University Hospitals of Derby and Burton NHS Foundation Trust

IONISING RADIATION SAFETY - TRUST POLICY & PROCEDURE

Reference Number POL-RM/1209/20	**Version:** 4.0		**Status** Final	**Author:** **Penny Owens** **Job Title** Divisional AHP Director & Co-Chair of Trust RPG
Version / Amendment History	Version	Date	Author	Reason
	V3.0	01/04/2020	Penny Owens	Review following organisational change and major updates to relevant regulations. To replace separate policies at Derby (RMK/2014/039) and Burton (119) and the IRMER policy at Derby (RMK/2014/038).
	V3.1 - 3.21	30/04/2020	Penny Owens	Changes following initial consultation with Advisers and Experts
	V4	13/07/2021	Penny Owens	Changes following consultation with Advisers and Experts regarding lines of reporting, responsibilities & accountabilities.
	V5	22/2/2022	Mic Heaton	Changes following consultation with Advisers and Experts regarding lines of reporting and the undertaking of research exposures

Intended Recipients:

- Staff who act as statutory duty holders under IRMER.
- Staff who hold management roles in Divisions or Business Units who own ionising radiation equipment or employ duty holders.
- All staff who may be exposed to radiation as part of their employment.

Training and Dissemination: Mandatory Training at 3 levels:

Level 1 – All staff not undertaking level 2

Level 2 – All staff who work in areas where radiation is frequently used.

Level 3 – Staff who are duty holders under relevant regulations (e.g. Referrers, Operators and Practitioners under IRMER)

Training for managers, and clinicians in managerial roles, in their responsibilities under this policy. (Please see UHDB Training and Appointment Requirements for Radiation Users, Managers, Advisers, Experts and Duty Holders)

To be read in conjunction with:

Health and Safety Policy (UHDB Combined Policy POL-RM/1920/19)

Patient ID Policy (UHDB Combined Policy POL-CL/37/15/20)

Incident and Serious Incident Management (Burton Hospital Sites Policy POL-RISK/2875-256/2018-RISK)

Incident Reporting, Analysing, Investigating and Learning Including Serious Incidents (Policy Derby Hospital Sites POL-RKM/1448/07-RISK)

Linked Documents:

UHDB Procedures for the Control of Medical and Non-medical Exposures to Ionising Radiation

UHDB Training and Appointment Requirements for Radiation Users, Managers, Advisers, Experts and Duty Holders

SOP/RCL/001 Research Involving Medical Research Exposures

In consultation with :

All appointed Radiation Protection Advisers, Medical Physics Experts and Radioactive Waste Advisers.

Head of Clinical Trials and Research Governance.

Trust Strategic Health, Safety and Wellbeing Group

Trust Patient Safety Group

Approving Body and Date Approved	Trust Board

Date of Issue	June 2020
Review Date and Frequency	30/06/ 2023 and then every 3 years
Contact for Review	Mike Barnard – Clinical Manager (Compliance) Imaging BU
Executive Lead Signature	Dr Magnus Harrison – Executive Medical Director

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IONISING RADIATION SAFETY - TRUST POLICY & PROCEDURE

1. Introduction

The use of ionising radiations is an essential part of the diagnostic and therapeutic activity carried out by University Hospitals of Derby and Burton NHS Foundation Trust (UHDB). This policy will apply to all areas of the Trust, including locations where services are provided by the Trust in facilities belonging to other organisations. The policy applies to all individuals employed by the Trust and outside workers (e.g. contractors, volunteers and students).

The Trust is committed to:-

1.1 Ensuring the safety of employees, patients, members of the public, and outside workers on its premises with regard to ionising radiation.

1.2 Complying with the requirements of legislation, codes of practice and guidance notes including:-

- The Ionising Radiations Regulations (IRR) and subsequent amendments.
- The Ionising Radiation (Medical Exposure) Regulations (IRMER) and subsequent amendments.
- The Environmental Permitting Regulations (EPR) and amendment Regulations and any subsequent amendments

1.3 Achieving safe practices by ensuring that:-

- The risk resulting from an exposure to ionising radiation is exceeded by the benefit it produces.
- The dose from any such exposure is as low as reasonably practicable.
- The sum of doses and committed doses to staff and to members of the public do not exceed statutory limits.
- All its employees are appropriately trained and undergo relevant continuous training and development.

1.4 Maintaining a radiation safety management structure to implement and monitor this policy.

2. Purpose and Outcomes

The purpose of version 3 of this policy is to:-

2.1 Bring previous policies and procedures together into a single document which applies throughout University Hospitals of Derby and Burton NHS Foundation Trust, taking into account the most recent versions of the Ionising Radiation Regulations and the Ionising Radiation Medical Exposures Regulation, which have come into force since the previous version of these policies.

2.2 Incorporate statutory requirements and standards of good practice associated with these regulations which have been produced since the previous

policies were last issued.

2.3 Describe the procedures and arrangements adopted by the Trust to achieve compliance with current statutory requirements and standards of good practice using ionising radiation.

2.4 Define the responsibilities of individuals employed by the Trust and organisational bodies within the Trust, whose lines of reporting and accountability are given in Appendix 1 of this policy.

3. Definitions

3.1 The Trust is University Hospitals of Derby and Burton NHS Foundation Trust. The Trust has the duties and responsibilities of the Employer for the regulations listed above (section 1.2).

3.2 All mentions of 'radiation' in this policy referrer to ionising radiation. "Ionising radiation" includes the radiation from external X-ray and electron beam generating equipment, and from sealed and unsealed radioactive sources.

3.3 All mentions of 'radiation equipment and ancillary equipment in this policy includes both external X-ray and electron beam generating equipment and equipment used in relation to sealed and unsealed radioactive sources used for diagnostic or therapeutic purposes.

3.4 Radioactive materials for the purposes of this policy are substances which emit ionising radiation due to nuclear decay that are within the scope of the Environmental Permitting Regulations.

3.5 Individuals who perform certain tasks associated with a medical exposure to ionising radiation are defined as a "Referrer", "Practitioner" or "Operator" by IRMER and are assigned specific statutory responsibilities by these regulations.

3.6 A "Radiation Protection Adviser" (RPA) is defined by IRR as an individual who meets the criteria of competence specified by the Health and Safety Executive.

3.7 A "Medical Physics Expert" (MPE) is defined by IRMER as an individual or group of individuals having the knowledge, training and experience to act or give advice on matters relating to radiation physics, applied to radiation exposure, whose competence in this respect is recognised by the Secretary of State.

3.8 A Radioactive Waste Adviser (RWA) is defined by the Environment Agency (EA) as a person who has been certified as being competent by a recognised assessing body on a range of issues relating to Radioactive Waste Management.

