Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

DRIVING IMPROVEMENT THROUGH INDEPENDENT AND OBJECTIVE REVIEW

Ionising Radiation (Medical Exposure) Regulations Inspection (announced)

Radiotherapy Department
Velindre Cancer Centre
Cardiff

10 and 11 March 2016

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1. Introduction

Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of all health care in Wales.

HIW's primary focus is on:

- Making a contribution to improving the safety and quality of healthcare services in Wales
- Improving citizens' experience of healthcare in Wales whether as a patient, service user, carer, relative or employee
- Strengthening the voice of patients and the public in the way health services are reviewed
- Ensuring that timely, useful, accessible and relevant information about the safety and quality of healthcare in Wales is made available to all

HIW is responsible for monitoring compliance against the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000 (and its subsequent amendments 2006 and 2011). We achieve this through a programme of assessment and inspection of services in the NHS and independent sectors that use ionising radiation as part of a medical exposure.

The current regulations place responsibilities on practitioners, operators, those who refer patients for medical exposure and the employers of these three groups. The employer is required under the regulations to create a framework for the safe, efficient and effective delivery of ionising radiation by the provision of standard operating procedures and protocols. A breach of the regulations can result in the issue of prohibition, improvement notices or criminal proceedings.

For the purpose of this report, we refer to the responsibilities of groups/persons defined under IR(ME)R, known as duty holders. IR(ME)R duty holders include the following:

- Employer - any natural or legal person who, in the course of a trade, business or other undertaking, carries out, or engages others to carry out, medical exposures at a given radiological installation
- Referrer - a registered health care professional who is entitled in accordance with employer's procedures to refer individuals for medical exposure to a practitioner

- Practitioner – a registered health care professional who is entitled in accordance with employer's procedures to take responsibility for an individual medial exposure

- Operator - any person who is entitled by the employer, to carry out practical aspects of medical exposures. An operator does not have to be a registered healthcare professional, but is required to be adequately trained for their scope of practice.

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 (justification)

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

- Adequate training of practitioners and operators.

We publish our findings within our inspection reports under four themes:

- Quality of the patient experience

- Compliance with IR(ME)R

- Management and leadership

- Delivery of a safe and effective service

2. Methodology

The inspection was announced in advance and was conducted by a small team which included an inspection manager from HIW, who was supported by a Senior Clinical Officer from Public Health England (PHE)[1] acting in an advisory capacity. During each of the inspections we considered and reviewed:

- Information held by HIW
- Interviews with staff (where appropriate) and senior management
- Conversations with patients, relatives (where appropriate)
- Examination of a sample of patient records
- Examination of policies and procedures
- Examination of treatment rooms and the environment
- HIW patient questionnaires

At the end of each inspection, we provide an overview of our main findings to representatives of the service to ensure that they receive appropriate feedback.

Inspections capture a snapshot on the day of the inspection of the extent to which services are meeting essential safety and quality standards and regulations

[1] Given the specialist nature of this area of work, HIW works with the Medical Exposures Group of Public Health England. PHE provides HIW with support on matters relating to radiation protection and radiological practice in the context of IR(ME)R. There is a service level agreement between HIW and PHE which sets out the terms of this working relationship.

3. Context

A compliance inspection against IR(ME)R for radiotherapy was undertaken on 10 and 11 March 2016 at the radiotherapy department at Velindre Cancer Centre, Velindre NHS Trust, Cardiff.

Velindre Cancer Centre is a nationally recognised specialist centre of excellence for the provision of non-surgical oncology including radiotherapy and chemotherapy; specialist palliative care; blood transfusion, specialist immunohematology; antenatal blood testing reference work and transplant immunology.

Velindre Cancer Centre provides specialist cancer services to over 1.5 million people in South East Wales and beyond. It is one of the largest cancer centres in the UK which receives over 5,000 new referrals each year and around 50,000 new outpatient appointments. It also employs over 670 staff.

Patients referred to Velindre Cancer Centre come under the care of clinical and medical oncologists. Oncologists specialise in the non-surgical treatment of cancer. Velindre Cancer Centre is the main centre for these services; however they also provide outpatient clinics and other out-based chemotherapy services at other sites.

