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

Nuclear Medicine Department, Glan Clwyd Hospital, Betsi Cadwaladr University Health Board

Inspection date: 16 and 17 May 2023

Publication date: 17 August 2023

















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

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

In writing:

Communications Manager

Healthcare Inspectorate Wales

Welsh Government

Rhydycar Business Park

Merthyr Tydfil

CF48 1UZ

Or via

Phone: 0300 062 8163

Email: hiw@gov.wales Website: www.hiw.org.uk

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	5
2.	Summary of inspection	6
	What we found	
	Quality of Patient Experience	9
	Delivery of Safe and Effective Care	12
	Quality of Management and Leadership	21
4.	Next steps	26
Ap	pendix A - Summary of concerns resolved during the inspection	27
Ар	pendix B - Immediate improvement plan	28
Αp	ppendix C - Improvement plan	29

1. What we did

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

Healthcare Inspectorate Wales (HIW) completed an announced Ionising Radiation (Medical Exposure) Regulations inspection of the Nuclear Medicine Department at Glan Clwyd Hospital, Betsi Cadwaladr University Health Board on 16 and 17 May 2023. During our inspection we looked at how the department complied with the Regulations and met the Health and Care Quality Standards.

Our team for the inspection comprised of two HIW Senior Healthcare Inspectors and a Scientific Advisor from the Medical Exposures Group (MEG) of the UK Health Security Agency (UKHSA), who acted in an advisory capacity. The inspection was led by a HIW Senior Healthcare Inspector.

Before the inspection we invited patients or their carers to complete a questionnaire to tell us about their experience of using the service. We also invited staff to complete a questionnaire to tell us their views on working for the service. A total of three questionnaires were completed by patients or their carers and 16 were completed by staff. Feedback and some of the comments we received appear throughout the report.

Where present, quotes in this publication may have been translated from their original language.

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:

Very positive feedback was provided by patients about their experiences when attending the department. However, this was based on only three completed patient questionnaires.

We saw that arrangements were in place to promote privacy and dignity of patients in the nuclear medicine department within radiology and that staff treated patients in a kind, respectful and professional manner.

There were adequate arrangements in place to meet the communication needs of patients attending the department. However, the supporting information sent out with the appointment letters sent to patients were in English only.

There were several members of the department who could speak Welsh, which allowed the service to provide the "Active Offer" to patients in Welsh.

This is what we recommend the service can improve

- Providing all information to patients bilingually
- Ensure staff have full visibility of patients in the department.

This is what the service did well:

- Very positive patient experience comments
- Promote privacy and dignity of patients
- Have in place a number of communication tools to help people with difficulties in communication.

Delivery of 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 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.

The information provided relating to employer's written procedures was good and would further benefit from shared learning across the three sets of procedures in use.

The location where nuclear medicine therapies were provided was considered to be not fit for purpose.

Some minor issues were identified to improve compliance with IR(ME)R 2017.

This is what we recommend the service can improve

- The area where nuclear medicine therapies were given
- Shared learning and shared information between the three sets of employer's procedures relating to nuclear medicine, medical physics and radiopharmacy.

This is what the service did well:

- All staff understood their roles under IR(ME)R
- Compliance with IR(ME)R 2017 regulations
- Effective infection prevention and control (IPC)
- Written employer's procedures.

Quality of Management and Leadership

Overall summary:

The management structure had clear lines of reporting with effective governance arrangements in place to support ongoing regulatory compliance. Visible and supportive leadership was evident within the department.

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

Staff feedback provided in the questionnaires was generally positive, with some mixed responses in certain areas.

Training records for staff, in relation to IR(ME)R, showed staff had completed training relevant to their area of work and had their competency assessed. They should be reviewed annually.

This is what we recommend the service can improve

Review the records of entitlement and training annually.

This is what the service did well:

- Compliance with mandatory training records for staff was good
- A 100% compliance with annual appraisals
- Visible effective management with positive engagement with the inspection process.

