

Ionising Radiation (Medical Exposure) Regulations Inspection (Announced)

Nuclear Medicine Department,
Royal Glamorgan Hospital, Cwm
Taf Morgannwg University
Health Board

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

Our purpose

To check that people in Wales receive good quality healthcare

Our values

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

- Independent
- Objective
- Caring
- Collaborative
- Authoritative

Our priorities

Through our work we aim to:

Provide assurance:

Provide an independent view on the quality of care

Promote improvement:

Encourage improvement through reporting and sharing of good practice

Influence policy and standards:

Use what we find to influence policy, standards and practice

1. What we did

Healthcare Inspectorate Wales (HIW) completed an announced Ionising Radiation (Medical Exposure) Regulations inspection of the Nuclear Medicine Department within the Royal Glamorgan Hospital on the 4 and 5 October 2021.

Our team, for the inspection comprised of two HIW Inspectors and a Senior Advisor from the Medical Exposures Group of the UK Health Security Agency, previously known as Public Health England, who acted in an advisory capacity.

HIW explored how the service:

- Complied with the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R 2017)
- Met the Health and Care Standards (2015).

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

2. Summary of our inspection

Overall staff we spoke with had a clear understanding 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.

Some areas for improvement were identified.

This is what we found the service did well:

- Staff treated patients with dignity, respect and kindness
- Overall, we found good compliance with the Ionising Radiation (Medical Exposure) Regulations 2017
- Good working links between Medical Physics Experts (MPEs)¹ and staff working within the 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
- We saw visible and supportive leadership being provided by senior staff.

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.

This is what we recommend the service could improve:

- Implementing arrangements to routinely collate patient feedback on the services provided within the department
- Ensure staff appraisals are being carried out, to allow for training and development needs to be identified and monitored
- Ensure all staff are up to date with mandatory training requirements
- Explore and identify actions to tackle any potential areas of discrimination.

3. What we found

Background of the service

Cwm Taf University Health Board was established on 1 October 2009. It was renamed Cwm Taf Morgannwg University Health Board following the transfer of Bridgend County Borough from the former Abertawe Bro Morgannwg University Health Board.

It provides primary, community, hospital and mental health services to the people of the counties of Merthyr Tydfil, Rhondda Cynon Taf, and Bridgend. The health board as a whole provides service to a population of around 450,000 people

The Nuclear Medicine Department at the Royal Glamorgan Hospital (the hospital) near Llantrisant consists of equipment including a gamma camera², dose calibrators³ and gamma probes⁴. The department employs a number of staff including Radiographers and Consultant Radiologists.

The department also has advice and support provided by Medical Physics Experts (MPEs) employed by RPS Cardiff, part of Velindre University NHS Trust and Clinical Scientists employed by Cardiff and Vale University Health Board.

² A gamma camera is a device used to image the radiation emitted from a patient's body after the administration of a radiopharmaceutical.

³ The dose calibrator is a gas-filled ionisation chamber used in nuclear medicine to measure the amount of radioactivity to be administered to patients.

⁴ A gamma probe is an instrument used to detect radiation in patients. It is designed principally for use in surgery

Quality of patient experience

We collated the views of patients, their relatives, representatives and/or advocates (where appropriate) to ensure that the patients' perspective was 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 overall that there were adequate arrangements in place to meet the communication needs of patients attending 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.

HIW issued both online and paper surveys to obtain patient views on the services provided at the nuclear medicine department of the hospital. A total of 20 completed questionnaires were received, not all the respondents answered all of the questions. Patients were asked in the questionnaire to rate their overall experience of the service. All 20 that responded, rated the service as 'very good'. Patients told us:

"Excellent service"

"The staff were very professional and polite."

HIW also issued an online survey to obtain staff views on the nuclear medicine department at the hospital. In total, we received ten responses from staff at the department. Additionally, as above, not all respondents answered all of the questions.

Staying healthy

There was information displayed in the department's main waiting area and in the nuclear medicine waiting area, detailing the benefits and risks of the various types of medical exposures to ionising radiation 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. Due to potential infection prevention and control (IPC) issues, we were told that all the leaflets previously on display in the reception areas had been removed. Only wipe clean posters could be displayed. We were informed that plans were in place to install a new notice board within the main waiting area and to have leaflets available for patient use.

Posters were clearly displayed requesting individuals who were or may be pregnant or breast feeding to inform a member of staff. This is a regulatory requirement and important to promote patient safety. We saw posters about the radiation risk that patients may pose to others for a short period following their procedure. Patients were advised to avoid close contact with children and individuals who were pregnant. We saw nuclear medicine specific information posters displayed within the waiting area and main corridor within the department. Additional posters were displayed with regards to general radiology procedures throughout the department.

Dignified care

We found staff treated patients with dignity, respect and kindness. All patients who completed a questionnaire agreed they had been treated with dignity and respect by the staff at the hospital and felt they were always able to maintain their privacy, dignity and modesty during their appointments. This included all patients who responded to the question saying they were listened to by staff during their appointment.

Whilst we did not observe patients having their procedures, we saw staff greeting patients in a friendly way. Staff were mindful of respecting patient privacy and dignity and we saw that doors to treatment rooms were closed during use. Also, signs were displayed to indicate whether an examination was in process, or not, and not to enter.

Staff explained that nuclear medicine patients usually remained in their own clothes during their procedure. Lockable changing rooms were available adjacent to the nuclear medicine waiting area for patients to change clothing, if required.

The department's main waiting area had been reorganised to allow for social distancing between waiting patients. There were a limited number of seats available within this area. Senior managers confirmed that plans were in place to install new chairs and also clear plastic panels between chairs, to allow for additional seating within the area for patients.

Senior managers confirmed that they only allowed one patient (or two if accompanied by a family member), to wait in the nuclear medicine waiting area.

Staff explained that patients would be taken to a separate room to check their details prior to their procedure.

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 examination without being overheard by other people.

Patient information

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's 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 ensure patients were 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 were able to describe the information they gave to patients verbally regarding the benefits and risks from the exposure. They described how they would explain that the procedure involved small levels of radioactivity. They explained that there were associated risks but that these were small and that their doctor believed that this small risk was outweighed by the benefit to them. Staff could compare the radiation dose from nuclear medicine investigations to the equivalent exposure from background radiation. Support was available from consultant radiologists or MPEs if required.