Patient numbers have risen in recent years as advances in cancer treatment and diagnosis continue to be made. This increase is reflected by the increased need for highly skilled and experienced staff. The centre plays a significant role in educating and training health care professionals to meet these future demands. The cancer centre is host for the clinical oncology section of the University of Wales, College of Medicine.

As well as specialist oncology and palliative training, Velindre also provides training for cancer nurses, pharmacists, medical physicists and provides clinical placements for therapeutic radiography students from the University of Wales, College of Medicine.

The cancer centre has a comprehensive radiotherapy department, with external beam, superficial and brachytherapy treatments planned and delivered on site. Computed Tomography (CT), Positron Emission Tomography CT (PET/CT) and Magnetic Resonance Imaging (MRI) are available as part of the radiotherapy treatment planning process. On treatment imaging is available as 2D planar and conebeam CT (CBCT) imaging

The centre employs 24 consultant clinical oncologists and seven specialist registrars. In addition approximately 84 radiographers are employed along with

nine medical physics experts and eight registered clinical scientists and 4.5 trainee scientists. The service is also supported by 13.5 dosimetrists, nine medical technical officers, an assistant practitioner and an associate specialist. Radiotherapy also provides clinical placements for radiotherapy undergraduates from Cardiff University. It also provides placements for both the scientist and practitioner training programmes for medical physics.

4. Summary

This is the first IR(ME)R inspection of the radiotherapy department since the HIW report published in February 2009. The inspection was extremely well received by both management and staff and all required documentation was completed and received within timescales specified.

The team within the department approached the inspection in a very positive way and they were keen to receive constructive feedback to support their approach to maintaining high standards of care and continuous improvement. Particularly notable during this visit was that it was also attended by representatives from the other two Welsh radiotherapy departments, so that they too might learn from this experience. We also received a positive welcome from patients who provided feedback on their experiences.

There were two breaches of regulation identified during the inspection. The first relates to the lack of an equipment inventory and the second to the need to have referral criteria in place which was not evident at the time of the inspection. This was discussed with the team at the time of the inspection and they expressed a commitment to completing these tasks as a matter of urgency. The inspection team were content and reassured that there were no concerns about practice in relation to IR(ME)R.

Whilst we were satisfied there were no safety issues, some key issues for action were identified during our inspection. These were raised and discussed at the time of the inspection and focussed mainly on documentation.

HIW recognises that trusts are large, complex organisations and acknowledges the challenges this can pose in terms of the sustainable delivery of safe, effective, person centred care. Effective governance, leadership and accountability are, however, essential in this respect. The use by the trust of our inspections to improve the quality and safety of services by ensuring that our recommendations are actioned and not replicated elsewhere can play a significant part in helping ensure compliance and drive up standards. Of concern, therefore, was the lack of progress by the trust in addressing some of the recommendations that had been made following our visit in 2009.

The expectation, therefore, is that the trust will take appropriate action to address these historic matters and the improvements identified during this inspection.

5. Findings

Quality of the Patient Experience

Patients felt the quality of their experience at the radiotherapy department, within the hospital, was very good. Positive feedback was received about the staff, the department and the information they received but some people did comment they had experienced some delays.

In order to gather the views of patients and their families about the service they received, we issued a brief questionnaire to a number of individuals.

Twenty questionnaires were completed and returned. The responses we received were mainly extremely positive. For example:

- Arranging an appointment was straight forward
- The department was easy to find and clearly signposted
- The information received was good and appropriate
- The staff were exceptionally good
- All treatments were very well explained.

Some examples of comments made by patients included the following:

> *"Appointments were arranged around times that suited me and even when I asked to change a couple they were able to do this willingly."*

> *"A card was provided on the first day informing me of the times for the 15 days in advance. This made it much easier to plan lifts etc."*

One negative comment made was that parking can sometimes be difficult.

