Ionising Radiation (Medical Exposure) Regulations Remote Inspection (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 people in Wales receive good quality healthcare

Our values

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

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

Our priorities

Through our work we aim to:

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

1. What we did

Healthcare Inspectorate Wales (HIW) completed an announced remote Ionising Radiation (Medical Exposure) Regulations inspection of Spire Yale Hospital's Diagnostic Imaging Department on 12 and 13 January 2021.

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

HIW explored how the service:

- Complied with the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R).
- Complied with the Care Standards Act 2000 and requirements of the Independent Health Care (Wales) Regulations 2011
- Met the National Minimum Standards for Independent Health Care Services in Wales.

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

2. Summary of our inspection

Overall, staff awareness of their IR(ME)R responsibilities was generally good.

Discussions with managers and department staff provided assurance that appropriate arrangements were in place to ensure examinations were being undertaken safely. However, on review of the written procedures provided as evidence, it was clear that the practice that was described by staff exceeded the information detailed within the relevant procedures. All written procedures reviewed were lacking the level of detail required.

There was evidence of an experienced and committed workforce, with a good team working ethos. Staff were happy with the level of support provided by the department lead. However, concerns were highlighted in relation to the level of support and engagement provided by senior managers for the wider hospital.

Concerns were highlighted around available capacity to enable staff to carry out all relevant tasks required as part of their duty holder roles.

This is what we found the service did well:

- Information provided by staff indicated that adequate arrangements had been implemented by the service to allow for effective infection prevention and decontamination within the service. Arrangements which had been strengthened as a result of Covid-19
- There were good arrangements in place to collate patient feedback on the services being provided.

This is what we recommend the service could improve:

- All employer's written procedures must be reviewed to ensure that they accurately reflect the practices and procedures in place, and provide the required level of information to guide staff in performing their roles.

- Ensure that methods are implemented to improve the visibility, engagement and support being provided to the department from senior managers

- Ensure that clinical and IR(ME)R audits are reinstated as soon as possible

- Ensure a review is undertaken to confirm that staff have sufficient capacity to undertake their relevant roles

- Ensure routine supervision and appraisals are being carried out, to allow for training and development needs to be identified and monitored.

3. What we found

Background of the service

Spire Yale Hospital, which is part of the Spire Healthcare Group, is registered with Healthcare Inspectorate Wales to provide a range of inpatient and outpatient private healthcare services. A full description of the services provided can be seen on the hospital's website, or within their written Statement of Purpose[1].

The radiology department at Spire Yale Hospital consists of one general x-ray room which includes general fluoroscopy equipment. Examinations are also provided using a range of other equipment including a mobile x-ray unit, ultrasound, and a mobile fluoroscopy unit. Additionally, computed tomography (CT) and magnetic resonance (MR) scanning services are provided by Spire mobile scanners visiting the hospital on a regular basis.

There are five Radiographers employed to work within the department, which includes the department lead. There are also a number of Consultant Radiologists that have practicing privileges at the hospital, but are not employed by Spire Healthcare.

The department also has support and advice from Medical Physics Experts (MPEs), secured under contract with Integrated Radiology Services (IRS) Ltd.

[1] A statement of purpose must be completed by regulated services (such as independent hospitals). The document should describe what the business does and for whom. The independent health care regulations provide such businesses with a list of information that should be present within the statement of purpose.

Quality of patient experience

As part of our remote inspection, we reviewed some of the arrangements in place to communicate with and obtain feedback from patients regarding the services provide.

Information provided indicated that there were adequate arrangements in place to meet the communication needs of patients attending the department.

There were good arrangements in place to collate patient feedback on the services being provided, with a regular patient surveys carried out, as well as a clear process for dealing with and responding to concerns received by the service.

As part of our remote IRMER inspection methodology, we developed an online patient survey, to allow patients to provide their views and experiences on the services provided within the department. This survey was publicised via a poster displayed within the department in the lead up to our inspection, as well as on the HIW social media pages.

Unfortunately, for this inspection we did not receive any responses from patients to our online survey. Therefore, the findings set out below are based on staff discussions and evidence provided by the service.

Communicating effectively

We were informed by staff that there was a hearing loop installed within the main reception area, to assist patients wearing hearing aids, when communicating with staff. However, staff were unaware of any other aids available for patients with sensory impairments within the department, but informed us that no issues had occurred as a result of this. The department lead confirmed arrangements could be made to provide information in large print or Braille on request.

Staff informed us that access was available to telephone translation services, should a patient attend the unit who is unable to communicate in English. We were also informed that there were Welsh speaking staff available in the hospital, should a patient prefer to communicate in Welsh.

Citizen engagement and feedback

Arrangements were in place to allow patients to provide feedback on their experiences using the department. We were informed that there were feedback cards available within the department to allow patients to provide their views. Staff we spoke with also confirmed that feedback received was routinely shared with them.

Additionally, we were informed that a patient survey is completed on an annual basis by the department, following which the results are displayed within the main corridor of the department. As part of our inspection, we reviewed the results from the most recent survey completed in March 2020. Results from the survey were extremely positive with all patients rating overall experience using the department as ‘excellent’ or ‘very good’.

As well as the department survey, we were informed that Spire Healthcare also completes online inpatient and outpatient surveys, to collate the patient views. Previously this survey had not covered diagnostic services, however, senior staff confirmed that it had now been agreed that future surveys will cover diagnostics. This will mean additional feedback will be available to the department.

Staff we spoke to explained that on the occasions where verbal concerns were raised by patients, attempts were initially made, where possible, to try to resolve the issue with the patient quickly and efficiently. Where this is not possible, we were informed that patients are signposted to the concerns process. We were told that there was a poster displayed in the hospital main reception advising patients of the concerns procedure.

There is a designated concerns coordinator within the hospital responsible for dealing with any formal concerns received by the service. We were told that the coordinator analyses and responds to all concerns. Information about concerns raised by patients is also discussed with department leads and shared with department staff via email where required.

Delivery of safe and effective care

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

Overall, staff awareness of their IR(ME)R responsibilities was generally good.

Information provided by staff indicated that adequate arrangements had been implemented by the service to allow for effective infection prevention and decontamination within the service.

