

Ionising Radiation (Medical Exposure) Regulations Inspection (Announced)

Diagnostic and Interventional
Imaging/Royal Gwent
Hospital/Aneurin Bevan University
Health Board

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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 are receiving good care.

Our values

- **Patient-centred:** we place patients, service users and public experience at the heart of what we do
- **Integrity:** we are open and honest in the way we operate
- **Independent:** we act and make objective judgements based on what we see
- **Collaborative:** we build effective partnerships internally and externally
- **Professional:** we act efficiently, effectively and proportionately in our approach.

Our priorities

Through our work we aim to:

Provide assurance:

Provide an independent view on the quality of care.

Promote improvement:

Encourage improvement through reporting and sharing of good practice.

Influence policy and standards:

Use what we find to influence policy, standards and practice.

1. What we did

Healthcare Inspectorate Wales (HIW) completed an announced Ionising Radiation (Medical Exposure) Regulations inspection of Royal Gwent Hospital within Aneurin Bevan University Health Board on the 23 and 24 October 2018. The following clinical area was visited during this inspection:

- Diagnostic and Interventional Imaging department

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

HIW explored how the service:

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

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

2. Summary of our inspection

Overall, we found that the diagnostic and interventional imaging (X-ray) department delivered safe and effective care to patients. This was, in accordance with the Ionising Radiation (Medical Exposure) Regulations (2017) and aspects of the Health and Care Standards (2015).

However, we did identify the need for improvements to some administrative aspects of the service, none of which resulted in the issue of a non compliance notice.

This is what we found the service did well:

- The majority of patients who completed a HIW questionnaire, provided us with positive views of services provided by the department
- The vast majority of patients who completed a HIW questionnaire stated that they felt involved, as much as they wanted to be, in any decisions about their care
- Staff demonstrated that they had a good awareness of the risks associated with ionising radiation and their responsibilities in this regard.

This is what we recommend the service could improve:

- The health board must ensure it maintains the dignity, privacy and safety of patients who are transported to the holding bay of the department's in-patient area
- Aspects of the content of a number of the employers (IR(ME)R) procedures need to be updated and provide more detail, whilst other procedures need to be developed and formally adopted. This is to ensure that staff are provided with clear and current information to guide them in their work

- Staff training and entitlement records need to contain the full name of the employee. They also need to be signed and dated by the trainee, and include a countersignature of the trainer, for verification purposes.

We identified regulatory breaches during this inspection regarding patients' dignity and safety, employer's procedures and aspects of staff training. Such details can be found in Appendix C of this report.

Whilst our inspection findings have not resulted in the issue of a non compliance notice, there is an expectation that the health board takes meaningful action to address these matters, as a failure to do so could result in non-compliance with the regulations.

3. What we found

Background of the service

Aneurin Bevan University Health Board was established on 1 October 2009, and is responsible for the provision of NHS services to people living in Blaenau Gwent, Caerphilly, Monmouthshire, Newport, Torfaen and South Powys. The health board serves an estimated population of over 639,000 which equates to approximately 21 per cent of the total Welsh population.

The health board employs over 13,000 staff, two thirds of who are involved in the delivery of direct patient care.

At the time of our inspection 21.9 consultant radiologists, 3 specialist registrars, 76.9 radiographers, 6.2 reporting radiographers, 4 medical physics experts (MPEs)¹ and 5.7 assistant practitioners supported the diagnostics and interventional imaging department. No substantive long term vacancies were reported. We did, however, find that some vacancies existed in relation to radiographers and sonographers².

Please note that the department of interventional imaging will be referred to as the department throughout this report, for ease of reading. Similarly, the health board will be referred to as the employer.

¹ The functions of Medical Physics Experts (MPEs) are different to that of the radiation protection adviser, or radioactive waste adviser. Specifically, an MPE is a person who holds a science degree or its equivalent and who is experienced in the application of physics to the diagnostic and therapeutic uses of ionising radiation.

² A sonographer is a highly skilled medical imaging professional who uses ultrasound to perform specialised diagnostic examinations (sonography or ultrasonography).

Quality of patient experience

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

Patients who completed a HIW questionnaire indicated that they were satisfied with the service provided. Positive comments were also made regarding the approach and attitude of the staff team.

Prior to our inspection, we asked senior staff to distribute HIW questionnaires to patients to obtain their views on the services provided by the department. A total of 17 were completed and returned. We also spoke briefly to four patients during the visit.

Patients who completed a HIW questionnaire rated their overall experience provided by the department. Responses were positive; the majority of patients rating the service as either excellent or very good. Patients also told us:

"All very efficient and helpful, thank you to all staff"

"Service was excellent. Everyone was very kind and courteous. Thanks".

When patients were asked how the department could improve the service it provided; patient responses included:

"More seating outside X-ray"

"A diagram of the hospital would be useful. I knew my way because I have been here before. Car parking is always difficult. Clearer signs outside the hospital would be helpful for new patients".

Staying healthy

We were able to confirm that the health board promoted and supported smoking cessation and smoke free environment legislation.

Dignified care

Without exception, all patients who completed a HIW questionnaire indicated that they were listened to by staff during their appointment and were asked to confirm their personal details before the start of their procedure or treatment.

Changing cubicles were available within the department. These offered patients privacy should they need to change into/out of, dignity (hospital) gowns.

However, on day one of our inspection, we found that the section of the department where hospital in-patients are taken to wait for imaging (known as the holding bay), contained four patients. One patient was in receipt of oxygen therapy and another in receipt of intravenous fluids. On this occasion, none of the curtains were used to provide patients with privacy, and three of the patients were sat in close proximity to one another, with no room for staff to assist them with moving and handling (if required).

We observed this area for approximately ten minutes, and saw that no member of staff was present to ensure that patients' needs were being met. In addition, on day two of our inspection, a patient had been transported to this same area. On speaking with the person concerned, they stated that they had not been informed of what X-ray they were to receive, how long they could be expected to wait and no-one from the department had introduced themselves following their arrival (approximately twenty minutes).

On leaving the department on day two of our inspection though, we did hear a member of staff ask a patient with mobility difficulties whether they required assistance. We also heard staff speak with patients in a polite and courteous way on a number of occasions during our visit.

We saw that doors to X-ray rooms were closed when in use and patients who completed a HIW questionnaire indicated that they were able to speak to staff about their procedure or treatment without being overheard by other people.

Improvement needed

The health board is required to provide HIW with details of the action taken to ensure that patients' privacy, dignity and safety is maintained whilst present in the in-patient holding bay of the diagnostics and interventional imaging department.