Details of the concerns for patient's safety and the immediate improvements and remedial action required are provided in <u>Appendix B</u>.

3. What we found

Quality of Patient Experience

Patient Feedback

During the inspection HIW issued paper and online questionnaires to obtain views and feedback from patients and carers. As only three responses were completed, this low number needs to be borne in mind when considering these responses.

Overall, all patients would rate the service received as very good. Patient comments included the following:

"Staff were excellent, thank you."

"Difficulty parking at the hospital as usual. Staff were cheerful and professional. Kept me well informed before, during and after the scan."

Person Centred

Health Promotion

There were posters clearly displayed within the department advising patients to inform staff if they were pregnant or breastfeeding. We also saw a range of other health promotion related material displayed near the main reception area including bilingual information.

Dignified and Respectful Care

Staff were seen treating people with respect and kindness, communicating in a friendly manner and supporting patients to the relevant department. We heard staff speaking to patients in both English and Welsh, calling patients by their name, giving them time, being supportive and explaining delays as appropriate. Staff were discreet and sensitive when speaking to patients and when speaking about patients to other staff.

The waiting room used by the nuclear medicine department was spacious, clean, with sufficient seating and water available. However, the reception desk (where staff were situated) did not have visibility over the waiting area. Staff members were not able to see patients that were sitting in the reception area from their workspace. Should patients sitting here become unwell, they would not be seen by reception staff.

The health board is required to ensure that staff have full visibility of patients once they present to the department.

A changing room was available for patients to use and there were rooms available to staff to speak to patients where they could not be overheard by others. Doors to treatment rooms were closed when in use.

All patients who completed the questionnaire said they were able to speak to staff without being overheard by other patients. They stated that they were provided with enough information to understand the risks and benefits of the procedure and were involved as much as they wanted to be in decisions about their procedure.

Staff we spoke with demonstrated a good awareness of their responsibilities in protecting and promoting patients' rights when attending the department. All staff who completed a questionnaire agreed that patients' privacy and dignity was maintained and almost all believed that patients were informed and involved in decisions about their care. They were all satisfied with the quality of care and support they gave to patients.

Individualised Care

All patients who completed the questionnaire agreed that the wait between referral and appointment was reasonable and that they were able to find the department easily. Additionally, all patients said that staff explained what they were doing and that staff listened to them and answered their questions. Whilst all patients agreed that they were given information on how to care for themselves following their procedure treatment, one patient disagreed that they were given written information on who to contact for advice about any after effects.

The department had introduced the Welsh version of the document "Medical Imaging: What a patient needs to know" that had recently been translated by the All Wales Imaging Quality Forum with permission from UKHSA.

Timely

Timely Care

Patients appeared to be seen in a timely manner and arrangements were described to inform patients of delays in providing their procedures. We saw good informal communication with patients to inform of any delays on the unit. We were told that waiting lists were harmonised across the health board to ensure a fair distribution of work.

Equitable

Communication and Language

There was a hearing loop system available and staff we spoke with told us that additional arrangements would 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 were also told that large print information was available on request.

We were told that written information was provided to the patient before the scan. We also saw examples of scan specific information that was sent along with the appointment letter. This was double checked for understanding on arrival.

Bilingual information was available and we noted several staff wearing the Welsh language logo to indicate they could speak Welsh. Patients were able to access most, if not all, treatment in Welsh. We also heard patients and staff / staff with staff speaking Welsh to each other.

Rights and Equality

Wheelchair access was noted throughout the department. Whilst pre-treatment information was sent out in English only, it was available in Welsh. We were told that patients who did not attend were contacted to ensure another appointment was booked. Children would be supported by parents / guardians and there was an effective carers and comforters policy and guidelines in place. Staff confirmed about how conversations were held with patients and carers that have capacity challenges. This involved checking understanding and using the carer or advocate as available.

All information sent to patients in advance of the treatment should be sent out bilingually.

All patients knew how to complain about poor service, if needed. All patients said that staff treated them with dignity and respect and that measures were taken to protect their privacy.

