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Exposure of Patients to Ionising Radiation Procedure

Introduction and Aim

The Cardiff and Vale University Health Board (UHB) uses ionising radiation for a variety of clinical and other applications and this use presents a potential hazard to a range of people including patients, staff and members of the public.

The UHB has an Ionising Radiation Risk Management Policy the aim of which is to ensure that we manage the use of ionising radiation in such a way as to minimise adverse effects on people, provided that this is consistent with any desired clinical or related outcome.

This Procedure supports the Policy and translates its aim into practical implementation measures as regards the safety of patients.

Objectives

We will achieve our aim by:

- Providing a robust framework for the management and safe use of ionising radiation
- Ensuring that management of the use of ionising radiation is safe and compliant with current legislation, standards and guidance in order to protect the UHB, patients, staff and members of the public
- Ensuring that managers and staff are aware of their roles in the safe use of ionising radiation
- Keeping radiation doses and dose rates as low as reasonably practicable (ALARP)
- Restricting the use of ionising radiation to practices that are justified and ensure that each intentional exposure of a human subject is individually justified
- Optimising exposure to ionising radiation in order to reduce radiation dose, provided that this is consistent with any desired clinical or related outcome
- Managing radiation equipment in accordance with accepted best practice guidelines and manufacturer recommendations
- Entitling duty holders associated with the exposure of human subjects to ionising radiation
- Demonstrating compliance through record keeping and audit
- Appointing Radiation Protection Advisers, Medical Physics Experts and Radiation Protection Supervisors

Scope

This procedure applies to all of our staff in all locations including those with honorary contracts.

Equality Impact Assessment	An Equality Impact Assessment (EqIA) has not been completed as this procedure is a requirement to meet current legislation.
Health Impact Assessment	*A Health Impact Assessment (HIA) has not been completed*
Documents to read alongside this Procedure	• Ionising Radiation Risk Management Policy • Exposure of Staff and Members of the Public to Ionising Radiation Procedure • Health and Safety Policy • Medical Equipment Management Policy • Risk Management Policy • Radioactive Substances Risk Management Policy • Radioactive Substances Risk Management Procedure
Approved by	Radiation Protection Group
Accountable Executive or Clinical Board Director	Executive Director of Therapies and Health Science
Author(s)	Medical Physics Experts, Clinical Scientist, Director of M.P.C.E.

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.

Summary of reviews/amendments

Version Number	Date of Review Approved	Date Published	Summary of Amendments
1	13/12/2016	04/01/2017	New Document
2	25/07/2019	04/09/2019	Amendment
3			Legislation updated

Contents

1 Definition of terms

Absorbed dose
The fundamental type of radiation dose defined as the energy deposited by ionising radiation in unit mass of irradiated material.

Alpha radiation
Particulate ionising radiation in the form of helium-4 nuclei (a combination of two protons and two neutrons) emitted by nuclei during radioactive decay.

Beta radiation
Particulate ionising radiation in the form of electrons or positrons emitted by nuclei during radioactive decay.

Deterministic effect
An effect of ionising radiation on living tissue in which the severity of the effect increases with radiation dose above a threshold dose (below which the effect does not occur).

Diagnostic Reference Level (DRL)
Value of radiation dose, or administered activity in nuclear medicine, for typical diagnostic examinations in groups of standard-sized patients for broadly defined types of radiation equipment.

Dose constraint
A restriction on the prospective radiation dose to an individual that may result from a given radiation source.

Effective dose
The sum of the product of equivalent dose and tissue weighting factor taken over all irradiated tissues and organs.

Electron
A negatively charged particle that is one of the constituents of the atom.

Equivalent dose
The product of absorbed dose and radiation weighting factor for a particular irradiated tissue or organ.

Gamma rays (gamma radiation)
Ionising radiation in the form of photons emitted by nuclei during radioactive decay.

Gy
The gray, which is the unit of absorbed dose (equal to 1 joule of energy per kg).

Ionising radiation
Radiation that is sufficiently energetic to cause ionisation through the release of inner electrons in atoms of high atomic number.

Neutron
An uncharged particle that is one of the constituents of the atomic nucleus.

Particle
A unit of radiation that has mass e.g. electron, beta particle, proton, alpha particle and neutron.

Photon
A unit (quantum) of electromagnetic radiation such as infra-red, visible, ultra-violet, x and gamma radiation.