Patient information

We saw a poster in each of the department's waiting areas reminding female patients to inform staff if they were, or may be, pregnant.

The vast majority of patients who completed a HIW questionnaire stated that they felt involved, as much as they wanted to be, in any decisions about their treatment. They also indicated that they had received clear information about the risks and benefits of their treatment/X-ray imaging.

Patients also told us that they had been given information on how to care for themselves following their procedure and had been given written information about who to contact for advice following any treatments they had received.

However, almost two thirds of patients who completed a HIW questionnaire said they did not know how to raise a concern or complaint about X-ray services they had received. The health board should therefore consider improved ways of providing patients with such information.

Communicating effectively

Communicating Benefits and Risks

The employer had a draft procedure in place to assist staff when informing patients of the benefits and risks of proceeding with requested X-ray examinations and interventions (Number 19). This matter is not entirely new to radiology services. However, the new regulations which came into force on 6 February 2018, places an emphasis on the need for a formal procedure to be developed in this regard. The current employer's procedure therefore needs to be finalised as soon as is practicable.

We saw that posters were displayed in the department which offered patients some information about the benefits and risks associated with exposure to ionising radiation. However, the posters and print were small; which meant that patients and visitors may not easily see the information provided.

Conversations with staff confirmed that they had not yet received any training on their role with regard to communicating benefits and risks to patients. In addition, there was no evidence of a current, consistent approach to this practical aspect of patient care.

We were able to confirm however, that relevant information leaflets were provided to patients either at the point when they received their appointment letter, or when they visited the department. This was in order to ensure that patients received appropriate and timely communication.

Sixteen patients who completed a HIW questionnaire told us that it was 'very easy' or 'fairly easy' to find their way to the department once in the building. In addition, all patients told us they were always able to speak to staff in their preferred language.

Improvement needed

The health board is required to provide HIW with details of the action taken to ensure that patients have access to clearly displayed information about the benefits and risks associated with exposure to ionising radiation.

Timely care

All NHS bodies in Wales are required to comply with the Welsh Government diagnostic waiting times target which states that no patients should wait more than eight weeks to receive their diagnostic test. The diagnostic waiting time target applies to all radiological (X-ray) interventions (other than plain film X-rays)³.

The waiting times for radiology services at The Royal Gwent hospital were high at the beginning of 2017, but then continued to reduce until April 2018 according to information held by HIW. However, waiting times for radiology services started to increase again, after that date. Conversations with senior managers about this matter revealed that the increase was due to a combination of the long term absence of a consultant radiologist and annual leave of senior medical staff.

The health board had therefore put in place a daily monitoring system together with weekly management/performance meetings, where actions were agreed to minimise the effect the above situation was having on patient care. Senior managers also told us urgent imaging requests, and those relating to patients

³ Interventional radiology is a medical specialty which provides minimally invasive image guided diagnosis and treatment whereas a plain X-ray is a more straightforward low radiation dose examination (for example, a chest or limb X-ray).

whose waiting times were the longest, were prioritised to avoid compromising care and treatment.

When patients were asked whether they had experienced any delay in having their procedure, we were provided with a mixed response. Just over a half of patients who completed our questionnaire told us they had waited more than 15 minutes to have their procedure or treatment following arrival at the department and approximately 50 per cent said that they were not told on arrival how long they would have to wait.

The vast majority of questionnaire respondents also told us that it was very easy or fairly easy to get an appointment on a date and time that suited them.

Individual care

Listening and learning from feedback

The health board's annual quality statement stated that patient feedback was regarded as very important. People are able to provide such feedback in terms of how they are treated and whether their surroundings are considered to be safe and clean in a number of ways, for example, by completing paper surveys, via the health board website or by completing how are we doing feedback cards which were available in clinical areas during this inspection.

We were also provided with the details and outcomes of a patient satisfaction survey conducted within the department (not dated). Thirty two patients completed an anonymous questionnaire as part of this exercise. Positive responses were received from patients in terms of the helpfulness and friendliness of staff, being made to feel at ease and the information provided. Areas for improvement identified by patients included the need for:

- Better signs
- Better parking arrangements
- More comfortable seating
- The need for reception staff in the evenings

On the basis of the above, we were therefore satisfied, that there were suitable arrangements in place to seek, and respond to, patients' views.

Delivery of safe and effective care

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

It was evident that the service placed an emphasis on the health, safety and welfare of patients and its staff. This was with a view to providing a safe and effective service.

We did however; identify a number of areas of non-compliance which required a response/action from the health board, all of which related to existing IR(ME)R employer's procedures. Details can be found within Appendix C of this report.

Safe and Effective Care.

Compliance with Ionising Radiation (Medical Exposure) Regulations

Duties of employer

Patient identification

The employer⁴ had a written procedure (number 3) as a means of guiding staff to correctly identify individuals who were about to be exposed to ionising radiation. This set out that operators were responsible for ensuring the correct identification of individuals undergoing medical exposures. Staff also demonstrated a good working knowledge of this process.

⁴ The definition of employer under IR(ME)R regulations is someone other than an employee who, in the course of a trade or business carries out or engages others to carry out, medical exposures or practical aspects. In the case of NHS facilities, the employer is usually the Chief Executive.

However, the inspection team raised concerns about existing arrangements where radiographers were required to complete radiology referral forms (if they followed the process as outlined in the current patient identification procedure as it applied to operating theatres). In such instances, the radiographers need to be entitled as the referrer and current employer procedures did not provide such clarity. This issue has also been noted under the sub heading of justification later on in this section.

Females of child bearing age

The employer had a written procedure for making enquires with regard to pregnancy (number 4) to ensure that patient enquiries were made in an appropriate and consistent manner.

Conversations with staff confirmed that they knew this process well and had a clear understanding of when, how, or if, they should proceed to imaging. We found, however, that patients were never asked to sign the referral request form. The health board may therefore wish to consider revising its procedure to include such advice to staff. This is in order to provide evidence that this process has taken place.

Non medical imaging (previously known as medico-legal exposures)

The health board's completed audit of IR(ME)R compliance clearly stated that non medical imaging/exposures were not performed within diagnostic and interventional imaging services.

Referral criteria

The employer had a written procedure regarding patient referral (number 1).

Overall, the information provided by the service was considered to be satisfactory. This is because staff were able to describe the process in place, in accordance with legislative requirements. We were also provided with a copy of annual letters sent to groups of IR(ME)R referrers. This was, to remind them of

their role and scope of practice. We were also informed that i-refer⁵ was available for all referees to use.

