Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

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

Diagnostic Imaging Department, Spire Yale 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 (IR(ME)R) inspection of the Diagnostic Imaging Department at Spire Yale Hospital, 20 and 21 June 2023. The imaging is carried out over three sites; Abergele, currently closed for renovation; Spire Yale main building and Chesney Court outpatient department, known as hospital or department in this report.

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

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

Before the inspection we invited patients or their carers to complete a questionnaire to tell us about their experience of using the service. We also invited staff to complete a questionnaire to tell us their views on working for the service. A total of 11 questionnaires were completed by patients or their carers and seven 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.

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

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

2. Summary of inspection

Quality of Patient Experience

Overall summary:
We found staff were committed to provide patients with a good experience when visiting the department. Patients provided positive feedback about their experiences of attending the department at the hospital.

Suitable arrangements were in place to promote the privacy and dignity of patients and we saw staff treating patients with respect and kindness.

There were arrangements in place for patients to provide feedback of their experiences. We also saw information was displayed on how the department had acted on feedback received.

Whilst there was relevant information displayed to patients in English such as the treatment, benefits and risks and pregnancy status, little information was in Welsh.

This is what we recommend the service can improve

- Display more information in Welsh.

This is what the service did well:

- Patients provided very positive feedback about the service they had received and the approach of the staff
- Staff placed an emphasis on promoting the privacy and dignity of patients.

Delivery of Safe and Effective Care

Overall summary:
The employer's procedures need to reflect local service provision giving clear processes for staff to follow in one place, including information from the self-assessment questionnaire and information given at the meeting with senior staff. There was no doubt that staff were carrying out the correct clinical practice but this was not reflected in the employer's procedure. A number of the improvements needed listed in this report were also highlighted in the previous remote inspection in 2021.

Referrals checked were mainly completed correctly and in full.

Safeguarding and infection control were well managed with leads nominated in these and other areas who were aware of their role.

The environment appeared well maintained and in a good state of repair. Staff were also proud of the new outpatient department that had recently opened and explained this had resulted in improved facilities for patients visiting the department. The improvement works in the main hospital were also being managed to maintain health and safety of staff and patients.

This is what we recommend the service can improve

- Update employer's procedures to reflect the local service provision
- The entitlement process needs to be documented correctly.

This is what the service did well:

- Maintaining a safe and pleasant environment
- Managing the safeguarding and infection control processes
- Ensuring the relevant risk assessments were in place.

Quality of Management and Leadership

Overall summary:
The hospital director was the designated employer under IR(ME)R and clear lines of reporting and responsibilities were described and demonstrated.

Feedback from staff was generally positive.

Compliance with the hospitals mandatory training requirements was also generally positive and the appraisals were up to date. The training competencies required under IR(ME)R need to be completed in full.

Staff stated that the skill mix of staff at the department was good and that the department was well staffed to cover the workload at the department.

This is what we recommend the service can improve

- Complete the training matrices for staff training competencies.

This is what the service did well:

- Staff were dedicated to their role
- Management and leadership was positive
- Mandatory training compliance was generally good.

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

3. What we found

Quality of Patient Experience

Patient Feedback

Responses received through HIW questionnaires were positive across all areas considered, with all respondents rating the service as 'very good'. Patient comments included the following:

> *"Welcoming staff, nice bright and clean accommodation."*

Health promotion, protection and improvement

We saw posters clearly displayed in the department advising patients who were pregnant or breastfeeding to inform staff prior to having their X-ray. This was so a decision could be made as to whether to proceed with the medical exposure.

There were several posters noted on display informing patients about various health issues, including mental health, domestic violence, losing weight and stopping smoking. Whilst there were some bilingual posters, there could be more displayed in Welsh.

The setting would benefit from more posters in Welsh.

Dignity and respect

We noted staff were treating patients with respect and kindness and engaging with them in a friendly yet professional manner.

Sub waiting areas were located near the treatment rooms, which provided a greater level of privacy away from the main waiting room. There was an individual changing room available providing privacy when patients were required to change out of their clothes for their examination. We also saw doors to examination rooms were closed when being used.

Staff we spoke with confirmed rooms were available should patients wish to speak with staff in private.

All patients who completed a HIW questionnaire agreed staff treated them with dignity and respect and measures were taken to protect their privacy. They also agreed they were able to speak to staff about their treatment without being overheard by other patients, and staff listened to them and answered their

questions. In all, 86% of patients agreed they were satisfied with the quality of care they gave to patients.

Senior staff said that the opening of the new centre at Chesney Court, which was a nearby extension to the Spire Yale facilities, improved the access to imaging, orthopaedic and outpatients provided to patients.

Patient information and consent
Information for patients on the benefits and risks associated with having an X-ray was prominently displayed within the department. This was also available bilingually. There were also posters displaying information about how imaging results were sent and when they should be expected.

We were told patients would be informed of any delays and offered the opportunity to reschedule the appointment as necessary. During the course of our inspection, we saw that patients attending the department were seen promptly.

All patients stated that they were able to find the department easily at the hospital.

Communicating effectively
There was a hearing loop in the reception area for use by patients with hearing difficulties. We were told that a translation service was available for patients as required. Additionally, there were Welsh speaking staff available at the department who wore the ‘iaith gwaith’ badge to identify themselves to patients and staff as Welsh speakers.

Reception staff said that if a referral was received and there was a note on the records about the patient's language needs, they would accommodate these. Typically, they would be happy to discuss booking an appointment with a family member if they spoke English. The policy is to then book an interpreter to be physically present during the treatment, rather than relying on family members.