3.9 An "Outside Worker" means a person who is employed by another organisation to carry out duties in a radiation controlled area which is owned by UHDB Trust. This includes students who are considered to be employed by their Higher Education Institution.

3.10 All mentions of "owning" in this policy, in relation to equipment or facilities

include arrangements such as; leasing, rental, managed equipment services (MES) and funding under a public-private partnership mechanisms such as PFI.

3.11 'Local Rules' are documents required by the Ionising Radiation Regulations. These set out the key arrangements for restricting exposure to staff and visitors in and around areas where ionising radiations are used. These procedural documents must be followed by staff.

3.12 Employers Procedures are documents required by the Ionising Radiation (Medical Exposures) Regulations which set out the procedures staff must follow when undertaking a wide range of processes associated with the use of ionising radiation on patients.

4. Key Responsibilities / Duties

4.1 Trust Board

The Trust Board is responsible for:-

4.1.1 The radiation safety of employees, patients, members of the public, contractors and outside workers on its premises.

4.1.2 Ensuring the Trust fulfils all legal requirements relating to the safe use of ionising radiation.

4.1.3 All statutory obligations assigned to the "employer" by the above sets of regulations (1.2). The board exercises these responsibilities through the Chief Executive. The Executive Medical Director is the member of the executive board with direct responsibility for ionising radiation safety and the responsible officer.

4.1.4 Ensuring provision of adequate resources (including equipment and personal protective devices and staff protected time) which secure compliance with statutory requirements and with nationally accepted standards of good working and medical practice.

4.2 Chief Executive

The Chief Executive is responsible for:-

4.2.1 Ensuring that:-

- The Trust's Ionising Radiation Safety Policy is implemented.
- A management structure is maintained to allow the policy to be implemented.
- Appropriate arrangements exist to carry out, monitor and review the policy.
- Appropriate financial resources are provided for the management of radiation safety.

4.2.2 Providing adequate resources to Divisions and Business Units to ensure

that their use of ionising radiation is safe, well managed and monitored to ensure it meets regulatory requirements. Where it is identified that adequate resources, such as adequate staffing or suitable equipment, are not available; these must be provided or the under-resourced activity cease.

4.3 Executive Medical Director

The Executive Medical Director is responsible for:

4.3.1 Monitoring that Medical and Clinical Directors are fully discharging their responsibilities summarised in this policy.

4.3.2 Ensuring that all staff receive training in radiation protection appropriate to their role and duties.

4.3.3 Appointing sufficient Radiation Protection Advisers, Radioactive Waste Advisers and Medical Physics Experts to meet regulatory requirements and service needs. Such Advisers and Experts must have appropriate experience, qualifications, and a current certificate of competence; and be appointed in writing to advise on all matters concerning the use of ionising radiation and related issues.

4.3.4 Ensuring that:

- Good communication and co-operation is maintained between:
    - The Radiation Protection Advisers, Medical Physics Experts, the Radioactive Waste Advisers, the Trust board and senior managers.
    - Radiation Protection Advisers, Medical Physics Experts, the Radioactive Waste Advisers with Divisional and Business Unit management
- That Advisers and experts are given access to staff, equipment, facilities and data as necessary to perform their duties (training, audit, surveys, etc.)

4.4 Trust Secretary

The Trust Secretary is responsible for:

- Holding copies of documents relevant to the management and safe use of ionising radiation on behalf of the Trust. These include:
    - Copies of letters appointing Advisers and experts
    - Copies of certificates of competence, where required. E.g. ARSAC certificates
    - Copies of licenses, consents, registrations and permits
- Managing notifications of inspection and sharing with all appropriate staff to ensure planning and preparation as required
- Recording notifications of statutory inspections (HSE, CQC, EA etc.).

4.5 Strategic Health, Safety and Wellbeing Group (SHS&WG)

The Trust Strategic Health, Safety and Wellbeing Group is responsible for:-

4.5.1 Appointing a Trust Radiation Protection Group, fulfilling the requirements for a Radiation Protection Committee set-out in the Medical and Dental Guidance Notes (MDGN's).

4.5.2 Monitoring the radiation protection programme through reports received from the Radiation Protection Group and escalating issues of concern or significant non-compliance to higher level groups.

4.5.3 Providing advice on relevant aspects of clinical governance, quality improvement and patient safety issues.

4.5.4 Ensuring an appropriate organisational structure is in place to meet the requirements of the Radiation Protection Group as a statutory implementation group.

4.6 Radiation Protection Group

The purpose of the Trust Radiation Protection Group (formerly called the Radiation Protection Committee) is to provide the strategic direction for; and assurance of effective management and compliance with statutory requirements; to the Trust Board and the Responsible Officer in regard to radiation protection, ultrasound, MRI and optical (lasers and intense light sources).

The Trust's Radiation Protection Group has the following core responsibilities (please see the Terms of reference for the Radiation Protection Group for a full list):

4.6.1 Monitoring that the Trust fulfils all legal obligations relating to the safe use of ionising radiation arising from:

- The Ionising Radiation Medical Exposures Regulations.
- The Ionising Radiation Regulations.
- The Environmental Permitting Regulations.

4.6.2 Monitoring that the Trust meets best practice guidance and local standards relating to the safe use Ultrasound, Magnetic Resonance Imaging (MRI) in diagnostic Imaging and Optical.

4.6.3 In order to ensure the appropriate management of radiation safety the RPG is responsible for approving radiation safety documents on behalf of the Trust. These include the Local Rules, Employers Procedures and other procedural documents required by regulation; and associated documents stemming from best practice guidance. Such documents may apply locally (e.g. the employers procedure for patient identification in Cardiac Catheter labs); or apply Trust-wide to staff undertaking a particular role (e.g. the referral criteria for a specific imaging examination). Where necessary, the RPG will authorise the uploading of these documents to the Trust's intranet and internet sites.

4.6.4 Reporting to the Trust's Strategic Health, safety and Wellbeing Group on all aspects of ionising radiation, ultrasound, MRI and optical safety.

4.6.5 Reporting to the Trust's Patient Safety Group on matters specifically relating to the safe use of ionising radiation on patients.

4.6.6 Annual report to the Trusts Quality Performance Committee.

4.6.7 Ensuring that:

- Reports are received, in writing, from Radiation Protection Advisers, Radioactive Waste Advisers and Medical Physics Experts. Such reports will be scheduled so that all areas of the Trust are covered annually and combined to produce a joint Advisers and Experts report to the Health and Wellbeing Group annually.