Conversations with senior managers also demonstrated that in instances where referral forms failed to contain full and accurate information, forms were returned to the referrer (in cases of written referrals), or clinicians contacted (in cases of electronic referrals). On examination of the form used to return written referrals, we advised the health board of the need to include the name of the person returning the form, their role and date of return. Senior managers responded positively to this advice.

We saw that the referral process was available within the Computed Tomography⁶ (CT) and general room areas to assist staff. We also saw the list of entitled referees on the entitlement matrix. The electronic and hand written booking process was also well described by senior managers.

We were informed that all referrals for imaging were managed by the booking department at Nevill Hall hospital; clinical staff only being able to cancel or amend the request by making direct contact with radiology staff. Staff also described the action taken when an incomplete request was received. This meant that there was an emphasis on minimising errors and ensuring patient safety. However, we advised that it would be helpful to the department if a name and date could be added to cancellation return forms for clarity.

We found that the health board had established processes in place to minimise patient non attendance at organised appointments and to ensure that patient referrals were prioritised appropriately based on their clinical history/urgency.

We also looked at a sample of patient referrals and were satisfied that the process was robust.

⁵ iRefer helps referring GPs, radiographers, clinicians and other healthcare professionals to determine the most appropriate imaging investigation(s) or intervention for patients.

⁶ Computed tomography, more commonly known as a CT or CAT scan, is a diagnostic medical test that, like traditional x-rays, produces multiple 3D images or pictures of the inside of the body.

Clinical evaluation

We saw the employer's procedure relating to clinical evaluation for each medical exposure (Number 5) and found that the content needed to be revised to provide staff with clear guidance on this matter.

We were not provided with evidence of periodic audits of compliance of clinical evaluation; health board representatives being honest about the absence of such audits to date. The health board may therefore wish to consider the introduction of such activity in the future to ensure that diagnostic findings are documented in patients' records as required.

Justification of Individual Medical Exposures

The employer had a draft written procedure for the justification and authorisation of medical exposures (numbers 2 and 18).

However, we found that there were instances where radiographers were expected to justify the ionising radiation exposure to carers and comforters although they had not been trained in this regard. In addition, we could not find evidence of competencies, entitlement, or guidelines to support this element of radiological activity.

We held discussions with senior managers in relation to the justification process and found that that they had not been provided with a list of the practitioners who worked for the All-Wales third party (radiology) provider, as stated in their completed audit of compliance document (point 4.3). This meant that the health board lacked evidence to demonstrate that the department obtained the General Medical Council (GMC)⁷ number of each practitioner in advance of them justifying out of hours X-ray exposures, as a matter of established practice and in accordance with the regulations.

We therefore explored the information provided within a sample of X-ray reports and were, at least, able to verify the GMC numbers of radiologists associated with the out of hours third party provider. However, we found that the

⁷ The General Medical Council (GMC) is a public body that maintains the official register of medical practitioners within the United Kingdom.

practitioner justifying the X-ray request may not be the same radiologist who reports the images.

The above All-Wales issue is therefore to be brought to the attention of relevant officers within Welsh Government as the above matters are currently outside of the direct control of health boards across Wales.

We found that radiographers were also entitled as practitioners within general radiography. They were therefore able to justify exposures. There were also some operators working under Delegated Authorisation Guidelines⁸ (DAGs) to authorise imaging under these guidelines in the CT area.

Conversations with staff about the entitlement of radiographers working in theatres revealed that clarification was needed as to why they had the combined role of referrer, practitioner justifying the exposure and operator. This matter was discussed with senior managers, as the health board needs to demonstrate how it is assured that radiographers have enough information to make an intellectual and clinical assessment based on each patient, to justify the exposure.

Optimisation

The employer's procedure for dealing with carers and comforters within radiology (Number 18) was in draft form awaiting all-Wales agreement. The draft procedure indicated that a holding book was being used to record carer and comforter radiation doses, but on speaking with staff, we found that this was not the case. It was therefore unclear as to where radiation doses for carers and comforters were currently being recorded, as required.

We were able to confirm that radiation doses relating to some departmental equipment had a pre-programmed paediatric setting to ensure that radiation doses were as low as reasonably practicable. We were also able to confirm that staff had easy access to X-ray exposure charts for children to assist them. However, older equipment which was still in use did not have pre-programmed facilities.

⁸ Delegated authorisation guidelines (DAGs), must be produced by a named practitioner (often, but not always the lead radiologist). The individual who produces these guidelines takes responsibility for any exposure authorised using these guidelines.

We were also made aware of the arrangements in place across South East Wales regarding paediatric radiation dose audit activity, (specifically, neonatal optimisation in special care units). Similar work was also underway in relation to CT imaging.

Conversations with one of the MPEs revealed that high dose examinations were regularly discussed at the department's optimisation group to ensure that exposures were kept at an optimal level. We were also able to evidence MPE involvement in optimisation through the Diagnostic Reference Level (DRL⁹) audit which is carried out every three years.

Diagnostic reference levels

The employer had a written procedure for the use of DRLs (number 6) which set out arrangements to establish DRLs for procedures performed in the department. The procedure (which had been produced by relevant clinical staff) also set out the arrangements for recording and monitoring doses (of ionising radiation) delivered to patients. However, further detail was needed to advise staff of the action to be taken should DRLs be consistently exceeded.

We were informed that an audit of radiation doses for standard procedures was carried out every three years using a three month analysis of procedural doses; additional audit activity regularly taking place in support of the three year programme. This assisted in assuring staff that equipment was functioning correctly and continuing to deliver radiation doses, as they should. We were also told that an audit of new equipment was completed six months after its commissioning date; ad-hoc audits being carried out in response to requests from clinical staff.

Local DRLs were evidenced in a number of areas associated with diagnostic and interventional imaging and found to be below national DRLs. This was regarded as good practice.

⁹ Diagnostic Reference Levels (DRLs) refer to dose levels of radiation used during medical radio-diagnostic procedures. It is expected that these levels are not to be exceeded for standard procedures when good and normal practice is applied.

However, the current employer's procedure did not explain the process for establishing local DRLs. We therefore advised of the need to update the procedure to reflect actual practice as described by staff.

Discussions with staff revealed that it was clear that they were unaware of the process to follow if DRLs are consistently exceeded.

Managing risk and promoting health and safety

Equipment

We found that the department did not have a formal quality assurance programme or a corresponding employer's procedure in this regard, as required by the regulations.

We were provided with an example of a radiographer routine equipment quality assurance standard operating procedure. However, this did not fulfil regulatory requirements, as there was no reference to the annual quality assurance programme performed by the MPE's (together with the schedule of work that subsequently needed to be addressed).