Posters were also noted in the imaging suite corridor, in both English and Welsh saying that translation services were available and to ask a member of staff. There was also a poster about the "Accessible Information Standard", for patients to inform a staff member if they had any communication support needs. Staff we spoke with said that there was a hearing loop available in the imaging suite waiting area and some materials could be enlarged. As there were no materials in braille or sign language, the poster was taken down to be reviewed in line with what services were actually provided.

All patients said that they were given enough information to understand the benefits and risks of the examination and that staff explained what they were doing.

Care planning and provision
We viewed the patient journey at the hospital. At Chesney Court patients arrived at the main reception, were booked in, then were directed to the physiotherapy waiting area. Patients examined in the main hospital would normally be inpatients. There was a chair in the physiotherapy department that was raised for patients with mobility difficulties. Staff would then collect them to go for treatment. The small waiting area at the imaging suite reception was typically used by anyone accompanying the patient, or by patients waiting in between treatments.

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) 89% of patients said they had.

All patients who answered this question agreed that they were told at reception how long they would likely have to wait. Most patients agreed that the waiting time between referral and appointment was reasonable. Patient comments included the following:

"Fantastic care"

All staff said that patients were informed and involved in decisions about their care.

Equality, diversity and human rights
Staff we spoke with demonstrated a good awareness of their responsibilities in protecting and promoting patients' rights when attending the department.

At Chesney Court, all patient imaging and treatment areas were on the ground floor. There was easy access for wheelchair users and those with mobility problems. Accessible toilets were available.

We were also told that there was a Spire organisation-wide lesbian, gay, bisexual, transgender, queer (or sometimes questioning), intersex, asexual, and others (LGBTQIA+) network. The "plus" represents other sexual identities.

There were equality and diversity policies that staff could access through the company intranet. The hospital was also considered to be a centre of excellence

for patients transitioning gender and that the consultant involved in this surgery had given a training presentation to staff on this.

Citizen engagement and feedback
We viewed the complaints policy, which was a Spire wide policy that was in-date and referenced HIW. Complaints appeared to be well managed within the hospital and information was available on the number of complaints and any trends. The complaints summary was reported to the clinical governance committee on a quarterly basis There were suggestions from the committee on where the hospital could concentrate on reducing complaints such as managing expectations and keeping promises when a reply was due.

We noted cards in reception with a Quick Response (QR) code, encouraging patients to leave an online review. There was no provision of paper forms, potentially making it difficult for those unable to use QR codes to give feedback.

The patient experience noticeboard in the imaging suite waiting area, included chart of how patients rated the department. The noticeboard showed a 95% rating of the service as good or very good. There was also a dashboard poster covering various aspects across the hospital, for example admission, treatment, facilities, food and accommodation, discharge and staff, which was also up to date for quarter one of 2023. There was also a poster showing a sample of patient feedback comments.

There was a poster advising patients that were unhappy with the facilities or service to tell the person looking after them or another senior member of staff. The poster did not give any details of where patients could submit any complaint in writing or email. Staff told us that they would try to resolve complaints informally, if there was a need to escalate the complaint they would provide contact details as required. There was no evidence that contact details (email or address) were provided proactively and no provision of HIW details to escalate as necessary, escalation was seen as a 'within Spire' issue. We were told that the hospital were in the process of appointing a patient experience consultant.

A user-friendly leaflet summarising the complaints process called 'please talk to us' was available and we were told that the full policy was available on request. These leaflets need to be available in the public area for patients to view if they needed to make a complaint as not all patients (36%) knew how to complain about poor service.

The leaflet summarising the complaints process needs to be readily available to patients.

In all, 86% of staff, in the questionnaire, agreed patient experience feedback was collected within their department and agreed that they received updates on patient experience feedback in their department. All staff agreed that feedback from patients was used to make informed decisions and that their organisation acted on concerns raised by patients, with 86% agreeing the organisation took swift action to improve when necessary.

Delivery of Safe and Effective Care

HIW required senior staff within the department to complete and submit a self-assessment questionnaire (SAF) prior to our inspection. This was to provide HIW with detailed information about the department and the employer's key policies and procedures in respect of the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017. This document and the supporting documents submitted were used to inform the inspection approach.

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

Compliance with Ionising Radiation (Medical Exposure) Regulations

Duties of employer

Patient identification

There was an employer's written procedure in place to correctly identify the individual to be exposed to ionising radiation. However, additional detail was required to further improve this procedure, including the information supplied as part of the SAF. This related to, where there were two operators involved in the identification of the patient, the checklist used in theatre and the recording of who identified the patient. This was also required as part of the previous remote inspection in January 2021.

The employer must ensure the patient identification employer's written procedure is reviewed and updated to include additional detail setting out the process to be followed by staff.

Individuals of childbearing potential (pregnancy enquiries)

The employer had a written procedure for making enquiries of individuals of childbearing age. We were also provided with a copy of a pregnancy flow chart available to staff working within the department, that set out the steps to take following responses provided by the patient. The procedure would benefit from the inclusion of information detailed in the SAF relating to where more than one operator was involved in the exposure. This is of particular importance as the hospital was considered to be a national centre for gender transition surgery.

The employer must ensure the pregnancy enquiries employer's written procedure is reviewed and updated to include additional detail setting out the process to be followed by staff.

