

**Ref: QS 19**

## **IONISING RADIATION SAFETY POLICY**

<b>Executive Sponsor &amp; Function:</b>	Executive Medical Director
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<b>Approved by:</b>	Quality, Safety & Performance Committee
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## EXECUTIVE SUMMARY

<b>Overview:</b>	<p>This Policy establishes a framework for controlling the use of ionising radiation and restricting exposure to persons within all Services provided by the Trust.</p> <p>The Trust will only adopt those practices that are consistent with the ALARP Principle. ALARP stands for As Low As Reasonably Practicable and the ALARP Principle is that the residual risk shall be as low as reasonably practicable.</p>
<b>Who is the policy intended for:</b>	All Trust Staff working with ionising radiation
<b>Key Messages included within the policy:</b>	<p>Identification of the legislation governing the use of Ionising Radiation</p> <p>Roles and responsibilities of key personnel in the management of radiation protection issues in terms of safety of staff, public and patients.</p> <p>Introduction and implementation of control measures to restrict exposure to ionising radiation.</p> <p>Roles and responsibilities of personnel holding entitlements to take responsibility for aspects of the medical exposure of individuals.</p> <p>Responsibility of all staff to work in accordance with the control measures and to report any non-compliances</p>
<b>PLEASE NOTE THIS IS ONLY A SUMMARY OF THE POLICY AND SHOULD BE READ IN CONJUNCTION WITH THE FULL POLICY DOCUMENT.</b>	

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## **1. INTRODUCTION**

- 1.1 This document establishes a framework for controlling the use of ionising radiation and restricting exposure to persons within all Services provided by the Velindre University NHS Trust.
- 1.2 The Trust will only adopt those practices that are consistent with the ALARP Principle. ALARP stands for As Low As Reasonably Practicable and the ALARP Principle is that the residual risk shall be as low as reasonably practicable.
- 1.3 Within the Trust ionising radiation is primarily employed in medical diagnosis and therapy, medical research, quality assurance, the irradiation of blood components and other related applications. These applications are confined to the Velindre Cancer Centre site and the Welsh Blood Service site at Llantrisant.
- 1.4 The use of ionising radiation within the UK is governed by the following statutory instruments and the Trust is committed to ensuring that the provisions of these regulations, together with the highest standards of best practice in ionising radiation safety, are fully implemented at all times:
  - The Ionising Radiations Regulations 2017 (IRR 17)
  - The Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R17)
  - Environmental Permitting Regulations 2016,(as amended 2018 and 2020)
  - The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (as amended 2011 and 2019) (CDG2009)
- 1.5 These regulations are supported by various approved codes of practices (ACoP) and guidance notes published by the enforcing agencies and other organisations (Health and Safety Executive, Department of Health and Social Care, Welsh Government, Natural Resources Wales, Public Health England (formerly Health Protection Agency or NRPB)) and professional bodies (Royal College of Radiologists, Institute of Physics and Engineering in Medicine, College of Radiographers, Society for Radiation Protection etc.).
- 1.6 The Trust has followed the general guidance on good practice with respect to the radiation protection issues and legislation as detailed in the document “Medical and Dental Guidance Notes” 2002 (MDGN) and subsequent versions published by the Institute of Physics and Engineering in Medicine (IPEM).
- 1.7 The specific details regarding the implementation of all radiation protection requirements and associated issues are contained within the individual departments’ Local Rules, Employers Procedures (IR(ME)R 17 documents) and other associated documents.
- 1.8 This Policy must be read in conjunction with other relevant Trust and Division

Policies, including those on Waste Management, Clinical Evaluation, Pregnancy Tests, etc.

## **2. RESPONSIBILITIES**

- 2.1 The Trust's Chief Executive carries the overall responsibility for implementing the requirements of the regulations governing work involving ionising radiation throughout all Services managed by the Trust.
- 2.2 To assist in discharging this responsibility the Chief Executive requires all Service Directors and Service Managers, whose services are involved in working with ionising radiation, to assume the general responsibility for ensuring that radiation safety arrangements throughout their Services are representative of best practice and satisfy the requirements of the regulations.
- 2.3 The Medical Director carries specific responsibilities relating to compliance with ionising radiations legislation as detailed within this Policy.
- 2.4 To assist the Service Directors and Service Managers in discharging these responsibilities the Chief Executive requires managers, whose departments are associated with work involving ionising radiation, to implement all necessary radiation protection arrangements outlined in this policy and as advised by the Radiation Protection Adviser (RPA), Radioactive Waste Adviser (RWA) and Medical Physics Expert (MPE).
- 2.5 It is the responsibility of Service Directors, Service Managers and Department Managers to keep themselves aware of radiation protection issues within their Service and consult with the Radiation Protection Supervisors (RPS), the RPA, RWA and the MPE over any issues that have radiation protection implications.
- 2.6 It is the responsibility of Service Directors, Service Managers and Department Managers where appropriate to ensure that radiation risk assessments are prepared in respect of all work undertaken with ionising radiation. Radiation risk assessments must be updated no less frequently than two-yearly to ensure that they remain relevant to the work undertaken. A radiation risk assessment must be undertaken;
  - a) in advance of a new practice being introduced,
  - b) whenever a significant change in the work activity takes place
- 2.7 It is the responsibility of Service Directors, Service Managers and Department Managers where appropriate to ensure that local rules for radiation protection are drawn up to govern all work with ionising radiation undertaken within the department or area within the department. Local rules for radiation protection must be periodically updated to ensure that they remain relevant to the work undertaken and take into account the findings of relevant radiation risk assessments.
- 2.8 It is the responsibility of Service Directors and Service Managers to ensure that all managers responsible for operational and estates facilities maintain

an awareness of potential problem areas associated with all work with ionising radiation. This may include drainage systems for departments using unsealed radioactive sources, roof spaces with restricted access above areas where work with ionising radiation is conducted, any known weaknesses in radiation shielding, prevailing security measures, etc.