Everyone who completed a questionnaire made positive comments about the information they had received and in particular about the staff within the department. Some comments made about the staff were:

> *"Wonderful! All staff are welcoming, reassuring and extremely patient. Nothing appears to be too much trouble! Thank you!"*

> *"Fantastic, couldn't ask for better."*

> *“Excellent! Cheerful, helpful, positive, caring, considerate and understanding.”*

A number of patients did however comment that they had experienced delays of between 20 to 45 minutes. One person commented:

> *“Only when there are difficulties with machines and then the other departments work together to accommodate and support.”*

The majority of patients commented that the standards of cleanliness were very good or excellent. There were however two comments that identified issues that require action. These were:

> *“Someone had spat blood into the water dispenser tray – not your fault obviously but just to be aware.”*

> *“Excellent, everything looks very clean. The only comment I would make is that in the changing rooms the gowns look like they are sometimes mixed between clean and used. I think there should be a basket to put used gowns in.”*

Improvement needed

To undertake a review of delays in treatment to identify the main causes and take appropriate action where possible.

To review arrangements for monitoring the control of infection in the department.

To provide appropriate storage to ensure the separation of clean and dirty linen.

Compliance with IR(ME)R

Duties of employer

The employer is defined in IR(ME)R as any natural or legal person, who, in the course of a trade, business or other undertaking, carries out (other than as an employee), or engages others to carry out, medical exposures or practical aspects, at a given radiological installation.

The Chief Executive of the organisation is the "employer" in the context of IR(ME)R. He clearly articulated his role as the employer and how his responsibilities under IR(ME)R were discharged or delegated to clearly identified senior members of the organisation as appropriate.

There are two documents in place to reflect how IR(ME)R is implemented within the radiotherapy department. One is the Ionising Radiation Safety Policy, referred to as "Black 61". This document covers all legislation in relation to radiation safety. It is a trust wide overarching policy and clearly defines the duties and responsibilities of the employer as required under IR(ME)R. The policy clearly defines the Chief Executive as having the responsibility as the employer for ionising radiation for the trust. The policy clearly describes both organisational and individual responsibilities.

The second document is the Implementation of the IR(ME)R 2000 (amended 2006 and 2011). This is described as following on from the overarching policy document and outlines implementation of IR(ME)R with in the radiotherapy department. Despite both documents being relevant in the context of IR(ME)R, there are no clear references within either of the documents to the other one.

Improvement needed

To review the content of the two IR(ME)R policy documents in place to ensure they each reference the other.

Procedures and protocols

The regulations require the employer to have written procedures and protocols in place.

The document entitled 'Implementation of the Ionising Radiation (Medical Exposure) Regulations 2000 (amended 2006 and 2011)' either described how the regulations were implemented locally or contained reference to most of the procedures as required under IR(ME)R. It would be helpful if this document included direct references to where each of the Schedule 1 Employers

Procedures might be found, if not already described within this document and explicit statements where they do not apply.

The content of the policy document could also be improved to better reflect current practice. During the course of the inspection it was found that practice often exceeded what had been documented in the IR(ME)R procedures.

Work needs to be undertaken to review the content of some of the Schedule 1 procedures, details of which are included in the relevant sections of this report.

In reviewing some of the clinical protocols at the time of the inspection, a reference to the use of unplanned treatments for brick pelvic radiotherapy was seen. This was noted as unusual practice and HIW recommend that this method of planning pelvic treatments is reviewed in the interest of reducing the probability and magnitude of radiation incidents.

Uniquely, the department operates two oncology management systems concurrently. Explicit statements to reflect the department has completed a positive risk assessment of this practice to minimise the probability of occurrence and magnitude of unintended exposures would be helpful.

There are two quality management systems in place, one for radiography and clinical oncology staff groups and a separate one for the medical physics staff group. Both systems have up-to-date external accreditation in place. There is a robust process in place around document control. All new or amended policies and procedures have a front sheet which identifies the date it was reviewed, details of changes and who it was authorised by. Each month a reading list is issued to identify documents that have been reviewed and amended to support staff in familiarising themselves with the changes made.

Improvement needed

Review the content of the document 'Implementation of the Ionising Radiation (Medical Exposure) Regulations 2000 (amended 2006 and 2011)' to ensure the content reflects current practice and to include a reference to each of the procedures required under Schedule 1 of IR(ME)R.

Review the use of unplanned treatments for brick pelvic radiotherapy

Incident notifications

IR(ME)R states that where an incident has occurred in which a person, whilst undergoing a medical exposure, has been exposed to ionising radiation much greater than intended, this should be investigated by the healthcare organisation and reported to the appropriate authority (HIW).