There was no information included in the procedure on ensuring gender inclusivity for these enquiries. The Society of Radiographers had published guidance to assist practitioners in understanding the needs of individuals with gender diversity and those with diversity in their sexual characteristics. We were told in discussion with senior staff that the policy for inclusivity was being reviewed in line with national guidance to provide a corporate policy on this. This should be instigated as soon as possible to safeguard patients and staff.

Non-medical imaging exposures
The SAF described that referrals were accepted for non-medical imaging such as certain employments and emigration. Senior staff also confirmed that non-medical imaging exposures were performed at the department. Staff we spoke with were aware of the actions to ensure that the exposures were identified, justified and optimised.

There was an employer's written procedure in place for these types of exposures. Again, the procedure lacked the detail expected in the procedures, setting out how referrals were identified, who justified and authorised these exposures and also how these exposures were being optimised. This was discussed with senior staff who agreed the procedure would be amended. This was also required as part of the previous remote inspection in January 2021.

The employer must ensure the employer's written procedure relating to non-medical imaging is reviewed and updated to ensure that it includes additional clarity regarding the areas highlighted.

Referral guidelines
The employer had established referral guidelines for the range of exposures to be performed within the department. The SAF stated that the department would accept referrals from any valid referrer, provided it met referral criteria. All referrals had to be in accordance with the guidance in the Royal College of Radiologists i-Refer website. We were told that external referrers have a letter of entitlement which stated they must ensure they had access to i-Refer.

The IR(ME)R regulations states at Regulation 6(5)(a) that the employer must establish recommendations concerning referral guidelines for medical exposures, including radiation doses, and ensure that these are available to the referrer.

The letter of entitlement referred to above should further state that the referrer needs to inform the employer of how they will ensure this access.

The employer's written procedure included reference to verbal referrals, the improvement plan following the inspection in 2021 stated that Spire Yale's local policy would be updated to confirm verbal referrals were not accepted. Staff we spoke with said that verbal requests were not accepted. We were told by senior staff that the section relating to verbal referrals would be removed from the procedures. This was also required as part of the previous remote inspection in January 2021.

The employer must ensure that the procedures reflect actual practice and remove the reference to accepting verbal referrals.

Entitlement
Senior staff we spoke with described the entitlement process. The employer, in this case the hospital director, had ultimate responsibility for radiation protection. They delegated some tasks to the Imaging Manager through the IR(ME)R employer's procedures. Consultants granted practising privileges by the medical advisory committee at the hospital were entitled to refer when they were granted these privileges. The resident doctor was granted entitlement to refer in the resident doctor handbook. Staff were unsure whether the resident doctor would clinically evaluate the images they referred for and act on those findings. If they do, then the resident doctor should also be entitled as an operator for clinical evaluation as should the orthopaedic surgeons and these need to be included on the entitlement document.

The employer needs to update the entitlement information within the employer's procedures and ensure that all staff have the relevant entitlements.

The process of how referrers were informed of their entitlement was described. The list of the various staff groups referenced in the employer's procedure included groups that would not refer at the hospital. This was because the employer's procedures are Spire Group wide and needed to be adapted at each site to reflect the local provision. Additionally, regarding non-medical referrals by physiotherapists, the entitlement in place needs to be reviewed to ensure the process has been completed appropriately by Spire. This was because the relevant section where Spire individually entitles these individuals had not been completed on the examples provided.

The employer must update the entitlement document to only include those staff groups who need to be entitled at the hospital.

The entitlement employer's procedure did not currently reflect all duty holders as required. This was because the entitlement for practitioners in the employer's procedure states that radiographers were practitioners for plain film radiography.

However, this was not reflected in the duty holder's entitlement document, where they were listed as operators.

The employer needs to ensure that the various documentation reflects the relevant entitlements at the hospital.

Procedures and protocols
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 an employer's procedure in place in relation to the quality assurance programme for the employer's written procedures. The content of this procedure was similar in content to the procedure checked in the inspection in 2021. At this inspection we highlighted that additional detail was required to clarify the process for document version control, as well as the ratification process and review frequency arrangements in place for the review of IR(ME)R documentation.

As highlighted in both this and the previous report in 2021, following our review of the written procedures in place, all of the employer's procedures were lacking the required level of detail and clarity to provide meaningful procedures for staff to follow. During discussions with staff as part of that inspection, we were provided with assurances on the practices being carried out. Additionally, the improvement plan stated that "The review of Spire's Employer's Procedures and subsequent Spire Yale local policy review will include all requirements set out in HIW's report". However, the practice described by staff in the SAF continued to exceed the level of detail available within the written procedures. Therefore, a review must be undertaken of all employer's procedures in place, to ensure that relevant documents accurately reflect the detail, practices and arrangements in place, as well as address the issues highlighted within our report. This was also included in the inspection in 2021.

The employer must ensure all written employer's procedures are reviewed and updated to ensure they accurately reflect practices and arrangements in place, as well as address the issues highlighted throughout this report.

In addition to the above the employer's procedures lack the required detail relating to the ratification process, version control and frequency of review.

The employer must ensure that the employer's written procedures relating to quality assurance of employer's written procedures and protocols are reviewed and updated to include additional detail regarding the areas highlighted.

Significant accidental or unintended exposures (SAUE)
Senior staff we spoke with described the process in place should an incident occur or was suspected to have occurred, which may have caused an accidental or unintended exposure to patients. There was also an incident response flow chart in the X-ray room in the department that was developed following an incident.

