Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

HIW Ionising Radiation (Medical Exposure) Regulations Inspection Report (Announced)

Nuclear Medicine Department, Velindre Cancer Centre, Velindre University NHS Trust

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

Our purpose

To check that healthcare services are provided in a way which maximises the health and wellbeing of people

Our values

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

- Independent – we are impartial, deciding what work we do and where we do it
- Objective - we are reasoned, fair and evidence driven
- Decisive - we make clear judgements and take action to improve poor standards and highlight the good practice we find
- Inclusive - we value and encourage equality and diversity through our work
- Proportionate - we are agile and we carry out our work where it matters most

Our goal

To be a trusted voice which influences and drives improvement in healthcare

Our priorities

- We will focus on the quality of healthcare provided to people and communities as they access, use and move between services.
- We will adapt our approach to ensure we are responsive to emerging risks to patient safety
- We will work collaboratively to drive system and service improvement within healthcare
- We will support and develop our workforce to enable them, and the organisation, to deliver our priorities.

Contents

1. What we did

Full details on how we conduct Ionising Radiation (Medical Exposure) Regulations inspections can be found on our website.

Healthcare Inspectorate Wales (HIW) completed an announced Ionising Radiation (Medical Exposure) Regulations inspection of the Nuclear Medicine Department, Velindre Cancer Centre, Velindre University NHS Trust on 14 and 15 June 2022.

Our team for the inspection comprised of two HIW Senior Inspectors and a Senior Clinical Officer from the Medical Exposures Group (MEG) of the UK Health Security Agency (UKHSA), who acted in an advisory capacity. As part of this inspection, an additional Senior Clinical Officer was also present to observe, as part of the peer review programme within MEG. The inspection was led by a HIW Senior Healthcare Inspector.

Note the inspection findings relate to the point in time that the inspection was undertaken.

This (full) report is designed for the setting and describes all findings relating to the provision of high quality, safe and reliable care that is centred on individual patients.

A summary version of the report, which is designed for members of the public can be found on our website.

2. Summary of inspection

Quality of Patient Experience

Overall summary:

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 there were adequate arrangements in place to meet the communication needs of patients attending the department. The setting could improve these arrangements further by providing patients with the 'active offer'.

This is what we recommend the service can improve

- To provide more information on the 'active offer'
- The process in place to inform patients of the results of the patient experience feedback collected.

This is what the service did well:

- Well maintained environment with good signage
- Very positive patient experience comments
- A number of communication tools were available to help people with difficulties in communication.

Safe and Effective Care

Overall summary:

There was good compliance overall with the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R). 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 control within the department.

We identified some areas for improvement including the need to improve the robustness of electronic referrals, the Medical Physics Expert (MPE) support in the short and medium term and the risk assessment of the general area.

This is what we recommend the service can improve

- Operating at levels of MPE support that are consistent with national guidance
- Formalising the clinical audit programme
- Having a study of the risk associated with the therapies to consider accidental and unintended exposures.

This is what the service did well:

- All staff understood their roles under IR(ME)R
- Local DRLs were established at or below national DRLs
- Isostock system, with clear records and double checking of dose entries to minimise risk and audit easily.

Quality of Management and Leadership

Overall summary:

There was a 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.

This is what we recommend the service can improve

- Need to strengthen accountability by introducing document control onto employer's procedures (Eps) and other documents and protocols

- The competency records to be built into the document quality system to ensure a consistency in their format.

This is what the service did well:

- HIW Self-Assessment Questionnaire completed in a timely manner
- Good compliance with staff mandatory training and appraisals
- Good management evidenced.

3. What we found

Quality of Patient Experience

Patient Feedback

HIW issued both online and paper surveys to obtain patient views on the Nuclear Medicine Department (the department) at Velindre Cancer Centre. In total, we received 27 responses. Patient comments included the following:

> *"Staff at this hospital are fabulous, caring and friendly, and very reassuring to nervous patients."*
>
> *"All staff made my treatment and care feel amazing. Nothing was too hard for them. Thank you."*
>
> *"All staff I have encountered during … visits have been courteous, supportive and reassuring. I could not ask for any better treatment - I'm very grateful."*

Most responses to the questions asked indicated a positive patient experience by users of this service. Most comments were complimentary about staff and the overall service. Patients were asked in the questionnaire to rate their overall experience of the service; they all rated the service as 'very good'.