All of the patients who completed a questionnaire told us they felt involved as much as they wanted to be in any decisions made about their examination. Patients also said they had received clear information about the risks and benefits of their examination options. All patients also told us they had been given information on how to care for themselves following their examination. However only eight of the 19 patients who responded to the question said they had been given written information on who to contact for advice about any after effects from any examinations they had received.

Improvement needed

The employer must ensure that patients are given written information, where relevant, on who to contact for advice about any after effects from any treatments they had received.

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 had any other communication requirements. Staff confirmed that they had access to translation services to assist should a patient attend the unit unable to communicate in English. We were informed that staff were able to book a translator for the patient's appointment.

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. We also saw a poster with the Cymraeg symbol displayed to help deliver an 'Active Offer'⁵.

Timely care

All of the patients who completed a questionnaire told us it was 'very easy' or 'fairly easy' to arrange an appointment for their procedure or examination. 15 patients said they had waited less than 15 minutes to have their procedure or examination and five waited between 15 and 30 minutes.

Patients arrived at the main radiology department reception area for their appointment. We saw patients were then escorted or directed to the nuclear medicine department. On the days of our inspection, whilst we noticed there were times when the main reception area was busy, patients appeared to be seen fairly promptly. We did not hear patients being told of waiting times by reception

⁵ 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.

staff on arrival to the department. However, patients were not noted waiting any significant periods to be seen in the main radiology department.

We were informed that arrangements were in place to ensure that patients were routinely notified on arrival to the department if there was likely to be a significant delay to their scheduled appointment time. Within the nuclear medicine department, staff told us they aim to keep to the patient's appointment time. There was also a notice, in the nuclear medicine waiting area, advising patients to inform a staff member if they had been waiting for longer than 30 minutes.

Individual Care

Peoples' rights

Almost all patients who responded to the questionnaire, said it was 'very easy' or 'fairly easy' to find their way to the department. We noted that signposting from the main reception area was clear and there was bilingual signage.

Nine of the ten patients who answered the question said they felt they could access the right healthcare at the right time (regardless of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation).

Seven patients who answered the question, said their preferred language was English and one said it was Welsh. They all said they were able to communicate with staff in their preferred language and that healthcare information was available in their preferred language.

Listening and learning from feedback

The health board had arrangements in place for patients to provide feedback about their experiences and to raise concerns about their care and treatment. We saw health board patient feedback cards available in the main reception area. These cards were available in English and Welsh next to a locked box on the wall to allow patients to submit their comments confidentially.

Senior managers we spoke with confirmed that annual departmental patient surveys had been completed prior to the pandemic. However, information was not displayed with regards to how the service had learned or improved following patient feedback received. There were plans to have a three part board within the main reception waiting area, which would include information on feedback received.

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 departmental managers and the health board concerns process.

Senior staff described the methods for dealing with complaints. There was an on the spot concerns form which the health board used. The aim was to try and deal with the complaint locally using early resolution forms. Formal concerns would be forwarded to the relevant sites for staff had to investigate and provide information to respond to the complainant. The patient safety concerns team, within the health board, required a reply be made to the concern within two days. The patient would then be updated with the outcomes of the complaint, in due course.

Information leaflets and a poster were available within the department with regards to the all Wales NHS complaints procedure, known as Putting Things Right (PTR)⁶. There was also a poster highlighting the local community health council (CHC)⁷.

Nine of the ten staff respondents agreed patient and service user experience feedback was collected within their department. Six of eight staff, who expressed an opinion, said they received regular updates on patient and service user experience feedback in their department. One commented:

“Radiology provides feedback but there is no inter-departmental or ward feedback unless radiology has been involved with the incident.”

Eight of the nine respondents who expressed an opinion, said feedback from patients or service users was used to make informed decisions within their department.

⁶ '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.

⁷ A CHC is an independent statutory health 'watchdog' covering the health board that monitors the quality of local health services. It recommends improvements in the standard of health care, provides an enquiry and advocacy service to advise patients wanting to make a complaint, encourages the health service to make changes in partnership and in consultation with local people.

Improvement needed

The employer must ensure that:

- Arrangements are in place to routinely collate patient feedback on the services provided within the department
- Systems 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, we found good compliance with the Ionising Radiation (Medical Exposure) Regulations 2017. We found arrangements were in place to provide patients visiting the nuclear medicine department with safe and effective care.

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

We identified some areas for improvement including the need to specify all referral guidelines within procedures, improve detail within delegated authorisation guidelines and ensure consistency in approach regarding carers and comforters.

Compliance with Ionising Radiation (Medical Exposure) Regulations 2017

Prior to our inspection, HIW required senior staff within the department to complete and submit a self-assessment questionnaire. This was to provide HIW with detailed information about the department and the employer's key policies and procedures in place, in respect of IR(ME)R 2017. This document was used to inform the inspection approach.

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, date of birth and home address, known as unique identifiers.

This approach was in keeping with current UK guidance⁸. The procedure also described alternative approaches that staff could use should patients be unable to verbally confirm their identity themselves. The procedure also set out the process staff should follow when undertaking identification checks for paediatric patients.

Staff we spoke with were able to clearly set out the steps they routinely took to correctly identify patients prior to examinations within the department. Staff were able to consistently and accurately describe the correct procedure to identify patients. In addition to checking the three unique identifiers, staff would discuss the procedure with the patient to ask about their clinical condition and ensure they understood why they were having the particular examination. Staff described a number of additional resources or tools that were available to enable patients to be identified. These included, translation services, writing information down, use of the hearing loop or use of an ID wrist band for in-patients. All patients who responded to our survey said that they were asked to confirm their personal details prior to the procedure.

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 may be 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.

As previously detailed, staff confirmed that prior to any examination within the department a written appointment letter was sent to patients. The information included within this letter included pregnancy status and breastfeeding enquiries.

⁸ Royal College of Radiologists (2020); Implication for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine.

Staff accurately described the procedure for establishing pregnancy and breastfeeding status. Patients were asked to sign a disclaimer form that was scanned onto RADIS. Staff described a number of additional resources or tools that were available to establish pregnancy or breastfeeding status of patients who could not respond to this enquiry.

Non-medical imaging exposures

The employer had an up-to-date written procedure in place in relation to non-medical exposures⁹ undertaken within the health board. However, we were informed that non-medical exposures were not undertaken within the nuclear medicine department.

