Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

DRIVING IMPROVEMENT THROUGH INDEPENDENT AND OBJECTIVE REVIEW

Ionising Radiation (Medical Exposure) Regulations Inspection (announced)

Cardiff and Vale University Health Board: University Hospital of Wales, Nuclear Medicine Services

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1. Introduction

HIW completed a compliance inspection against the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000 as amended in 2006 and 2011, on 5 and 6 October 2016. This was specifically in relation to nuclear medicine services located at the University Hospital of Wales which forms part of Cardiff and Vale University Health Board. Consideration of the arrangements in place for non-imaging procedures, out-patient therapy and radiopharmacy were therefore included in this inspection.

Cardiff and Vale University Health Board is one of the largest National Health Service (NHS) organisations in the UK. It provides day to day health services to a population of around 472,400 people living in Cardiff and the Vale of Glamorgan who need emergency and scheduled hospital treatment and mental health care. It also delivers care in people's own homes and community clinics.

The delivery of NHS primary care services in Cardiff and the Vale of Glamorgan, including general practitioners, community pharmacists, dentists, and optometrists are also the responsibility of the Board. Additionally, it serves the population across Wales for specialties such as paediatric intensive care, specialist children's services, renal services, cardiac services, neurology, bone marrow transplantation and medical genetics.

Cardiff and Vale University Health Board includes nine hospitals and seventeen health centres.

HIW is responsible for monitoring compliance against 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 three 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

As previously stated, a compliance inspection against IR(ME)R in relation to nuclear medicine services was completed on 5 and 6 October 2016, at the University Hospital of Wales.

Patient Activity

A diagnostic and therapeutic nuclear medicine service is provided to the following numbers of patients each year (approximately):

- Nuclear Medicine Imaging[1]=2297
- Nuclear Cardiology[2]=627
- Non imaging nuclear medicine[3]=360

Equipment

The equipment that staff were using in the nuclear medicine service included a whole body counter, (which is a very sensitive scanner capable of measuring very small amounts of radioactivity in the body-everyone has a certain amount of this) radionuclide calibrators and various gamma counters and probes. We also saw four gamma cameras in use and were told that this number would be reduced in the near future as a result of improvements being made to the nuclear medicines services. This would include the replacement of existing gamma cameras[4] with new, more efficient equipment.

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[1] Nuclear medicine imaging uses radioactive materials to produce unique pictures of the body's inner workings. These images can be vital for a wide range of medical investigations including tests for cancer, kidney disease and Alzheimer's.

[2] Nuclear cardiology is a branch of nuclear medicine, specific to the heart.

[3] Non-imaging nuclear medicine uses radioactive materials to treat conditions or measure physiological processes.

[4] A gamma camera is a special camera that can produce an image of the radiation administered to patients.

The nuclear medicine service within Radiology had one injection room where the majority of patients received intravenous injections of ionising radiation substances (otherwise known as administrations) ahead of gamma camera imaging. In the absence of a designated waiting area, we saw that people had to wait in the injection room itself, at times when a patient was in the process of having their injection, albeit in an area enclosed by a curtain. This matter is discussed in more detail in section two of this report entitled 'Quality of the Patient Experience'.

The radiopharmacy's[5] nuclear cardiology, non-imaging and medical physics services were located in a building which was seen to be a short distance only away from the radiology department.

Staff working within nuclear medicine services

The provision of nuclear medicine services was supported by one full-time radiologist, one part-time cardiologist and a further part-time medical consultant. In addition, the nuclear medicine team included two full-time specialist registrars, a superintendent radiographer, two radiographers, a part-time assistant practitioner, seven full-time clinical technologists and part-time assistants. The team further included registered clinical scientists, trainee clinical scientists, radiopharmacists and nuclear medicine technician trainees. We were told that there were no substantive long term staff vacancies; some staff having worked in this area of service for many years. This meant that the staff team were extremely knowledgeable regarding all aspects of their work.

[5] Radiopharmacy is a branch of pharmacy that involves the manufacture of radioactive pharmaceuticals (radiopharmaceuticals).

4. Summary

Throughout our two day inspection visit, we saw staff treating patients, and each other, with respect and courtesy. We also received numerous positive comments from patients who completed one of our questionnaires regarding the helpful approach and attitude of the staff they met.