Staff Feedback

HIW issued an online survey to obtain staff views on the department at Velindre Cancer Centre. As we only received three responses, we have only been able to comment generally on the staff responses. The comments given should therefore be considered in light of the number of staff who responded.

Staying Healthy

Health Protection and Improvement

We found limited health promotion material was displayed within the department. However, a range of patient information leaflets were available and provided to patients prior to their appointments. Macmillan leaflets were also available in a designated area within the hospital. There was relevant information displayed on posters in the department.

Dignified care

Communicating effectively

Staff we spoke with confirmed that there was a hearing loop system available. They told us that additional arrangements could be made, where required, if patients had any other communication requirements. Staff confirmed access to translation services to assist, should a patient attend the unit and be unable to communicate in English and they were able to book a translator for the patient's appointment.

We saw good provision of bilingual information posters. However, there was no information displayed to inform patients that they could speak to staff in Welsh, also known as the 'active offer'. We were told, whilst there were no Welsh speaking staff at the department, there were Welsh speaking staff working in the hospital.

Only one of the 25 patients who answered indicated that Welsh was their preferred language. They said they were actively offered the opportunity to speak Welsh throughout their patient journey and indicated healthcare information was available in Welsh.

All patients who answered the question agreed staff treated them with dignity and respect and measures were taken to protect their privacy. They all agreed they were able to speak to staff about their procedure or treatment without being overheard by other patients and staff listened to them and answered their questions. We also viewed interactions between staff and patients that were respectful and professional with efforts made to protect patients' privacy and dignity.

All bar one patient agreed they were involved as much as they wanted to be in any decisions about their procedure or treatment.

Staff we spoke with told us that the patient information manager would provide aids for patients with impairments such as, language line, amplifiers and a hearing loop. The equipment was available on a stand that would be moved to the department. All documentation given to the patient was bilingual and staff tried to answer the phone in Welsh.

Patient information

Posters were clearly displayed requesting individuals who were, or may be, pregnant or breastfeeding to inform a member of staff. 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. Patients were also advised to avoid close contact with children and individuals who were pregnant. We saw nuclear medicine specific information posters displayed within the waiting area. There was

also evidence of sufficient bilingual signage to allow the patient to find the department and there were a number of bilingual posters on display.

All patients who answered the question agreed they were given enough information to understand the risks and benefits of the procedure or treatment. They all agreed they had been given information on how to care for themselves following their procedure or treatment. All bar one patient agreed they had been given written information on who to contact for advice about any 'after-effects' from their procedure or treatment.

Timely care

Timely Access

We identified that patients were seen promptly when attending the department. Suitable arrangements were described for informing patients of delays.

All patients who answered agreed it was easy to get an appointment and that they were able to find the department easily. Whilst 22 of the 27 respondents agreed they were told, at the department, how long they would likely have to wait, only three waited between 15 and 30 minutes and one waited for more than 30 minutes. Staff we spoke with also confirmed that if there were delays, they would inform the patients.

Individual care

People's rights

We were told that there was an equality and diversity policy within the organisation as well as mandatory training on this area. In addition to meeting communication requirements of patients, there were wide doors to the department and level access as well as a bed hoist available for patients.

All patients said they felt they could access the right healthcare at the right time.

Listening and learning from feedback

We saw evidence of the process in place for patients to provide feedback or raise concerns. We were also provided with copies of the feedback obtained through the external provider. We were told that there was a monthly report on feedback for the whole hospital and the relevant sections were extracted for the department. However, we did not see any information on learning from feedback being displayed for patients to see. More detailed information regarding how to make a complaint could also be displayed.

Compliments and concerns would be recorded on Datix. Concerns would be passed onto the line manager and attempts made to deal with the matter in house in the first instance.

