Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

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

Diagnostic Imaging Department, Spire Cardiff Hospital

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

Our purpose

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

Our values

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

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

Our goal

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

Our priorities

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

Contents

1. What we did

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

Healthcare Inspectorate Wales (HIW) completed an announced Ionising Radiation (Medical Exposure) Regulations inspection of the Diagnostic Imaging Department at Spire Cardiff Hospital, Cardiff on 24 and 25 September 2024. During our inspection we looked at how the department complied with the Regulations and met the National Minimum Standards for Independent Health Care Services in Wales.

Our team for the inspection comprised of two HIW senior healthcare inspectors and a two specialist clinical officers from the Medical Exposures Group (MEG) of the UK Health Security Agency (UKHSA), who acted in an advisory capacity. The inspection was lead by a HIW senior healthcare inspector.

During 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 ten questionnaires were completed by patients or their carers and nine 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.

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

2. Summary of inspection

Quality of Patient Experience

Overall summary:
Patients provided positive feedback about their experiences of attending the diagnostic imaging department at the hospital. Staff were seen speaking to patients in a polite, friendly and professional manner, showing dignity and respect to the patients. Efforts were also seen to ensure that patients' privacy was protected.

Information was available to patients on how to provide feedback and how to raise a concern about their care. The results of a recent survey of patients were displayed on a "you said, we did" board. Patients would be informed about the waiting times when they arrived if there was a delay, during our inspection patients were seen to be dealt with promptly with no delays.

This is what we recommend the service can improve:

- Displaying more information in Welsh in the department.

This is what the service did well:

- Displaying relevant health promotion material across the waiting areas
- Staff were seen being kind and caring to patients and treating them with respect
- Waiting times appeared to be short and acceptable
- There were arrangements in place to make the service accessible to patients.

Delivery of Safe and Effective Care

Overall summary:
Staff had a good overall knowledge of IR(ME)R, local diagnostic reference levels (DRLs) were in place and dose audits had been carried out. There was good support from the medical physics experts (MPE) especially as they were only recently in post.

The department had a good culture of reporting of incidents and near misses.

Improvements were required to employer's procedures. These employer's procedures were due for review at a corporate level in November 2024 and the recommendations need to feed into this corporate review. A recommendation was

made to refer to professional body guidance when defining the roles and responsibilities of duty holders.

Mammography screening referrals from one health insurance company were not compliant with the IR(ME)R or the employer's procedures as they did not include clinical information to allow the exposure to be justified.

This is what we recommend the service can improve:

- Employer's procedures content and compliance with IR(ME)R
- Authorisation guidelines
- Quality assurance of equipment
- Communication of benefit and risk information
- Referrals for mammography screening.

This is what the service did well:

- Staff had a good overall knowledge of IR(ME)R
- Local DRLs were in place and dose audits had been carried out
- There had been good support from the MPE.

Quality of Management and Leadership

Overall summary:
The hospital director was the designated employer under IR(ME)R. There were also clear lines of leadership and responsibility noted in the department, this was supported by staff comments in the questionnaires.

Responses from staff were generally very positive. All respondents were satisfied with the quality of care and support they gave to patients.

Staff demonstrated they had the correct knowledge and skills to undertake their respective roles within the department. All staff knew and understood the Duty of Candour and understood their role in meeting the Duty of Candour standards.

The department's compliance with the health board's face to face mandatory training and appraisals was generally good.

This is what the service did well:

- Staff had adequate knowledge and skills to undertake their respective roles within the department
- Staff feedback was generally very positive
- There was a process in place to analyse the feedback and concerns received.

3. What we found

Quality of Patient Experience

Patient feedback
HIW issued online and paper questionnaires to obtain patient views on services carried out by Spire Cardiff Hospital to complement the HIW inspection in September 2024. In total, we received 10 responses from patients at this setting. Not all respondents completed the questionnaire to the end and questions were skipped throughout. Responses were positive across all areas, with all respondents rating the service as 'very good'. The one comment we received about the service was:

> ***"Excellent service from start to finish. Could not fault."***

Health promotion, protection and improvement
There was relevant health promotion material displayed across the waiting areas. Posters were displayed which provided benefit and risk information to patients having an X-ray and posters with information for the patients to inform staff prior to the exposure, if they may be pregnant or breastfeeding.

Written information was also available on the benefits of stopping smoking, as well as providing details of support organisations for patients with cancer and their carers. There were several posters noted on display informing patients about various health issues, along with other posters relating to chaperones, complaints, and a 'you said, we did' board.

Whilst there were some bilingual posters, there could be more displayed in Welsh.

The department should display more information in Welsh on the posters displayed.

Dignity and respect
Staff were seen being kind and caring to patients and treating them with respect. Discreet and appropriate conversations were heard at the reception desk when patients booked in and in the waiting room. We also noted staff assisting patients with mobility difficulties. Rooms were available for sensitive conversations between patients and staff.

The waiting area for patients was light, bright, airy and clutter free and doors to examination rooms were noted to be closed when in use. There were appropriate

changing facilities throughout the unit, where patients were able to change next to imaging rooms.

All patients in the questionnaire felt they were treated with dignity and respect and felt staff listened to them and answered their questions. All patients agreed that measures were taken to protect their privacy (e.g. private room, curtains drawn, cover-up provided etc.). All patients were able to speak to staff without being overheard by other patients and service users.

All staff respondents in the questionnaire thought patients' privacy and dignity was maintained and agreed patients were informed and involved in decisions about their care. Most respondents felt there were enough staff to allow them to do their job properly and all said they had adequate materials, supplies and equipment to do their work.

Care planning and provision
During our time at the setting, we noted patients being called through for their examination promptly. Waiting times appeared to be short and acceptable. We were told that if there was a delay, patients would be informed accordingly.

There was a clearly displayed notice in the diagnostic imaging waiting area advising patients to inform staff if their wait was longer than 15/20 minutes. We also noted that there was a sign to indicate how long the wait for results from their X-ray may be.

All respondents agreed that the wait between referral and appointment was reasonable and that at the department, they were told how long they would likely have to wait to be seen.

Patient information and consent
All patient respondents felt they were involved as much as they wanted to be in decisions about their examination and that staff explained what they were doing. All patients said they were given information on aftercare following their examination or procedure.

Communicating effectively
There was a hearing loop available at reception and staff confirmed they could access a translation service, should this be required to assist communication with patients whose first language was not English. In addition, there was a sign on display relating to accessibility standards at the hospital. For those patients who were unable to speak English, a telephone interpreter would be arranged. Additionally, with notice, the department could obtain an in-person interpreter.

We also saw a sign relating to the 'Active Offer', this was when a service was provided in Welsh without someone having to ask for it. There were two Welsh speaking members of radiology staff working at the department during our inspection. Both wore the 'iaith gwaith' logo on their uniform to indicate they were Welsh speakers.

The results of the patient feedback were clearly displayed at the department, together with the actions taken as a result of the feedback. None of the patients said that Welsh was their preferred language. One member of staff in the survey said that they were a Welsh speaker.

People's rights

There were arrangements in place to make the service accessible to patients such as translation services, wide corridors and large treatment room doors to allow for wheelchair access.

