Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

Ionising Radiation (Medical Exposure) Regulations Inspection (Announced)

Diagnostic Imaging Department, St Joseph's Hospital, Newport

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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 (IR(ME)R) inspection of the Diagnostic Imaging Department of St Joseph's Hospital on 23rd and 24th March 2021.

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

HIW explored how the service:

- Complied with the Ionising Radiation (Medical Exposure) Regulations 2017
- 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.

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.

2. Summary of our inspection

Overall, from the evidence we examined, we found that compliance with IR(ME)R ensured that the department provided safe and effective care.

Both patients and staff who completed the survey were positive about their experiences whilst in the department.

The department was being well managed and comments from staff indicated that they felt supported by senior staff.

Discussions with managers and department staff throughout our inspection provided assurance and awareness of their responsibilities in line with IR(ME)R.

However, we highlighted a number of issues that need to be addressed by management, in particular the completion of referral forms in theatres.

This is what we found the service did well:

- Feedback from patients indicated that they were highly satisfied with the service provided
- Staff feedback was also positive
- Discussions with managers and department staff throughout our inspection provided assurance that arrangements were in place to ensure that examinations were being undertaken safely
- Senior staff were very receptive to our inspection and demonstrated a willingness to make improvements as a result

This is what we recommend the service could improve:

- Ensuring that all employer's written procedures, policies and protocols are reviewed to ensure they accurately reflect the

practices and procedures in place and provide the level of information required for staff to follow

- Discontinuing the practice where the radiographers complete referral forms in theatre
- The audit programme and associated documentation to include timeframes and frequency for the audits.

We identified regulatory breaches during this inspection regarding the completing of the referral form by radiographers who were not entitled as referrers to complete these forms. Further details can be found in Appendix B. Whilst this has not resulted in the issue of a non-compliance notice, there is an expectation that the registered provider takes meaningful action to address these matters, as a failure to do so could result in non-compliance with regulations.

3. What we found

Background of the service

St Joseph's Hospital is registered with Healthcare Inspectorate Wales (HIW) to provide an independent hospital at Harding Avenue, Newport, Gwent, NP20 6ZE. A full description of the services provided can be seen on the hospital's website, or within their written statement of purpose[1].

The equipment in the department at St Joseph's included:

- General X-ray unit
- Mobile radiography X-ray unit
- C-arm unit in theatres
- General fluoroscopy unit
- Computed Tomography (CT) scanner
- Static mammography unit
- Magnetic Resonance Imaging (MRI) and Ultrasound scanners.

The department employed a number of staff including six radiographers, three assistant radiographers and three bank[2] radiographers. The department is led by the Director of Advanced Diagnostics. There are also a number of Consultant

[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.

[2] Bank staff is an internal bank of casual staff, who are available to call on to cover shifts, sometimes at short notice.

Radiologists that have practising privileges[3] at the hospital, but were not employed by St Joseph's Hospital. The department also had support and advice from Medical Physics Experts (MPEs)[4], secured under contract with Radiation Protection Service (RPS) Cardiff. RPS Cardiff is part of the Department of Medical Physics at the Velindre Cancer Centre in Cardiff, which is part of the Velindre University NHS Trust.

[3] Practising Privileges or PPs are a discretionary personal licence for Doctors to undertake consultations, diagnosis, treatment and surgery in accordance with relevant legislation, regulation and General Medical Council's (GMC's) Good Medical Practice (GMP).

[4] An MPE is an individual, or, if provided for in national legislation, a group of individuals having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure, whose competence in this respect is recognised by the competent authority.'

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.

Feedback from patients indicated that they were highly satisfied with the service provided by staff within the radiology department.

Staff feedback was also positive on the standards of care provided.

The department had processes in place to ensure they could communicate effectively with patients. There were good arrangements in place to collate patient feedback on the services being provided.

Prior to the inspection HIW 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. A total of 14 questionnaires were completed. Patient comments included the following:

> *"The person who dealt with me was very helpful, pleasant and professional."*
>
> *"Great service and friendly staff!"*
>
> *"The staff were kind and considerate."*
>
> *"I've always had a lot of respect for the staff at St Joseph's. Always very professional, knowledgeable, and any concerns are taken seriously and into consideration."*

Staff were also invited to complete a staff survey through a similar on-line questionnaire, to find out what working conditions were like and to obtain their views on the standard of care. We received eight completed questionnaires from a wide range of staff grades. Respondents had been in place from under six months to between two to ten years.

All staff who completed the questionnaire agreed the care of patients was the organisation's top priority and all agreed the organisation acted on concerns raised by patients. The overall majority of staff agreed they would recommend the organisation as a place to work. They said they would be happy with the standard of care provided by the organisation if a friend or relative needed treatment.

Dignity and respect

All the patients who completed a questionnaire agreed that they had been treated with dignity and respect by the staff at the hospital. All patients felt they were able to speak to staff about their procedure or treatment without being overheard by other people. All felt that they were able to maintain their own privacy, dignity and modesty during their appointments. All staff who completed the questionnaire said that patient's privacy and dignity was maintained.

All patients felt that they were listened to by staff during their appointment and all but one patient were asked to confirm their personal details before starting their procedure or treatment.

Patient information and consent

All patients who completed a questionnaire told us that they felt involved as much as they wanted to be in any decisions made about their treatment. Nearly all patients said that they had received clear information to understand the risks and benefits of their treatment options.

Most of the patients who completed a questionnaire told us that they had been given information on how to care for themselves following their treatment. A minority of respondents said they had been given written information on who to contact for advice about any after effects from any treatments they had received.

> *"It was excellent as far as I am concerned, more information would be good"*

Staff we spoke with told us that there were posters in all rooms explaining the benefit versus the risk in terms of the dose relative to background radiation. Staff

told us that they would not give extra information beyond that given by the posters[5] unless asked.

It was also unclear if patients in theatres received information on benefits and risks prior to their procedure as this was not part of the World Health Organisation (WHO) checklist[6]. The benefits and risks of the radiation, during the procedure in theatre, must be explained to the patient during the checklist process.

Improvement needed

The employer is required to ensure that the benefits and risks of the radiation, during the procedure in theatre, must be explained to the patient when the WHO checklist is carried out. This must also be documented as completed on the checklist.

Communicating effectively

All patients who completed a questionnaire said they preferred to communicate in English. Around half of the patients who completed a questionnaire told us that staff asked them which language they preferred to communicate in. Nearly all patients felt that it was very easy to find their way to the department once in the building.

Whilst staff we spoke with said that a translation service was available, they were not aware that a hearing loop was available for patients who were hard of hearing. This point is further covered in the induction process later in this report. We were also told that there were some Welsh speakers in the hospital, who could be called upon to translate for patients, should the need arise.

