Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

DRIVING IMPROVEMENT THROUGH INDEPENDENT AND OBJECTIVE REVIEW

Ionising Radiation (Medical Exposure) Regulations Inspection (announced)

Nuclear Medicine Department

Singleton Hospital Swansea

Inspection date: 4 and 5 August 2016

Publication date: 7 November 2016

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Digital ISBN 978-1-4734-8021-6

Contents

1. Introduction

A compliance inspection against the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000 and regulation amendments 2006 and 2011 for diagnostic imaging was undertaken on 4 and 5 August of the nuclear medicine department of Singleton Hospital, Swansea. Non-imaging, Therapy and Radiopharmacy were also included in the inspection.

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.

The regulations place responsibilities on practitioners, operators, those who refer patients for medical exposures 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 written procedures and protocols. A breach of regulations can result in the issue of prohibition notices, improvement notices or criminal proceedings.

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)
- Practitioners and operators do not undertake any medical exposure without being adequately trained. Employers ensure adequate training is provided and records of this training are maintained.

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

- Quality of the Patient Experience
- Compliance with IR(ME)R
- Staffing Management and Leadership

2. Methodology

During the inspection we gather information from a number of sources including:

- Information held by HIW
- Information provided by the department in the HIW Self Assessment Form
- Discussions 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.

These inspections capture a snapshot of the standards of care patients receive; the extent to which services are meeting essential safety and quality standards and regulations and may point to wider issues about the quality and safety of services provided.

3. Context

A compliance inspection against the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) for nuclear medicine was undertaken on 4 and 5 August 2016 at the nuclear medicine department at Singleton Hospital, Swansea part of Abertawe Bro Morgannwg University Health Board.

Activity

The nuclear medicine department located at Singleton hospital provides a diagnostic and therapeutic nuclear medicine service.

In the last year, 2935 diagnostic nuclear medicine procedures and 214 therapeutic nuclear medicine procedures were carried out by the nuclear medicine department.

Equipment

The department has two gamma cameras[1], one of which is capable of SPECT/CT, a sample counter, five radioactive medicinal product (RMP) dose calibrators[2] and a number of contamination monitors[3].

Environment

The nuclear medicine out-patient department has two gamma camera rooms and one injection room where the majority of patients receive administrations. In the absence of a waiting room for Nuclear Medicine, patients wait in seating along the corridor.

The radiopharmacy is located in another building a short distance away from the department. Out-patients receiving radioiodine treatment (^{131}I for benign

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[1] A gamma camera, also called a scintillation camera or Anger camera, is a device used to image gamma radiation emitting radioisotopes,

[2] Dose Calibrators are devices used in Nuclear Medicine to ensure that the dose delivered is what is intended.

[3] When working with unsealed radioactive materials, it generates potential contamination of surfaces. Contamination monitors provides early warnings of the presence of surface contamination helping to prevent inadvertent transfer of radioactivity.

thyroid conditions and thyroid cancer patients) will be administered in a non-sterile dispensary room within radiopharmacy. Stock control is managed by radiopharmacy.

The department also has use of a shielded en-suite cubicle (room 18) on ward 12 at Singleton Hospital for in-patients receiving high activity radioiodine treatment (^{131}I for thyroid cancer).

Staff providing Nuclear Medicine Services

The department employs 8.1 (Whole Time Equivalent) Clinical Technologists, 2.6 (WTE) Medical Physics Expert/ Registered Clinical Scientist, and 1 Trainee Clinical Scientist. There are 15 Medical Consultants who hold an Administration of Radioactive Substances Advisory Committee (ARSAC) certificate on site however, not all are permanently based at Singleton Hospital. The department does not have a dedicated Medical Consultant for nuclear medicine.

4. Summary

This is the second IR(ME)R inspection by HIW of the nuclear medicine department at Singleton Hospital. A report of the first inspection was published in July 2009.