Notifications for accidental, unintended or much greater than intended exposures are described in ‘Black 62’ and the incident reporting procedure. However there is no reference in either document of who to report the incident to.

All staff are encouraged to report any non-compliance with the procedure or any incident which occurs within the department. These would then be investigated by a member of the quality team, who liaises with all disciplines, to undertake a root cause analysis as appropriate. As a result, we were informed that any improvements required or learning achieved to prevent further incidents are put in place.

We saw noteworthy practice of quarterly reports of incidents and near miss events which is shared across radiotherapy departments in Wales. This information included an analysis of the incidents as well as an identification of any resultant learning.

In addition to these quarterly reports, a monthly report and analysis is shared internally with staff. Finally the department also contributes to the UK data set via the National Learning and Reporting System in the interests of minimising these events across the UK.

Improvement needed

To review the incident reporting procedure to include details about where incidents need to be reported

Entitlement

The regulations require that duty holders must be entitled, in accordance with the employer’s procedures for the tasks they undertake. They must also be adequately trained and the employer must keep up to date records of this training.

An entitlement matrix for all duty holders was reviewed as part of the inspection. Whilst this was inclusive of all duty holders, there was an inconsistent approach to describing the scope of practice for each duty holder and this was absent in some cases. For example, it was not clear for which operator functions radiation oncologists had been entitled to act. The process for entitlement of locum radiation oncologists needs to be strengthened.

Training records and documented induction training were in place and up to date for staff working in the department, however it was disappointing that we did not see any records for oncologists at the time of the inspection.

We observed four different recording systems for training during our inspection. The system in place for radiographers was the clearest and most comprehensive and provided clear accountability and traceability, with the system being an exemplar of good practice. There is a need however to include a comment rather than inserting a tick to those areas where training was completed prior to the system being in operation to ensure clarity.

It was suggested that references to this could be included in the documentation as part of entitlement to underpin the scope of practice. There was a clear link between training, competency and entitlement across the radiography staff. This needs to be strengthened for the clinical oncologist and medical physics groups.

Improvement needed

The scope of practice for entitlement of each duty holder needs to be clearly defined.

To review and amend the systems in place as necessary for recording training, to demonstrate an integrated approach within the department that provides the same level of detail.

Referral criteria

IR(ME)R states that the employer shall establish recommendations concerning referral criteria for medical exposures, including radiation doses and shall ensure that these are available to the referrer

Decisions to refer each individual patient for radiotherapy are made as part of a multidisciplinary team meeting. This practice is to be commended. However, written referral criteria were not seen at the time of the inspection. This was disappointing to note especially as it was highlighted at the previous inspection and was identified then as an area for development.

As part of this, there is a requirement that an estimate of the associated doses is made available to the referrers. This includes the doses associated with radiotherapy planning imaging. Estimates of doses associated with treatment were included in clinical protocols and verification dose estimates were included in an imaging protocol. This could be better reflected in the IR(ME)R documentation.

Improvement needed

Develop written referral criteria for radiotherapy

Establish dose estimates for radiotherapy planning imaging

Justification of individual medical exposures

The regulations require that all medical exposures should be justified and authorised prior to the exposure. The practitioner is responsible for the justification of the medical exposure. Authorisation is the means by which it can be demonstrated that justification has been carried out and may be undertaken by the practitioner or, where justification guidelines are used, an operator.

The process of authorisation for all medical exposures undertaken in the department was clearly outlined in terms of planning, treatment and verification exposures. However there was some confusion surrounding the difference between acting as a practitioner and an operator acting under guidelines. An example of this was physics staff entitled for 'delegated plan approval'. The documentation seemed to suggest that this was a practitioner rather than an operator working under guidelines. In addition some specialist registrars were working under supervision and as such would not be entitled as practitioners for those functions they completed under supervision. All of the above could be better described in the supporting documentation.

Improvement needed

A written procedure describing authorisation responsibilities for all types of exposures is required.

Identification

The regulations state that written procedures for medical exposures should include procedures to correctly identify the individual to be exposed to ionising radiation.