Senior managers stated that the administrative staff at the hospital would send out information to all patients prior to attending the department. Similarly, the local health boards had been asked to ensure the department was made aware of any patients with communication difficulties so that the necessary

[5] https://www.rcr.ac.uk/posts/new-patient-information-posters-benefits-and-risks-imaging

[6] https://www.rcophth.ac.uk/wp-content/uploads/2015/01/WHO_-_NPSA_generic_checklist.pdf

arrangements could then be made. The hospital had also sourced a supply of clear fronted masks to communicate with patients. Whilst there was a patient information board, the leaflets, which were previously available in the department, were removed due to the risk of infection during the current pandemic.

Care planning and provision

Most of the patients who completed a questionnaire told us it was very easy to arrange an appointment for their procedure or treatment. Most patients told us they had waited less than 15 minutes to have their procedure or treatment, very few waited between 15 and 30 minutes and only one respondent waited more than 30 minutes. Around half said they were not told on arrival how long they would likely have to wait before having their procedure or treatment. It would be good practice for reception staff to tell all patients how long they will need to wait even if only to confirm no delays are expected.

Senior staff told us that waiting times were written on a white board in the department and that reception staff were informed of any delays. Staff we spoke with also said that they kept in regular contact with the reception desk to inform them of any delays. Additionally, we were told that as there were longer appointment slots, to allow for COVID-19 measures such as additional cleaning and patients not meeting each other, there were few delays.

All staff said they were always satisfied with the quality of care they were able to give to patients and agreed patients and their relatives were involved in decisions about their care.

Citizen engagement and feedback

Patients were asked in the questionnaires how the setting could improve the service it provided; several patients commented, including:

> *"No improvements extremely happy with all aspects."*
>
> *"I thought it was of a high standard and don't wish to add anything more."*

Most of the staff respondents agreed patient experience feedback (e.g. patient surveys) was collected. All but one said they received regular updates on the patient experience feedback and said it was used to make informed decisions within their directorate or department. Most staff said senior managers try to involve them in important decisions and that they acted on staff feedback. All staff

said senior managers were committed to patient care. Most staff said they were content with the efforts of the organisation to keep staff and patients safe.

We were told by staff we spoke with that QR codes[7] were displayed in the various rooms to encourage patients to provide feedback. We also saw the patient information and feedback section on the St Joseph's Hospital website that showed examples of the feedback provided by patients. Senior managers told us that the hospital were looking at a hospital wide patient engagement group prior to the pandemic. An example of how a complaint was resolved was also described to us during the inspection.

[7] QR Code is a two-dimensional version of the barcode, typically made up of black and white pixel patterns.

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 throughout our inspection provided assurance that arrangements were in place to ensure that examinations were being undertaken safely. However, we made several recommendations where the employer could further improve the compliance with IR(ME)R. This included a review of employer's procedures, training records and the documentation of audits and that the practice of the radiographers completing the referral forms is discontinued.

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 patient's full

name, home address and date of birth. This approach was in keeping with current UK guidance[8].

Staff we spoke with were able to describe the correct procedure to identify patients. They also confirmed that the operator exposing the patient to the X-rays would check the patients' identity, even if that patient had been handed over to them from another member of staff. Also, all patients who completed our questionnaire told us that they were asked to confirm their personal details by staff before starting their examination.

Individuals of childbearing potential (pregnancy enquiries)

The employer had a written procedure in place in relation to the process for establishing if a patient was or may be pregnant, prior to undergoing any procedure. This procedure aimed to ensure that such enquiries were made in a standard and consistent manner.

Staff we spoke with confirmed that they would ask the necessary questions and document the evidence provided in the pregnancy checking form. The patient would then sign the form. It was noted that the referral form had a section for the last menstrual period (LMP)[9], but this was not included on the pregnancy checking form. The patient also signed a pregnancy disclaimer form which was scanned onto the patient's records. We noted that the employer's procedure (EP4), which dealt with pregnancy enquiries, did not refer to the patient signing the form. Additionally, the flow chart included within this procedure differed to the flow chart in the department, which staff used when questioning patients. The procedure and documentation need to be amended to include reference to the patient signing the form, the date of the LMP and to the correct flow chart.

We were told that there were multilingual posters displayed within the department advising patients to speak with staff if they either were, or thought they may be pregnant. We were also provided with a copy of the poster. This was important to minimise potential harm to an unborn child from the exposure to ionising radiation.

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

[9] Last menstrual period (LMP) refers to the start date of the most recent menstrual period.

Non-medical imaging exposures

The employer had a written procedure in place which set out the criteria for carrying out non-medical imaging exposures[10]. Referrals for non-medical imaging examinations would only be accepted from registered healthcare professionals. All these referrals had to be justified by a Consultant Radiologist. Medical insurance chest referrals would be passed to the appropriately entitled nominated staff.

Referral guidelines

We spoke with senior staff about the process for booking referrals for a future date. We were told that referrals were booked in the order they were received unless they were marked urgent or the patient has arranged a follow up for the results sooner than a routine appointment and report would be available. In this situation the referral would be prioritised.

It was the responsibility of the referring clinician to identify if the patient was clinically urgent. All referral forms marked “urgent” were offered an appointment the same day or next working day.

Staff stated that they would always ask patients if they had received any imaging in the last six months. This was particularly important, as the hospital were contracted to perform a number of X-rays on behalf of the NHS during the pandemic. The online clinical records for those patients would not, currently, be available, for staff to view. Where the imaging was requested by the NHS, the department would follow the protocol of the health board. Referrals were justified and authorised by the health board radiologists.

The self-assessment form provided, stated that only those clinicians and non-medical referrers listed in the referrer list, maintained by the department were eligible to request radiological examinations. The referrer needed to follow the referral criteria detailed in the Royal College of Radiologists Referral Guidelines

[10] Non-medical imaging is defined as any deliberate exposure of an individual for imaging where the primary intention of the exposure is not to bring a health benefit to the individual being exposed. Such exposures include those performed for insurance or legal purposes without a medical indication, or exposures for suspected concealed drugs.

(version 8) – iRefer[11] “Making the Best Use of Clinical Radiology.” We were told that iRefer was present in all of the consultation rooms within the hospital. All referrals had to be made using the advanced diagnostic imaging request form (paper copy or electronically where available). Telephone requests were not permitted.

We were informed that iRefer was freely available to all healthcare professionals. The radiologist and general practitioners who worked with the hospital had been emailed the referral link. Additionally, reminders were sent on how to access iRefer, the referral pathway and how to complete the form and cancel a referral.

Improvement needed

The employer needs to ensure that the employer’s procedures, actual processes in the department and the documentation aligns relating to:

- The referral form and pregnancy checking form having a section on the LMP
- That the employer’s procedure includes reference to the need for the patient to sign the pregnancy checking form
- The flowchart in the employer’s procedure is updated to match the chart used in the department.

