Ionising Radiation (Medical Exposure) Regulations Inspection (Announced)

Nuclear Medicine: Wrexham Maelor Hospital

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

Our purpose

To check that people in Wales receive good quality healthcare

Our values

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

- **Independent**
- **Objective**
- **Caring**
- **Collaborative**
- **Authoritative**

Our priorities

Through our work we aim to:

Provide assurance:	**Provide an independent view on the quality of care**
Promote improvement:	**Encourage improvement through reporting and sharing of good practice**
Influence policy and standards:	**Use what we find to influence policy, standards and practice**

1. What we did

Healthcare Inspectorate Wales (HIW) completed an announced Ionising Radiation (Medical Exposure) Regulations inspection of Wrexham Maelor Hospital within Betsi Cadwaladr University Health Board on the 23 and 24 January 2019. During this inspection, we visited the nuclear medicine department.

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

HIW explored how the service:

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

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

2. Summary of our inspection

Overall, we found good compliance with the Ionising Radiation (Medical Exposure) Regulations 2017, but we identified some areas of improvement.

We were assured that patients received a safe and effective service.

A management structure was in place and clear lines of reporting were described and demonstrated.

This is what we found the service did well:

- Staff treated patients with dignity, respect and kindness
- Overall, we found good compliance with the Ionising Radiation (Medical Exposure) Regulations 2017
- The health board had been proactive in creating new procedures to meet the requirements of the new regulations
- The health board actively sought patient feedback specific to their experiences in radiology
- We saw visible and supportive leadership being provided by senior staff
- There were good working relationships with medical physics experts who provide support in relation to nuclear medicine.

This is what we recommend the service could improve:

- Consider how written patient information can be made more accessible and consistent with practice
- Ensure information for patients is clear on how they may provide feedback and raise a concern about their care and treatment
- Improve the level of detail within the delegated authorisation guidelines for the justification of exposures
- Update the procedure for carers and comforters to reflect the appropriate designation of individuals as carers and comforters in

diagnostic nuclear medicine and ensure consistency of approach with other areas

- Clarify the responsibilities under IR(ME)R regarding the mobile Positron emission tomography–computed tomography[1] (PET-CT) service.

Whilst we found areas for improvement, there were no areas of non-compliance identified at this inspection.

[1] Positron emission tomography–computed tomography (better known as PET-CT) is a nuclear medicine technique. A PET-CT scan combines a CT scan and a PET scan. It gives detailed information about the body such as cancer. The CT scan takes a series of X-rays from all around the body and puts them together to create a 3D picture. The PET scan uses a mildly radioactive drug to show up areas of your body where cells are more active than normal.

3. What we found

Background of the service

Betsi Cadwaladr University Health Board provides services for a population of around 678,000 people across the six counties of North Wales (Anglesey, Gwynedd, Conwy, Denbighshire, Flintshire, and Wrexham).

Wrexham Maelor Hospital is located in Wrexham and provides a range of in-patient and out-patient services together with a 24 hour emergency department.

The nuclear medicine department is located within the radiology (X-ray) department and supports a number of services including:

- Nuclear medicine imaging using a Single-photon emission computed tomography – computed tomography scanner (SPECT-CT[2])
- Positron emission tomography–computed tomography (PET-CT) imaging
- Iodine 131 therapy for treatment of benign thyroid disease[3].

[2] Single-photon emission computed tomography (SPECT) is a type of nuclear imaging test that shows functional processes such as how blood flows to tissues and organs. A SPECT scanner can be combined with a CT scanner to provide anatomical information as well.

[3] Iodine 131 therapy is a form of radiation therapy that has been used for many years to treat a number of conditions including thyroid diseases and cancer.

Quality of patient experience

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

We found staff treated patients with dignity, respect and kindness.

Overall, we found that patients were provided with enough information about their procedure. However, we recommended that written information is made more accessible for patients so that key messages stand out.

It was positive to find that the radiology department encouraged patient feedback. However, we recommended the health board clarify the ways in which patients can provide feedback or raise concerns.