Staff we spoke with had a good awareness of their responsibilities in protecting and promoting patients' rights when attending the department, as well as staff rights when working in the department. We were also told that there were freedom to speak up champions, including a Lesbian, Gay, Bisexual, Transgender, Queer plus (LGBTQ+) freedom to speak champion.

Equality, diversity and human rights awareness formed part of the organisations mandatory staff training programme and there were relevant policies in place. Information provided confirmed that most staff were up to date with this training.

When asked whether they could access the right healthcare at the right time (regardless of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation), all but one patient who answered this questionnaire felt they could.

Delivery of Safe and Effective Care

Compliance with The Ionising Radiation (Medical Exposure) Regulations 2017

Employer's duties: establishment of general procedures, protocols and quality assurance programmes

Procedures and protocols
The employer had most of the written procedures and protocols in place as required under IR(ME)R. They included some good points which were highlighted during the inspection. The procedures in place were produced by the central corporate team and we were told these should be amended at a local level to reflect local requirements.

The self-assessment form (SAF) completed for the inspection stated that Spire issued a corporate template for all IR(ME)R documentation which was reviewed every three years or if there were any relevant changes requiring review. This template was then adapted locally to reflect local practice and reviewed annually to ensure all aspects still relevant or if any other changes instigated a review. Once reviewed, all IR(ME)R documents were ratified and signed by the hospital director, lead radiologist, imaging manager and MPE. It would also be discussed at the annual radiation protection committee (RPC) meeting.

Staff we spoke with confirmed that they had access to relevant policies and procedures, when required. Senior staff confirmed that arrangements were in place to notify staff when updates were made to the written procedures in place. Staff we spoke with were aware of where to find employer's procedures, should they need to refer to them. There was disparity between duty holders, for example radiographers were required to read the employer's procedures and sign to say they had understood them. No other staff group was required to do this. There was also a list of health care professions council registration numbers for radiographers included in the employer's procedures but not the corresponding GMC information for radiologists or cardiologists.

There was evidence that procedures were read and complied with by radiographers. However, the procedures must be agreed and signed by all staff groups, not just radiographers.

Some improvement had been made to the employer's procedures since a previous inspection at a Spire site in Wales and it was recognised employer's procedures were up for review in November 2024. This would be the opportunity to pick up on

the items identified in this inspection that would feed into this corporate review. This corporate level review should also consider the use of professional body guidance to address gaps in the procedures, as this was particularly evident in inconsistencies when defining the roles and responsibilities of duty holders and clinically significant and accidental unintended exposures.

IR(ME)R terminology was confused throughout the procedures. Some statements were not in keeping with IR(ME)R, for example referrers not needing IR(ME)R awareness, and justifying exposures, which was incorrect.

Not all employer's procedures required under Schedule 2 were included in the procedures reviewed at inspection. The employer's procedures that were missing include: procedures for carers and comforters, research, quality assurance programme in relation to equipment and giving information and written instruction in relation to nuclear medicine."

Quality of Management and Leadership

Staff Feedback

HIW issued an online questionnaire to obtain staff views on services carried out at the diagnostic imaging department at Spire Cardiff Hospital and their experience of working there. The questionnaire complemented the HIW inspection in September 2024. In total, we received nine responses from staff.

Responses from staff were generally very positive. All respondents were satisfied with the quality of care and support they gave to patients. All staff agreed that they would be happy with the standard of care provided by their hospital for themselves or for friends and family and would recommend their organisation as a place to work. We received one comment on the service, as follows:

> ***"I think more effort is needed to help new starters navigate the intranet and how to locate policies and how to complete incident reports."***

Governance and accountability framework

The hospital director was the designated employer under IR(ME)R. Where appropriate the employer had delegated tasks to other professionals working in the hospital to implement IR(ME)R.

There was also a clear governance and management structure demonstrated within the self-assessment, which was completed within the timescale required. The management team demonstrated a commitment to learn from HIW's inspection findings and make improvements where identified.

Management described the process to engage with staff on a regular basis, this included an open-door policy at the department, as well as visiting the department on a regular basis.

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

There were also clear lines of leadership and responsibility noted in the department, this was supported by staff comments in the questionnaires. Percentages agreeing with the comments of the organisation were as follows:

- My organisation was supportive --100%
- My organisation supported staff to identify and solve problems - 100%
- My organisation took swift action to improve when necessary - 89%.

Similarly, the percentage agreement with the questions below relating to staff's immediate and senior manager were as follows:

- My immediate manager can be counted on to help me with a difficult task at work - 89%
- My immediate manager gave me clear feedback on my work - 67%
- My immediate manager asked for my opinion before making decisions that affected my work - 56%
- Senior managers were visible - 89%
- Communication between senior management and staff was effective – 89%
- Senior managers were committed to patient care – 100%.

Staff we spoke with felt supported by all management and said that they were always visible in the department. They said that they were always provided with sufficient information that had risen from events, incidents, discussions held in meetings by management. Information was provided by email or verbally, this could be a one-to-one or in the morning huddle.

Senior staff we spoke with said that they engaged with staff on a regular basis through daily huddles, team meetings and appraisals. They said they operated an

open-door policy. They also described the way information was shared between management and staff.

Workforce planning, training and organisational development
We saw clear evidence that staff had completed relevant mandatory training to the required level, this included safeguarding training, safe moving and handling, and IPC training. Compliance with the appraisal process was at 100%, which was good practice. All staff in the survey, who could remember, said that in the last 12 months, they had an appraisal, annual review or development review.

Training records were maintained online and was used to monitor compliance and highlight any issues, overall compliance was at 100%. We were told that in addition to the regular training days, there were additional training opportunities to request for study days and payment for training. Opportunities were available for staff to take part in the Driving Clinical Excellence in Practice Programme which was a bespoke educational initiative that covered a comprehensive framework of necessary competencies and skills for registered nurses and allied health professionals. We were also told that one member of the department had been supported through a master's in science course and another completing a management course.

We viewed a sample of competency records for five staff and the training and entitlement matrix maintained by the department. The training records held were minimal. Competency and entitlement had been recently signed off but was incorrect in places. The corporate form used did not assist in this process. Additionally, there was no agreed review period for entitlement.

The employer must ensure that competency and entitlement are correct with an agreed review period.

Staff also described the cover for out of hours imaging. However, the arrangements were not documented to ensure staff knew the correct process of imaging out of hours and how to contact the appropriate practitioner.

The hospital must ensure that the arrangements for providing out of hours cover are documented to ensure staff know the correct process and how to contact the appropriate practitioner.

In the staff questionnaire, regarding their health and wellbeing at work, all staff agreed that, in general, their job was not detrimental to their health and that their organisation took positive action on health and wellbeing. All stated that their current working pattern and off duty allowed for a good work-life balance and all were aware of the occupational health support available to them.

All staff in the questionnaire felt they had appropriate training to undertake their role, one member of staff commented:

"In house training, not just e learning."

For the questions asked about the duty of candour in the questionnaire, all staff agreed that they knew and understand the duty of candour and understood their role in meeting the duty of candour standards. All staff said that their organisation encouraged them to raise concerns when something had gone wrong and to share this with the patient. Staff we spoke with were able to describe the duty of candour. There was a hospital policy in place, on the duty, which was located on the hospital intranet.

