

Ionising Radiation (Medical Exposure) Regulations Inspection (Announced)

Radiotherapy Department /
The Rutherford Cancer Centre
South Wales

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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 of The Rutherford Cancer Centre South Wales operated by Rutherford Cancer Centres Ltd on 29 and 30 January 2019. The following area was visited during this inspection:

- Radiotherapy Department

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

HIW explored how the service:

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

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

2. Summary of our inspection

Patients provided very positive comments about their experiences of using the radiotherapy department at The Rutherford Cancer Centre South Wales.

Discussions with both managers and staff working in the department provided us with assurance that day to day practice took into account the requirements of IR(ME)R 2017. However we found that these arrangements were not clearly evidenced within the employer's formal written procedures.

A management structure was in place and clear lines of reporting were described and demonstrated. Effective governance arrangements were also found to be in place.

This is what we found the service did well:

- We found staff treated patients with dignity, respect and kindness
- The department was very clean and promoted patients' privacy
- We were assured that day to day practice took into account the requirements of the Ionising Radiation (Medical Exposure) Regulations 2017
- Effective governance systems were demonstrated.

This is what we recommend the service could improve:

- The employer's written procedures need to be reviewed so that they clearly demonstrate the arrangements in place to ensure compliance with the Ionising Radiation (Medical Exposure) Regulations 2017
- Some of the employer's written procedures need further clarification added
- Training records demonstrating that radiation oncologists had completed training in respect of the operator functions they perform must be available for inspection by HIW on request.

We identified a regulatory breach during this inspection regarding incomplete training records for radiation oncologists. Further details can be found in Appendix B.

Whilst this has not resulted in the issue of an improvement notice, there is an expectation that the provider takes meaningful action to address these matters, as a failure to do so could result in non-compliance with regulations.

3. What we found

Background of the service

Rutherford Cancer Centres Limited provide cancer care and treatments including radiotherapy at locations across England and Wales.

The Rutherford Cancer Centre South Wales is located in Newport, South Wales and provides a range of oncology services including radiotherapy.

At the time of our inspection, the Rutherford Cancer Centre was registered with Healthcare Inspectorate Wales as an independent clinic to provide a range of private oncology services.

The radiotherapy department offered proton beam therapy¹ and standard radiotherapy² treatments.

¹ Proton beam therapy is a type of radiotherapy that uses a beam of high energy protons, which are small parts of atoms, rather than high energy X-rays (called “photons”) to treat specific types of cancer.

² Radiotherapy uses high-energy rays, such as X-rays, to treat cancer. It destroys cancer cells in the area where it is given.

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 very positive comments about their experiences of using the radiotherapy department at The Rutherford Cancer Centre South Wales.

We found staff treated patients with dignity, respect and kindness and the design of the department promoted patients' privacy.

Patients told us that they were provided with enough information about their procedures and we found that patients received timely care. However, a system needed be put in place to demonstrate that patients or their representatives have been informed of the benefits and risks associated with the radiation dose from exposures.

Suitable arrangements were in place to seek patients' views and we found that feedback received was acted upon to improve the patient experience.

Before our inspection, we asked senior staff to hand out HIW questionnaires to patients to obtain their views on the service. A total of five were completed and returned. We also spoke to patients during the inspection. Patient comments included the following:

"Excellent. Probably the most professional medical organisation that I have had the pleasure to work with."

"...very happy so far."

Health promotion, protection and improvement

We saw that information was displayed about how patients can look after their own health and wellbeing.

Health promotion material was displayed within the department. This included information about smoking cessation and healthy eating. Information was also displayed advising patients to inform staff of any medical conditions they had.

There was no information displayed requesting individuals who are or may be pregnant or breast feeding to inform a member of staff. It is acknowledged that staff would discuss this with patients before they commenced their radiotherapy treatment. However, displaying information could act as an additional reminder to patients to inform staff if their condition has changed, further promoting patient safety and as required by IR(ME)R.

Improvement needed

The employer is required to provide HIW with details of the action taken to raise awareness of the effects of ionising radiation amongst individuals who are/maybe pregnant or currently breastfeeding.