Delivery of Safe and Effective Care

Compliance with Ionising Radiation (Medical Exposure) Regulations

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

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

Duties of the employer

Patient identification

Staff we spoke with were able to describe the employer's procedure to correctly identify individuals. This included how to correctly identify individuals who may not be able to identify themselves. All patients agreed they were asked to confirm their personal details. However, we noted that Appendix 1 - Patient Identification procedure (of the Nuclear Medicine IR(ME)R document) was not as clear as it should be as it did not specify the questions to ask the patient.

Individuals of childbearing potential (pregnancy enquiries)

Staff were able to describe the procedure for making enquiries of individuals of childbearing potential to ensure they were not pregnant or breastfeeding. This included the procedure where individuals may not be able to respond to this enquiry. The relevant appendix also covered pregnancy and breastfeeding questions.

The SAF stated that two members of staff were always present at the time of the administration of the radiopharmaceuticals. Where more than one operator was involved in the exposure, the patient ID checks, radiopharmaceutical details, pregnancy and breastfeeding status were checked by both operators.

The SAF provided evidence that there were regular monthly audits of referrals to ensure pregnancy and breastfeeding checks and justification/authorisation was carried out.

Non-medical imaging exposures

The documentation provided stated that as non-medical imaging was not carried out at the centre, there was not an employer's procedure for this. However, a procedure is still required, stating that this is the case.

Referral guidelines

The process of how the employer ensures referral guidelines were established and made available to all referrers was described. The induction training for new referrers was also explained and that referral guidelines were included in the training package relating to request forms used within the department.

Currently referrals were made on up to five different coloured forms depending on the type of referral. The reasons for this system were also explained. If the referral was completed on the wrong form, then it would be returned. We were also told that the requirement for electronic referrals was being developed.

Staff were able to describe the referral criteria used. There was a list of entitled referrers listed in IR(ME)R documents and a printed copy was displayed in the office.

Duties of practitioner, operator and referrer

The SAF explained how practitioners, operators and referrers were entitled to carry out their duties which was included in an employer's procedure. We were told that referrers completed the induction and practitioners were entitled by the medical director and the Head of Nuclear Medicine entitled the operators. They all received a letter giving their entitlement.

The employer's procedure used in this section included more than one entitlement matrix and the entries against the named personnel were ticked to demonstrate tasks that staff were entitled to do. As these were not dated it was not clear when this entitlement happened or when this would be reviewed.

The example of a completed entitlement letter provided with the SAF showed that the scope of practice was clear for the practitioner role but it was not clear how this reflected operator or referrer tasks. Delegation of authority to entitle operators was also included in this example and allowed this individual to entitle operators to administer radiopharmaceuticals.

Regarding practitioner support there were many individuals providing low whole time equivalent support as well as remote practitioner support for therapies. The department needs to consider future requirements for these services to improve the service resilience. This is particularly the case with remote practitioner support. Best practice is for the practitioner to be based on site, especially for therapies.

Justification of Individual Medical Exposures

There was a set of supplementary employer's procedures for the department, which included the justification of individual exposures. The SAF stated that justification was recorded in the appropriate place on the form and included the date and signature of the practitioner. Where operators authorised exposures according to guidelines, this process was described. An electronic signature was accepted from a remote practitioner, providing the referral form was sent from that practitioner's email account.

We discussed justification of exposures to carers and comforters 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 procedure in place in relation to dose constraints and guidance for nuclear medicine exposures of carers and comforters. Currently only the practitioner licence holders were entitled to act as practitioners for this process. We were told that individual risk assessments were carried out if the dose was expected to go above the recorded limit and the three instances where this was carried out, were described.

Staff we spoke with described the process to consider when justifying exposures. They also knew where the authorisation of exposures was recorded. They were also able to describe the guidance in relation to carers and comforters.