Duties of practitioner, operator and referrer

There was a system in place to identify the different types and roles of the professionals involved in referring and performing radiology examinations for patients. The employer's procedure on how IR(ME)R 2017 was implemented within the department identified, by individual or staff group, who were entitled to

[11] http://guidelines.irefer.org.uk /

be referrer[12], practitioner[13] and operator[14] (known as duty holders). The procedure also stated that referrers and practitioners must be registered healthcare professionals and operators and practitioners must receive appropriate training to undertake these duties.

The training records supplied lacked detail as regards, version control and include the name of the individual at the top of the training record with their role. One training record was also ticked as Yes and No against all the entries. Training records need to be reviewed and completed to a higher standard with the name and role at the top of the form. They should also be version controlled to ensure the up-to-date training record is used.

We were provided with evidence, in the form of the audit of referrals in theatre, which showed that the radiographers completed the referral forms in theatres. We were told that radiographers would be involved in the procedure when an X-ray was required and would complete the form at this stage. We were told that the referral was verbally agreed by the surgeon and that the anaesthetist had checked the patient identity and made the necessary pregnancy enquiries. The radiographer would also aim to be there when the WHO checklist was completed, so they could also confirm the patients' identity at this stage. We were further told that the procedures that required X-rays would normally be known two weeks in advance of the procedure so the radiographer can be arranged.

There is a need to change the theatre referral process to comply with IR(ME)R. We recommend that referral forms are completed by the healthcare professional making the referral, normally the surgeon. When this was discussed with senior management, they said they had already started to put a process in place at the hospital. This process involved the theatre manager ensuring that the necessary documentation was completed in advance of the exposure. However, we stress

[12] 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.

[13] 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.

[14] 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.

that this referral must be completed by the person making the referral and not the theatre manager or the radiographer. We were also told that in the future any instance where the documentation is not completed correctly would be highlighted on DATIX, the incident reporting system used by the hospital. In addition, management said they would be carrying out more audits, particularly extending the area of surgeons' compliance with notes and referral forms.

Improvement needed

The employer is required to ensure that training records need to be reviewed and completed to a higher standard including:

- Ensuring the training records are updated to ensure version control
- The name of the person being trained and their duty role is at the top of the form
- Completing the training records accurately and in a timely manner.

The employer is to ensure that the referral forms are completed correctly, in a timely manner, by the correct individual and signed by them.

Justification of Individual Medical Exposures

The process of justification and authorisation was clearly understood by the staff we spoke with. We were told that there were delegated authorisation guidelines for CT that were included in the employer's procedures.

We were told that radiographers in the general area were entitled as practitioners to justify exposures. We discussed with senior managers the aspect of carers and comforters[15] within the service delivery. There was an employer's procedure

[15] carers and comforters means individuals knowingly and willingly incurring an exposure to ionising radiation by helping, other than as part of their occupation, in the support and comfort of individuals undergoing or having undergone an exposure.

(EP11) in place relating to the exposures of carers and comforters. We were told that the practitioner justifying the patient exposure would also act as the practitioner for the carer and comforter exposure. In justifying the exposure of the carer and comforter, the practitioner had to satisfy themselves that the patient truly required the close support of another individual for the examination to take place successfully. Carers and comforters would only in exceptional circumstances be required to physically participate in an exposure of a patient. We were also provided with a response in the self-assessment form relating to carers and comforters which went into more detail than that included in the employer's procedures. We recommended that this detail be included in the procedure for added clarity and consistency.

We were told that the NHS work carried out at the hospital, was reported at the local health board. Scan protocols were agreed for CT and MRI from the requesting health board. Forms were justified and authorised by the requesting health board prior to being sent to the hospital to book the procedure.

Improvement needed

The employer should ensure that the carer and comforter section of the employer's procedures includes all the detail relating to the exposure of carers and comforters.

Optimisation

The self-assessment form stated that dose audits were sent to the MPE for analysis and feedback to provide advice and support on optimisation. Additionally, the MPE referred to the image optimisation team (IOT)[16] which was part of the CT User group. We were told that MPE involvement in the CT user group had improved and the MPE would attend relevant meetings in the future.

[16] Responsible for consistent improvement and optimisation of all examinations using ionising radiation - including CT scans - to support dose and image quality.

Examples of optimisation techniques and training were provided. These included kidney, ureters, bladder (KUB)[17] CT scan range reduced and low dose study optimisation, CT colonography (CTC)[18] low dose[19] scanning and attendance at a training course by members of staff for dose optimisation. In addition, we were told of the transcatheter aortic valve implantation (TAVI)[20] protocol set up initially by the MPE to help optimise dose.

Diagnostic reference levels (DRLs)[21]

There was an employer's procedure in place for determining, implementing and reviewing diagnostic reference levels (DRLs). We were informed that the DRLs were displayed within the X-ray rooms, to assist staff when undertaking procedures. We were told that both Local and National DRLs were available in the department and that they were reviewed every three years by the RPS service. The local DRLs were lower than the national DRLs and this was evidence of optimisation in the department. Local DRLs were adopted, based on advice from an MPE in the written report of DRL audits. However, the procedure for DRLs lacked detail on how the recommended DRLs were ratified by the employer prior to being put into clinical practice.

The MPE provided further advice on the application and use of local DRLs, for example in the form of a guidance note on recording individual patient doses

[17] https://www.rcr.ac.uk/audit/audit-optimise-ct-kub-imaging-investigation-renal-colic.

[18] CT colonography is known in full as computerised tomography colonography (sometimes the word computed is used instead of computerised). It is a test that uses a CT scanner to produce pictures of the inside of the colon and rectum (the colon is the last part of the intestines or guts, the rectum is the passage between the colon and the anus).

[19] A low dose CT scan provides an image of inside the patient's body with minimal radiation.

[20] Pre-operative assessment before TAVI includes several tests and imaging examinations that are performed to evaluate the current vascular status, potential anatomic problems (e.g. severe iliac calcifications) and best surgical approach.

[21] DRLs are a level used in medical imaging to indicate whether, in routine conditions, the dose to the patient or the amount of radiopharmaceuticals administered in a specified radiological procedure for medical imaging is unusually high or unusually low for that procedure.

exceeding the DRL. Where it was identified that DRLs were being consistently exceeded, MPEs are available to help investigate and optimise.

Further, we were told that the MPE looked at a range of views specifically the lateral (side to side) knee and this showed a 20 percent change above the local DRL. Following a meeting by the team to review the technique it was noted that radiographers had slightly different techniques. The practice was then changed to keep the patient standing which improved technique, reduced dose and reduced the need for repeats.

The audit of DRLs was in line with the Institute of Physics and Engineering in Medicine (IPEM). Guidance on the Establishment and Use of Diagnostic Reference Levels for Medical X-Ray Examinations. (IPEM report 88).