Dignity and respect

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

Every patient who completed a questionnaire agreed they had been treated with dignity and respect by the staff working in the department and felt that they were always able to maintain their own privacy, dignity and modesty during their appointments. This was also confirmed by patients we spoke to.

All patients who completed a questionnaire felt that they were listened to by staff during their appointment. Patients also told us that they were able to speak to staff about their procedure or treatment without being overheard by other people (e.g. in a private room).

Whilst we did not observe patients having their procedures, we saw staff greeting patients in a friendly manner and asking about their welfare.

The department's environment promoted patient privacy. Seating was arranged so that patients could choose whether to socialise with other patients or spend time in a more private area. Changing cubicles were available for patients so that they could change into dignity gowns in private before their procedures.

Patient information and consent

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

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

All patients also told us that they had been given information on how to care for themselves following their treatment and who to contact for advice about any associated after effects.

The employer had an up-to-date written policy on the provision of information to patients. This was a general policy that covered the creation and format of a range of information that can be provided to patients. We saw that a range of leaflets about cancer care and treatments was readily available in the waiting area for patients to read and take away.

Staff also confirmed that patients were provided with information when first seen and reviewed by their oncologist in the outpatient clinic. Radiotherapy staff also attended the outpatient clinic with oncologists and contributed to information provided to patients or their representatives.

Staff confirmed that 'carers or comforters'³ who are relatives or friends of patients were not able to be present in treatment rooms when patients received their radiotherapy treatment. This was for safety reasons due to the high level of doses associated with radiotherapy. However, where patients or their representatives chose to do so, visits to the radiotherapy treatment rooms could be arranged to help alleviate their anxiety.

The employer had an up to date written procedure on the provision of information to patients about the benefits and risks associated with their radiotherapy treatment. However, patients or their representatives must also be provided with information on the benefits and risks associated with the radiation dose from the

³ Carers and comforters are individuals who are knowingly and willingly exposed to ionising radiation through support and comfort of those undergoing exposure.

IR(ME)R makes clear that individuals undertaking this role are not those doing so as part of their employment. Carers and comforters are commonly relatives or friends of those undergoing exposure.

exposure. This is required by the regulations and helps ensure that patients or their representatives are fully informed about their care and treatment.

Improvement needed

The employer is required to provide HIW with details of the action taken to demonstrate that patients or their representatives have been informed of the benefits and risks associated with the radiation dose from the exposure.

Communicating effectively

We found arrangements were in place to meet the communication needs of patients.

All patients who completed a questionnaire preferred to speak in English and told us that they were always able to speak to staff in their preferred language.

Signage was displayed within the clinic to assist patients to find their way around. A reception desk was located near the main entrance and reception staff were available to greet and direct patients to the department. All patients who completed a questionnaire felt that it was 'very easy' to find their way to the department once in the building.

Signage was displayed in English only. As an independent healthcare service, there was no requirement to display bilingual signage.

However, many information leaflets were routinely available in Welsh and English. Staff also confirmed that they had access to an interpreter service should this be needed to meet the communication needs of patients.

Care planning and provision

We found that patients were provided with timely care.

All patients who completed a questionnaire felt it was very easy to get an appointment at time that suited them. The majority of patients also told us that when they arrived at the clinic, staff had told them how long they would likely have to wait for their procedures.

All patients who completed a questionnaire told us that they had a wait of less than 15 minutes to be seen and have their procedures.

Citizen engagement and feedback

We found there were systems in place to seek feedback from patients and their carers about their experiences.

The department had a complaints procedure. This included appropriate timescales for acknowledging and responding to complaints and concerns raised by patients. It also included the contact details of HIW so that patients could make us aware of concerns.

Senior staff explained that patients were routinely invited to complete a questionnaire following their treatment to seek feedback on their experiences. We saw an example of the questionnaire used which asked patients a range of relevant questions about their experiences. Comments cards and a post box were clearly visible in the waiting room so that patients could provide ad hoc comments about their visits to the department. Arrangements were described to consider the feedback received with a view to making improvements to the service as appropriate.