Citizen engagement and feedback

We were told that all patient experience information was gathered from emails sent to patients asking them about their experiences at the hospital by an external experience management company. The results were displayed in the department, a board detailing "You Said, We Did" information on how patient feedback has been used to improve services and experiences.

We saw information clearly displayed for patients on how they could make a compliant. Complaints were managed by the hospital governance team and logged onto datix. The time frame for acknowledging complaints and for sending the reply outcome letter were documented. There had been four complaints relating to the department in the last six months. Additionally, there had been ten compliments received over the same period.

Senior staff we spoke with described the arrangements in place to allow patients to provide feedback or raise concerns, this included verbal concerns. They described the process in place to analyse the feedback and concerns received to highlight themes and determine relevant action. This was done in conjunction with the governance team. There were quarterly governance meetings and patient experience meetings.

When staff were asked in the questionnaire whether they had fair and equal access to workplace opportunities, regardless of any protected characteristics, all but one agreed. All staff agreed that the workplace was supportive of equality and diversity.

All but one member of staff agreed that patients and service user experience feedback was collected within the department. All staff said that they received regular updates on patients and service user experience feedback. All staff who

had an opinion said that feedback from patients and service users was used to make informed decisions within the department.

All but two patients said they would you know how to complain about poor service, if they wanted to.

Responses in the staff questionnaire were as follows:

- Care of patients was my organisation's top priority - 100%
- Overall, I am content with the efforts of my organisation to keep me / patients safe - 100%
- I am involved in deciding on changes introduced that affect my work area - 67%
- I am able to meet the conflicting demands on my time at work - 89%.

The procedure for carers and comforters was included as an appendix rather than in the body of the employer's procedures. There were no procedures for research and giving information and written instruction in relation to nuclear medicine, which were not undertaken at the hospital. There was not an employer's procedure for the quality assurance of equipment, although there was reference to the detail included at the end of the employer's procedures under "Equipment Quality Assurance Programme".

Employer's procedure D, (related to the ensuring that quality assurance programmes in respect of written procedures, written protocols, and equipment) lacked the necessary detail required for this procedure for example version control criteria e.g. author, review and issue dates. The procedures seen had corporate footers that could cause confusion. The procedures were listed as version 1 with dates that were not relevant to local versions and dates. Furthermore, the ratification process for the employer's procedures were not outlined.

The employer must ensure that:

- **All duty holders are required to read the employer's procedures and sign to say they had understood them.**

- **The corporate level review should consider referring to professional body guidance to ensure IR(ME)R terminology and definitions are correct and consistent**

- **All employer's procedures as listed in Schedule 2 are included in the departments employer's procedures.**

- **Employer's procedure D, which related to the quality assurance of policies and procedures, has the necessary detail included relating to version control criteria and the ratification process for the employer's procedures are outlined.**

- **Local procedures must give the necessary detail relating to version control criteria for the procedures written in accordance with the updated procedure D.**

Referral guidelines

There was an employer's procedure on how to make a referral and where to access referral guidelines. The clinical referral guidelines, 'iRefer Making the best use of clinical radiology', were used. We were told that only some referrers had access to the corporate level system iRefer and provided on the organisation's intranet for

all healthcare professionals entitled to follow. We were told that access to the referral guidelines were included within the entitlement letter sent to referrers. On review of the referral forms, it was not possible to identify the operator who performed patient identification or the practitioner responsible for justification and authorising the exposure, due to the layout of the corporate level referral form.

The employer must ensure the practitioner who justified a referral and the operator who identified the patient are clearly identified and evidenced. This may involve adapting the existing referral form, to capture this information.

Senior staff we spoke with referred to various referral pathways which included, by post, paper form and e-mail as well as referrals where the patient would walk into the department from the orthopaedic clinic. These referrals go into the administration office and were entered onto the System Applications and Products in Data Processing (SAP), a software solution for business and then onto the radiology information system (RIS). This would then be sent to the relevant modalities, who would protocol and update the documents to confirm that the patient can be booked to attend the department.

During an examination of the referrals, we noted mammography screening referrals from one health insurance company were not compliant with IR(ME)R or the employer's procedures, as they did not include clinical information to allow the exposure to be justified. Another private health insurance providers referral for breast screening were found to be in order and the same process should be followed for all referrals and a procedure drafted for non-routine breast screening.

The employer must ensure that

- **Referral guidelines are made available to all referrers prior to referring**
- **A procedure is written and agreed for non-routine breast screening**
- **Referrals are only appointed where fully completed referral forms have been received, including sufficient medical data relevant to the exposure to allow justification of the referral**
- **Authorisation guidelines are put in place for breast screening, where appropriate.**

Diagnostic reference levels (DRLs) and dose recoding
Staff we spoke with described the action they would take should they identify a DRL had been consistently exceeded. They also told us that DRLs had recently

been updated due to a change of the MPE service. We saw evidence that local DRLs were in place and dose audits had been completed. However, the DRL for fluoroscopy were missing from the chart provided but they were in MPE dose audit.

The employer had a written procedure describing the process for the establishing, auditing and reviewing of DRLs for imaging examinations performed in the department.

The employer's procedure for dose assessment and recording lacked the necessary detail on where doses for each modality should be recorded by the operator.

The employer must ensure that dose recording for each modality is specified within the employer's procedure for all modalities.

Medical research
Medical research was not currently performed at the hospital

Entitlement
Staff we spoke with told us how they were made aware of their duties and scope of entitlement under IR(ME)R.

There was an employer's procedure in place to identify individuals entitled to act as referrer, practitioner or operator within a specified scope of practice. However, the process for entitlement within the employer's procedure was not clear and did not include all staff groups. There was work needed at corporate level to ensure documents that were being provided to sites were fit for purpose and the process was clear. The procedures did not use correct IR(ME)R terminology and definitions. Entitlement of groups such as referrers was not robust and they were not always being provided with referral guidelines. Entitlement for staff groups requires further development and should ensure all staff groups are included. The entitlement matrix needed to be further developed. The information held should reflect the individual duty holders scope of practice and review dates for entitlement, which could be done during annual appraisals.

The employer must ensure that the employer's procedure for entitlement includes:

- **A clear process that includes all staff groups**
- **At corporate level to ensure documents that are being provided to sites are fit for purpose and the process is clear**
- **Procedures which use correct IR(ME)R terminology and definitions**

- **Entitlement of groups such as referrers is robust and include access to referral guidelines**

- **Entitlement for staff groups captures all relevant staff groups.**

The employer must further ensure that the entitlement matrix reflects the individual duty holders and records review dates.

We also noted a number of issues as follows:

- Non-medical referrers were entitled at a corporate level, this included physiotherapists. It was unclear of how this process occurred and when entitlement was reviewed. Additionally, evidence of training was checked at corporate level and was not checked locally

- GP referrals were being assigned to the head of practice rather than the individual making the referral

- Some duty holders did not have the appropriate entitlement to perform the relevant practical aspects for example, surgeons were not entitled as operators to clinically evaluate images

- There was no process to inform referrers of their entitlement and scope of practice or how to access referral guidelines

- Entitlement forms did not capture the operator task of authorising exposures under authorisation guidelines.