- Such reports must include sufficient information to assure the group of compliance with regulations and identify areas of non-compliance. They should be produced by the responsible expert / Adviser in conjunction with a person in a similar role from another area where this is required to provide a degree of impartiality.

- Issues which could result in censure in the event of external inspection or audit are promptly escalated within the Trust so that the Executive Medical Director, as responsible officer, is aware.

- Reports into adverse incidents involving ionising radiation are reviewed in a forum where issues relating to ionising radiation are well understood and that learning is identified and shared with all relevant areas.

4.6.8 Monitoring that:-

- Divisional and Business Unit management teams are fulfilling their responsibilities and duties with regard to equipment replacement, maintenance, quality assurance, staff training, patient and staff dose assessment and audit.

- Divisional and Business Unit management teams consider and take appropriate advice on relevant radiation protection issues in future plans and developments.

4.6.9 Drawing up the Trust's Ionising Radiation Safety Policy and reviewing it in the context of revised or new legislation, or because of changes in operational practice. Review should be performed at intervals of no more than 3 years.

4.6.10 Seeking the advice of the RPA(s), RWA(s) and MPE(s) and consulting with stakeholders, including referrers, operators and practitioners, on changes to the Trust's Ionising radiation Safety Policy.

4.6.11 Auditing compliance with, the Trust's 'Reporting Agreement'; which outlines responsibilities for recording the clinical evaluation of medical exposures when this is not done by the Business Unit performing the examination.

4.6.12 Issuing an annual reminder to Clinical Directors of Business Units where Referrers have responsibilities for clinical evaluation of medical exposures under the Reporting Agreement; outlining these responsibilities and asking each Clinical Director to cascade this reminder to all their relevant staff.

4.6.13 Receiving evidence based assurance of compliance with employer's procedures and other radiation safety procedures from Business Units owning ionising radiation equipment. Where significant non-compliance with IRR, IRMER and EPR is identified this must be escalated to SH&WG or directly to the Trust Delivery Group.

4.6.14 The RPG will set up Sub-Group's as considered necessary to meet its responsibilities. These may be standing sub-groups to focus on particular areas within the RPG's overall remit, or task and finish groups to address specific issues.

4.7 Radiation Protection Adviser(s)

The Radiation Protection Adviser(s) are accountable to the Chief Executive, and are responsible for:-

4.7.1 Maintaining a current certificate of competence from an assessing body recognised under IRR.

4.7.2 Maintaining a thorough and up-to-date knowledge of all matters relevant to their role within the Trust.

4.7.3 Advising the Trust Board and its employees on all matters concerning the use of ionising radiation, in particular in regard to compliance with statutory and regulatory requirements; and for maintaining records of all such advice including the outcome of any relevant measurements and incident investigations.

4.7.4 Submitting written reports to the Trust's Radiation Protection Group in accordance with the agreed schedule. Such reports must include the results of an audit of equipment, documents and practice in the Adviser's area(s) of responsibility and, where required should be jointly conducted with a person in a similar role from another area to ensure impartiality,

4.7.4 Advising Business Units and Trust Facilities / Estates teams on any change to Trust infrastructure which may impact on Radiation safety.

4.7.5 Advising Business Units on appropriate arrangements with a Dosimetry Service in order to satisfy statutory requirements, approved codes of practice and guidance.

4.7.6 **Urgent Escalation issues.** The advisers should follow the management structure and escalate through it as they see fit based on the urgency and risk to the Trust. E.g. In the case of a very serious staff or patient accident then appropriate escalation is immediately to the executive Medical Director or the director responsible for H&S for the Trust.

4.7.7 **Non-urgent Escalation issues.** The Advisers reporting structure from RPG upwards through the Trust committees to eventually reach to the

CEO is the correct route.

4.8 Medical Physics Expert

Medical Physics Experts are accountable to the Chief Executive and are responsible for:

4.8.1 Maintaining appropriate certification

4.8.2 Maintaining a thorough and up-to-date knowledge of all matters relevant to their role within the Trust.

4.8.3 Providing advice to the Trust on the justification, optimisation, dosimetry and radiation safety of medical exposures.

4.8.4 Ensuring they are available for involvement with medical exposures to meet regulatory requirements.

4.8.5 Liaising with the Radiation Protection Adviser, as appropriate, over any matter resulting from a medical exposure which directly affects the radiation safety of a person covered by IRMER.

4.8.6 **Urgent Escalation issues**. The advisers should follow the management structure and escalate through it as they see fit based on the urgency and risk to the Trust. E.g. In the case of a very serious staff or patient accident then appropriate escalation is immediately to the executive Medical Director or the director responsible for H&S for the Trust.

4.8.7 **Non-urgent Escalation issues.** The Advisers reporting structure from RPG upwards through the Trust committees to eventually reach to the CEO is the correct route.

4.9 Radioactive Waste Adviser(s)

The Radioactive Waste Adviser(s) are responsible to the Chief Executive and are responsible for:

Maintaining a current certificate of competence as an RWA and will provide advice to the Trust on radioactive waste management and environmental radiation protection, in order to achieve and maintain an optimal level of protection of the environment and of the population from radioactive materials.

A Radioactive Waste Adviser (RWA) will also be appointed Site Officer for radioactive materials, and will have the following additional responsibilities:-

Advising managers on the appropriate permits required under EPR for the holding and disposal of radioactive materials, and that these are kept up-to-date as necessary.

4.9.1 Advising managers on arrangements for record keeping regarding the quantities of radioactivity kept and used, and of the rates of accumulation and disposal of radioactive waste, in order to satisfy the requirements of EPR, and for keeping these records available for immediate inspection.

4.9.2 Monitoring these quantities and rates, and advising the relevant manager, and the respective HoD, if they are likely to exceed the respective limits in the Trust's Permits for holding and disposal of radioactive materials; preparing annual summaries for submission to the Environment Agency of these quantities and rates for the entire Trust.

4.9.3 Advising managers on appropriate arrangements for the collection and disposal of radioactive waste from the Trust so as to satisfy all statutory transport requirements, including maintaining the appropriate records for this waste, as required by both CDGR and TDGSAR99;

4.9.4 Advising managers on appropriate arrangements for the periodic review of the location of all radioactive material held in the Trust, including where materials are held by different Business Units. Advice should include the frequency of such reviews and arrangements for the disposal of material no longer required.

4.9.5 Updating the Radiation Protection Group as appropriate on these matters, and liaising in regard to these responsibilities with the EA, the RPAs, other RWAs, other site officers and with other relevant third-party organisations whose staff are working on Trust premises with radioactive materials.