Delivery of safe and effective care

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

We found arrangements were in place to provide patients visiting the radiotherapy department with safe and effective care.

Discussions with both managers and staff working in the department provided us with assurance that day to day practice took into account the requirements of IR(ME)R 2017. However, we found that these arrangements were not clearly evidenced within the employer's formal written procedures.

Compliance with Ionising Radiation (Medical Exposure) Regulations

Duties of employer

Patient identification

The employer had a written procedure⁴ to correctly identify patients prior to them having their exposure. This included exposures (X-rays) taken as part of planning treatment and exposures (radiotherapy) for treatment. This aimed to ensure that the correct patient had the correct exposure and is one of the written procedures required under IR(ME)R.

The procedure identified those staff responsible for correctly identifying patients. Staff were expected to ask patients to confirm their name, date of birth and address. It also described alternative ways that staff must use should patients be unable to verbally confirm their identity themselves. The procedure should be updated so that it is clear what staff should do in the event of an interpreter being required.

⁴ CORP-RT-00-29 V.5

Patients were asked their permission for staff to take an up-to-date photograph that could be used as an identification check to further promote patient safety.

Staff we spoke to correctly described the procedure to positively identify patients.

All patients who completed a questionnaire told us that staff asked them to confirm their personal details before starting their procedures.

Individuals of child bearing potential

The employer had a written procedure⁵ for making enquires with regard to pregnancy.

This aimed to ensure that such enquires were made in an appropriate and consistent manner. The procedure clearly identified those staff responsible for making relevant enquires and set out the actions they must follow depending on the individual's responses. However, the procedures were inconsistent with regards to when a blood test and a urine test to confirm pregnancy should be done. This needs to be clarified.

The written procedure included the age range of patients who should be asked about pregnancy in accordance with UK guidance⁶.

Staff we spoke to were able to describe their responsibilities with regards to the above procedure. It was obvious that staff were sensitive to the feelings of patients who for some reason pregnancy was not possible.

⁵ CORP-RT-00-29 V.5 and CORP-CLIN-00-12

⁶ Department of Health and Social Care (2017) Guidance to the Ionising Radiation (Medical Exposure) Regulations 2017

Non-medical imaging exposures

Senior staff confirmed that non medical exposures⁷ were not performed at the clinic.

This was clearly stated in the employer's overarching IR(ME)R compliance policy, updated during the course of our inspection.

Referral criteria

The employer had an overarching policy and associated task specific procedures to support the requirement for written protocols to be in place for every type of standard radiological practice.

Whilst IR(ME)R does not specify how such protocols should be presented, it is usual practice for these to be presented as (anatomical) site specific documents and we recommended that consideration be given to this approach. However, anatomical sites were listed in the documentation.

Whilst anatomical sites were listed, we identified inconsistency in the order these were listed within the documentation. If this approach to written protocols is to be continued, the same order should be used in each document.

Referral guidelines for radiotherapy treatment were in place. However, these may also benefit from being (anatomical) site specific and be usefully included in site specific clinical protocols.

Diagnostic reference levels

The employer's overarching IR(ME)R compliance policy confirmed that diagnostic exposures were not performed. Therefore establishing diagnostic reference levels⁸ is not necessary.

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 The objective of diagnostic reference levels is to help avoid excessive radiation doses to patients. DRLs are used as a guide to help promote improvements in radiation protection practice.

Improvement needed

The employer is required to provide HIW with details of the action taken to:

- Clarify within the written procedures when a blood test and a urine test to confirm pregnancy should be done
- Promote consistency with regards to the listing of anatomical sites within written protocols.

Duties of practitioner, operator and referrer

The employer had a system in place to identify the different types and roles of the professionals involved in requesting and providing radiotherapy treatment to patients.

The employer's overarching IR(ME)R compliance policy identified those staff groups who were entitled to be practitioners⁹, operators¹⁰ and referrers¹¹ (known as duty holders). The employer's procedures set out the responsibilities of each duty holder.