The inspection was well received by both management and staff and all required documentation was completed and received within timescales specified. It was however disappointing to note that there were some recommendations that had been made in the 2009 report that still had not been completed. HIW expects that the health board uses our inspections to improve the quality and safety of its services by ensuring that our recommendations are actioned. A non compliance letter was, therefore, issued to the site within two working days of the inspection and HIW require Abertawe Bro Morgannwg University Health Board to complete any outstanding actions within three months from the date of the publication of this report.

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. We also received a positive welcome from patients who provided feedback on their experiences.

There were six breaches of Regulation identified during the visit.

1. Regulation 4(1)(a) - Written procedures need to be updated to reflect current working practice.

2. Regulation 11(4) - Training records for medical staff acting as practitioners and operators were not available for review by the inspection team.

3. Regulation 4(1) Schedule 1(b) Medical staff entitled to act as practitioners or operators were not clearly identified.

4. Regulation 4(1) Schedule 1(e) and Regulation 4(3)(b)- The version control system for documentation was inconsistent across the procedures and protocols we reviewed and it was not clear whether documents were being reviewed in line with local procedures.

5. Regulation 6(5) - The ‘Delegated Authorisation Guidelines’ document used by operators to authorise an exposure did not clearly identify the practitioner or their scope of practice.

6. Regulation 4(3)(a)- Issues were raised regarding access for the Referrers to the indicated referral guidelines iRefer. Referral criteria must be made available to individuals who have been entitled to act as 'referrer'

These were discussed with the team at the time of the visit and they expressed a commitment to completing these tasks as a matter of urgency.

During the inspection clinical practice was seen to exceed the related documentation. Whilst the inspection team were satisfied there were no safety concerns, some key issues for action were identified during the visit. Details of these are highlighted and described in the body of the report.

At the end of the inspection we provided feedback on our main findings and key recommendations. The management team will be submitting an improvement plan in response to our findings.

5. Findings

Quality of the Patient Experience

Patients felt the quality of their experience at the nuclear medicine department, within Singleton hospital was very good. Positive feedback was received about the staff, the department, 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 three questionnaires were completed and returned. The responses 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
- Patients didn't experience delays with their treatment
- Cleanliness of the department was extremely good

Some examples of comments made by patients were

> "Could not be better. Felt very comfortable and cared for"
>
> "The department provided the highest standards of care and professionalism "
>
> "I have been to various departments/ hospitals over the last few months and I have to say this was the most pleasant visit of them all"

One negative comment made was that the waiting list was longer than first informed, resulting in the doctor having to write to the department again. Another comment made was that staff should remind patients that tea and coffee is made available in the red cross shop located around the corner from the department. However, if a patient had mobility problems then this is a fair distance to walk. Another comment made was that the clinic room was a little cold whilst laying on the bed for their scan.

Most respondents 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:

> "All the staff were very friendly and informative. They talked me through the procedures step by step and were always able to answer questions. Well trained and professional staff"

> "Highly professional, polite, friendly, reassuring and knowledgeable"

> "The staff are extremely polite, professional, empathetic. There is an obvious team at work here. Delivery a first class service. How reassuring, refreshing, respected. Thank you with appreciation"

Everyone commented that the standards of cleanliness were very good or excellent. Some comments made about the department were:

> "Everywhere I went in the department was clean, including facilities. Staff had a clean as you go approach"

> "Immaculately clean in all areas"

> "Department very clean and tidy"

During the inspection, concerns were raised by the Inspection Team with regard to the departmental layout. The designated patients waiting area for nuclear medicine is situated in a corridor. Although not ideal, patients did not express that this was unsatisfactory in HIW's patient questionnaire. Additionally consultations with patients prior to outpatient radioiodine therapy are held in an office area in the radiopharmacy. The Inspector's felt that this arrangement does not maintain patient confidentiality or satisfy standards for dignity or respect.

Recommendations

The consultation area used for patients in the radiopharmacy should be reviewed to ensure patient confidentiality and discussions of a sensitive nature should be held in a private area to maintain patients' dignity and respects.

Compliance with IR(ME)R

Duties of Employer

The employer is defined in Regulation 2(1) 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.