Prior to and during the inspection we asked staff to distribute HIW questionnaires to patients and carers to obtain their views on the services provided. A total of 11 questionnaires were completed. On this occasion, it was not possible to speak to patients during the inspection.

Staying healthy

We saw health promotion material was displayed within patient waiting areas. This included posters about the benefits of having a flu vaccine and awareness of sepsis, stroke and dementia.

Posters were clearly displayed requesting individuals who are or may be pregnant or breast feeding to inform a member of staff. This is a regulatory requirement and important to promote patient safety.

We saw patients were provided with information about the radiation risk they may pose to others for a short period following their procedure. Patients were advised to avoid close contact with children and individuals who are pregnant.

Dignified care

We found staff treated patients with dignity, respect and kindness. Patients who completed a questionnaire agreed they had been treated with dignity and

respect by the staff at the hospital and felt they were always able to maintain their privacy, dignity and modesty during their appointments.

Where applicable, patients who completed the questionnaire felt they were listened to by staff and were asked to confirm their personal details prior to their procedure. Patients also told us that they were able to speak to staff about their procedure or treatment without being overheard by other people.

Whilst we did not observe patients having their procedures, we saw staff greeting patients in a friendly way. Staff were mindful of respecting patient privacy and dignity and we saw that doors to treatment rooms were closed during use. We also saw there was a privacy line on the floor by the main reception to reduce the chances of patients being overheard when speaking to staff at the reception desk.

Staff explained that nuclear medicine patients usually remained in their own clothes during their procedure, but we saw that cubicles were available for patients to change into hospital dignity gowns if required.

The nuclear medicine department had its own waiting area. Staff explained that patients would be taken to a separate room to check their details prior to their procedure.

Patient information

Communicating benefits and risks

Overall, we found that patients were provided with enough information about their procedure.

All of the patients who completed a questionnaire told us they felt involved as much as they wanted to be in any decisions made about their treatment. Patients also said they had received clear information about the risks and benefits of their treatment options. The majority of patients also told us they had been given information on how to care for themselves following their treatment. Just over half of the patients said they had been given written information on who to contact for advice about any after effects from any treatments they had received. The majority of patients also said they would know how to raise a concern or complaint about the service.

We saw that information was displayed about nuclear medicine procedures for patients and their carers to read to further promote their understanding.

The employer had a procedure in place which they were developing further to guide staff when providing information to individuals relating to the benefits and

risks associated with having a nuclear medicine procedure. This is required by the regulations and helps ensure that patients and their carers are fully informed about their care and treatment.

We looked at the information about nuclear medicine procedures sent to patients with their appointment booking letter. Whilst this information was comprehensive, we noticed that a large amount of information was provided meaning that key information may be more difficult for patients to identify. We also highlighted the importance of ensuring that written information is consistent with the verbal information provided by staff and advice recommended by medical physics experts. We discussed this with staff during the inspection.

Improvement needed

The health board must ensure that written information provided to patients is easy to understand so that key messages are prominent and is consistent with verbal information given by staff.

Communicating effectively

We found arrangements were in place to meet the communication needs of patients, including provision for Welsh speaking patients.

All but one of the patients who completed a questionnaire told us they were ‘always’ or ‘sometimes’ able to speak to staff in their preferred language.

A working hearing loop system was available to assist those patients with hearing difficulties (and who wear hearing aids) to communicate with staff.

We saw there were large colour coded arrows on the floor to assist patients to navigate to the appropriate area within the radiology department. Staff explained they would escort any patients who needed assistance to the appropriate area.

Timely care

The majority of patients who completed a questionnaire told us it was 'very easy' or 'fairly easy' to get an appointment at a time that suited them.

Patients arrived at the main reception area for their appointment within nuclear medicine. We saw patients were then escorted or directed to the nuclear medicine department. On the days of our inspection, whilst we noticed there were times when the main reception area was busy, patients appeared to be seen fairly promptly.

Patients were verbally informed by reception staff of any delays in their appointment time.