Referral guidelines

The referral guidelines in place used the Royal College of Radiologist (RCR) iRefer publication. This set out the referral guidelines and provided an indication of the radiation dose for individuals wanting to refer a patient for imaging. We were informed that this guidance was readily available to all healthcare professionals employed by the hospital and also available on the health board intranet site. However, there was not information in this document relevant to sentinel lymph node biopsy (SLNB),¹⁰ which was carried out in the hospital. The employer must therefore ensure that referral guidelines are written to cover this procedure in nuclear medicine.

We noted that medical practitioners were entitled to refer for nuclear medicine investigations. We were also provided with the full list of entitled, non-medical referrers. We verified that a sample of referrals received for nuclear medicine scans were made by appropriately entitled individuals.

The self-assessment questionnaire completed, listed the process to be followed in the event of a cancellation by both the department and the referrer. However,

⁹ 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.

¹⁰ An SLNB is a test to find the first lymph node that a cancer may spread to. A radioactive dye is used to help the surgeon identify and remove the lymph nodes. The removed nodes are then checked to see if they contain cancer cells.

the referral policy did not describe the process for cancelling referrals. The employer must ensure this is included.

Improvement needed

The employer must ensure that:

- Referral guidelines are written for sentinel lymph node biopsies
- The referral policy is updated to include the process for cancelling referrals.

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 examinations. The Ionising Radiation Safety Policy detailed the specific duty roles and responsibilities in line with IR(ME)R, which were referrer¹¹, practitioner¹² and operator¹³. This policy also outlined the processes employed by the employer to ensure, as far as reasonably practicable, the health and safety of everyone who may be exposed to the hazards arising from the use of ionising radiation.

Whilst the flow chart within the policy showed that the MPE¹⁴ was entitled by the Executive Director of Therapies and Health Services, this was not listed in the responsibilities. Corporate IR(ME)R Procedure A specified that operators

¹¹ 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.

¹² 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.

¹³ 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.

¹⁴ 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.

(including MPEs) and practitioners are entitled by the Clinical Director. The employer must ensure that the policy is updated to clarify the current arrangements for entitlement and appointment of the MPE.

Staff confirmed there were arrangements for induction, which included awareness of the procedures required to be complied with under IR(ME)R. Staff were informed of updates and where appropriate, they signed to say they have received them.

Improvement needed

The employer must ensure that the Ionising Radiation Protection Policy is updated to clarify the current arrangements for entitlement and appointment of the MPE.

Justification of Individual Medical Exposures

There was a set of supplementary employers procedures for the nuclear medicine department, which included the justification of individual exposures. All nuclear medicine referrals were paper based. The self-assessment questionnaire stated that justification was recorded in the appropriate place on the radiology request form. The form also included the date and signature of the practitioner or authorising operator acting under a delegated authorisation guideline (DAG).

We discussed justification of exposures to carers and comforters¹⁵ with senior staff, including considering pregnancy status and levels of patient care required as part of the justification decision. There was a specific nuclear medicine employer's written procedure in place in relation to dose constraints¹⁶ 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. Additionally, the procedure ensured that the individual was provided with adequate information, including the benefits and risk. Radiographers had been appropriately entitled to act as practitioners to be able to justify exposures

¹⁵ Carers and comforters are defined in IR(ME)R 2017 as 'individuals knowingly and willingly incurring an exposure to ionising radiation by helping, other than as part of their occupation, in the support and comfort of individuals undergoing or having undergone an exposure.'

¹⁶ A restriction on the prospective doses to individuals which may result from a defined source, for use at the planning stage in radiation protection whenever optimisation is involved

to carers and comforters. The dose constraint could be lowered to a more realistic value in view of the estimated doses in the employer's procedures.

Improvement needed

The employer should ensure that the dose constraints set for exposures to carers and comforters, in the relevant procedure, be lowered to a more realistic value.

Optimisation

Senior staff we spoke with said that all syringes containing administrations for patients were measured before administration. The dose calibrators used had regular quality control tests to ensure the measurements were accurate. We were told that most local diagnostic reference levels (DRLs) used were set at levels below the national DRLs. For children, administered activity was scaled down from the adult local DRLs according to the patient weight.

We were also told by senior staff that written information, as described above, was given to patients with appointment letters describing the procedure. This also gave the patient information on risks and benefits of the procedure and also described any restrictions after the test. Staff would advise patients to avoid prolonged and close contact with children and pregnant people for the remainder of the day. Additionally, staff would advise patients to drink plenty of fluids to aid the excretion of the radiopharmaceutical¹⁷. This written information met the requirements of the relevant regulation.

Diagnostic reference levels

There was an employer's written procedure in place relating to the use and review of DRLs. The radiology procedure detailed that local DRLs were established for all typical examinations but this procedure did not consider how local DRLs are established in nuclear medicine. The supplementary employer's procedures for the nuclear medicine department stated that local nuclear medicine DRLs were established at levels at or below the national DRLs in consultation with the MPE, and the supplier of radiopharmaceuticals.

¹⁷ Radiopharmaceuticals are radioactive compounds administered to the patient, and monitored via specific imaging devices, for diagnosis and therapeutic purposes.

We observed that local DRLs were displayed on the wall in the nuclear medicine rooms. The local DRLs were at or below the national DRLs. Individual syringes were measured when they were received in the department. The activity was adjusted for radioactive decay¹⁸ to the time of administration. Staff used the sticky label put onto the syringe packet and attached this to the referral form. Recent audits in the nuclear medicine department demonstrated some variation in administered activity and this was being investigated further with the support of the MPE and Clinical Scientist.

Paediatrics

Administrations of radiopharmaceuticals for children were kept as low as possible by both the practitioner and operator. The administered activity was scaled by weight in accordance with the Administration of Radioactive Substances Advisory Committee (ARSAC)¹⁹ notes for guidance as implemented by the Cardiff and Vale University Health Board Radiopharmacy²⁰. They were routinely calculated based on the child's weight but if that was not available, it would be calculated using the average weight for a child of that age using the World Health Organisation charts. The scaling factors were listed in an appendix of the nuclear medicine supplementary procedures. Recent audits in the nuclear medicine department demonstrated that some administered activities for paediatric patients were low. We were told that this may be because the WHO charts were not reflective of the local paediatric population. This was being investigated further with the support of the MPE and Clinical Scientist.