Only one patient stated that Welsh was their preferred language and that they were not offered the opportunity to speak Welsh during their patient journey. However, they stated that information was available to them in Welsh. Staff we spoke with demonstrated a good awareness of their responsibilities in protecting and promoting patients' rights when attending the department.

Delivery of Safe and Effective Care

Compliance with The 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 (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.

Employer's Duties: Establishment of General Procedures, Protocols and Quality Assurance Programmes

Procedures and Protocols

The employer's procedures and protocols written and supplied as part of the SAF were of a good standard. They included good points which were highlighted during the inspection.

Staff we spoke with knew where to find the written procedures relevant to their practice and said that they were clear and easy to understand. Senior staff we spoke with described how procedures were made available to staff, through the health board intranet and a shared area called sharepoint.

There were three sets of employer's procedures noted during the inspection, for nuclear medicine, medical physics and radiopharmacy. The departments would benefit from learning and shared information within these procedures. These learnings include the good practice points in the patient identification procedure and removal of references to Administration of Radioactive Substances Advisory Committee (ARSAC) certificates from the radiopharmacy procedures.

The three sets of employer's procedures should include learnings and shared information from each other.

Referral Guidelines

The SAF described that the referral guidelines were identified in the radiology procedure for entitlement. The i-refer guidelines were available on the intranet and referrers were informed via the annual notification. For non-medical referrers

their referral guidelines would be included in their entitlement letter and also on their annual renewal notice.

Whilst the sentinel node referral criteria for head and neck were specific and included in the Radiology SOP for this procedure, no referral guidelines were in place for sentinel lymph node biopsy procedures.

Referral guidelines were required for sentinel lymph node biopsies.

The procedure for entitling non-medical referrers was undergoing a major revision and senior staff explained the review of this procedure. This included following the British Institute of Radiology guidance and the removal of non-medical referrers entitlement from those who had referred beyond their scope.

Information on radiation risks from nuclear medicine procedures was not included in the letter to entitled referrers

The information included in letters to non-medical referrers needs to include radiation risks.

Diagnostic Reference Levels (DRLs)

DRLs were displayed in the injection room and were set annually based on ARSAC guidance. The DRL given were recorded on the day sheet for the injections and also on the request form.

The DRL chart on display did not include the acceptable ranges.

The DRL chart on display would benefit from the inclusion of the acceptable range of activities to administer.

Medical Research

There was an employer's procedure in place for research involving ionising and non-ionising radiation.

The SAF included the governance arrangements in place for research trials involving ionising radiation exposures as well as briefly describing how dose constraints were established and the measures in place to ensure these were adhered to.

Entitlement

The SAF explained how the employer had delegated the task of carrying out IR(ME)R duties to others through the Ionising Radiation Protection Policy, which

identified the responsibilities of the Health Board, Board Directors, Heads of Department and individuals.

Non-medically qualified referrers had to complete a training programme and formally request entitlement - this is reviewed via a radiology panel who will then provide formal entitlement if the application is accepted and added to the register.

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.

Senior staff described a clear process for the entitlement of duty holders. This process was reflected in the employer's written procedure to identify individuals entitled to act as referrer, practitioner or operator within a specified scope of practice.

Patient Identification

There was an employer's written procedure in place to correctly identify the individual to be exposed to ionising radiation.

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.

Individuals of Childbearing Potential (Pregnancy Enquiries)

There was an employer's written procedure in place for making enquiries of individuals of childbearing potential to establish whether the individual was or may be pregnant or breastfeeding.

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.

Benefits and Risks

Staff explained how they would ensure that adequate information was provided to individuals or their representatives relating to the benefits and risks associated with the radiation dose from exposures. Staff we spoke with were confident in being able to ensure that adequate information was provided to individuals or their representatives relating to the benefits and risks associated with the radiation dose from exposures.

Clinical Evaluation

There was an employer's written procedure in place for carrying out and recording an evaluation for each medical exposure performed at the department.