- 2.9 All managers responsible for operational and estates facilities must, in consultation with the RPAs, RPSs and Department Managers, formulate systems to facilitate access by contractors, service engineers and other persons, into these problem areas. Such arrangements will involve facilities managers in the production and issuing of “Permits to Work” that detail the conditions under which work may be carried out as specified by the RPAs, the RPSs supervising the work with ionising radiation in the affected area and the department manager.
- 2.10 It is the responsibility of all Service Directors and Service Managers and managers responsible for departments where the medical exposure of individuals takes place to establish procedures in accordance with the IR(ME)R 17 regulations. These are listed in schedule 2 of the regulations.
- 2.11 Service Directors and Service Managers are required to ensure that sufficient funds are made available to department managers to implement all relevant radiation protection requirements and risk reduction measures associated with this policy or as advised by the RPA, RWA, RPS and the MPE.
- 2.12 Service Directors and Service Managers, Department Managers and managers responsible for operational and estates facilities are required to involve the RPA, RWA, RPS and MPE at the earliest opportunity in the planning for refurbishment or site development work, changes to existing services or the development of new services. They are further required, based on risk assessments, to make arrangements for the funding and implementation of all necessary radiation protection requirements as advised by the RPA, RWA and the MPE.
- 2.13 It is a requirement that all staff, working with ionising radiation, to;
- a. exercise reasonable care and follow the provisions of the Local Rules, IR(ME)R 17 Policies and Procedures, Natural Resources Wales Permits and other related working instructions
  - b. use, as instructed, any protective equipment and personal radiation dose meters provided, to report to the Trust’s Chief Executive via the line manager, and to inform the Radiation Protection Supervisor, of any defects in such equipment and dose meters
  - c. undertake any training specified by the Service Director, Service Manager or Department Manager.
  - d. report immediately to the Service Director, Service Manager or Department Manager if an incident occurs in which a member of staff or public is unintentionally exposed to radiation

- e. report immediately to the Service Director, Service Manager or Departmental Manager if they suspect that a radioactive source has been damaged, lost or stolen. Further advice on managing the incident should be sought from the Radiation Protection Adviser and Radioactive Waste Adviser.
  - f. not recklessly endanger the safety of others
  - g. report to the departmental manager when it is suspected that an “accidental or unintended exposure due either to equipment malfunction or failure of IR(ME)R 17 procedures has taken place.
- 2.14 All medical, radiotherapy, radiology, nuclear medicine, medical physics, clinical trials and nursing staff must pay particular attention to their roles and responsibilities as detailed in the IR(ME)R 17 Policies and Procedure.
- 2.15 It is a requirement that Velindre University NHS Trust holds the appropriate authorisations to work with ionising radiations. This includes the provisions for prior notification, registration and consent under IRR 17, the issue of permits for the use and disposal of radioactive materials under EPR16 and having an Employer licence to authorise the administration of radioactive medicinal products to patients under IR(ME)R17.
- 2.16 All medical practitioners who intend to administer radioactive medicinal products for diagnostic investigations or therapy applications must also have an appropriate licence granted under the IR(ME)R 17 by the Administration of Radioactive Substances Advisory Committee (ARSAC) on behalf of the Secretary of State. It is the responsibility of the Medical Director to ensure that all such medical practitioners are appropriately licensed in advance of commencement of a new procedure for the first time and continue to remain licensed.
- 2.17 It is the responsibility of departmental managers to ensure that periodic reviews are undertaken of individual’s compliance with the provisions of local rules for radiation protection made under the IRR 17. Reviews of procedures should also be undertaken no less frequently than annually to identify any necessary amendments. A record should be kept of these reviews.
- 2.18 Based on risk assessment the departmental managers will make arrangements to prioritise funding, to cover the cost of implementing unforeseen expenditure with respect to radiation safety, patient dosimetry and security issues from changes in the regulations, technological advances in radiation protection, as advised by the RPA, RPS and MPE.
- 2.19 Failure to follow the provisions of this policy and the local arrangements in place for radiation safety within a department or service may result in disciplinary action.

### **3. ORGANISATION**

- 3.1 The Chief Executive has established a Radiation Protection and Medical Exposures Strategic Group (RPMESG) and a Radiation Protection and Medical Exposures Operational Group (RPMOSG) to formulate appropriate policies, monitor the level of compliance in the various components of the Trust, identify areas of non-compliance and initiate remedial action, and to keep him/her informed of specific issues that require his attention. The terms of reference and membership of the RPMEOG and RPMESG are linked in Appendix 1.
- 3.2 The Chairperson of the RPMESG reports directly to the Chief Executive.