Discussions with managers and department staff provided assurance that appropriate arrangements were in place to ensure examinations were being undertaken safely. However, on review of the written procedures provided as evidence, it was clear that the practice that was described by staff exceeded the information detailed within the relevant procedures. Our findings within this section include the areas where the requirement for additional detail within the documentation reviewed was highlighted.

Compliance with Ionising Radiation (Medical Exposure) Regulations

Duties of employer

Patient identification

The employer had an up to date written procedure for staff to follow to correctly identify patients prior to their exposure. This aimed to ensure that the correct patient had the correct exposure in accordance with the requirements of IR(ME)R 2017. The procedure set out that staff were expected to confirm the patients name, date of birth, address and body part expected to be imaged, before proceeding with any exposure. This approach is in keeping with current UK guidance[2].

[2] Department of Health and Social Care (2018); Guidance to the Ionising Radiation (Medical Exposure) Regulations 2017

On review of the employer's written procedure, we identified that additional detail was required in a number of areas, to clarify the action that should be taken by staff to confirm the identification of different types of patients they may encounter. This included unconscious patients in theatre, individuals who may lack capacity and paediatric patients. Additionally, the employer's procedure should clearly detail where identification checks are recorded, how the individuals responsible for completing checks are identified and the required action if there are any discrepancies in demographics.

The areas requiring further clarity were discussed with senior managers as part of our inspection, and assurance was provided around the department's actual practice. Additionally, department staff we spoke to, were able to describe the correct procedure to identify patients before carrying out an exposure. However, the employer must ensure the written procedure accurately reflects the required steps relating to patient identification and that additional detail is added setting out the action staff should take for all types of patients they may encounter.

Improvement needed

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 for all types of patients they may encounter.

Individuals of childbearing potential (pregnancy enquiries)

There was an employer's written procedure in place in relation to the process for carrying out pregnancy enquiries for individuals of childbearing age, prior to any exposures. This procedure aimed to ensure that such enquiries were made in a standard and consistent manner.

The procedure identified the staff responsible for making the relevant enquiries and set out the process to follow depending on the individual's response. The procedure also included the age range of patients who should be asked about pregnancy.

We identified a number of areas within the procedure which would benefit from additional detail for staff. These included clarity around where pregnancy enquiries are recorded, detail around gender diversity, including links to safeguarding procedures and also the required action when engaging with patients with learning difficulties or communication challenges.

We were informed that there are posters displayed within the department advising individuals to speak with staff if they either are or think they may be pregnant. This is important to minimise potential harm to an unborn child from the exposure to ionising radiation.

Evidence was provided of a pregnancy flow chart available to staff working within the department. This document set out the steps to take following responses provided by the patient. Staff we spoke to were able to describe their responsibilities in regards to the pregnancy enquiries, which were in line with the procedure in place.

Improvement needed

The employer must ensure that a review of the employer's written procedure relating to pregnancy enquires is undertaken to ensure that there is sufficient detail on the process to be followed by staff for all types of patients they may encounter.

Non-medical imaging exposures

There was a brief written procedure in place in relation to non-medical imaging exposures[3]. The procedure set out the categories that are accepted within the department and included assessments relating to insurance and litigation. However, it was identified that additional detail should be included in the employer's procedure to set out how referrals are identified, who justifies and authorises these exposures and also how these exposures are being optimised.

Improvement needed

The employer should 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 referral guidelines in place use the Royal College of Radiologists (RCR) iRefer publication which sets out the referral criteria and provides an indication

[3] Non-medical imaging exposures include those for health assessment for employment purposes, immigration purposes and insurance purposes. These may also be performed to identify concealed objects within the body

of the radiation dose for individuals wanting to refer a patient for imaging. Information provided indicated that referrals are accepted from entitled referrers, on condition that it is in accordance with the set guidance for referral. The required information includes relevant patient details, name of referring clinician, signature of the referrer, examination required and sufficient clinical information to justify the exposure. The required information was set out in the department's radiology request form.

It was unclear from information provided and discussions with staff, how the referral guidelines are being made available to all potential referrers to the department, specifically those based outside of the hospital. Therefore, the relevant written procedures need to be updated to provide additional clarity around how this information is being made available to all referrers.

Following review of the information provided and discussions with senior staff, it was highlighted that the procedures describe a process for verbal referrals to be received by the department. This was discussed with senior staff as there was evidence of past radiation incidents from this practice within the service. Assurances were given by senior management that the practice of verbal referrals was being addressed. The employer must ensure that a robust written process is in place, setting out the correct practice for staff to follow in relation to referrals, to mitigate the risks of any incidents occurring in the future.

Improvement needed

The employer should update the relevant written procedures to set out how referral guidelines are made available to all entitled referrers.

The employer must ensure there is a robust written process in place for referrals received by the Radiology Department and review the practice of verbal referral.

Duties of practitioner, operator and referrer

The employer had a system in place to identify the different IR(ME)R roles of the professionals involved in referring and performing radiology examinations for patients. The Radiation Safety Policy in place for the department detailed

the specific duty roles and responsibilities in line with IR(ME)R, which are employer referrer[4], practitioner[5] and operator[6].

Some information was available within the policy setting out the training requirements for each duty holder role. The policy states that individuals will not act as practitioner or operator, unless they are adequately trained under IR(ME)R as part of their professional qualifications or separately, and have received appropriate practical training where necessary. However, following review of this policy, as well as other relevant employer's procedures, it was highlighted that documents would benefit from more clarification in relation to the specific training required for each of the duty holder roles and include those working remotely from the diagnostic imaging department.

Staff we spoke with had a clear understanding of their relevant duty holder roles and scope of entitlement under IR(ME)R. Staff also confirmed that they were able to access copies of the relevant policies and procedure when required. However, as previously detailed, the employer must ensure that relevant documentation is updated to clearly set out the specific duty holder training, competencies and scope of entitlement for relevant duty holder roles.

Senior staff described the arrangements for notifying staff of any changes to the policies and procedures in place. This involved updates being discussed with staff and/or provided to staff via email. All staff are required to sign to confirm they have read and understood the written policies and procedures in place.

Improvement needed

The employer must ensure that the Radiation Safety Policy, as well as other relevant employer's procedures, are updated to include specific training requirements for each duty holder role.