Within the nuclear medicine department, staff told us they aim keep to the patient's appointment time. There was also a poster informing patients to alert staff if they felt they had been waiting longer than expected.

Individual Care

Listening and learning from feedback

The health board had arrangements in place for patients to provide feedback about their experiences and to raise concerns about their care and treatment.

It was positive to find that the radiology department encouraged patient feedback. We saw there were suggestion boxes available with radiology questionnaires specific for the type of procedure patients received. The results from this questionnaire were displayed on posters in the corridor.

Staff described how they are open to feedback and try to use this to improve the information they give patients about their procedures.

Although feedback was encouraged, we saw there were three different types of posters displayed on how patients could provide their feedback. This means patients may be uncertain about which would be the most appropriate avenue to raise their views or concerns.

We also noticed there was another complaints procedure displayed for patients receiving a PET-CT scan on a mobile unit run by a private organisation. Therefore, it is unclear for patients which complaints procedure they should follow if they receive care from both the health board and the private organisation.

Improvement needed

The health board must ensure there is clarity on the ways in which patients can provide feedback or raise concerns, including patients receiving PET-CT through the mobile service.

Delivery of safe and effective care

We considered the extent to which services provide high quality, safe and reliable care centred on individual patients.

Overall, we found good compliance with the Ionising Radiation (Medical Exposure) Regulations 2017. We found arrangements were in place to provide patients visiting the nuclear medicine department with safe and effective care.

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

Compliance with Ionising Radiation (Medical Exposure) Regulations

Duties of employer

Patient identification

The employer had a written procedure to correctly identify patients prior to their exposure (nuclear medicine procedure). This aimed to ensure that the correct patient had the correct exposure. Staff we spoke to were able to describe the procedure to correctly identify patients.

The procedure required operators to ask patients to confirm their name, date of birth and address. We also saw that the I-131 procedure requested the same patient identification check be made. The procedure described alternative checks which should be performed if patients are unable to confirm their identity themselves.

Individuals of child bearing age

The employer had a written procedure for making pregnancy enquires to help ensure such enquires were made in an appropriate and consistent manner. The written procedure included the age range of pateints who should be asked about pregnancy or breastfeeding. Staff were able to describe their responsiblities with regards to this procedure.

Referral criteria

The employer had written procedures for making and accepting referrals for nuclear medicine exposures. The procedure describes how requests for exposures should be cross-checked against a list of individuals, entitled to make referals for nuclear medicine procedures, which is held within health board's electronic systems.

All referrals had to be made in accordance with nationally recognised referral guidelines. The aim of these guidelines is to help healthcare professionals decide on the most appropriate examination to answer the clinical question posed.

Senior staff explained that referral guidelines used for Iodine 131 therapy are the current clinical guidelines released by the Royal College of Physicans[4], however, this was not specificed within the procedures.

Improvement needed

The employer must ensure all referral guidelines are clearly specified within the procedures, including for Iodine 131 therapy.

Duties of practitioner, operator and referrer

The employer had a written policy and procedure for the entitlement and identification of practitioners, operators and referrers (known as duty holders). This clearly set out their respective roles. The employer also had a detailed entitlement matrices for radiology and PET-CT so the scope of practice for individuals who are entitled as duty holders is clear.

[4] Royal College of Physicians: Radioiodine in the management of benign thyroid disease, clinical guidelines

https://cdn.shopify.com/s/files/1/0924/4392/files/radioiodine-management-benign-thyroid-disease.pdf?15599436013786148553

The overarching ionising radiation policy also identified how the employer delegates the IR(ME)R tasks through the organisation.

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

Justification of Individual Medical Exposures

The employer had a written procedure for the justification and authorisation of exposures. This is important to ensure that patients only have exposures that they need as part of their care and treatment.

We saw examples of patients' records that demonstrated authorisation (i.e. evidence of justification) of exposures.