Optimisation

The SAF included good examples of responses to the questions asked. These included:

- How exposures to individuals in whom pregnancy cannot be excluded or were breastfeeding were optimised
- How the operator selected protocols for individual examinations to ensure optimisation of the exposure
- How the MPE was involved in optimisation for all nuclear medicine practice and a good range of examples were given
- The procedure for providing written instructions and information to each patient or patient's representative.

We were also told by senior staff that written information, as described above, was given to patients with their appointment letters describing the procedure, this information was provided bi-lingually. This also gave the patient information on the benefits and risks of the procedure and 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 and to drink plenty of fluids to aid the excretion of the radiopharmaceutical.

Staff also described the process to ensure that the administered activities and x-ray exposures given were as low as reasonably practicable, with particular attention being paid to certain patient groups.

Diagnostic reference levels (DRLs)

We were told that local DRLs were available and were lower than national DRLs. These had been optimised in collaboration with other centres in South-East Wales. Clinicians had not requested any change to these DRLs as there had not been concerns with image quality.

Staff we spoke with were aware of the DRLs set and their understanding of these was clear and consistent with procedures as well as how to apply them. The table of DRLs for radiopharmaceuticals was displayed by the equipment. Isostock software would also alert staff during the measurement, if the activity to be administered was not within 10% of what had been requested. Staff were able to describe the isostock computer software system used to account for the acquisition, use and disposal of radioactively labelled compounds and that the measurements were double checked.

Paediatrics

We received a comprehensive response in the SAF provided on paediatric optimised protocols. The patient's weight would be provided to Cardiff and Vale Radiopharmacy and they adjusted the activity for administration, based upon that weight. Whilst paediatric patients were not routinely imaged at Velindre, slower bed speed resulting in longer scanning time would be employed, if a paediatric bone scan was required.

Clinical evaluation

There was both an appendix to the Nuclear Medicine IR(ME)R document and an employer's procedure on clinical evaluation. The SAF described how clinical evaluation was undertaken and evidenced for each type of exposure. We were able to check two records to show that there had been a clinical evaluation performed by an appropriately entitled member of staff.

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 SAF gave a detailed schedule of the quality assurance programme in place for all relevant equipment. An appendix and an employer's procedure for the quality assurance programme was also provided.

There was also a comprehensive response on how the QA programme ensured accurate verification of the administered activity. Similarly, the response was comprehensive on the measures in place to improve inadequate or defective equipment and any corrective actions that may be taken.

Safe Care

Managing risk and promoting health and safety

The department was easy to find from the main entrance. There were no obvious hazards identified within the public areas and the corridors were clear of obstructions. However, the layout and location of the department could present challenges should spillages occur. The department was located along a main thoroughfare and arranged either side of this corridor. There was level access and there were facilities for people with mobility difficulties. We were told that the environmental constrictions identified, were well recognised by the Trust and were being addressed in the new hospital build.

All staff were positive in their replies to the care they gave to patients. All staff agreed that the care of patients and service users was the organisation's top priority, that they acted on any concerns raised and staff would recommend their organisation as a place to work.

Staff described the process to ensure that adequate information was provided to individuals or representatives relating to the benefits and risks associated with the radiation dose from exposures.

Infection prevention and control (IPC) and Decontamination

All areas seen appeared to be clean and well maintained. We discussed the arrangements with staff regarding spillages or contamination. Staff confirmed that if the corridor outside the department was contaminated, it would be monitored to prevent exposure to staff and patients. The use of the dedicated toilet in the department was limited to Nuclear Medicine patients for contamination control.

There were sharps bins lined with orange bags and used for swabs that covered the injection site. Whilst there were no lids on the bins, staff confirmed that swabs were dry and did not need to be in a lidded bin. We spoke to the infection control nurse who confirmed these arrangements were in keeping with the Trust policy.

Handwashing and drying facilities were viewed around the department. Personal protective equipment (PPE) was available for staff to use and all staff were observed to be wearing masks. Chairs within the waiting area were seen to be socially distanced and information was displayed for patients and staff regarding COVID-19 precautions.