Staff working within the department were expected to comply with the employer's procedures. This was clearly stated within the employer's overarching compliance policy. Staff could access the procedures electronically via a secure IT system. This helped reduce the likelihood of staff accessing 'out of date' procedures. Staff we spoke to confirmed they could access the procedures.

Senior staff described a system for notifying staff of any changes to the employer's procedures. This was via email and staff were expected to confirm

⁹ Under IR(ME)R a practitioner is registered healthcare professional who is entitled, in accordance with the employer's procedures, to take responsibility for an individual medical exposure. The primary role of the practitioner is to justify medical exposures.

¹⁰ Under IR(ME)R an operator is any person who is entitled, in accordance with the employer's procedures, to carry out the practical aspects of a medical exposure.

¹¹ Under IR(ME)R a referrer is a registered healthcare professional who is entitled, in accordance with the employer's procedures, to refer individuals for medical exposures

they had acknowledged the changes via a voting button system attached to the email. Staff we spoke to confirmed this process.

Justification of Individual Medical Exposures

The employer's overarching compliance policy set out the arrangements for the justification and authorisation¹² of exposures. This stated that practitioners were responsible for justifying exposures.

We saw examples of patients' records that demonstrated authorisation (i.e. evidence of justification) of exposures.

Optimisation

The employer had arrangements in place for the optimisation¹³ of exposures.

These were set out within the employer's overarching compliance policy and included quality assurance systems and maintenance programmes for equipment. In addition written procedures were in place that covered optimisation at various points in the patient's care pathway.

These arrangements aimed to ensure that radiation doses delivered to patients and their carers and comforters as a result of exposures are kept as low as reasonably practicable (also referred to as ALARP).

Paediatrics

In accordance with the conditions of HIW registration, the clinic was able to provide a range of oncology services to adults and children. However, at the time of our inspection, senior staff confirmed that no children had been treated at the radiotherapy department.

Therefore, we did not explore the arrangements in place for children.

¹² Justification is the process of weighing up the expected benefits of an exposure against the possible detriment for that individual from the exposure. Authorisation is the evidence that justification has taken place.

¹³ Optimisation refers to the process by which individual doses are kept as low as reasonably practicable.

Under IR(ME)R, practitioners and operators must pay particular attention in relation to exposures of children. The employer may wish, therefore, to take the opportunity to review relevant written procedures, taking into account our findings, to ensure they clearly demonstrate the arrangements for providing radiotherapy to children.

Clinical evaluation

Arrangements were in place for the clinical evaluation of exposures. Clinical evaluation is important to help inform the next stage of a patient's care and treatment.

The employer had written procedures for each part of the patient care pathway including the planning, verification and treatment sessions.

Senior staff confirmed that staff involved in the patient's treatment regularly monitored the effects of treatment and recorded findings within the individual patient care record.

Equipment: general duties of the employer

Senior staff provided an up-to-date inventory (list) of the equipment used within the department to deliver radiotherapy to patients.

Whilst this contained relevant details of the equipment required under IR(ME)R, the list should include other equipment which directly controls or which influences the extent of the exposure as recommended by guidance¹⁴ produced by the Institute of Physics and Engineering in Medicine.

We informed senior staff of our findings who agreed to add this additional equipment.

Improvement needed

The employer is required to provide HIW with details of the action taken to include within the equipment inventory other equipment which directly controls or which influences the extent of the exposure.

¹⁴ Medical and Dental Guidance Notes. Institute of Physics and Engineers in Medicine, 2002.

Safe care

Managing risk and health and safety

The environment was very well maintained and arrangements were in place to promote the safety of staff, patients and visitors to the department.

There was level access to the main entrance of the clinic and the radiotherapy department was located on the ground floor. This allowed patients with mobility difficulties enter and leave the clinic safely.

The department was very clean and free from clutter and obvious trip hazards. Appropriate signage and restricted access arrangements were in place to deter and prevent unauthorised persons entering rooms where radiotherapy equipment was being used. This helped promote the safety of patients and visitors to the department.

We found staff placed an emphasis on safety and were aware of the safety procedures to follow when using the equipment.