A comprehensive patient identification procedure was in place however the following issues were highlighted:

- Direct references to documents mentioned in this procedure should be included.
- In the case of pre-treatment exposures the document should explicitly state which primary source documents should be used for confirmation of patient identification.
- The procedure should be explicitly state how a paediatric patient can identify themselves.

Practice observed during the inspection highlighted that operators also confirmed the patient ID against the relevant patient datasets being used. This is important in reducing the probability and magnitude of radiation incidents associated with the selection of the incorrect dataset. This is another example of practice exceeding the associated documentation for the process.

Improvement needed

Review and develop the patient identification procedure to include the points identified

Females of child bearing age

IR(ME)R states that written procedures for medical exposures should include procedures for making enquiries of females of child bearing age to establish whether the individual is or maybe pregnant.

There is a procedure in place for checking the pregnancy status of females of child bearing age, which includes an appropriate age range.

There is no reference in the procedure however to pregnancy testing and how this happens and neither is there reference to language barriers and any support needed as part of this process.

Whilst not an IR(ME)R issue it would be good practice to include reference to the child protection procedure for situations where a child provides a positive response to the pregnancy question.

All staff we spoke to at the time of the inspection were clear about how they check the pregnancy status of females and they all referenced how they issue an information sheet to all patients - a copy of this was provided to us. This was extremely positive, however there is no reference made to it in the procedure.

Improvement needed

Work needs to be undertaken to consolidate this procedure to ensure all information is contained within it regarding checking the pregnancy status for females of child bearing age.

In the revised procedure it would be good practice to include reference to the child protection procedure for situations where a minor provides a positive response to the pregnancy question.

Medico-legal exposures

The regulations state that written procedures for medical exposures shall include procedures to be observed in the case of medico-legal exposures.

It is understood that these types of exposures are not undertaken in the radiotherapy department. This should be explicitly stated as part of the Schedule 1 Employers Procedures.

Improvement needed

To explicitly state as part of the Schedule 1 Employers Procedures that these types of exposures are not undertaken.

Optimisation

The regulations require that exposures for radiotherapeutic purposes are individually planned, taking into account that doses of non-target volumes are kept as low as reasonably practicable (ALARP) consistent with the intended purpose.

Current practice in terms of optimisation could be better reflected in the IR(ME)R documentation. For example, explicit statements are needed in terms of all treatments being individually planned; all treatment prescriptions are defined as part of an evidenced clinical protocol and are discussed as part of a multi-disciplinary meeting at time of referral; all equipment that delivers or influences the delivery of the exposure is part of a rigorous quality assurance programme; optimisation of the planning and verification imaging settings for adults and paediatrics has been completed. Much work had been undertaken to optimise the imaging setting on the CBCT devices to ensure the image quality and associated dose were consistent with the clinical requirement of the images captured.

Improvement needed

Current practice in terms of optimisation could be better reflected in the document entitled 'Implementation of the Ionising Radiation (Medical Exposure) Regulations 2000 (amended 2006 and 2011)'

Clinical evaluation

The regulations state that the employer shall ensure a clinical evaluation of the outcome of each medical exposure is recorded in accordance with written procedures.

The documentation could better reflect departmental practice of clinical evaluation of exposures. This was clearly illustrated by the staff members we spoke to during the inspection however was not described in any of the

documents shared in advance of the inspection. The clinical evaluation of planning, treatment and verification exposures could be better described.

Improvement needed

The local process of clinical evaluation could be documented to reflect current practice within the document entitled 'Implementation of the Ionising Radiation (Medical Exposure) Regulations 2000 (amended 2006 and 2011)'.

Medical research programmes

Schedule 1(h) of IR(ME)R requires there to be a procedure in place for medical exposures undertaken as part of research programmes.

A written procedure is contained within the 'Implementation of the Ionising Radiation) Medical Exposure) Regulations 2000 (amended 2006 and 2011)' document regarding medical exposures undertaken as part of research. It states that all trials follow protocols which are quality assured and approved by a multi-disciplinary team.

All patients involved in research trials participate on a voluntary basis and consent to do so. This process is the responsibility of the referring clinician.

Paediatrics

IR(ME)R states that the practitioner and operator shall pay special attention to the optimisation of medical exposures of children.