Staff described the daily and weekly quality testing being carried out within the department. We were also told that in instances when a routine equipment quality assurance test failed, the senior radiographer removed the equipment from use pending an investigation. The fault is then reported to the medical physics service. The employer had a procedure in place with regard to room equipment breakdown (Number 17), to support the above approach, the content of which provided sufficient guidance about what staff needed to do in such instances.

We were able to confirm that quality assurance reports were always sent directly to the relevant departmental superintendent. This was, in order that appropriate and timely action could be taken to maintain the safety of patients and staff. We were also told that a summary of radiation protection reports was shared with health board executive staff to promote effective communication. However, we advised that such reports should also be made available to radiology service managers in the future.

There was no evidence of an employer's procedure for the system of recording and analysis of events involving accidental or unintended exposures as required in Regulation 8(3).

There was also no evidence of an employer's procedure to ensure that the probability and magnitude of accidental or unintended exposures is reduced (Schedule 2 (k)).

However, we were able to confirm that staff received sufficient, appropriate training on the use of new equipment.

Infection prevention and control

During the course of our inspection, we saw that all areas within the department appeared visibly clean and uncluttered. Hand cleaning gel was available to promote effective infection prevention and control and staff who spoke with us, were able to show us the infection prevention and control policy stored on the health board's intranet.

No concerns were raised by patients regarding the cleanliness of the department.

Safeguarding children and adults at risk

Conversations with staff within the department demonstrated an awareness of current safeguarding procedures.

A senior member of staff also described how the department had responded to a possible safeguarding matter in recent months.

Quality improvement, research and innovation

Expert advice

We found that involvement of MPEs in the work of the department needed to be reviewed and strengthened. This is because we found the following:

- MPEs were not routinely involved in the tendering process for new equipment
- MPEs had not been involved in applications training, to assist staff in the safe use of equipment (where appropriate)
- The health board was not as pro-active as it should be in seeking involvement from MPEs. Similarly, we found that the MPE service needed to be more pro-active in its support of the department
- The last audit of compliance completed by the radiation protection service was dated 2013 (against the former requirements of IRR99 and IR(ME)R 2000). This was not in-keeping with the information

provided by the health board within the HIW audit of compliance completed by the department ahead of this inspection, which stated that such audits should be completed on a two yearly basis.

We did, however, find evidence of MPE support and involvement in relation to radiation dose optimising protocols.

We saw that contact details for expert advice had been prepared. However, such details were not in general circulation. This meant that radiology staff needed to report any equipment issues of concern to the relevant superintendent who would then contact MPEs if required.

We were provided with evidence of MPE involvement in dosimetry through monitoring staff through their radiation badges: finger, eye and whole body. This was, to ensure their ongoing safety.

MPEs who spoke with us were able to describe that there was a robust radiation dose audit system in place that was compared to national bench marks. We were also informed that departmental requests for advice regarding foetal, high skin doses and accidental and unintended exposures were responded to, and logged appropriately.

We found that there was some MPE involvement in the acceptance and commission phase of testing new equipment and the design of the room where the equipment was to be used.

The department employed a research radiographer. This assisted with undertaking relevant departmental based research with a view to improving services to patients.

Clinical audit

Senior managers described aspects of audit activity completed by the radiation protection service together with the 'in-house' radiologist and radiographer audits which took place as part of the rolling programme of agreed activity to date. Topics covered during 2018 related to side markers¹⁰ and the use of

¹⁰ Anatomical side markers should be placed (right or left) to mark patient orientation. This is, in order to prevent errors.

gonad shields¹¹. We were also provided with copies of other completed audits associated with PICC¹² line infections and peer review of Breast MRI imaging; action was being taken to improve services as necessary.

In addition, we requested sight of the written, agreed, radiology audit programme but this was not available during the inspection. Rather, we were provided with minutes from the last two audit meetings where discussion relating to audit topics for the next six months had taken place. We were also unable to confirm how the results of completed audit activity had influenced change in clinical practice.

Medical research

Discussions with CT staff confirmed that medical research was not performed routinely. They did however describe the X-ray request form used to identify the study (specifically, the research study name would always be written across the top) as well assigned Radiologists to report.

Staff also told us that in instances where the research protocol for imaging was not routine a radiologist would justify the request.

There were no medical research studies underway at the time of our inspection.

Information governance and communications technology

Information management systems were described and demonstrated by members of staff. This allowed for relevant patient details and information about diagnostic and interventional procedures performed, to be recorded, and easily accessed by staff.

¹¹ Gonad shielding during diagnostic X-ray procedures is a way of reducing the radiation dose to patients' reproductive organs and reduces the risk of genetic effects in future generations.

¹² A peripherally inserted central catheter (PICC) line is a long, thin, hollow tube that a doctor or nurse puts into a vein. It is used to give patients chemotherapy and other medicines. It can stay in place until treatment is over.

Quality of management and leadership

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

There was a clear organisational structure in place. We also found that staff understood their responsibilities and were supported to complete training relevant to their roles.

We found that senior managers were visible and made every effort to provide staff with effective leadership on a day to day basis.

Governance, leadership and accountability

Procedures and protocols

We found that, in general, senior managers placed considerable emphasis on improving performance and the provision of safe and effective care. For example, radiation protection committee and management and performance meetings were held regularly.

The Chief Executive of the health board was designated as the employer. This is in keeping with the national guidance¹³ on implementing IR(ME)R regulations as they apply to diagnostic and interventional imaging services.

¹³ British Institute of Radiology, Society and College of Radiographers and the Royal College of Radiologists. 'A guide to understanding the implications of the Ionising Radiation (Medical Exposure) Regulations in diagnostic and interventional radiology'. London: The Royal College of Radiologists, 2015. https://www.rcr.ac.uk/sites/default/files/bfcr152_imer.pdf

However, we found that All-Wales clarity was needed in terms of who should be the designated employer (as defined by IR(ME)R), at times when a significant event occurred involving a third party radiology provider used by all health boards for the justification¹⁴ and reporting of imaging-outside of normal working hours. This matter however, is not within the direct control of health boards, so will be brought to the attention of relevant Welsh Government officers by HIW.

The radiation protection service's review of all employer's procedures was completed during 2013. This was, we were told, despite an agreed arrangement for a two yearly review. Senior managers however, told us that they were in the process of pursuing a further date for the next required two year review.

Conversations with senior managers revealed that staff were expected to read all relevant employer's policies and procedures; providing their signature on completion. Whilst we were not provided with written evidence of this at inspection, discussions with staff made it clear that they understood their responsibilities regarding IR(ME)R legislation. We also saw some staff information and updates displayed on notice boards as memos in clinical areas.