We saw that the nuclear medicine service environment was clean and tidy, however the gamma camera and injection rooms respectively, posed considerable challenges in terms of maintaining patients' privacy, dignity and confidentiality.

Patients confirmed that they had rarely experienced delays when attending the department for their medical imaging procedures or treatment.

We found that the health board's Chief Executive was identified as the employer under IR(ME)R; the Executive Board also having responsibility for the monitoring arrangements in place.

The employer had established written procedures to assist staff in their work as required by IR(ME)R and with the aim of delivering a safe and effective service to patients. We identified that a number of those needed to be reviewed and revised to promote further clarity for departmental staff teams.

Discussion with staff revealed that there was no formal procedure in place in respect of staff entitlement (as defined by the IR(ME)R regulations). Consequently, this matter resulted in the issue of a HIW compliance letter. This meant that the health board had seven days to respond to us with details of the action taken and that which it intended to take. Since that time, the health board has provided us with a comprehensive response which offers sufficient information about the prompt action already taken, and that which is planned, to ensure the on-going delivery of a safe and effective service to patients.

Arrangements were in place to ensure medical exposure doses are kept as low as reasonably practicable. Arrangements were also in place to pay special attention to optimising medical exposures for children and adults. We did however identify the need for some improvement with regard to the labelling of radiopharmaceutical activity dispensed for patients.

People can be confident that the service is safe, well managed and run in accordance with relevant professional standards. This is because we found strong and effective leadership being provided by senior departmental personnel. In addition, conversations with all levels of staff involved during the inspection revealed that there was a strong commitment to learn from the

inspection and to make improvements to the service for the benefit of patients, as far as possible.

This inspection has however resulted in the need for the service to complete an improvement plan to address the improvement needed identified during this inspection. The details of this can be seen within Appendix A of this report.

5. Findings

Quality of the Patient Experience

Patients who completed HIW questionnaires indicated that they were highly satisfied with the service provided. Very positive comments were also made regarding the approach and attitude of the staff team, verbally, and in writing. We were able to confirm that information about therapeutic and diagnostic nuclear medicine services was readily available to patients in English and Welsh. In addition, we were provided with a full description of how staff supported patients whose first language was not English, through the use of information in a variety of languages as well as interpreters. There were also well established arrangements in place to support patients with short term memory loss and visual and hearing difficulties, as and when required.

We found however that improvement was needed with regard to some areas of the nuclear medicine service's environment.

Prior to the inspection, we asked staff working within nuclear medicine to distribute HIW questionnaires to patients to obtain their views on the services provided. We also spoke briefly with two patients attending the service during our inspection. Both were complimentary of the attitude and helpfulness of the staff. Twenty six HIW patient questionnaires were completed and returned.

Without exception, all patients who provided comments within HIW questionnaires told us they were happy with the service they had received and praised the approach and attitude of the staff team. Three individuals indicated that they had experienced a little delay in being seen on the day of their appointment on occasions, one person stating that the reason for their delay was due to the breakdown of equipment. Other comments included:

> *'X and his team very calming with the way they explain every step of the treatment-very reassuring'*
>
> *'A very well run unit. A happy patient!!'*
>
> *'X was one of the kindest and empathetic staff I have ever met. She was very thorough and looked after me so well. I am so grateful for her care'*
>
> *'Staff are excellent'*
>
> *'I have everything explained clearly. Excellent'*

'It was nice to be treated nicely and politely by the staff compared with some other departments'

'The staff were friendly and very wiling to converse and answer my questions. A happy painless appointment'

The inspection team was also able to confirm that patients were treated with respect and kindness by staff throughout the inspection.

During our discussions with senior nuclear medicine staff, it was clear that the team placed a strong emphasis on promoting patients' privacy and dignity. However, they faced particular challenges in this regard within the existing gamma camera room in radiology. Staff also faced difficulties when speaking with patients about aspects of their care in the injection room where they were 'prepared' prior to administration. More specifically, whilst staff took great care to speak with patients in a quiet voice to maintain their confidentiality at times when their identity needed to be checked and aspects of their medical history needed to be obtained, the curtain used for screening purposes could obviously not prevent other patients overhearing the information exchange. This was because other patients had to wait in the injection room itself using the seating provided. This may prevent patients from providing intimate information about their general health, which could potentially result in procedure error.