Clinical evaluation

There was reference to clinical evaluation in the employer's procedure. The self-assessment went into more detail relating to all examinations that were reported on by a consultant radiologist. Reports were saved in the picture archiving and communication system[22] (PACS) system and the secure web based system used at the hospital. Pre and post-operative orthopaedic X-rays are evaluated by the referring orthopaedic surgeon. This evaluation was documented in the patients' hospital notes.

Equipment: general duties of the employer

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

An independent contractor performed the servicing, repair and maintenance on the equipment. Staff described the handover process and the use of a handover form. Forms were completed and signed by the contractor and operator prior to accepting the equipment back into clincial practice. Where indicated, RPS Cardiff would carry out the necessary QA testing after a service or repair. Staff we spoke

[22] A picture archiving and communication system (PACS) is a medical imaging technology which provides economical storage and convenient access to images from multiple modalities (source machine types).

with were able to describe the process used to communicate equipment issues to the appropriate staff. This included informing senior managers in the department and ensuring the equipment was taken out of service and not used, until repaired.

Safe care

Managing risk and health and safety

Staff we spoke with were able to describe the risk management arrangements and assessments in place within the department. Additionally, responses received via our staff survey detailed that all staff respondents felt that they would feel secure raising concerns about any unsafe clinical practice within the department. They also felt that their concerns would be appropriately dealt with.

Every staff member who completed a questionnaire said that if they were concerned about unsafe clinical practice, they would know how to report it and also said they would feel secure raising concerns about unsafe clinical practice. All but one felt confident their organisation would address their concerns once reported.

In the questionnaires, staff were given a number of statements relating to how the organisation had adapted to become COVID-19 compliant. All respondents agreed the organisation had implemented the necessary environmental and practice changes. Also, they agreed that decontamination arrangements for equipment and relevant areas had been implemented and that there had been a sufficient supply of PPE.

We were told that the hospital had undertaken a number of X-rays on behalf of the NHS during the pandemic. Staff we spoke with told us that patients were routinely asked for information about their last X-ray, even if this information was on the referral form provided. Senior managers told us that they were in the process of arranging a link with the two local health boards, so that this information would be available online.

Senior managers stated that risk assessments were in place including environmental risk assessments. The risk register was held on the hospital shared drive, with access available to all staff. Staff were informed of additional or new risks through the daily nine at nine (described further below), notice boards and the various staff meetings.

Infection prevention and control (IPC) and decontamination

Nearly all patients who completed the questionnaire felt that, in their opinion, the department was very clean. We asked a question about COVID-19 compliant procedures being evident during patient visits. Of the patients who had visited during the last year (i.e. since February 2020), nearly all said COVID-19 compliant procedures were very evident during their time at the setting.

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.

All staff respondents who completed the questionnaire said infection prevention and control procedures were followed and patient's privacy and dignity was maintained.

Staff informed us of the cleaning processes that were in place, which set out the frequency of required cleaning for relevant rooms and equipment throughout the department. Staff confirmed that relevant areas were cleaned after every patient and that the level of cleaning depended on the risk level of the patient. In response to COVID-19, additional time was allocated to complete the procedures and to also ensure sufficient time was available for the required cleaning and decontamination.

Staff we spoke with confirmed that they had received IPC training and were aware of their responsibilities with regards to infection control within the department.

Members of the senior staff that we spoke with stated that there was routine screening for COVID-19. There were additional hand washing stations now available and chairs were easy wipe clean. We were told that longer appointment times were allocated and not all X-ray rooms were operating at once.

The department arranged training sessions with theatre staff and the pathology manager on donning and doffing of personal protective equipment (PPE). Additionally, a further module was added to the hospital training database, for staff to complete, relating to a hand washing refresher and lateral flow testing.

Safeguarding children and safeguarding vulnerable adults

Staff we spoke with said that they had received online training relating to safeguarding of children and vulnerable adults. They were also aware of where to find the relevant policies and procures for this area.

Effective care

Participating in quality improvement activities

Clinical audit

As part of the pre-inspection self-assessment form and supporting evidence, we were provided with a spreadsheet of the completed audit checklist. Additionally, there was an employer's procedure (EP5) relating to the quality assurance and audit programme. However, the two documents did not correlate regarding the types of audits being performed, the timeframe and frequency for the audits, how the findings were shared and how recommendations were actioned. In addition, there is no reference to when re-audit was required following the implementation of changes. The hospital was required to amend the documentation and the process in place to ensure that these omissions are corrected.

The clinical audit information provided showed that audits were taking place at the hospital. However, we noted that the audits had identified areas of non-compliance which caused concern. One such audit was of referral forms completed by the radiographer in theatre. The audit checked 18 referral forms and identified that:

- 14 did not have a practitioner recorded
- 11 did not have a record of justification
- eight forms did not have a dose recorded
- four did not have the screening time recorded
- four were not dated
- four did not include a record of the identity check.

We were told that the department had put in a process to ensure future compliance and to re-audit the area. This area is also covered above relating to theatre referrals.

We noted that the clinical evaluation of theatre notes for cases involving the C-arm[23] were not audited for theatre compliance. We recommend that the audit of clinical notes elsewhere is extended to include theatre notes.

The audit of pregnancy checking in CT also showed that 16 percent of patients had no evidence of this check. For the general X-ray area this audit showed that 20 percent of patients were not checked. As described above, staff stated they were aware of the correct procedure. As a result of this audit we were told that departmental management spoke to all staff and reminded them of the importance of checking patients' pregnancy status, and of the need to document this check in accordance with EP4.

A further example of action taken following an audit was when it was noted that 12 percent of the X-rays were not reported. We were told that a letter was sent to surgical and orthopaedic consultants to remind them of their responsibility of writing in patient notes. In accordance with IR(ME)R exposures that are not clinically evaluated are not justified.

We saw evidence of the Governance and Framework Radiation Protection Audit completed by the RPS on the hospital's Diagnostic Imaging Department. This was the first in a series of six audits planned to be conducted over three years, which would assess the compliance of the organisation against IR(ME)R. The purpose of this audit was to clarify the governance surrounding IR(ME)R compliance within the organisation, including any associated organisational framework. Future audits would look in more detail at different aspects of IR(ME)R (such as entitlement of operators, use of local DRLs and incident management). The audit was completed recently and we were told that an action plan was in place to address the issues, which include some of the recommendations in this report.

We were also told the follow up audits relating to cannulation were still in progress, although the initial findings showed a lot of improvement. Additionally, the reject analysis follow up audit had been completed with repeats now very low.

[23] A C-arm is an imaging scanner intensifier. The name derives from the C-shaped arm used to connect the X-ray source and X-ray detector to one another. C-arms have radiographic capabilities, though they are used primarily for fluoroscopic intraoperative imaging during surgical, orthopedic and emergency care procedures.