We noted the department use delegated authorisation guidelines for general nuclear medicine procedures, so that an operator can authorise an exposure against guidelines set out by a practitioner. However, we noticed the detail and formatting of these guidelines needed to be improved in some areas. We also advised linking appropriate protocols to the authorisation criteria used for each procedure, to provide greater clarity for staff. With regard to PET–CT, we noted that the guidelines for operators to use was informally agreed between the practitioner and operators and that this should be formalised.

Improvement needed

The employer must ensure delegated authorisation guidelines are appropriately detailed for general nuclear medicine and PET-CT and where appropriate are linked to the appropriate protocols.

Optimisation

The employer had arrangements in place for the optimisation[5] of exposures.

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

These arrangements aimed to ensure that radiation doses delivered to patients and their carers and comforters as a result of exposures are kept as low as reasonably practicable (also referred to as ALARP).

Senior staff clearly described how medical physics experts[6] (MPE) are involved in the optimisation of exposures.

We noted that the employer had been proactive in developing a new procedure in relation to carers and comforters who receive an ionising radiation dose whilst supporting an individual undergoing a procedure (such as by holding their hand).

However, we noticed there appeared to be some inconsistencies in practice in different areas with how carers and comforters are viewed. For example, differences in practice between the X-ray and nuclear medicine departments regarding when an individual was considered a carer and comforter. We discussed with staff the need for consistency of approach and also for situations (not included in the procedure) where an individual would need to be regarded as a carer and comforter for diagnostic nuclear medicine.

We also identified that the procedure and practice for carers and comforters needed to be updated to reflect the justification of the dose to these individuals, in accordance with regulatory requirements. We also discussed with senior staff the need to ensure clarity within the procedure regarding a dose constraint for different types of exposures.

Improvement needed

The employer must ensure there is consistent practice within and across departments with regards to carers and comforters and to update the procedure to consider the exposure to comforters and carers in diagnostic nuclear medicine.

The employer must ensure the justification of exposures to carers and

[6] A medical physics expert is a person who is nationally recognised as having knowledge, training and experience relating to the application of physics to diagnostic and therapeutic uses of ionising radiation.

comforters is adequately reflected in procedures and practice.

Diagnostic reference levels

The employer had a written procedure for the use of diagnostic reference levels[7] (DRLs). This sets out the arrangements for recommending DRLs for exposures performed in the department. We saw DRLs were displayed and available to staff working in the department in accordance with the above procedure. We were told that work was currently being completed to establish local DRLs for computed tomography (CT) undertaken as part of cardiac procedures.

Staff were aware of the procedure to follow for checking and recording the doses delivered. Where DRLs are regularly exceeded, this may indicate issues relating to equipment or practice and would need to be investigated. The employer's procedure confirmed that reviews would be undertaken regularly and whenever DRLs' are consistently exceeded to ensure that corrective action is taken where appropriate. Reviews would be carried out by the nominated DRL lead and MPE and reported to the radiology protection committee within the health board.

Paediatrics

The employer had procedures for performing exposures of children. These aimed to ensure that the radiation doses involved were kept to a minimum. The procedure also set out the process to follow when referrals were received in respect of suspected physical abuse.

Staff we spoke to were aware of their responsibilities and the employer's procedures in respect of exposures of children. Staff also explained they have specific sessions during the week for performing exposures of children to ensure doses are kept as low as possible and that children are comfortable within the environment.

[7] The objective of diagnostic reference levels is to help avoid excessive radiation doses to patients. DRLs are used as a guide to help promote improvements in radiation protection practice.

Clinical evaluation

The employer had a written procedure for the clinical evaluation (reporting) of all medical exposures performed within the department. This is important to promote the timely care of patients.

This clearly set out who could perform the clinical evaluation of exposures and the reporting process, including when urgent reports are needed.

Equipment: general duties of the employer

Senior staff provided an up-to-date inventory (list) of equipment used within the department. This included the information required by IR(ME)R.

We were told that some of the equipment used in the department was old, but there was a plan in place for its replacement. The health board maintained an up-to-date risk register regarding the replacement of equipment and resources were allocated accordingly using a risk based approach.