The employer must ensure that the entitlement process is clear, to include:

- **Non-medical referrers are entitled locally and reviewed regularly. Evidence of the training must be available to be reviewed at a local level**

- **The radiology department receiving the referral needs to assign the referral to the individual GP making the referral and not the head of GP practice**

- **Staff roles are reviewed to include roles and responsibility for surgeons being entitled as operators to clinically evaluate, where appropriate**

- **All referrers are made aware of their entitlement, scope of referral and be given access to referral guidelines**

- **Entitlement forms need to be amended to include operator task of authorising an exposure under authorisation guidelines.**

Patient identification
The employer had an employer's procedure in place to correctly identify the individual to be exposed to ionising radiation. This also set out the procedure to follow when patients were unable to confirm their identity, such as patients who were unconscious. In addition, it addressed those situations where more than one operator was involved in the examination.

Staff we spoke with also had a clear understanding of the correct patient identification process. This was consistent with the relevant employer's procedure. The procedure stated the radiographer would carry out the final identity check and would tick and initial the relevant form. This form would be scanned into the operating system and recorded in RIS. However, the layout of the referral form meant that there was no specific place on the form for this information to be recorded in a consistent way.

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 we spoke with described the action they would take to make enquires of individuals, which was consistent with the employer's procedure.

However, the form used did not have a section where if the patient was pregnant and the examination went ahead, evidence of the justification and authorisation for this exposure could be recorded with this additional information.

The employer must ensure that referral forms included a section to allow the operator to record identification checks, pregnancy checks and evidence of authorisation for the exposure.

Communicating benefit and risk information
We saw posters explaining the benefits and risks clearly displayed within the waiting areas. Staff we spoke with referred to the information provided to individuals about the benefits and risks, such as 'How safe is your X-ray' leaflet, the safety questionnaire and the posters.

There was an employer's procedure on communicating benefit and risk information in place. This procedure needed to be updated to help staff understand what

information should be provided rather than directing them to resources. Additionally, some of the resource materials were found to be superseded and out of date. A consistent approach needed to be developed when providing this information for example, in theatre and catheterisation laboratory, consideration should be given to include it on the consent form, which will provide evidence that this is being carried out in a consistent way.

The employer must ensure that the employer's procedure on communicating benefit and risk information, includes the following:

- **What specific information will be provided by duty holders prior to the exposure to the individual**
- **A consistent approach when providing this information**
- **Consideration should be given to adding the information supplied on the consent form to provide evidence that this is being carried out**
- **Any resource materials provided, are in-date.**

Clinical evaluation
There was an employer's procedure in place for carrying out and recording an evaluation of medical exposures performed at the department.

The self-assessment form (SAF) described for diagnostic imaging, how clinical evaluation was undertaken and evidenced for each type of exposure. Clinical evaluation was undertaken by consultant radiologists in the form of a formal report.

Additionally, for exposures in theatre, the SAF stated that surgeons would clinically evaluate the images and record this in the patient's notes. For these exposures in theatre, the surgeons were not entitled as operators to perform this task. We were not provided with evidence that audits were being carried out on the clinical evaluation of theatre cases, in patient notes.

The employer must ensure that:

- **Audits are carried out on the clinical evaluation by surgeons on image exposures in theatre. These need to be recorded in the patient's notes to ensure compliance with the employer's procedures**
- **The surgeons carrying out the clinical evaluation are entitled as operators to perform this task.**

Non-medical imaging exposures
Senior staff confirmed that non-medical imaging exposures were performed in the department. There was also an employer's procedure in place for these types of exposures. We were told that radiologists justified these exposures.

The employer's procedure for making a referral included customs officers by special arrangement and local protocol with documented entitlement making referrals. As custom officers are not registered health care professional they cannot be entitled as referrers. This should be removed from the procedure.

The employer must ensure that the reference to customs officers as referrers is removed from employer's procedures.

Employer's duties - clinical audit
The electronic audit programme used (AMaT) included some clinical audits. We were told that following the recent radiation protection advisor's audit in August, the hospital planned to introduce more clinical audits with a focus on image quality. There was insufficient evidence noted during the inspection to ensure that there were clinical audits across all the modalities. We also noted that IR(ME)R audits were observational only and not a retrospective review, in keeping with best practice.

For clinical audits, more detail is required to identify who is responsible for carrying out the audit, who actions the outcomes and timelines for re-audit. The inclusion of these would support a more robust audit process.

Results were reviewed and discussed at team meetings and the monthly hospital clinical audit and effectiveness meeting. Any audit scoring below 95% had an action assigned in order to make improvements. The target of 95% was not in keeping with the requirements of IR(ME)R audit programme. We were told that the target is set at 95% in the software used and across all hospitals within Spire Healthcare and actions were developed when the audit compliance was <95%.

Cardiology was not included on the IR(ME)R audit programme and the audit of clinical evaluation written into the patient notes is currently not being carried out.

The employer must ensure that:

- **Compliance audit scores below 100% are reviewed and an action plan put in place**

- **Cardiology are included as part of the audit programmes**

- **The audit of recording clinical evaluation in patient notes is carried out.**

Employer's duties - accidental or unintended exposures
Staff members we spoke with were able to describe the processes for reporting incidents related to accidental or unintended exposures, this included submitting a report on Datix and considering the duty of candour. The incident reporting data showed a good culture of reporting of incidents and near misses. The process of sharing information was also described.

There was an employer's procedure in place for reporting and investigating accidental and unintended exposures. However, the definition of clinically significant, accidental and unintended exposures (CSAUE) did not consider or include psychological or moderate harm. This should be included in line with the definition found in the professional body guidance.

The employer must ensure that the employer's procedure for reporting and investigating accidental and unintended exposures includes an appropriate definition of a clinically significant accidental or unintended exposure. This should include reference to moderate harm or psychological harm in line within professional body guidance.

All staff respondents in the questionnaire said their organisation encouraged them to report errors, near misses or incidents, all felt staff who were involved were treated fairly. All staff also felt that when errors, near misses or incidents were reported, the organisation took action to ensure that they did not happen again and were given feedback about changes made in response to reported errors, near misses and incidents. All but one member of staff said they would feel secure raising concerns about unsafe clinical practice and all were confident their concerns would be addressed. All but one member of staff also said that if they were concerned about unsafe practice, they knew how to report it.

Duties of referrer, practitioner and operator
Staff we spoke with demonstrated a good understanding of their roles and responsibilities under IR(ME)R.

Justification of individual exposures
The process of justifying an exposure and how and where authorisation was recorded, was explained in the SAF provided. There was a procedure in place that covered the justification and authorisation of medical exposures involving ionising radiation.

The authorisation guidelines used at the department must be updated to include:

- Correct IR(ME)R terminology for example, using the term practitioner and not endorsement

- The purpose and objective of the authorisation guidelines

- An index of examinations included and list of exemptions for example pregnant individuals and children

- Authorisation of exposures to carers and comforters.