Following the lateral hips audit, a peer review was carried out and the technique had been adapted.

Expert advice

There was one MPE working with the hospital under the service level agreement with the RPS. The MPE was listed on the approved list for Radiation Protection Advisors (RPA)[24] 2000, the certification body for MPEs. We were told MPEs were entitled as operators to enable them to perform the required tasks and that this was included as part of their appointment letter. However, the appointment letter provided to the MPE was not dated and the employer should consider amending this to include the issue date.

We were also told that the CT user group was one of a number of forums for the sharing of information. This monthly group also took on some of the functions of an Image Optimisation Team (IOT). The CT superintendent radiographer at the hospital chairs the group to look at technique, a range of case findings, and discussed ways to adapt techniques to help minimise dose. It had not long started as a group and it is intended to invite a cardiac CT radiologist and MPE to attend in the future.

Medical research

We were informed by senior managers that research involving medical exposures was not being performed at the hospital at the time of our inspection and had not completed any research exposures in several years.

Improvement needed

The employer is to ensure that:

- There are regular and complete audits of theatre notes
- The table in the employer's procedure is updated to ensure that all the audit and assurance programmes are included

[24] A Radiation Protection Adviser (RPA) is a title used in the UK and is given to those who are competent to advise employers on the safe and compliant use of Ionising Radiations. The post is a legally recognised position and is a requirement of the Ionising Radiations Regulations 2017.

- The spreadsheet used to record the audits includes full information such as all the audits being performed, as well as the timeframe and frequency for the audits, how the findings are shared and how recommendations are actioned
- Consultant radiologists carry out audits of work undertaken at the hospital
- Appropriate follow up audits are carried out where the results of the audit show areas where improvement is needed
- The MPE appointment letter is reissued, dated and signed.

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 and of senior managers.

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.

Governance and accountability framework

There was a management structure in place, with clear lines of reporting, which was described and demonstrated. We found that governance arrangements were in place to support the effective operation of the department.

The hospital held nine at nine meetings where all heads of departments or representatives met in the conference room at for updates and exchanges of relevant items of information. This meeting was minuted and distributed to all members of staff. Staff we spoke with were positive about how information was shared between management and staff, describing the various meetings and methods used to pass on information.

Most staff who completed a questionnaire said that they know who the senior managers were in the organisation. Most said there is effective communication with senior management. Staff we spoke with during our inspection felt supported by their line managers. We were also told that senior managers within the department were very visible and approachable.

Prior to the inspection, HIW required senior staff within the department to complete and submit a self-assessment questionnaire. This was to provide HIW with information about the department and the employer's key policies and procedures in respect of IR(ME)R. This document was used to inform the inspection approach. The self-assessment form was returned to HIW within the agreed timescale. Whilst we did highlight discrepancies in the responses provided, senior staff provided additional information or clarification 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.

Senior staff stated that they engaged with staff in a number of ways, through being visible within the department and through feedback and communications from monthly meetings. We were told of the fortnightly newsletter to all staff. In addition to emails and meetings there was also a staff notice board to communicate any changes to written procedures to staff. Question and answer sessions were held during departmental meetings to confirm staff awareness of any changes. All staff were required to sign a form to confirm that they had read and understood the changes. We were provided with a recent example of this form.

Regarding ensuring that equality and a rights based approach was embedded across the service, we were told that everyone was treated with the same degree of respect. Senior staff provided us with an example of how a situation had been dealt with in the recent past, including initially a suspension and subsequent investigation. Most staff respondents to the questionnaire said their organisation acted fairly with regard to career progression or promotion, regardless of ethnic background, gender, religion, sexual orientation, disability or age. All but one respondent said they were offered full support in the event of challenging situations. Every respondent said they had not personally experienced discrimination at work in the last 12 months.

The department was small with only 11 members of permanent staff and there was a lot of reliance placed on the two senior managers, the Director of Advanced Diagnostics and the Superintendent Radiographer. As it was a small department perhaps that reliance was more evident. However, based on the conversations with staff we believe that there is a need for staff to take on more responsibility for incidents and issues without having to rely so heavily on the two senior managers.

Duties of the employer

Entitlement

Overall, the department staff we spoke with had an understanding of their duty holder role and their scope of entitlement under IR(ME)R. However, the evidence provided showed that entitlement certificates needed to be update and amended to better reflect duty holders roles and scope of practice. We were provided with examples of entitlement certificates that were not signed or dated by the assessor. The forms were also incomplete as regards registration numbers, signature of entitlement from the employer and whether the IR(ME)R procedure had been read. The entitlement certificates need to be update, completed correctly and changed as necessary.

Procedures and protocols

The chief executive of the hospital was the designated employer as defined by IR(ME)R regulations. This arrangement was detailed within the hospital's Policy for the Safe Use of Ionising Radiations and the Employer's Procedures document. These documents also set out the tasks which had been delegated to the other professionals within the service in relation to IR(ME)R. A number of suggestions were provided during our conversations with senior managers with regard to the current detail included within these and other documents to assist the ongoing revision of the documents. These included:

- The induction pack needs to be reviewed and more detail added such as the benefits to staff, including occupational health arrangements, and the location of the hearing loop etc. Additionally, reference to patient contact shielding needs to be removed from the CT induction pack
- EP 1 Identity checks, reference to wristband checking for patients that cannot identify themselves. From discussions with staff very little in-patients were examined, therefore this EP should be updated to better reflect practice
- EP 2, the use of the term medical legal in relation to visa applications instead of non-medical imaging needs to be changed. Additionally, in Appendix 5 to EP2, the conflict with reference to

non-medical referrers needs to be updated together with the use of non-medical referrer radiographers in MRI for orbital X-rays25.

- EP4 – Schedule 2.1(c), “Procedure for Checking Pregnancy in Patients of childbearing potential – Plain X-ray Flow Chart”. The flow chart needs to be replaced with the flow chart being used in the X-ray rooms. Also clarification is needed on recording the LMP date and any other additional information. Pregnancy checks need to be more robust with a record that the patient has been asked. Pregnancy checking forms provided were only used in CT, this was not clear from the form or the EP as to what process was being used as staff indicated they record LMP on the referral form.

- EP7 – DRLs. This procedure needs to include detail on how the recommended DRLs were ratified by the employer prior to being put into clinical practice.

- EP 11. This needs to include more detail on what is recorded for carers and comforters and where this information is recorded, in addition to the information referenced in the section below

- Version control on all documents is required including training records and protocols

- MPEs did not have training records available as they were currently being established. MPEs hold their own CPD records. More detail is needed as the scope of practice for MPEs was very generic in the EP under group entitlement

- The policy for the Safe Use of Ionising Radiations does not mention the appointment of the MPE, it only refers to the RPA and makes reference to much greater than intended (MGTI) instead of significant accidental or unintended exposure (SAUE).