Staff we spoke with confirmed that all equipment was cleaned after each patient and that staff wore PPE such as masks, aprons, gloves and visors. We were also

told of the weekly report sheet to infection control to confirm that staff had been checked wearing PPE and that all surfaces were cleaned twice a day. We were also told that appointments were arranged to minimise footfall and patients were told to wait in their car or in the main waiting area, until called into the department.

All 27 patients said the setting was 'very clean' and that COVID-19 infection control measures were being followed, where appropriate.

We checked a sample of three staff records and noted that they had all completed the relevant training up to the required level.

Safeguarding children and safeguarding adults at risk

Staff and senior staff we spoke with stated that safeguarding training was completed up to level two. Staff were aware of the procedures in place and the actions that needed to be taken in the event of there being a safeguarding concern.

We checked a sample of three staff records and noted that they had all completed safeguarding training up to the required level.

Effective care

Quality improvement, research and innovation

Clinical audit

There was not a defined nuclear medicine specific clinical audit programme. Whilst there was evidence provided that some audits were taking place, these were not formalised. We were told that there was a Trust clinical audit programme which focuses on local tumour site specific and National Cancer audits. This was modified to focus on COVID-19 specific local and national audits in 2020 and 2021. The nuclear medicine department need to develop a formal clinical audit plan which is reflected in the Trust Clinical Audit programme.

Expert advice

The SAF showed that the MPEs and Radiation Protection Advisors (RPAs) played a full role in the department. This involvement included developing procedures for diagnostic, non-imaging and therapies as well as advice on radiation protection related to patients, carers, comforters and family members. The MPEs also reported into the radiation protection (incorporating medical exposure) committee. The report would include departmental optimisation work in the future.

Staff we spoke with were aware of who the MPEs were in the department and how to access them in a timely manner.

We were told of the honorary contract and service level agreements (SLA) with Cardiff and Vale University Health Board in place for clinical scientist support. The department had not reviewed the SLA for some time and support under the SLA was not defined. We were told that the Trust has given notice to end the SLAs and to have staff employed by the Trust in the future.

We were told that the number of principal clinical scientists had reduced by 1.7 whole time equivalents. We were told that several meetings had been held between the Chief Operation Officer of the Trust, lead clinicians and the Head of Physics of Swansea Bay University Health Board to ensure good candidates were interviewed to fill the vacancies.

In addition, the discussion also included the supply of support in this area in the short term. This highlighted that the department would be operating at levels of MPE support below national guidance. Although there were arrangements to recruit in the interim, the department should complete a gap analysis until someone is recruited and there is a need to think about future level of support for new therapies and across the region. We were told there had been an agreement corporately not to extend services until MPE resource was secured.

Medical Research

The department participated in research involving medical exposures. There was an appendix and an employer's procedure for this. The governance arrangements in place for research trials involving ionising radiation exposures were well described in the terms of reference provided.

Record keeping

We checked a sample of five current patient referral documents and four retrospective documents. A range of different coloured paper forms were used, and these could potentially be rationalised.

For the current forms, there was a process noted for the referrals where electronic justification and authorisation was sought and recorded. The robustness of this process should be considered and comparison made with other local departments. This was because the practitioner would be sent scanned copies of the referral and the email text included 2 identifiers (name and ID number) instead of 3 required by a verbal procedure. Whilst there was no record of authorisation seen on one (out of five) referral, this referral could have been authorised under the delegated authorisation guidelines (DAG). The authorising operator did not sign the referral form.

For the retrospective referrals we noted a carers and comforters consent form signed for a 17-year-old patient. There was evidence seen of dose recording on the form for the carer and comforter.

Quality of Management and Leadership

Governance, Leadership and Accountability

A management structure with clear lines of accountability and reporting was noted. Whilst we found that governance arrangements were in place to support the effective operation of the department, there had been some recent staffing changes.

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

The limited number of staff who completed the questionnaire were mainly positive in their replies about the organisation. They were also mainly positive regarding the statements about their immediate manager and senior managers.