Senior staff confirmed that MPEs are directly involved with procurement and acceptance testing of new nuclear medicine equipment, and routine testing of existing equipment.

Safe care

Managing risk and promoting health and safety

Overall, we found the environment appeared to be in a good state of repair. At the time of inspection, we saw that fire alarms were in the process of being moved and some minor redecoration would be required.

We saw the department was accessible to patients and their carers and was visibly well maintained. The department appeared clean and was free from obvious trip hazards. We did notice that the department had limited space, particularly storage space. As a result, we saw that radiology beds (trollies) were stored along the wall of the corridor. Whilst this did not appear to directly limit patient access, we advised that this issue should continue to be monitored by the health board.

As patients undergoing nuclear medicine procedures would become radioactive for a period of time, we looked at the arrangements to manage patient radioactivity within the department. We saw there were dedicated and signposted toilets for patients to use, once they received radioactive substances. The department did not have space for separate waiting area for patients and their carers to use before and after their administration, but staff

described the process to manage exposures to patients and carers appropriately.

Signage was in place to deter unauthorised persons entering rooms where nuclear medicine equipment was being used.

We found staff were aware of the safety procedures to follow when using nuclear medicine equipment.

Infection prevention and control

Whilst we could not observe infection control arrangements between patients in the nuclear medicine department during this inspection, the environment appeared visibly clean and well cared for.

Staff explained the arrangements to ensure patients were protected from the risk of infection.

We also saw that handwashing facilities were available for staff. Good hand hygiene is important to help prevent the spread of infection. Staff we spoke to were aware of their responsibilities in relation to infection control procedures.

Safeguarding children and adults at risk

The health board had arrangements in place to promote and protect the welfare and safety of children and adults at risk.

Senior staff confirmed that staff were expected to attend safeguarding training as part of the health board's mandatory training programme.

Staff we spoke to confirmed they knew what to do should they have any concerns about a child or adult's welfare and where they would seek advice.

Effective care

Quality improvement, research and innovation

Clinical audit

Senior staff confirmed that the radiology service had a clinical audit programme in respect of IR(ME)R that is revised annually.

We saw examples of recent audits that had been conducted. Senior staff were also able to explain how these had contributed to promoting consistent practice across the different radiology departments within the health board, for the benefit of patient care and wellbeing.

Expert advice

The health board's overarching Ionising Radiation Safety Policy set out the role of the MPE and this reflected the requirements of IR(ME)R.

Senior staff clearly described how MPEs are involved in exposures. We found there were good working relationships between MPEs and staff inside and outside of radiology. Staff we spoke to during the inspection were positive about the support they received from MPEs and the timeliness and quality of information they provided. We noted this as good practice.

Research

The employer had a written procedure for identifying the criteria for carrying out research.

The procedure clearly set out the criteria for accepting referrals for such exposures.

Senior staff explained that the research radiographer receives all requests for research trials. They would review all research protocols and ensure that research trials had the appropriate license and approvals in place prior to approval being given by the health board.

We advised the health board to update their research procedure and flow charts to reflect the need for Administration of Radioactive Substances Advisory Committee approval, regardless of whether exposures were considered standard care at by the research sponsor.

Information governance and communications technology

We found there were appropriate information management systems in place. This allowed for relevant patient details and information about nuclear medicine performed in the department to be recorded and easily accessed by staff.

Record keeping

We reviewed a sample of patient referral records and saw that these had been completed with appropriate details by those staff involved in the medical exposure. They also demonstrated that staff had adhered to the relevant employer's procedures. We were also told that staff were develoing a new proforma as a way of improving record keeping in nuclear medicine.

Quality of management and leadership

We considered how services are managed and led and whether the workplace and organisational culture supports the provision of safe and effective care. We also considered how the service review and monitor their own performance against the Health and Care Standards

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

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

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

We saw evidence of relevant staff training.