We saw that the designated toilet for use by patients, who received intravenous injections of radio-active substances, was integral to the injection room and patient waiting area. This existing arrangement had the potential to compromise patient's safety, dignity, privacy and confidentiality.

In addition, the gamma camera room contained three such pieces of equipment which were separated only by curtains which would not prevent confidential information being overheard.

Whilst we were made aware of plans to provide some new equipment within the gamma camera room, it is important that any imminent re-configuration of the environment takes full account of the need to maintain patients' privacy, dignity and confidentiality in the future.

Improvement needed

The health board is required to provide HIW with a detailed description of how patients' privacy, dignity and confidentiality will be improved and maintained with the nuclear medicine injection and imaging areas respectively.

Changing cubicles were available to people if needed. These offered patients privacy when needing to change in to/out of dignity (hospital) gowns.

During a tour of the nuclear medicine service environment, we saw that all areas were clean and tidy. Patients who provided comments within HIW questionnaires also told us that they were satisfied with the cleanliness of the department.

Bi-lingual (English and Welsh) patient Information leaflets were readily available and we were told that the relevant leaflet would be sent to patients prior to their hospital appointment together with a prompt to ring the service if anything was unclear. We were also provided with a detailed description of how staff enabled patients (whose first language was not English) to be supported by information leaflets in the language of their choice and interpreters who were used to the confidential work of the NHS. Additionally, the inspection team was made aware that patients who had short term memory loss, poor vision and/or hearing difficulties were provided with additional support when attending for therapy and diagnostic procedures. Patients who provided comments within HIW questionnaires also told us they felt they had been provided with enough information about the care they received.

Senior staff explained how they worked closely with other members of the nuclear medicine team. Conversations with a range of professionals during the inspection confirmed that this was the case. This meant that patients were in receipt of care and support from a cohesive group of healthcare staff who could provide specialist help and advice, in accordance with their needs.

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.

The Chief Executive of the health board was defined as the employer in the context of IR(ME)R.

The health board's existing *Safe Use of Ionising Radiation Policy* (date approved-22 February 2011) also described that the responsibility for *monitoring* the use of ionising radiation rested with the Executive Board of the health board through its line management structure.

The policy document did set out the employer's duties. These, however, could have been made clearer to staff in its description of what was meant to happen operationally, and in more practical terms.

At the time of our inspection, the above policy was in the process of review; the draft document (entitled Cardiff and Vale UHB IR(ME)R Employer's Procedures) having recently completed a period of consultation. Whilst we observed that the newly drafted document provided staff with useful information about aspects of the medical exposure of patients to ionising radiation, there remained a need for clearer descriptions of staff responsibility, accountability and delegation in respect of IR(ME)R. We further found there was a need to make reference to key procedures and protocols which should guide the nuclear medicine team as to what was required of them on a day to day basis. In addition, we advised staff of the need to clarify the purpose of the document (that is, to be clear as to whether it is a replacement for the previous Safe Use of Ionising Radiation Policy, or a document which only provides details of Employer's procedures). We also advised of the need to ensure that any newly devised policy in this regard needed to be agreed (ratified) by the health board when finalised, so that staff understand its corporate status.

Improvement needed

The employer is required to review and revise the Safe Use of Ionising Radiation Safety Policy for the purposes of clarity and to reflect current service arrangements in respect of IR(ME)R.

Procedures and Protocols

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

We were provided with numerous procedures in advance of the inspection, some of which were at an employer level and others at a departmental level. The employer level procedures provided an overarching view of the implementation of IR(ME)R. Local procedures provided further detail of how IR(ME)R was implemented within each of the three nuclear medicine services**.**

Overall, we saw that the corporate, health board procedures were detailed. Senior clinical staff also described the process for reviewing written procedures and protocols and the system for informing staff of any changes made.

We noted however that although the documents were relevant to diagnostic radiology and radiotherapy, they did not make any reference at all to nuclear medicine services.

We also saw that a number of procedures that had been developed locally (that is, within nuclear medicine services) needed to be reviewed and revised to reflect current practice. We also found that review periods varied which may be confusing to staff, as they need to be certain that they always refer to the most up to date information. Conversations with senior staff demonstrated that they were well aware of the situation. We were also told that such matters were to be addressed in the near future at such time that the nuclear medicine service was re-configured and linked more closely with other radiology services.