Proton
A positively charged particle that is one of the constituents of the atomic nucleus.

Radiation
A stream of energy, usually in the form of photons or particles, emitted from a source, moving through a material and interacting with it to deposit energy in the material.

Radiation dose
A measure of the energy deposited by ionising radiation in a material and its potential harmful effects.

Radiation employer
An employer who in the course of a trade, business or other undertaking carries out, or engages others to carry out, work with ionising radiation.

Radiation weighting factor
A quantity that indicates the relative harmfulness of different types of ionising radiation to living tissue.

Radioactive decay or disintegration
The transformation of one nuclide (a radionuclide) into another with the emission of ionising radiation.

Radioactive substance (material)
Substance (material) that contains one or more radionuclides.

Radioactive waste
Any material that is either radioactive in its own right or is contaminated by radioactive substances and for which no further use is envisaged.

Radioactivity
The phenomenon associated with radioactive decay or disintegration.

Radiopharmaceutical
A radioactive medicinal product that is administered to human subjects for medical diagnosis or treatment or a related purpose such as medical research.

Radiosensitivity
The sensitivity or susceptibility of different tissues and organs to the harmful effects of radiation.

Stochastic effect
An effect of ionising radiation on living tissue in which the probability of the effect occurring increases linearly with radiation dose without a threshold.

Sv
The sievert, which is the unit of equivalent dose and effective dose.

Tissue weighting factor
A quantity that indicates the relative sensitivity or susceptibility of different tissues and organs to the harmful effects of ionising radiation.

Tissue reaction
This is the same as a deterministic effect.

X-rays (x-radiation)
Ionising radiation in the form of photons emitted by electron interactions in atoms, possibly as a consequence of radioactive decay.

X-ray tube
An evacuated chamber in which electrons are accelerated towards a target to produce x-rays.

2 Use and harmful effects of ionising radiation

Ionising radiation takes the form of either high energy photons (such as x-rays and gamma rays) or high energy particles (such as alpha radiation, beta radiation, electrons, protons and neutrons). It is produced by electrical radiation generators (such as x-ray tubes) and by radioactive substances.

Ionising radiation has a wide range of beneficial applications but it also has the potential to cause harm.

The UHB uses ionising radiation at Barry Hospital, Cardiff Royal Infirmary, St David's Hospital, University Hospital Llandough (UHL), the University Hospital of Wales (UHW) (including the Children's Hospital and the Dental Hospital) and at community medical and dental sites in the following practices:

- Production of radioactive products (including radiopharmaceuticals and radioactive sources)
- Application of radioactive tracers (for medical and biological techniques)
- Diagnosis (medical)
- Treatment (medical)
- Medical and biomedical research
- Examinations performed for insurance or legal purposes without a medical indication
- Teaching including further and higher education and training
- Ionising radiation metrology
- Transport of radioactive material

All these practices are justified [1-3] i.e. they produce sufficient benefit to individuals exposed to ionising radiation or to society in general to offset the detriment that they cause. Justification is one of the basic tenets of radiation protection, the others being optimisation and dose limitation [4].

The majority of the above practices are associated with radiology (diagnostic and interventional) and nuclear medicine (diagnostic and therapeutic). In radiology, human subjects are exposed to x-rays from an external source (x-ray tube). Radiology is practised widely throughout the UHB. Nuclear medicine, on the other hand, involves the administration of radioactive substances (in the form of radioactive medicinal products or radiopharmaceuticals) to humans such that the subjects are irradiated internally by beta and gamma radiation. Nuclear medicine is practised only at UHW and UHL.

The potential of ionising radiation to cause harm is usually expressed in terms of radiation dose, which is a measure of the energy deposited by radiation and its impact on living tissue [4]. The basic quantity is absorbed dose, which is an expression of the energy deposited by ionising radiation per unit mass of the material which it irradiates; its unit is the gray (Gy). Absorbed dose is used to quantify the energy deposited by ionising radiation in tissues and organs.

The same absorbed dose delivered to living tissue by different types of ionising radiation causes biological damage to different extent. This variation is expressed by the radiation weighting factor, which is unity (one) for x, beta and gamma radiation (since they are equally harmful) and greater for alpha radiation and neutrons (because they are relatively more harmful for the same absorbed dose). The equivalent dose is given by the absorbed dose multiplied by the radiation weighting factor. It is indicator of harm to a particular tissue or organ due to ionising radiation irrespective of the type (and energy) of the radiation; its unit is the sievert (Sv).

