

Ionising Radiation (Medical Exposure) Regulations Inspection (Announced)

Radiology Department / Prince Charles Hospital / Cwm Taf 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 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 Ionising Radiation (Medical Exposure) Regulations inspection at Prince Charles Hospital – Cwm Taf University Health Board on the 11 and 12 December 2018. The following clinical area was visited during this inspection:

Radiology department

Our team, for the inspection comprised of two HIW Inspectors and a Senior Clinical Officer 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 lonising Radiation (Medical Exposure) Regulations inspections can be found in Section 5 and on our website.

2. Summary of our inspection

Overall, we found that there was an emphasis on the delivery of safe and effective care within the radiology (X-ray) department. This was, in accordance with the Ionising Radiation (Medical Exposure) Regulations (2017) and aspects of the Health and Care Standards (2015).

However, we identified the need to issue the employer¹ with an improvement notice with regard to three aspects of non-compliance with the regulations. In addition, we highlighted the need for improvements to administrative aspects of the service. Such details can be found within Appendices B and C of this inspection report.

This is what we found the service did well:

- Staff who spoke with us were happy in their roles. In addition, radiography students and new members of staff said that they felt supported by their colleagues
- We found staff to be respectful, professional and kind toward patients throughout our inspection
- Most patients said that they had received clear information which helped them to understand the risks and benefits of their X-ray procedure/treatment

¹ The definition of employer under IR(ME)R regulations is someone other than an employee who, in the course of a trade of 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.

• Efforts had been made to develop the skills of radiographers working in the department, to enable them to perform extended roles.

This is what we recommend the service could improve:

- There is a need for the employer to develop and implement a suitable written procedure in respect of a quality assurance programme for equipment used for medical exposures
- The employer is required to provide HIW with details of the action to be taken, to ensure that patients are fully aware of their right to raise concerns about their NHS care or treatment
- Aspects of the content of a large number of employer's IR(ME)R procedures need to be updated and provide more detail. This is to ensure that staff are provided with clear and current information to guide them in their work.

Whilst the above findings have not resulted in the issue of an improvement notice, there is an expectation that the employer takes meaningful action to address these matters, as a failure to do so could result in further action by HIW.

However, we identified the service was non-compliant with the regulations as follows:

 We found a number of instances whereby national Diagnostic Reference Levels² (DRLs) were being exceeded and no action had been taken. We also found that the establishment of local DRLs was inconsistent

² 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.

- We found that departmental staff were not consistently recording patient radiation doses on RADIS³, in accordance with the Employer's procedure as stated (number 5)
- We could not be assured that there was a robust employer process in place to ensure that action was taken following advice and reports prepared by the external Radiation Protection Service (RPS) in terms of dosimetry and immediate action required, the identification of potential dose reduction strategies for those procedures identified in the RPS reports, and the RPS recommendations about the immediate actions required by the employer, (as stated within their reports).

These are serious matters and resulted in the issue of an improvement notice to the employer. At the time of publication of this report, HIW had received a response from the employer which provided assurance, sufficient detail and clarification of the actions taken, to address the improvements needed.

³ An All Wales **Radiology** Information System (WRIS), **RADIS**, which allows the sharing of information in order to support seamless patient care across all NHS Wales organisations is available to all health boards in Wales.

3. What we found

Background of the service

Cwm Taf Health Board was established in October 2009 and achieved University status in July 2013. The health board provides primary, community, hospital and mental health services to people living in Merthyr Tydfil, Rhondda Cynon Taf and surrounding areas.

Prince Charles Hospital provides acute emergency and elective medical and surgical services together with a range of diagnostic facilities.

At the time of our inspection, the following professionals supported the radiology department:

- Four consultant radiologists (plus up to four rotational consultants daily from the Royal Glamorgan Hospital (RGH))
- One specialist registrar (on rotation from RGH)
- Thirty eight radiographers and six reporting radiographers
- Medical Physics Experts (MPEs)⁴ from the Radiation Protection Service (RPS) based at Velindre Hospital.

No substantive long term departmental vacancies were reported. We did, however, find that some vacancies existed in relation to radiographers; although senior managers told us that the number of such vacancies had reduced considerably within the past twelve months.

Please note that the radiology department 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.

⁴ Medical Physics Expert (MPE) means an individual or group of individuals having the knowledge, training and experience to act, or give advice on, matters relating to radiation physics applied to exposure, whose competence in this respect is recognised by the Secretary of State.

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 provided us with positive comments about their experiences of using the radiology department at Prince Charles Hospital.

Overall, we found that patients were provided with enough information about their procedures/treatment.

We found staff treated patients with dignity, respect and kindness.

The employer had arrangements in place for patients to provide feedback about their experiences. However, some patients told us they would not know how to raise a concern about the services they received.