Improvement needed

The health board is required to provide HIW with details of how it will ensure that IR(ME)R policies and procedures are reviewed and updated within nuclear medicine services alongside other radiology services. The health board is also required to describe how it will ensure that information about all newly developed policies and procedures is communicated clearly between staff in direct contact with patients and the IR(ME)R Employer. This is in order to ensure compliance with IR(ME)R legislation.

We did identify some written procedures and protocols that would benefit from being revised to avoid unnecessary duplication and promote further clarity. For example:

- revising some of the terminology used to ensure that terms used are consistent with those used within IR(ME)R

- We highlighted the above to senior staff who agreed to give thought to how the written policies, procedures and protocols could be improved and take action as appropriate.

Improvement needed

The health board is required to describe the action to be taken in order to consolidate IR(ME)R procedures to reduce duplication of information and offer further clarification to all relevant staff.

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.

We found there were suitable arrangements in place for investigating and reporting incidents as required by IR(ME)R legislation in the form of a written procedure and flow chart.

Conversations with staff also served to demonstrate their full understanding of the responsibility to notify relevant personnel in the event of a suspected radiation incident in a timely way.

Senior departmental staff confirmed that there had been no recent incidents that required reporting to HIW in relation to nuclear medicine services.

Diagnostic reference levels[6]

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.

As well as national DRLs being available, we saw that local (departmental) diagnostic reference levels were established within nuclear medicine services

[6] It is a requirement under IRMER regulations that local/departmental Diagnostic Reference Levels (DRLs) are agreed, regarding the amount of radiation that people are exposed to during common patient examinations. Radiation dose values should then be audited and compared with published data as a means of ensuring that patients receive safe and effective care.

to take account of the patient equipment being used; copies of which were placed in key areas to remind staff what they were. There was also a robust procedure in place for ensuring that DRL's were not exceeded during normal practice. This is considered to be good 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.

We discussed in detail, the system in place to ensure that the IR(ME)R Employer's Procedures included one which specifically related to the identification of individuals entitled to act as referrer or practitioner or operator as required by the regulations*.*

Whilst we were provided with very good written and verbal evidence to support past and current relevant and effective staff training and competence, the Employers Procedures did not however formally identify any nuclear medicine staff 'entitled' to act as outlined in the above paragraph. Such an omission had the potential for staff to be uncertain as to what procedures they could undertake, which in turn could lead to error. Consequently, this matter resulted in the issue of a HIW compliance letter. This meant that the health board had seven days to respond to us, providing details of what action had been taken and that which it intended to take. Since that time, the health board has provided us with a comprehensive response which offers sufficient information about the prompt action already taken, and that which is planned to ensure the on-going delivery of a safe and effective service.

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

The employer made available The Royal College of Radiologists' referral guidelines, and 'iRefer, Making the Best Use of Clinical Radiology Services', for use by referrers.

Patient referrals for procedures were received by the department in hardcopy request form, letter or fax. There was no mechanism in place for electronic requests to be made at the time of this inspection.

We found that the list of referrers was managed by the manager of the IT system used by all radiology staff. For example, the systems manager validated referrers' names against the Health Boards official register and General Practitioner lists. This means that there were suitable arrangements in place to ensure that patients were always referred for imaging by relevant professionals only.

We were further informed that 'Referrers' responsibilities were made clear to healthcare professionals at the point of their induction. We were also made aware of the day to day conversations that took place between nuclear medicine staff and other medical staff where advice was given to ensure that the process of referral was consistent and correct.

There was a clear process for the staff to follow around inadequate referrals which included a log of returned forms. This was considered to be good practice; action being taken in the form of additional training or advice as and when 'trends' became apparent.

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.

Each nuclear medicine service had a written procedure concerning the justification and authorisation of medical exposures. To act as a practitioner and justify exposures, a doctor must hold an appropriate ARSAC[7] certificate. We were able to confirm that the practitioners working within nuclear medicine services held an ARSAC certificate as required.

The justification and authorisation procedure also set out in detail the practical arrangements for the justification and authorisation of medical exposures.

[7] The Administration of Radioactive Substances Advisory Committee (ARSAC) advises the government on the certification of doctors and dentists who want to use radioactive medicinal products on people.

In addition, we saw examples of a small number of completed referral forms. In each case they had been correctly completed and signed by practitioners to show that the medical exposures had been justified and authorised as required.