Conversations with a variety of staff revealed that they felt supported by their direct line and senior managers respectively. Additionally, staff clearly understood their roles and responsibilities and there was evidence of effective teamwork across the department.

However, during this inspection, we found that aspects of current IR(ME)R practice (as described by staff and senior managers) were not accurately or fully reflected in a number of written employer's procedures. The health board was also unable to provide us with the required employer's procedures in respect of the following:

- A procedure to describe the quality assurance programme in respect of equipment used in the department
- A procedure incorporating guidance about the need for the assessment of patient radiation dose and administered activity

¹⁴ Justification is the process of weighing up the expected benefits of an exposure against the possible detriment of the associated radiation dose.

- A procedure to ensure that the probability and magnitude of accidental or unintended exposure to individuals from radiological practices are reduced so far as reasonably practicable
- A procedure to ensure that IR(ME)R radiation protection staff referrers, practitioners and individuals exposed to ionising radiation, or their representative, are informed of the occurrence of any relevant clinically significant unintended or accidental exposure, and the outcome of the analysis of that exposure.

These matters could lead to errors in service delivery. We have also referred to the need for the development of, and amendments to, a number of other employer's procedures throughout this report.

Whilst the above has not resulted in the issue of a non compliance notice, the employer is required to take meaningful action in the form of revised, clear and ratified procedures for staff to follow.

Specific details of the improvements required to bring about compliance with IR(ME)R regulations (2017) in relation to procedures, protocols and quality assurance programmes can be seen within Appendix C.

Duties of practitioner, operator and referrer

The regulations require that each staff group and duty holders' scope of practice for referral, justification and what they can perform as operator, is made clear to all those working within radiology services. This process is known as entitlement.

During this inspection, we found that the employer had written procedures to demonstrate the arrangements for entitlement and identification of practitioners,¹⁵ operators¹⁶ and referrers¹⁷ (known collectively as duty holders).

¹⁵ A practitioner must be a registered health care professional, as defined by the Regulations. Practitioners are entitled by the employer to take responsibility for an individual (X-ray) exposure. Schedule 2 (1) (b) of the Regulations requires entitlement and the scope of practice of practitioners to be clearly defined within the employer's written procedures.

¹⁶ An operator is a person who is entitled in accordance with the employer's procedures to carry out the practical aspect of a medical exposure.

The information we considered, also set out the expected level of training for each entitled staff group together with their scope of practice.

Entitlement process

Overall, we found that the process of entitlement was good; staff receiving an entitlement letter after they had completed training which had been signed off by senior staff to confirm competence. We also saw that there was an electronic matrix in place which contained a record of all staff entitlement (including reference to third party providers involved in authorising, justifying and reporting on, X-ray imaging). However, we found that the overarching entitlement process (as described by senior managers) needed to be made clearer to all staff within the employer's procedure (number 14). Specifically, the procedure did not provide clarity about staff scope of practice, who entitles whom, or what examinations non-medical referrers and GPs could request (although managers told us that GPs could refer patient for all types of examinations).

We also found an absence of evidence of entitlement relating to instances when radiographers are expected to justify exposure to carers and comforters¹⁸.

Incident notifications

The employer's written procedure (number 7) concerning the reporting of incidents had been updated in terms of removing reference to the former

¹⁷ A referrer must be a registered health care professional. Referrers are responsible for referring individuals to the practitioner for specific medical exposures to be undertaken in accordance with the employer's recommendations for referral criteria in regulation 6(5) (a). Schedule 2 of the regulations requires entitlement and the scope of practice to be clearly defined within the employer's procedures.

¹⁸ Carers and comforters are individuals who are knowingly and willingly exposed to ionising and radiation through support and comfort of those undergoing exposure. The IR(ME)R definition makes clear that this does not apply to individuals undertaking this role as part of their employment. Carers and comforters are commonly relatives or friends of those undergoing exposure.

IRR99¹⁹. We were also provided with a list of anonymised near miss events²⁰ and an example of an action plan associated with a recent notifiable incident. In addition, we were provided with a copy of an updated, clear flow chart for staff to follow at times when a notifiable incident took place. Otherwise, the procedure lacked detail.

Conversations with senior managers confirmed that all serious adverse events²¹ were recorded on datix²², the details of which were always brought to their attention. They are then investigated via a root cause analysis²³ approach in order to identify where improvements need to be made to the service.

Senior managers also explained that action plans produced after an incident, were shared across the radiology modalities²⁴. However, the inspection team was unclear how this was achieved, as staff told us that communication about work related matters was inconsistent at times and formal meetings were irregular.

We found that the health board did not currently have a procedure to ensure that the probability and magnitude of accidental or unintended exposure to individuals from radiological practices are reduced so far as reasonably

¹⁹ New Ionising Radiation Regulations (IRR17) came into effect from 1 January 2018, replacing and updating the existing regulations (IRR99).

²⁰ A near miss in medicine is an event that might have resulted in harm but the problem did not reach the patient because of timely intervention by healthcare providers or the patient or family. Near misses may also be referred to as "close calls".

²¹ Serious Incidents in health care are adverse events, where the consequences to patients, families and carers, staff or organisations are so significant or the potential for learning is so great, that a heightened level of response is justified

²² Datix software is a tool used within the NHS to record, investigate, analyse causes of adverse events and near misses.

²³ Root cause analysis (RCA) was developed for the health services to promote a systematic approach to the investigation of serious incidents. The NHS has adopted the RCA process to investigate serious incidents that result in moderate, severe harm or death.

²⁴ Radiology is the medical specialty that uses medical imaging for diagnostic and treatment purposes.

practicable. Neither was the department able to provide us with a procedure to ensure that IR(ME)R radiation protection staff referrers, practitioners and individuals exposed to ionising radiation, or their representatives (that is carers and comforters), are informed of the occurrence of any relevant clinically significant unintended or accidental exposure, and the outcome of the analysis of that exposure.

Improvement needed

Please see Appendix C of this report for specific details of the non compliance matters and improvements identified in respect of Governance, leadership and accountability.

Staff and resources

Workforce

Training

We were able to confirm that staff were encouraged and supported to complete health board mandatory training, as well as learning associated with their respective roles within the department. However, we found that staff had not received any specific training regarding their enhanced role associated with communicating benefits and risks of patient exposure to ionising radiation. Such training therefore needs to be provided as soon as is practicable.