Prior to our inspection, staff working within the department distributed HIW questionnaires to patients and carers on our behalf, to obtain their views on the services provided. A total of 24 were completed. We also spoke with patients during the inspection. A number of patients indicated that parking arrangements at the hospital were very difficult. Other patient comments received, included the following:

"Reception staff were very friendly and helpful"

"Staff throughout the hospital were friendly, efficient and respectful"

"The service is excellent"

"The service provided for me today was excellent. The nurse with me was really lovely. Very helpful"

Patients who completed a HIW questionnaire also rated their overall experience provided by the department. Responses were very positive; 22 patients rating

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the service as either excellent or very good, the remaining two indicating that the service (in their opinion), was good. Such views we re-iterated by patients who spoke with us.

Staying healthy

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

Dignified care

Of the 24 patients who completed a HIW questionnaire, 22 answered our question as to whether staff had treated them with dignity and respect. Without exception, all 22 provided a positive response.

The vast majority of patients who completed a HIW questionnaire indicated that they were able to speak with staff about their procedure without being overheard by other people. We also saw that doors to X-ray rooms were closed when in use. This meant that there was an emphasis on patients' privacy, as well as safety.

Changing cubicles were available within the department. These offered patients privacy should they need to change into/out of, dignity (hospital) gowns. Patients also told us that they were able to maintain their privacy and dignity during their time within the 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.

Patients who completed a HIW questionnaire, and those who spoke with us during the inspection, 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 procedure/X-ray imaging/treatment.

Conversations with staff confirmed that they had been provided with examples of what they should say to patients with regard to communicating the benefits and risks of ionising radiation. In addition, we saw that the employer's procedure (number 9) contained such examples to support and remind staff about what was expected of them regarding this aspect of patient care. The majority of patients (where applicable), 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 received. Five patients who completed a questionnaire, stated that this question was not applicable to them. In addition, one patient commented:

"Results could be much clearer as sometimes just basic information is relayed back to the patient"

However, a third of patients who completed a HIW questionnaire said they did not know how to raise a concern or complaint about X-ray services they received. In addition, there were no posters on display, offering details about Putting Things Right⁵ arrangements.

Improvement needed

The employer is required to provide HIW with details of the action to be taken, to ensure that patients are fully aware of their right to raise concerns about their NHS care or treatment.

Communicating effectively

We saw that posters were displayed (In English and Welsh) within the department, which offered patients some information about the benefits and risks associated with exposure to ionising radiation and what certain scans involved. These supported verbal information provided by staff, as described above.

Twenty three patients who completed a HIW questionnaire said that they were able to speak with staff in their preferred language, one person indicating that they were not. Unfortunately, we were not given any additional information about their experience in this regard.

⁵ Putting Things Right is the process for managing concerns in NHS Wales. <u>http://www.wales.nhs.uk/sites3/home.cfm?orgid=932</u>

Patients stated that they felt they were listened to by staff during their appointments at the department.

Twenty patients who completed a HIW questionnaire told us that hospital signs made it very easy to find their way to the department once in the building, four indicating that they found it fairly easy.

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)⁶.

The health board had therefore put monitoring arrangements in place to ensure that the All-Wales waiting times target was being met (as far as possible).

Twenty three out of 24 HIW questionnaire respondents completed our question about the ease of getting an appointment at the department at a time that suited them. Of the 23, 17 said that it was very easy; six stating that it was fairly easy.

When patients were asked whether they had experienced any delay in having their procedure on the day of their appointment, we were provided with a mixed response from 18 patients. Just over a half told us they had waited 15 minutes to have their procedure following arrival at the department, the remainder stating that they had needed to wait between 15-30 minutes. One patient commented:

"At the X ray department for a CT scan. Never had to wait long"

However, 14 patients told us that no-one had told them how long they could be expected to wait for their procedure on the day of appointment. The employer

⁶ Interventional radiology is a medical specialty which provides minimally invasive x-ray 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).

may therefore wish to consider how to improve communication with patients about this matter.

Individual care

Listening and learning from feedback

The health board's annual quality statement (2017/18) stated that "the views of our patients, carers and the public are at the heart of improving the way we deliver our service".

The report also goes on to outline how the health board engages with patients, members of the public and its local community. For example:

- Up and coming public events are advertised
- Information/feedback is collated from the public to assist with the development and/or improvement to services
- Feedback on the outcome of all engagement and consultation activities is made available
- Close working with the local community health council.

We saw Have Your Say slips and a drop box, were available in the department for patients to offer their views on services received.

We were also provided with the details, outcomes and recommendations associated with a patient satisfaction survey conducted within the department (September 2017). This largely resulted in positive feedback with regard to the professionalism and friendliness of staff, prompt service and clean surroundings. Issues of concern identified related to the inability of some patients to distinguish between the different roles of staff within the department and aspects of the environment, due to building work.

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

We did however; identify the need to issue the employer with an improvement notice in respect of the assessment, monitoring and recording of patient radiation doses and the need to strengthen the employer's response to reports provided by the external radiation protection service. (Please see Appendix B of this report)

We also identified a number of other areas of non-compliance which resulted in an improvement notice required a response/action, all of which related to existing IR(ME)R employer's procedures. Details can be found within Appendix C of this report.