Within the Health Board, the document entitled 'Policy for Ionising Radiation Safety (including corporate IR(ME)R Procedures)' described how the regulations were implemented locally. The Chief Executive of the organisation is the "employer" in the context of IR(ME)R and this was clearly defined in this policy. Staff clearly articulated his role as the employer and how his responsibilities under IR(ME)R were discharged. The Health Board has recently gone through an organisational restructure and as a result the documentation was not clear on which senior members of the organisation were responsible for undertaking tasks on behalf of the employer. The IR(ME)R procedures must be updated to reflect any changes that may impact on the department in relation to IR(ME)R and in particular this should be reflected in the entitlement flow chart.

Three of the procedures required for the employer under Schedule 1 of IR(ME)R were in place on a corporate level and were attached to the Policy for Ionising Radiation Safety (including corporate IR(ME)R Procedures) document. All other employer procedures were held on a local level within the department. It would be helpful to review the corporate policy to include direct references to where each of the Schedule 1 Employers Procedures might be found, if not already described and explicit statements where they do not apply. Consideration should also be given to the appropriateness of the titles of these local procedures. The corporate policy should have a clear line of accountability for all local procedures as required by Schedule 1, and this should be reviewed to reflect current practice.

Recommendation

IR(ME)R Documentation must be reviewed to reflect organisational restructure changes

To review the 'Policy for Ionising Radiation Safety (including corporate IR(ME)R Procedures)' to include direct reference to where each of the Schedule 1 Employers Procedures might be found.

Procedures and Protocols

Regulation 4(1) and 4(2) requires the employer to have written procedures and protocols in place.

The 'Policy for Ionising Radiation Safety (including corporate IR(ME)R Procedures)' contained reference to most of the procedures as required under IR(ME)R or described the local implementation of the regulations. The content of this policy document could 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 a number of the Schedule 1 Employer Procedures, details of which are included in the relevant sections of this report.

The version control system for documentation was inconsistent across the documentation we reviewed and it was not clear whether documents were being reviewed in line with the departments' local procedure. Documentation should include the version number, date of issue and the date of review. It was observed at the time of the inspection that some procedures contained hand written changes, with no indication of when or by whom these changes had been made. We also noted that some procedures contained the use of words such as 'normally' and 'in general'. Of concern is that these were both highlighted as recommendations in HIW's 2009 report. HIW expects that the health board uses our inspections to improve the quality and safety of its services by ensuring that our recommendations are actioned. The expectation therefore is that action is now taken to address this matter. We were told that when changes are made to procedures then an all staff email is sent which identifies documents that have been reviewed and amended to support staff in familiarising themselves with the changes made. Staff complete an online spreadsheet to confirm they have read and understood the changes. Staff we spoke with at the time of our visit confirmed that this practice is in place.

IR(ME)R procedures and clinical protocols were all available as controlled hard copies and electronically. Staff we spoke to at the time of the visit confirmed that electronic copies were most often referred to. Whilst not a requirement under IR(ME)R, the benefits of having a single document management system in place were discussed, particularly given the accessibility of authorised documents. It is proposed that procedures and protocols should only be kept electronically and can be protected by restricting the documents to read only.

In reviewing some of the clinical protocols at the time of the visit it was noted that the documents were well laid out however they lacked consistency with

regard to the level of detail contained. Additionally many of the protocols had not been reviewed in line with the quality control procedure and no longer reflected current practice.

Recommendation

Review the content of the document 'Policy for Ionising Radiation Safety (including corporate IR(ME)R Procedures)' to ensure the content reflects current practice

Review the version control system for all IR(ME)R documentation.

Consideration should be made on the removal of hardcopy procedures and protocols to minimise the probability and magnitude of errors.

Written procedures must be amended to remove words such as 'normally' and 'in general' and include more explicit statements.

Clinical protocols must be updated to ensure that the content reflects current practice.

Incident notifications

Regulation 4(5) 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.

There is a clear process in place for the notification of incidents.