Governance, leadership and accountability

We found there was a robust management structure with clear lines of reporting in place. Effective governance arrangements were in place to support the implementation and ongoing compliance of the Ionising Radiation (Medical Exposure) Regulations 2017 as they apply to the nuclear medicine department at Wrexham Maelor Hospital.

Staff we spoke to confirmed they felt supported by their line manager. We found visible and supportive leadership being provided within the department.

Prior to the inspection, HIW required senior staff within the department to complete and submit a self-assessment questionnaire. This was to provide HIW with detailed information about the department and the employer's key policies and procedures in respect of IR(ME)R. The self-assessment form was returned to HIW within the agreed timescale and was comprehensive.

Duties of the employer

Entitlement

As previously stated, the employer had a written policy and procedure for the entitlement and identification of practitioners, operators and referrers (known as duty holders).

These clearly described the arrangements for entitlement and identified duty holders by staff group. The procedure set out the expected level of training for each entitled staff group together with their scope of practice.

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

Procedures and protocols

The chief executive of the health board was designated as the employer. This is usual practice. The health board's ionising radiation safety policy clearly set out that the chief executive was responsible for complying with the duties of the employer as described by IR(ME)R.

We saw that clear and concise written procedures and protocols had been developed and implemented in accordance with IR(ME)R. We saw that these were up-to-date and review dates were clearly stated.

We noted that the health board are currently working to improve their document management system to make the access and review of procedures and protocols easier.

However, we noticed that some areas of improvement were needed to procedures and protocols to ensure consistency and to reduce repetition. This is particularly the case for documentation in relation to radionuclide therapies and where separate nuclear medicine proceudres had been developed as part of the radiology framework.

We also discussed with senior staff the responsibilities under IR(ME)R in relation to the mobile PET-CT service (provided by a different employer). We noted that the health board had started work on a joint procedure for co-operation between the two employers/organisations. However, we identified the need to further clarify the responsibilities under IR(ME)R for different tasks and to improve the forum for discussion of protocols. Specifically, to clarify which employer is undertaking which tasks under the regulations and considering how information is shared regarding concerns and incidents.

Improvement needed

The employer needs to continue with the improvements to procedures and protocols to ensure these are clear and consistent.

The employer must clarify the responsibilities under IR(ME)R in relation to the mobile PET-CT service.

Incident notifications

The employer had a written procedure for reporting and investigating accidental or unintended exposures within the department. This is important to help identify themes and trends and share learning from incidents to help prevent similar incidents happening again. This clearly set out the procedure staff should follow should they suspect that an accidental or unintended exposure has occurred. The procedure correctly guided staff to inform HIW of such incidents in a timely manner.

We found that where incidents had occurred, that learning from these was shared amongst staff within the department. Arrangements were also in place to share any learning with staff teams working with ionising radiation in other departments within the health board.

Staff and resources

Workforce

During the course of our inspection, staff demonstrated they had the correct skills and confirmed they were supported to perform their respective roles within the department.

We understood the department had a stable workforce and did not typically use agency or locum staff.

As described earlier, the employer had a written policy and procedure for the identification and entitlement of practitioners, operators and referrers. These set out the expected level of training for each entitled staff group.

We looked at a sample of training records for staff working within the department. Generally, these were complete and included signatures to demonstrate that training required by IR(ME)R had been provided and received.

We found that a new member of staff to the department had received an appropriate induction and fel they had been well supported in their role.

The nuclear medicine department consists of a small staff team. We were informed that compliance with mandatory training was appropriate and this was monitored by managers within the department.

4. What next?

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

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

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

The improvement plans should:

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

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

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

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

5. How we inspect services that use ionising radiation

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

The regulations are designed to ensure that:

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

We look at how services:

- Comply with the Ionising Radiation (Medical Exposure) Regulations 2017
- Meet the Health and Care Standards 2015
- Meet any other relevant professional standards and guidance where applicable

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

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

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

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

Further detail about how HIW inspects the NHS can be found on our website.