Compliance with lonising Radiation (Medical Exposure) Regulations

Duties of employer

Patient identification

The employer had a written procedure (number 1) as a means of guiding staff to correctly identify patients 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 understanding of this process, in-keeping with the employer's procedure. We also found that where patient identification could not be established (for example, if a patient was not fully conscious, or unable to verify who they were), patients were returned to the referring ward/department and imaging would not take place. This was, in support of patient safety. Patients who completed a HIW questionnaire, and those who spoke with us, also confirmed that staff had asked them for their personal details (for example, their name address and date of birth) before their procedure, or treatment. However, we were unable to verify the operator carrying out this practical aspect of the X-ray imaging process, within the sample of request forms that we looked at.

Further work is needed by the employer however, in terms of establishing a procedure where more than one operator is involved in an X-ray exposure. This is, in order to ensure that there is clarity about who the duty holder is, in respect of this task.

In addition, the inspection team raised concerns about existing arrangements where radiographers were required to complete radiology referral request 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 3) to ensure that this aspect of the X-ray imaging process was completed 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 also found that the pregnancy enquiry/check completed whilst operators were working in theatres was not consistent with the process across radiology. Specifically, the theatre form in use only indicated that the pregnancy question was asked, whereas the outcome of the enquiry was not recorded.

Non-medical imaging exposures

The employer had a written procedure (number 13) which set out the criteria for carrying out non-medical imaging exposures⁷. However, we found that the procedure needed to be fully revised to reflect the name change (from medicolegal imaging to non-medical imaging); additional categories needing to be specified within the procedure in accordance with the new regulations.

Referral criteria

There was an employer's policy and procedure in place with regard to referrals from clinical and non-medical staff respectively. We also saw that X-ray imaging referral criteria was displayed within the department.

We found that paper referral requests only, were currently received, and processed, by the department. Conversations with a senior clinical member of staff, revealed that work was currently underway to revert to an electronic referral system, in the foreseeable future. Staff described how referral requests were checked, together with the process in place for the return, (to the referrer), in instances where incomplete requests, or those with discrepancies, were received.

We were able to confirm that information about entitled referrers was coordinated and updated by RADIS. In the event that a referral request was received from a referrer who was not listed, the GP practice or consultant associated with the clinical area concerned was contacted to confirm the referrer's details. In addition, we found that locum referral codes were available for short term locum positions. This meant that there was an ongoing emphasis on patient safety.

Conversations with staff resulted in confirmation that iRefer⁸ version 8 was available to them.

⁷ Non-medical imaging exposures include those for health assessment for employment purposes, immigration purposes and insurance purposes. These may also be performed to identify concealed objects within the body.

⁸ iRefer helps referring GPs, radiographers, clinicians and other healthcare professionals to determine the most appropriate imaging investigation(s) or intervention for patients.

Discussions with senior managers also resulted in the provision of a list of approved (third party) radiologists with General Medical Council (GMC) numbers included.

Justification of Individual Medical Exposures

The employer had a written procedure for the justification⁹ and authorisation of medical exposures (number 14).

Given the IR(ME)R 2017 definition of carers and comforters, we held discussions with senior managers about this aspect of service delivery. As a result, we found that the employer did not currently have a formal process for justifying the exposures of individuals performing the role of carer/comforter. Rather, the employer's procedure states that the operator should seek advice from a practitioner regarding the benefits and risks. However staff explained that this may not be practical on a day to day basis and could result in delays in procedures being undertaken.

Nevertheless, the justification of the exposure to carers and comforters was currently being carried out by the operators. This matter needs to be addressed by the employer.

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 Guidelines¹⁰ (DAGs) to authorise imaging under these guidelines in the CT and mammography areas of the department.

⁹ Justification is the process of weighing up the expected benefits of an exposure against the possible detriment of the associated radiation dose.

¹⁰ Delegated Authorisation Guidelines (DAGs) must be produced by a named practitioner (often, but no always, the lead radiologist). The individual who produces these guidelines takes responsibility for any exposure authorised using these guidelines.

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 employer needs to demonstrate how it is assured that radiographers are entitled as referrers and when taking on the role of practitioner, that they have received appropriate training and are entitled to justify the exposure.

We were able to confirm that justification was recorded on X-ray request forms; the practitioner signing and dating the form in the appropriate section. Similarly, authorisation for imaging procedures was evidenced on a sample of request forms.

We held discussions with senior managers in relation to the justification process and found that that they had a list of current practitioners who worked for the current All-Wales third party (radiology) provider. We were also provided with a copy of the Service Level Agreements (SLAs) in relation to a former third party radiology provider and a copy of the SLA with the RPS at Velindre, respectively. However, we were unable to see the current service level agreement with the third party provider. This is because such agreements are held centrally by Welsh Government procurement, copies of which are not made available to health boards.

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.

Optimisation

The employer had a procedure in place for the assessment of patients' radiation doses (number 5). However, the procedure lacked sufficient detail to guide staff. We therefore suggested that the procedure be cross referenced with the proposed new procedure within which staff are to be guided regarding the need to input patients' radiation doses onto RADIS (as indicated within the completed improvement notice action plan).

We found that staff recorded radiation doses in relation to carers and comforters in a file within each X-ray room. The employer may, however, wish to consider the need to record carers' and comforters' names within such files, instead of using the words parent, mother or father, as this may create difficulties in the future, in terms of calculating cumulative radiation doses.