The procedure for the notification of incidents was one of the three corporate Schedule 1 Employer Procedures and staff were able to explain the notification process clearly.

Further detail on notifications can be found in the Procedure for Minimising the Risk of Accidental or Unintended Radiation Exposure to a Patient (8.31.5). Reference is made within the procedure that incidents should be reported to the 'relevant authority' but this needs to be defined. These two documents should also include reference to each other.

All staff are required to report any non-compliance with the procedure or any incident which occurs within the department and are recorded on DATIX. These would then be investigated by the Service Manager 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.

Incidents are also reviewed and discussed in the Health Board's Medical Exposure Committee.

Recommendation

To review the incident reporting procedure to include details about the 'relevant authority' that incidents need to be reported to.

Diagnostic reference levels

Regulation 4(3)(c) requires the employer to establish diagnostic reference levels (DRL) for radio diagnostic examinations. These are not expected to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied.

Diagnostic reference levels (DRL's) had been established and there was a robust procedure in place for ensuring that DRL's were not exceeded during normal practice.

Entitlement

Regulation 2(1) requires that duty holders must be entitled, in accordance with the employer's procedures for the tasks they undertake. Regulations 11(1) and 11(4) states that practitioners and operators must also be adequately trained and the employer must keep up to date training records of this training.

A written Entitlement procedure is contained within the 'Policy for Ionising Radiation Safety (including corporate IR(ME)R procedures)' document.

Within nuclear medicine an entitlement matrix for duty holders was reviewed as part of the inspection. Whilst this was inclusive of the entitlement of all non-medical duty holders, there were no details of the entitlement for medical duty holders.

There was also an inconsistent approach to describing the scope of practice for each duty holder. For example, some duty holders had a tick, while others had a particular Radioactive Medicinal Product (RMP) in the box. The need to include the date when staff were entitled, following successful completion of training and competences, was discussed. Of concern is that this was highlighted as a recommendation in HIW's 2009 report. HIW expects that the health board uses our inspections to improve the quality and safety of its services by ensuring that our recommendations are actioned. The expectation therefore is that action is now taken to address this matter.

Training records and documented induction training were in place and up to date for non-medical staff working in the department. The training records and competency assessments for non-medical staff were of a very good standard.

However it was disappointing that we did not see any training records for medical staff at the time of the visit despite this being specifically requested. Regulation 11(4) states that the employer shall keep and have available for inspection by the appropriate authority and up to date record of all practitioners and operators and their own training. Again, of concern is that these were both highlighted as recommendations in HIW's 2009 report. HIW expects that the health board uses our inspections to improve the quality and safety of its services by ensuring that our recommendations are actioned. The expectation therefore is that action is now taken to address this matter. It was noteworthy, that the Chief Clinical Technologist in the nuclear medicine department had expanded their training into 'advanced practice' by attending the 'Reporting Skills in Nuclear Medicine' Course offered by the University of the West of England. Two of the departments' operators had also been trained as myocardial perfusion cardiac stress leaders.

Recommendation

Details of the entitlement of medical staff to perform operator tasks needs to be made available to all staff within the department

The scope of practice for entitlement of each duty holder needs to be clearly defined including the date staff completed training

To review the systems in place for recording training to demonstrate an integrated approach within the department that provides the same level of detail for medical and non-medical staff

Referral Criteria

Regulation 4(3)(a) 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

Referrals for procedures are received to the department by a hardcopy request form, letter or fax. There is currently no mechanism in place for electronic requests.

The list of referrers is managed by the systems manager of the *Radiology Information System (*RIS*)*. The systems manager validates referrers' names against the Health Boards official register and General Practitioner lists.

Inspectors were informed that Referrers' responsibilities are made clear to them at induction. Consideration should be given to providing an update of their responsibilities and requirements on a regular basis.

Written referral criteria were not seen at the time of the inspection. The department indicated that the referral criteria used was The Royal College of Radiologists' referral guidelines, 'iRefer, Making the Best Use of Clinical Radiology Services'. However, issues were raised at the time of our visit regarding the Health Board's access to the indicated referral guidelines. This is a Health Board wide issue and has been highlighted to Welsh Government as a concern. Referral criteria must be available to all referrers as specified in Regulation 4(3)(a).