Infection prevention and control (IPC) and decontamination

Arrangements were in place for effective infection prevention and control and decontamination.

All areas of the department were clean and tidy. Staff explained that the cleanliness of the clinic and staff compliance with hand hygiene procedures were regularly audited. Where shortfalls were identified, the frequency of audit would be increased until the expected standards were reached and maintained. Effective links with an external infection prevention control advisor were described. This helped promote compliance with current best practice. Staff we spoke to confirmed that they always had access to personal protective equipment (PPE) such as disposable gloves. The use of PPE together with effective handwashing is important to reduce cross infection.

The department employed an external cleaning company. Effective arrangements were described to monitor the service provided and highlight any cleaning issues so that these could be resolved quickly.

No concerns were raised by patients in respect of the cleanliness of the department.

Safeguarding children and safeguarding vulnerable adults

Arrangements were in place to promote and protect the welfare and safety of children and vulnerable adults.

The department had a safeguarding policy and posters were displayed that included the contact details of other statutory organisations that could provide advice on safeguarding matters.

Department staff we spoke to were able to describe their responsibilities and the action they would take should they have concerns about a patient's welfare. Senior staff confirmed that staff were expected to complete safeguarding training at an appropriate level depending on their role. This training formed part of the department's mandatory training programme.

Effective care

Participating in quality improvement activities

Clinical audit

The department conducted a number of audits as part of the overall quality improvement activity and examples of these were provided to HIW.

Expert advice

Medical Physics Experts¹⁵ were appointed to provide advice on exposures in accordance with IR(ME)R.

Senior staff confirmed that Medical Physics Experts were appointed. The department's overarching compliance policy set out the role of the MPE and this broadly reflected the requirements under IR(ME)R. These arrangements were also confirmed by the MPE whom we spoke to during our inspection.

Department staff also told us that they were able to contact an MPE for advice.

¹⁵ A medical physics expert is a person who holds a science degree or its equivalent and who is experienced in the application of physics to diagnostic and therapeutic uses of ionising radiation.

Medical research

Senior staff confirmed that medical research studies involving exposures were not conducted in the department. Therefore there was no need to have a written procedure in this regard.

This was clearly stated in the employer's overarching IR(ME)R compliance policy, updated during the course of our inspection.

Information management and communications technology

Comprehensive information management systems were described and demonstrated by department staff.

An electronic patient information system allowed for relevant patient details and information about procedures performed in the department to be recorded and easily accessed by department staff.

Senior staff also demonstrated comprehensive management information systems in respect of the operation of the department and the wider clinic.

Records management

We reviewed a sample of electronic patient records. We saw that these had been completed with appropriate details by those staff involved in the exposure.

Quality of management and leadership

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

A management structure was in place and clear lines of reporting were described and demonstrated. Effective governance arrangements were also found to be in place.

The employer's written procedures needed to be reviewed so it is clear that those required under IR(ME)R 2017 are in place.

Staff demonstrated that they had the correct knowledge and skills to undertake their respective roles within the department.

We saw evidence of relevant staff training for radiographers, clinical scientists and medical physics experts working in the department. However, training records for radiation oncologists were incomplete.

Governance and accountability framework

A management structure with clear lines of reporting was described and demonstrated. We found that governance arrangements were in place to support the effective operation of the radiotherapy department and other departments located within the clinic.

During the course of the inspection we found visible and supportive leadership being provided by the lead radiographer. Staff we spoke to confirmed that they felt supported by their line manager.

Senior management staff made themselves available on the days of the inspection, provided support to staff and facilitated the inspection process. They were receptive to our feedback and demonstrated a willingness to make improvements as a result of the inspection.

Ahead of the inspection, HIW required senior staff within the department to complete and submit a self-assessment questionnaire. This was to provide HIW

with detailed information about the department and the employer's key policies and procedures in respect of IR(ME)R. This document was used to inform the inspection approach.