We looked at a sample of patient's records during our inspection and found that departmental staff were not consistently recording patient radiation doses on RADIS, in accordance with the above procedure and regulatory requirements. This matter had also been highlighted within the audit of patient radiation doses, provided by the RPS.

The above was included in an improvement notice issued by HIW to the employer within 48 hours of the inspection. Since then, we have received a satisfactory response from the employer, the details of which can be seen within Appendix B of this report.

We were able to confirm that radiation doses relating to some departmental equipment had a pre-programmed paediatric setting to ensure that they 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, although staff explained that older equipment with higher radiation doses were avoided wherever possible, when imaging paediatric patients.

We were provided with details of the newly established Optimisation Group; the first meeting to be held in the New Year. The intention of the group is to oversee the monitoring and implementation of optimisation processes within the department. This is, with a view to ensuring compliance with relevant standards and legislation.

Diagnostic reference levels (DRLs)

The employer's procedure (number 6), in relation to DRLs did not explicitly state who was responsible for establishing DRL's or how they were established.

We therefore looked at local DRLs on display within the department and recent reports produced by the RPS, together with the overarching annual report produced by them which was subsequently submitted to the Cwm Taf University Health Board's Radiation Protection Committee on 7 December 2018.

Discussions with departmental staff and senior managers revealed that they had challenged the RPS advice, following their recent analyses of local DRLs. Following their initial representations to the RPS however, no further challenges were made by the department and we could find no evidence of further analyses being undertaken by the RPS. We also found that the establishment of local DRLs was inconsistent.

Ultimately, this resulted in local DRLs being displayed for staff to follow which in some instances exceeded national DRLs and would not assist staff in identifying issues with specific equipment local to their own department. Neither would the local DRLs assist with prompting staff to optimise equipment to

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ensure that patient exposures were kept As Low As Reasonably Practicable (ALARP).

Conversations with an MPE from the RPS revealed that the RPS had recently revised the process/methodology for analysing patient dose data setting of diagnostic reference levels. When asked to review reports that the RPS had previously provided to the health board during this inspection, the MPE was honest and told us that the revised methodology that had been applied by the RPS (at the health board-during November 2018), was flawed and had led to miscalculation in the local DRLs to be used by staff. The MPE also stated that a sentence within the RPS service report for 2018 (point 3 "for all three modalities, no procedures exceeded national or previous DRLs"), was incorrect.

This created confusion, in terms of the action that needed to be taken by the Employer following the analysis of patient dose data recently completed by the RPS (in The Audit of patient radiation dose in Fluoroscopy Computed Tomography and Pain X-ray in Cwm Taf University Health board -November 2018). In addition, the RPS service report indicated that some equipment and protocols needed immediate investigation as the patient doses in some rooms in the department significantly exceeded the local DRLs. There was no evidence that such recommended actions had been taken following the issue of the service report.

The above meant that we could not be assured that there was a robust employer process in place to ensure that action was taken following advice and reports prepared by the RPS (see titles above), in terms of dosimetry and immediate action required, regarding the identification of potential dose reduction strategies for those procedures identified in the RPS report. There was also a lack of evidence to support that actions were taken to correct equipment issues highlighted in the report issued by the RPS after annual quality assurance testing (for example-ghosting¹¹ on processor, engineer required to attend).

The evidence gathered during this inspection, as outlined above, resulted in the issue of a HIW improvement notice, the details of, and employer's response to, can be seen in Appendix B of this report.

¹¹ Ghosting, is known to undermine the quality of X-ray imaging.

Clinical evaluation

There was an employer's procedure in place (number 10) which described the process for staff to follow regarding clinical evaluation.

However discussions with senior managers and staff confirmed that audit activity in relation to clinical evaluation was not currently being carried out. Additionally, whilst staff told us that ad hoc audits concerning clinical evaluation within patients' notes were carried out, the department was unable to provide us with any evidence to support such activity.

Equipment: general duties of the employer

The employer's policy and procedure (number 4) failed to include any reference to, or evidence of, a quality assurance programme in relation to departmental equipment. The document also needed to be updated, to remove reference to Regulation 33 IRR 17 as this has been revoked; IR(ME)R 17 now applying to this aspect of service delivery. Staff need to be made aware of this change.

We found that there were arrangements in place to complete annual checks on X-ray equipment to ensure their functionality. Additionally, we were able to confirm that details of any defective equipment were added to the employer's risk register, with a view to arranging a replacement.

Staff also described the daily and weekly quality testing being carried out within the department with regard to general and mobile equipment. However, no such evidence could be provided for the Computed Tomography (CT¹²) scanners.

We were told that when a routine equipment quality assurance test failed, the senior radiographer removed the equipment from use, pending an investigation. The fault would then be reported to the medical physics service. The employer had a procedure in place with regard to room equipment breakdown (called Equipment Handover) to support the above approach, the content of which provided sufficient guidance about what staff needed to do in such instances.

¹² 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.