The explanation by senior staff together with the explanation in the SAF and the flow chart should be added to the employer's procedure. Senior staff were advised that the employer's procedure should contain information about the immediate response and detail investigation processes, who was involved, timelines, process and staff were referred to the IR(ME)R guidance document.

We also advised management that further detail was required in relation to clinically significant accidental or unintended exposures (CSAUE) as this was not explicitly described in the current procedures. An employer's procedure for the management of clinically significant accidental or unintended exposures was a requirement of IR(ME)R. We were told that both SAUE and CSAUE were managed in the same way. This was also reported in the last inspection in 2021.

The employer must ensure that the relevant employer's written procedures relating to significant accidental or unintended exposures are reviewed and updated to ensure they accurately reflect the process at the hospital.

The employer must ensure that there is an employer's written procedure which includes specific detail around the management of clinically significant accidental or unintended exposures.

Senior staff demonstrated the trend analysis of incidents, this was well-presented and what was required under IR(ME)R. Staff we spoke with also confirmed that feedback was provided by the department following reported incidents by a variety of means.

All staff responded positively in the questionnaire to the following statements:

- Their organisation treated staff who were involved in errors, near misses or incidents fairly

- My organisation supports staff to identify and solve problems

- When errors, near misses or incidents were reported, their organisation took action to ensure that they do not happen again

- They were given feedback about changes made in response to reported errors, near misses and incidents

- If they were concerned about unsafe practice, they would know how to report it.

All bar one member of staff responded positively to the statements that they felt secure raising concerns about unsafe clinical practice, were confident that their concerns would be addressed and that their organisation encouraged them to report errors, near misses or incidents.

Duties of practitioner, operator and referrer
There was a local radiation safety policy in place which had been signed by the IR(ME)R employer. This and other documentation referred to Spire Yale but they are also used in Abergele and the Imaging Centre at Chesney Court. To avoid any doubt all documentation needs to ensure it relates to all three sites and this needs to be amended across the IR(ME)R documentation, as noted above.

The employer needs to ensure that the employer's procedures relate to all three sites, to avoid doubt.

All staff we spoke with were aware of their duty holder roles but were unclear in some instances where local rules and IR(ME)R were relevant. Senior staff described suitable arrangements for how referrals for medical exposures were made to the department. There was as an employer's written procedure in place providing guidance on making a referral for medical exposures.

A referral form audit was undertaken to check compliance with the referral criteria set out in the IR(ME)R Employers procedures. Also, an imaging request return form was in use to inform referrers when they have made an incomplete referral or any required information has been omitted.

Justification of individual exposures
Justification and authorisation of exposures was included within the employer's written procedures under the section on duty holders. We were told that justification was made via a protocol from the reporting radiologist and we were assured that all scans were protocoled and justified by the radiologists.

The carers and comforters' policy covered the relevant information. However, discussions with some staff demonstrated a lack of knowledge around where to

find the procedure to follow for carers and comforters or how justification for these exposures happened. That is that the radiographers were acting as operators authorising to guidelines in the carers and comforters' procedure. Additionally, the entitlement documentation did not describe or entitle radiographers to act as operators authorising exposures to carers and comforters.

During discussions with radiographers, it was clear that the use of authorisation protocols (authorisation guidelines) were not well understood by staff or how they were to be used. Clarification was needed with staff about their role in the justification and authorisation process to help them understand how the authorisation guidelines were used and who the practitioner was.

The employer needs to ensure that all staff are fully conversant with the various policies and procedures including those relating to carers and comforters.

The entitlement documentation needs to describe the entitlement process relating to carers and comforters.

Optimisation
Information provided by senior staff showed consideration had been given to ensure doses arising from medical exposures performed in the department were kept as low as reasonably practicable.

There was a poster displayed in the department on how safe a scan was, which provided the individual to be exposed, or their representative, with information on benefits of having the exposure and the risks associated with the radiation dose. However, the employer's written procedures in this area lacked the detail to support staff in supplying additional information if requested from a patient.

We asked staff how exposures to individuals in whom pregnancy cannot be excluded were optimised. This was answered well by the more experienced radiographers but less well by the newer team members, some of whom stated lead protection would be provided which is not current national practice. This is an example of where the employer's procedure could be better written to assist staff with these discussions.

The benefits and risk in the employer's written procedures should include detail on how the information will be provided, including where verbal communication is not possible, who will provide the information, how staff can access further support and the staff training required should be included in the procedure.

The SAF described how the medical physics expert (MPE) was involved in optimisation for all radiological practice. This included routine equipment performance quality assurance, acceptance testing, annual patient dose audits and the process for procuring new equipment.

Following review of the evidence provided and discussions with staff, it was identified that there were no exposure charts available within the mobile x-ray unit for children and young people aged 16-18 years. This would help to further ensure that exposure doses were kept as low as reasonably practicable and optimised. The Imaging manager stated there were no paediatric exposures included on the mobile equipment exposure charts.

The employer must ensure that these exposure charts are developed, with the paediatric exposure chart being based on the child or young person's weight and age for patients aged 16-18 years.

Diagnostic reference levels
The employer had a written procedure for the use and review of diagnostic reference levels (DRLs) established for X-ray examinations performed at the department.

The procedure would benefit from information included in the SAF, such as the information from the retrospective review by the MPE, how DRLs were set, when they were set and how changes were communicated. There was also information in the SAF about what to do if DRLs were exceeded that would benefit from inclusion in the procedures. As a result, staff may not be aware of what to do in these instances. This was reflected in some of the conversations with staff, as we were not assured that they were fully aware of the use and meaning of DRLs or what to do if they were consistently exceeded.