The sample of referral forms we examined included five retrospective referral forms. These all showed evidence of a timely clinical evaluation being completed.

Non-medical Imaging Exposures

Non-medical imaging exposures were not performed at the department.

Employer's Duties - Clinical Audit

The SAF described the process for clinical audit including the structure of the programme, staff groups and IR(ME)R duty holders involved. We were told that all members of the department would participate in these audits. Audits had to be appropriately registered and reported to the various governance groups in the department. We were told that clinical audits in nuclear medicine were difficult to perform because of the low numbers of patients.

Employer's Duties - Accidental or Unintended exposures

Staff we spoke with were able to describe the procedure for reporting accidental or unintended exposures and how learning from incidents was shared.

Senior staff also described suitable arrangements for informing the referrer, the practitioner and the patient or their representative of accidental or unintended exposures together with the outcome of the analysis of the incident.

A study of the risk involved was documented for each radionuclide therapy in individual documents that were part of the Medical Physics ISO9001 quality system. This was considered to be a notable good practice and compliance here.

In relation to reporting incidents, responses on the questionnaire from staff were generally very positive as follows:

- My organisation encouraged us to report errors, near misses or incidents -100%
- My organisation treats staff who are involved in an error, near miss or incident fairly - 92%
- When errors, near misses or incidents were reported, my organisation took action to ensure that they do not happen again 92%

However, only 58% agreed that they were given feedback about changes made in response to reported errors, near misses and incidents.

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.

Practitioners would be informed of their entitlement in writing and were included in the entitlement matrix, which included the scope of practise. For the examinations carried out in the medical physics department, there was a set of IR(ME)R employer's procedures which included specific identification of entitled practitioners. Relevant clinical directors or the director of therapies were responsible for entitlement by signing off these procedures.

Staff we spoke with demonstrated a good understanding of their duty holder roles and responsibilities under IR(ME)R.

Justification of Individual Exposures

The processes of how justification was performed and where this was recorded were described in the SAF. These were set out within the associated employer's written procedure.

A medical exposure would not be carried out unless it had been justified and authorised by the practitioner, or an operator is authorising an exposure in accordance with guidelines issued by the practitioner.

The consultant radiologist (who was also a practitioner) we spoke with was able to describe the considerations when justifying exposures. There were authorisation guidelines in place and anything outside guidelines would need to be reviewed by the practitioner. Information was available on sharepoint relating to justification and authorisation for carers and comforters.

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 provided examples of how the operator selected protocols for individual examinations to ensure optimisation of the exposure. These included paediatric optimisation and when a patient had uncontrollable pain.

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.

The SAF stated that all diagnostic nuclear medicine patients received written information by post (or by email as requested). As well as the appointment letter, information was included which explained the particular test further. The requirements were detailed in the relevant procedure for issuing information and written instructions following administration of radiopharmaceuticals.

Patients having iodine-131 treatment were given an instruction sheet and card on leaving the hospital. This gave details of contact restrictions and periods and provided a point of contact for advice. For radium-223 therapy, patients were given a yellow card in case they needed medical attention within a week of administration.

Expert Advice

The SAF described the MPEs involvement in various areas including employer and practitioner licence applications and reviews of their status, investigating incidents and training staff. MPEs were members of local and overarching health board radiation protection committees to advise on medical exposure aspects. The MPEs were also members on various radiology governance meetings.

We spoke with members of the medical physics team who said that the department was managed through the same structure as radiology. They were also based on the same site, allowing for informal arrangements for support. Staff described the support that they provided to the department, this included quality assurance checks of equipment. They advised on this as well as providing advice on DRLs and being involved in protocol development.

MPEs were also involved in acceptance testing of equipment and the design installation and technical specification of equipment. They also, through the radiation protection committee provided advice to the employer on compliance with the regulations, including updates on licensing status and when renewal was required.

Staff we spoke with said that they could access this expert advice, they were aware of who the MPEs were and that they were able to access them in a timely manner.