[4] Under IR(ME)R a referrer is a registered healthcare professional who is entitled, in accordance with the employer's procedures, to refer individuals for medical exposures

[5] Under IR(ME)R a practitioner is registered healthcare professional who is entitled, in accordance with the employer's procedures, to take responsibility for an individual medical exposure. The primary role of the practitioner is to justify medical exposures.

[6] Under IR(ME)R an operator is any person who is entitled, in accordance with the employer's procedures, to carry out the practical aspects of a medical exposure..

Justification of Individual Medical Exposures

The employer had a written procedure in place for the justification[7] and authorisation of medical exposures within the department. Staff we spoke with had a clear understanding of the justification process.

We were informed that justification of individual medical exposures was being recorded on the radiology request forms, with a date and signature of the practitioner. We were told that forms were then scanned onto the electronic radiology information system.

On review of the documentation provided, we highlighted a number of areas where there were inconsistencies with the terminology in relation to justification and authorisation. During discussion with senior staff, we recommended that relevant written procedures should be reviewed, and where required updated, to ensure that all documents are clear and consistent, to avoid confusion. This issue is detailed further in the 'Procedures and Protocols' section of our report.

Any carer and comforter medical exposures must also be justified. The employer had an employer's written procedure in place and evidence provided indicated that this justification should be recorded using the same process used for justification of the associated patient medical exposure. Evidence was also provided of the form used to record carer and comforter consent by the department, which was clear and concise. However, following review of the information provided a number of areas were highlighted as requiring additional clarity within the employer's written procedure. This included detail around who is responsible for justifying the exposures to carers and comforters, where information needs to be recorded and what information is provided to carers and comforters around benefits and risks of the exposure.

Improvement needed

The employer must ensure the employer's written procedure relating to carers and comforters is reviewed and updated to include additional detail regarding the areas highlighted.

[7] Justification is the process of weighing up the expected benefits of an exposure against the possible detriment of the associated radiation dose.

Optimisation

The employer had arrangements in place for the optimisation[8] of exposures. For example, there is an operator general procedure in place which sets out the required actions to be taken to ensure that patient exposure doses are as low as reasonably practicable. Additionally, the service MPE also provides advice and contributes to optimisation of exposures by carrying out routine equipment performance quality assurance and completing annual patient dose audits which may include recommendations to optimise specific procedures.

Evidence was provided of the most recent dose audit report completed by the MPE, which was clear and provided recommendations to the department for optimising examination protocols and updating the local diagnostic reference levels (LDRLs).

Following review of the evidence provided and discussions with staff, it was identified that there were no exposure charts available within the department for the mobile x-ray unit or for paediatric patients. The employer must ensure that these exposure charts are developed, with the paediatric exposure chart being based on the child's weight and age. This will help to further ensure that exposure doses are kept as low as reasonable practicable and optimised.

Improvement needed

The employer must ensure that exposure charts are developed and exposures optimised for the mobile x-ray unit and for paediatric patient exposures within the department.

Diagnostic reference levels

There was an employer's written procedure in place for determining, implementing and reviewing diagnostic reference levels (DRLs). Where possible, local DRLs (LDRL) for the department have been established and we were informed that they are displayed within the x-ray room, to assist staff when undertaking procedures. This information was also available in the Radiation Safety Policy, Local Rules, and Employer's Procedures document.

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

Following review of the information included within the employer's procedure it was highlighted that additional information was required in regards to the review of DRLs. This information should include the frequency of reviews, the review process, detail explaining ratification process for the department and required action if DRLs are consistently exceeded.

A copy of the DRL information displayed in the x-ray room was provided as evidence and we noted that the majority of LDRLs, were in line with the national DRL for the specified areas. The employer's written procedure detailed that where LDRLs have not yet been established for a specific procedure, the department adopts the relevant national or European dose level. However, it was clear from discussions with staff and the MPE that LDRLs have been established at Yale, with a recommendation that further optimisation of the examination exposure factors was advised to bring the LDRLs below the national level where possible.

The employer should ensure that the service continues to work towards reducing LDRLs below national levels, where possible.

Senior staff confirmed that LDRLs were reviewed regularly. We were informed that if any exposures are noted to be consistently exceeding DRLs displayed in the x-ray room, the department manager is to be informed. Subsequently, a review may then be undertaken, with input from the MPE, with a view to reduce doses to a level as low as reasonable practicable. It was identified that additional clarity setting out this process should be added to the relevant employer's procedure, to ensure staff are aware of the required action. The employer should consider including additional information regarding dose audits completed by the MPE and how recommendations arising from dose audits are actioned.

As previously mentioned, the MPE undertakes an annual patient dose audit and subsequently, where required, provides a written report which may include recommendations for new or modified LDRLs. Additionally, we were informed that the Radiation Protection Committee (RPC), also serve as a Medical Exposures Committee (MEC) in reviewing the level of patient dose in relation to DRLs. These meetings are held annually. Again, the employer should consider including this information within the employer's procedure.

On review of the DRL information within the Radiation Local Rules and Employers Procedure document and the information displayed in the department x-ray room, we highlighted that the DRLs detailed in each were different. This issue was raised with the department lead during our inspection and we were informed that the information displayed within the x-ray room was

the most up to date and correct version. It was acknowledged that the information included within the employer's procedure document had not been updated to reflect any changes to the dose levels.

Improvement needed

The employer must ensure the employer's written procedure relating to DRLs is reviewed and updated to include additional detail regarding the areas highlighted.

The employer must ensure DRL information is reviewed to confirm available information is accurate and consistent throughout all relevant documentation available.

Clinical evaluation

There was an employer's procedure in place which detailed the process regarding clinical evaluation of medical exposures. This procedure sets out that all medical exposure must be evaluated and the resulting findings recorded.

During discussions with senior managers, we were informed that the operator would be responsible for undertaking the clinical evaluation of the exposures. Information provided indicated that following the evaluation, a report is produced and returned to the referrer for inclusion in the patients' notes.

On review of this procedure, we highlighted that there were a number of areas which had not been detailed. These included, how evaluations are recorded and where, the process for evaluating exposures undertaken outside of the department, relevant entitlement and training for staff and the process in place for unexpected findings.