[25] Orbital X- rays are a radiographic study of the area and structures containing the eyes. The orbits are bony cone-shaped cavities that contain and protect the eyes.

Accidental or unintended exposures

Part of the employer's procedures included two sub sections relating to the investigation of accidental or unintended exposures. These were:

- EP11 – Schedule 2.1 (k) Procedure for the Investigation of a Significant Accidental Unintended Exposure (SAUE) and
- EP11-Schedule 2.1 (l) Procedure for the investigation of Clinically Significant Accidental Unintended Exposure (CSAUE).

These should set out the process staff should follow if they suspected that a SAUE or CSAUE had occurred. The procedure should guide staff through the process including incidents which result in HIW being informed in a timely manner, as necessary. However, the procedure did not include detail on CSAUE as defined by the Royal College of Radiologist guidance[26]. The CSAUE detail is separate and this part of the procedure lacked sufficient detail. This needs to include who will establish a CSAUE, how it will be reported, who would inform the patient or if the decision was not to inform the patient, and how was this recorded. Additionally, there needs to be more detail on who writes the letter to the patient after an accidental or unintended exposure incident. We were told by senior staff that there have not been any accidental or unintended exposure incidents at the department.

All staff who completed the questionnaire said they had not reported an accidental or unattended exposure incident affecting patients within the last month. Most respondents said the last time they/colleague saw an error, near miss or incident it was reported. Senior managers 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 a patient. In the first instance, staff notified the department manager or clinical lead. The incident would then be investigated and the relevant information would be collected, including the relevant exposure information. This information would then be sent to the MPE for review, who would subsequently advise whether a notification needed to be submitted to HIW or any another external regulator.

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[26] https://www.rcr.ac.uk/system/files/publication/field_publication_files/irmer-implications-for-clinical-practice-in-diagnostic-imaging-interventional-radiology-and-nuclear-medicine.pdf

Staff we spoke with, as part of our inspection, confirmed that they had access to current versions of the policies and procedures in place. Also, senior staff confirmed that when any changes to documents occur, notifications were circulated to department staff, who were subsequently asked to confirm that they had read and understood the relevant changes.

Improvement needed

The employer is required to ensure that entitlement certificates are up to date, completed correctly and changed as necessary to reflect the relevant scope of practice.

The employer is to ensure that the all procedures (including employer's procedures), are reviewed and updated. They must ensure they are up to date, reviewed in a timely manner and reflect practices and arrangements in place, including addressing the issues highlighted in the procedures and protocols section of this report.

The employer is to make the necessary changes to the employer's procedure relating to a SAUE or CSAUE to ensure that it guides staff in full through the process. This must also include, who establishes a CSAUE, how it will be reported and who would inform the patient or if the decision was not to inform the patient, how was this recorded and the completion of the relevant letters.

Workforce planning, training and organisational development

Staff were asked in the questionnaires to rate how often a number of statements relating to their organisation applied in their experience. All of the staff said the organisation always encouraged teamwork and nearly all felt the organisation was supportive. All but one staff member agreed that front line professionals who dealt with patients were empowered to speak up and take action when issues arose.

Every staff member said there was a culture of openness and learning within the organisation that supported staff to identify and solve problems. They also agreed the organisation had access to the right information to monitor the quality of care across all clinical interventions and take swift action when there were shortcomings.

Staff were asked in the questionnaire about their immediate manager, and the feedback received was generally positive. All respondents said their immediate manager encouraged them to work as a part of a team and could always be counted on to help with difficult tasks. All respondents said their immediate

manager gave them clear feedback and said they asked for their opinion before making a decision that could affect their work. Every respondent said their manager was supportive in a personal crisis.

All staff respondents agreed, when asked, if their job was good for their health and also agreed their immediate manager took a positive interest in their health and well-being. All agreed their current working pattern allowed for a good work life balance. Additionally, not all staff we spoke with were aware of the occupational health and well-being support available. The senior managers that we spoke with, described the arrangements in place to support staff including their well-being. This included welfare support and that the hospital had recently entered into a contract with a local independent GP counselling service. Staff also had the opportunity to contact a private medical healthcare provider. Senior managers should make this known to all staff so that they can use the opportunities available; this area is also covered above in the recommendation on the induction pack.

Most respondents agreed that staff who were involved in an error, near miss or incident were treated fairly and agreed that their organisation encouraged them to report errors, near misses or incidents. Most of the respondents agreed the organisation would treat reports of an error, near miss or incident confidentially. All but one respondent said they were offered full support in the event of challenging situations.

The majority of staff said the organisation would not blame or punish the people who were involved in such incidents. Most agreed action would be taken on incidents identified so they would not happen again. Most agreed they were informed about errors, near misses and incidents that happened in the organisation and were given feedback about changes made in response to reported errors, near misses and incidents. Those interviewed felt supported in their role and that there was an open door policy at the hospital from the chief executive downwards.

Most staff indicated in the questionnaires that they had undertaken learning and development, in areas such as health and safety, fire safety, infection control and safeguarding. This was in addition to IR(ME)R training relevant to the functions as practitioner or operator, and other training relating to their specialist area of practice. A majority of respondents said they had undertaken learning and development in mental health capacity.

Most of those who completed a questionnaire said training or learning and development usually helped them to do their job more effectively and helped them to stay up to date with professional requirements. All said it helped them

deliver a better experience for patients. Staff we spoke with said that they had been offered additional training opportunities including Cardiac MRI[27] training and management courses.

Staff were asked to name the training they would wish to attend, one response was received:

"Fire Marshal and Train the trainer for manual handling"

All but two of the staff who completed a questionnaire told us they had an appraisal, annual review or development review of their work in the last 12 months. This was confirmed by the staff interviewed, although this may relate to the new staff recently employed. Most said their learning or development needs were identified and that their manager always supported them to achieve these needs.

The method used to ensure compliance with mandatory training was also described. This included reference to the system used, that gave live training management, tracking, reporting, automated compliance, and customised training plans. The Director of Advanced Diagnostics had an objective to ensure staff were fully compliant with mandatory training. We were told that the need to ensure compliance with mandatory training had also been discussed as a team.

The radiologist training record provided, for CT interventional work, was signed and dated in 2016. We recommend that training records are reviewed regularly and should be defined in the hospital policy.

The continuous professional development (CPD) sessions held were described. This was part of the monthly team meetings. Staff were asked to describe a procedure that would be of interest to the whole group. Additionally the training on cardiac scanning as described above was discussed. The interventional radiology nurse was also involved in this discussion and CPD opportunity.

[27] Cardiac MRI is used to diagnose a wide range of heart conditions. These include coronary heart disease, congenital heart disease (in children and adults), inherited heart conditions (such as hypertrophic cardiomyopathy or dilated cardiomyopathy), heart valve disease and cardiac tumours.