The employer must ensure that the authorisation guidelines used at the department include:

- **Correct terminology such as using the terms practitioner and not endorsement**

- **The purpose and objective of the guidelines**

- **An index and list of exemptions such as pregnant individuals**

- **Carers and comforters authorisation guidelines.**

The Radiology Information System (RIS) used did not have a list of cardiologists embedded in the drop-down box in the system to allow staff to identify who had justified the exposure in the catheterisation laboratory.

The employer must ensure that the RIS includes a list of entitled cardiologists embedded in the drop-down box in the system to allow staff to record correctly who had justified and authorised the exposure in the catheterisation laboratory.

Optimisation
The SAF stated that the operator selected equipment and protocols for individual examinations to ensure optimisation of the exposure by using specific equipment with lower dose capability, where available. The MPE was involved in optimisation for all radiological practice, optimisation was discussed in the radiation protection committee as part of the MPE work.

Currently, any local DRLs set were aligned to or below the national DRL which demonstrated good optimisation of doses. Staff we spoke with were able to describe how they ensured that doses were as low as reasonably practical (ALARP).

Paediatrics
Senior staff confirmed that medical exposures were not performed on children at the department.

Carers or comforters
The employer's procedure relating to carers and comforters was well written. However, the procedure was not contained in the same document as the other employer's procedures

The employer must ensure that the carers and comforters procedure is included in the same document as the other employer's procedures.

Expert advice
Spire Cardiff had a contract with IRS Ltd for radiation protection services, which included provision of appropriately trained and competent radiation protection advisors (RPA) and MPEs.

The involvement of the MPEs in the department was described as being good and the involvement was described in detail in the SAF. This was particularly positive to note as they had only recently been appointed and staff described the amount of work they had completed in a short period of time. The involvement of the MPE was listed in the SAF included quality control (QC) testing of equipment prior to clinical use, testing at regular intervals and dose collection for audits and establishment of local DRL's, where sufficient data was available.

During discussion with the MPE, we were told that level B testing of equipment was up to date.

Equipment: general duties of the employer
Senior staff we spoke with discussed capital funding and the central replacement programme, where the hospital was working through a rolling replacement for the number of items of equipment that needed replacement. Whilst the MPE was involved from the start of the process, the organisation had an approved supplier for each modality.

We reviewed the equipment inventory and noted that this was not fully compliant with IR(ME)R requirements. This included a lack of a manufacturers date and installation date. There was a list of the date of purchase/acquired but that might not be the date of installation. Additionally, there was not an employer's procedure for the quality assurance of equipment, although there was reference to the detail included at the end of the employer's procedures under "Equipment Quality Assurance Programme". The employer's procedure also needed to include

detail on the handover process and when medical physics were required to be called in to test equipment prior to putting the equipment back into clinical use.

The employer must ensure that:

- **The equipment inventory is completed in full**

- **There is an employer's procedure for the quality assurance of equipment which includes the quality assurance programme in place, details on the handover process and when medical physics were required to be called in to test equipment prior to being put back into clinical use.**

Furthermore, there was only one member of staff trained locally to carry out the level A QC testing currently. This was considered a potential single point of failure and there was a need to have a more robust QC team and to develop a quality assurance manual specific to this site. There had been a potential issue with QC testing in the past, but the MPE had been providing support to put this right.

The employer must ensure that additional staff are trained to carry out the QC testing of equipment.

Safe

Managing risk and health and safety
The department was accessible and easy to find, with disabled access and facilities for people with mobility difficulties. The department was clearly signposted with open double doors. The environment was clean and generally well maintained. The treatment rooms were spacious with mobility aids seen in the rooms. Signage was clearly displayed to alert patients and visitors not to enter controlled areas where ionising radiation was being used.

Senior staff we spoke with told us that there were a number of risk assessments in place including the equipment risk assessments and individual staff risk assessments for staff who were pregnant or had an illness. Information on the top five hospital risks and top three departmental risk assessments were in a folder in the department to ensure staff were aware of these risks.

Safety notices, details of incidents and other information was shared with the heads of department, for dissemination to staff at the daily morning hospital safety brief.

All patients said they were able to find the department easily. Staff we spoke with described the knowledge, skills and training required to undertake their respective roles and scope of practice within the department.

Infection prevention and control (IPC) and decontamination
There were suitable handwashing and drying facilities available and staff were seen using relevant personal protective equipment (PPE). All areas seen in the department were clean and well maintained.

Senior staff were able to describe how medical devices, equipment and relevant areas of the unit were decontaminated. The equipment seen was visibly clean. Additionally, staff we spoke with were aware of their responsibilities in relation to IPC and decontamination. The specific arrangements in place to treat symptomatic patients or patients with confirmed infections when attending the unit were also described.

Information was also displayed on the infection rates and hand hygiene results within the hospital as a whole. There was also information displayed on infection prevention expectations from staff and visitors to keep patients safe.

All patients in the questionnaire said that IPC measures were being followed and that the setting was very clean.

All staff who answered the questionnaire thought their organisation implemented an effective infection control policy and that appropriate PPE was supplied and used. All thought there was an effective cleaning schedule in place and that the environment allowed for effective infection control.

Safeguarding children and safeguarding vulnerable Adults
Staff we spoke with were aware of the organisation's policies and procedures on safeguarding and where to access these. They were also able to describe the actions they would take should they have a safeguarding concern.

Information was also displayed in the department on the safeguarding champions at the hospital. We were told that the safeguarding lead for the hospital for the day would be named at the morning meeting.

There was evidence from the sample of five training records we examined that showed that all staff were up to date with training, which had been completed at an appropriate level according to their role within the department.

Effective

Record management
A sample of five current patient referral documentation were examined. The sample showed that the referral records had been completed fully to demonstrate appropriate patient checks had been performed. This included patient identification and relevant clinical information from the referrer. Additionally, the canned reports (automatically generated reports based on pre-set specifications) were considered to be good.

The referral documentation required additional sections to evidence identification checks, pregnancy checks and authorisation.

The employer must ensure that referral documentation is revised to include additional sections to evidence identification checks, pregnancy checks and authorisation.

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: Spire Cardiff Hospital

Date of inspection: 24 and 25 September 2024

The table below includes any immediate non-compliance 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.

Risk/finding/issue		Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
1.	There were no immediate assurance issues					
2.						

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

Service representative:

Name (print):

Job role:

Date:

Appendix C - Improvement plan

Service: Spire Cardiff Hospital

Date of inspection: 24 and 25 September 2024

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.