Conversations with senior managers revealed that one of the X-ray rooms (Room 2) was to be de-commissioned in the near future. This was, as a result of the need to replace X-ray equipment that was no longer fit for its intended purpose. We saw evidence of a risk assessment for this piece of equipment and of its inclusion on the hospital risk register.

Safe care

Infection prevention and control

During the course of our inspection, areas seen within the department were clean, uncluttered and free from trip hazards. Hand cleaning gel was available to promote effective infection prevention and control and staff who spoke with us, were able to describe, in some detail, the health board's infection prevention and control approach adhered to, within the department.

We saw signs on display to guide staff on those occasions when patients presented at the department with diarrhoea and vomiting, or other similar infections. This was, in order to minimise the spread of infection and to protect patients and staff.

Discussions with staff revealed that they completed online annual training on the topic of infection prevention and control. We were also able to confirm the presence of cleaning checklists for staff to follow. In addition staff had ready access to aprons, gloves and cleansing wipes for use between patients.

Nineteen patients who completed a HIW questionnaire indicated that the department was very clean; five stating that it was fairly clean.

However, some seating in the main X-ray waiting area was torn. This matter needs to be addressed as part of the ongoing changes to the X-ray environment.

Safeguarding children and adults at risk

Conversations with staff within the department demonstrated an awareness of current safeguarding procedures. We also found that staff completed online training on an annual basis, to help them keep up to date with these issues.

Effective care

Quality improvement, research and innovation

Clinical Audit

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Senior managers described aspects of audit activity completed by the radiation protection service together with the in-house audits which took place as part of the rolling programme of agreed activity to date. Topics related to a retrospective audit looking at head CT referrals from primary care and a review of requests made to the All-Wales third party radiology services. We were also provided with the proposed list of audits for 2018-19. These included activity in relation to a variety of X-ray procedures. We also found evidence of a multi-disciplinary approach to audit activity.

Staff confirmed that reject analyses¹³ was being carried out. We were also provided with details of a completed audit (dated July 2016).

Expert advice

We were able to confirm that MPEs provided support and advice to departmental staff about new and existing employer's procedures and the reporting of radiation incidents to HIW. MPEs were also involved in new equipment performance and acceptance testing and follow up testing at approximately 12-14 months post installation.

We found that MPEs were involved with the annual quality assurance testing of departmental equipment; providing reports to specialty leads with remedial actions highlighted where action needed to be taken. They also completed radiation dose audits every three years. However, as already stated above (under the sub-heading of diagnostic reference levels) we found a number of discrepancies within the most recent (2018) reports on radiation dose optimisation provided by the MPEs.

However, 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 involved in the optimisation of high dose CT procedures other than annual dose audits

¹³ **Reject analysis** provides information that would assist with the identification of over radiation exposure of patients. Film **reject analysis** has therefore become a major parameter as a quality control tool in diagnostic radiography service delivery.

- There was no involvement in training practitioners or departmental staff
- MPEs were not routinely involved in the tendering process for new equipment or applications training
- There was no monitoring of the service level agreement between the employer and the RPS
- 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.

Medical research

The employer had an established procedure in place with regard to Medical Research Exposures (number 7) which required a very minor amendment.

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.

Record keeping

We reviewed a sample of patient referral records (for X-ray procedures) and saw that these had been completed with appropriate details by those staff involved in the medical exposure. They also demonstrated that staff had adhered to the relevant employer's procedures.

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.

We found that staff understood their responsibilities and were supported to complete training relevant to their roles. We also found that the staff team worked well together and were very professional in their approach toward patients and visitors throughout our inspection.

We were able to confirm that senior managers employed within the department were visible and made every effort to provide staff with effective leadership on a day to day basis.

Governance, leadership and accountability

Duties of the employer

Entitlement

The process of entitlement was described in an employer's procedure (number 2).

Overall, we found that the process of entitlement was good; the clinical director for radiology being entitled by the employer to entitle all staff within the department to undertake their respective roles. This was, in accordance with IR(ME)R regulations.

We found that staff received an entitlement certificate which contained a defined scope of practice after they had completed training (which had been signed off by senior staff to confirm competence). We also saw that there was an overarching matrix in place, which contained a record of staff entitlement. This meant that all those working within the department were able to understand who, was entitled to do, what.

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However, we did not find evidence of any monitoring mechanisms to ensure that entitled duty holders outside of radiology services were complying with IR(ME)R procedures (other than non-medical referrers).

The employer is also required to undertake an appropriate form of action to ensure staff training is included as part of the requirement for duty holders as practitioners and operators.

There were no non-medically qualified registered healthcare professionals, entitled as practitioners.

Procedures and protocols

We found that, in general, senior managers placed an emphasis on improving performance and the provision of safe and effective care. For example, radiation protection and management and performance meetings were held regularly. We were also informed that the top five departmental risks were forwarded to the quality and safety patients committee, so that appropriate action could be agreed and undertaken. We did, however, find that since the departure of the previous Director of Health and Care Sciences, the post remained unfilled. This had evidently created particular challenges in relation to the effectiveness of the exchange of information between the department, the employer and health board executives. This matter was highlighted by HIW at the feedback meeting.