In addition, some living tissues and organs are more sensitive or susceptible to the harmful effects of ionising radiation. This variation is expressed by the tissue weighting factor, which is relatively larger for those tissues and organs which are most radiosensitive (i.e. most susceptible to the harmful effects of radiation). The effective dose is the sum of the equivalent dose multiplied by the tissue weighting factor for all irradiated tissues and organs. It is an indicator of harm to the whole body from either total or partial exposure to radiation regardless of the number of tissues and organs exposed; it is also expressed in Sv.

There are two broad types of harmful effect of ionising radiation: deterministic effects (also called tissue reactions) and stochastic effects [4]. Deterministic effects occur in the irradiated individual and are characterised by a threshold absorbed dose (below which the effect does not occur) and the fact that the severity of the effect increases with absorbed dose (above the threshold). An example would be erythema (reddening) of the skin with a threshold of 2-5 Gy and progression to blistering and ulceration as absorbed dose increases.

For stochastic effects, the probability of the effect occurring increases in proportion to effective dose; there is no threshold. Stochastic effects may occur in irradiated individuals and in future generations. The most important stochastic effect is the induction of cancer in an irradiated individual. For a general population, the risk of fatal cancer is about 5% per Sv, although the risk varies with age and is greater for children than for adults [4].

Irradiation of the embryo and foetus may cause both deterministic and stochastic effects [4].

3 Regulation of ionising radiation

The use of ionising radiation is governed by legislation that is designed to control its adverse effects on people and the environment. This involves keeping radiation doses as low as reasonably practicable (ALARP). The legislation is supported by codes of practice and guidance and compliance is assessed through a programme of inspections by statutory external agencies.

The exposure of patients to ionising radiation is governed by the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017 and a subsequent amendment to the regulations [5,6]. The regulations are supported by official and professional body guidance [7,8]. They apply to the deliberate exposure of human subjects to ionising radiation as follows:

- To patients as part of their medical diagnosis or treatment
- To individuals as part of health screening programmes
- To patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes
- To carers and comforters
- To asymptomatic individuals
- To individuals undergoing non-medical imaging using medical radiological equipment

For the purposes of this Procedure, those subject to exposures in these categories are collectively called ‘patients’. Practices that involve the deliberate exposure of humans under circumstances other than the above do not fall within the scope of IR(ME)R 2017. Such practices are permitted only if their justification is confirmed by the most recent version of the national Justification Register [1-3,9]. The regulations specify the responsibilities of employer, referrer, practitioner, operator and Medical Physics Expert (MPE)

The regulations are enforced by Healthcare Inspectorate Wales (HIW), which reports on its activities. In England, similar reports are published by the Care Quality Commission (previously Healthcare Commission) [10-11].

In nuclear medicine, radiopharmaceuticals may be administered to humans only by a person who holds a licence from Health Ministers or someone acting under the authority of such a person. In addition, a separate licence is required by the employer at each site where such administrations take place [12]. Radiopharmaceuticals are prepared in a specialised radiopharmacy at UHW under a regime [7, 13-15] that is regulated by the Medicines and Healthcare products Regulatory Agency (MHRA).

The Ionising Radiations Regulations (IRR) 2017 [16] address all aspects of work with ionising radiation. They are made under the Health and Safety at Work Act 1974 [17] and are supported by an Approved Code of Practice (ACOP) and official guidance [18] as well as professional body guidance [9]. IRR 2017 deal with the radiation protection of workers and the members of the public who are exposed as a result of work with ionising radiation. They are not concerned directly with the radiation protection of patients. The

regulations specify the responsibilities of a radiation employer; these include making risk assessments, appointing a Radiation Protection Adviser (RPA) and one or more Radiation Protection Supervisors (RPSs) and writing Local Rules. IRR 2017 are enforced by the Health and Safety Executive (HSE).