Risk/finding/issue		Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
1.	Whilst there were some bilingual posters, there could be more displayed in Welsh.	The department should display more information in Welsh on the posters displayed.	Health promotion, protection and improvement	The imaging department will source further health information in Welsh to display in the waiting area.	Rachel Bartley Hospital Imaging Manager	30th November Completed
2.	The procedures were not agreed and signed by all staff groups.	The employer must ensure that: • All duty holders are required to read the employer's procedures and sign to say they had understood them.	IR(ME)R 2017 regulation 6(1) & Schedule 2	All duty holders will read and sign the employer's procedures to confirm they have understood them.	Fiona Conway Hospital Director	31st March 2025

	It was recognised that employer's procedures were up for review in November 2024. This would be the opportunity to pick up on the items identified in this inspection that would feed into this corporate review. This corporate level review should also consider the use of professional body guidance to address gaps in the procedures. As this was particularly evident in inconsistencies when defining the roles and responsibilities of duty holders and clinically significant and accidental unintended exposures.	• The corporate level review should consider referring to professional body guidance to ensure IR(ME)R terminology and definitions are correct and consistent		Spire Healthcare provides a corporate template for each individual site to adapt to local practice. This template has a 3-year review period, which coincided with both the HIW Inspection, and an update to the IR(ME)R regulations. A short extension to the review date (due November 2024) has been granted to ensure improvements and updates from both the HIW Inspection Report and the updated IR(ME)R 2024 regulations are included within the corporate template.	Geraint Evans National Clinical Specialist for Imaging	28th February 2025

	Not all employer's procedures required under schedule 2 were included in the procedures reviewed at inspection. Employer's procedure D, (related to the ensuring that quality assurance programmes in respect of written procedures, written protocols, and equipment) lacked the necessary detail required for this procedure for example version control criteria.	• All employer's procedures as listed in Schedule 2 are included in the departments employer's procedures. • Employer's procedure D, which related to the quality assurance of policies and procedures, has the necessary detail included relating to version control criteria and the ratification process for the employer's procedures are outlined. • Local procedures must give the necessary detail relating to version control criteria for the procedures written in accordance with the updated procedure D.		The Employer's procedures, as listed under Schedule 2, will be included in the department's employer's procedures. Employer's Procedure 'D', in the corporate template will be updated to include explicit instruction as per the RCR guidance for sites to specifically document their version control criteria and outline their ratification process for the employer's procedures. As above	Rachel Bartley Hospital Imaging Manager Geraint Evans National Clinical Specialist for Imaging	28th February 2025 28th February 2025

3.	On review of the referral forms, it was not possible to identify the operator who performed patient identification or the practitioner responsible for justification and authorising the exposure, due to the layout of the corporate level referral form.	The employer must ensure the practitioner who justified a referral and the operator who identified the patient are clearly identified and evidenced. This may involve adapting the existing referral form, to capture this information.	IR(ME)R 2017 regulation 10	A new, best practice version of the referral form will be developed alongside the new corporate policy template to capture all of the required information. Prior to publication of the updated referral form, the hospital will adapt their local referral form to include this information.	Geraint Evans National Clinical Specialist for Imaging Jennie Palmer Director of Clinical Services	28th February 2025 31st December 2024
4.	During an examination of the referrals, we noted mammography screening referrals from one health insurance company were not compliant with IR(ME)R or the employer's procedures	The employer must ensure that • Referral guidelines are made available to all referrers prior to referring	IR(ME)R 2017 regulation 6(1)	Legacy contracts will be reviewed centrally with commercial teams to ensure all referrers have received referral guidelines and entitlement as a referrer.	Geraint Evans National Clinical Specialist for Imaging	31st March 2025

	as they did not include clinical information and were outside national guidance to allow the exposure to be justified. Another private health insurance providers referral for breast screening were found to be in order and the same process should be followed for all referrals and a procedure drafted for non-routine breast screening.	• A procedure is written and agreed for non-routine breast screening	IR(ME)R 2017 regulation 10 (5)	A local audit of Mammography referrals has been completed, and identified one Oncology Consultant referrer within one referral group was not supplying sufficient clinical information on the mammography referrals. The agreement with this referral group is to follow standard NHS breast screening guidance, however, local authorisation guidelines for this referral group's referrals will be documented. A communication will be sent to the referral group to specify requirements to include referral guidelines and confirm that incomplete referrals will be returned. Authorisation guidelines in accordance with NHS	Fiona Conway Hospital Director	31st January 2025

				breast screening guidelines will be locally documented and justified by the site lead breast practitioner.		
		• Referrals are only appointed where fully completed referral forms have been received, including sufficient medical data relevant to the exposure to allow justification of the referral	IR(ME)R 2017 regulation 6 (5) (a)	Referrers will be advised that incomplete or insufficient referrals will be returned.	Jennie Palmer Director of Clinical Services	31st December 2024
		• Authorisation guidelines are put in place for breast screening, where appropriate.	IR(ME)R 2017 regulation 11 (5)	Authorisation guidelines for breast screening will be updated where appropriate.	Fiona Conway Hospital Director	31st January 2025
					Jennie Palmer Director of Clinical Services	31st December 2024

5.	The employer had a written procedure for the assessment of patient dose.	The employer must ensure that dose recording for each modality is specified within the employer's procedure for all modalities.	IR(ME)R 2017 regulation 10 (4) & Schedule 2 (1) (e)	The Employer's procedures will be updated with all radiation areas DRLs. The Diagnostic reference levels room posters will be updated and displayed in each radiation area. Employer's Procedure 'E', within the corporate template will be enhanced to include the RCR guidance for sites to specifically document dose recording for all modalities.	Jennie Palmer Director of Clinical Services Geraint Evans National Clinical Specialist for Imaging	31st December 2024 28th February 2025
6.	There was a written employer's procedure in place to identify individuals entitled to act as referrer, practitioner or	The employer must ensure that the employer's procedure for entitlement includes:		Employer's Procedure 'B', within the corporate template will be reviewed to document a clear process of identifying IRMER duty	Geraint Evans National Clinical Specialist for Imaging	28th February 2025

	operator within a specified scope of practice. However, the process in the employer's procedure was not clear and did not include all staff groups.	• A clear process that includes all staff groups	IR(ME)R 2017 Schedule 2 (1) (b)	holders from all staff groups.		
	There was work needed at corporate level to ensure documents that were being provided to sites were fit for purpose and the process was clear.	• At corporate level to ensure documents that are being provided to sites are fit for purpose and the process is clear	IR(ME)R 2017 regulation 6(1)	An update to the entitlement documentation templates will be carried out to facilitate this process. Best practice examples will be obtained from Spire Radiation Protection Advisors, review and approval of documentation will be completed by the Imaging Steering Group.	Geraint Evans National Clinical Specialist for Imaging	28th February 2025
	The procedures did not use correct terminology	• Procedures which use correct IR(ME)R	IR(ME)R 2017 regulation 6 (1)	IRMER terminology will be corrected where required.	Geraint Evans	28th February 2025

		terminology and definitions			National Clinical Specialist for Imaging	
	Definitions and entitlement of groups such as referrers was not robust and they were not being provided with referral guidelines.	• Entitlement of groups such as referrers is robust and include access to referral guidelines	IR(ME)R 2017 regulation 6 (5) (a) Schedule 2 (1) (b)	All IRMER referrers will receive updated referral guidelines, with advice on accessing i-Refer.	Geraint Evans National Clinical Specialist for Imaging	28th February 2025
	In addition, entitlement for staff groups needed further development and ensured they included all staff groups.	• Entitlement for staff groups captures all relevant staff groups.	IR(ME)R 2017 Regulation 6 Schedule 2 (1) (b)	A procedure for ongoing review of entitlement and timescales for review will also be included.	Geraint Evans National Clinical Specialist for Imaging	28th February 2025
	Also, the entitlement matrix needed to be on an individual basis as a live document and a review of entitlement would be at different stages for example during appraisal.	The employer must further ensure that the entitlement matrix reflects the individual duty holders and records review dates.	IR(ME)R 2017 Regulation 6 Schedule 2 (1) (b)	The hospital will capture all individual duty holders and record review dates on the entitlement matrix	Rachel Bartley Hospital Imaging Manager	28th February 2025