Improvement needed

The employer must ensure the written procedure relating to clinical evaluation is reviewed and updated to include additional detail regarding the areas highlighted.

Equipment: general duties of the employer

The employer had an up-to-date inventory (list) of the equipment used within the department. The inventory contained the information required under IR(ME)R 2017.

Senior staff confirmed that a quality assurance (QA) programme was in place, which detailed the quality control (QC) tests undertaken on all imaging equipment.

We were informed that one of the radiographers within the department is the QA lead, responsible for ensuring that the required QC checks are completed. Senior managers confirmed that the quality assurance and check programme does have MPE involvement, for example the MPE designs the QC tests required and also completes annual testing. Information provided detailed that routine performance checks on equipment was undertaken by medical physics service, the radiographers and manufacturer's service engineers.

We were informed that due to the increased demand on the service over the past year as a result of the additional support being provided to the NHS, in dealing with Covid-19, the department has had to prioritise tasks. This has subsequently had an impact on the department's ability to complete other, more routine tasks, as and when required. This has included the frequency of quality assurance checks on equipment. However, on review of the quality assurance timetable maintained by the service, whilst some gaps were highlighted, the information detailed that the majority of equipment had received routine checks throughout 2020.

On review of the employer's written procedure in place relating to quality assurance of equipment , it was highlighted that additional detail was required to ensure that the process in place which was describe by senior staff, mirrors the written procedure. The additional detail required includes how are where results are recorded, training for staff carrying out checks, who is responsible for acting on the results and the process for corrective action.

Improvement needed

The employer must ensure that the employer's written procedures relating to QA and QC checks of equipment, are reviewed and updated to ensure that they accurately reflect the arrangements in place.

Safe care

Managing risk and health and safety

We were informed that there are department leads for each relevant risk area. This individual is responsible for ensuring that associated risk assessments are maintained and that necessary actions are implemented where required. Staff

we spoke to informed us that they were aware of the risks assessments in place for the department.

Infection prevention and control (IPC) and decontamination

Information provided by staff indicated that adequate arrangements were in place for effective infection prevention and decontamination within the department. We were informed that these arrangements had been strengthened as a result of Covid-19.

Senior staff confirmed that any patient attending the hospital must complete a questionnaire prior to their appointment, to check for any infectious symptoms. On arrival, the patient's temperature is taken and they are given a mask to wear. The hospital has introduced zones and colour coded patient pathways, which means that patients are provided with a clear journey to guide them through the hospital ahead of their appointment. The relevant hospital zones are based on the level of infection risk to patients, for example any patients having surgery would be in the higher risk zone.

Staff informed us that daily cleaning schedules were in place, which set out the frequency of required cleaning for relevant areas and equipment throughout the department. In response to Covid-19, additional time was allocated to complete procedures, to also ensure sufficient time was available for the required cleaning and decontamination.

There is a department lead for IPC whose responsibilities include attending relevant meetings and ensuring the required updates to department procedures and practice are disseminated to staff.

Staff we spoke with confirmed that they had received IPC training and demonstrated a good awareness of their responsibilities in regards to infection control within the department.

Senior managers confirmed that there is a staff member within the hospital responsible for monitoring the availability of personal protective equipment (PPE). Staff confirmed that access to PPE is sufficient and that training had been provided in relation to safely donning and doffing PPE. We were also informed that information was displayed within the department in relation to PPE requirements.

Safeguarding children and safeguarding vulnerable adults

Discussions with staff within the department demonstrated an awareness of the current safeguarding procedures in place. We were informed that there was a

process flow chart available to staff outlining the required steps and a safeguarding lead was available to provide staff with advice and guidance. We were also informed that all staff had completed online training to help them keep up to date with relevant safeguarding issues.

Effective care

Participating in quality improvement activities

Clinical audit

Information provided evidenced that there was a clinical audit schedule available within the department, setting out the frequency of audits required. However, senior staff informed us that due to the additional support being provided to health boards in supporting NHS work throughout 2020, audits were paused by Spire Healthcare. The employer must ensure that clinical and IRMER audits are reinstated as soon as possible, to ensure that services are being provided in line with the required standards and regulations.

There is an audit lead within the department, responsible for undertaking the majority of the audits required and providing updates to staff on the findings.

Senior staff confirmed that whilst previously the audit schedule was maintained locally within the department, Spire Healthcare has now implemented a new standardised and centralised electronic clinical audit system for all hospital teams within the service. This new system was implemented on 1 January 2021 and now means that audits will be coordinated centrally; audit results will be fed into a centralised team and the radiology department will receive more standardised instructions in relation to the audit programme. We were also informed that the new system will allow for results to be benchmarked across the relevant services within Spire Healthcare via a centralised dashboard.

The new audits to be completed as part of the new system were provided as evidence. The list provided contained the required audits to comply with IR(ME)R 2017 and should provide assurance to the employer of compliance with the regulations.

Improvement needed

The employer should ensure that the clinical and IR(ME)R audits are reinstated as soon as possible.

Expert advice

The service has a contract in place with Integrated Radiologist Services (IRS) Ltd to provide registered Medical Physics Experts (MPEs), under IR(ME)R 2017. There were two MPEs allocated to provide support and advice to the service. The contract also made provision for additional MPE support to be provided if required. The two MPEs allocated to provide support to the department, were listed on the approved list for RPA 2000, the certification body for MPEs.

Evidence of the appointment letter for the two MPEs was provided. This document had been signed by the department lead. It is a requirement under IR(ME)R that the employer is responsible for appointing MPEs, unless it is documented that this task has been delegated to another individual, in line with the relevant duty holder responsibilities. On review of the information provided, there was no evidence to indicate that this task had been delegated. The employer must ensure that the relevant written procedures are updated to reflect the arrangement in place for appointing MPEs.

On review of the information detailed within the Radiation Safety Policy document, it was highlighted that there was a discrepancy with the names of the appointed MPEs detailed within the appointment letter to the information included within the Radiation Safety Policy document. The employer must ensure that all documents accurately detail the MPE arrangements in place for the service.

As previously detailed, staff confirmed that the MPEs provide support and advice in a number of areas. Areas of support included providing training to staff, undertaking relevant audits and equipment testing, and providing relevant reports and recommendations relating to equipment performance, LDRLs and optimisation of procedures. Senior staff also confirmed they were able to contact an MPE for advice where necessary, on an ad hoc basis.