Radioactive material is kept on UHW and UHL premises only, in accord with the stipulations of the Environmental Permitting (England and Wales) Regulations (EPR) 2016 [19-20] and under conditions that are specified in Environmental Permits issued by Natural Resources Wales (NRW). The same applies to the accumulation and disposal of radioactive waste. The permits are site-specific for UHW and UHL. In addition, there is a requirement [21] to appoint a suitable Radioactive Waste Adviser (RWA). Radioactive materials are transported in a manner [22-23] that is consistent with the requirements of the Office for Nuclear Regulation, which includes the appointment of a Dangerous Goods Safety Adviser (DGSA). Regulations governing the keeping and transportation of radioactive substances and the management of radioactive waste do not have a direct impact on the radiation safety of patients.

4 General arrangements for the protection of patients against the harmful effects of ionising radiation

For the deliberate irradiation of patients, the goal of radiation protection is to achieve the desired clinical outcome while restricting radiation exposure as much as possible i.e. keeping radiation doses ALARP. The mechanisms for achieving this goal are the justification of individual exposures and the optimisation of processes. For diagnostic and interventional procedures this means minimising the risk of stochastic effects and avoiding deterministic effects. For therapeutic procedures, doses to non-target volumes should be as low as reasonably practicable consistent with the intended therapeutic purpose. IR(ME)R [5-6] provide a regulatory framework within which the UHB works to achieve these goals.

The exposure of patients to ionising radiation is mainly carried out in three Clinical Boards within the UHB: Specialist Services, Clinical Diagnostics and Therapeutics and Surgery.

The Employer as defined in the regulations is the UHB and the Chief Executive takes overall responsibility for compliance with legislation on behalf of the UHB. The Chief Executive has delegated the task of ensuring compliance with radiation safety legislation to the Executive Director of Therapies and Health Science (DoTH). The DoTH has further delegated this task to individuals throughout the UHB's line management structure. This includes the identification and entitlement of various duty holders and the

appointment of Medical Physics Experts to provide expert advice regarding the medical exposure of patients.

The UHB has established a Radiation Protection Group (RPG) that reports to the Quality, Safety and Patient Experience Committee and onwards to the Executive Board. The RPG discusses all aspects of radiation safety including the exposure of patients and its work includes what would otherwise be done by a Medical Exposures Committee.

5 Specific arrangements for the regulation of medical exposures to ionising radiation

The UHB must provide standard operating procedures (SOPs) for all aspects the medical exposure of patients to ionising radiation. These include the following employer's procedures (IR(ME)R Schedule 2):

(a) to identify correctly the individual to be exposed to ionising radiation;
(b) to identify individuals entitled to act as referrer or practitioner or operator within a specified scope of practice;
(c) for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breastfeeding;
(d) to ensure that quality assurance programmes in respect of written procedures, written protocols, and equipment are followed;
(e) for the assessment of patient dose and administered activity;
(f) for the use and review of such diagnostic reference levels as the employer may have established for radiodiagnostic examinations falling within regulation 3(a), (b), (e) and (f);
(g) for determining whether the practitioner or operator is required to effect one or more of the matters set out in regulation 12(4) including criteria on how to effect those matters and in particular procedures for the use of dose constraints established by the employer for biomedical and medical research programmes falling within regulation 3(c) where no direct medical benefit for the individual is expected from the exposure;
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(i) providing that wherever practicable, and prior to an exposure taking place, the individual to be exposed or their representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the exposure;
(j) for the carrying out and recording of an evaluation for each exposure including, where appropriate, factors relevant to patient dose;
(k) to ensure that the probability and magnitude of accidental or unintended exposure to individuals from radiological practices are reduced so far as reasonably practicable;
(l) to ensure that the referrer, the practitioner, and the individual exposed or their representative are informed of the occurrence of any relevant clinically

significant unintended or accidental exposure, and of the outcome of the analysis of this exposure;
(m) to be observed in the case of non-medical imaging exposures;
(n) to establish appropriate dose constraints and guidance for the exposure of carers and comforters.

Those procedures that apply throughout the UHB, especially at corporate level, are addressed in this document. More detailed procedures are tailored to the work of individual services. The content of these procedures may vary considerably from one service to another, reflecting the diversity of the UHB's clinical and research work.