As already stated, the health board's chief executive was designated as the IR(ME)R employer. This is in keeping with the national guidance¹⁴ on implementing IR(ME)R regulations as they apply to diagnostic and interventional imaging services.

The employer's overarching lonising Radiation Policy required some revision, the nature of which was discussed with senior managers during our inspection.

¹⁴ 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. <u>https://www.rcr.ac.uk/sites/default/files/bfcr152_irmer.pdf</u>

The employer's quality assurance process for written procedures and protocols was outlined in an employer's procedure (number 4). However, we saw that version control was inconsistent in some instances.

We found that the frequency of procedure review, was stated as every three years or when new legislation or guidance came into effect. However, we saw evidence that some documentation had not been updated since the implementation of IR(ME)R 17. Discussions with senior managers resulted in the need to consider adopting a shorter time frame for the review of employer's procedures. This was, in order to ensure that staff had access to current and up to date information in their day to day work.

Staff told that they are asked to read all new procedures and were required to sign a form confirming this. We did not ask to see any evidence to verify this matter.

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 justification 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.

Incident notifications

We were told that all incidents (regarded unintended radiation doses), were recorded on the Datix system and then reported to radiology services managers and the RPS for further investigation, regardless of the radiation dose involved. We also saw recorded evidence in support of the reporting of other clinical incidents and near misses.

Discussions with senior managers revealed that specific training and support was made available to all non-medical referrers regarding accidental and unintended radiation exposures.

We also found that there were well established arrangements in place, in terms of shared learning and the cascading of information about clinical incidents, from governance leads and radiation safety committee, to superintendents and staff across radiology services.

The above meant that there was an emphasis on the prompt reporting and investigation of all incidents, to minimise the risk of their recurrence.

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, operators¹⁵ and referrers (known collectively as duty holders).

We also saw evidence of Delegated Authorisation Guidelines (DAGs) within Xray rooms. However, we were unable to confirm the name of the authorising practitioner in each case.

Improvement needed

Please see Appendix C of this report for details about the non-compliance matters and improvements identified in respect of Governance, Leadership and Accountability (specifically in relation to a large number of employer's procedures, as cited throughout this inspection report).

Staff and resources

Workforce

We were able to confirm that the department had a number of staff vacancies. Specifically, these were five Band 6 and three Band 5 radiographers. However, as a result of pro-active recruitment and advertising (which has included open days, good relationships with academic institutions in Wales and other parts of the UK and the provision of a positive learning environment for student placements, the employer had successfully recruited 14 Band 5 radiographers in the past twelve months. Senior managers also described the arrangements

¹⁵ 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.

in place to offer awards to staff such as trainer of the year. The inspection team commended the department for their efforts in this regard.

We found that radiographers were encouraged to expand their roles professionally, six being entitled to report the outcome of a number of X-ray procedures. Senior managers also described their intention to undertake a further review of the skill mix of staff within the department. This was, with a view to ensuring that all staff are being utilised in the best way; a number of Band 2/3 staff currently carrying out certain tasks, to release radiographers to undertake patient procedures.

Staff confirmed there was no formal structure for staff meetings; information being communicated through memos, e-mails and face to face updates as far as possible.

We looked at the training records associated with two radiographers and found them to contain satisfactory evidence of ongoing professional development. We were also made aware that the department had an overarching staff training matrix. This assisted managers with determining compliance with mandatory/other training.

We did not look at any evidence in support of the department's induction programme during this inspection.

Discussions with staff revealed that they were presented with opportunities to attend feedback sessions associated with completed departmental audit activity. Staff also told us that in-house training was provided through continuing professional development sessions, led by radiologists and via online courses.

We were able to confirm that non-medical referrers received trained through a two day Cardiff University based programme, the successfully completion of which, resulted in a certificate and defined scope of practice. There is, however, no refresher training available at this stage.

We were informed that equipment training for radiologists is not currently recorded within the department.

Staff confirmed that they received an annual appraisal of their work, IR(ME)R entitlement and training records being updated by departmental managers on an ongoing basis. Superintendent radiographers also described the newly developed appraisal/personal development programme which was due to be implemented early in 2019. The new approach was stated as having a much greater focus on compliance with IR(ME)R and individual staff development.

Conversations with radiography students indicated that they felt well supervised and supported and were working within a positive departmental culture.

Given the nature and number of service areas for improvement identified during this inspection, the employer should give due consideration 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 an <u>improvement notice</u>. The issuing of an improvement 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 <u>lonising Radiation</u> (<u>Medical Exposure</u>) Regulations (IR(ME)R) 2017 and its subsequent amendment (<u>2018</u>).

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 <u>Health and Care Standards 2015</u>
- 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 escalated during this inspection.			