Improvement needed

The employer must ensure that the relevant written documentation and procedures are updated to accurately reflect the arrangements in place for the appointment of MPEs.

The employer must ensure that written procedures accurately detail the appointed MPE support arrangements in place for the service.

Research exposures

There was an employer's written procedure in relation to research procedures in place. Senior staff confirmed that no research exposures are performed at the hospital. The employer should consider removing the detail around research exposures and including the employer's procedure, to state 'no research exposures are performed at Yale or Abergele'.

Quality of management and leadership

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

Organisational management structures were in place with clear lines of reporting and accountability.

There was evidence of an experienced and committed workforce, with a good team working ethos. Staff were happy with the level of support provided by the department lead. However, concerns were highlighted in relation to the level of support and engagement provided by senior managers within the service.

As outlined in the previous section, our inspection highlighted the requirement for the employer to ensure that all employer's written procedures are reviewed to ensure they accurately reflect the practices and procedures in place and provide the level of information required for staff to follow.

Concerns were highlighted around available capacity to enable staff to carry out all relevant tasks required as part of their duty holder roles.

Governance and accountability framework

There were organisation structure documents in place for the overall service, as well as the radiology department, which set out clear lines of reporting. Staff informed us that they were happy with the level of support provided by the department manager. However, concerns were highlighted around the support, visibility and engagement from senior managers within the service.

As previously mentioned, as a result of the additional support being provided to the NHS throughout the majority of 2020, due to Covid-19, a number of the working practices in place were changed. This included ceasing the formal department staff meetings, which were previously held on a quarterly basis. At

the time of our inspection these meetings had not been reconvened for the department.

Whilst we acknowledge that the service has introduced daily staff huddles for the hospital, information from which is shared with all staff via email, given the concerns raised by staff around the limited engagement and support, senior managers should liaise with staff to identify ways to improve the engagement and information sharing between senior managers and staff working within the department.

Within the information provided, there was no evidence to demonstrate the safety governance structure and process in place for service. Therefore, it was unclear what governance arrangements were in place in relation to the services being provided by the department. The employer should ensure that a safety governance structure chart or written description is developed outlining the arrangements/processes in place, which covers all of the relevant services provided. This document should detail how governance is managed and reported within the Spire Yale service, as well as to Spire Healthcare.

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

The self-assessment form 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.

On the days of our inspection, senior management staff made themselves available and facilitated the inspection process. They were receptive to our feedback and demonstrated a willingness to make improvements as a result of the issues highlighted.

Improvement needed

The Registered Provider should consider methods to improve the visibility, engagement and support being provided to the department by senior managers.

The employer must develop a document which sets out the safety governance

structure/processes in place, which covers all of the relevant services provided.

Duties of the employer

Entitlement

As previously outlined, department staff we spoke with had a clear understanding of their relevant duty holder roles and scope of entitlement under IR(ME)R. However, following review of the information provided as evidence, it was unclear how duty holders were being entitled by the employer. Staff were unable to provide evidence of their entitlement and scope of practice. Additionally, there was no comprehensive written employer's procedure in place in relation to identifying individuals entitled to act as referrer, practitioner or operator within a scope of practice, which is required under IR(ME)R 2017.

During discussions with senior staff, assurance was provided around the arrangements in place. However, this did not reflect the information in the available written procedures. The employer must ensure that an employer's written procedure is developed which clearly details how staff are entitled. Additionally, the procedure should include the training required to allow individuals to become entitled for a scope of practice and how individuals are made aware of their duty holder entitlement.

Improvement needed

The employer must ensure that a comprehensive employer's written procedure is developed which clearly outlines the arrangements in place relating duty holder entitlement for all duty holder roles.

Procedures and protocols

The Hospital Director was designated as the IR(ME)R employer. This arrangement was detailed within the hospital's Radiation Safety Policy/ Radiation Local Rules and Employers Procedure document. This document also set out the tasks which had been delegated to the other professionals within the service in relation to IR(ME)R. However, as previously detailed, the delegation of task information within the documentation reviewed was lacking in detail and did not encompass all staff groups or duty holder roles.

As previously detailed, staff we spoke with as part of our inspection confirmed that they had access to relevant policies and procedures when required. Also,

senior staff confirmed that arrangements were in place to notify staff on the occasions where updates are made to the written procedures in place and to confirm staff have read and understood the procedures in place.

There was an employer's procedure in place in relation to the quality assurance programme for the employer's written procedures, which detailed that regular reviews of documents are to be undertaken by the department manager and radiation protection supervisor, where appropriate. The procedure sets out that the purpose of this review is to ensure departmental procedures and practices are in compliance with the relevant employer's procedures. However, following review of this procedure, it was 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 throughout our report, following our review of the written procedures in place, it was highlighted that 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 our inspection, we were provided with assurances on the practice being carried out. However, the practice described by staff exceeded 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.

Improvement needed

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.

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.

Accidental or unintended exposures

Senior managers described the process in place should an incident occur or is suspected to have occurred, which may have caused an accidental or unintended exposure to patients. In the first instance, staff are required to notify either the department manager and/or radiation protection supervisor. The incident will then be investigated and a dose assessment form will be

completed, to record the relevant exposure information. This information is then sent to the MPE for review, who will subsequently advise whether a notification needs to be submitted to HIW or another external regulator.

Additionally, we were informed that all incidents and near misses are recorded via Datix, the electronic incident reporting system. We were told that all incidents and concerns reported via Datix are reviewed daily by the local clinical governance team. This team will then advise if the incident should be escalated to the central Spire Healthcare governance team via a 'serious incident requiring investigation' (SIRI) notification. Subsequently, this team will advise as to whether a more in depth route cause analysis investigation is required in addition to the standard procedure.

If it is determined that the incident may have been due to an equipment malfunction, the equipment would be removed from service pending an investigation.

Senior managers confirmed that if the incident relates to a patient being exposed to a significant accidental or unintended exposure as defined in the enforcing authorities' guidance (SAUE), the patient would be notified in writing and invited for a discussion. The referrer for this patient will also be notified.