### **4. ADVICE and ASSISTANCE**

#### **4.1. Radiation Protection Adviser**

- 4.1.1 In accordance with the requirements of the Ionising Radiation Regulations 17 the Chief Executive will appoint in writing one or more individuals as the Trust's Radiation Protection Adviser (RPA). The appointment requirements and the scope of advice required under IRR 17 are given in Appendix 2.
- 4.1.2 Suitably experienced individuals who hold certificates issued by a body recognised by the Health and Safety Executive that enable them to act as radiation protection advisers are appointed as the Trust's RPAs.
- 4.1.3 Apart from fulfilling the function of an RPA as detailed in IRR 17 and the accompanying approved code of practice (ACoP), these individuals are required to be proactive in advising the Chief Executive, and those persons assigned specific tasks, on the general requirements for ionising radiation safety and the specific means of achieving compliance with the requirements of all regulations governing the use of ionising radiation in the UK.
- 4.1.4 The RPA is required to be proactive in keeping the Chief Executive, Chairperson of the RPMESG, Service Directors and Service Managers, Department Managers, RPSs and MPEs up to date with advances in radiation protection practice, pertinent guidance from professional bodies, Government Organisations and Enforcement Agencies, etc., and proposals to amend existing legislation or introduce new legislation associated with work involving ionising radiation as applicable to the health care environment.
- 4.1.5 In instances where such changes only affect the working practices within specific departments or across a Service the RPA will advise the Service Directors and Service Managers, department managers, RPSs and MPEs as to the appropriate means of implementing such changes.



- 4.1.6 In instances where such changes must be implemented on a Trust wide basis the Chairperson of the RPMESG with the RPA will convene a sub group (to include representatives from the services) to scrutinise the changes, formulate an action plan for the production of any new policy or the amendment of existing policies as required, the implementation of the changes into working practices and the production of all necessary documentation associated with the changes. The Chairperson of the RPMESG will be responsible for ensuring that changes in Trust-wide Policy documents (new, replacement or amended) will be developed and approved in accordance with the Trust's Policy for Policies.
- 4.1.7 The RPAs are ex officio members of the RPMESG and RPMEOG, and normally report to the Chief Executive through the committee structure. In instances where the RPAs believe that immediate action is required to remedy instances of non-compliance or potential noncompliance the RPAs are required to report directly to the Service Directors and Service Manager and if necessary to the Chief Executive.
- 4.1.8 The RPAs are required to;
- a. Respond to requests to advise and assist the Chief Executive and all Service Directors and Service Managers, department managers and staff in performing all duties and tasks associated with radiation protection issues
  - b. Maintain and make available to all Trust employees a comprehensive library of all relevant radiation protection documents. These will include Statutory Instruments, ACoP, Guidance Notes, advice and guidance provided by the government, its agencies and professional bodies, text books, advice and guidance provided by the European Community, advice and guidance provided by international organisations (International Commission of Radiological Protection), etc.
  - c. Advise and assist Service Directors and Service Managers, Department Managers and Radiation Protection Supervisors in all safety, security and transport issues (in consultation with a Dangerous Goods Safety Adviser, (DGSA), and a Radioactive Waste Adviser (RWA) where necessary) associated with the delivery, keeping, use and disposal of radioactive materials.
  - d. Advise and assist Divisional Directors, Department Managers, Clinical Staff and Radiation Protection Supervisors in all relevant patient safety issues.
  - e. Be involved in the tendering for an approved dosimetry service to provide radiation monitoring facilities in accordance with the requirements of IRR 17.

- f. In conjunction with department managers, formulate an effective personal radiation dose monitoring programme for staff working with ionising radiation reflecting the outcome of relevant radiation risk assessments.
- g. To assist Departmental Managers in assessing the results of the personal radiation dose monitoring programme and initiating all appropriate action. To interface, on behalf of the Chief Executive, with the approved dosimetry service, on matters relating to dose results and record keeping issues, as required by IRR 17.
- h. Ensure that, in instances where individuals may be required to be designated as “Classified Persons” under the requirements of IRR 17, the matter is referred to the head of the department concerned and that the Chairman of the RPMESG is notified.

*When designating classified workers the Chief Executive will assign the task of ensuring compliance for the medical surveillance of such employees as required under IRR 17, for classified persons, cases of overexposure, etc., to the Trust Medical Director.*

- i. Interface on behalf of the Chief Executive with individuals responsible for enforcing or monitoring compliance with legislation governing work with ionising radiation

#### **4.2. Radioactive Waste Adviser**

In accordance with the requirements of the Environmental Permitting Regulations 2016 (EPR16) the Chief Executive will appoint in writing one or more individuals as the Trust’s Radioactive Waste Adviser (RWA). The appointment requirements and the scope of advice required under IRR 17 are given in Appendix 3.

Suitably experienced individuals who hold certificates issued by a body recognised by the Environmental Agencies that enable them to act as RWAs are appointed as the Trust’s RWAs.

The RWAs are required to;

- a. Make all necessary arrangements for the permitting of radioactive substances and of radioactive waste for each of the Trusts sites under the requirements of the EPR.
- b. Set individual department limits for the holding of radioactive substances on each of the Trusts sites and monitor compliance with each of the sites’ EPR permits.
- c. Set individual department limits for the accumulation and disposal of radioactive waste from Trust sites, co-ordinate the disposal records from all departments on each of the Trust’s sites and monitor overall compliance with each of the sites’ EPR permits.

- d. Provide advice on and undertake compliance audits with respect to the requirements of the EPR regulations including the management of sealed sources (including High-activity Sealed Radioactive Sources)
- e. Liaise with Natural Resources Wales regarding regulatory matters including (but not limited to) pollution inventory and other submissions.
- f. Undertake environmental impact assessments regarding the discharges of radioactive wastes within the Trust.
- g. Produce a Trust statement of the application of Best Available Techniques (BAT) within the Trust to minimise the radiological impact of radioactive discharges on the environment.