4.9.6 **Urgent Escalation issues.** The advisers should follow the management structure and escalate through it as they see fit based on the urgency and risk to the Trust. E.g. In the case of a very serious staff or patient accident then appropriate escalation is immediately to the executive Medical Director or the director responsible for H&S for the Trust.

4.9.7 **Non-urgent Escalation issues.** The Advisers reporting structure from RPG upwards through the Trust committees to eventually reach to the CEO is the correct route.

4.10 Divisional Medical Directors

The Medical Director of each Division is responsible for ensuring that:-

4.10.1 All employees are aware of their responsibilities as defined in this policy and are adequately trained.

4.10.2 Occupational and medical radiation protection considerations are included in the annual clinical audit programmes

4.10.3 Clinical Directors in the Business Units within their Division are discharging their responsibilities and duties listed in this policy.

4.11 Business Unit Clinical Directors

4.11.1 The Clinical Directors of all Business Units within UHDB, in conjunction with the General Manager and Heads of Service/Clinical Managers, are responsible for ensuring that:

- An appropriate and adequately resourced structure is in place within the Business Unit to ensure compliance with this policy. This structure should

be documented and submitted to the RPG for approval.

- That any delegation of tasks involving the implementation of this policy or the management of radiation safety is to staff with appropriate knowledge to undertake the task.

- Appropriate measures are taken to ensure that Referrers from within their Business Unit fulfil all statutory and other responsibilities described in this policy.

- Any requirement for a Referrer to record a clinical evaluation of a medical exposure, as described in the 'reporting agreement' is implemented, that existing staff are reminded of this requirement on a regular basis, and that all newly appointed medical staff are informed of this requirement.

- Where appropriate to the use of ionising radiation by the Business Unit, procedures are designed and implemented for radiation protection surveys of the working environment, staff dose monitoring, patient dosimetry and audit, and equipment surveys which include acceptance, commissioning and routine periodic performance tests.

- All staff have received training which satisfies statutory requirements, they undergo appropriate Corporate induction, and specific local induction training when they commence employment with the Trust, and they undergo continuous training where appropriate; training records are maintained.

4.11.2 In addition, Clinical Directors of Business Units owning ionising radiation equipment, in conjunction with the General Manager and Heads of Service/ Clinical Managers for ensuring that:-

- The responsibilities listed in section 4.10 of this policy are assumed by an appropriate member(s) of staff.
- Radiation Protection / Dose Optimisation / Medical Exposures Working Group(s) are established with an appropriate membership, and that appropriate terms of reference are written for the Group.

- A quality assurance programme is established to review, on a regular basis, all written procedures, examination protocols, risk assessments, other statutory documentation, and radiation equipment usage with the aim of minimising occupational and medical exposures. All revisions resulting from these reviews are implemented and all relevant members of staff are informed of these revisions.

- Local rules and working instructions, designed to minimise personal exposure, have been drawn up with the approval of a Radiation Protection Adviser for all areas of work in their Business Unit involving the use of ionising radiation, and are displayed in those areas.

- That appropriate arrangements are in place for research exposures.

- Radiation Protection Supervisors are appointed in writing, after consultation

with the relevant Head of Department or Line Manager and with the Radiation Protection Adviser(s), the letter of appointment defines the scope of their appointment and is copied to the Radiation Protection Advisers.

- If a clinician in their Business Unit is issued with an ARSAC certificate, then a copy is sent to the Radiation Protection Adviser(s); and for ensuring that their duties, training needs and the number of Radiation Protection Supervisors in the Directorate are kept under continual review;

- "Employer's Procedures" are written and implemented which satisfy the requirements of IR(ME)R, and that these are readily accessible by all relevant staff. See 'UHDB Standards for Employers Procedures Document'.

- There are also "Employer's Procedures" providing staff with written documents which entitle individuals to act as Referrers, Practitioners and Operators, define the scope of the entitlement for each individual, specify the training and experience required, and identify the member(s) of staff who confer(s) that entitlement by signature on behalf of the employer.

- There is a written version of any other procedure which may affect the dose received by a patient, and these procedures are implemented.

- Protocols are written for each type of examination or treatment technique, are available to staff and are implemented.

- Written referral criteria are available to all Referrers (including those outside of the Trust).

- The responsibilities for justification and authorisation of all medical exposures carried out in their Business Unit are clearly defined and recorded.

- A clinical evaluation is recorded except where it is the Referrer's responsibility under the Reporting Agreement.
- Referrers within their Business Unit are aware of the Reporting Agreement an when it is their responsibility to provide a clinical evaluation of a medical exposure.

- Local diagnostic reference levels are established and implemented for as wide a range of the examinations and procedures undertaken by the Business Unit as practicable. Audit of actual patient doses must be undertaken and reviews must take place when the local diagnostic reference levels are consistently exceeded, and corrective action is taken where appropriate.

- Appropriate occupational and medical radiation protection considerations are included in the clinical audit programmes for their Business Unit.

- A Radiation Protection Adviser is consulted over any matter concerning ionising radiation where necessary for the Trust to comply with all statutory requirements.

- A Medical Physics Expert is involved in every medical exposure, with the degree of involvement to comply with that IRMER, and that their advice is

sought, as appropriate, on matters of the justification, optimisation, dosimetry and radiation safety of medical exposures.

- Advice is sought from Radiation Protection Adviser and Medical Physics Expert on every service development involving the use of ionising radiation including room design and the selection of the type and model of equipment to be used. This must be done at the earliest practicable stage.

- An equipment inventory is maintained which satisfies the requirements in Regulation 15(2) of IRMER.

- A plan is maintained for a rolling programme to replace ionising radiation equipment, and other equipment affecting radiation doses, in their Business Unit at appropriate intervals. This should include the actions to be taken when equipment is not replaced at the specified date.

- The Health & Safety Executive, Medicines and Healthcare Products Regulatory Agency, Care Quality Commission, and/or Environment Agency are notified, as appropriate, of any incident involving ionising radiation, after consultation with the Radiation Protection Adviser or Medical Physics Expert as appropriate.

- The Chief Executive, the appropriate Clinical Director(s) and the Referrer are informed of any incident which requires external notification to the relevant external inspectorate and/or agency.
- Their responsibilities for handling incidents are covered in their absence.

4.12 The Director of Patient Experience, Facilities and Estates

Is responsible for ensuring :

- That the physical infrastructure Trust buildings are maintained to a standard that ensures compliance with the Ionising Radiations Regulations and the Environmental Permitting Regulations and associated permits.

- That security arrangements for high activity sealed sources are managed and maintained to the required standards as specified in the site security plan.