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

¹⁸ Radioactive decay is the process by which an unstable atomic nucleus loses energy by radiation. A material containing unstable nuclei is considered radioactive.

¹⁹ 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.

²⁰ Radiopharmacy involves preparation of radioactive materials for patient administration that will be used to diagnose and treat specific diseases in nuclear medicine.

operator and that a record of the evaluation is recorded. Therefore, the employer must ensure that adequate clinical evaluation arrangements were in place. We reviewed a selection of patient records and found that all examinations had a clinical evaluation (report) performed by an appropriately entitled member of staff. Nuclear medicine supplementary procedures confirmed that surgeons were required to record clinical findings from sentinel node procedures in the patient notes.

The procedure also stated that all non-medical referrers had been informed that a clinical evaluation of the outcome of the examination must be recorded in the patient's notes. This must be recorded by the supervising medical officer or by the non-medical referrer who received and acted upon the report. This statement was included in all non-medical referral protocols. We were not able to check patient notes to confirm that this had happened, as these notes would be filed in the medical records department.

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. We reviewed the employer's procedure in place in relation to the quality assurance (QA) programme. We also viewed the quality assurance programme in place, as well as employer's procedures and written protocols, these were in date.

The duties relating to equipment QA were outlined within a Service Level Agreement (SLA). This was between the department's health board and Medical Physics, Cardiff & Vale University Health Board, for the provision of the medical physics expertise for nuclear medicine. The SLA stated that MPEs gave advice on QA only. When we spoke to senior staff and the MPEs they confirmed that they also completed tests on the camera, calibrators, and gamma probes. We were told that a plan was in place to review the contents of this SLA next year to better reflect advice and the operational role. An SLA aimed to ensure that the services to be provided to the customer are as agreed upon in the contract. Any additional work carried out should also be included in the SLA.

Improvement needed

The employer must ensure that the SLA accurately reflects the work of the MPE within the department and the health board.

Safe care

Nine staff expressed an opinion on the areas of the survey relating to the organisation. All nine agreed that care of patients and service users was the organisation's top priority and that the organisation acted on concerns raised by patients or service users. Additionally, all nine respondents agreed they would recommend their organisation as a place to work. They would also be happy with the standard of care provided by their organisation for them or for their friends or family.

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. The department appeared clean, in a good state of repair and was free from obvious trip hazards.

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 nuclear medicine equipment was being used.

Infection prevention and control

At the time of our inspection the environment was visibly clean and free from clutter. The department had a designated member of the domestic staff who maintained the cleanliness of the department and was available to clean relevant areas of the department as and when required. 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 described the cleaning arrangements in place, including ensuring that relevant areas were routinely cleaned after every patient in addition to enhanced cleaning. They said that these arrangements had meant that fewer patients could be seen within nuclear medicine. They also said there was a lot of communication throughout the service from the outset of COVID-19 to ensure staff were aware of the relevant guidance and requirements. During the pre-screening process, if someone telephoned and had tested positive for COVID-19 there would be a clinical decision made regarding whether the patient still needed to attend or whether treatment could be delayed. Where a delay was not possible staff outlined the procedure that would be followed so that the risk of transmission to staff and other people visiting the hospital was minimised.

We asked a question about COVID-19 compliant procedures being evident during patient visits. 19 patients said they were 'very evident' during their time at the setting, and all 20 patients said that the setting was 'very clean'. We also asked a series of questions about COVID-19 compliance in the staff survey. Of the seven respondents that expressed an opinion, all agreed that their organisation has implemented the necessary environmental changes and the necessary practice changes. Additionally, they all agreed that there had been a sufficient supply of PPE and that there were decontamination arrangements for equipment and relevant areas. One comment received in relation to COVID-19 arrangements was that:

“At the start of the pandemic, information changed frequently and this caused confusion... The situation has become far more stable.”

Staff we spoke with 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 had been fit tested for relevant masks and they had received training regarding donning and doffing²¹.

Handwashing facilities were available within the injection room and within the toilets near the department. Hand sanitiser was available throughout the department areas, including the main corridor and adjacent to the waiting room areas.

There were clear plastic screens installed on the reception desks to protect patients and staff. There were stickers displayed on the floor throughout the department reminding people to keep left when walking through the department and to keep to the two metre social distancing rule.

We checked a sample of six staff training records. Whilst all staff had completed the relevant IPC training, the training for four members had expired.

²¹ Donning – putting on personal protective equipment (PPE); Doffing – taking off personal protective equipment (PPE)

Improvement needed

The employer must ensure that all staff are up to date with their IPC training to the required level.

Safeguarding children and adults at risk

The health board had arrangements in place to promote and protect the welfare and safety of 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. Additionally, contact details for safeguarding leads and a flow chart were included in one of the employer's procedures for staff to follow. We were also informed that all staff were required to complete mandatory online training.

We checked a sample of six staff training records. Whilst all staff had completed the relevant safeguarding training, the training for two members had expired. Senior staff informed us that they were arranging safeguarding training, called Multi Agency Safeguarding Hub (MASH training²²).

Improvement needed

The employer must ensure that all staff are up to date with their safeguarding training to the required level.

Effective care

Quality improvement, research and innovation

Clinical audit

The employer had a written procedure in place that was included in the quality assurance programmes employer's procedure. We also saw the audit programme for nuclear medicine. All audit results would be discussed in the

²² (MASH) MASH provides triage and multi-agency assessment of safeguarding concerns - in respect of vulnerable children and adults. It brings together professionals from a range of agencies into an integrated multi-agency team.

image optimisation group. Whilst clinical audit should have been carried out every 6 months, we were told that the audits had been curtailed during the pandemic. Clinical audits were organised and managed by the superintendent radiographer with assistance from the clinical scientist. All results would be authorised by the MPE.

Evidence of observational and IR(ME)R audits were provided in advance of the inspection. Additional areas to further enhance these audits were suggested as part of the inspection discussion. MPE and DRL audits were also provided as part of the inspection. These were both detailed and comprehensive documents and identified a number of actions. Progress has been made against a number of these actions and repeat audits were planned for the future.