#### **4.3. Radiation Protection Supervisor**

- 4.3.1 The Radiation Protection Service will arrange for departmental managers' nominated Radiation Protection Supervisors to be appointed in writing by the Medical Director (delegated from the Chief Executive) in accordance with the requirements of IRR 17. The suitability of the individual for this role will be assessed by the departmental manager with input from the RPA who will advise on suitable training schemes for the RPS. Managers must draw up a role specification for the RPS that details all of the tasks delegated to him or her by the manager and this can either be issued to the individual or incorporated into the individual's Job Description.
- 4.3.2 Under IRR 17, the only duty assigned to the RPS is to supervise the work undertaken with ionising radiation to ensure that this is carried out in accordance with the Local Rules. Other tasks, associated with the day to day practical aspects and or management of radiation protection issues, may be assigned to the RPS by the department managers. A template role description for the Radiation Protection Supervisor is included in Appendix 5, including both the supervision duty and other duties which department managers may wish to delegate to them in the context of a broader supervisory role.
- 4.3.3 Department managers will consult with the RPA over documents (copies of legislation, ACoP, Guidance Notes, etc) to be provided to the RPS to assist in discharging the duties, and as reference documents for all staff working within the department. The manager will ensure that all such documents are purchased and available to the RPS.
- 4.3.4 All RPSs are automatically members of the RPMEOG.

#### **4.4. Medical Physics Expert**

- 4.4.1 It is a requirement of IR(ME)R 17 that a Medical Physics Expert (MPE) is involved as appropriate in providing expert advice for every medical exposure.

- a. There shall be at least one MPE available to be involved in standardised therapeutic nuclear medicine practices and in diagnostic nuclear medicine practices. In non-standard radionuclide therapy the MPE will be closely involved in each procedure.
- b. There shall be at least one MPE closely involved in every radiotherapy exposure.
- c. In diagnostic radiology, MPEs shall be available to be involved as appropriate for consultation and optimisation and to be involved with high dose interventional radiology and high dose computed tomography.

4.4.2 The MPE must contribute to the matters detailed in appendix 4.

4.4.3 The Head of Radiation Services, with advice from the heads of nuclear medicine, radiation protection and radiotherapy physics, is responsible for advising the Chief Executive on making appropriate and sufficient MPE appointments.

4.4.4 All MPEs appointed on behalf of the Employer must hold certification as MPEs in their specialty by a body recognised by the Department of Health and Social Care that enables them to act in that capacity.

#### **4.5. Qualified Person**

4.5.1 The Head of the Radiation Protection Service is responsible for appointing suitably qualified individual(s) to act as the Qualified Person for the purposes of testing radiation protection instruments in accordance with IRR 17.

### **5. DUTY HOLDERS under IR(ME)R 17**

The mechanism for entitlement of operators and practitioners is considered in section 6.2.

#### **5.1 Employer:**

In the context of IR(ME)R 17, the employer is considered to be Velindre University NHS Trust. If the Trust contracts a third party to provide services then the Trust will be the employer as regards the operators for the purpose of the Regulations, but the third party is the employer of the operators for employment law purposes.

Equipment ownership has no impact on the employer responsibilities under IR(ME)R 17.

#### **5.2 Operator:**

The operator is any person who is entitled, in accordance with departmental

written procedures, to undertake the practical aspects of a medical exposure and is adequately trained. Operators may include radiographers, medical practitioners, clinical scientists/medical physicists, clinical technologist/medical physics technicians and nurses.

### **5.3 Practitioner:**

The practitioner is a registered medical practitioner, dental practitioner or other health professional who is entitled in accordance with the Trust's written procedures to take responsibility for an individual medical exposure. The primary responsibility of the practitioner is to justify medical exposures.

In some cases the practitioner may also undertake practical aspects of an exposure and so become an operator with regard to these specific functions.

The practitioner in Nuclear Medicine must hold an ARSAC licence specifying the range of radionuclides and pharmaceuticals that they may prescribe.

Arrangements may be put in place for an individual to authorise justification of the medical exposure on behalf of the practitioner under a Delegated Authorisation Guideline (DAG) drawn up by the practitioner. Under such an arrangement, the individual acts as IR(ME)R 17 operator for this function. This arrangement may also apply to justification of exposures involving radionuclides and pharmaceuticals.

Arrangements must also be put in place for the justification of exposures to carers and comforters.

### **5.4 Referrer:**

The referrer is a registered medical practitioner, dental practitioner or other health professional who is entitled in accordance with departmental written procedures to refer individuals to a practitioner for medical exposure.

## **6. ARRANGEMENTS FOR COMPLIANCE WITH IR(ME)R 17**

### **6.1 Written Procedures**

- a. Employer's standard operating procedures, covering the areas specified in schedule 2 of IR(ME)R 17 and specific to individual departments where medical exposures are undertaken, must be formulated and maintained within the work instructions and local policies and procedures of those departments. A listing is maintained by each department summarising, as a minimum, the local versions of the fourteen standard operating procedures specified. Further standard operating procedures may be added as required, but it should be borne in mind that such procedures will then be legally binding upon the organisation and its employees. The MPE must be involved in the formulation and maintenance of these procedures.

- b. Clinical protocols for all standard procedures involving medical exposures are maintained within the work instructions of each department and are made available for use by all staff.
- c. Where patient referrals under IR(ME)R 17 are made, referral procedures are part of each department's IR(ME)R 17 standard operating procedures and permit the referral of patients for diagnostic radiological/nuclear medicine investigations and therapy applications. Appropriate instruction regarding the referral process must be given to all relevant staff.
- d. All new IR(ME)R 17 policies and standard operating procedures must be submitted to the RPMOSG for ratification and formal adoption on behalf of the Trust. Only those documents that have been confirmed as "suitable for purpose" will be ratified.
- e. Quality Assurance programmes must be introduced, in consultation with the MPEs, to assess the effectiveness of policies and procedures.
- f. All IR(ME)R 17 Policies, Procedures, Inventory, Protocols (Standard Operating Procedures), Diagnostic Reference Levels and all written arrangements concerning IR(ME)R 17 must be reviewed no less frequently than once every two years or whenever there are changes of equipment or working practices.
- g. Whenever departments' activities overlap the managers must liaise to ensure compatibility between both departments IR(ME)R 17 Policies and Procedures. Formal written procedures must be established between these departments to detail all agreed arrangements.