The local justification and authorisation procedure included guidelines about how operators can authorise a list of specifically agreed investigations following criteria provided by the practitioner. Such a procedure is known as Delegated Authorisation Guidelines (DAG) as the responsibility for justification always remains with the practitioner. The purpose of this is to enable trained, competent healthcare professionals to provide a safe service to patients. We were told however that these arrangements were only ever used in an emergency situation within radiology; however the DAG was commonly used for lower dose non-imaging procedures.

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.

We found that there was a well established patient identification procedure in place in each of the three areas of nuclear medicine. The procedure clearly assisted staff to understand the vital importance of, and the agreed means of, identifying patients prior to an injection, or a therapeutic/diagnostic procedure. The procedure also clearly advised staff what to do if there were any discrepancies with the information held by nuclear services and the information that patients provided.

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.

The local *Pregnancy Procedure* documents described the process to be followed by referrers, practitioners and operators to identify potentially pregnant women (and those who may be breastfeeding) prior to medical exposures. This provided detailed instructions for staff to follow depending on the outcome of enquiries. It also referred to the need for referrers to advise women of child bearing age not to become pregnant following certain procedures (such as treatment for thyrotoxicosis), due to associated risks.

We saw that information for female patients was displayed in waiting and clinical areas, advising them to inform operators if they were, or may be, pregnant.

Staff who spoke with us were well aware of the correct procedure to follow.

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

We were informed that these types of exposures were not undertaken within nuclear medicine services unless undertaken with the prior agreement of the appropriate IR(ME)R Practitioner. This however should be made explicit within the Employers Procedures (as cited within Schedule 1 of the Regulations).

Improvement needed

The health board is required to inform HIW of the arrangements to be established within the local procedures regarding the specific use/circumstances of medico-legal exposures undertaken within nuclear medicine services.

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.

Overall, we witnessed a positive culture and attitude towards keeping doses ALARP and optimising exposures. The department had a list of suggested administered activities for paediatric imaging for a number of procedures as well as details of adjusting the activity for other forms of imaging. This meant that patients can be confident that they will receive care and treatment in a safe and effective way.

Conversations with staff however highlighted that the information generally requested ahead of the preparation of a radiopharmaceutical for adult patients did not include their date of birth as a unique identifier. This raised the possibility of patient error on occasions when two patients with the same name are required to attend for a nuclear imaging procedure. Conversation with a senior member of staff indicated that where this situation currently arises, the patients concerned are provided with appointments at different times of the day. There remains however the potential for patient error in this regard.

Improvement needed

The health board is required to review its current patient identification procedure ahead of the preparation of radiopharmaceuticals to further reduce the risk of patient error. The health board is also required to provide HIW with written evidence of this.

Discussions with staff revealed that radiopharmaceutical labels (for individual patients' syringes) currently only referred to local diagnostic reference levels (DRLs). This meant that the actual activity dispensed for the patient did not feature on the label. Whilst we were assured that the laboratory had a retrospective means of logging the amount actually dispensed for each patient, we advised that labelling in future should contain the dispensed activity as well as the DRL. Senior staff who spoke with us were willing to consider this matter for the purposes of clarity and as a means of increasing patient safety.

Improvement needed

The health board is required to provide HIW with details of how the labelling of radiopharmaceuticals is to be improved in the future.

Paediatrics

Regulation 7 (7) (b) states that the practitioner and operator shall pay special attention to medical exposures of children.

We held conversations with staff about how they calculated the activity of radiopharmaceutical to be administered to each child. As a result, we discovered that although staff placed an emphasis on getting details of a child's weight at the time when imaging was requested, it was not always possible to be provided with such information. In such instances, we were told that the activity would therefore be calculated based on the child's age using recognised growth (percentile) charts. While, not ideal, this arrangement provides some form of optimisation.

The employer's written protocols concerning justification and authorisation of exposures and quality assurance made reference to special attention being needed when optimising medical exposures for children.

We also saw clear protocols for medical exposures concerning children who receive services from nuclear medicine services.

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 draft employer's procedure 'exposure of patients to ionising radiation' included measures to ensure that all medical exposures were clinically evaluated.