Expert advice

Staff were aware of who the local MPE was and how to contact them, as required. Staff also confirmed that MPE advice was easy to access. We were informed that an MPE attends the department each month. They provide advice and support, as well as undertaking tasks including equipment QA and testing, staff training and patient dose assessments. Additionally, evidence was provided of the audit undertaken by the MPE. 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 MPE. We were also informed that staff were able to contact the MPE for advice and support where necessary, on an ad hoc basis.

We were provided with a copy of the MPE entitlement certificate and noted that this document did not include a record of competency assessment.

Medical research

The department had a written procedure relating to medical research exposures. This was not applicable to nuclear medicine currently, as the department were not undertaking any research. However, the department wished to keep the procedure as an option for the future. The procedure would benefit from being updated with further information on the actual procedure to be followed for research exposures. Additionally, the procedure referred to the involvement of

the Radiation Protection Adviser (RPA)²³, but it did not include the MPE role in setting dose constraints or targets. The employer must ensure that the procedure is updated.

Improvement needed

The employer must ensure that the:

- MPE entitlement certificate is correctly completed, including the record of competency assessment
- Written procedure for research exposures is revised to reflect the actual procedure and includes reference to the MPE role.

Record keeping

We reviewed a sample of four current patient referral records. Three had been received on the current referral form and were completed to a good standard in accordance with the referral policy. The one referral completed on the old form contained sufficient information, including the identity and administration checks, in accordance with the procedure.

Two of the referrals related to SLNB, with iRefer as referral guidelines. There was no information in this document relevant to SLNB (also described above under the referral guidelines section). The referrals seen included an example from an entitled non-medical referrer and these were completed accurately. It was also verified that they had been entitled appropriately.

We reviewed a sample of three retrospective patient referrals and noted that all three were received on the current referral form. They were completed to a good standard in accordance with the referral policy. As part of this sample we checked to ensure there was evidence to demonstrate that pregnancy status checks had been carried out and recorded by staff. However, we identified that, out of two relevant referrals, one out of two had no record of the required pregnancy check. The employer must ensure that all staff are reminded of the employer's procedure relating to pregnancy status checks and recording the results of these checks.

²³ An RPA is an individual, or corporate body, which meets the Health and Safety Executive criteria of competence, and, has the necessary experience and expertise to advice on the organisation's uses of ionising radiation.

The wider department was currently piloting electronic referrals via the Welsh Clinical Portal but nuclear medicine has not been included as yet.

Improvement needed

The employer must ensure that all staff are reminded of the employer's procedure relating to pregnancy status checks, including the need to record that the check had been completed.

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.

We found there was a robust management structure with clear lines of reporting in place. There were effective governance arrangements in place to support ongoing regulatory compliance.

We found visible and supportive leadership being provided within the department.

Staff demonstrated they had the correct knowledge and skills to undertake their respective roles within the department.

Some issues were identified that needed to be addressed by the employer.

Governance, leadership and accountability

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.

Staff we spoke with confirmed they felt supported by their line manager. We found visible and supportive leadership being provided within the department. This was also reflected in the staff survey results. Regarding their immediate manager nine staff expressed an opinion, in the staff survey. Their replies included:

- All said their immediate manager encouraged those who worked for them to work as a team
- Eight said their immediate manager could be counted on to help with a difficult task at work and one said they “sometimes” do
- Six said their immediate manager gave clear feedback on their work, two said they “sometimes” do

- Six said their immediate manager asked for their opinion before making decisions that affect work, and three said they “sometimes” do
- Eight respondents said their immediate manager is supportive in a personal crisis and one said they “sometimes” were.

As described in the previous section, prior to the inspection, HIW required senior staff within the department to complete and submit a self-assessment questionnaire. The self-assessment was returned to HIW within the agreed timescale and was comprehensive. Whilst, we highlighted some issues, 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.

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. Staff we spoke with understood their roles within IR(ME)R and were aware of their own scope of practice. Entitlement certificates and an entitlement matrix were used to manage this process.

There were paper copies of the nuclear medicine procedures and protocols stored in the department. The paper copies were used as reference material rather than those on document management and storage system. Staff said they were notified of changes to procedures by email or within user group meetings. The number of staff working within nuclear medicine was small and so it was easier to communicate changes to staff directly within the group. Staff agreed that the procedures were clear and easy to follow.

We noted that observational audits were carried out to monitor compliance with the employer’s procedures. Results from the audit reports were provided in advance of the inspection.

Requirement to hold a licence

We were told that five consultants were regularly available for the staff to refer any queries to, on a day to day basis. The practitioner licence holder was normally available on site one day per week. Arrangements for remote practitioner support and reliance on DAG to authorise procedures are compliant with regulations but are not best practice. ARSAC guidance is available on this topic and the employer may wish to review this.

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 a 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 licences were also covered as part of the MPE biannual audit.

We were supplied with a copy of a recent MPE audit that identified that lacrimal drainage studies had been carried out using a different radiopharmaceutical to that listed on the practitioner and employer licence. Whilst this was not reportable as a significant accidental or unintended exposures, we recommend that this is considered to be notified as a voluntary notification.

Improvement needed

The employer should consider:

- Informing HIW of the lacrimal drainage studies that have been carried out using a different radiopharmaceutical to that listed on the practitioner and employer licence, as a voluntary notification
- The arrangements for remote practitioner support. The reliance on DAG to authorise procedures are compliant with regulations but are not best practice.

Duties of the employer

Entitlement

As previously stated, the employer had a written policy and procedure for the entitlement and identification of practitioners, operators and referrers (known as duty holders). 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 with a certificate of entitlement as referers, practitioners and operators. This was to ensure that entitled staff were routinely informed of their entitlement and scope of practice.

Staff we spoke with were able to explain the employer's procedure for entitlement and confirmed that they had received written notification (an entitlement certificate) of their entitlement to perform tasks associated with medical exposures.

The self-assessment questionnaire stated that medical staff were made aware of their responsibilities at induction. General practitioners had been made aware of their entitlement to refer and their responsibilities via a letter from the radiology

clinical director or head of radiography. Non-medical referrers were made aware of their responsibilities at their training course and also at a meeting with the superintendent radiographer prior to being entitled to refer.

Procedures and protocols

The chief executive (CEO) of the health board was designated as the employer. The health board's ionising radiation safety policy clearly set out that the chief executive was responsible for complying with the duties of the employer as described by IR(ME)R. Senior managers also confirmed that the health board CEO was designated as the IR(ME)R employer. Whilst the CEO retained 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.