## **6.2 Entitlement of Practitioners and Operators**

- a. The Medical Director has delegated authority from the Chief Executive to entitle duty holders including Referrers, Operators and Practitioners. The Medical Director further delegates authority to the departmental managers or service leads to entitle duty holders for specific IR(ME)R 17 functions in accordance with the flow chart in appendix 6. Entitlement of RPAs, RWAs, MPEs and Medical Director is by letter from the Chief Executive. Further cascaded entitlement is undertaken according to local procedure.
- b. It is the responsibility of departmental managers or service leads to ensure that only individuals formally identified and entitled by the Employer can undertake Practitioner and/or Operator roles.
- c. Before any individual is formally entitled to act as Practitioner or Operator, arrangements must be made to assess their experience and to determine what training must be undertaken before entitlement can take place. If an individual is entitled to undertake an IR(ME)R role by another organisation, this does not lead to automatic entitlement by Velindre University NHS Trust to undertake a similar role. Any relevant certification held by an individual (e.g. the holding of a licence issued by ARSAC) may

be taken into consideration in establishing their competence to be entitled to undertake an IR(ME)R role. Systems must be in place to provide new staff with the necessary training and expertise to permit them to act as practitioners or operators.

- d. Entitlement should only be undertaken by authorised individuals as per delegation pathways from the Chief Executive and reflect prevailing professional guidance. The entitlement must follow an auditable pathway and documentation kept to show
  - i) the date on which entitlement took place
  - ii) the task and scope of practice for which entitlement has taken place
  - iii) the identity of the person undertaking the entitlement and their delegated authority

Details of this process are recorded in the procedures of each department. The individual being entitled shall receive formal notification and details of the scope of the entitlement

- e. A list will be held by each department of its practitioners and operators, detailing the specific functions for which they are entitled to act. This list forms part of the IR(ME)R documentation and it must be made readily available to all departmental staff. This list must be updated whenever there are changes in personnel.
- f. Individual procedures are in place in each department detailing how entitlement of Practitioners and Operators takes place within the framework in Appendix 6.

### **6.3 Referrers**

- a. Entitlement of Referrers is via the process described in 6.2.a.
- b. It is the responsibility of departmental managers or service leads to ensure that only individuals formally identified and entitled by the Employer can undertake Referrer roles.
- c. Individuals entitled to refer patients must be identified and their names recorded on the divisional list. This list forms part of the IR(ME)R 17 documentation and it must be made available to all departments. The list must be updated whenever there are changes in personnel. It is the responsibility of the Director of Cancer Services to ensure that administrative arrangements are in place to enable all those justifying a medical exposure or authorising a medical exposure on behalf of a practitioner to have at their disposal a current list of entitled IR(ME)R 17 referrers.
- d. The Employer must establish referral criteria for medical exposures, reflecting prevailing national professional guidance and these are referenced in departmental documentation.

- e. Systems must be in place to provide new staff with the necessary training and expertise to permit them to act as referrers. Department managers must ensure that appropriate instruction regarding the referral process must be given to all relevant staff.
- f. Medical staff wishing to refer patients for radiological/nuclear medicine investigations must be given instruction on completing request forms and information on referral criteria during their induction. Referrals from General Practitioners for radiological imaging procedures are accepted according to radiology department policies.
- g. Policies/procedures are required to enable referrals for diagnostic radiological/nuclear medicine investigations from non-medically qualified registered health care professionals where this is to be undertaken. In all such instances referral guidelines and the scope of referral must be agreed in consultation with the senior radiologist and department manager.

#### **6.4 Practitioners and Operators**

- a. The IR(ME)R 17 Practitioner and Operator have a legal duty to comply with the procedures established by the Employer.
- b. All staff acting as practitioners and operators must be aware of and conversant with the IR(ME)R 17 policies, procedures, protocols and the relevant Standard Operating Procedures. This may also include delegated authorisation guidelines issued by the practitioner.
- c. Systems must be introduced to monitor and audit compliance with the IR(ME)R 17 Policies and Procedures and Standard Operating Procedures and the Results of the Audits will be submitted to the RPMEOG for comment and where necessary advice on remedial action.

#### **6.5 Optimisation of Exposure**

- a. Arrangements must be made, in consultation with the MPE, to implement a dose optimisation strategy for all radiological practices and introduce and monitor Diagnostic Reference Levels (DRL), as required by IR(ME)R 17, for all standard radiological investigations and standard nuclear medicine procedures.
- b. Quality Assurance programmes must be introduced, in consultation with the MPEs, to assess the effectiveness of equipment.
- c. All IR(ME)R Policies, Procedures, Inventory, Protocols (Standard Operating Procedures), Diagnostic Reference Levels and all written arrangements concerning IR(ME)R 17 must be reviewed annually or whenever there are changes of equipment or working practices.



## **6.6 Administration of Radioactive Substances to Patients**

- a. In departments employing sealed and unsealed radioactive sources for diagnostic or therapeutic purposes, cross reference with the Employer licence and practitioner ARSAC licence must be undertaken before new radioactive medical products are introduced into clinical practice. Where the licence(s) does not cover such products the medical practitioner and/or Employer must obtain an endorsement to their licence to cover this new work in accordance with the requirements of IR(ME)R 17.
- b. Research ARSAC licence applications are required for clinical trial procedures if they are not covered by existing licences.
- c. Arrangements must be in place that medical practitioners are reminded, well in advance of the date of expiry of their licence, of the need to renew their licence issued under the IR(ME)R 17 or certificates under previous legislation. At present, an automatic reminder is generated by the ARSAC secretariat in advance of expiry of current certificates or licences.