The UHB as employer should pay special attention to the following:

- Exposures that have no direct health benefit to the exposed individuals including setting dose constraints for research
- Medical exposure of children because of their relatively high radiosensitivity compared with adults
- Medical exposure for health screening, which can involve large numbers of symptomless individuals
- Medical exposures involving high radiation dose to patients because of the increased stochastic risk and the possibility of tissue reactions
- Medical exposures to individuals of childbearing potential in whom pregnancy cannot be excluded, in particular if pelvic or abdominal anatomic regions are involved, considering the exposure of both the expectant individual and the unborn child, the urgency of the exposure and the relatively high radiosensitivity of the foetus
- Radiopharmaceutical administrations in nuclear medicine to individuals who are breast feeding, considering the exposure of both the individual and the child and the urgency of the exposure

The UHB should perform other duties imposed upon the employer; these include ensuring that:

- Referral criteria, such as those developed by the Royal College of Radiologists for diagnostic investigations [24], are made available to referrers, together with the appropriate radiation doses
- Research involving radiation exposure has been approved by the appropriate Ethics Committee
- Individuals who administer radiopharmaceuticals in nuclear medicine hold appropriate licences issued under advice from officials of the Administration of Radioactive Substances Advisory Committee (ARSAC) on behalf of the Licencing Authority.
- In nuclear medicine, the role of practitioner is undertaken by an ARSAC licence holder

- Duty holders are identified for each exposure, with particular attention to the use of portable radiation equipment and exposures conducted in multi-disciplinary settings (such as an operating theatre or a catheterisation laboratory)
- Adequate training, including that for new techniques, and continuous professional development (CPD) is provided for practitioners and operators
- Records of training are kept and made available for inspection by HIW
- Duty holders (including referrers, practitioners and operators) carry out the duties assigned to them in Section 6 of this Procedure
- The radiation exposure of individual patients is justified and authorised and different types of exposure are optimised
- Practitioners and operators comply with SOPs
- Written protocols are provided for each type of standard radiological practice for each item of equipment
- The expertise of Medical Physics Experts (MPEs) as specific operators is used as appropriate, depending upon the hazards and radiation doses associated with the particular type of exposure
- Appropriate clinical audit is carried out
- An inventory is kept of equipment used for medical exposure
- Incidents involving radiation doses to patients much greater than intended or are clinically significant [25] are reported to HIW

6 Duties

To ensure the implementation of its Ionising Radiation Risk Management Policy as regards the exposure of patients, the UHB assigns the duties described here.

The duties of the Executive Director of Therapies and Health Science include:

- Ensuring that the UHB provides suitable management arrangements, including sufficient resources and competent persons, to comply with legislation and guidance governing the safe use of ionising radiation
- Providing assurance to the UHB Board that the use of ionising radiation is managed in compliance with the UHB's policies and procedures
- Informing the UHB Board about issues related to the use of ionising radiation
- Ensuring that Clinical Board Directors have arrangements in place for the entitlement of referrers, practitioners and operators for services provided within their Clinical Boards
- Appointing suitably qualified and experienced MPEs in writing
- Maintaining a list of appointed MPEs including their scope of practice
- Delegating duties to other managers as appropriate

- Ensuring that the UHB holds licences for the sites at which radiopharmaceuticals are administered

The duties of Clinical Board Directors include:

- Providing assurance to the Executive Director of Therapies and Health Science that the use of ionising radiation is managed in compliance with policies and procedures and regulatory requirements
- Ensuring that Directorate Clinical Directors have arrangements in place for the entitlement of referrers, practitioners and operators for services provided by their Directorates
- Communicating and liaising with the Chair of the Radiation Protection Group, Practitioners, MPEs, Clinical Directors and other managers about issues related to the use of ionising radiation
- Reporting confirmed incidents of exposure much greater than intended to HIW in a timely manner
- Disseminating information about reported incidents within the UHB as appropriate
- Delegating duties to other managers as appropriate

The duties of Directorate Clinical Directors include:

- Ensuring that members of staff are aware of their roles and duties as regards medical exposures
- Entitling registered healthcare professionals as referrers, defining their scope of practice (with due regard to their qualifications and training) and making referral guidelines available to them
- Entitling registered healthcare professionals as practitioners and defining their scope of practice (e.g. in terms of type of medical exposure)
- Entitling operators and defining their scope of practice (e.g. in terms of operator tasks, including making and recording a clinical evaluation of each exposure)
- Withdrawing entitlement for persistent non-compliance with policies and procedures
- Maintaining a list of referrers, practitioners and operators
- Ensuring that practitioners and operators are qualified, adequately trained, receive update training as appropriate and participate in continuous professional development
- Maintaining training records and making such records available for inspection
- Providing SOPs and exposure protocols for their services and reviewing these documents at appropriate intervals
- Ensuring that a record is kept of all medical exposures including the names of the referrer, practitioner and operator(s) and an estimate of radiation dose for each individual exposure