- That possible impacts on radiation safety on are considered when any change to the physical infrastructure of Trust buildings is planned. When a possible impact on radiation safety is identified, the advice of the RPA must be sought at the start of the planning process.

- That the advice of the RPA is sought at the start of the planning process when the installation of new or replacement radiation equipment is planned.

- All facilities and estates staff including contractors and staff working for outsourced services must undergo appropriate Corporate and Department-specific training in radiation protection prior to working in radiation areas, and that they undergo continuous training where appropriate.

- Training records are maintained where relevant to work with radiation equipment or to radiation safety; and that these are made available to the

Radiation Protection Group or to statutory inspectors (HSE, CQC, EA etc.) within appropriate timescales.

4.13 Heads of Departments and Service/Clinical Managers Owning Ionising Radiation Equipment

Heads of Department and Clinical/Service Managers owning ionising radiation equipment are responsible for:-

4.13.1 Deciding:-

- The practice and procedures necessary, in consultation with the Radiation Protection Adviser, to ensure that all working activities involving the use of ionising radiation comply with statutory requirements, local rules, working instructions and the Trust's policy.

- The remedial action to be taken, in consultation with the Radiation Protection Adviser, when difficulties are found in securing these compliances.

4.13.2 Recommending to their Clinical Director appropriate members of staff for appointment as Radiation Protection Supervisors who satisfy the requirements described in Health and Safety Executive's Information Sheet: Ionising Radiation Protection Series No. 6.

4.13.3 Ensuring that:

- A Radiation Protection Adviser or Medical Physics Expert is consulted where appropriate, following maintenance, repair or modification of equipment which could affect the radiation dose to patients and staff, and appropriate re-commissioning and/or routine performance tests are carried out satisfactorily before the equipment is returned to clinical use.

- The Radiation Protection Adviser is informed of plans for new facilities, or changes to existing facilities where ionising Radiation will be used.

- The Medical Physics Expert is informed of plans for new or replacement equipment.

- Risk assessments of existing practices are reviewed, and new practices involving the use of ionising radiation are carried out, in consultation with the Radiation Protection Adviser. Records of these risk assessments must kept in the department, copies sent to the Radiation Protection Adviser, and all risk assessments are reviewed at least once every three years.

- Contingency plans are drawn up to deal with accidents involving ionising radiation, that these plans are regularly reviewed and rehearsed.

- Staff working in their area are appropriately trained in their duties and on any equipment they may use.

- In the event of an equipment fault or procedural error which may have resulted in a medical exposure greater then intended (see Significant

Accidental or Unintended Exposure (SAUE) Guidance):

- The Practitioner who justified the exposure, and the Medical Physics Expert are informed. The incident is reported on the Trusts DATIX incident reporting system and is investigated in accordance with Trust Policy (in consultation with the Radiation Protection Adviser and Medical Physics Expert where appropriate).

- A departmental action plan, based on the outcome of the investigation, is drawn up and implemented.

- A written record is maintained of all such incidents in the department where the incident occurred.

- All documents relating to an externally notifiable incident are stored indefinitely in accordance with the Trust retention and destruction schedule.
- Their responsibilities for handling incidents are covered in their absence.

- The quantities of radioactive material and sealed sources kept and used, and the rates of accumulation and disposal of radioactive waste, do not exceed the respective limits assigned to their designated area.

- A log book, or electronic record, is maintained for each item of equipment, which contains:-
  - Handover procedures and records copies of all reports of maintenance, service, repair and modification.

  - For fixed installations, a copy of its critical examination report.

  - Results of acceptance, commissioning and routine periodic performance tests (user / Level A and non-user/ Level B).

  - Reports of radiation protection surveys of the equipment and its environment.

4.13.4 Storing a written record of any notifiable incidents indefinitely, and if the incident is not notifiable, storing a record of the preliminary investigation for 2 years in accordance with the Trust's retention and destruction schedule.

4.14 Local Managers / Superintendent Radiographers

4.14.1 Local Managers / Superintendent Radiographers are responsible for the day to day management of ionising radiation safety in their area of responsibility; and particularly for:

Ensuring that:-

- All members of staff working with ionising radiation in their designated area(s) of responsibility have received appropriate instruction in the procedures (including emergency procedures) and the use of equipment involved with exposure to ionising radiation; or are working under appropriate supervision.

- All members of staff working with ionising radiation in their designated area(s) of responsibility have read and understood the local rules.

- Appropriate and sufficient personal protective equipment is available.
- Defective protective equipment is removed from service.

- If an Outside Worker has to work in a controlled area on the Trust's premises, then appropriate information is made available as required to the Worker and to their employer; or the controlled area is formally handed over to the Outside Worker to work under the local rules of their employer.

- Any employee of another organisation who has to carry out duties in a controlled area is informed of the nature of the radiation hazard and the written working instructions.

- Appropriate instructions are given to other members of staff and visitors according to the circumstances of any potential exposure

- Radiographer (Level A) and Medical Physics (Level B) Quality Assurance and Safety Survey programmes on X-ray equipment are being conducted in accordance with prescribed schedules, including appropriate tests following maintenance and repair.

- Planned Preventative Maintenance is performed on all equipment in accordance with manufactures recommendations.

- Informing the Medical Physics Expert of any equipment repair or modification which may affect the radiation output, and whenever user quality assurance testing has demonstrated a significant change in radiation output.

4.15 Staff in Supervisory Roles

4.15.1 Radiation Protection Supervisors are required by IRR and their role is specific to these regulations, (please see HSE Ionising Radiation Protection Sheet 6). They are responsible for supervising all work involved with ionising radiation in their designated area(s) to ensure it is carried out in accordance with IRR; and in particular for:-

- Supervising those working in their area with regard to compliance with the local rules and working instructions.

- Checking that:-

- All members of staff working with ionising radiation in their designated area(s) of responsibility have received appropriate instruction in the procedures (including emergency procedures) and the use of equipment involved with exposure to ionising radiation; or are working under appropriate supervision.

- All members of staff working with ionising radiation in their designated area(s) of responsibility have read and understood the local rules

- If an Outside Worker has to work in a controlled area on the Trust's premises, then appropriate information is made available as required to the Worker and to their employer; or the controlled area is formally handed over to the Outside Worker to work under the local rules of their employer.

- Any employee of another organisation who has to carry out duties in a controlled area is informed of the nature of the radiation hazard and the written working instructions.