Local procedures also set out the arrangements and the staff group that were entitled to assess and record the outcome of medical exposures. It became apparent through our conversations with senior departmental staff that there were individuals who were clinically evaluating exposures who, according to the current Safe Use of Ionising Radiation Policy, were not *formally* entitled by the employer to do so.

Clinical evaluation is an entitled operator function and we have already identified that improvement and clarity was needed regarding the entitlement of operators earlier in this report (see sub section *Entitlement*)

Medical Research Programmes

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

We were provided with a draft of the revised health board policy for the safe use of ionising radiation within which there was particular reference to the above. More specifically, the draft document stated that it was the policy of the nuclear medicine service to ensure that any research work undertaken was approved by the Local Research and Ethics Committee and also ARSAC.

The above arrangement was re-iterated and well described by senior staff who spoke with us at this inspection.

Clinical audits

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

We were provided with a sample of evidence which confirmed the stated rolling programme of audit across nuclear medicine services. We also saw the notes of one of the regular clinical audit meetings held, where a range of topics were discussed and agreed. This meant that the service had a suitable system in

place to focus on elements of service provision in order to identify areas for improvement, and that which was working well.

Conversations with a senior member of staff further confirmed that staff working within nuclear medicine services were encouraged to complete relevant audit activity within each twelve month period. This was directly linked to the health board's approach to individual appraisal and staff development.

Discussions with a variety of staff within the nuclear medicine service however revealed that a number had not been actively involved in, or informed about, the clinical audit process in place, to date.

Improvement needed

The health board is required to describe how it will ensure that clinical audit information and activity within nuclear medicine services is shared with all staff for the purpose of improving services to patients.

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.

We were able to confirm that experienced Medical Physics Experts (MPE's) were readily available to provide advice and support to staff regarding all aspects of diagnostic and therapeutic exposures conducted within nuclear medicine services. The MPE's also provided expertise in relation to the equipment in use within the nuclear medicine department.

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.

We were provided with a completed, up to date equipment inventory prior to the inspection. As a result, we were able to confirm that all equipment in use was subject to regular servicing/maintenance and calibration.

Management and Leadership

People can be confident that the service is safe, well managed and run in accordance with relevant professional standards. This is because we found strong and effective leadership being provided by senior departmental personnel. In addition, conversations with all levels of staff involved during the inspection revealed that there was a strong commitment to learn from the inspection and to make improvements to the service for the benefit of patients, as far as possible.

It was further evident from our conversations with all levels of staff involved during the inspection, that they were committed to providing patients with a safe and effective service. We also found staff to be extremely motivated, respectful and supportive of one another.

Governance arrangements

We found that there were governance systems in place to identify risks associated with the provision of nuclear medicine services and for quality monitoring and control. There was however a disconnect between the risks and issues described by staff in direct contact with patients, and those reported to, and understood, by senior management and the health board. This included the vital issue of 'entitlement' as required by IR(ME)R regulations, the development and dissemination of employers procedures and protocols and the lack of privacy for patients in relation to outdated, cramped clinical areas within the nuclear service environment. Details of the Improvements needed in respect of the above, can be found within the previous sections of this report entitled 'Quality of the Patient Experience and 'Compliance with IR(ME)R'.

Discussions with staff who had clear and significant management and clinical responsibilities revealed that they were not provided with any supernumerary time during their working week. This meant that they were unable to fully utilise their skills in supporting and leading staff as required. The health board may wish to consider this issue In the light of our inspection findings.

We saw a report that had been completed by the professional lead for quality, safety and patient experience. The report set out the actions taken by the health board in relation to the HIW annual (All-Wales) report associated with IR(ME)R regulations and showed the emphasis placed on compliance and service improvement.

Staff training

We selected and scrutinised the content of a sample of staff training records at this inspection. This included a completed induction workbook where it was very clear how the individual concerned had been supported in undergoing competence assessments and how they were 'signed off. This was prior to being identified on the relevant part of the staff matrix which showed which aspects of nuclear medicine services they were considered competent to undertake. The matrix however did not identify clarify the important issue of staff entitlement

Improvement needed

The health board is required to describe how it will ensure that staff training records include a record of entitlement rather than being 'signed off'.

All staff records seen provided sufficient evidence of relevant past and recent training. This meant that patients can be assured that they will receive services from professionals who are competent and confident in delivering nuclear medicine services.