The employer's procedures in relation to DRLs needs to include additional information in relation to setting of DRLs and what to do if they were exceeded.

Staff we spoke with were aware of what DRLs to use. We were also told that the units of measurement differed between some of the equipment used and the DRLs.

The unit of measurement of radiation dose needs to be consistent between the equipment and the DRLs.

Both national and local DRLs were clearly displayed within the department for staff to use. A small number of local DRLs were higher than national DRLs, this was referenced in the radiation protection advisors (RPA) report dated January 2023,

where it was also referenced that local DRLs were not relevant due to the change in equipment. During discussion with senior staff, they confirmed that the DRLs were set on aging equipment with a small sample. These local DRLs should not be used until there is a larger enough sample of doses to set new local DRLs.

Paediatrics
Senior staff confirmed that medical exposures were not performed on children below the age 16 in the imaging department, patients aged 16-18 were treated as small adults. However, paediatric guidance states patients under 18 should be considered as children and not small adults.

We were told that paediatric exposure charts were not available and the radiographer had to use their own clinical judgement.

The employer must ensure that these exposure charts are developed, with the paediatric exposure chart being based on the child's weight and age.

Clinical evaluation
There was an employer's written procedure in place for the carrying out and recording an evaluation for each medical exposure. All medical exposures must be evaluated and the resulting diagnostic findings recorded. If the practitioner or operator knows that an evaluation will not take place then the exposure is not justified and should not be carried out.

The records we examined had a clinical evaluation recorded for each medical exposure carried out.

Equipment: general duties of the employer
Senior staff provided an equipment inventory that contained all the information required under IR(ME)R. A quality assurance (QA) programme which was in accordance with recommended standards was also in place. A separate quality check (QC) manual detailed the measurements to be undertaken on all imaging equipment, including computed radiography readers, digital detectors and reporting workstations.

Routine performance checks were carried out both by the service engineers and medical physicists (level B) and in-house radiographers (level A). We reviewed a sample of two quality checks (QCs) provided by staff, one was incomplete. Senior staff provided an explanation of what happens when the equipment fails a QC. Senior staff explained that the incomplete QC document provided should have been completed.

We also discussed with senior managers and the MPE the actions taken with regard to the QC test fail on 23 May 2023. However, neither were aware of this fail.

A robust QA of equipment employer's procedure needs to be in place to detail the immediate safety actions to be taken, timelines and who to discuss a fail test with.

We were told that equipment issues were communicated to staff at the various daily meetings, completion of Datix and the 'equipment out of service' form displayed on equipment. The Imaging Manager receives the service or MPE reports directly and was responsible for ensuring that their recommendations are actioned. This usually entails requesting an engineer visit.

The QC of equipment and the employer's procedure for QA for the equipment needs more detail and a robust process including actions and time frames for the new radiation protection supervisor and other staff to follow. The documentation of the QC records require completing and to be kept up to date.

Regarding the QA of equipment, the employer's procedures must reflect the process where results are recorded, the training for staff carrying out the QC, who acts on the results and the corrective action process. Additionally, staff must be given protected time to perform the QCs.

Safe Care

Managing risk and health and safety
We found suitable arrangements were in place to promote the health and safety of patients visiting the department and staff working there.

We saw the environment appeared well maintained and in a good state of repair. Senior staff described upgrading works were being completed and explained this will result in improved facilities for patients visiting the department.

The department was clearly signposted from the main entrance of the hospital. There was level access to the hospital and the department was located on the ground floor making it accessible to patients using wheelchairs or with mobility difficulties. We saw waiting areas were of a sufficient size for the numbers of patients attending the department.

Clear signage was displayed to alert patients, visitors and staff to the areas where X-ray equipment was located. Access to these areas was also controlled to prevent unauthorised access when equipment was in use.

We did not identify any obvious hazards to the health and safety of staff working in the department or to patients and other individuals visiting the department.

Infection prevention and control (IPC) and Decontamination
All areas of the department and the equipment we inspected were visibly clean and tidy. There were suitable arrangements were in place to promote effective infection prevention and control.

The environment was well maintained, as befitted a new building. We saw that personal protective equipment was readily available for staff to use. Suitable handwashing and drying facilities and hand sanitiser were also readily available within the department.

The hospital had an appointed IPC lead who could be contacted for any advice.

We did notice a sharps bin in the X-ray treatment room that was positioned on top of a cabinet so may be difficult to access. This was subsequently moved to a more accessible location.

Staff we spoke with were aware of their responsibilities in relation to infection prevention control and decontamination. They were able to explain the arrangements for infection control and how medical devices, equipment and relevant areas of the unit were decontaminated.

All patients agreed that the setting was clean and 86% felt that infection prevention and control measures were being followed.

All staff agreed that their organisation implemented an effective infection control policy and that there was an effective cleaning schedule in place. They all agreed that appropriate PPE was supplied and used and that the environment allowed for effective infection control.

Safeguarding children and safeguarding vulnerable adults
Senior staff described a suitable process for responding to safeguarding concerns. There was an appointed safeguarding lead within the hospital and there was a flowchart for staff to follow should they be required to report any issues.

Staff we spoke with were aware of the safeguarding policies and procedures in place and where to access these. They were also able to describe the actions they would take should they have a safeguarding concern.