Equipment: General Duties of the Employer

There was an employer's written procedure in place to ensure a quality assurance programme in respect of equipment was followed.

The SAF described the quality assurance programme in place for all relevant equipment including the relevant procedure and where in the procedure this was evidenced. The quality assurance programme ensured accurate verification of the administered activity

Medical physics staff completed acceptance testing of equipment before first use. They also carried out quality control testing at regular intervals as stated in the quality assurance programme. Routine performance testing was carried out by the relevant department on a daily and weekly basis.

Performance data was compared with relevant national guidance and compared with the manufacturer's specifications and acceptance test findings. MPEs were consulted and would advise on the acceptability of the performance.

All equipment had a maintenance contract in place that included planned preventative maintenance as per the original equipment manufacturer prescribed schedule and breakdown call outs and parts cover. The quality assurance programme in place for all equipment included both remedial and suspension levels.

An inventory of equipment installed at the department was available. For the equipment listed, this included the information required under the regulations.

Safe

Risk Management

The department for nuclear medicine (NM) was not signposted specifically but was included in the second radiography reception. This was highlighted in appointment letters and whilst in the department staff were seen to effectively support patients to the right area. The corridors in the nuclear medicine diagnostic and waiting rooms were bright, clean and in a good state of repair with sufficient chairs.

The nuclear medicine department was a self-contained, single gamma camera department with a separate injection room, a small waiting area and a separate toilet. We were shown plans that were subject to a business case to consolidate the nuclear medicine and a static positron emission tomography and computerised tomography (PET-CT) scanner onto one location with the project boards preference being Glan Clwyd.

The room used for nuclear medicines therapies was considered to be not fit for purpose. It was located in the medical physics department (next to the North Wales cancer centre) and not co-located near other treatment areas. The radiopharmaceuticals would be drawn up into syringes or capsules measured in a laboratory next to the room where the injections were administered. The patient administration room was a laboratory that had not been sufficiently converted into a patient consultation room and is separate from other consultation rooms. The room included a decommissioned washing machine and range of other clutter and equipment that would make effective cleaning difficult. The department had put in a business case for the redesign of this area to provide a better experience for patient, but no further action had been made since the submission of the business case.

We were shown plans of the changes proposed from 2021, that had not yet been approved or implemented. We informed the Head of Professional Services, who subsequently informed us that this had now been escalated to the Executive Director of Therapies and Health Sciences and was on the risk register.

In addition, this room was separate from other patient facing areas and may mean that patients would not feel valued when compared to the experience of other patients requiring cancer treatment (using other modalities).

The location for the provision of therapies needs to be improved.

Conversely, the inpatient therapies room (on the ward in cancer centre) was bright, well-lit and well-ventilated with a television, fridge and ensuite facilities. The decor was good and the personal protective equipment (PPE) and radiation checking air lock was effective. There had not been an inpatient since November 2022 as there was not a practitioner licence holder. A practitioner licence holder was now in place and inpatient treatment would recommence in June 2023.

Infection Prevention and Control (IPC) and Decontamination

The environment appeared visibly clean and we were told equipment was cleaned after each patient and at the end of day. All equipment was in a good state of repair to enable effective cleaning. Sharps boxes were seen, they were not over full and were in date. There were sufficient hand washing facilities and multiple hand gel stations in the area. PPE stock was available for staff and patients.

Staff we spoke with were aware of their responsibilities in relation to IPC and decontamination. All staff stated that their organisation implemented an effective infection control policy, there was an effective cleaning schedule in place and appropriate PPE was supplied and used. Only one member of staff disagreed with the comment that the environment allowed for effective infection control.

All patients stated that in their opinion, the setting was very clean. and agreed that infection and prevention control measures were being followed.

Safeguarding of Children and Safeguarding Adults

Staff members that we spoke with understood the importance of safeguarding and could describe the process for making a referral, as well as detailing the support available locally and within the health board. Staff were also aware of the safeguarding policies and procedures in place and where to access these.