- Appropriate instructions are given to other members of staff and visitors according to the circumstances of any potential exposure

- Reporting to their Head of Department / Clinical Manager / Local Manager / Superintendent Radiographer immediately on any difficulties encountered with complying with the local rules and working instructions, and suggest proposals for remedial action

4.15.2 Managers may appoint staff to supervise practice with regard to other regulations and delegate responsibilities with regard to local areas where appropriate to role. Responsibilities may include:

- Supervising those working in their area with regard to compliance with employers procedures to comply with IRMER

- Checking at regular intervals that equipment quality assurance programmes are being conducted on schedule, including appropriate tests following maintenance and repair.

Where the practice in an area includes the use of radioactive material delegated tasks may include:-

- Supervising staff to make sure up-to-date records are held of the quantities of radioactive material and sealed sources kept and used, and of the rate of accumulation and disposal of radioactive waste for their designated area, and that these quantities and rates are communicated to the Site Officer on a monthly basis.

- A plan and records are maintained of radioactive contamination and dose rate monitoring in their designated area.
- Records are maintained of the transport and movement of radioactive material from their designated storage area(s) or Department.

- A monthly audit is conducted of the location of any sealed radioactive sources.

- The contents of emergency radioactive decontamination kits are regularly checked and maintained.

- Leak tests are carried out and recorded on all sealed sources at the time of purchase, and at least once every two years thereafter.

- All records mentioned in this section of the policy are maintained ready for immediate inspection.

4.16 Referrers

4.16.1 The Trust will entitle qualified medical staff on the GMC register and qualified dental staff on the GDC register as referrers.

4.16.2 Where the Trust agrees to entitle non-medically qualified staff to act as referrers for investigations or procedures involving ionising radiation, the arrangements for this must be set out in written procedures, which indicate:

- Non-medical access to refer is granted to an individual on the basis of their current role and training. Individuals meeting the requirements are added to an approved Trust Registers of Approved Referrers (held by the Business Units accepting referrals) and other lists such as those in relevant IT systems.

- Non-medical staff should be approved by the both the Medical Lead for the area of practice and their Professional Lead to ensure that the extension of their scope of practice to include referral, is appropriate, formally documented and agreed practice.

- Non-medical staff who are not Trust employees may act as non-medical referrers under similar arrangements to those for Trust Employees, but their employers take on any employer's responsibilities stemming from legislation / regulations.

- Non-medical staff refer only under a specific limited referral protocol approved by the department who will be receiving the referrals.
- Non-medical access to refer is not transferable and does move with a staff member when they move to a job role not covered by the protocol under which they refer or to the same job role elsewhere.

- Non-medical staff must successfully complete a radiation protection course, including the responsibilities of the Referrer under IRMER, approved by the Trust.

- Non-medical staff must referrer electronically wherever practicable and must include their designation on all their referrals.

All medically qualified, and any non-medically qualified, staff acting as Referrers are responsible for complying with all relevant processes and employers procedures including:-

4.16.2 Providing all relevant clinical data to enable the Practitioner to justify the medical exposure, paying particular attention to the accuracy of patient identification details.

4.16.3 Ensuring the requested procedure will have a bearing on patient management, and has not already been performed in a clinically relevant timescale.

4.16.4 Ensuring the patient is sufficiently informed of the risks and benefits of the procedure. Radiation from diagnostic and therapeutic procedures poses a material risk to patients. Referrers must consider this risk when deciding whether an examination or procedure will benefit a patient; and should discuss this risk with the patient where appropriate.

4.16.5 Ensuring that patients are aware of the arrangements for receiving the result of their examination.

4.16.6 Ensuring that requests are made electronically whenever possible; are submitted by themselves under their own account login and are made from an appropriate visit / episode of care. Referrers are individually responsible for requests made from their account and must take reasonable care to prevent unauthorised requests on their electronic account.

4.16.7 Where electronic referrals are not possible, Referrers must ensure that the request form/card is fully completed and carries their legible name and signature and contact details.

4.16.8 Immediately informing the relevant diagnostic or treatment service when a medical exposure is no longer required.

4.16.9 Ensuring that an examination report is received from the Imaging Department and acted upon in a timely manner; or in the case of some non-medical referrers to ensure that the staff responsible for clinical evaluation of their referrals are aware of the need to ensure a report is received and promptly acted upon.

4.16.10 Providing a written clinical evaluation of a medical exposure when required by the 'Reporting Agreement', or seek an Imaging Department report when they need specialist advice on the interpretation of exposures covered by the Reporting Agreement. In the case of some non-medical referrers to ensure that the staff responsible for clinical evaluation of their referrals are aware of the need to do so.

4.17 IRMER Practitioners and Operators

All staff acting as Practitioners or Operators are responsible for complying with all relevant processes and employers procedures including:-

4.17.1 Every individual medical exposure must be justified and authorised prior to exposure by an IRMER practitioner; or must be authorised by an Operator acting under written instructions issued by an IRMER Practitioner. An IRMER practitioner must be a registered healthcare professional who has received adequate training and has been entitled by the Trust to act in this capacity.

4.17.2 Operators are persons entitled, in accordance with the employer's written

procedures, to carry out practical aspects of a medical exposure involving ionising radiations. Their legal responsibilities include ensuring that the radiation doses arising from each medical exposure are as low as reasonably practicable (ALARP) consistent with the intended purpose.

4.17.3 The Trust takes a graduated approach to providing patients with information about the risks from ionising radiation when they attend for their examination or treatment as described in the employers procedures.

4.17.4 The Operator or Practitioner must ensure that any person acting as a 'carer and comforter' is informed of the risks before the exposure is made. Written information can support the provision of this information, but does not replace the need for a discussion.

4.17.5 The process of entitlement, together with the practical implementation of these responsibilities, is outlined in this policy, and is also set-out in greater detail in the IRMER procedures drawn up by each Business Unit owning ionising radiation equipment.

4.18 Clinical Lead for Corporate Induction

The Clinical Lead for Corporate Induction is responsible for ensuring that:-

4.18.1 Training on the duties of a referrer and instruction on the Trust's Employers Procedures is included in the corporate induction of all Doctors in Training.

4.18.2 Training in Radiation protection is included in the corporate induction of all Doctors in Training.

4.19 Trust Learning and Development Manager

4.19.1 Training on the duties of a referrer and the Trust's Employers Procedures is included in the corporate induction of all medical staff with a substantive contract.

4.19.2 Refresher training in the duties of the referrer and the Trust's Employers Procedures in part of the mandatory / essential to role training requirement for medical staff with a substantive contract.

4.19.3 Training in radiation protection is part of the mandatory / essential to role training requirement of all staff. This consists of initial training as part of induction with refresher training as appropriate to their role.

4.20 Trust Security Manager

The Security Manager is responsible for:-

4.20.1 Writing a site security plan for radioactive substances which complies with the guidance given in the booklet "Security Requirements for Radioactive Sources" (SRRS).