The self-assessment form was returned to HIW within the agreed timescale and was comprehensive. However, some of the key policies were not provided and the presentation of some of the information meant it was not clear how IR(ME)R was being complied with. We informed senior staff of our observations so that they could consider how they could improve the completion of the self-assessment form for future inspection activity.

Duties of the employer

Entitlement

Arrangements were in place for the entitlement of duty holders.

Radiation oncologists working within the department and who were not directly employed by the department had been granted practising privileges. A policy was in place that set out the process for this and the entitlement process for this group of staff as referrers and practitioners. However this required further clarification to set out the entitlement process for oncologists acting as operators.

Senior staff updated the overarching IR(ME)R compliance policy to clarify the above process during our inspection. However, it needed to be clearer in the policy whether staff deemed competent to perform a procedure were also entitled as a duty holder to perform the function of operator or practitioner for that procedure.

We spoke to staff within the department and whilst radiography and medical physics staff were able confirm their entitlement under IR(ME)R to perform duty holder functions, oncologist staff were less clear in this regard.

Procedures and protocols

We identified that improvements were needed across a number of the employer's written procedures in respect of IR(ME)R.

Whilst written procedures had been developed for use within the department, it was not immediately clear whether they met the requirements under IR(ME)R. This was because a number of procedures had to be cross referenced with others and the naming convention used made it difficult to easily identify those procedures required under IR(ME)R. In addition some written procedures made reference to the previous and out of date (2000) regulations. These needed to be updated to reflect the current (2017) regulations.

Conversations with senior staff provided us with assurance that the practice within the department was compliant with IR(ME)R and that radiotherapy treatment was being safely provided.

Senior staff were receptive to our feedback around the employer's written procedures. Before the end of the inspection, arrangements had been made to start reviewing the employer's overarching IR(ME)R compliance policy so that it demonstrated more clearly the arrangements for complying with IR(ME)R including better signposting and identification of those written procedures required under IR(ME)R.

In addition some written procedures needed to have further details added for clarity (see previous section - Delivery of safe and effective care)

Improvement needed

The employer is required to provide HIW with details of the action taken to:

- Clarify the arrangements for training and entitling oncologists to act as operators
- Make clear whether staff deemed competent to perform a procedure are also entitled as a duty holder to perform the function of operator or practitioner for that procedure.
- Make radiation oncologists aware of their entitlement under IR(ME)R to perform duty holder functions
- Review the employer's written procedures so that it is clear those required under IR(ME)R are in place. Consideration must be given to updating references so that they relate to current regulations and guidance.

Dealing with concerns and managing incidents

Incident notifications

A system was in place for reporting and investigating accidental or unintended exposures within the department.

A policy for reporting and investigating incidents had been developed. This considered all types of incidents, not just those reportable under IR(ME)R. The overarching IR(ME)R compliance policy provided more detail that was specific to the types of accidental or unintended exposures that must be reported to HIW.

The policy clearly set out the procedure staff should follow should they suspect that an accidental or unintended exposure has occurred. However, the policy should be reviewed so that the types of radiotherapy incidents that need to be reported are consistent with those listed in the overarching compliance policy. Specifically, in relation to patients receiving radiotherapy doses that are significantly lower than expected and those related to equipment malfunction.

Improvement needed

The employer is required to provide HIW with details of the action taken to update the policy for reporting and investigating incidents so that it includes reference to the types of radiotherapy incidents that must be reported under IR(ME)R.

Workforce planning, training and organisational development

During the course of our inspection, staff demonstrated they had the appropriate skills and confirmed they were supported to perform their respective roles within the department.

As described earlier, the employer had arrangements in place for the entitlement of practitioners, operators and referrers.

Senior staff described an induction process for new staff and provided evidence of this.

We looked at a sample of training records for staff working within the department. These were kept electronically and we saw training and competency records for radiographers and medical physics staff. These included individuals' scope of practice.

Training records for oncologists were incomplete and did not demonstrate that radiation oncologists had completed training in respect of the operator functions they perform. This needed to be addressed.

