to ensure there is sufficient detail regarding the review process and frequency of nuclear medicine DRLs.	Sch 2(f)	This is currently under Health Board review with advice being sought from MPEs. This will be ratified at the next scheduled Exposures Group Meeting in November 2021.	Radiology services manager	November 2021
The employer should ensure that the written procedure in relation to the use and review of diagnostic reference level is updated to reflect the role of the Radiation Protection Group.	Sch 2(f)	This is currently under Health Board review with advice being sought from MPEs. This will be ratified at the next scheduled Exposures Group Meeting in November 2021.	Radiology services manager	November 2021
The employer must ensure that relevant documents are updated to clearly set out the agreed administered activity tolerance levels and ensure that staff are reminded of the importance of recording the exact measured value of patient administered activity.	Sch 2(e)	Required information is now available within the Employers' Procedures	Radiology services manager	Completed
The employer must ensure that the inventory of equipment used within the department is updated to include the information required under IR(ME)R 2017.	Reg 15(2)	Required information is now available within the Employers' Procedures.	Radiology services manager	Completed

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
The health board must ensure that electrical safety tests are completed for all equipment listed on the inventory as being overdue.	2.1 Managing risk and promoting health and safety	This recommendation is currently being actioned, with the majority of equipment PAT tested. Completion expected by December 2021	Site lead	December 2021
The employer must ensure that there is a written procedure in place which clearly sets out the equipment quality assurance arrangements.	Reg 15(1), Sch 2(d)	Equipment quality assurance arrangements are now available within the Employers' Procedures.	Radiology services manager	Completed
The health board must ensure that remedial actions are taken to address the issues highlighted in the department waiting room area.	2.1 Managing risk and promoting health and safety	Damaged chairs have been removed and replaced. Estates have been contacted in order to repair plaster, with expected completion in December 2021	Site lead	December 2021
The health board should ensure that the views of department staff are collated to ensure that, where possible, the necessary adaptations have been made to the environment and practice undertaken, in regards to COVID-19.	2.4 Infection Prevention and Control (IPC) and Decontamination	New site lead in post, this is currently under review. Site lead is engaging with staff to ensure they feel safe within their working environment given current social distancing requirements. Advice has been sought from Health Board H&S advisor. New reporting room actioned currently awaiting works from Estates in order to adhere to social distancing requirements.	Site lead	November 2021

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
The employer should ensure that there is a written procedure in place that accurately reflects and formalises the clinical audit arrangements in place within the nuclear medicine department.	Reg 7	Health Board will adopt a clinical audit schedule within employers procedures	Radiology services manager	November 2021
The employer should ensure that outcomes and changes to practice following clinical audits are clearly documented.	Reg 7	Health Board will adopt a clinical audit schedule within employers procedures	Radiology services manager	November 2021
The employer should ensure that information is available setting out the capacity requirements and scope of practice for MPEs that provide advice and support to the department.	Reg14(1)	This is currently in progress, with completion of the recommendation expected by March 2022.	Radiology services manager	March 2022
Quality of management and leadership				
The health board should consider methods to improve the visibility, engagement and support being provided to the nuclear medicine department by senior managers.	Governance, Leadership and Accountability	New site lead in post, and based on site so that staff have regular access to management. Currently engaging with NM staff and establishing regular forums between manager and staff within the department. GM of Radiology attends Radiology Forum, whilst awaiting the	Site lead	Completed

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		new Head of Radiology to commence in post.		
The employer must ensure that evidence is available to demonstrate that all duty holders have been entitled, in line with the agreed written procedure in place.	Sch 2(b)	Review of duty holder's entitlement of currently underway, and requests for additional documentary evidence to be asked from staff where necessary to prove competency.	Radiology services manager	March 2022
The employer must ensure that a review of the entitlement documentation is undertaken to confirm that detail accurately reflects the agreed procedure, and to reduce the level of duplication within relevant documents.	Sch 2(b)	Review of duty holder's entitlement currently underway, and requests for additional documentary evidence to be asked from staff where necessary to prove competency,	Radiology services manager	March 2022
The employer must ensure that up to date employer's procedures are readily available to all department staff.	Reg 6(1)	Latest versions of employer's procedures are available as paper copies in all modalities, accessible to all staff. All staff have been facilitated to read and sign declaration. Documents are also on site shared drive and available for reference to the four site leads across the HB.	Radiology services manager	Completed
The employer must ensure that written procedures in place are reviewed to ensure that	Reg 6(1)	Latest versions of employer's procedures are available as paper copies in all		Completed

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
they are accurate and reflective of actual practices in operation within the nuclear medicine department.		modalities, accessible to all staff. Procedures are reviewed each time an amendment is made. Documents are also on site shared drive and available for reference to the four site leads across the HB. All staff have been facilitated to read and sign declaration.	Radiology services manager	November 2021
The employer should ensure that all written protocols in place include the required level of detail as set out within the employer's procedure for document control.	Reg 6(5)(b)	When in post, the new Radiology Services Manager will engage with MPEs and review. Ratification will be obtained at the Exposure Group Meeting in November,	Radiology services manager	November 2021
The employer must ensure that the written procedure in relation to reporting and investigating accidental or unintended exposures is updated to include a functional link to the relevant section on the HIW website.	Reg 8(4)	The written procedure is currently under Health Board review and expected to be finalised in November 2021 at the Exposures Group Meeting	Radiology services manager	November 2021
The health board must undertake a workforce capacity review to ensure that all staff working	7.1 Workforce	This will be escalated as a risk by site lead for the attention of the radiology	Radiology services manager	March 2022

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
within the nuclear medicine department have sufficient capacity to undertake their relevant roles.		services manager for review to be undertaken. Current managerial changes are on-going. New Radiology services manager in post November 2021		
The health board should ensure that adequate space is available to enable relevant staff to undertake reporting tasks as part of their roles.	7.1 Workforce	A new reporting room has been allocated and works have been approved and financed	Site lead	November 2021
The health board must ensure that all staff working within the department receive regular appraisal discussions with their line manager, which cover their training and development requirements.	7.1 Workforce	This statement has been challenged within the factual accuracy. New site lead in post who is attending PDR training 14.10.21, after which a programme will be rolled out to update all outstanding PDRs within Radiology WGH	Site lead	March 2022
The health board must ensure that all department staff are up to date with mandatory training requirements.	7.1 Workforce	New site lead to perform performance review and allocate time to staff to complete mandatory training. To liaise with course leaders regarding face to face training courses which were halted due to Covid 19 – staff are currently enrolled and on waiting lists for courses where face to face training options are available, with other face to face training	Site lead	March 2022

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		(such as fire training) being held virtually due to Covid restrictions. Management monitor the uptake of training via ESR metrics.		
The health board must review the current arrangements in place relating to access to occupational health support.	1.1 Health Promotion, Protection and Improvement 7.1 Workforce	The previously reported back-log in occupational health referrals has now been resolved within the Health Board. Staff are now being seen within a timely manner. New site lead engaging with staff and well-being services face to face within the department	Site lead	March 2022
The health board must ensure that all staff are provided with information on the additional wellbeing support available to them and how to access it.	1.1 Health Promotion, Protection and Improvement 7.1 Workforce	This information is available on the Health Board intranet. Site lead to ensure modality leads are able to sign post staff to this information via team meetings. Information on well being services to be placed on the staff room notice board	Site lead	November 2021

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): Gillian Lingwood

Job role: Site Lead Radiographer Withybush Hospital

Date: 01/10/2021