An information log of all IRMER incidents is maintained by the service. However, on review of this information there was no evidence to demonstrate that trend analysis was being undertaken on these IR(ME)R incidents and near misses or how the learning from that process would be used to inform practice.

All staff we spoke to were able to describe the process to follow in regards to reporting incidents and near misses. Staff also confirmed that feedback was provided to the department following reported incidents.

The employer had written procedures in place relating to reporting accidental or unintended exposures within the department. However, it was highlighted that additional detail was required to reflect the process in place that was described by staff. The employer should consider including more detail including clarity on where relevant information is recorded, who undertakes the investigations and who informs the referrer and patient (if required).

It was highlighted following review of the available employer's procedures, that further detail was required in relation to clinically significant accidental or unintended exposures as this was not explicitly described in the current procedures. An employer's procedure for the management of clinically significant accidental or unintended exposures is a requirement of IR(ME)R.

Additionally, it was highlighted that the procedures currently detailed that equipment malfunctions should be reported the Health and Safety Executive. However, these notifications should be submitted to HIW in the first instance as they are now covered under IR(ME)R. The employer should also consider including more detail within the relevant employer's procedures in relation HIW incident reporting process, including information required and reporting timescales.

Improvement needed

The employer must ensure detailed analysis (including themes and trend analysis) of accidental or unintended exposures is being undertaken to ensure any learning is shared and changes implemented.

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 required process.

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.

The employer must ensure that the relevant written procedures relating to accidental or unintended exposures are updated to accurately reflect the HIW incident reporting process requirements.

Workforce

As part of our inspection, discussions were held with senior managers for the service as well as a selection of staff working within the department. Additionally, a staff survey was made available to allow all staff working within the department to provide their views.

Staff we spoke with felt that staffing levels within the department were adequate, however, they said that the increased demand on the service over the past year had made it difficult to maintain the level of tasks required as part of their roles. Staff confirmed that they felt sufficient time was available to undertake the clinical elements of their roles, however, it was challenging to complete the additional elements of their roles, for example, QA and audit.

It was clear from our discussions that the department consists of experienced and committed staff, with a good team working ethos. As previously outlined, overall staff were happy with the level of support provided by the department

lead. However, concerns were highlighted around the support and engagement from senior managers within the service.

During our inspection, we were informed that the department lead was scheduled to leave her role in the coming weeks. We were told that the role had been advertised and that interviews were planned. However, concerns were raised by department staff in regards to this issue, specifically in relation to the limited information that had been provided to them in regards to the plans to replace the department lead and the arrangements for the interim period. This had resulted in the team feeling apprehensive and unsettled. As previously outlined, senior managers should ensure arrangements are implemented to improve the engagement and information sharing with staff working within the department.

As previously detailed, due to the increased demand on the service over the past year, a number of standard practices have been affected. This included formal quarterly meetings being ceased and also we were informed that staff appraisal and supervision discussions with line managers had not been occurring as regularly as intended. The employer should ensure these meetings are re-established to allow for staff training and development needs to be identified and monitored.

Senior staff informed us that arrangements were in place to allow staff to access additional wellbeing support if required. However, feedback received from staff indicated that not all staff were aware of the available support or how to access it. The employer must ensure that all staff are provided with information relating to the support arrangements that are in place and provided with details on how to access.

Improvement needed

The Registered Provider must ensure a review is undertaken to confirm staff have sufficient capacity to undertake their relevant roles.

The Registered Provider must ensure routine supervision and appraisals discussions take place for staff, to allow for training and development needs to be identified and monitored.

The Registered Provider must ensure that all staff are provided with information on the additional wellbeing support available to them.

4. What next?

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

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

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

The improvement plans should:

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

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

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

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

5. How we inspect services that use ionising radiation

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

The regulations are designed to ensure that:

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

We look at how services:

- Comply with the Ionising Radiation (Medical Exposure) Regulations
- Comply with the Care Standards Act 2000
- Comply with the Independent Health Care (Wales) Regulations 2011
- Meet any other relevant professional standards and guidance where applicable

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

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

Prior to the inspection, the service is required to complete a self-assessment form and provide supporting documentation as evidence. The two day remote inspection consists of discussions with senior managers and operational staff working within the department, in relation to the policies and procedures in place.

To allow us to collate additional views, relevant patient and staff surveys are conducted in the weeks leading up to our inspection.

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

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

Further detail about how HIW inspects independent services can be found on our website.

Appendix A – Summary of concerns resolved during the inspection

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

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

Appendix B – Immediate improvement plan

Hospital: Spire Yale

Ward/department: Diagnostic Imaging

Date of inspection: 12 and 13 January 2021

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

Immediate improvement needed	Standard	Service action	Responsible officer	Timescale
No immediate improvements were identified.				

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

Service representative:

Name (print):

Job role:

Date:

Appendix C – Improvement plan

Hospital: Spire Yale

Ward/department: Diagnostic Imaging

Date of inspection: 12 and 13 January 2021

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	Service action	Responsible officer	Timescale
1. Delivery of safe and effective care				
1.1 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 for all types of patients they may encounter.	Regulation (6) Schedule 2(a)	Spire's corporate Employer's Procedures are currently under review. This is being completed by our corporate external Radiation Protection Advisor. The update will include a greater level of standardisation and less need for Spire hospitals to localise their documentation for standard procedures common to all locations. The review will include clarification of the procedure for positive identification of competent adults, Children and Young People, patients that are lacking capacity, and unconscious/sedated patients.	Geraint Evans, Spire Healthcare National Clinical Specialist for Imaging/ Laura Gauntlett, Radiographer	30/04/21 for national policy 31/05/21 for local adoption