Safeguarding training was mandatory for staff. Training records provided to HIW showed that staff were expected to complete training to a level suitable to their

role. We were told that a several members of clinical staff would be completing safeguarding training relevant to their role before the end of the month.

Effective care

Participating in quality improvement activities

Clinical audit

The SAF described the clinical and IR(ME)R audits that were carried out at the setting. Senior staff explained that the audits were completed and logged on a Spire wide electronic audit management tool, which were centrally monitored.

Most of the audits described in the SAF were not considered to be clinical audits and the hospital were given examples of what should be subject to a clinical audit such as plain film image quality and laterality. One audit described relating to reject analysis was completed. More detail was required to explain who was responsible for the audit, who actions outcomes and timelines for reaudit, that could form part of the template for the audit. The required clinical audits that would be expected was discussed with staff.

Any issues or improvements required would be discussed at the daily meetings and the monthly Clinical Audit and Effectiveness meetings as well as the Senior Hospital Management Meetings.

We recommend that the hospital carry out the clinical audits as described during the inspection. The audits completed need to include background information to support the management of the audit.

There was reference in the employer's procedures to clinical audit, but this was only one sentence. The procedure should include purpose, responsibilities and the procedure as well as the programme, information to be contained in the audit reports and who is informed of the results.

The clinical audit employer's procedure needs to be completed in full.

Expert advice

We confirmed the employer had appointed and entitled MPEs to provide advice on radiation protection matters and compliance with IR(ME)R. The SAF described suitable arrangements for the MPE to be involved in, and provide advice on, medical exposures performed at the department.

There were references to two different MPEs in the documentation with one name of the appointed MPE for the hospital in the employer's procedure and another

name in the radiation protection committee terms of reference. Both were entitled as operators in the hospital.

The documentation needs to reflect both MPEs.

We were told that the MPE provided regular advice on the optimisation of the radiation protection of patients and other individuals subject to exposures, including the application and use of diagnostic reference levels.

Medical Research
Senior staff confirmed that research involving medical exposures was not performed at the department. The employer had a written procedure in place in relation to research involving medical exposures. However, as this was not applicable to the hospital, this should be clearly stated.

The employer's procedure needs to be updated to include reference to research not being carried out at the hospital.

Records management
There were suitable arrangements in place for the management of records used within the department.

We checked a sample of five current referrals and two retrospective referrals. Both retrospective referral records we examined had been completed fully to demonstrate checks had been conducted to promote patient safety. This included timely clinical evaluation. The sample of current referrals included three theatre cases that did not have the justification box ticked, this was completed correctly in general radiography.

The employer is to ensure that referrals are completed correctly and in full.

Quality of Management and Leadership

Staff Feedback

Almost all responses received through the HIW questionnaires from staff were positive, with most being satisfied with the quality of care and support they gave to patients and all agreeing that they would be happy with the standard of care provided by their hospital for themselves or for friends and family. As only seven responses were completed, this low number needs to be borne in mind when considering these responses.

Staff comments included the following:

> *"Our team works closely together to provide a exceptional service to our patients. Safety of staff and patients is a clear priority of management. The department is a happy place to work."*

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. Senior staff submitted details of the organisational structure and clear lines of reporting and responsibilities under IR(ME)R were described and demonstrated. It was positive to note that a member of the corporate team was present during the inspection. It was also positive to note that staff were dedicated and experienced. However, the imaging manager is leaving the organisation and a newly trained RPS is taking over QC programme –

All staff spoke with pride about the new outpatient and diagnostic centre at Chesney Court that was located within a mile of the main hospital. We were told that the new Chesney Court Imaging, Orthopaedic and Outpatient Centre increased the number of patients the hospital could treat, expand the range of patient services available and provide faster care for day case patients.

There were several methods used to pass information, both from senior management to staff and in reverse. Staff were able to describe these methods in full.

The majority of staff we spoke with said that senior managers were visible and that information was shared between management and staff.

Senior staff said that there were meetings on a Monday to discuss mandatory training compliance, on a Wednesday to discuss any issues related to risk and on Friday, feedback would be discussed.

All staff in the questionnaire agreed that:

- They were content with the efforts of their organisation to keep them and patients safe
- Care of patients was their organisation's top priority
- Senior managers were visible
- Communication between senior management and staff is effective
- Senior managers were committed to patient care
- Their immediate manager can be counted on to help them with a difficult task at work
- Their organisation was supportive.

Additionally, all bar one member of staff agreed that their immediate manager gives them clear feedback on their work and asked for their opinion before making decisions that affected their work.

Workforce planning, training and organisational development
Staff we spoke with said that the skill mix of staff at the department was good and that the department were well staffed to cover the current workload.

Most staff felt they had received appropriate training to undertake their role and that there were enough staff to enable them to do their job properly.

We examined the training competency and entitlement records, in relation to IR(ME)R, for four members of staff working in the department. There was evidence of numerous online Spire training completed. However, more radiology specific training and competencies should be undertaken. Whilst the Spire competency tracker was found to be adequate to record the training, the documented evidence also needs to be available to support this tracker.

We were also told that the training records and competency paperwork was a work in progress that required completion.

The training records and competency training and paperwork needs to be completed in full. The record of the training needs to be maintained in full to support the competency tracker.

Compliance with the appraisal process, known as Enabling Excellence was at 100%, which was good practice. The half yearly updates were also planned for July 2023. However, in the staff questionnaire 43% of staff said they had not had an appraisal, annual review or development review in the last 12 months. Additionally, we were told that one to one reviews with staff were carried out bi-monthly.