7.	The entitlement process is not clear or robust and we also noted a number of issues as follows: • Non-medical referrers were entitled at a corporate level, this included physiotherapists. It was unclear of how this process occurred and when entitlement was reviewed. Additionally, evidence of training was checked at corporate level and was not checked locally • GP referrals were being assigned to the head of practice rather than the individual referring	The employer must ensure that the entitlement process is clear, to include: • Non-medical referrers are entitled locally and reviewed regularly. Evidence of the training must be available to be reviewed at a local level • GP referrals are assigned to the individual making the referral	IR(ME)R 2017 Regulation 6 Schedule 2 (1) (b) & regulation 17 (4) IR(ME)R 2017 regulation 6 (2)	The hospital will develop a process to locally entitle non-medical referrers and will review this process on a regular basis. They will ensure that evidence of training is available at local level. Review current process to understand why the referrals are being picked up by the Head of Practice and not the referrer. The hospital	Rachel Bartley Hospital Imaging Manager Jennie Palmer Director of Clinical Services	31st March 2025 31st March 2025

				will put a pathway in place to support a 'refer to refer' process.		
	• Review of staff and roles and responsibility for example surgeons were not entitled as operators to clinically evaluate	• Staff roles are reviewed to include roles and responsibility for surgeons being entitled as operators to clinically evaluate, where appropriate	IR(ME)R 2017 regulation 6 (1) Schedule 2 (1) (b)	The hospital will update the entitlement documentation to ensure surgeons are entitled for clinical evaluation where appropriate.	Rachel Bartley Hospital Imaging Manager	31st March 2025
	• Referrers need to be made aware of entitlement, scope of referral and be given access to referral guidelines	• All referrers are made aware of their entitlement, scope of referral and be given access to referral guidelines	IR(ME)R 2017 regulation 6 (5) (a)	The hospital will make all referrers aware of their entitlement.	Jennie Palmer Director of Clinical Services	31st December 2024
	• Entitlement forms need to be amended to include operator tasks of authorisation under authorisation guidelines.	• Entitlement forms need to be amended to include operator task of authorising an exposure under authorisation guidelines.	IR(ME)R 2017 Regulation 6 Schedule 2 (1) (b) & regulation 11 (5)	The hospital will update the entitlement documentation to include operating task of authorising and exposure.	Jennie Palmer Director of Clinical Services	31st December 2024

8.	However, the form used did not have a section where if the patient was pregnant and the examination went ahead, evidence of the justification for this exposure could be recorded with this information.	The employer must ensure that referral forms included a section to allow the operator to record identification checks, pregnancy checks and evidence of authorisation for the exposure.	IR(ME)R 2017 regulation 11 (1) (b) (f) & 10 (4)	A new, best practice version of the standard imaging referral form will be developed alongside the new corporate policy template. Prior to publication of the updated referral form, the hospital will adapt their local referral form to record identification checks, pregnancy checks and evidence of authorisation for the exposure.	Geraint Evans National Clinical Specialist for Imaging Jennie Palmer Director of Clinical Services	28th February 2025 31st December 2024
9.	There was an employer's written procedure on benefits and risks,	The employer must ensure that the employer's procedure on communicating benefit				

		and risk information, includes the following:				
	This procedure needed to be updated to help staff know what information should be provided rather than directing them to resources.	• What specific information will be provided by duty holders prior to the exposure to the individual	IR(ME)R 2017 regulation 11 (2) (d)	Employer's Procedure 'I', in the corporate template update will be enhanced to include the RCR guidance for sites to specifically document procedures for discussing risks with patients.	Geraint Evans National Clinical Specialist for Imaging	28th February 2025
	A consistent approach needed to be developed when providing this information for example in theatre and catheterisation laboratory.	• A consistent approach when providing this information	IR(ME)R 2017 Schedule 2 (1) (i)	The updated employer's procedure 'I' will be shared with all relevant colleagues to ensure consistency in all departments.	Rachel Bartley Hospital Imaging Manager	28th February 2025
	Which should be added to the consent form to provide evidence that this is being carried out	• Consideration should be given to adding the information supplied on the consent form to provide evidence that this is being carried out	IR(ME)R 2017 Schedule 2 (1) (i)	The hospital will ensure consultants document risks and benefits of exposure to patients on the consent form.	Fiona Conway Hospital Director	31st December 2024

	Additionally, some of the resource materials were found to be superseded and out of date.	• Any resource materials provided, are in-date.	IR(ME)R 2017 Schedule 2 (1) (i)	The hospital will ensure that they source up to date resource materials for staff to use.	Jennie Palmer Director of Clinical Services	31st December 2024
10.	We noted that for exposures in theatre, the SAF stated that surgeons would clinically evaluate the images and record this in the patient's notes.	The employer must ensure that:				
	We were not provided with evidence that audits were being carried out on the clinical evaluation of theatre cases in patient notes.	• Audits are carried out on the clinical evaluation by surgeons on image exposures in theatre. These need to be recorded in the patient's notes to ensure compliance with the employer's procedures	IR(ME)R 2017 regulation 7	Monthly audits have been undertaken in AMaT with a compliance score of 100% consistently recorded.	Rachel Bartley Hospital Imaging Manager	30th November Completed
	For exposures in theatre, the surgeon	• The surgeons carrying out the clinical	IR(ME)R 2017 regulation 10 (4)	Entitlement of Surgeons and Cardiologists as	Fiona Conway Hospital Director	28th February 2025

	would clinically evaluate the images, but, they were not entitled as operators to perform this function.	evaluation are entitled as operators to perform this task.	Schedule 2 (1) (b)	operators for clinical evaluation will be completed in combination with point 6.		
11.	The employer's procedure for making a referral included customs officers by special arrangement and local protocol with documented entitlement making referrals. As custom officers are not registered health care professional they cannot be entitled as referrers. This should be removed from the procedure.	The employer must ensure that the reference to customs officers as referrers is removed from employer's procedures	IR(ME)R 2017 regulation 6, 10 & Schedule 2 (1) (b)	The reference to customs officers will be removed from the employer's procedures.	Jennie Palmer Director of Clinical Services	31st December 2024
12.						