4.21 Employees

All Trust employees are responsible, as appropriate, for:-

4.21.1 Maintaining current knowledge of legislation (IRR, IRMER, EPR, etc.), employer's procedures, written protocols, local rules and written systems of work, as appropriate, and complying with all aspects when carrying out any duties which involve the use of ionising radiation.

4.21.2 dosimeter, they wear it/them appropriately whenever they are in a controlled area, they take all reasonable steps to prevent their dosimeter from becoming mislaid, and they exchange it for a new dosimeter after the appropriate time interval.

4.21.3 Reporting any incident, problem / fault with equipment or operational procedures, any medical exposure greater than intended, and any other incorrect exposure or any other incident involving ionising radiation to their Head of Department or Line Manager and their Radiation Protection Supervisor. Any incident involving a significant additional radiation dose should also be reported, using the Trust DATIX incident reporting system, by the person identifying the incident.

4.21.4 Any Trust employee who works with ionising radiation should inform the appropriate Trust RPA, annually in writing, of the details of any other radiation employment conducted for other employers. All such employees should ensure that appropriate personal radiation monitoring arrangements are in place for their other employments involving exposure to ionising radiation.

5. Operational Implementation of Trust Policy for Ionising Radiation Safety.

5.1 Overarching principles:

5.1.1 All facilities where activities will involve the use of ionising radiation will be designed to satisfy relevant statutory requirements and codes of practice, and to reduce exposure to as low as reasonably practicable. In addition, the security arrangements for facilities where radioactive material is kept or used must comply with the requirements given in SRRS.

5.1.2 Ionising radiation working areas will be designated as controlled or supervised areas where the annual dose or derived limits are likely to exceed the values specified in IRR ACP. Working areas will also be designated if deemed necessary by the Radiation Protection Adviser to restrict exposure.

5.1.3 The Radiation Protection Adviser must be consulted on and approve the plans for new facilities and modifications to existing facilities where ionising radiation will be used, and on proposals for designation of working areas

5.1.4 A Medical Physics Expert must be consulted as part of the selection process for any radiation equipment and approve it as suitable for the intended purpose.

5.2 Occupational Exposures

5.2.1 The Trust will take all possible steps to ensure:

- That doses to staff are kept as low as reasonably practicable
- That doses to staff are kept below the level at which it becomes necessary to classify staff wherever practicable.
- That doses to whole body; eye and extremities remain below relevant non-classified dose levels for each body area for all staff.

Any member of staff who needs to enter a controlled area on a regular basis is required to wear a whole body personal dosimeter on these occasions, (unless specifically agreed otherwise with the Radiation Protection Adviser and alternative systems are in place).

Environmental monitoring will be conducted at intervals of no greater than 5 years or on the advice on the RPA.

Where significant eye or extremity doses are likely, extremity and/or eye dosimeters must also be worn, and additional environmental monitoring may also be carried out, in consultation with the Radiation Protection Adviser.

5.2.2 If an employee of this Trust has a working commitment, other than as an employee of this Trust, which requires the employee to enter on a regular basis a controlled area outside the Trust, then he/she should wear the whole body personal dosimeter issued by this Trust during their work for their other employer(s) also. They should ensure they are also issued with a whole-body dosimeter at their other place(s) of work which is to be worn only when working in the other employer's premises.

5.2.3 A system must be in place to control the exposure of members of staff (e.g. nurse, anaesthetist, ODP) who are required to remain in a controlled area in order to care for a patient during a diagnostic X-ray procedure but who do not have their radiation exposure monitored directly. This system must be kept under continuous review by the use of risk assessments to take account of changes in working practices, and the installation of new and replacement X-ray equipment.

5.2.4 If an employee of another organisation has a regular working commitment which requires entering a UHDB Trust controlled area, then he/she will be issued with a whole body personal dosimeter in accordance with the local rules.

5.2.5 Heads of Service / Clinical Managers must monitor dosimetry results and inform the Radiation Protection Adviser of unusually high individual doses or an upward trend in doses from a particular area of practice.

5.2.6 Where investigation levels are exceeded, these must be investigated by the Head of the relevant Department, in consultation with the Radiation Protection Adviser and Radiation Protection Supervisor and remedial action taken where necessary.

5.3 Medical Exposures

5.3.1 Individuals entitled to act as Referrers, Practitioners and Operators will be defined in an "Employer's Procedure", as specified in Schedule 1 of IR(ME)R, drawn up by each Business Unit owning ionising radiation equipment. This Procedure must also satisfy the requirements of written entitlement specified in

this policy. Non-medically qualified staff who are registered healthcare professionals may only act as Referrers for diagnostic procedures if they have been individually entitled by the Trust to act in this capacity, have been appropriately trained and the referrals are made according to a written protocol agreed by the relevant Medical and Professional Leads.

5.3.2 All Referrers, Practitioners and Operators must comply with all written procedures and protocols, and must pay particular attention to patient identification and the appropriate actions required for pregnant or breastfeeding patients.

5.3.3 Where the referrer is not themselves the IRMER Practitioner, a medical exposure to ionising radiation will be conducted only in response to a Request received via an approved electronic requesting system under the unique log-in of the Referrer, who must make the request using an appropriate visit / episode of care and provide sufficient medical data to enable the Practitioner to justify the exposure. Where electronic referral is not available a written request containing the required information and signed by the Referrer is required. Where the referrer is themselves the IRMER practitioner an appropriate written record of the 'referral' must be made.

5.3.4 Every medical exposure must be justified individually as showing a net benefit to the patient and authorised by a Practitioner, who must also ensure that this process results in keeping the dose to the patient as low as reasonably practicable. Alternatively, an Operator may authorise an individual exposure in accordance with guidelines written by a Practitioner. In either case, there must be a traceable record of the individual(s) who has (have) justified and authorised the exposure.

5.3.5 The Operator must select equipment and methods which will ensure that the dose to the patient is as low as reasonably practicable, consistent with the intended diagnostic or therapeutic purpose, and in so doing, must pay special attention to the performance of the equipment, its adherence to the relevant diagnostic reference level, and the ability to assess the patient dose.

5.3.6 In discharging their statutory responsibilities for justification and optimisation of the exposure, the Practitioner and Operator must pay special attention to non-medical exposures, to health screening exposures, to medical exposures of children, to referrals for exposures to individuals with childbearing capacity, individuals who are pregnant or breastfeeding, and to high dose procedures.