Other issues

During our verbal feedback meetings we spoke with senior departmental staff and clinical board hospital managers. All were receptive to our comments with regard to future service delivery and demonstrated a strong commitment to learn from the inspection and make improvements as appropriate.

Next Steps

This inspection has resulted in the need for the service to complete an improvement plan to address the recommendations identified during this inspection. The details of this can be seen within Appendix A of this report.

The improvement plan should clearly state when and how the findings identified within nuclear medicine services at the University Hospital Wales will be addressed, including timescales. The health board should ensure that the findings from this inspection are not systemic across other departments/ units of the health board.

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: University Hospital of Wales

Department: Nuclear Medicine Services

Date of Inspection: 5 and 6 October 2016

Page Number	Improvement needed	Service Action	Responsible Officer	Timescale
	Quality of the Patient Experience			
10	The health board is required to provide HIW with a detailed description of how patients' privacy, dignity and confidentiality will be improved and maintained with the nuclear medicine injection and imaging areas respectively.	It is a key priority for the CD&T Clinical Board, and the UHB, to address the issues of patient dignity, privacy and confidentiality within this clinical area. The Health Board has received funding to provide replacement gamma cameras across the UHB. The three existing cameras in the Nuclear Medicine department will be replaced by two cameras which due to advances in technology are capable of providing greater productivity than the three previous cameras. This has allowed for	Clinical Board Director (MB) Clinical Board Director of Operations (MTe)	March 2017

Page Number	Improvement needed	Service Action	Responsible Officer	Timescale
		a complete redesign of the imaging area (see indicative plan attached as an example). The new design will optimise the space available and provide two separate imaging rooms which will give patients privacy, dignity and confidentiality during the imaging tests. The redesign also includes the injection area and addresses the concerns that have been identified during the inspection (see indicative plan attached).		
	Compliance with IR(ME)R			
13	The employer is required to review and revise the Safe Use of Ionising Radiation Safety Policy for the purposes of clarity and to reflect current service arrangements in respect of IR(ME)R.	The Safe Use of Ionising Radiation Policy has been replaced by the Ionising Radiation Risk Management Policy. This policy is supported by the Exposure of Patients to Ionising Radiation Procedure. This has been revised in light of the comments noted from the HIW inspection. The policy and procedure have been through consultation and will be submitted for ratification at the UHB Quality and Safety Committee in December 2016.	Head of Medical Physics (WE)	December 2016

Page Number	Improvement needed	Service Action	Responsible Officer	Timescale
13/14	The health board is required to provide HIW with details of how it will ensure that IR(ME)R policies and procedures are reviewed and updated within nuclear medicine services alongside other radiology services. The health board is also required to describe how it will ensure that information about all newly developed policies and procedures is communicated clearly between staff in direct contact with patients and the IR(ME)R Employer. This is in order to ensure compliance with IR(ME)R legislation.	A business case is in the final stage of development for the purchase of a quality/document management system (QMS e.g. Q-pulse) for Radiology/Medical Physics. This system will allow for electronic management and control of documents including prompts for review dates, prompts to read revised documents, records of sign-off etc. In the absence of the QMS a central folder has been set-up on the shared drive which is accessible to all staff across the Directorate. All newly developed policies and procedures are submitted for consultation via the Intranet for all staff to review and comment. The policies and procedures are ratified by the Radiation Protection Group and the UHB Quality, Safety and Experience committee which is the governance and assurance body of the UHB. It is through this mechanism that the Executive and the CEO, as the IR(ME)R Employer, receive information about newly developed policies and procedures. Staff will be informed of changes through the communication cascade and bespoke training	Director of QSE (SB) Professional Heads of Radiography (AB/LH) Head of Medical Physics (WE)	March 2017 Complete February 2017

Page Number	Improvement needed	Service Action	Responsible Officer	Timescale
		sessions. Staff will be required to sign to demonstrate that they have read the newly developed policies and procedures and this will form part of their staff training record. A training session describing the roles and responsibilities of duty holders is to be delivered as part of the training plan. The CEO as employer, and their delegated Executive, will receive written communication of their responsibilities under IR(ME)R.	Professional Heads of Radiography (AB/LH) Head of Medical Physics (WE) MTa/ RV-R/CO'C Director of QSE (SB)	February 2017 December 2016 December 2016
14	The health board is required to describe the action to be taken in order to consolidate IR(ME)R procedures to reduce duplication of information and offer further clarification to all relevant staff.	A Task and Finish group has been established to review all existing IR(ME)R documentation to reduce the number of procedures by consolidation of procedures and removal of duplication across Nuclear Medicine and Radiology. These revised documents will follow the procedure outlined above for training and communication.	Professional Heads of Radiography (LH/AB) Head of Medical Physics (WE)	February 2017