Training records inspected by HIW showed that staff had completed safeguarding training at a suitable level.

Effective

Record Keeping

We checked a sample of three current patient referral documents and five retrospective documents. The referrals checked were completed to a good standard in accordance with referral guidelines with sufficient clinical details included. We found suitable arrangements were in place for the management of records used within the department.

However, the radiation software system (RADIS) records included the DRL not the actual measured activity.

We recommend that the actual administered activity is recorded in the RADIS records.

Efficient

Efficient

Senior staff we spoke with described the proposed introduction of the electronic radiology information systems. This would mean there was the same system across Wales and no paper records. Also, in order to ensure appropriate scanning, this involved moving patients around the health board as necessary.

Quality of Management and Leadership

Staff Feedback

HIW issued a questionnaire to obtain staff views on services carried out by the Nuclear Medicine Department at Glan Clwyd Hospital and their experience of working there. The questionnaire complemented the HIW inspection that took place in April and May 2023.

In total, we received 13 responses from staff, the responses from staff were generally positive. The feedback was generally positive with some mixed responses for staffing levels, as well as for patient experience feedback. Feedback on line-managers was generally positive, but feedback for senior management was mixed. Staff believed that the setting was clean with there was effective infection control. The majority of staff also felt safe in raising concerns about unsafe clinical practices. There were five staff comments relating to staffing levels and waiting lists mentioned as key issues.

Staff comments included the following:

"I'm very proud to work in this department. I look forward to coming to work, knowing that we, as a team, do our utmost to ensure that our patients are dealt with in a friendly, welcoming and understanding manner. We have received many cards, chocolates and messages of thanks from patients over the years, and this solidifies my belief that we are providing an excellent service.

Staff work ethic is very good but at times of sustained staff shortages it gets challenged and morale declines.

Investment in staff recruitment and training is essential for service sustainability.

Staffing is not very robust within certain areas of the department, creating difficulty during periods of annual leave and sickness which leads to lone working at times. We will be training staff in the near future but it will be some time before we have a robust staffing model. However this is my only criticism and I enjoy working here, immediate management very supportive and I believe we offer a great service to our patient.

Leadership

Governance and Leadership

The Chief Executive of the organisation was the designated employer under IR(ME)R and had overall responsibility for ensuring the regulations were complied

with. Where appropriate, the employer had delegated tasks to other professionals working in the organisation to implement IR(ME)R.

Staff we spoke with were able to describe how they were made aware of their duties and scope of entitlement under IR(ME)R. They were aware of where to find the written procedures relevant to their practice and found the written procedures clear and easy to understand.

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.

There was clear, positive engagement with the inspection process. Senior staff were keen to ensure the processes were current and in place across the health board. This was evidenced by the attendance of the lead nuclear medicine radiology staff from the other two main hospitals in the health board.

Staff were seen to be working well together in the department, they were a small team but they said they were feeling the pinch with one member of staff absent currently.

The department had also recently introduced a a separate quality and governance newsletter that would summarise information following the radiology meetings, as well as acting as a reference document for all quality and governance information

Workforce

Skilled and Enabled Workforce

Compliance with mandatory training at the setting was good. All staff said that they had appropriate training to undertake their role. This included mandatory and role-specific training.

There was clear evidence that staff had completed suitable training on radiation production, radiation protection and statutory obligations relating to ionising radiations. We were told that regarding training records, the review of entitlement and scope of practice was reviewed at appraisal but not recorded formally.

The records of entitlement / training should be reviewed annually and formally recorded in appraisals.

Staff we spoke with believed that the numbers and skill mix were sufficient to meet the needs of the service, providing there were no absences. Senior staff described the plans for the proposed move to the new department. They were

currently reviewing the staffing model and mix ahead of this. Identified gaps and post graduate qualifications were being considered and they were working through the revised leadership support. The department were currently advertising for another consultant radiologist. The department was a small team, divided over three sites currently and they believed that the skill mix was not where the department wanted it to be, but they believed there was a pathway to addressing this issue. However, the majority of staff, 62%, believed that there were not enough staff to enable them to do their job properly.