We saw that clear and concise written procedures and protocols had been developed and implemented in accordance with IR(ME)R. The written protocols had been developed for all standard diagnostic nuclear medicine procedures. The protocols covered the radiopharmaceutical required, reference to DRLs, imaging and processing parameters. Staff were required to follow these protocols while undertaking nuclear medicine activities. The protocols supplied were set out in a consistent format, they were up-to-date and review dates were clearly stated. However, all three protocols stated that examinations were "agreed by" the practitioner or operators working under DAG. However, the correct IR(ME)R terms were justification and authorisation and the employer must update the procedure to reflect this.

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.

We saw that there were corporate employer's procedures, radiology employer's procedures and supplementary nuclear medicine employer's procedures. The employer may wish to consider rationalising these in the future.

We were told that any revisions to documents would be placed on the radiology shared area and all staff would be notified of changes via e-mail. Depending on the change, the email may be for information or requesting a reply confirming that staff had read and understood the changes. Additionally, there may be a face to face discussion, which would require staff to sign a form to say they were aware and understand the changes. However, the relevant employer's procedure did not describe the process for communicating changes of procedures to staff.

Improvement needed

The employer must ensure that the process for communicating changes of procedures to staff, is described in the employer's procedures.

The employer should consider rationalising the different employer's procedures (corporate, radiology and supplementary nuclear medicine)

Significant accidental or unintended exposures

Senior Managers described the process in place should an incident occur or was suspected to have occurred, which may have caused an accidental or unintended exposure to patients. We were informed that following a suspected incident, staff were required to notify the department manager or radiation protection supervisor. They would discuss the incident with the individuals involved, ensure that the relevant information with regards to the exposure was collated and then contact the MPE.

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

The incident would be discussed at the relevant modality²⁴ (or modalities) user group. We were also told that on occasion, there would be an alert notice displayed for staff and we were provided with an example of this (but not related to nuclear medicine). Additionally we were told that the incident would also be reported and discussed at quality governance meetings. However, this process in full was not specified in the relevant employer's procedure. The employer must amend the relevant employer's procedure to include this method of ensuring that lessons learned are informed to the relevant staff.

²⁴ Modality is the term used in radiology to refer to one form of imaging e.g. CT scanning. It is often used in the plural form. More generally, in clinical medicine, the term modality is used for different types of procedures and therapies.

In response to the staff survey, eight members of staff expressed an opinion relating to what happens when incidents and errors occur. One said they had seen an accidental or unattended exposure incident affecting staff and one said they had seen an accidental or unattended exposure incident affecting patients, in the last month. No member of staff said they had seen patient safety errors, near misses, or incidents in the last month.

All staff said that the last time they saw an unintended exposure, error, near miss or incident they reported it. All staff agreed their organisation treated staff who were involved in an error, near miss or incident fairly and agreed their organisation encourages them to report errors, near misses or incidents. All staff also said that they agreed their organisation treated reports of errors, near misses or incidents confidentially.

Staff who expressed an opinion, all agreed their organisation did not blame or punish people who were involved in errors, near misses or incidents. They also all agreed that when errors, near misses or incidents were reported, their organisation took action to ensure that they did not happen again. Staff were also asked whether they were informed about errors, near misses and incidents that happen in the organisation. Also staff were asked about changes made in response to reported errors, near misses and incidents. Five of the six who expressed an opinion confirmed they had been informed and had seen changes.

All staff who expressed an opinion, said that if they were concerned about unsafe clinical practice, they would know how to report it and that they would feel secure raising concerns about unsafe clinical practice. Additionally, almost all said that they were confident that their organisation would address their concerns.

Improvement needed

The employer must amend the relevant employer's procedure to include the information contained in the self-assessment questionnaire relating to incidents or near misses. This includes how the investigation is carried out and ensuring that lessons learned are informed to the relevant staff.

Staff and resources

Workforce

We were concerned to find that one member of staff, of the ten who completed our survey, ticked an option relating to the question 'have you faced discrimination at work within the last 12 months'. Additionally, one member of staff disagreed with the comment that staff had fair and equal access to

workplace opportunities. (Regardless of Age, Disability, Gender reassignment, Marriage and civil partnership, Pregnancy and maternity, Race, Religion or belief, Sex and Sexual orientation). However, all respondents agreed that their workplace was supportive of equality and diversity. The health board must ensure that processes are in place to allow any member of staff to report any issues of concern internally, as well as to ensure that any concerns raised are appropriately investigated and responded to.

We were told that the radiology department as a whole, operated with a set number of staff. Qualified and trained staff would then work in nuclear medicine on a rota basis. The department lead worked on the nuclear medicine department permanently and other staff were sourced as and when required to meet the demand of the patients.

There were four vacancies currently at band five level, throughout the radiology department. The department were currently shortlisting for these vacancies. We were told that there were generally sufficient staff to work in nuclear medicine. On the odd occasion, management were required to carry out the duties to ensure the service could run. They would complete dose checking when required. However it was confirmed that they were not entitled as operators to check doses. The department needs to ensure that they are entitled as an operator to carry out the dose checks to ensure compliance with IR(ME)R 2017.

Senior staff stated that there was equal access in the workplace to opportunities and that everyone within the department was treated equally. All staff were made aware of the opportunities that were available. These courses and job opportunities were normally posted within the staff room.

We were told that there was an equality and diversity policy in place that was available on the health board shared area and e-learning equality and diversity training was mandatory for all staff.

With regard to senior management, eight staff expressed an opinion. Their responses included

- Almost all said they knew who senior managers were and one said they “sometimes” do
- Four said communication between senior management and staff is effective, and four said it sometimes was
- Three respondents said senior managers try to involve staff in important decisions, and five said they sometimes do
- Two respondents said senior managers acted on staff feedback, and six said they sometimes do

- All said senior managers were committed to patient care.

Workload

Only two staff expressed an opinion relating to areas such as workloads, equipment, staffing and changes to their work. As a result these opinions have not been reported further. However, eight respondents said their organisation always or usually encourage teamwork and two said it sometimes did. Four respondents said the organisation was always or usually supportive and six said it sometimes was. One member of staff commented

“I have been successful with a flexible working application where I work my weekly hours over [fewer] days. This arrangement provides me with 'quiet' times outside of normal working hours where I can work without interruption and I feel I am more productive”

Eight respondents said front-line professionals who deal directly with patients, were always or usually sufficiently empowered to speak up and take action. That is, if they identified issues in line with the requirements of their own professional conduct and competence and two said they sometimes are. Seven respondents said there was always or usually a culture of openness and learning within the organisation that supported staff to identify and solve problems, and three answered sometimes.