Appendix B – Improvement notice-completed action plan

Hospital:	Prince Charles Hospital
Ward/department:	Diagnostic and Interventional Imaging
Date of inspection:	11 and 12 December 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 / Regulation	Service action	Responsible officer	Timescale
The Employer was found to be non- compliant with Regulation 12 (1) and (3), Regulation 6, Regulation 15 (6) and Schedule 2 (1) (f).	See column to the left.	Optimisation Team – Draft terms of reference attached.		18 th December 2018
This is because we found a number of instances whereby national Diagnostic Reference Levels (DRLs) were being exceeded and no action had been taken. We also found that the establishment of local DRLs was inconsistent.		First meeting scheduled for 3 rd		
Evidence				
During the course of our two day inspection, we spoke with a number of departmental staff, senior managers and a Medical Physics Expert		Designate a single point of receipt for all Radiation Protection Service reports – Directorate Manager,		

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Immediate improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
(MPE) from the Radiation Protection Service (RPS) with which the health board has a service level agreement. This was in order to explore how local DRLs, in current use within the department, had been calculated and agreed.		Radiology. Staff updates through user group meetings and annually at PDR.		18 th December 2018
We also looked at local DRLs on display within the department and recent reports produced by the RPS, together with the overarching annual report produced by the RPS which was subsequently submitted to the Cwm Taf University Health Board's Radiation Protection Committee on 7 December 2018. Specifically, these included:		All reports should be presented and discussed at the Image Optimisation Team meetings		
 The Audit of patient radiation dose in Fluoroscopy Computed Tomography and Pain X-ray in Cwm Taf University Health board (November 2018) Radiation Protection Services Report (December 2018). 		Any specific actions arising from the reports should be detailed, minuted and appropriate staff designated to act. (See '1' below).		
Our conclusions from these discussions and observations were: Discussions with departmental staff and senior managers revealed that 		The Image Optimisation Team, as per its terms of reference, will report activity and outcomes to the Radiology Governance Group and annually to the Radiation Safety		

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Immediate improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
 they had challenged the RPS advice following their recent analyses of local DRLs. Following their initial representations to the RPS however, no further challenges were made by the department and we could find no evidence of further analyses being undertaken by the RPS. Ultimately, this resulted in local DRLs being displayed for staff to follow which in some instances exceeded national DRLs and would not assist staff in identifying issues with specific equipment local to their own department. Neither would the local DRLs assist with prompting staff to optimise equipment to ensure that patient exposures were kept As Low As Reasonably Practicable (ALARP) Conversations with an MPE from the RPS revealed that the RPS had recently revised the process/methodology for analysing patient dose data setting of diagnostic 		Committee. An initial report detailing actions and outcomes will be prepared for the next meeting of the Quality, Safety and Risk Committee In addition, all relevant information relating to departmental reports (either received from Radiation Protection Service or initiated within the Radiology Directorate) will also be provided to the Health Board Quality, Safety and Risk Committee as part of the Radiology quarterly exception reports and to the monthly Radiology Clinical Business Meeting Any actions requiring urgent attention will be communicated directly to the relevant Executive Director by the		30 th April 2019 31 st December 2018 - this should allow all staff to be seen personally by senior staff member taking in to account availability due to shift patterns. 31 st December 2018 – this should allow all staff to be seen personally by senior staff member taking in to account availability due to shift patterns.

Immediate improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
reference levels. When asked to review reports that the RPS had previously provided to the health board during this inspection, the MPE was honest and told us that the revised methodology that had been applied by the RPS (at the health board-during November 2018), was flawed and had led to miscalculation in the local DRLs to be used by staff. The MPE also stated that a sentence within the RPS service report for 2018 (point 3 "for all three modalities, no procedures exceeded national or previous DRLs"), was incorrect. This has created confusion, in terms of the action that needed to be taken by the Employer following the analysis of patient dose data recently completed by the RPS (in The Audit of patient radiation dose in Fluoroscopy Computed Tomography and Pain X- ray in Cwm Taf University Health board -November 2018) □ In addition, the RPS service report indicated that		Radiology Directorate Manager via the Assistant Director of Therapies. Communication regarding current improvement notice has also taken place with the Chief Scientific Advisor (Health) Briefing for the Chief Medical Officer to be provided on submission of this action plan		31 st December 2018 To commence 1 st February 2019 (reviewing January 2019 data) 3 rd January 2019 19 th December 2018

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Immediate improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
some equipment and protocols needed immediate investigation as the patient doses in some rooms in the department significantly exceeded the local DRLs. There was no evidence that such recommended actions had been taken following the issue of the service report.				3 rd January 2019
 We could not find evidence to demonstrate that the service level agreement between the health board and the RPS was being monitored. This meant that there was a lack of management and oversight (on the part of the Employer) in relation to the issues described above. 				As reports are received
Impact on the people using the service				
Whilst we did not seek any evidence to verify whether the above matters had impacted negatively on patients, to date, the potential exists for patients to receive exposures that are not ALARP or consistent with the intended				As reports are received

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Immediate improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
diagnostic or therapeutic purpose. The Employer should therefore investigate the impact of our findings.				
The service was found to be non-compliant with Regulation 6, Regulation 13 and Schedule (2) (1) (e).				Next meeting date to be confirmed
This is because we found that departmental staff were not consistently recording patient radiation doses on RADIS, in accordance with the Employer's procedure as stated (number 5).				As reports are received
Evidence				
During the course of our two day inspection, we spoke with staff to determine the day to day process they adopted in terms of recording patient doses following exposure to ionising radiation. We also looked at a sample of patient records within RADIS to see whether patient radiation doses had been recorded there, as well as on patient referral forms				
From these discussions and review of				