It was reported that all paediatric patients are treated under specialist paediatric protocols. In addition, evidence of optimisation of chest CBCT exposure settings was seen during the inspection. However, explicit statements are needed in terms of the optimisation of all planning and verification imaging settings for paediatrics within the documentation.

Improvement needed

Procedures in place affecting the special attention to the optimisation of paediatrics could be better described in the document entitled 'Implementation of the Ionising Radiation (Medical Exposure) Regulations 2000 (amended 2006 and 2011)'.

Clinical audits

IR(ME)R states that employers' procedures shall include provision for carrying out clinical audits as appropriate.

There is a clinical audit department at the cancer centre that manages and supports the clinical audit function. There is a clinical audit steering group in place that meets monthly which is a multi-disciplinary group assisting in audit design and data analysis and presentation.

There is an extensive audit programme in place and there was evidence of a number of audits having been undertaken at the hospital, which was positive.

Expert advice

IR(ME)R states that the employer shall ensure a Medical Physics Expert (MPE) is involved as appropriate in every radiological medical exposure.

Medical Physics Experts (MPEs) from within the radiation protection service at the radiotherapy department are available for advice for all planning, treatment and verification exposures conducted in the radiotherapy department and the equipment within the radiotherapy department.

The MPEs also ensure the accuracy of calibration of the treatment equipment, the provision of beam data for all dose calculations, the scientific aspects of the treatment process and are closely involved with the introduction of any new equipment and techniques.

Equipment

IR(ME)R requires that the employer has an up to date inventory of equipment that contains the name of manufacturer, model number, serial number, year of manufacture and the year of installation.

The document 'Implementation of the Ionising Radiation (Medical Exposure) Regulations 2000 (amended 2006 and 2011)' refers to the fact that the inventory of equipment is maintained as part of the trust asset list. On examination of the list however not all of the fields had been completed and not all of the information required under IR(ME)R was contained within it.

Improvement needed

To ensure that appropriate complete inventory of equipment is developed in line with the requirements of the regulations.

Management and Leadership

It was clear from the inspection that the management team, heads of department and staff are committed to providing a high standard of service that is safe and in line with the requirements of IR(ME)R.

The team recognised and accepted the work that needs to be undertaken to achieve this based on the feedback provided at the time of the inspection.

All managers and staff that met with the inspection team engaged positively in the process as a whole and in particular in the inspection itself. The management team demonstrated they were keen to receive feedback with a view to improving the service they provide.

It was pleasing to note that the team had chosen to engage with colleagues from other radiotherapy units in Wales and invite them to attend the inspection in order to share learning from it. The feedback from this experience was extremely positive.

Our discussions with staff ,during a tour of the clinical department, at inspection confirmed that they were all clear about their roles and responsibilities as duty holders under IR(ME)R. The importance of developing the documentation to ensure that what happens in practice is clearly written into the documents is fundamentally important and was reinforced at the time of the inspection.

The organisation was reviewed as being in breach of two of the regulations. Both of these issues have been highlighted in the report and relate to the development of an equipment inventory as well as the establishment of referral criteria with associated dose estimates. Both these issues will require urgent action.

HIW recognises that trusts are large, complex organisations and acknowledges the challenges this can pose in terms of the sustainable delivery of safe, effective, person centred care. Effective governance, leadership and accountability are, however, essential in this respect. The use by the trust of our inspections to improve the quality and safety of services by ensuring that our recommendations are actioned and not replicated elsewhere can play a significant part in helping ensure compliance and drive up standards. Of concern, therefore, was the lack of progress by the trust in addressing some of the recommendations that had been made following our visit in 2009.

The expectation, therefore, is that the trust will take appropriate action to address these historic matters and the improvements identified during this inspection.

Delivery of a Safe and Effective Service

People's health, safety and welfare must be actively promoted and protected. Risks must be identified, monitored and where possible, reduced or prevented.

The inspection team were content that whilst there were two breaches of regulation as mentioned earlier in the report, it was clear from our discussions with managers and staff that patient and staff safety was the key priority for the department. We were content that at the time of the inspection we observed safe and effective practice.