Senior management described how they ensured and could demonstrate that the IR(ME)R duty holders were appropriately qualified, trained and state registered, where appropriate. This included checking the Health and Care Professions Council registration of permanent and bank staff. A record of all staff registration was held in the main hospital management suite.

The annual appraisal process was described that included an annual appraisal with objectives being set at the beginning of the year, reviewed in mid-year and reflected on at the end of the year.

The MPE we spoke with said that training records previously were not maintained to an appropriate standards but a new system is being implemented, in the RPS to rectify the issue. There were also authorising staff at RPS Cardiff that could sign off the training records. All MPEs maintain a record of their own CPD record.

Improvement needed

The employer must ensure that the training records are regularly checked and defined in hospital procedures.

Workforce recruitment and employment practices

In the questionnaires, staff were given a number of statements relating to patient care and were asked to rate how often those applied in their experience. Most of the respondents said they were able to make suggestions to improve the work of their team or department. All said they were involved in decisions which affected them, their team or department.

The majority said they were sometimes unable to meet all the conflicting demands on their time at work. All respondents said they had adequate materials, supplies and equipment to do their work. Two thirds felt there were usually enough staff at the organisation to enable them to do their job properly and two respondents said there were sometimes enough staff. Staff we spoke with felt that staffing levels within the department were sometimes challenging. We were told that three new members of staff had been employed recently to manage the increased demand on the department. However, staff said that at times they were stretched, but that the work was always carried out safely. Senior staff told us that whilst the department was busy, staffing levels were appropriate and safe. Appointments could be changed should the staffing dictate this need.

The process of allowing consultant radiologists to obtain practising privileges[28] was explained by the senior staff we spoke with. Initially, the radiologist would send in an expression of interest with their area of expertise. They also needed two years experience as a consultant. The hospital then sent out a pack to the radiologist asking for information including their experience and General Medical Council registration details. Further checks would be carried out by the hospital administration. Once agreed by the clinical governance group, the application would be reviewed at board level. Once accepted the radiologist would be informed of their entitlement and PACS training arranged in addition to an induction.

[28] Practising privileges, in relation to a medical practitioner, refers to the grant to a person who is not employed in an independent hospital of permission to practise in that hospital;

4. What next?

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

Appendix A: Includes a summary of any concerns regarding patient safety which were escalated and resolved during the inspection

Appendix B: Includes any immediate concerns regarding patient safety where we require the service to complete an immediate improvement plan telling us about the urgent actions they are taking

Appendix C: Includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

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

The improvement plans should:

Clearly state when and how the findings identified will be addressed, including timescales

Ensure actions taken in response to the issues identified are specific, measurable, achievable, realistic and timed

Include enough detail to provide HIW and the public with assurance that the findings identified will be sufficiently addressed.

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

Ensure that findings are not systemic across other areas within the wider organisation

Provide HIW with updates where actions remain outstanding and/or in progress, to confirm when these have been addressed.

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

5. How we inspect services that use ionising radiation

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

The regulations are designed to ensure that:

Patients are protected from unintended, excessive or incorrect exposure to medical radiation and that, in each case, the risk from exposure is assessed against the clinical benefit

Patients receive no more exposure than necessary to achieve the desired benefit within the limits of current technology

Volunteers in medical research programmes are protected

We look at how services:

Comply with the Ionising Radiation (Medical Exposure) Regulations 2017

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 twelve weeks notice of an inspection.

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

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

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

Further detail about how HIW inspects 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: St Joseph's Hospital

Ward/department: Diagnostic Imaging

Date of inspection: 23 and 24 March 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
There are 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

Hospital: St Joseph's Hospital

Ward/department: Diagnostic Imaging

Date of inspection: 23 and 24 March 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 / Regulations	Service action	Responsible officer	Timescale
Quality of the patient experience				
The employer is required to ensure that the benefits and risks of the radiation, during the procedure in theatre, must be explained to the patient when the WHO checklist is carried out. This must also be documented as completed on the checklist.	Regulation 6 Schedule 2 1(i)	An e mail was sent to all consultants informing them of a change in process. It is the responsibility of the clinician performing the surgery to go through the Risk /Benefits of using X ray during the surgery. This now forms part of the consent process and will be documented in the patients notes and signed. The Radiographer will check the patients' notes at the time of the WHO checklist at the beginning of surgery .The	Jane Carpanini Director of Advanced Diagnostics	May 2021 May 2021

Improvement needed	Standard / Regulations	Service action	Responsible officer	Timescale
		radiographer will then countersign to say the documentation has been checked. An audit will be performed after 1 month of implementation to monitor compliance. Audits will then continue every 3 months or sooner if required.		August 2021
Delivery of safe and effective care				
The employer needs to ensure that the employer's procedures, actual processes in the department and the documentation aligns relating to: • The referral form and pregnancy checking form having a section on the LMP • That the employer's procedure includes reference to the need for the patient to sign the pregnancy checking form • The flowchart in the employer's procedure is updated to match the chart used in the department.	Regulation 6, Schedule 2 (1)(c) Regulation 11(1)(f)	Employers procedures have been amended and all documentation aligned.	Jane Carpanini	Completed May 2021

Improvement needed	Standard / Regulations	Service action	Responsible officer	Timescale
The employer is required to ensure that training records need to be reviewed and completed to a higher standard including: • Ensuring the training records are updated to ensure version control • The name of the person being trained and their duty role is at the top of the form • Completing the training records accurately and in a timely manner. The employer is to ensure that the referral forms are completed correctly, in a timely manner, by the correct individual and signed by them.	Regulation 6(3)(b), 17 (4) and Schedule 3 Regulation 10(5)	Existing training records updated with version control. Future training records will reflect the required standards All referring clinicians have been reminded of the importance of completing referral forms in line with IRMER regulations. Repeat audit is planned to include the last 3 months of referrals.	Charity Mukwenya	May 2021 August 2021
The employer should ensure that the carer and comforter section of the employer's procedures includes all the detail relating to the exposure of carers and comforters.	Regulation 12(5) Regulation 6 Schedule 2 (1)(n)	Employers Procedures have been updated to reflect the recommendations. Additional training has been given to all operators. Documentation and signage updated in all areas to reflect the Carers and Comforters policy.	Jane Carpanini	Completed May 2021

Improvement needed	Standard / Regulations	Service action	Responsible officer	Timescale
The employer is to ensure that: • There are regular and complete audits of theatre notes • The table in the employer's procedure is updated to ensure that all the audit and assurance programmes are included • The spreadsheet used to record the audits includes full information such as all the audits being performed, as well as the timeframe and frequency for the audits, how the findings are shared and how recommendations are actioned • Consultant radiologists carry out audits of work undertaken at the hospital • Appropriate follow up audits are carried out where the results of the	Standard 6 Participating in Quality Improvement Activities Regulation 7	Audits are planned and documented in the Employers Procedures in addition to the Hospital wide Audit template reviewed at Clinical Governance meetings. The spreadsheet has been updated to reflect recommendations. Audit is to be implemented to include all Consultant radiologists working out of St Josephs. This will include 10% of all MRI and CT and 2% of plain radiographs.	Jane Carpanini Director of Advanced Diagnostics Rachel Davies MRI Lead	June 2021 Completed May 2021 August 2021