Page Number	Improvement needed	Service Action	Responsible Officer	Timescale
15/16	**Regulation 4(1) Schedule 1(b).** Specifically, the Employers procedures did not identify any individuals 'entitled' to act within nuclear medicine services either as a referrer, practitioner, or operator.	This matter/finding resulted in the issue of a HIW compliance letter. The health board has since responded within the timescale prescribed. As a result, HIW has received sufficient information about the prompt action taken by the health board, and that which is planned.		
18	The health board is required to inform HIW of the arrangements to be established within the local procedures regarding the specific use/circumstances of medico-legal exposures undertaken within nuclear medicine services.	There are very few circumstances under which nuclear medicine imaging examinations are requested or performed for medico-legal purposes, however any such requests will be individually justified and authorised by an IR(ME)R practitioner (that is by a Consultant Radiologist in Nuclear Medicine/Administration of Radioactive Substances Advisory Committee (ARSAC) licence holder). The process for medico-legal service provision has been clearly documented within the Employer Procedures. This will be disseminated to all staff groups as described above.	Radiology Quality Lead (RV-R)	Complete
19	The health board is required to review its current patient identification procedure ahead	Requesting of all radiopharmaceuticals (RMP) now requires the date of birth on the 'Daily RMP	Radiopharmacy Lead (MW)	Complete

Page Number	Improvement needed	Service Action	Responsible Officer	Timescale
	of the preparation of radiopharmaceuticals to further reduce the risk of patient error. The health board is also required to provide HIW with written evidence of this.	Request' sheet. The Radiopharmacy Hotlab are in the process of changing the labels to reflect this (as detailed below).		February 2017
19	The health board is required to provide HIW with details of how the labelling of radiopharmaceuticals is to be improved in the future.	The decay corrected activity at the time of proposed administration will be added to the radiopharmaceutical label. For example: Joe Bloggs DOB HDP Bone Scan DRL 400 MBq (at planned time of injection 12:00) Measured: 405 MBq at 12:00	Radiopharmacy Lead (MW)	Requires an update to the IT system, for completion February 2017
21	The health board is required to describe how it will ensure that clinical audit information and activity within nuclear medicine services is shared with all staff for the purpose of improving services to patients.	All clinical audit will be registered on the UHB clinical audit database through the 'clinical audit project proposal form'. The outcomes of the audit will be presented at the Radiology, Medical Physics and Clinical Engineering (RMPCE) Quality and Safety session (audit session) which is open to all staff (including Nuclear Medicine) to attend. The outcomes/actions will be reported	Clinical Audit lead (RK) Director of QSE (SB)	December 2016

Page Number	Improvement needed	Service Action	Responsible Officer	Timescale
		using the clinical audit assurance proforma. The proformas will be reviewed at the RMPCE Directorate Quality, Safety and Experience group who will be seeking assurance on implementation of improvement actions. These proformas are reviewed by the Clinical Board and the Clinical Audit team for the UHB and inform the Annual Report. All outcomes and action plans will be shared with staff through the communications cascade within the Directorate and will be centrally available for review.		
	Justification of individual medical exposures			
	No formal improvements identified	-		
	Management and leadership			
24	The health board is required to describe how it will ensure that staff training records include a record of entitlement rather than being 'signed off'.	The staff records will now include a copy of the formal letter of entitlement for IR(ME)R duty holders. The IR(ME)R matrix has been updated to define the scope of practice of individual duty holders and their date of entitlement.	Professional Heads of Radiography (AB/LH) Head of Medical Physics (WE) Clinical Director RMPCE (AW)	The IR(ME)R matrix has been updated as described. Letters of entitlement for all IR(ME)R duty

Page Number	Improvement needed	Service Action	Responsible Officer	Timescale
				holders will be issued by 30/11/16

Service Representative:

Name (print): **...Sue Bailey,**

Title: **.. Clinical Board Director for Quality, Safety and Patient Experience**

Date: **November 16th2016**