Requirement

Consideration should be given to regularly reminding Referrer's of their requirements and their responsibilities under IR(ME)R

Develop written referral criteria and make available to individuals who have been entitled to act as 'referrer'

Justification of Individual Medical Exposures

Regulations 6(1)(a) and 6(1)(b) 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 by which all medical exposures undertaken in the department are justified and authorised, is outlined in the 'Policy for Ionising Radiation Safety (including corporate IR(ME)R procedures)' document.

The Health Board currently has fifteen medical Consultants who hold an ARSAC certificate at Singleton hospital. Some of these work routinely at other sites across Abertawe Bro Morgannwg University Health Board as well as the neighbouring health Board, Hywel Dda. This leads to considerable overlap in terms of specialism. The department needs to review the practical issues around having fifteen ARSAC certificate holders with specific regard to supporting and maintaining their training. Of concern is that this was

highlighted as recommendation in HIW's 2009 report. HIW expects *that the health board uses our inspections to improve the quality and safety of i*ts services by ensuring that our *recommendations are actioned.* The expectation therefore is that action is now taken to address this matter.

The department has in place a 'delegated authorising guidelines' document, however there was some confusion surrounding who was acting as the practitioner for these guidelines. An example of this was only four of the fifteen ARSAC holders were listed under the 'delegated authorising guidelines' and only three had signed the document. It was not clear who the practitioner was for exposures authorised under the guidelines nor was there a clear line of accountability visible. The scope of practice for each practitioner needs to be better described in the documentation to ensure clarity for operators authorising under these guidelines. This will ensure that the practitioner for each procedure is clearly identifiable.

Recommendation

The department needs to review the practical issues around having fifteen ARSAC certificate holders

The 'Delegated Authorisation Guidelines' document used by operators to authorise an exposure must clearly identity the practitioner for each procedure.

Identification

Schedule 1(a) states that written procedures for medical exposures should include procedures to correctly identify the individual to be exposed to ionising radiation.

A patient identification procedure was in place. The procedure clearly identifies the person who is responsible for identification when administering the radiopharmaceutical and also explains what happens when a person is unable to identify themselves. The procedure also explains what to do if there are discrepancies with the information they hold and the information the patient provides. It also includes the use of patient identification bands, although it could include a paragraph stating that staff should check with clinical staff escorting the patient as well as with relatives and or carers.

The procedure doesn't address situations where more than one operator is directly involved in the medical exposure. The procedure should explain who has overall responsibility for the identification of the patient. This is referenced within the Radiopharmaceutical Administrations procedure (W8.31.9) but needs

to be reflected specifically in the patient identification procedure to ensure clarity.

Patient identification errors constitute a significant number of notifications across the UK and there is a campaign to promote and introduce 'Pause and Check' factors into the procedure of identification. Reference to this could be included in the Identification Procedure. Inspectors were informed that other departments have their own patient identification procedures and that these were recently reviewed. Discussions were had regarding reviewing and harmonising the nuclear medicine procedure in line with other departments.

Recommendation

To review and develop the patient identification procedure to include the points identified

Consideration should be given to harmonising patient identification procedures.

Females of child bearing age

Schedule 1 (d) 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 mention within the Radiopharmaceutical Administrations procedure (W8.31.9) for the checking of pregnancy status of females of child bearing age as well as checking if females are breast feeding.

Although mentioned within this procedure, this is not a robust or comprehensive procedure. For example, there is no reference to verifying pregnancy status and how this happens and neither is there reference to language barriers and any support needed as part of this process. It does state the operator responsible for the exposure must ask any female patients between the ages of 12 and 55 years whether she is or might be pregnant and also whether she is breast feeding. The patient will then either sign the Pregnancy and Breast Feeding Declaration form or the declaration on the reverse of the request form prior to administration. These two declarations require the patient to provide different information. One method of recording this information is required and this should be made clear in the procedure.