Appendix A – Summary of concerns resolved during the inspection

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

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

Appendix B – Immediate improvement plan

Hospital: Wrexham Maelor

Ward/department: Nuclear Medicine

Date of inspection: 23 and 24 January 2019

The table below includes any immediate concerns about patient safety identified during the inspection where we require the service to complete an immediate improvement plan telling us about the urgent actions they are taking.

Immediate improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
No immediate assurance issues were identified on this inspection.				

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

Service representative:

Name (print):

Job role:

Date:

Appendix C – Improvement plan

Hospital: Wrexham Maelor

Ward/department: Nuclear Medicine

Date of inspection: 23 and 24 January 2019

The table below includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
Quality of the patient experience				
The health board must ensure that written information provided to patients is easy to understand so that key messages are prominent. The health board must ensure that written information is consistent with verbal information given by staff.	4.2 Patient Information IR(ME)R Regulation 12(6)	As part of ongoing work towards achieving the (Imaging Services Accreditation Scheme ISAS) a programme of review of all patient information across radiology is being implemented. The findings of formal research work on patient information and anxiety in MRI and the use of the BCU readers panel form part of the improvement work on patient information. All patient information will be reviewed	Head of Radiography services and Head of Quality & Governance Radiology	Initial review To be completed by 29/6/19 Full project completed across all radiology modalities December

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		and updated across radiology services. Monitoring of the whole project will be by the Radiology Quality & Safety Committee Review and update of nuclear medicine written information		2019
The health board should ensure there is clarity on the ways in which patients can provide feedback or raise concerns, including patients receiving PET-CT through the mobile service.	6.3 Listening and Learning from feedback	All versions of feedback replaced by the current BCU feedback forms. Alliance Medical to use the BCU feedback forms for all concerns and patient feedback for Welsh patients Alliance Medical to inform the Radiology Department at Wrexham Maelor Hospital of any concerns raised whilst the patient is on the PET scanner	Head of Quality & Governance Radiology & Regional manager for Alliance Medical	Completed

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
Delivery of safe and effective care				
The employer is required to ensure that all referral guidelines are clearly specified within the procedures, including for Iodine 131 therapy.	IR(ME)R Regulation 6(5)(a)	The procedure has been updated to include a reference to the relevant Royal College of Physicians clinical guidelines	MPE for Iodine 131	Completed
The employer must ensure that delegated authorisation guidelines are appropriately detailed for general nuclear medicine and PET-CT and where appropriate are linked to the appropriate protocols.	IR(ME)R Regulation 11(5)	Review and update delegated authorisation guidelines with the IR(ME)R Practitioner Licence Holders	Principal Radiographer for Nuclear Medicine & Regional manager for Alliance Medical	30/04/19
The employer is required to ensure there is consistent practice within and across departments with regards to carers and comforters and to update the procedure to consider the exposure to comforters and carers in diagnostic nuclear medicine. The employer must ensure that the justification of exposures to carers and comforters is adequately reflected in procedures and practice.	IR(ME)R Regulation 12(5)	Carers and Comforters procedure reviewed and updated to confirm the following:- • Practitioners for general X-ray and CT scanning identified in procedure and entitlement matrix • Practitioners for cares & comforters for Nuclear medicine • Carers and Comforters for nuclear medicine identified.	Head of Quality & Governance Radiology And MPE	04/04/19

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		IR(ME)R entitlement matrices updated appropriately		
Quality of management and leadership				
The employer should continue with the improvements to procedures and protocols to ensure these are clear and consistent. The employer is required to clarify the responsibilities under IR(ME)R in relation to the mobile PET-CT service.	IR(ME)R Regulation 6(5)(b) & Schedule 2 (1)(d)	Complete update to the procedure to demonstrate clearly responsibilities under IR(ME)R with respect to the PETCT Review nuclear medicine protocols to ensure they are all consistent and clear Establish regular governance review meetings between Alliance medical and BCU	Head of Quality & Governance Radiology & Regional manager for Alliance medical	29/05/19

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: Head of Quality & Governance Radiology

Date: 21st March 2019