From what the inspection team observed and discussed during the course of the inspection we are satisfied that the above statement is upheld.

6. Next Steps

This inspection has resulted in the need for the service to complete an improvement plan to address the recommendations that were identified.

The details of this can be seen within Appendix A of this report.

As part of this, the organisation must review the recommendations made in the report in 2009 together with the specific requirements noted in this report and these actions should be completed within three months of the date of issue of this report.

The improvement plan should clearly state how the improvement identified at Cancer Centre, Velindre NHS Trust, Cardiff will be addressed, including timescales.

The improvement plan, once agreed, will be published on HIW's website. Where actions within the improvement plan remain outstanding and/or in progress, we ask that the trust provide HIW with updates, to confirm when these have been addressed.

Appendix A

IR(ME)R: Improvement Plan

Hospital: Velindre Cancer Centre

Ward/ Department: Radiotherapy Department

Date of Inspection: 10 and 11 March 2016

Page	Improvement needed	Trust Action	Responsible Officer	Timescale
	Quality of the Patient Experience			
9	To undertake a review of delays in treatment to identify the main causes and take appropriate action where possible To review arrangements for monitoring the control of infection in the department To provide appropriate storage to ensure the separation of clean and dirty linen	Review of capacity and Breakdowns to identify possible areas where delays could be minimised further Review signage and water fountains to ascertain if infection control risk could be reduced, consider type of equipment purchased in the future Review storage of linen, linen baskets are available in all clinical areas however the position and visibility of the baskets will be reviewed	Bernadette McCarthy	15th July 2016
	Compliance with IR(ME)R			

Page	Improvement needed	Trust Action	Responsible Officer	Timescale
10	To review the content of the two IR(ME)R policy documents in place to ensure they each reference the other	Review of Implementation of the Ionising Radiation (Medical exposures) Regulations 2000 (amended 2006 & 2010) and Black 61Ionising Radiation Safety Policy	Bernadette McCarthy	15th July 2016
11	Review the content of the document 'Implementation of the Ionising Radiation (Medical Exposure) Regulations 2000 (amended 2006 and 2011)' to ensure the content reflects current practice and to include a reference to each of the procedures required under Schedule 1 of IR(ME)R.	Content of document to be reviewed, and to include suite of documents associated with specific schedule Make reference to anticipated doses from radiotherapy planning imaging	Bernadette McCarthy	15th July 2016
11	Review the use of unplanned treatments for brick pelvic radiotherapy	Multidisciplinary team to review current practice of unplanned treatments for brick pelvic radiotherapy including referral pathway in the interest of reducing the probability and magnitude of radiation incidents.	Jacinta Abraham	15th July 2016
12	To review the incident reporting procedure to include details about where incidents need to be reported	Review Black 62 (QS01) Incident Reporting and Investigation and QPWI07 Radiation Incidents Reporting to include definition of Much Greater than Intended and identify external bodies to whom these are reported	Bernadette McCarthy	15th July 2016
13	The scope of practice for entitlement of each	Clarify for which operator functions radiation	Jacinta Abraham	15th July

Page	Improvement needed	Trust Action	Responsible Officer	Timescale
	duty holder needs to be clearly defined.	oncologists are entitled to act. Review process for entitlement of locum radiation oncologists.		2016
13	To review and amend the systems in place as necessary for recording training, to demonstrate an integrated approach within the department that provides the same level of detail.	Review system of recording training for radiation oncologists to demonstrate clear accountability and traceability	Jacinta Abraham	15th July 2016
14	Develop written referral criteria for radiotherapy Establish dose estimates for radiotherapy planning imaging	Review clinical protocols to include referral criteria and investigations, include anticipated doses for radiotherapy planning imaging	Bernadette McCarthy	20th May 2016
14	A written procedure describing authorisation responsibilities for all types of exposures is required.	Review documentation including entitlement of medical physics staff to act as practitioners rather than operator under guidelines	Geraint Lewis	15th July 2016
15	Review and develop the patient identification procedure to include the points identified	Develop current identification procedure to include direct references to documents mentioned in this procedure. In the case of pre-treatment exposures the document should explicitly state which primary source	Bernadette McCarthy	15th July 2016