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.

At the time of the visit, we were told that the department had recently reviewed and drafted a pregnancy and breast feeding procedure, although this was not provided to the inspection team prior to our visit. It may also be beneficial to staff to introduce the use of a flowchart as it may help to make the procedure more concise and user friendly.

Recommendation

A single procedure for checking the pregnancy and breast feeding status for females of child bearing age needs to be implemented to ensure consistency across the department.

The department should consider the introduction of a flowchart into the pregnancy checking procedure to assist with clarity

It would be good practice to include reference to the child protection procedure should a minor provide a positive response to the pregnancy question.

Medico-Legal Exposures

Schedule 1 (c) states 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 nuclear medicine department. This should be explicitly stated as part of the Schedule 1 Employers Procedures.

Recommendation

To explicitly state as part of the Schedule 1 Employers Procedures that Medico-Legal exposures are not undertaken in this department.

Optimisation

Regulation 7(1) requires that doses for all diagnostic medical exposures are kept as low as reasonably practicable (ALARP) consistent with the intended purpose.

Generally, we witnessed a good culture and attitude towards keeping doses ALARP and optimising exposures. The department has a list of suggested administered activities for paediatric imaging for a number of procedures as well as details of adjusting the activity for cardiac imaging. However, current practice in terms of optimisation could be better reflected in the IR(ME)R

documentation. Additionally regular audits of administered activity and image quality would enable further optimisation specific to equipment on site and ensure that exposures remain ALARP.

The Medical Exposure Committee ensures health board wide learning and optimisation of protocols.

Recommendation

Consider performing audits to provide assurances that exposures are optimised

IR(ME)R documentation must be reviewed to better reflect current practice in terms of optimisation

Clinical evaluation

Regulation 7(8) states that the employer shall ensure a clinical evaluation of the outcome of each medical exposure is recorded in accordance with the employer's procedures.

The department has a procedure in place for the processing of nuclear medicine imaging investigations; however, this has not been updated since 2009. The procedure needs to reflect current practice describing how clinical evaluation of exposures are undertaken.

Recommendation

The clinical evaluation procedure must be reviewed to reflect current practice

Medical Research Programmes

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

A written procedure is contained within the 'Policy for Ionising Radiation Safety' 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 have to consent to take part and to the treatment and information on the risks of the treatment are provided to them in advance.

Clinical audits

Regulation 8 states that employer's procedures shall include provision for carrying out clinical audits as appropriate.

There was no evidence of audit activity being carried out nor was there a dedicated audit programme in place for the department.

Example of clinical audits could include, reporting times, diagnostic reference levels (DRL's) and completeness of request forms. The learning from the audit process should be shared across all staff disciplines within the department and used to develop practices in the future.

Recommendation

To develop and implement an audit programme for the department ensuring that the learning is shared with staff and used to develop practices

To develop guidelines for undertaking and reporting on audits

Expert advice

Regulation 9(1) and 9(2) states that the employer shall ensure a Medical Physics Expert (MPE) is available in standardised therapeutic nuclear medicine practices, in diagnostic nuclear medicine practices and involved as appropriate in every other radiological medical exposure

Medical Physics Experts (MPE's) are available in the department for advice on all diagnostic and therapeutic exposures conducted in the nuclear medicine department. The MPE's also oversee the equipment within the nuclear medicine department. It was noted from the Self Assessment Form that numbers of scientific staff were below the most recent guidance detailing recommended staffing levels.

Equipment

Regulation 10 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 department maintains a current and up to date equipment inventory which includes all information required under IR(ME)R within it.

Management and Leadership

It was clear from the inspection that the management team, head of department and staff are committed to providing a standard of service that is safe

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 visit.

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

Our discussions with staff at the time of the visit 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 visit.