Opportunities to improve the training records were discussed with senior staff. These included asking staff to record that they had completed the training, had read, understood and would comply with the relevant local procedures and policies. An indication of when refresher training was received could also be added. This is particularly important in situations where it is difficult to maintain competence (e.g. the number of patients being treated is low). This approach would evidence when refresher training has been completed.

Radiography staff confirmed they had good access to training and were supported by senior staff to meet their continuing professional development needs in their chosen field of work.

We saw that staff were required to complete a range of mandatory training as part of the organisation's mandatory training programme.

Improvement needed

The employer is required to provide HIW with details of the action taken to ensure that records demonstrating that radiation oncologists have completed training in respect of the operator functions they perform are available for inspection by HIW on request.

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 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 improvement notice and/or a [non-compliance notice](#). The issuing of an improvement and/or non-compliance notice is a serious matter and is the first step in a process which may lead to civil or criminal proceedings.

The improvement plans should:

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

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

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

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

5. How we inspect services that use ionising radiation

HIW are responsible for monitoring compliance against the [Ionising Radiation \(Medical Exposure\) Regulations \(IR\(ME\)R\) 2017](#) and its subsequent amendment ([2018](#))

The regulations are designed to ensure that:

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

We look at how services:

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

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

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

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

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

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

Appendix A – Summary of concerns resolved during the inspection

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

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

Appendix B – Improvement plan

Service: The Rutherford Cancer Centre South Wales

Ward/department: Radiotherapy Department

Date of inspection: 29 and 30 January 2019

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 taken to raise awareness of the effects of ionising radiation amongst who are/maybe pregnant or currently breastfeeding.	Regulation 6(8)	The information currently provided to those who maybe/are pregnant and or breastfeeding has been reviewed and updated (Pregnancy procedure and declaration form - a copy is given to the patient) and posters are being created to be displayed in areas such as back of changing rooms. Information is also being displayed on digital screens in the waiting areas	Lead Therapy Radiographer	14 th June 2019
The employer is required to provide HIW with details of the action taken to demonstrate that	Regulation 6 (Schedule 2(1)(i))	The current process is:	Lead Therapy Radiographer	14 th June 2019

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
<p>patients or their representatives have been informed of the benefits and risks associated with the radiation dose from the exposure.</p>		<ul style="list-style-type: none"> • Patients are given a copy of the site-specific consent form which explains benefits and risks of the radiotherapy treatment. • They are consented using site-specific consent forms with a full explanation of benefits and risks of treatment. • Patients are also given patient information leaflets (e.g. Macmillan) which explain the benefits and risks of treatment. <p>Up to now the risks associated with the CT planning scan had not been described separately. This will now be described separately on the consent form, and during the consent process, and the policy and procedure documents will be updated to reflect this.</p>		
Delivery of safe and effective care				
<p>The employer is required to provide HIW with details of the action taken to:</p>	<p>Regulation 6 (Schedule 2(1)(c))</p>	<p>The procedure is being updated.</p>	<p>Lead Therapy Radiographer</p>	<p>14th June 2019</p>

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
<ul style="list-style-type: none"> Clarify within the written procedures when a blood test and a urine test to confirm pregnancy should be done 				
<ul style="list-style-type: none"> Promote consistency with regards to the listing of anatomical sites within written protocols. 	Regulation 6(4)	The employer's clinical protocols are arranged in task-specific procedure documents in which there is anatomical-site-specific clinical detail for that task. The employer shall update the task-specific procedure documents to make the anatomical-site-specific detail more uniform (i.e. refer to the same anatomical-sites in the same order in each task-specific document).	Lead Therapy Radiographer	14 th June 2019
The employer is required to provide HIW with details of the action taken to include within the equipment inventory other equipment which directly controls or which influences the extent of the exposure.	Regulation 15	The radiotherapy equipment inventory register is being updated with the additional equipment.	Chief Physicist	14 th June 2019