Generally, training records appeared to be well maintained and thorough. There was an electronic system used to monitor compliance and highlight any issues, overall compliance was at 74%. The training records supplied showed a good compliance with mandatory training, considering that the monitoring system relates to the current year only (April to March). For example, whilst safeguarding compliance for the current year was showing at 35%, the individual training records showed that all staff had completed the safeguarding training in the last year.

Staff also agreed in the questionnaire that they knew and understood the duty of candour and understood their role in meeting the duty of candour standards.

All staff agreed that they had fair and equal access to workplace opportunities. Additionally, all staff agreed that their workplace was supportive of equality and diversity. No staff who answered the question indicated they had faced discrimination at work within the last 12 months.

A total of 71% of staff agreed that their job was not detrimental to their health and 85% of staff agreed that their current working pattern and off duty allowed for a good work-life balance. However, whilst only 41% of staff agreed they would recommend their organisation as a place to work, all staff said they could meet the conflicting demands on their time at work.

It was positive to note that the majority of staff said they were aware of the occupational health support available to them and agreed the organisation took positive action on health and wellbeing.

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: Diagnostic Imaging Department, Spire Yale Hospital

Date of inspection: 20 and 21 June 2023

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

Improvement needed	Standard/ Regulation	Service action	Responsible officer	Timescale
No immediate assurance issues.				

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

Service representative:

Name (print):

Job role:

Date:

Appendix C - Improvement plan

Service: Diagnostic Imaging Department, Spire Yale Hospital

Date of inspection: 20 and 21 June 2023

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

Improvement needed	Standard/ Regulation	Service action	Responsible officer	Timescale
The employer is to ensure that more bilingual posters are displayed at the setting.	Health Promotion, Protection and Improvement	The service will source additional bilingual information posters to display.	Sue Jones Hospital Director	31st October 2023
The employer is to ensure that the leaflet summarising the complaints process needs to be available to patients.	Citizen Engagement and Feedback	The complaints leaflet will be available on the reception area for all patients to access	Sue Jones Hospital Director	31st October 2023
The employer must ensure the employer's written procedures are reviewed and updated to include additional detail setting out the	IR(ME)R 2017, Schedule 2, 1 (a), 1 (c), 1 (m)	The Employer's procedures will be updated to include procedures in respect to patient identification where there is more than one operator present	Geraint Evans National Clinical Specialist for Imaging	31st October 2023

process to be followed by staff in relation to: • Patient identification • Pregnancy enquiries • Non-medical imaging.		for an examination, and how this is documented and/or recorded electronically. This will be shared group-wide for implementation at other sites as required. The Employer's procedures will be updated to include procedures in respect to pregnancy enquiries where there is more than one operator present for an examination, and how this is documented and/or recorded electronically. This will be shared group-wide for implementation at other sites as required. The Employer's procedures will be reviewed for non-medical exposures and duplicate the current justification procedure for medico-legal referrals, where each request is individually		

		reviewed and justified by a practitioner.		
The letter of entitlement should further state that the referrer needs to inform the employer of how they will ensure access to i-Refer.	IR(ME)R 2017, Schedule 2, 1 (b)	i-Refer is no longer available in hardcopy. Spire is currently arranging a multi-user on-line corporate access arrangement with i-Refer. This is currently in initial set-up phase, and details of referral access are to be finalised following corporate account setup. The entitlement communication will be updated with reference to access to i-Refer by the referrers and what action to take if they do not have access.	Geraint Evans National Clinical Specialist for Imaging	31st October 2023
The employer must ensure that the employer's procedures are updated to reflect actual practice and	IR(ME)R 2017, Regulation 6 (5) (a)	Verbal requests are not accepted in current practice. The Employer's Procedures will be updated to reflect that verbal	Geraint Evans National Clinical Specialist for Imaging	31st October 2023

remove the reference to accepting verbal referrals.		requests are not acceptable and only written requests will be accepted.		
The employer needs to update the entitlement information within the employer's procedures to ensure that: • All staff have the relevant entitlements • The entitlement document only includes those staff groups who need to be entitled at the hospital • The various documentation reflects the relevant entitlements at the hospital.	IR(ME)R 2017, Regulation 6 (5) (b), 10 (3), Schedule 2, 1 (b)	The entitlements documented in the Employer's Procedures were adapted from a corporate template, and as such, included referral procedures and entitlements for services, such as mammography, which are not actually offered by the site. The Employer's Procedures regarding entitlement will be reviewed and updated to reflect actual practice at the site.	Geraint Evans National Clinical Specialist for Imaging	31st October 2023
The employer must ensure all written employer's procedures are reviewed and updated to ensure they accurately reflect practices and arrangements in place, as well	IR(ME)R 2017, Schedule 2	The site Employer's Procedures were adapted from a corporate template, and included procedures which are not actually offered by the site.	Geraint Evans National Clinical Specialist for Imaging	31st October 2023

as address the issues highlighted throughout this report.		The Employer's Procedures will be reviewed and updated to reflect actual practice at the site.		
The employer must ensure that the employer's written procedures relating to quality assurance of employer's written procedures and protocols are reviewed and updated to include: • Additional detail regarding the areas highlighted • That the procedures relate to all three sites, to avoid doubt.	IR(ME)R 2017, Schedule 2, 1 (D)	The Employer's procedures will be updated to detail the frequency and ratification process of the Employer's procedures. This will include clarification of the sites that the Employer's procedures pertain to, and will be tabled for discussion in the next radiation protection committee meeting.	Geraint Evans National Clinical Specialist for Imaging	31st October 2023
The employer must ensure that the relevant employer's written procedures relating to significant accidental or unintended exposures: • Are reviewed and updated to ensure they accurately	IR(ME)R 2017, Regulation 8, Schedule 2, 1 (l)	A flowchart describing each step of the SAUE process will be created. This will also be included into corporate policy.	Geraint Evans National Clinical Specialist for Imaging	31st October 2023