During the inspection, we found a number of regulations which were not being complied with. It is of particular concern that action does not appear to have been taken in relation to a number of recommendations identified following HIW's last inspection report of this department in 2009. Furthermore, in our letter to the health board regarding our announced inspection, the health board was reminded of its responsibilities under the regulations and was advised to consult the regulations and standards to ensure that the necessary documentation and information were available for inspection. It was therefore disappointing that the health board had not been sufficiently proactive in this respect.

All of these issues have been highlighted in the report and these will require urgent action. The inspection team were content that whilst there were breaches of regulation, 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 visit we observed safe and effective practice.

6. Next Steps

This inspection has resulted in the need for the service to complete an improvement plan to address the recommendations identified during this visit.

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

As part of this the Health Board 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 3 months of the date of issue of this report.

The improvement plan should clearly state how the improvement identified at the Nuclear Medicine department at Singleton Hospital will be addressed, including timescales.

The improvement plan, once agreed, will be published on HIW's website and will be evaluated as part of the ongoing inspection process.

Appendix A

IR(ME)R: Improvement Plan

Hospital: Singleton Hospital

Ward/ Department: Nuclear Medicine

Date of Inspection: 4 and 5 August 2016

Page Number	Recommendation	Health Board Action	Responsible Officer	Timescale
	Quality of the Patient Experience			
9	The consultation area used for patients in the radiopharmacy should be reviewed to ensure patient confidentiality and discussions of a sensitive nature should be held in a private area to maintain patients' dignity and respects.	A new aseptic laboratory is being constructed currently. Aseptic work will be relocated to the new suite in May 2017. The existing facility will then be re-designed as a more user-friendly patient facility for therapy patients	Head of Nuclear Medicine	2 years
	Duties of Employer			

Page Number	Recommendation	Health Board Action	Responsible Officer	Timescale
10	IR(ME)R Documentation must be reviewed to reflect organisational restructure changes	Changes to be established by Medical Exposure Committee on 4th November 2016. 'Policy for Ionising Radiation Safety (including corporate IR(ME)R Procedures)' to subsequently be revised to improve clarity on roles undertaken by senior staff on behalf of the employer.	Hamish Laing	3 months
10	To review the 'Policy for Ionising Radiation Safety (including corporate IR(ME)R Procedures)' to include direct reference to where each of the Schedule 1 Employers Procedures might be found.	Changes to be established by Medical Exposure Committee on 4th November 2016. Policy to be revised and issued within 2 months following meeting.	Hamish Laing	3 months
12	Review the content of the document 'Policy for Ionising Radiation Safety (including corporate IR(ME)R Procedures)' to ensure the content reflects current practice	Policy to be reviewed by Medical Exposure Committee on 4th November 2016. Policy to be revised and issued within 2 months following meeting.	Hamish Laing	3 months
12	Review the version control system for all IR(ME)R documentation.	All documents will be reviewed and revised with date of issue and review date, together with the revision number	Head of Nuclear Medicine	2 months review, 6 months implementation
12	Consideration should be made on the removal of hardcopy procedures and	All paper copies will be removed and published electronically for access by all relevant staff, with read only access	Head of Nuclear Medicine	1 month

Page Number	Recommendation	Health Board Action	Responsible Officer	Timescale
	protocols to minimise the probability and magnitude of errors.			
12	Written procedures must be amended to remove words such as 'normally' and 'in general' and include more explicit statements.	All procedures in Nuclear Medicine will be reviewed and re-issued	Head of Nuclear Medicine	6 months
12	Clinical protocols must be updated to ensure that the content reflects current practice.	All protocols in Nuclear Medicine will be reviewed	Head of Nuclear Medicine	6 months
13	To review the incident reporting procedure to include details about the 'relevant authority' that incidents need to be reported to.	Procedure to be reviewed by Medical Exposure Committee on 4th November 2016.	Radiation Protection Adviser	3 months
14	Details of the entitlement of medical staff to perform operator tasks needs to be made available to all staff within the department	To be reviewed by Medical Exposure Committee on 4th November 2016. Entitlement records for nuclear medicine practitioners to be established and provided for nuclear medicine staff.	Medical Director Clinical Director Radiology	3 months 3 months
14	The scope of practice for entitlement of each duty holder needs to be clearly defined including the date staff completed training	To be reviewed by Medical Exposure Committee on 4th November 2016. Delivery Unit Medical Directors to advise relevant Clinical Directors (or nominated Clinical leads) of the need for medical practitioners and operators to improve availability of training records.	Medical Director Clinical Director Radiology	3 months 3 months