Seven respondents said their organisation always or usually had the right information to monitor the quality of care across all clinical interventions and took swift action when there were shortcomings, and three said it sometimes did.

Nine respondents said they were always or usually content with the efforts of their organisation to keep them and patients safe and one said they sometimes were.

Appraisals

We asked staff various questions regarding their annual appraisal process. Two respondents said they had an annual review or appraisal within the last 12 months, eight said they had not. Of the nine who answered the question, eight said their training, learning or development needs were not identified, during the appraisal. Additionally of the six who answered the question, one respondent said their manager supported them to received training and development, and five said they did not.

Senior staff confirmed that staff were not up to date with appraisals due to COVID-19 and the resulting staffing absences. They confirmed that there were plans in place to complete these appraisals. Regular reports were provided to senior managers relating to appraisal compliance.

We were told that as part of the appraisal process, staff would be asked about their career aspirations for the next five years. There was a reliance on the staff members to state how they wanted to develop and then the training could be concentrated on those areas.

Training

From the check of six staff mandatory training records we noted that a number of areas of mandatory training were not in date. This included five out of six staff being out of date with resuscitation training, in addition to the IPC and safeguarding areas described in the relevant sections above. Additionally, all staff were out of date with fire safety and moving and handling training. However, all staff had completed their health and safety training.

Senior staff said they were aware that some staff mandatory training was out of date. Normally, staff completed eLearning and level two training for clinical staff, but due to COVID-19 this had stopped. They stated that there was a plan to release staff to do this training. Senior staff had identified four training modules to focus on completing, these include IPC, resuscitation and manual handling.

Staff were asked various question in the staff survey relating to training. All ten respondents said they had received training in Health and Safety, Fire Safety and Awareness, Infection Control, Safeguarding, and Mental Health Capacity.

As part of our inspection, we reviewed a sample of duty holder training, competency and entitlement records. Overall, the training records were good. These included a detailed breakdown of types of scans or procedures that could be undertaken within the department. However, nuclear medicine training record documents were not part of the document quality assurance system. The employer needs to include these to ensure consistent management of records.

All ten staff who completed the questionnaire said they had received training in IR(ME)R relevant to their functions as practitioner or operator. They also confirmed that they were up to date with training in accordance with IR(ME)R relevant to their specific area of practice. Six of the seven who expressed an opinion, said they had received other training relevant to their area of work. We received comments on training staff would find useful, some of which are shown below:

“Image interpretation”

“Training regarding quality improvement tools and methods”

All ten respondents said training always or usually helped them do their job more effectively. Nine respondents said training always or usually helped them stay up-to-date with professional requirements and one said it sometimes did. Nine

said it always or usually helped them deliver a better patient experience and one said it sometimes did. We received one comment relating to training, shown below:

“Could be more supportive with additional learning opportunities”

Wellbeing

Staff stated that they would approach the department leads if they had any concerns with their wellbeing. Due to the nature of the department, senior managers worked on a one to one basis with other staff, regularly, which allowed staff to raise any concerns. If they had any concerns they could also go to lead superintendent for radiology directly. Occupational health referrals would be made as required. We were also told there was a counselling service available, to which a lot of staff had access. There was also a wellbeing team within the hospital.

We also asked staff questions in the survey relating to their wellbeing. All eight staff who expressed an opinion agreed their job was not detrimental to their health. Seven of the eight who expressed an opinion, agreed their current working pattern and off duty allowed for a good work life balance, one disagreed. All staff who expressed an opinion, agreed their immediate manager took a positive interest and positive action on their health and wellbeing. Additionally, all staff who expressed an opinion agreed they were aware of the occupational health support available and that they are offered full support in the event of challenging situations.

Improvement needed

The health board must ensure that processes are in place:

- To allow any member of staff to report any issues of concern internally, as well as to ensure that any concerns raised are appropriately investigated and responded to
- To ensure that staff are treated fairly and equally and that any instances of discrimination will not be tolerated and appropriate action taken.

The employer must ensure that:

- Mandatory training for staff is improved and plans put in place to ensure in date compliance with the required training
- Appraisals are carried out for all staff in a timely manner

- All staff have the relevant entitlements to carry out their duties and all training and entitlement records are up to date, complete and available for all staff
- Nuclear medicine training record documents are part of the documented QA system.

4. What next?

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

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

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

The improvement plans should:

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

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

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

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

5. How we inspect services that use ionising radiation

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

The regulations are designed to ensure that:

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

We look at how services:

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

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

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

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

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

Further detail about [how HIW inspects the NHS](#) can be found on our website.

Appendix A – Summary of concerns resolved during the inspection

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

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

Appendix B – Immediate improvement plan

Hospital: Royal Glamorgan Hospital
Ward/department: Nuclear Medicine Department
Date of inspection: 4/5 October 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 assurance issues				

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

Service representative:

Name (print):

Job role:

Date:

Appendix C – Improvement plan

Hospital: Royal Glamorgan Hospital
Ward/department: Nuclear Medicine Department
Date of inspection: 4/5 October 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 must ensure that patients are given written information, where relevant, on who to contact for advice about any after effects from any treatments they had received.	4.2 Patient Information	To review and amend patient information in line with the requirement.	Superintendent Radiographer	14 th January 2022
The employer must ensure that: <ul style="list-style-type: none"> • Arrangements are in place to routinely collate patient feedback on the services provided within the department 	6.3 Listening and Learning from feedback	Annual patient experience survey is currently underway and will be maintained on a regular basis. Results will be fed back at audit for staff and also to patients via noticeboards in relevant waiting areas.	Superintendent Radiographer	25 th February 2022