	The target of 95% was not in keeping with the requirements of IR(ME)R Audit programme. We were told that the target is set at 95% in the software used and action was put in place when the figure was 95%	The employer must ensure that: • Compliance audit scores below 100% are reviewed and an action plan put in place	IR(ME)R 2017 regulation 7	The audit management system will be updated for Q1 2025 to allow individualised compliance targets, this will allow imaging audits to have a 100% compliance target. The hospital will complete a review of any IR(ME)R related audits to include actions if scores are below 100%.	Geraint Evans National Clinical Specialist for Imaging Jennie Palmer Director of Clinical Services	31st March 2025 31st December 2024
	Cardiology was not included on the IR(ME)R audit programme.	• Cardiology are included as part of the audit programmes		All relevant Imaging audits will be assigned to cardiology within the AMaT.	Geraint Evans National Clinical Specialist for Imaging	31st March 2025
	The audit of clinical evaluation written into the notes is	• The audit of recording clinical evaluation in patient notes is carried out.		The hospital will complete the audit of clinical evaluation written into patient notes on a quarterly basis going forwards and	Jennie Palmer Director of Clinical Services	31st March 2025

	currently not being carried out.			this activity will be monitored by the Clinical Audit & Effectiveness Committee (CAEC).		
13.	There was an employer's procedure in place for reporting and investigating accidental and unintended exposures. However, the definition of clinically significant, accidental and unintended exposures (CSAUE) was not correct and did not appear to consider psychological or moderate harm. There was also no mention of moderate harm or psychological harm. This needs to be included in line with	The employer must ensure that the employer's procedure for reporting and investigating accidental and unintended exposures includes an appropriate definition of a clinically significant accidental or unintended exposure. This should include reference to moderate harm or psychological harm in line within professional body guidance.	IR(ME)R 2017 regulation 8 (1) & regulation 6 Schedule 2 (1) (l)	Employer's Procedure 'L', in the corporate template update will be enhanced to include the RCR guidance for sites to specifically document procedures for Significant Accidental & Unintended Exposures, Clinically Significant Accidental & Unintended Exposures in line with RCR guidance.	Geraint Evans National Clinical Specialist for Imaging	28th February 2025

	professional body guidance.					
14.	The authorisation guidelines used at the department needed to be improved to include: • Correct terminology such as using the terms practitioner and not endorsement • The purpose and objective of the guidelines • An index and list of exemptions such as pregnant individuals	The employer must ensure that the authorisation guidelines used at the department include: • Correct terminology such as using the terms practitioner and not endorsement • The purpose and objective of the guidelines • An index and list of exemptions such as pregnant individuals	IR(ME)R 2017 regulation 6 (1) & regulation 11 (5)	The protocol folders will be updated to remove non-IRMER terminology. Protocols folders will be reviewed to include guidance as to where the protocols are for exposure authorisation, and where they are for technical instruction only. Protocol folders for authorisation will be	Jennie Palmer Director of Clinical Services Jennie Palmer Director of Clinical Services	31st December 2024 31st December 2024 31st December 2024

	• Carers and comforters authorisation guidelines.	• Carers and comforters authorisation guidelines.	IR(ME)R 2017 regulation 6 Schedule 2 (1) (n)	reviewed to include detail of authorisation guidelines and exclusions, including carers and comforters.	Jennie Palmer Director of Clinical Services	
15.	The Radiology Information System (RIS) used did not have a list of cardiologists embedded in the drop-down box in the system to allow staff to choose who had justified the exposure in the catheterisation laboratory.	The employer must ensure that the RIS includes a list of entitled cardiologists embedded in the drop-down box in the system to allow staff to record correctly who had justified and authorised the exposure in the catheterisation laboratory.	IR(ME)R 2017 Regulation 10 (2)	A list of entitled cardiologists will be added to the drop-down box within the RIS system, to allow staff to record who has justified and authorised the exposure in the Cath Lab.	Rachel Bartley Hospital Imaging Manager	30th November 2024 Completed
16.	The procedure relating to carers and comforters was well written. However, the procedure was not contained in the same	The employer must ensure that the carers and comforters procedure is included in the same document as the other employer's procedures.	IR(ME)R 2017 regulation 6 (5) (d) (ii) & Schedule 2 (n)	Employer's Procedure 'N', (Carers and Comforters) will be incorporated into the main template when	Geraint Evans National Clinical Specialist for Imaging	28th February 2025

	document as the other employer's procedures			updated, rather than as an appendix.		
17.	We reviewed the equipment inventory and noted that this was not fully compliant with IR(ME)R requirements, this included a lack of a manufacturers date or installation date. There was a list of the date of purchase/acquired but that might not be the date of installation. Additionally, there was not an employer's procedure for the quality assurance of equipment, although there was reference to the detail included at the end of the	The employer must ensure that: • The equipment inventory is completed in full • There is an employer's procedure for the quality assurance of equipment which includes the quality assurance programme in place, details on the handover process and when medical	IR(ME)R 2017 regulation 15 (2) IR(ME)R 2017 regulation 15 (1) (a)	The imaging equipment inventory will be updated to comply with IR(ME)R and will include the date of manufacture and installation date. The hospital will update the employer's procedures to detail the quality assurance schedule, handover process and testing of medical equipment	Jennie Palmer Director of Clinical Services Jennie Palmer Director of Clinical Services	31st December 2024 31st December 2024

	employer's procedures under "Equipment Quality Assurance Programme". The employer's procedure also needed to include detail on the handover process and when medical physics were required to be called in to test equipment prior to putting the equipment back into clinical use.	physics were required to be called in to test equipment prior to being put back into clinical use.		process prior to being used clinically.		
18.	Furthermore, there was only one member of staff trained to carry out the quality control (QC) testing currently.	The employer must ensure that additional staff are trained to carry out the QC testing of equipment.	IR(ME)R 2017 regulation 15 (1) (a)	Training will be arranged for additional staff to undertake quality control (QC) testing of equipment.	Rachel Bartley Hospital Imaging Manager	30th November 2024 Completed
19.	The referral documentation	The employer must ensure that referral		A new, best practice version of the referral	Geraint Evans	28th February 2025

	required additional boxes to evidence identification checks, pregnancy checks and authorisation.	documentation is revised to include additional sections to evidence identification checks, pregnancy checks and authorisation.	IR(ME)R 2017 regulation 10 (4) & 11(b)(c)	form will be developed alongside the new corporate policy template. Prior to the release of the updated referral form, the site will adapt their local referral form to include this information.	National Clinical Specialist for Imaging Jennie Palmer Director of Clinical Services	31st December 2024
20.	The training records held were minimal. Competency and entitlement had been recently signed off but was incorrect in places. The corporate form used did not assist in this process. Additionally, there was no agreed review period for entitlement.	The employer must ensure that competency and entitlement are correct with an agreed review period.	IR(ME)R 2017 regulation 17, Schedule 3 & Schedule 2 (b)	Review and update the current training and competency records for all staff. These will then be used to update the entitlement documentation for all duty holders. Review dates will be included – in combination with finding 6 above.	Rachel Bartley Hospital Imaging Manager Geraint Evans	31st January 2025

				The corporate template will be enhanced to assist in this process.	National Clinical Specialist for Imaging	31st March 2025
21.	Staff also described the cover for out of hours imaging. However, the arrangements were not documented to ensure staff knew the correct process of imaging out of hours and how to contact the appropriate practitioner.	The hospital must ensure that the arrangements for providing out of hours cover are documented to ensure staff know the correct process and how to contact the appropriate practitioner.	Workforce planning, training and organisational development	Formalise the current informal documented process for out of hours imaging cover, to include the process for contacting the appropriate practitioner.	Fiona Conway Hospital Director	30th November 2024 Completed

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): **Fiona Conway**

Job role: **Hospital Director**

Date: **29th November 2024**