Duties of the employer

Entitlement

The SAF explained how the employer had delegated the task of carrying out IR(ME)R duties to others. This included a note that an amendment is required to Appendix 6 for entitlement of Medical Referrers and Medical Practitioners as the document listed the Clinical Director when it should be the Medical Director.

There were two relevant procedures for this area both the Nuclear Medicine IR(ME)R document; Appendix 2 – Referrer, Practitioners and Operators and the employer's procedure on duty holders and entitlement. The employer's procedure included the entitlement flow chart from the ionising radiation policy. There was an amount of duplication in this procedure and some inconsistencies. There were no dates listed in the operator matrices, which meant that dates for review and update could not be identified. This also meant that the appendix had to be changed frequently with changes in medical staff. We were told that future changes would be managed through the operational steering group. Training records were maintained for individual members of staff.

Staff we spoke with were made aware of their duties and entitlement through IR(ME)R documentation and entitlement letters. Staff were told of changes to written procedures both verbally and by email.

Procedures and protocols

We reviewed the employer's procedures provided as evidence to support the SAF and found that document control was inconsistent. Some improvements could be made in the consistency of the document control. Examples included:

- Employer's procedure part d (EP d), did not specify the document review timescale, review dates were being added to procedures as they were reviewed

- There are no details on who was involved in establishing or reviewing procedures or how they were agreed by the employer

- Different document formats for all supplied protocols

- Administration of radiopharmaceuticals to patient version two. This document did not appear to be part of the QA system (no footer with author/review date for example).

We were also told of the arrangements in place to strengthen the accountability structure and to ensure that the employer (the Chief Executive) was informed of radiation protection compliance and assurance and was aware of their responsibilities. These included setting up an operational group and strategic group to discuss trust wide radiation protection issues as well as reviewing the ionisation radiation policy. These groups reported to the radiation protection committee and eventually via the Quality, Safety and Performance Committee to the Trust's board.

Significant accidental or unintended exposures

The SAF gave a description of how the referrer, practitioner and the individual (or their representative) would be informed (or not) of a clinically significant unintended or accidental exposure (CSAUE) and provided with the outcome of the investigation into the event. The employer's procedure should be updated to match the regulation requirement that if a CSAUE occurs, they should always inform the patient (or their representative).

Additionally, there was not a document in place for studying the risk of accidental or unintended exposures for nuclear medicine therapies. The study of risk should be separate to the radiation risk assessments required under the Ionising Radiations Regulations 2017 (IRR).

Only one member of staff in the survey stated that they observed an accidental or unintended exposure in the last month and they said that they reported it. All staff we spoke with knew how to raise a concern about unsafe clinical practice and felt secure in raising these concerns. They would also be confident that the organisation would address their concerns.

Workforce

Staff we spoke with said that the staff numbers and skill mix were appropriate with appointments booked based on the number of staff on duty. However, there was not any administrative support and technologists arranged the appointments, manned the reception and imaged patients.

Senior staff stated that there was a need to employ one further technologist, otherwise the level was right currently because appointments were booked based on who was working, with staff available to cover for sickness or absence.

Senior staff also stated that they were trying to encourage new members of staff into the department from the next qualified student graduates from Swansea University. The department were also looking to have student placements from the university.

All staff agreed that their training, learning and development had helped them in their role.

We checked the records held and noted that all appraisals were up to date. Training compliance was almost 95 percent. There was an electronic system in place to monitor training and appraisal compliance.

Staff we spoke with were also aware of the wellbeing support offered by the department and the Trust.

4. Next steps

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.

The improvement plans should:

- Clearly state how the findings identified will be addressed
- 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
- Ensure required evidence against stated actions is provided to HIW within three months of the inspection.

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.

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

Service: Nuclear Medicine Department, Velindre Cancer Centre

Date of inspection: 14 and 15 June 2022

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.