Quality of management and leadership

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
<p>The employer is required to provide HIW with details of the action taken to:</p> <ul style="list-style-type: none"> Clarify the arrangements for training and entitling oncologists to act as operators 	<p>Regulation 17)</p>	<p>Oncologists are entitled as operators on the treatment planning system (TPS) only. Currently they receive the following training:</p> <ol style="list-style-type: none"> 1) An induction on the TPS when they visit the centre prior to making their first referral, during which they complete RT/proton specialties forms, and; 2) they are assisted/supervised when they carry out contouring or plan review on their patients until they are deemed competent to carry out those tasks on the TPS independently. <p>The inspector noted that this training is not formally recorded.</p> <p>The TPS induction will be added to the RT/proton specialties forms and the forms will prompt to add the Consultant to a Consultant TPS training register. The induction and subsequent supervised</p>	<p>Chief Physicist</p>	<p>14th June 2019</p>

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		training and competence sign-off will be recorded in that register.		
<ul style="list-style-type: none"> Make clear whether staff deemed competent to perform a procedure are also entitled as a duty holder to perform the function of operator or practitioner for that procedure. 	Regulation 6 (Schedule 2(1)(b))	<p>The Radiotherapy Policy describes that Oncologists granted Practising Privileges (PPs) are entitled to act as referrers, practitioners and operators and that:</p> <p>“A Competency Register (CORP-RT-00-10) is in place which details and records the Rutherford Cancer Centre staff who act as operators during the patient pathway.”</p> <p>A statement will be added to clarify that RCC staff cannot act as practitioners or referrers.</p> <p>The Radiotherapy Staff Competency Register records all staff who have been signed-off as competent to carry out the specified tasks and states that the staff listed are authorised and ‘entitled’ to act as ‘operators’ (IRMER) for the specified tasks for which they have been signed-off as competent. The register specifies who is permitted to sign staff off as</p>	Chief Physicist	14 th June 2019

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale	
		competent (e.g. Lead Radiographer), the statement that they are entitling the staff member to act as a duty holder will be added.			
<ul style="list-style-type: none"> Make radiation oncologists aware of their entitlement under IR(ME)R to perform duty holder functions 	Regulation 6 Schedule 2(1)(b))	<p>An email will be sent to all current Consultants to confirm/remind them of their entitlement.</p> <p>Consultants who have been granted Practising Privileges (PPs) are entitled to act as referrers, practitioners and operators for their specialties and this is recorded in the Consultants Register. Previously this stated that they are 'designated' as 'referrers', 'practitioners' and 'operators' for their listed specialties but the word 'designated' will be changed to 'authorised and entitled'.</p> <p>Prior to being granted PPs the Consultants have a clinical induction with clinical staff on-site and an RT/proton Specialties form is completed at this induction. This form will be changed to specifically state that (once PPs have</p>	<p>Lead Therapy Radiographer</p> <p>Head of Professional Standards</p>	<p>14th June 2019</p> <p>14th June 2019</p>	

Improvement needed	Standard / Regulation	Service action	Responsible officer	Timescale
		been granted) they are 'entitled' to act as 'practitioners', 'referrers' and 'operators' for their clinical specialties and that they will be shown the register during their induction.		
<ul style="list-style-type: none"> Review the employer's written procedures so that it is clear those required under IR(ME)R are in place. Consideration must be given to updating references so that they relate to current regulations and guidance. 	Regulation 6 (Schedule 2)	The IRMER policy will be updated to state every regulation and detail from the current IR(ME)R regulations, and to state where in the employers policies and procedures the detail and requirements for each regulation can be found.	Chief Physicist	14 th June 2019
The employer is required to provide HIW with details of the action taken to update the policy for reporting and investigating incidents so that it includes reference to the types of radiotherapy incidents that must be reported under IR(ME)R.	Regulation 8	To ensure IRMER policy and Incident Policy are consistent	Chief Physicist	14 th June 2019
The employer is required to provide HIW with details of the action taken to ensure that records demonstrating that radiation oncologists have completed training in respect of the operator functions they perform are available for inspection by HIW on request.	Regulation 17(4)	The training records for radiation oncologists to act as 'operators' of the treatment planning system are being revised as described in the previous section of this form.	Chief Physicist	14 th June 2019

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): Kate Leaver

Job role: Lead Therapy Radiographer

Date: 10th May 2019