- Providing procedures to ensure that a clinical evaluation is made and recorded for each exposure and that the record (report) is received by the referrer in a timely manner
- Ensuring that medical exposures and associated procedures are subject to suitable clinical and other types of audit
- Investigating suspected incidents of accidental, unnecessary or unintended exposure in association with the appropriate MPE and reporting confirmed incidents of exposure much greater than intended to the Clinical Board Head of Operations and Delivery
- Keeping records of incidents for the appropriate time
- Delegating duties to duty holders and other managers as appropriate

In nuclear medicine:

- Ensuring that practitioners hold ARSAC licences for the administrations of radiopharmaceuticals for procedures that they wish to undertake and that there is an employer licence to cover the required procedure(s).

The duties of the Chair of the UHB Radiation Protection Group include:

- Providing advice on the implementation of relevant UHB policies and procedures
- Receiving compliance reports with respect to relevant UHB policies and procedures
- Reviewing relevant UHB policies and procedures at least every three years and ensuring that they are amended and updated as necessary
- Reviewing reports from Medical Physics Experts and taking action as necessary
- Liaising with members of the Radiation Protection Group and others as necessary

The duties of the Medical Physics Expert (MPE) include:

- Being involved as appropriate in clinical exposures with external radiation beams
- Working closely with practitioners as regards the justification of medical exposures
- Working closely with operators, maintenance engineers and others as regards the optimisation and practical aspects of medical exposures
- Measuring radiation dose and providing calibrated systems for radiation dose measurement
- Estimating radiation dose and assessing radiation risk to patients and, where appropriate, embryo or foetus, in cases of both intended and unintended exposure
- Providing advice to patients as regards radiation risk including individuals of child bearing potential who are or may be pregnant
- Providing advice and assessing the radiation dose implications of introducing new equipment and techniques

- Setting and reviewing diagnostic reference levels (DRLs) for clinical exposures and dose constraints and target doses for research exposures
- Monitoring and reviewing patient radiation doses and developing dose reduction strategies
- Evaluating image quality in relation to patient dose
- Providing a quality assurance programme for equipment and liaising with other operators as regards routine equipment quality control
- Reviewing and communicating the outcome of equipment quality assurance
- Advising on equipment management including the specification, selection and purchase of clinical and related radiation equipment and the maintenance of an equipment inventory
- Advising on the application and quality assurance of clinical software for the purpose of recording and optimising dose
- Performing acceptance testing and participating in commissioning new equipment including communicating with equipment supplier applications specialists
- Advising on the suspension of the use of existing equipment
- Reviewing equipment replacement policies and processes
- Developing and performing suitable audits for medical exposures and participating in multi-disciplinary clinical audit programmes
- Investigating incidents including making patient radiation dose assessments
- Advising on the radiation protection of comforters and carers in association with the RPA
- Participating in inspections by statutory authorities
- Contributing to the development, implementation and quality assurance of employer's procedures, SOPs and exposure protocols
- Providing training
- Participating in multi-disciplinary clinical audit and review
- Liaising with the RPA as regards the design and construction of clinical and related radiation facilities
- Liaising with the RPA and agreeing on the demarcation of duties associated with radiation safety and compliance with legislation
- Communicating with practitioners, operators, managers and other employees as appropriate

In nuclear medicine

- Being available for diagnostic investigations and standard radionuclide therapies
- Being present and closely involved with all therapeutic administrations of radiopharmaceuticals that are non-standard or being undertaken for the first time

- Supporting applications for ARSAC licences by the UHB and by practitioners.
- Providing advice as regards radiation risk to infants in the case of individuals who are breast feeding
- Working closely with practitioners and others as regards the development and implementation of protocols for the diagnostic and therapeutic administration of radiopharmaceuticals
- Providing radiation protection advice to patients leaving hospital after radiopharmaceutical administration and to those who care for or come into contact with such patients, in liaison with the RPA
- Measuring radioactivity and providing calibrated systems for radioactivity measurement
- Liaising with the RWA and DGSA as regards the storage and transportation of radioactive substances and the accumulation and disposal of radioactive waste