Improvement needed	Standard/ Regulation	Service action	Responsible officer	Timescale
No immediate assurances 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

Service: Nuclear Medicine Department, Velindre Cancer Centre

Date of inspection: 14 and 15 June 2022

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
The Trust is required to ensure that action is taken to promote the availability of Welsh speaking staff or support within the department to help deliver the 'Active Offer'.	3.2 Communicating effectively	The Nuclear Medicine service will place posters at key positions in the department promoting the 'active offer'. They will inform patients that if they wish to converse in Welsh to ask a member of staff.	Trust Welsh Language Manager / Head of Nuclear Medicine	30th September 2022
		A list of Welsh speaking staff within VCC will be held in the department and work contact details so can be contacted if no Welsh speaking staff available in Dept to support department meeting patients Welsh Language	Trust Welsh Language Manager / Head of Nuclear Medicine	30th November 2022

		needs for the duration of their procedure.		
		All Welsh Speakers to have the required Logo displayed on their uniform.	Trust Welsh Language Manager (Trust wide)	30th November 2022
		A Trust wide audit of 'Active Offer' to be undertaken across all patient / donor facing clinical areas and local action taken to ensure any 'Active Offer' deficits are addressed	Trust Welsh Language Manager	31st March 2023
The Trust must ensure that the results of any feedback or satisfaction questionnaires are made know to patients.	6.3 Listening and Learning from feedback	A fixed CIVICA patient experience feedback terminal will be put in place in nuclear medicine.	Head of Nuclear Medicine / Head of Nursing Professional Standards & Digital	30th November 2022

		Nuclear medicine to be fully set up on the CIVICA patient feedback system – QR code and web links to be made available and provided to patients as they leave the department (pending the fixed terminal being available.	Head of Nuclear Medicine / Head of Nursing Professional Standards & Digital	30th September 2022
		The department will implement a 'You Said, we did' feedback board in the department to visually display patient feedback and subsequent actions by the department - will be updated monthly.	Head of Nuclear Medicine	30th September 2022
The employer must ensure that various appendices are updated as follows: • Appendix 1 - Patient Identification procedure (of the Nuclear Medicine IR(ME)R document) to specify the questions to ask the patient to	IR(ME)R Reg 6 Schedule 2 1 (a)	The patient identification procedure in the Nuclear Medicine IR(ME)R document will updated to specify the exact line of questioning to ask patients to ensure they are appropriately identified using three patient	Head of Nuclear Medicine	30th November 2022

ensure the correct patient is identified		specific indicators being their full name, date of birth and address.		
• Appendix 6 for entitlement of Medical Referrers and Medical Practitioners is amended to read the Medical Director	IR(ME)R Reg 6 Schedule 2 1 (b) and IR(ME)R Reg 10 (3)	The entitlement structure is being reviewed as part of the scheduled review of the Velindre University NHS Trust Ionising Radiation Policy. The policy once approved will dictate the entitlement chain for Medical Referrers and Practitioners. This chain will be imbedded in the Nuclear Medicine IR(ME)R procedures and updated accordingly referring to the Medical / Clinical Director as appropriate.	Head of Nuclear Medicine	30th November 2022
The employer must ensure that there is an employer's procedure written for non-medical imaging.	IR(ME)R Reg 6 Schedule 2 1 (m)	A procedure for non-medical imaging will be produced and included in the Nuclear Medicine IR(ME)R documentation. The procedure will state that no non-medical imaging is undertaken within the Nuclear Medicine Department.	Head of Nuclear Medicine	30th November 2022

The employer must ensure that the entitlement matrix is updated to include dates, as opposed to ticks, so that management are aware of when the documents need to be reviewed. The documentation must also be in a consistent format as part of the document quality system.	IR(ME)R Reg 6 Schedule 2 1 (b)	The entitlement matrix will be reviewed to include the date on which entitlement was granted and in addition the specified period of review of individual entitlements.	Head of Nuclear Medicine	30th November 2022
		This and other documents will be transitioned to an electronic document management system to ensure a robust document management and review system is in place for all documentation. This will include either the purchase of additional licenses for an existing document management system in radiation services or the purchase of a new system.	Director of Operations / Head of Nuclear Medicine	28th February 2023