Improvement needed	Standard	Service action	Responsible officer	Timescale
		Once this work has been completed, Spire Yale will adopt the national rules and adapt for local variation and key contacts, personalising to the hospital service.	and Radiation Protection Supervisor/ Pamela Mackie Director of Clinical Services	
1.2 The employer must ensure that a review of the employer's written procedure relating to pregnancy enquires is undertaken to ensure that there is sufficient detail on the process to be followed by staff for all types of patients they may encounter.	Regulation (6) Schedule 2(c) Regulation 11(1)(f)	As in 1.1, Spire's corporate Employer's procedures are being updated, after which Spire Yale's local Employers procedures will reflect these changes and be updated. The procedure for pregnancy status enquiries of all individuals of child-bearing potential, including patients that are lacking capacity, and unconscious/sedated patients will be clearer include a greater level of detail.	Geraint Evans, National Clinical Specialist for Imaging	31/05/21
1.3 The employer should 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.	Regulation 3 (f) Regulation (6) Schedule 2(m)	Once Spire's updated Employer's Procedures are issued, the Spire Yale local policy will be reviewed to include clarification that non-medical exposures are only to be justified by a Radiologist, and do not fall under delegated authorisation protocols.	Laura Gauntlett Radiographer and Radiation Protection Supervisor/ Pamela Mackie Director of Clinical	31/05/21

Improvement needed	Standard	Service action	Responsible officer	Timescale
			Services	
1.4 The employer should update the relevant written procedures to set out how referral guidelines are made available to all entitled referrers.	Regulation 6(5)(a)	It is not possible for Spire Healthcare to supply all entitled referrers with access to iRefer. Instead, Spire Yale will send a communication to all local referrers to advise that they should ensure that they have access to iRefer. Spire Healthcare's position on access to iRefer will be included in the updated issue of the Employer Procedures, currently under review	Customer Services/Sue Jones Hospital Director	31/05/21
1.5 The employer must ensure there is a robust written process in place for referrals received by the Diagnostic Imaging Department and review the practice of verbal referral.	Regulation 10(5)	Spire Yale's local policy will be updated to confirm verbal referrals are not accepted. The nature of the service at Spire Yale is for planned elective care and non-emergency services. Spire Yale has a Resident Medical Officer (RMO) on duty at all times. Any unforeseen urgent referrals would be a written referral following assessment by the RMO.	Laura Gauntlett Radiographer and Radiation Protection Supervisor/ Pamela Mackie Director of Clinical Services	31/05/21
1.6 The employer must ensure that the Radiation Safety Policy, as well as other relevant employer's procedures, are	Regulation 6(3)(b) Regulation	Local training and competency documents are in place and will be added to the updated Employer's Procedures as part of the planned wider review.	Geraint Evans National Clinical	31/05/21

Improvement needed	Standard	Service action	Responsible officer	Timescale
updated to include specific training requirements for each duty holder role.	17(1)		Specialist for Imaging	
1.7 The employer must ensure the employer's written procedure relating to carers and comforters is reviewed and updated to include additional detail regarding the areas highlighted.	Regulation 6 Schedule 2 (n) Regulation 12(5)	The Spire Yale local policy will be reviewed to include the process and delegation of justification, and the communication of risk and benefits for the exposure of comforters and carers as part of the wider update to Spire's corporate and the local Yale Employer's Procedures review.	Laura Gauntlett Radiographer and Radiation Protection Supervisor/ Pamela Mackie Director of Clinical Services	31/05/21
1.8 The employer must ensure that exposure charts are developed and exposures optimised for the mobile x-ray unit and for paediatric patient exposures within the department.	Regulation 12(1) & (3) & (8)(a)	IRS Medical Physics are attending Spire Yale on 5th March 2021 to develop and optimise the X-ray exposure charts and paediatric exposure charts. Once this review is completed, these will be issued to the team.	Laura Gauntlett Radiographer and Radiation Protection Supervisor	31/03/21
1.9 The employer must ensure the employer's written procedure relating to DRLs is reviewed and updated to include additional detail regarding the	Regulation 6 Schedule 2(f) Regulation 6(7)	IRS Medical Physics and Spire Yale Radiation Protection Supervisor will review DRL documents for appropriate DRLs, investigation levels and escalation processes should DRLs be exceeded. The written procedure will be	Laura Gauntlett Radiographer and Radiation Protection	31/03/21

Improvement needed	Standard	Service action	Responsible officer	Timescale
areas highlighted.		updated to reflect this review once completed	Supervisor	
1.10 The employer must ensure DRL information is reviewed to confirm available information is accurate and consistent throughout all relevant documentation available.	Regulation 6(5)(c)	Once the review described in 1.9 is completed, all documentation in folders and on display will be reviewed and updated to ensure consistency	Laura Gauntlett Radiographer and Radiation Protection Supervisor	31/03/21
1.11 The employer must ensure the written procedure relating to clinical evaluation is reviewed and updated to include additional detail regarding the areas highlighted.	Regulation 6 Schedule 2(j) Regulation 12(9)	All exposures undertaken within Spire Yale imaging department are clinically evaluated and reported by a radiologist. Outside of the imaging department, a medical notes audit is now in place to ensure a clinical evaluation of exposure is documented in the patient's operation notes with results available to benchmark performance across the Spire group. The updated Employer's Procedures will make it clearer and include the further detail required.	Sue Jones Hospital Director/ Pamela Mackie Director of Clinical Services	31/05/21
1.12 The employer must ensure that the employer's written procedures relating to QA and QC checks of equipment, are reviewed and updated to ensure that they accurately reflect	Regulation 15(1)(a) Regulation 6 Schedule 2(d)	The Spire Yale local policy will be reviewed to include equipment specific Quality Assurance test procedures, frequency and reference levels This is part of the wider corporate update to the	Laura Gauntlett Radiographer and Radiation Protection	31/05/21

Improvement needed	Standard	Service action	Responsible officer	Timescale
the arrangements in place.		Employer's Procedures described above	Supervisor	
1.13 The employer should ensure that the clinical and IR(ME)R audits are reinstated as soon as possible.	Regulation 7	Clinical and IR(ME)R audits have recommenced and are being documented on the corporate audit system (AMaT). This allows oversight of all Spire sites and monitors non-compliance and action completion	Sue Jones Radiographer	28/02/21
1.14 The employer must ensure that the relevant written documentation and procedures are updated to accurately reflect the arrangements in place for the appointment of MPEs.	Regulation 14(1) Regulation 6 Schedule 2(b)	Letters are being reviewed and updated to include the signature of the Hospital Director and the correct names of the appointed MPEs. These will be reissued by the authorised signatory	Laura Gauntlett Radiographer and Radiation Protection Supervisor / Sue Jones Hospital Director	31/03/21
1.15 The employer must ensure that written procedures accurately detail the appointed MPE support arrangements in place for the service.	Regulation 14(1)	In the same letters in 1.14, support arrangements will be documented and reissued.	Laura Gauntlett Radiographer and Radiation Protection Supervisor / Sue Jones Hospital Director	31/03/21