The duties of the Radiation Protection Adviser (RPA) include:

- Liaising with MPEs and agreeing on the demarcation of duties associated with radiation safety and compliance with legislation
- Liaising with MPEs as regards the design and construction of clinical and related radiation facilities

In nuclear medicine:

- Providing radiation protection advice to patients leaving hospital after radiopharmaceutical administration and to those who care for or come into contact with such patients, in liaison with MPEs

The duties of the Referrer include:

- Providing the practitioner with accurate and legible information to permit unambiguous identification of the patient and a decision on justification (i.e. whether a net benefit is associated with the exposure)
- Ensuring that referrals or medical exposure are made within their scope of practice, in accordance with referral guidelines and after discussion with the practitioner where appropriate
- Ensuring that in the case of referrals made for clinical purposes, the required information has not already been provided by previous diagnostic investigations
- Assessing and acting upon reports and clinical evaluations in an appropriate and timely manner
- Identifying exposures that are requested for research purposes
- Ensuring that in the case of referrals made for research purposes, the research protocol has received ethics approval and that outcomes are included in the data analysis

The duties of the Practitioner include:

- Justifying individual exposures taking account of information supplied by the referrer, the specific objectives of the exposure, the characteristics of the patient, the benefit of the exposure vs. the nature and risk of potential detriment and the usefulness of alternative techniques
- Paying special attention to the justification of exposures on children and individuals of childbearing potential in whom pregnancy cannot be excluded, with due regard to the urgency of the exposure and the possible irradiation of an unborn child
- Paying special attention to the justification of exposures to carers and comforters and those who derive no direct health benefit from the exposure
- Authorising individual exposures (by physical or electronic signature) and delegating authorisation to operators under written Delegated Authorisation Guidelines (DAGs) as appropriate
- Liaising with referrers regarding referrals that may not be justified i.e. ones for which there is insufficient net benefit
- Returning referrals when there is insufficient or incorrect information to unambiguously identify the patient
- Ensuring that radiation doses for research exposures are consistent with dose constraints (where there is no health benefit to the individual) or target doses (where there is such a benefit) as specified in the research protocol
- Co-operating with operators, MPEs and others as regards practical aspects of exposures to keep radiation doses ALARP, consistent with the intended purpose
- Discussing incidents of accidental, unnecessary or unintended exposure with patients
- Engaging in continuous professional development and keeping a personal record of such activity

In nuclear medicine:

- Obtaining an ARSAC licence for clinical administrations of radiopharmaceuticals and ensuring that research administrations are authorised if relevant.
- Paying special attention to the justification of an exposure to individuals who are breast feeding, taking account of possible radiation dose to the infant
- Prescribing administered activities and routes of administration for diagnostic and research investigations that are in accord with ARSAC recommendations and trial protocols.
- Making an individual assessment of each patient referred for radionuclide therapy and prescribing an administered activity and route of administration that takes account of professional guidance

The duties of the Operator include:

- Selecting equipment and methods to keep doses ALARP, consistent with the intended diagnostic, therapeutic or other purpose
- Paying special attention to quality assurance, assessment of radiation dose and adherence to DRLs
- Paying special attention to the restriction of radiation dose and the optimisation of exposures for children and individuals of childbearing potential in whom pregnancy cannot be excluded
- Paying special attention to the optimisation of exposures made for health screening purposes and those that impart a relatively high radiation dose
- Co-operating with practitioners, MPEs and others as regards practical aspects of exposures
- Authorising individual exposures (by physical or electronic signature) under written Delegated Authorisation Guidelines (DAGs) from the practitioner
- Making and recording a clinical evaluation of each exposure including diagnostic findings and therapeutic implications as appropriate within the scope of practice
- Engaging in continuous professional development and keeping a personal record of such activity

In nuclear medicine

- Taking care to administer an appropriate activity of the correct radiopharmaceutical through the correct route of administration
- Paying special attention to the optimisation of an exposure to an individual who is breast feeding, taking account of possible radiation dose to the infant

The duties of all individual members of staff include:

- Following SOPs and protocols for medical exposure
- Reporting suspected incidents of accidental, unnecessary or unintended patient exposure to the Directorate Clinical Director through the line management structure

7 References

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