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
<ul style="list-style-type: none"> Systems 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. 		Civica Patient Experience system due to be launched for all patients to access from January 2022. Several members of Radiology department being trained during December 2021.	Locality Nurse Director	
Delivery of safe and effective care				
<p>The employer must ensure that:</p> <ul style="list-style-type: none"> Referral guidelines are written for sentinel lymph node biopsies The referral policy is updated to include the process for cancelling referrals. 	IR(ME)R 2017 section 6(5)(a)	To prepare and amend guidelines and policy as indicated.	Superintendent Radiographer	14 th January 2022
<p>The employer must ensure that the Ionising Radiation Protection Policy is updated to clarify the current arrangements for entitlement and appointment of the MPE.</p>	IR(ME)R 2017 Section 10 (3) & Schedule 2 para 1(b)	Entitlement arrangements to be clarified within the policy.	Superintendent Radiographer	24 th December 2021
<p>The employer should ensure that the dose constraints set for exposures to carers and comforters, in the relevant procedure, be lowered to a more realistic value.</p>	IR(ME)R 2017 Regulation 6(5)(d)(ii)	Dose constraint to be lowered in line with discussions with MPE.	Superintendent Radiographer	24 th December 2021

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
	Schedule 2 para 1(n)			
The employer must ensure that the SLA accurately reflects the work of the MPE within the department and the health board.	IR(ME)R 2017 Section 14	To review the content of the service level agreement in line with renewal for 1 st April 2022.	Clinical Support Services Group Manager	31 st March 2022
The employer must ensure that all staff are up to date with their IPC training to the required level.	2.4 Infection Prevention and Control (IPC) and Decontamination	To identify relevant staff who are in need of renewing their training and identifying appropriate time for the training to be completed.	Superintendent Radiographer	25 th February 2022
The employer must ensure that all staff are up to date with their safeguarding training to the required level.	2.7 Safeguarding children and adults at risk	To identify relevant staff who are in need of renewing their training and identifying appropriate time for the training to be completed.	Superintendent Radiographer	25 th February 2022
<p>The employer must ensure that the:</p> <ul style="list-style-type: none"> MPE entitlement certificate is correctly completed, including the record of competency assessment 	3.3 Quality Improvement, Research and Innovation IR(ME)R 2017 Section 14(2)	Issue MPE entitlement certificate appropriately.	Superintendent Radiographer	24 th December 2021

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
<ul style="list-style-type: none"> Written procedure for research exposures is revised to reflect the actual procedure and includes reference to the MPE role. 	IR(ME)R 2017 Schedule 2 para 1(g)	Amend procedure as appropriate.	Superintendent Radiographer	14 th January 2022
The employer must ensure that all staff are reminded of the employer's procedure relating to pregnancy status checks, including the need to record that the check had been completed.	3.5 Record keeping IR(ME)R 2017 Section 11(1)(f)	To inform all staff of this requirement.	Superintendent Radiographer	Complete – 7 th December 2021
Quality of management and leadership				
<p>The employer should consider:</p> <ul style="list-style-type: none"> Informing HIW of the lacrimal drainage studies have been carried out using a different radiopharmaceutical to that listed on the practitioner and employer licence, as a voluntary notification The arrangements for remote practitioner support. The reliance on DAG to authorise procedures are compliant with regulations but are not best practice. 	<p>IR(ME)R 2017 Regulation 5(1)</p> <p>IR(ME)R Regulation 11(5)</p>	<p>To liaise with MPE and Superintendent Radiographer and submit a voluntary notification regarding lacrimal drainage studies.</p> <p>New Consultant has recently been appointed to the Health Board specifically for nuclear medicine. This Consultant has recently received their licence and entitlement will be updated</p>	<p>Superintendent Radiographer</p> <p>Clinical Director</p>	<p>24th December 2021</p> <p>24th December 2021</p>

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		which should further limit the use of a DAG for authorisation of procedures.		
<p>The employer must ensure that the process for communicating changes of procedures to staff, is described in the employer's procedures.</p> <p>The employer should consider rationalising the different employer's procedures (corporate, radiology and supplementary nuclear medicine).</p>	IR(ME)R 2017 Sections 6(1), (2), (5)(b)	<p>To document within Employer's Procedures.</p> <p>To be done in line with ongoing renewals of procedures either in line with appropriate review date or changes in legislation.</p>	Superintendent Radiographer	<p>24th December 2021</p> <p>Ongoing</p>
<p>The employer must amend the relevant employer's procedure to include the information contained in the self-assessment questionnaire relating to incidents or near misses. This includes how the investigation is carried out and ensuring that lessons learned are informed to the relevant staff.</p>	IR(ME)R 2017 Section 8	To document within the appropriate Employer's Procedure.	Superintendent Radiographer	14 th January 2022

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
<p>The health board must ensure that processes are in place:</p> <ul style="list-style-type: none"> To allow any member of staff to report any issues of concern internally, as well as to ensure that any concerns raised are appropriately investigated and responded to To ensure that staff are treated fairly and equally and that any instances of discrimination will not be tolerated and appropriate action taken. 	<p>Standard 7.1 Workforce Standard 6.2 Peoples Rights</p>	<p>Inform staff of recent concerns raised and to provide assurance and commitment to all staff that any concerns raised will be treated appropriately.</p> <p>As above.</p>	<p>Clinical Support Services Group Manager</p>	<p>24th December 2021</p>
<p>The employer must ensure that:</p> <ul style="list-style-type: none"> Mandatory training for staff is improved and plans put in place to ensure in date compliance with the required training Appraisals are carried out for all staff in a timely manner 	<p>7.1 Workforce</p>	<p>Improvements in mandatory training are ongoing for all staff with site leads tasked to prioritise training appropriately.</p> <p>As above, there is a schedule for staff PDRs to be completed (in line with increment dates as per policy).</p>	<p>Superintendent Radiographer</p> <p>Superintendent Radiographer</p>	<p>Immediately and ongoing</p> <p>Immediately and ongoing</p>

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
<ul style="list-style-type: none"> All staff have the relevant entitlements to carry out their duties and all training and entitlement records are up to date, complete and available for all staff. 	IR(ME)R 2017 Section 17 and Schedule 3	Entitlement documentation for all staff will be reviewed and as appropriate to ensure all records are up to date and include the relevant entitlements for duty holders.	Superintendent Radiographer	14 th January 2022
<ul style="list-style-type: none"> Nuclear medicine training record documents are part of the documented QA system. 	IR(ME)R 2017 Section 6, 17 and Schedule 3	To be amalgamated with next review of QA programme documentation.	Superintendent Radiographer	31 st March 2022

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

Service representative

Name (print): Paul Johnston

Job role: Superintendent Radiographer

Date: 8 December 2021