The Trust must risk assess the location of the department in view of the risks posed should spillages occur outside the department on a main hospital thoroughfare.	Standard 2.1 Managing Risk and Promoting Health and Safety	A review of the existing radiation risk assessment under IRR17 is currently underway. This is to be completed and to include risks and mitigations regarding spillages outside of the department.	Head of Nuclear Medicine / Velindre University NHS Trust Radiation Protection Advisers	30th November 2022
		A review of the plans for the new Cancer Centre to be undertaken to ensure the Nuclear Medicine Department is not within a thoroughfare and is segregated from unnecessary footfall.	Head of Nuclear Medicine / Director of TCS	30th November 2022
The employer must ensure that there is a defined programme in place for clinical audit.	IR(ME)R Reg 7	A Nuclear Medicine Specific Clinical Audit programme will be introduced and integrated into the Trust existing Clinical audit and feedback programmes.	Clinical Director for Radiology / Head of Nuclear Medicine	30th November 2022
The employer must ensure that all documented SLAs are in date, regularly reviewed and define the	Standard 7.1 Workforce	The SLA with Cardiff and Vale for the provision of Physics support is no longer operational as from the 14th July 2022.	Head of Radiation Services	Complete

support to be given as part of the SLA.				
The employer must ensure that the system used for referrals made by electronic methods such as emails, uses the same controls as paper referrals.	IR(ME)R Reg 10 (5)	All electronic confirmations of justification and authorisation now include the same three patient specific identifiers as would be used for verbal confirmation of identity.	Head of Nuclear Medicine	Complete.
The employer must ensure that a consistent system of document control is introduced into employer's procedures. This must include the document review timescale, review dates, who is involved in establishing or reviewing procedures and how they are agreed by the employer	IR(ME)R Reg 6 (5) (b)	Documents will be transitioned to an electronic document management system to ensure a robust document management and review system is in place for all documentation. This will include either the purchase of additional licenses for an existing document management system in radiation services or the purchase of a new system.	Director of Operations / Head of Nuclear Medicine	28th February 2023
		New and revised documents will be subject to governance oversight by the Radiation Protection and Medical Exposures Operational Group.	Director of Operations / Head of Nuclear Medicine	With immediate effect

The employer must ensure that the employer's procedure which covers clinically significant unintended or accidental exposure is updated to match the regulatory requirement that if this occurs, they should always inform the patient (or representative).	IR(ME)R Reg 8 (1)	The clinically significant unintended or accidental exposure in the Nuclear Medicine IR(ME)R document will updated to match the regulatory requirements.	Head of Nuclear Medicine	30th September 2022
The employer must ensure that a document is written on the study of the risk of accidental or unintended exposures for nuclear medicine therapies.	IR(ME)R Reg 8 (2)	A document will be prepared covering the study of the risk of accidental or unintended exposures for nuclear medicine therapies and incorporated into the document management system.	Head of Nuclear Medicine	30th November 2022
The Trust must ensure that appropriate staff are employed to carry out functions appropriate to their role. This includes administrative support to complete administrative functions.	Standard 7.1 Workforce	One administrative assistant has been recruited and is currently undertaking training in Nuclear Medicine to provide secretarial support to the service.	Head of Radiation Services	Complete
The employer must ensure there is sufficient MPE support available to meet minimum national guidelines.	IR(ME)R Reg 14 (1)	A gap analysis will be conducted on the provision of Nuclear Medicine MPE support to the	Head of Radiation Services	30th November 2022

Furthermore, the employer should complete a gap analysis to establish the number and qualifications of MPE required to cover all the therapies in place and those intended to be introduced.		service. No new diagnostic or therapeutic procedures will be initiated until MPE capacity is improved. In discussions with Welsh Government and local Directors of Therapies and Health Care Science, the department is actively engaged in recruiting new Clinical Scientist and MPE resource and building a regional advisory service to improve resilience. As part of the regional delivery of MPE services additional scientific resource has been recruited including two Band 7 Clinical Scientists and an 8B Clinical Scientist.		

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): Kathy Ikin

Job role: Head of Radiation Services

Date: 02/09/2022