Page Number	Recommendation	Health Board Action	Responsible Officer	Timescale
14	To review the systems in place for recording training to demonstrate an integrated approach within the department that provides the same level of detail for medical and non-medical staff	To be reviewed by Medical Exposure Committee on 4th November 2016.	Medical Director	3 months
15	Consideration should be given to regularly reminding Referrer's of their requirements and their responsibilities under IR(ME)R	To be reviewed by Medical Exposure Committee on 4th November 2016.	Medical Director	3 months
15	Develop written referral criteria and make available to individuals who have been entitled to act as 'referrer'	Access to iRefer was restored within ABMU in September 2016 and available to referrers via the learning and development section of the ABMU intranet.	Medical Director	Completed
	Justification of individual medical exposures			
16	The department needs to review the practical issues around having fifteen ARSAC certificate holders	This will be discussed at the next MEC committee and a review agreed	Head of Nuclear Medicine	1 month
16	The 'Delegated Authorisation Guidelines' document used by operators to authorise an exposure must clearly identity the practitioner	The Delegated Authorisation Guideline will be reviewed and a practitioner identified for each test	Head of Nuclear Medicine	completed

Page Number	Recommendation	Health Board Action	Responsible Officer	Timescale
	for each procedure.			
17	To review and develop the patient identification procedure to include the points identified	Patient identification procedure is being reviewed	Head of Nuclear Medicine	3 months
17	Consideration should be given to harmonising patient identification procedures.	To be reviewed by Medical Exposure Committee on 4th November 2016.	Medical Director	3 months
18	A single procedure for checking the pregnancy and breast feeding status for females of child bearing age needs to be implemented to ensure consistency across the department.	This is being written currently	Head of Nuclear Medicine	3 months
18	The department should consider the introduction of a flowchart into the pregnancy checking procedure to assist with clarity	A flow chart is being considered	Head of Nuclear Medicine	3 months
18	It would be good practice to include reference to the child protection procedure should a minor provide a positive response to the pregnancy question.	We will consider this when writing the pregnancy and breast feeding procedure	Head of Nuclear Medicine	3 months
18	To explicitly state as part of the Schedule 1	Add this particular requirement to a Nuclear Medicine Schedule 1 procedure	Head of Nuclear Medicine	3 months

Page Number	Recommendation	Health Board Action	Responsible Officer	Timescale
	Employers Procedures that Medico-Legal exposures are not undertaken in this department.			
	Optimisation			
19	Consider performing audits to provide assurances that exposures are optimised	Carry out an audit of doses given to patients compared with the Diagnostic Reference Levels	Head of Nuclear Medicine	6 months
19	IR(ME)R documentation must be reviewed to better reflect current practice in terms of optimisation	All procedures are being reviewed and will reflect current practice	Head of Nuclear Medicine	6 months
19	The clinical evaluation procedure must be reviewed to reflect current practice	Reviewed and Issued	Head of Nuclear Medicine	Completed
	Clinical audits			
20	To develop and implement an audit programme for the department ensuring that the learning is shared with staff and used to develop practices	An audit programme to look at DRL's and doses given will be developed, together with an audit of referral forms and reporting times. This will be discussed at regular Nuclear Medicine staff meetings	Head of Nuclear Medicine	3 months

Page Number	Recommendation	Health Board Action	Responsible Officer	Timescale
20	To develop guidelines for undertaking and reporting on audits	Audits conducted in Nuclear Medicine will be discussed at regular staff meetings	Head of Nuclear Medicine	3 months

Health Board Representative:

Name (print): **Professor Hamish Laing**

Title **Executive Medical Director**

Signature: 

Date: **04 October 2016**