We were able to find evidence of induction packs, and training records for radiographers and radiologists were provided. Staff training was recorded and monitored by managers through electronic staff records and reviewed annual at staff appraisals. Staff explained that appraisals were carried out annually via staff grouping/modality. It was noted though, that dates and staff signatures were missing from the majority of the Policy and Procedure Checklists.

We found that a study leave committee reviewed staff training applications; assessment and agreement being made on a case by case basis. The acceptance process considered the benefit of the course to the person applying, the benefit to the department and also the cost of the course.

Student radiographers were supervised by qualified staff. A mentor is assigned to the students; however this post is currently unfilled due to staffing shortages. Senior staff are trained to carry out student assessments. In addition, the

Induction process for new staff consisted of two weeks rotation through all areas of the department followed by two weeks in each area. Competency was signed off by senior staff and an entitlement letter issued to each staff member as appropriate.

We found that training records for the MPEs were held at Velindre Hospital. We were provided with such information as requested, during our inspection.

Departmental information

Discussions with staff revealed that they faced challenges with working in a timely way across the department. This was, due to existing staff vacancies (six Band 6 radiographers, six Band 5 radiographers, four sonographers), and also the layout of the diagnostic and interventional service across three floors of the hospital.

We therefore held conversations with senior managers about the above matters and found that the department at the Royal Gwent is likely to be subject to some changes, when the new Grange University Hospital becomes operational. We were also provided with an update on the pro-active approach adopted by the health board, to recruit more radiographers in the form of conventional advertising, open days, and working relationships with University training departments.

As a result of those efforts, a number of new radiographers were due to take up employment within the department during July 2019. In the interim, senior managers informed us that three locum radiographers were currently working at the hospital on a regular basis, four current Band 5 radiographers were to be promoted to Band 6 and there was a sustainability plan in place for the service. This was, to ensure that patients continued to receive timely and safe and effective care. Senior managers were, however, honest in telling us that they continued to experience significant challenges in recruiting sonographers.

We were told that there was a third party provider contracted to support when reporting turnaround times increase and that it also supported the out of hours service. Reporting radiographers wish to extend their role in an effort to support the reporting backlog. However senior managers are finding this a challenge to move forward. No business case as yet has been put forward for agreement.

Despite the above, however, the department currently had six Band 6 radiographer vacancies (which will reduce to two, by July 2019), six Band 5 radiographer vacancies and long term absence associated with one senior member of the medical staff.

Senior managers described the departmental arrangements and processes in place in relation to regular meetings in respect of quality, performance, clinical audit and finance. We were also provided with minutes from some of those meetings.

However, we could not find evidence of regular meetings with radiographers.

Improvement needed

The health board is required to provide HIW with details of the action taken/to be taken to ensure that staff training and entitlement records contain the full name of the employee, are signed and dated by the trainee, and include a countersignature of the trainer, for verification purposes.

The health board is also required to inform HIW of the action taken/to be taken to ensure that staff receive training with regard to the following:

- The use of new equipment
- The role of staff associated with communicating benefits and risks of patient exposure to ionising radiation.

Given the areas for improvement identified during this inspection with regard to aspects of the employer's duties regarding general procedures and quality assurance, consideration should be given to ensuring that there are more effective and proactive arrangements in place at the service to monitor compliance with relevant regulations and standards. Whilst no specific recommendation has been made in this regard, the expectation is that there will be evidence of a notable improvement in this respect at the time of the next inspection.

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 service who use ionising radiation

HIW are responsible for monitoring compliance against the [Ionising Radiation \(Medical Exposure\) Regulations \(IR\(ME\)R\) 2017](#).

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
- Meet the [Health and Care Standards 2015](#)
- Meet any other relevant professional standards and guidance where applicable

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

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

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

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

Further detail about [how HIW inspects the NHS](#) can be found on our website.

Appendix A – Summary of concerns resolved during the inspection

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

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

Appendix B – Immediate improvement plan

Hospital: Royal Gwent Hospital
Ward/department: Diagnostic and Interventional Imaging
Date of inspection: 23 and 24 October 2018

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
We did not identify the need to issue an improvement (non-compliance) notice as a result of this inspection.				

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

Service representative:

Name (print):

Job role:

Date:

Appendix C – Improvement plan

Hospital: [Royal Gwent Hospital]
Ward/department: [Diagnostic and Interventional Imaging]
Date of inspection: [23 and 24 October 2018]

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
Quality of the patient experience				
[The health board is required to provide HIW with details of the action taken to ensure that patients have access to clearly displayed information about the benefits and risks associated with exposure to ionising radiation.]	[3.2 Communicating effectively.]	[The existing information is available in A4 format. These posters will be printed on A3 and displayed as an interim measure until the 'All Wales' agreed publications are distributed. Once published, the 'All Wales' information will replace our local documents.]	[Andrew Carter]	[01.12.2018 For A3 posters 01.03.2019 for All Wales info. Meeting of All Wales Quality Forum 23.1.2019.]
[The health board is required to provide HIW with	[4.1 Dignified Care	[A member of staff will be assigned into	[Andrew Carter]	[20.1.2019]

Improvement needed	Standard	Service action	Responsible officer	Timescale
<p>details of the action taken to ensure that patients' privacy, dignity and safety is maintained whilst present in the in-patient 'holding bay' of the diagnostics and interventional imaging department.</p>		<p>the holding bay area to monitor patient care. This member of staff will be available to provide basic care and assurance to the patient. There will be a monthly spot audit of patients to assess the effectiveness of this solution. <i>This will require additional support staff being employed. Recruitment for vacant support staff was recently completed and the successful candidates are being processed. In the interim we will use existing staff to supervise this area to ensure the patients' privacy, dignity and safety are maintained.</i></p>		
Quality of management and leadership				
<p>[The health board is required to describe the action taken regarding the identified absence of four employer's procedures as required by IR(ME)R legislation. These were:</p> <p>A procedure to describe the quality assurance programme in respect of</p>	<p>[Governance, Leadership and Accountability.</p> <p>Employers Procedures.</p>			

Improvement needed	Standard	Service action	Responsible officer	Timescale
<p>equipment used in the department</p> <p>A procedure incorporating guidance about the need for the assessment of patient radiation dose and administered activity</p> <p>A procedure to ensure that the probability and magnitude of accidental or unintended exposure to individuals from radiological practices are reduced so far as reasonably practicable</p> <p>A procedure to ensure that the referrer, practitioner and the individual or their representative exposed to ionising radiation, are informed of the</p>	<p>Schedule 2</p>	<p><i>The existing procedure document covering QA of documentation will be reviewed and updated to include details of the regular equipment QA checks performed by the operators entitled to do so. Liaison will be had with the MPE to ensure details of Radiation Protection Service QA equipment checks are also included in the documentation.</i></p> <p>A procedure document has been drafted for approval by the RPS group and RPC.</p> <p>A procedure document has been drafted for approval by the RPS group and RPC.</p> <p>Further detail is to be included in the</p>	<p>Mark Wilkes</p> <p>Mark Wilkes</p> <p>Mark Wilkes</p> <p>Mark Wilkes</p>	<p>January 2019</p> <p>Completed</p> <p>Completed</p> <p>January 2019</p>