All staff said they had an appraisal in the last 12 months. There was evidence seen of 100% compliance with appraisals.

All bar one member of staff stated that in general, their job was not detrimental to their health. The majority (70%) stated that their organisation took positive action on health and wellbeing, with 77% stating that their current working pattern/off duty allowed for a good work-life balance. Almost all staff were aware of the occupational health support available.

No members of staff said that they faced discrimination at work within the last 12 months. All bar one member of staff stated that they had fair and equal access to workplace opportunities. All staff said that the workplace was supportive of equality and diversity.

Culture

People Engagement, Feedback and Learning

Staff we spoke with said that verbal comments and complaints were encouraged and resolved at the time. The NHS Wales complaints process 'putting things right' was displayed in a number of locations at the setting to inform patients on how to make complaints.

Information was also displayed on the patient advisory and liaison service to assist patients to raise concerns should they need too. We also saw a 'you said, we did' board displayed showing information on how the organisation had learned and improved based on feedback received.

Regarding patient experience and whether the patient user experience feedback was collected within the department, such as patient surveys, whilst only 38% of staff agreed, 31% answered they did not know. As a result, 62% of staff said they did not receive regular updates on patient experience feedback in the department.

Again, whilst only 23% stated that feedback from patients / service users was used to make informed decisions within their department, 54% did not know.

A total of 77% of staff said their organisation was supportive, with 70% stating that their organisation supported staff to identify and solve problems, with a lesser amount 61% agreeing that their organisation took swift action to improve when necessary.

All bar one member of staff who completed the questionnaire agreed that care of patients was their organisation's top priority and overall they were content with the efforts of the organisation to keep themselves and patients safe.

Almost 77% of staff would recommend their organisation as a good place to work and would be happy with the standard of care provided for themselves or friends and family.

The majority of staff (77%) stated that their immediate manager could be counted on to help with a difficult task at work.

Over 84% stated that their immediate manager gave clear feedback on their work and their immediate manager asked for their opinion before making decisions that affected their work.

Whilst only 46% of staff believed that senior managers were visible, 77% stated that senior managers were committed to patient care and 62% said that communication between senior management and staff was effective.

Regarding the duty of candour, staff responded:

- I know and understand the duty of candour 73%
- I understand my role in meeting the duty of candour standards 73%
- My organisation encourages us to raise concerns when something has gone wrong and to share this with the patient - 91%

Almost 85% of staff agreed that if they were concerned about unsafe practice, they would know how to report it, 77% of staff felt secure raising concerns about unsafe clinical practice. Whilst only 54% were confident that the organisation would address these concerns, over 38% did not know.

Staff we spoke with said that they were supported in their role and they felt able to raise concerns to seniors. The only challenges flagged, were the number of specialist staff available, although they appreciated that recruitment was difficult as there was a shortage of these staff in general.

Almost all staff said they were able to meet the conflicting demands on my time at work and that they had adequate materials, supplies and equipment to do their job.

All staff were able to access ICT systems needed to provide good care and support for patients.

Over 76% of staff said that they were involved in deciding on changes introduced that affected their work area.

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, Glan Clwyd Hospital

Date of inspection: 15/16 May 2023

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
There were 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.

<i>c</i> ·		4 4 4 4
Service	represe	ntative:
JCI VICC	I CPI C3C	mative.