reflect the process at the hospital • Includes specific detail around the management of clinically significant accidental or unintended exposures.				
The employer needs to ensure that in relation to carers and comforters that: • All staff are fully conversant with the various policies and procedures • The entitlement documentation needs to describe the entitlement process.	IR(ME)R 2017, Regulation 12 (5), Schedule 2 (n)	A teaching session will be arranged to clarify the justification and authorisation procedure and entitlements for the carers and comforter's policy. The entitlement document will describe the entitlement process.	Site Radiation Protection Advisors and Radiation Protection Supervisor	31st October 2023
The benefits and risk in the employer's written procedures should include detail on how the information will be provided, including where verbal	IR(ME)R 2017 Regulation 11 (2)	There are safety information posters available. To enhance this information, best practice ideas will be tabled	Site Radiation Protection Advisors and Radiation Protection Supervisor	31st October 2023

communication is not possible, who will provide the information, how staff can access further support and the staff training required should be included in the procedure.		for discussion in the next Radiation Protection Committee meeting.		
The employer must ensure that these exposure charts are developed, with the paediatric exposure chart being based on the child or young person's weight and age for patients aged 16-18 years.	IR(ME)R 2017, Regulation 12 (8) (a)	The site does not X-ray patients under the age of 16. The exposure charts will be reviewed and updated, and as an adjunct to the updated Employer's procedures, make clear how to use the exposure charts for 16–18-year-old patients.	Site Radiation Protection Advisors and Radiation Protection Supervisor	31st October 2023
The employer needs to ensure that the employer's procedures in relation to DRLs includes additional information in relation to the setting of DRLs and what to do if they were exceeded.	IR(ME)R 2017, Regulation 6 (5) (c), 6 (7)	The Employer's procedures will be updated to include procedures in respect to actions to take when DRLs are regularly exceeded. Data collection for establishing DRLs is still underway due to new equipment being installed across	Site Radiation Protection Advisors and Radiation Protection Supervisor	31st October 2023

		the site, so progress on establishment of DRLS will be tabled for discussion in the next Radiation Protection Committee meeting.		
The unit of measurement of radiation dose needs to be consistent between the equipment and the DRLs.	IR(ME)R 2017, Regulation 15	This will be raised with the RPA and tabled for discussion in the next Radiation Protection Committee meeting.	Site Radiation Protection Advisors and Radiation Protection Supervisor	31st October 2023
The employer needs to ensure that the equipment employer's procedure includes: • A robust QA process that needs to be in place to detail the immediate safety actions to be taken, timelines and who to discuss a fail test with. • Reflect the process where results are recorded, the training for staff carrying out the QC, who acts on the results and the corrective	IR(ME)R 2017 Regulation 15 (1)	The site uses the RPA QA system QADRIS. The Employer's procedures will be reviewed and updated to more clearly detail the QA tests for each item of imaging equipment, recording of results and action to take in the event of QA failure.	Site Radiation Protection Advisors and Radiation Protection Supervisor	31st October 2023

action process. Additionally, staff must be given protected time to perform the QCs.				
The employer must ensure that: • The clinical audit employer's procedure contains the relevant information • The hospital carry out clinical audits as described during the inspection. • The clinical audits completed need to include full information to support the management of the audit.	IR(ME)R 2017, Regulation 7	Presentation and education session on clinical audit will be shared with site. Further group-wide education events on clinical audit to be arranged. The hospital will carry out clinical audits adding actions where compliance is below 95%	Geraint Evans National Clinical Specialist for Imaging Amy Watkins Director of Clinical Services	31st October 2023
The employer's procedure needs to be updated to include reference to research not being carried out at the hospital.	IR(ME)R 2017, Schedule 2, 1 (g)	The Employer's procedures will be reviewed and updated to clarify that research	Geraint Evans National Clinical Specialist for Imaging	31st October 2023

		examinations are not carried out at the site.		
The employer is to ensure that referrals are completed correctly and in full.	IR(ME)R 2017, Regulation 6 (5) (a)	Site to conduct audit of referrals, as they are received, to ensure they are being correctly and fully completed. The employer's procedure will be updated to include a reference to referral information.	Site Radiation Protection Supervisor Geraint Evans National Clinical Specialist for Imaging	31st October 2023
The employer must ensure that all documentation at the hospital refers to all MPEs involved in the operation of the hospital.	IR(ME)R 2017, Regulation 14 (1)	A full list of MPEs to be obtained and included in the Employer's procedures, with each MPE involved in the operation of the hospital named individually.	Site Radiation Protection Advisors and Radiation Protection Supervisor	31st October 2023
The employer is to ensure that competency training records and paperwork is completed in full. The record of the training needs to be maintained in full to support the competency tracker.	IR(ME)R 2017, Regulation 17	The competencies of all staff will be updated and recorded on a competency tracker.	Amy Watkins Director of Clinical Services	31st October 2023

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

Service representative

Name (print): Sue Jones

Job role: Hospital Director

Date: 14 August 2023