Improvement needed	Standard	Service action	Responsible officer	Timescale
2. Quality of management and leadership				
2.1 The employer should consider methods to improve the visibility, engagement and support being provided to the department by senior managers.	Standard 24 Workforce Recruitment and Employment Practices	Imaging staff are invited to attend the daily hospital MDT huddles led by the SMT, and other key hospital meetings, and a rota is in place to enable attendance from the imaging team. There are now regular visits to the imaging department by the SMT	Pamela Mackie Director of Clinical Services/Imaging staffs	28/02/21
2.2 The employer must develop a document which sets out the safety governance structure/processes in place, which covers all of the relevant services provided.	Regulation 8(4)	A corporate organogram is available detailing the structure of central functions. The local organogram for local governance structure is being updated and will be displayed once finalised.	Laura Gauntlett Radiographer and Radiation Protection Supervisor / Pamela Mackie Director of Clinical Services	31/03/21
2.3 The employer must ensure that a comprehensive employer's written procedure is developed which clearly outlines the arrangements in place relating duty holder entitlement for all	Regulation 6 Schedule 2 (b)	There are localised group duty holder and role charts, competencies, scopes of practice and training records for referrers, practitioners and operators in place. The review of Employer's Procedures underway will include the term 'entitlement' to make the process	Geraint Evans National Clinical Specialist for Imaging/	30/06/21

Improvement needed	Standard	Service action	Responsible officer	Timescale
duty holder roles.		clearer and individualised entitlement documents will be developed.	Pamela Mackie Director of Clinical Services	
2.4 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.	Regulation 6(1)(a)(b) & (2) Regulation 10(1)	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. A gap analysis is being prepared with the draft update of the procedures to ensure there are no gaps.	Laura Gauntlett Radiographer and Radiation Protection Supervisor / Pamela Mackie Director of Clinical Services	31/05/21
2.5 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.	Regulation 6 Schedule 2 (d)	As Action 2.4	Laura Gauntlett Radiographer and Radiation Protection Supervisor / Pamela Mackie Director of Clinical Services	31/05/21

Improvement needed	Standard	Service action	Responsible officer	Timescale
2.6 The employer must ensure detailed analysis (including themes and trend analysis) of accidental or unintended exposures is being undertaken to ensure any learning is shared and changes implemented.	Regulation 8 (3)	Though difficult to identify trends with very low numbers of accidental or unintended exposure incidents, this will be added as a regular agenda item at the hospital governance committee meeting to evidence this has been considered and reported. Such incidents will be reviewed in conjunction with previous incidents and analysed for any themes or trends. Outcomes will also be discussed and documented at staff meetings, and escalated to the RPA as appropriate for advice.	Laura Gauntlett Radiographer and Radiation Protection Supervisor / Pamela Mackie Director of Clinical Services	31/05/21
2.7 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 required process.	Regulation 8(4)	Please see point 1.1 above. The corporate Employer's Procedures are being updated and will include further clarity on the correct process to follow in response to the reporting and escalation of significant accidental or unintended exposures. Spire Yale's written procedures will reflect the corporate process once issued.	Laura Gauntlett Radiographer and Radiation Protection Supervisor	31/05/21
2.8 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	Regulation 8 (1) Regulation 6 Schedule 2(l)	See 2.7 above This updated document will include a reference to the corporate policy FIN01 (Incident Reporting Policy) and to appendix 5G – (Investigation of dose greater than intended), and appendix 5H (Investigation of Wrong site	Laura Gauntlett Radiographer and Radiation Protection	31/05/21

Improvement needed	Standard	Service action	Responsible officer	Timescale
exposures.		imaging) as templates for investigation of any such incidents.	Supervisor	
2.9 The employer must ensure that the relevant written procedures relating to accidental or unintended exposures are updated to accurately reflect the HIW incident reporting process requirements.	Regulation 8(4)(b)(iv)	See 2.7 above Spire Yale's procedures will be updated to reflect the local requirements for reporting such incidents to HIW	LG Laura Gauntlett Radiographer and Radiation Protection Supervisor	31/05/21
2.10 The employer must ensure a review is undertaken to confirm staff have sufficient capacity to undertake their relevant roles.	Standard 25 - Workforce Planning, Training and Organisational Development	Staffing in the imaging department is currently in line with needs of the business for clinical activity. Staffing rotas are being reviewed to ensure that staff are allocated sufficient time to undertake their additional responsibilities. This will be formalised when a new Imaging Manager is recruited and has an opportunity to review working processes, staff skills and capability	Nicola Margerrison Senior Radiographer	30/06/21
2.11 The employer must ensure routine supervision and appraisals discussions take place for staff, to allow for training and development needs to be identified and monitored.	Standard 25 - Workforce Planning, Training and Organisational Development	All staff have now completed their 2020 appraisals and objectives for 2021 are in process of being discussed with all staff with a Spire deadline of 31/03/21. Training and development needs are discussed as part of the Enabling Excellent (appraisal) process, and every staff	Laura Gauntlett Radiographer and Radiation Protection Supervisor /	31/03/21

Improvement needed	Standard	Service action	Responsible officer	Timescale
		member has a personal development plan.	Pamela Mackie Director of Clinical Services/Nicola Margerrison Senior Radiographer	
2.12 The employer must ensure that all staff are provided with information on the additional wellbeing support available to them.	Standard 22 Managing Risk and Health and Safety	Spire has enhanced its wellbeing services throughout the COVID-19 pandemic and there are a range of new resources available across the group, shared via Spire's intranet. To ensure that staff are more aware of these services Spire Yale will: • Display information of how staff can access Employee Assist Program • Send an e-mail notification of group-wide well-being initiatives • Display information on mental health first-aiders • Send a regular email notification of when an Occupational Health advisor is on site	Laura Gauntlett Radiographer and Radiation Protection Supervisor / Pamela Mackie Director of Clinical Services	31/03/21

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: 01/03/2021