Improvement needed	Standard / Regulations	Service action	Responsible officer	Timescale
audit show areas where improvement is needed • The MPE appointment letter is reissued, dated and signed.	Regulation 14(1)	Under review in conjunction with RPS Cardiff. New letter will be issued and SLA amended accordingly	Jane Carpanini Director of Advanced Diagnostics	Aug 2021
Quality of management and leadership				
The employer is required to ensure that entitlement certificates are up to date, completed correctly and changed as necessary to reflect the relevant scope of practice.	Regulation 6 Schedule 2 (1)(b)	Entitlement certificates have been updated as recommended	Jane Carpanini Director of Advanced Diagnostics	Completed May2021
The employer is to ensure that the all procedures (including employer's procedures), are reviewed and updated. They must ensure they are up to date, reviewed in a timely manner and reflect practices and arrangements in place, including addressing the issues highlighted in the procedures and protocols section of this report.	As below Regulation 6 (5)(b) Schedule 2 (1)(d)	Documentation has been updated and aligned	Jane Carpanini Director of Advanced Diagnostics	Completed May2021

Improvement needed	Standard / Regulations	Service action	Responsible officer	Timescale
• The induction pack needs to be reviewed and more detail added such as the benefits to staff, including occupational health arrangements, and the location of the hearing loop etc. Additionally reference to patient contact shielding needs to be removed from the CT induction pack	Standard 24 Workforce Recruitment and Employment Practices	New HR manager has been employed. Induction process is being reviewed and improved to reflect recommendations. The reference to patient shielding has been removed from the CT induction pack	Vanessa Steele HR Manager Charity Mukwenya CT Lead Radiographer	September 2021 Completed May2021
• EP 1 ID check. Reference to wristband checking for patients that cannot identify themselves. From discussions with staff very little in-patients were examined, therefore this EP should be updated to better reflect practice	Regulation 6 Schedule 2 (1) (a)	EP1 updated. The inpatients examined in Advanced Diagnostics are post-operative and able to come identification. If there is a situation when a patient is unable to identify themselves staff will check the patient's wrist band.	Jane Carpanini Director of Advanced Diagnostics	Completed May2021
• EP 2, the use of the term medical legal in relation to visa applications instead of non-medical imaging needs to be updated. Additionally, in Appendix 5 to EP2, the conflict with reference to non-medical referrers needs to be updated together with	Regulation 6 (4) Schedule 2 (1) (m)	EP2 has been amended to reflect the recommended wording with regards non-medical imaging. Appendix 5 has been updated	Jane Carpanini Director of Advanced Diagnostics	Completed May2021

Improvement needed	Standard / Regulations	Service action	Responsible officer	Timescale
the use of non-medical referrer radiographers in MRI for orbital X-ray.				
• EP4 – Schedule 2.1(c), "Procedure for Checking Pregnancy in Patients of childbearing potential – Plain X-Ray Flow Chart". The flow chart needs to be replaced with the flow chart being used in the X-ray rooms. Also clarification is needed on recording LMP date and any other additional information. Pregnancy checks need to be more robust with a record that the patient has been asked. Pregnancy checking forms provided was only used in CT, this was not clear from the form or the EP what process is being used as staff indicated they record LMP on the referral form.	Regulation 12 (8) (d) Regulation 6 Schedule 2 (1) (c)	Flow chart in EP 4 has been replaced and the original flow chart removed Staff have been informed of the correct process for LMP documentation. Audit will be performed, reviewed and repeated quarterly until 100% compliance achieved.	Jane Carpanini Director of Advanced Diagnostics Rachel Davies MRI Lead radiographer	Completed May 2021 Completed May 2021 Oct 2021
• EP7 – DRLs. This procedure needs to include detail on how the recommended DRLs were ratified by the employer prior to being put into clinical practice.	Regulation 6(5)(c) Schedule 2 (1)(f)	EP7 updated to reflect the recommendation. MPE and Medical Physics Cardiff informed of changes.	Jane Carpanini Director of Advanced Diagnostics	Completed May2021
• EP 11. This needs to include more detail on what is recorded for carers and comforters	Regulation 6 (5) (d) (ii)	EP 11 has been updated with the information required.	Jane Carpanini Director of	Completed May2021

Improvement needed	Standard / Regulations	Service action	Responsible officer	Timescale
and were this information is recorded, in addition to the information referenced in the section below	Schedule 2 (1) (n)		Advanced Diagnostics	
• Version control on all documents is required including training records and protocols	Regulation 6 (5) (b) Schedule 2 (1) (d)	Version control has been added	Jane Carpanini Director of Advanced Diagnostics	Completed May 2021
• MPEs did not have training records available as they were currently being established. MPEs hold their own CPD records. More detail is needed as the scope of practice for MPEs was very generic in the EP under group entitlement	Regulation 6 (3) (b) Schedule 2 (1) (b)	Under review with Cardiff MPS records to be sent to St Joseph's Hospital.	Arnold Rust Medical Physics Expert and Radiation Protection Advisor	August2021
• The policy for the Safe Use of Ionising Radiations does not mention the appointment of MPE only the Radiation Protection Advisors (RPA) and makes reference to much greater than intended (MGTI) instead of 'significant accidental or unintended exposure' (SAUE).	Regulation 14(1) Regulation 8 and Regulation 6 Schedule 2 (1) (l)	This policy has been updated and correct terminology amended.	Jane Carpanini Director of Advanced Diagnostics	Completed May2021

Improvement needed	Standard / Regulations	Service action	Responsible officer	Timescale
The employer is to make the necessary changes to the employer's procedure relating to a SAUE or CSAUE to ensure that it guides staff in full through the process. This must also include, who establishes a CSAUE, how it will be reported and who would inform the patient or if the decision was not to inform the patient, how was this recorded and the completion of the relevant letters.	Regulation 8 (1) and Schedule 2 (1) (l)	Employers Procedure has been updated and information regarding CSAUE and SAUE disseminated to staff.	Jane Carpanini Director of Advanced Diagnostics	Completed May 2021
The employer must ensure that the training records are regularly checked and defined in hospital procedures.	Regulation 17 (4)	All training records are under review with the appointment of the New HR Manager	Vanessa Steele HR Manager	September2021

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): Jan Green

Job role: Director of Clinical services/ Registered Manager

Date: 17/05/2021