## **7. ARRANGEMENTS FOR COMPLIANCE WITH IRR 17**

- 7.1 Radiation risk assessments must include all reasonably foreseeable fault or accident situations and a consideration of the radiation dose received by relevant individuals under such circumstances. This should include the patient under examination, other patients, staff and public. They will consider the need for and type of personal radiation dosimetry to be undertaken and whether classified radiation worker status is required. An RPA must be consulted in the preparation of any radiation risk assessment.
- 7.2 The Local Rules are intended to protect staff, the general public and the environment and they will specify general radiation protection requirements and specific requirements identified in IRR 17. The RPMEOG must be kept aware via RPS reports of when local rules are reviewed and the broad extent of any revisions made.
- 7.3 Systems must be in place to ensure that all new or modified installations that are used in connection with ionising radiation(s) are subject to a critical examination under IRR 17 prior to first use.
- 7.4 The Local Rules identify potential hazards and provide measures that enable staff to work safely and arrangements must be in place to ensure that all staff working within the department are made aware of all issues detailed in the Local Rules and given training in their implementation and observance.
- 7.5 The service manager is responsible for ensuring that all staff are adequately supervised. The RPS is responsible for ensuring that the provisions of the local rules for radiation protection are followed. The RPS must report any noncompliance with the Local Rules to the department manager who, in consultation with the RPA, will investigate the reasons for the noncompliance and put in place measures to ensure that such breaches are not repeated. In instances where breaches are identified by the RPA as

serious or in instances where breaches cannot be resolved within the department the department manager will seek a solution by referring the issue to the Service Directors and Service Manager and the chairman of the Radiation Protection and Medical Exposures Operational Group.

- 7.6 Arrangements must be in place to ensure that Local Rules are reviewed at a frequency advised by the RPA and that radiation risk assessments are reviewed no less frequently than every two years or whenever there are changes to equipment or working practices.
- 7.7 A handover document must be used when transferring managerial control of a radiation controlled area between parties from within VUNHST and between VUNHST employees and those employed by other parties.
- 7.8 Systems must be in place to communicate with the employer of any Outside Worker who needs to enter a designated area. Outside Workers are defined as any party not employed by VUNHST who need to enter a radiation controlled or supervised area which has been designated as such by VUNHST in order to provide a service. This communication must include sufficient information to enable the employer to comply with their obligations under IRR 17 and must, in all but exceptional cases, happen before the outside worker is required to enter the designated area.
- 7.9 Systems must be implemented to ensure that any radiation protection instruments used to demonstrate compliance with IRR 17 are fit for use and are sent for testing before first use, for annual testing, or for testing after repair, to the Qualified Person. Before purchasing any new or replacement instruments the department manager will seek the advice of the RPA and Qualified Person with respect to the selection of the most appropriate instrument.

## **8. ARRANGEMENTS for RADIOACTIVE SUBSTANCES**

- 8.1 In departments where unsealed radioactive materials are employed (Nuclear Medicine and radioisotope cubicles) detailed instructions must be included in or referenced by the Local Rules regarding the transportation, delivery, storage, security, use, and disposal of the radioactive materials. Additional instructions will be required with respect to hygiene, the care of patients, monitoring for the presence of radioactive materials and the selection and testing of radiation protection instruments.
- 8.2 In departments where sealed radioactive sources are employed (Nuclear Medicine, Research, Radiotherapy, Brachytherapy, Welsh Blood Service and RPS Cardiff) detailed instructions must be included in or referenced by the Local Rules regarding the transportation, delivery, storage, security, use, leak testing and ultimate disposal or transfer of the radioactive materials.
- 8.3 For security reasons suitable procedures must be in place to ensure that all necessary signage and notices do not advertise the details of radioactive materials to the general public.
- 8.4 The department manager will ensure that detailed records are kept of the purchase, storage, use and disposal of all radioactive materials together with

quantitative records of the disposal of sealed and unsealed radioactive materials. They will make arrangements to return copies of the disposal records to the RWA on a regular basis as determined by the RWA.

- 8.5 Control measures must be introduced to check at appropriate intervals the presence of all sources on a regular basis or whenever used and to monitor that activities detailed in the EPR 2016 permits and associated department limits are not breached. An annual audit should be undertaken to ensure that this process is taking place. With respect to the disposal of sealed or unsealed radioactive materials, monitoring to prevent breaches will be based on the department limits assigned by the RWA.