Improvement needed	Standard	Service action	Responsible officer	Timescale
<p>occurrence of any relevant clinically significant unintended or accidental exposure, and the outcome of the analysis of that exposure.</p> <p>A number of the existing employer's procedures would also benefit from being reviewed and further revised to reflect current practice and promote consistency across the department. We have referred to these procedures throughout this report and they include:</p> <p>The overarching ionising radiation safety policy needed to be updated and revised to provide staff with more detail about their responsibilities</p> <p>Justification and authorisation of medical exposures (number 2). Conversations about the entitlement of radiographers working in theatres revealed that clarification was needed as to why</p>		<p>procedure document 7 to satisfy Schedule 2(l). Details will include process for informing those associated with the exposure of incident and outcome. An associated flowchart will accompany the document as a 'quick reference guide' for staff.</p> <p>ABUHB policy to be updated to include more detail on staff entitlements, who entitles and how they entitle. Being a HB policy this will have approval by the RPS group followed by submission to the RPC. Advice will be sought from the MPE.</p> <p><i>The role, under IRMER, of the radiographer in theatres was agreed</i></p>	<p>Andrew Carter</p> <p>Mark Wilkes</p>	<p>April 2019</p> <p>January 2019</p>

Improvement needed	Standard	Service action	Responsible officer	Timescale
<p>they have the combined role of referrer, practitioner-justifying the exposure and operator. The employer's procedure therefore needs to demonstrate that radiographers have enough information to make an intellectual and clinical assessment based on each case. The procedure also needs to make appropriate reference to the third party provider in terms of their role in justifying exposures</p>		<p><i>to be only the operator. The role of practitioner (in addition to their role as referrer) would lie with the surgeon performing the procedure. This will be communicated to all surgeons, Divisional & Directorate Managers and procedure document 2 will be updated to provide appropriate guidance for staff.</i></p> <p><i>The role of 3rd party providers under IRMER will be detailed in procedure document 2 to demonstrate their role in justifying exposures. Everlight confirm details of GMC qualification as part of their recruitment requirements</i> (https://www.everlightradiology.com/uk/about-us/clinical-quality/). <i>They are also CQC, UKAS, ISOQAR regulated and their services are acquired via an All Wales contract with WAG. Identification of the Radiologist acting as the Practitioner</i></p>	<p>Mark Wilkes</p>	<p>January 2019</p>

Improvement needed	Standard	Service action	Responsible officer	Timescale
<p>Patient identification (number 3). The health board is required to describe the action taken in order to clarify the role of radiographers who work in theatres. This is because they currently act as operator; they justify the exposure and act as practitioner. In addition, requests for imaging in theatre tends to be made verbally, radiographers therefore also take on the role of referrer, as they complete the referral form; a second signature from an entitled IR(ME)R professional being absent</p> <p>Establishing if a female patient is, or maybe pregnant. (Number 4). We found that patients were never asked to sign the X-ray request form to</p>		<p><i>will be made on the appropriate section of the request form. This will be confirmed by the call handler from Everlight who contacts the operator (Radiographer).</i></p> <p>A communique will be sent out to all surgeons, Divisional and Directorate Managers stating that a referral form must be completed prior to the examination as per regulations. Detailed in this will be the requirement to sign the request as the referrer. <i>It has recently been agreed that their role as practitioner (for justifying exposure) will be clarified in the communique.</i></p> <p>This will be audited Bi monthly by Radiology and results feedback to the relevant Directorates.</p>	<p>Andrew Carter</p> <p>Mark Wilkes</p> <p>Andrew Carter</p>	<p>January 2019</p> <p>Dec 2019</p> <p>January 19</p>

Improvement needed	Standard	Service action	Responsible officer	Timescale
<p>demonstrate that the pregnancy checking process had taken place. The health board may therefore wish to consider revising its procedure to include such advice to staff</p> <p>An evaluation for each medical exposure (number 5). Exceptions whereby images are available to the referrer without clinical evaluation, (for example, a number of trauma and orthopaedic images), needs to be made clearer within the procedure. In addition, the role of radiographers when working in the theatre environment requires clarification and revision. The health board may also wish to consider the introduction of audit activity in the future, to ensure that diagnostic/clinical findings are documented in patients' records as required</p>		<p>A meeting has been set with the legal team in January 2019, a solution will need to reflect current Health Board policy for Nursing. The outcome will be reflected in the procedure documents which satisfy Schedule 2(c).</p> <p>Procedure document 5 has been updated to include details of the exceptions to issuing an official Radiology report.</p> <p>The role of the Radiographer in theatre will be addressed as described previously</p> <p>Reporting agreements will be revised and re-issued to include the need to provide annual audit evidence of clinical</p>	<p>Mark Wilkes</p> <p>Mark Wilkes</p> <p>Mark Wilkes</p> <p>Rebecca Wallace</p>	<p>February 19</p> <p>January 19</p> <p>January 19</p> <p>January 19</p>

Improvement needed	Standard	Service action	Responsible officer	Timescale
<p>Diagnostic Reference Levels (number 6). This written procedure was incomplete and did not provide clear evidence about what staff needed to do in the event that DRLs were consistently exceeded. Neither did the procedure provide evidence about how the department had achieved local DRLs at 50 per cent of published national DRLs, nor any reference to the five</p>		<p>evaluation.</p> <p><i>In conjunction with the annual audit information requested from the relevant Directorates, Radiology will undertake quarterly audits. Radiology will provide the relevant Directorates, with non-reporting agreements, a list of patients and they will be asked to provide evidence of clinical evaluation. The outcome of the quarterly audits can be compared against the annual audit information. If the quarterly audits give cause for concern then a more in depth audit may be triggered.</i></p> <p>The document has been revised and satisfies the requirements of Schedule 2(f). Details include a schedule for DRL review. This will be submitted for review</p>	<p>Mark Wilkes</p>	<p>January 19</p>