Page	Improvement needed	Trust Action	Responsible Officer	Timescale
		documents should be used for confirmation of patient identification. The procedure should be explicitly state how a paediatric patient can identify themselves.		
15	Work needs to be undertaken to consolidate this procedure to ensure all information is contained within it regarding checking the pregnancy status for females of child bearing age. In the revised procedure it would be good practice to include reference to the child protection procedure for situations where a minor provides a positive response to the pregnancy question.	Review of QPWI 61 Pregnancy Policy to include reference to language barriers and any support needed as part of this process, and reference to the child protection procedure for situations where a child provides a positive response to the pregnancy question. In relation to pregnancy testing the following information is included in QPWI 61: If the patient **cannot give a definite NO** reply, i.e. <u>not sure if pregnant</u> then the operator **must not** proceed with the exposure. The operator must make arrangements for a pregnancy test to be performed. This must be done with the patient's consent following the Trust Policy Green 29 Pregnancy Tests for Patients Undergoing Medical Exposures.	Bernadette McCarthy	15th July 2016

Page	Improvement needed	Trust Action	Responsible Officer	Timescale
		If the patient refuses a pregnancy test or if the result of the pregnancy test indicates that the patient is pregnant the operator must refer the matter to the patient's Consultant Clinical Oncologist or SpR. If the result of the pregnancy test indicates that the patient is not pregnant the operator can proceed with the exposure as detailed above.		
16	To explicitly state as part of the Schedule 1 Employers Procedures that these types of exposures are not undertaken.	Review of Implementation of the Ionising Radiation (Medical exposures) Regulations 2000 (amended 2006 & 2010) to include statement that medico legal exposures are not applicable as they are not undertaken in the radiotherapy department	Bernadette McCarthy	15th July 2016
16	Current practice in terms of optimisation could be better reflected in the document entitled 'Implementation of the Ionising Radiation (Medical Exposure) Regulations 2000 (amended 2006 and 2011)'	Document to be reviewed to include explicit statements in terms of treatments being individually planned; all treatment prescriptions are defined as part of an evidenced clinical protocol and are discussed as part of a multi-disciplinary meeting at time of referral; all equipment that delivers or influences the delivery of the exposure is part of a rigorous quality	Bernadette McCarthy	15th July 2016

Page	Improvement needed	Trust Action	Responsible Officer	Timescale
		assurance programme; optimisation of the planning and verification imaging settings for adults and paediatrics has been completed. Much work had been undertaken to optimise the imaging setting on the CBCT devices to ensure the image quality and associated dose were consistent with the clinical requirement of the images captured		
17	The local process of clinical evaluation could be documented to reflect current practice within the document entitled 'Implementation of the Ionising Radiation (Medical Exposure) Regulations 2000 (amended 2006 and 2011)'.	Review document including the clinical evaluation of planning, treatment and verification exposures, and make reference to monitoring of care procedure	Bernadette McCarthy	15th July 2016
17	Procedures in place affecting the special attention to the optimisation of paediatrics could be better described in the document entitled 'Implementation of the Ionising Radiation (Medical Exposure) Regulations 2000 (amended 2006 and 2011)'.	Review documentation to include explicit statements of the optimisation of all planning and verification imaging settings for paediatrics within the documentation	Bernadette McCarthy	15th July 2016
18	To ensure that appropriate complete inventory of equipment is developed in line with the requirements of the regulations.	Undertake complete inventory to be included in an appendix to Implementation of the Ionising Radiation (Medical Exposure) Regulations 2000 (amended 2006 and 2011)	Geraint Lewis	20th May 2016
21	Review the recommendations made in the report in 2009 together with the specific	Training Matrix to be reviewed and all ticks replaced with dates to identify when training was	Bernadette McCarthy	15th July 2016

Page	Improvement needed	Trust Action	Responsible Officer	Timescale
	requirements noted in this report	undertaken. Referral criteria for radiotherapy to be included in all clinical protocols. Review documentation to reflect practice:		
	Management and leadership			
	None			
	Delivery of a Safe and Effective Service			
	None			

Trust Representative:

Name (print): **Bernadette McCarthy**

Title: **Radiotherapy Services Manager**

Date: **19/04/2016**