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Immediate improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
documentation we found evidence that patient radiation doses were not routinely recorded on the RADIS system which would make it challenging for the Employer to comply with Regulation 13, effectively.				As reports are received
Impact on the people using the service				
The absence of patient radiation doses within RADIS would create challenges in terms of investigating incidents involving a number of patients. In addition, the above would create difficulties in securing advice from MPEs in terms of optimisation, which in turn may have a negative effect on the delivery of a safe and effective service to patients.				17 th December 2018
The service was found to be non-compliant with Regulation 6.				
This is because we could not be assured that there was a robust Employer process in place to ensure that action was taken following advice and reports prepared by the RPS.				19 th December 2018

Immediate improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
Evidence				
During the course of our two day inspection, we spoke with staff and senior managers and found that key individuals had not had sight of a number of RPS reports; specifically the reports dated November 2018.				
Impact on the people using the service				
The absence of a robust system for sharing and acting on, advice and reports provided by the RPS meant that aspects of patient and staff safety may be missed, resulting in error and harm.				

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:

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Appendix C – Improvement plan

Hospital:	Prince Charles Hospital
Ward/department:	Diagnostic and Interventional Imaging
Date of inspection:	11 and 12 December 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 / Regulation	Service action	Responsible officer	Timescale
Quality of the patient experience				
The employer is required to provide HIW with details of the action to be taken, to ensure that patients are fully aware of their right to raise concerns about their NHS care or treatment.	4.2 Patient Information			
Delivery of safe and effective care				
Quality of management and leadership				

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Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
The employer is required to describe the action taken/to be taken with regard to existing employer's procedures:	Governance, Leadership and Accountability			
The employer's overarching lonising Radiation Policy requires some revision, the nature of which was discussed with senior managers during our inspection				
 Patient Identification (number1). There is a need for request forms to be completed by the referrer in theatre, prior to elective cases. In addition, further work is also needed on the part of the employer, in terms of establishing a procedure where more than one operator is involved in an X- ray exposure. This is because we 				
were unable to identify who the operator was, when we looked at a sample of patient referral request forms. It was therefore not possible to verify who had completed the patient				

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Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
identification check				
 Entitlement of Duty Holders (number 2). We were unable to find evidence of any monitoring mechanisms to ensure that entitled duty holders outside of radiology services were complying with IR(ME)R procedures (other than non-medical referrers). The employer is also required to undertake an appropriate form of action to ensure staff training is included as part of the requirement for duty holders as practitioners and operators. 				
 Checking for Pregnancy-High Dose Examinations (number 3). The pregnancy enquiry/check completed whilst operators were working in theatres was not consistent with the process across radiology. Specifically, the referral request form only indicated that the pregnancy question was asked, whereas the response to the enquiry (and who provided that), 				

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
was not recorded				
 Quality Assurance Programmes (number 4). We found there was an absence of reference to, and details of, a specific quality assurance programme in relation to equipment as required by the regulations 				
 Assessment of Patient Dose (number 5) needs further clarification about what staff should record and how radiation doses are assessed 				
 Diagnostic Reference Levels (number 6). Further information is required with regard to who, is responsible for establishing DRLs 				
 Medical Research Exposures (number 7) required a very minor amendment. Specifically, the words 'a certain dose' needs to be replaced with a specific dose, as discussed 				
Clinical Evaluation of the Outcome of				

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Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
an Exposure (number 10) Discussions with senior managers and staff confirmed that audit activity in relation to clinical evaluation was not currently being carried out. Additionally, whilst staff told us that ad hoc audits concerning clinical evaluation within patients' notes were carried out, the department was unable to provide us with any evidence to support such activity				
 Reducing the Probability and Magnitude of Accidental or Unintended Doses to Patients (number 11). The employer needs to consider including the correct identification of patients as a way of reducing probability and magnitude within this document 				
 Procedure for the Investigation of Exposures Much Greater Than Intended (MGTI) (number 12). The employer needs to review the entire 				

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Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
document as PM77 only deals with equipment failures, not procedural failures. Staff therefore need to be guided in accordance with MGTI 17				
 A procedure is needed in order to inform the referrer, practitioner and individual or representative, of the occurrence of a clinically significant unintended or accidental exposure 				
 Medico Legal Imaging (number 13). We found that the procedure needed to be updated to reflect the name change (from medico-legal imaging to non-medical imaging); additional categories needing to be specfiied within the procedure in accordance with the new regulations. 				
 Carers and Comforters (number 14). We found that the employer did not currently have a formal process for justifying the exposures of individuals performing the role of carer/comforter. Rather, the employer's procedure 				

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Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
states that the operator should seek advice from a practitioner regarding the benefits and risks. However staff explained that this may not be practical on a day to day basis and could result in delays in procedures being undertaken. This matter needs to be addressed by the employer, especially if it is not practical for the operator to hold a discussion with the practitioner to seek justification for the exposure of a carer/comforter.				
	7.1 Workforce			

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:

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