Improvement needed	Standard	Service action	Responsible officer	Timescale
<p>local DRLs stated as having been agreed within the department. In addition, the procedure did not provide evidence of periodic audit of radiation doses, or interventional and high dose CT²⁵ DRLs</p> <p>Reporting Exposures Greater Than Intended (number 7). Whilst managers were able to describe the process in place, this current procedure lacked sufficient detail to guide staff and incorrectly referred to IRR17 instead of IR(ME)R17. Additionally, there is no longer a requirement for an employer's procedure in this regard. Instead there needs to be a system in</p>		<p>and comment at the RPS meeting (17.12.18).</p> <p>This procedure document will be reviewed and amended to include guidance on the recording analyses of events involving or potentially involving</p>	<p>Mark Wilkes</p>	<p>February 19</p>

²⁵ A computerised tomography (CT) scan uses X-rays and a computer to create detailed images of the inside of the body. CT scans are sometimes referred to as CAT scans or computed tomography scans

Improvement needed	Standard	Service action	Responsible officer	Timescale
<p>place for recording analyses of events involving or potentially involving accidental or unintended exposures proportionate to the radiological risk posed by the practice. This is, in-keeping with the new IR(ME)R regulations</p> <p>The review of standard operating procedures (number 8). We found there</p>		<p>accidental or unintended exposures. <i>It is intended that all patients will receive notification of any unintended exposure with information on associated risk factors. If it is deemed that it is in the patients best interest not to be informed of the incident or they are unable to process the information this will be documented in the investigation notes with an explanation of why the patient has not been informed.</i></p> <p>An associated flowchart will accompany the document as a 'quick reference guide' for staff.</p> <p>References to the appropriate regulations will be corrected.</p>	Andrew Carter	February 19

Improvement needed	Standard	Service action	Responsible officer	Timescale
<p>was an absence of a single system of document control. This was despite the support and use of Q Pulse²⁶ software. This meant that we could not be assured that procedures had been reviewed on a regular basis, or by whom, as required</p> <p>Medical Research Studies (number 10). This procedure required more detail to assist staff</p>		<p>A document management flowchart will be developed detailing responsibilities and review dates. This will be ratified by the Radiation Protection supervisors group and the radiation protection committee.</p> <p>Q-pulse will remain as the document management software used.</p> <p>Review and update of document following discussion at RPS meeting</p>	Rebecca Wallace	January 19

²⁶ Q Pulse is an electronic quality management system which assists organisations to automate and streamline business processes for standards and regulatory compliance, safety management and risk management.

Improvement needed	Standard	Service action	Responsible officer	Timescale
<p>Procedure to ensure that all those with Entitlement Under IR(ME)R Are Identified (number 14). This procedure lacked clarity in respect of operators working under a DAG and who entitles whom for specific delegated tasks. The term generic entitlement needs to be replaced with a form of words that makes entitlement clear to all. In addition, further detail is needed to advise staff of the action to be taken should DRLs be exceeded.</p> <p>Procedure for Dealing with Carers and Comforters within radiology (Number 18) was in draft form awaiting all-Wales agreement. At the time of this inspection, it was therefore unclear as to where the radiation dose for carers and comforters was currently being recorded, as required. Whilst this</p>		<p>(17.12.18)</p> <p>Procedure 14 will be reviewed and updated to ensure there is clarity in respect of DAGs. Terminology will relating to entitlements will be clarified and 'generic' will be replaced.</p>	<p>Andrew Carter</p>	<p>January 19</p>
		<p>Actions for exceeding DRLs have been addressed in the document satisfying Schedule 2(f).</p>	<p>Andrew Carter</p>	<p>February 19</p>
		<p>The next All Wales Quality Forum meeting is 23.1.19. We are expecting clarity on this issue to progress the procedure document.</p> <p>In the absence of guidance we will continue to use the 'holding' log books and this will be reinforced at the RPS</p>		

Improvement needed	Standard	Service action	Responsible officer	Timescale
<p>issue, had been addressed in the past through recording of doses in a separate log book, there is clearly a need to capture such information in ways which will assist with calculating individual doses (as a means of minimising risks to individuals). In addition, the draft procedure refers to operators as practitioners. The procedure does not, however, provide staff with clarity about the need for radiographers to fulfil such responsibilities in accordance with a DAG</p> <p>Procedure to inform patients of the benefit and risk from exposure to Ionising Radiation prior to examination (Number 19) was in draft form pending all-Wales agreement on wording to be used when speaking with patients. The third point (under the sub heading of Process within the draft document needed to be revised to provide clarity about what is meant</p>		<p>meeting (17.12.18).</p> <p>When dealing with the justification of exposing carers & comforters to ionising radiation the radiographers will be practitioners for justification. This will be reflected in the procedure document dealing with this.</p> <p>This requires feedback from All Wales Quality Forum, next meeting 23.01.18</p> <p>In the interim we will confirm a phrase that can be used as an explanation to the patient. This will be agreed on at the Radiation protection Supervisors meeting (17.12.18), a training plan will be developed including sign off for all the Radiographers on completion. This</p>	Andrew Carter	February 19

Improvement needed	Standard	Service action	Responsible officer	Timescale
by a risk weighted statement.		will be disseminated to all staff.		
<p>[The health board is required to provide HIW with details of the action taken/to be taken to ensure that staff training and entitlement records contain the full name of the employee, are signed and dated by the trainee, and include a countersignature of the trainer, for verification purposes.</p> <p>The health board is also required to inform HIW of the action taken/to be taken to ensure that staff receive training with regard to the following:</p> <p>The use of new equipment</p>	<p>[7.1 Workforce]</p>	<p>[It is intended that the entitlement documentation will be reviewed each January with sign off for the following year. We will ensure that full signatures and dates are included on the new documentation.</p> <p>Any new piece of equipment has an applications specialist brought in to undertake core training. We ensure as many staff as possible having training with the apps specialist who goes through a checklist and it signs off for</p>	<p>[Andrew Carter</p> <p>Andrew Carter</p>	<p>[February 19</p> <p>February 19</p>

Improvement needed	Standard	Service action	Responsible officer	Timescale
<p>The role of staff associated with communicating benefits and risks of patient exposure to ionising radiation.</p>		<p>each member of staff. Core trainers are identified and these then deal with future cascade training.</p> <p>Following agreement of the All Wales approach staff will receive training and guidance on their role associated with communicating the risks & benefits of patient exposure to ionising radiation. This will be included in the departmental induction process and will be included as an operator function in the entitlement documentation.</p>	<p>Andrew Carter]</p>	<p>February 19]</p>

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): [**ANDREW CARTER**]

Job role: [**PROFESSIONAL HEAD OF RADIOGRAPHY**]

Date: [**12.12.2018**]