## **9. GENERAL ARRANGEMENTS for RADIATION PROTECTION**

- 9.1 Before any individual is permitted to work with ionising radiation, arrangements must be made to assess the individual's training requirements and implement means of delivering any required training (as identified by the department manager with support from the MPE and RPA if required), monitoring the training programme and assessing the individual's performance.
- 9.2 Department managers must discuss any new proposed or planned uses of ionising radiation with the RPA and MPE at the planning stage.
- 9.3 Department Managers must ensure that any member of the department staff who has been allocated duties associated with ionising radiation is given written instructions regarding the role involvement: e.g. formulating and documenting Local Rules, quality assurance activities, IR(ME)R 17 policies and procedures; performing specific duties under the provisions of these documents; or performing other tasks directly related to or loosely associated with the Trust's radiation protection policy or general radiation protection matters. The manager must ensure that all such individuals are given adequate resources and protected time in which to carry out the assigned tasks.
- 9.4 Systems must be in place to keep all staff aware of their general responsibilities with regard to radiation protection (2.10) and keep all staff aware of the need to report any incident or near misses involving ionising radiation that may have resulted in the uncontrolled release of radioactive materials or the unintended exposure of patients, staff or other persons.
- 9.5 All incidents, involving unintended exposures of patients or staff, significant spillages of unsealed radioactive materials, theft/loss/damage of radioactive materials, breaches of disposal limits etc., must be investigated by the department manager in consultation with the RPS, the RPA/RWA and relevant MPE where appropriate. The department manager must ensure that a written report is produced following the investigation to detail the circumstances, findings and remedial measures required to reduce the possibility of such incidents occurring in the future. The MPE will be involved for the purposes of estimating doses to patients and the necessity for reporting such incidents to government agencies. The RPA may also need to be involved in to assess the risks associated with the incident and to provide any further advice. The following examples are not exhaustive;

- Incidents of significant accidental or unintended exposure (SAUE) of patients, whether due to breakdown in procedures or equipment fault,,are reportable under IR(ME)R 17 to the Healthcare Inspectorate Wales (HIW). It should be noted that such incidents may also be regarded as clinically significant (CSAUE), as defined by relevant professional guidance.
- Incidents involving over-exposure of staff or public are reportable under IRR 17 to HSE.
- Incidents involving radioactive materials are reportable to Natural Resources Wales under the Environmental Permitting Regulations 2016 and the Health and Safety Executive under IRR 17.
- Loss or theft of radioactive materials must also be reported to the police.

All such incidents must be reported following the Trusts normal incident reporting procedure.

- 9.6 The Divisional Directors shall ensure that adequate arrangements are in place for reporting radiation incidents, obtaining advice from Radiation Protection Advisers and Medical Physics Experts, and making external reports to enforcing agencies.
- 9.7 Disposal of radiological equipment shall be undertaken with advice from the Specialist Estates Services branch of NHS Wales Shared Services Partnership (NWSSP).

**Appendix 1 – Radiation Protection and Medical Exposures Strategic  
Group (RPMESG) and Radiation Protection and Medical Exposures  
Operational Group (RPMOSG)**

**The Terms of Reference are available via the following Link:**

**[https://nhswales365.sharepoint.com/sites/VEL\\_Intranet/SitePages/Quality-and-Safety-Policies-\(Q&S\).aspx](https://nhswales365.sharepoint.com/sites/VEL_Intranet/SitePages/Quality-and-Safety-Policies-(Q&S).aspx)**

## **Appendix 2**

### **RPA appointment requirements and Scope of Advice**

#### **RPA Appointment**

Under the requirements of the Ionising Radiation Regulations 2017 (IRR 17) radiation employers are required to appoint and consult with a Radiation Protection Adviser (RPA). The Health and Safety Executive requires that the individuals wishing to act as an RPA must demonstrate that they meet the HSE's criteria of competence and that employers select from such RPAs one or more who have suitable knowledge and experience for the employers type of work [Regulation 14 and Paragraphs 257 to 270 of the Approved Code of Practice (ACOP)].

If more than one RPA is appointed, duties will be shared between them. The scope of the advice that will be provided by these individuals will include the items for statutory consultation listed in IRR 17, Schedule 4 and the issues listed in the draft Approved Code of Practice, paragraph 263 as detailed below.

#### **Scope of Advice.**

In general the RPA will be required to advise on the measures to be taken to comply with IRR 17, together with other relevant legislation on use of ionising radiation. The scope of the advice required will include:

#### **IRR 17, Schedule 4 RPA must be consulted on the following:-**

1. Implementation of requirements as to controlled and supervised areas.
2. The prior examination of plans for installations and the acceptance into service of new or modified sources of ionising radiation in relation to any engineering controls, design features, safety features and warning devices provided to restrict exposure to ionising radiation.
3. The regular calibration of equipment provided for monitoring levels of ionising radiation and the regular checking that such equipment is serviceable and correctly used.
4. The periodic examination and testing of engineering controls, design features, safety features and warning devices and regular checking of systems of work provided to restrict exposure to ionising radiation.

#### **Approved Code of Practice (ACOP), Paragraph 263**

The advice of the RPA should cover, where relevant, but not limited to, the following:

- (a) Optimisation and establishment of appropriate dose constraints;

- (b) Plans for new installations and the acceptance into service of new or modified radiation sources in relation to any engineering controls, design features, safety features and warning devices relevant to radiation protection;
- (c) Categorisation of controlled and supervised areas;
- (d) Classification of workers;
- (e) Outside workers;
- (f) PPE;
- (g) Workplace and individual; monitoring programmes for exposed workers;
- (h) Investigation and analysis of accidents and incidents and appropriate remedial actions;
- (i) Employment conditions for pregnant and breastfeeding workers;
- (j) Preparation of appropriate documentation such as prior risk assessments and written procedures.

In addition to the specific matters set out in Schedule 4, radiation employers are required to consult a Radiation Protection Adviser where advice is necessary for the observance of the Regulations.

Additional guidance on these matters is given in ACOP paragraphs 257 to 270.

## **Appendix 3**

### **Radioactive Waste Adviser**

The Basic Safety Standards Directive (BSSD)<sup>1</sup> requires employers to appoint 'qualified experts' to advise them about work with radioactivity that may affect people and the environment. Parts of the BSSD place specific requirements on permit holders and require qualified experts to be involved in the discharge of specific duties. The BSSD also requires that arrangements are in place to recognise the capacity of such qualified experts.