Name (print):

Job role:

Date:

Appendix C - Improvement plan

Service: Nuclear Medicine Department, Glan Clwyd Hospital

Date of inspection: 15/16 May 2023

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 health board is required to ensure that staff have full visibility of patients once they present to the department.	Dignified and Respectful Care	Due to the structural design of the reception area relative to the waiting room estates works to install mirrors is required.	Radiology Service Manager Central	30 September 2023
The health board is to ensure that all information sent to patients in advance of the treatment is bilingual.	Rights and Equality	Welsh versions of the patient information for nuclear medicine are now included in the information being sent to patients an audit will take place during August to confirm this action.	Principal Radiographer Nuclear medicine and the lead radiographer nuclear medicine central	1 September 2023

The employer is to ensure that information included in letters to non-medical referrers includes radiation risks.	IR(ME)R 2017 Schedule 2 (e) and (i)	The radiation dose information sent in the medical annual declaration letter to be added to the non-medical referrers annual declaration.	Head of Quality & Governance Radiology	Complete
The employer is to ensure that the DRL chart on display includes the acceptable range of activities to administer.	IR(ME)R 2017 Schedule 2 (e)	Updated DRL version (v7b) for Nuclear Medicine Diagnostic Procedures (Effective from 20/7/23) - updated with the following requirement from inspectors:	Principal Radiographer Nuclear Medicine	Completed
		The employer is to ensure that the DRL chart on display includes the acceptable range of activities to administer. IR(ME)R 2017 Schedule 2 (e)		
		There have been NO changes to the DRL values themselves - however an additional final column has been added with a +/- 10% range - to aid operators with checking the product to be administered is within the acceptable local range.		
The employer is to ensure that referral guidelines for	IR(ME)R 2017 Regulation 6(5)(a)	Sentinal node biopsy procedure to be update to include referral criteria.	Professional head of radiography	Completed

sentinel lymph node biopsies are available.		Separate annual entitlement letters developed specifically for sentinel node biopsies.		
The health board is to provide HIW with the actions taken: In relation to the business case for the changes to the location for the provision of therapies To ensure that in the meantime, the area where these therapies	Safe (Risk Management)	In relation to the business case the funding has now been approved. Funding has been allocated for this financial year and the implementation plan is currently being drafted. A risk assessment has been performed in relation to the radiation safety. Alternative locations have been assessed as well as the impact of suspending the service until the	Associate Director Diagnostic & Clinical Support Services	January 2024 31 August 2024
take place is fit for purpose.		remedial work has been completed. As these are cancer patients it was not felt appropriate to suspend the service. Efforts are being taken to make the room more inviting by removing non-essential equipment and temporary curtain screens in place.		

The employer is to ensure that RADIS records include measured activity instead of the DRL.	IR(ME)R 2017 Schedule 2 (e)	The important sentence that was added is 'The patients visit on the RIS system (RadIS) is to be completed. The dose recorded should equal the measured dose immediately prior to performing the injection in MBq (i.e. the dose recorded on the 'Daily Patient Dose Register'). Any CT dose should also be recorded (in DLP).' This action was implemented on the day of the inspection with the procedure being updated and ratified at the June 2023 radiology QSE.	Lead Radiographer Nuclear Medicine central	Completed
The employer is to ensure that the records of entitlement and training are reviewed annually and formally recorded in appraisals.	IR(ME)R 2017 Regulation 17 and Schedule 2 (b) 7	It is a radiology requirement that entitlement and training/competency is completed at PADR. An example record is attached. An audit will be undertaken to confirm this documentation is being used in PADRs.	Professional Service Manager Radiography	End of September 2023
The employer is to ensure that the three sets of employer's procedures include learnings and shared information from each other.	IR(ME)R 2017 Regulation 6 and Schedule 2	Evidence of references to ARSAC removed from pharmacy procedures	Pharmacy Technical Services Lead	Complete

The ADoTh will convene an annual meeting of nuclear medicine, radio-pharmacy and medical physics lead for radio-nuclide therapies to share learning and information. The outcome of this meeting will be shared at the Radiation Protection Committee - For 2023 this will be in December 2023.	Assistant Director of AHPs & Healthcare Scientists MPE Pharmacy Technical Services Lead Head of Quality and Governance Radiology	December 2023
---	--	---------------

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): Helen Hughes

Job role: Professional Service Manager Radiography/ADoTH

Date: 20 July 2023