The UK environment agencies have issued a joint statement on radioactive waste advisers<sup>2</sup> which includes requirements in terms of appointment of individuals in this capacity and arrangements for their accreditation.

#### Recognition of Radioactive Waste Adviser

To be recognised formally in this capacity, an individual must be able to demonstrate that they are competent in radioactive waste management and environmental radiation protection. A syllabus has been developed detailing the competences required of a radioactive waste adviser. An approvals board established by the UK environment agencies is charged with assessing the competence of radioactive waste advisers and of maintaining a register.

The environment agencies consider a suitable Radioactive Waste Adviser (or Corporate Radioactive Waste Adviser) to have "the specific knowledge, experience and competence required for giving advice on the particular radioactive waste management and environmental radiation protection issues for which the permit holder is making the appointment".

#### Appointment of Radioactive Waste Adviser

A permit holder (Employer) must appoint suitable Radioactive Waste Advisers if the permit is for the accumulation or disposal of radioactive waste. The permit holder is responsible for ensuring that any Radioactive Waste Adviser appointed is "suitable" to give relevant advice on the permit holder's business. This appointment must be in writing and should include the scope of advice which the Radioactive Waste Adviser is required to give.

The permit holder is required to consult a Radioactive Waste Adviser on the following matters and will have due regard to the advice provided by the Radioactive Waste Adviser:

- ☐ Achieving and maintaining an optimal level of protection of the environment and the population
- ☐ Checking the effectiveness of technical devices for protecting the environment and the population



- ☐ Acceptance into service, from the point of view of surveillance of radiation protection, or equipment and procedures for measuring and assessing, as appropriate, exposure and radioactive contamination of the environment and the population
- ☐ Regular calibration of measuring instruments and regular checking that they are serviceable and correctly used.

Staff of the Radiation Protection Service holding accreditation act as Radioactive Waste Adviser and are formally appointed by the permit holder (Employer).

1. Council Directive 96/29/EURATOM 1996 (laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation).
2. Environment Agencies' Statement on Radioactive Waste Advisers, RWA-S-01 v 1.0 7 May 2011

## **Appendix 4**

### **Medical Physics Expert**

A medical physics expert must contribute to the following matters:

- (a) Optimisation of the radiation protection of patients and other individuals subject to exposures, including the application and use of diagnostic reference levels.
- (b) The definition and performance of quality assurance of the equipment
- (c) Acceptance testing of equipment
- (d) The preparation of technical specifications for equipment and installation design
- (e) The surveillance of the medical radiological installations
- (f) The analysis of events involving or potentially involving accidental or unintended exposures
- (g) The selection of equipment required to perform radiation protection measurements
- (h) The training of practitioner and other staff in relevant aspects of radiation protection
- (i) The provision of advice to an employer relating to compliance with these regulations.

## **Appendix 5**

### **Radiation Protection Supervisor role specification**

Base Location

Department

Accountable to

Reports to

Liaises with                      Radiation Protection Adviser

**Job Summary:** The Radiation Protection Supervisor (RPS) will play a supervisory role in assisting the Trust to comply with the requirements of the Ionising Radiation Regulations 2017 (IRR 17). The RPS will be directly involved in the work with ionising radiation and will exercise close supervision to ensure that the work is done in accordance with Local Rules.

The only responsibility of the Radiation Protection Supervisor specified under IRR 17 is to supervise the work with ionising radiations. Overall responsibility for radiation protection matters lies with the departmental manager. However, additional duties may be delegated to the RPS as detailed below.

### **MAIN DUTIES AND RESPONSIBILITIES**

#### **1.     Restriction of Exposure**

To observe, from time to time, all procedures involving ionising radiation and to and to keep a record of this process for audit purposes. To issue instructions necessary to maintain radiation doses as low as reasonably practicable.

#### **2.     Notification of work and certain occurrences**

To notify, in writing, the responsible manager:

- (i)    of any proposed changes in, or additions to, work activity
- (ii)   immediately of any damage to a radioactive source, spillage, loss or suspected loss of radioactive substances.
- (iii)   of any change of equipment, usage or conditions, which might affect radiological safety; of any monitoring instrument used to demonstrate compliance with the Regulations which has not been calibrated to acceptable national standards.
- (iv)   immediately of any incident involving equipment malfunction resulting in patient exposure much greater than intended or significantly lower than

those considered proportionate (in radiotherapy).

- (v) immediately of any incident or suspected incident involving staff exposure much greater than intended.

### **3. Local Rules and Systems of Work**

- (i) To assist in the writing of Local Rules and Systems of Work and to ensure that these are adhered to.

### **4. Information, Instruction and Training**

- (i) To attend courses and receive training as recommended by the RPA.
- (ii) To promulgate local Rules and Systems of Work to ensure that necessary safety information and guidance is given to all staff, outside contractors and any other persons who enter controlled or supervised radiation areas.

### **5. Additional Duties**

- (i) Dependent on the work carried out in the Department the responsible manager may delegate to the RPS specific tasks to comply with IRR 17 These requirements must be listed and attached to both this Role Specification and to the Local Rules.
- (ii) The RPS must provide a six-monthly report to the Radiation Protection and Medical Exposures Operational Group.

### **NOTE:**

The duties and responsibilities outlined in this role specification should be read in conjunction with the following where relevant to the work undertaken:

- (a) The Ionising Radiations Regulations 2017
- (b) Working with ionising radiation-draft Approved Code of Practice and Guidance 2017
- (c) The Ionising Radiation (Medical Exposure) Regulations 2017
- (d) The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 Amended 2011
- (e) The Environmental Permitting Regulations 2016 and subsequent versions.

## Appendix 6

### IR(ME)R 17 Entitlement Responsibilities