5.3.7 IRMER practitioners responsible for radiopharmaceutical administrations have the additional responsibility of ensuring that they maintain a current valid ARSAC licence for all relevant radiopharmaceuticals under their scope of practice and that this includes relevant permissions for research studies as well as routine clinical practice. They must also liaise with the Trust's Medical Physics Expert(s) as necessary to confirm that the Trust has a valid ARSAC licence in place covering all routine and research radiopharmaceuticals which they propose to administer.

5.3.8 Administration of a radiopharmaceutical must be carried out only for radiopharmaceuticals listed on the Trust's ARSAC licence; and may be carried out

only by a clinician holding the appropriate ARSAC licence who acts as the IRMER practitioner; or by a member of staff acting under a protocol authorised by that clinician. These members of staff must be trained in phlebotomy and intravenous injection techniques, and they must also have an individually written entitlement issued by the ARSAC certificate holder to carry out these duties.

5.3.9 A clinical evaluation must be recorded of the outcome of every type of medical exposure, including surgical localisation procedures. Evaluations of diagnostic exposures will be normally provided from the service undertaking the examination or procedure; either by entitled medical staff, Radiologist, Cardiologist etc.; or appropriately trained healthcare staff entitled to act as a Non-medical Reporter. Where examinations are covered by the Reporting Agreement, the referrer must provide the documented clinical outcome or, when advice on image interpretation is required, seek a report from the Imaging Department.

5.3.10 Local Diagnostic Reference levels (DRLs) will be established for X- ray procedures and reviewed annually according to the guidelines in the Institute of Physical Sciences in Medicine's (IPEM) Report No. 88 "Guidance on the Establishment and Use of Diagnostic Reference Levels for Medical X-ray Examinations", and according to current guidance and national DRLs published by the Department of Health's DRL Working Party or other national bodies. Local DRLs will be set for selected examinations using patient dosimetry results from audits and electronic dose management systems. If a DRL is consistently exceeded, a review will be undertaken by the relevant Business Unit, and corrective action taken where appropriate.

5.3.11 Diagnostic X-ray doses to patients will be audited according to the methods given in the NRPB publication "National Protocol for Patient Dose Measurements in Diagnostic Radiology", in the IPEM Report No. 91: "Recommended Standards for the Routine Performance Testing of Diagnostic X-Ray Imaging Systems", and other IPEM and BIR publications as appropriate.

5.3.12 Sufficient diagnostic X-ray exposure parameters, particularly dose area product (DAP) and screening times in fluoroscopic procedures, CT dose indices (DLP), DAP and/or kVp and mAS in general radiography, and nuclear medicine administered activity must be recorded to allow a retrospective estimate of the dose to every patient and to the foetus of every pregnant patient. Whenever possible doses should be recoded per examination / CRIS Code / body area rather than the total dose for an attendance. Where it is impractical to record exposure parameters, then the exposure must follow an agreed protocol which will allow doses to be estimated retrospectively.

5.3.13 Trust systems and facilities for the determination, collection and recording of patient radiation doses must be sufficient to enable these radiation dose results for its patient population to be supplied to the Secretary of State when so requested. This requirement will be met via automated electronic systems where possible.

5.3.14 Referrers must ensure the patient is sufficiently informed of the risks and benefits of the procedure to make informed decisions and give valid consent. Radiation from diagnostic and therapeutic procedures poses a material risk to patients. Referrers must consider this risk when deciding whether an examination or procedure will benefit a patient; and should discuss this risk with the patient

where appropriate.

5.3.15 Departments performing examinations / procedures will provide patients with information regarding the risks from radiation associated with their examination / procedure using a graduated approach. For lower dose procedures information will be made available when the patient attends for their procedure, typically via posters or leaflets available in waiting areas. For higher dose procedures the Operator or Practitioner will provide this information verbally, if appropriate. Where the procedure requires documented consent; radiation will be discussed alongside other risks.

5.4 Research Exposures

5.4.1 Refer to the SOP/RCL/001 *Research Involving Medical Research Exposures* which sets out the arrangements and resources required to sign off and review research which include radiological procedures.

5.4.2 Any research project involving the exposure of patients or volunteers to ionising or non-ionising radiation must be approved by a Research Ethics Committee (REC) and appropriate MPE.

5.4.3 Staff involved in the conduct of research exposures must comply with the additional requirements in the employer's procedures relating to research exposures in addition to the normal process for medical exposures. In particular:

The Referrer is responsible for ensuring:-

- Appropriate consent has been obtained and the subject is entering the research programme voluntarily.
- That the requests are clearly marked with the name / title of the research programme.

The Practitioner is responsible for:-

- Justifying the examination according to the referral criteria as given on the Research Protocol.
- Providing the Operator with the examination protocol to be followed.

Operator responsibilities:-

- To follow all relevant Employer's Procedures (e.g. Patient Identification).
- To record the parameters relevant to the estimation of patient dose.
- Not to proceed with the examination if he/she believes that the research protocol is not being followed or that a dose constraint / target dose will be exceeded.
- To submit the images for clinical evaluation.

5.5 Public Exposures

5.5.1 Where appropriate, specific instructions should be issued to patients and to staff in order to minimise the exposure of critical groups in the public (e.g. young children) to patients who have undergone a diagnostic or therapeutic nuclear medicine procedure.

5.6 Equipment and the Working Environment

5.6.1 An important consideration in the purchase, selection and use of all ionising radiation equipment involved with diagnostic or therapeutic procedures must be to minimise the exposure of patients and staff, whilst ensuring the optimum image quality. Appropriate Medical Physics expert advice must be sought at the earliest stage in any process to select radiation equipment which should have the ability to connect to a dose management system where appropriate.

5.6.2 All Business Units owning ionising radiation equipment must have a formal signing over procedure recorded in a log book for each item of equipment, as follows:-

- Accepting new equipment into clinical use.
- Taking equipment out of clinical use.
- Handing over for repair, testing, calibration or survey.
- Specifying a requirement to carry out re-commissioning or routine periodic performance tests after maintenance or repair.
- Completion of any of the above procedures.
- Taking back into clinical use.

5.6.3 All ionising radiation equipment and their installation must undergo satisfactory critical examination, acceptance and commissioning tests before first use, and repeat commissioning and/or routine periodic performance tests as appropriate, after maintenance, repair, or modification.

5.6.4 Appropriate acceptance, commissioning and routine performance tests (user and non-user) and surveys will be carried out on radiation equipment according to current professional guidance for the type and usage of the equipment

5.6.5 All non-user routine performance tests will be carried out at six monthly intervals on mammography equipment and facilities, and annually on all other types of diagnostic X-ray equipment including dental X-ray equipment advised by the MPE.Appropriate routine performance tests will be carried out on radionuclide calibrators and multi-sample radionuclide counters advised by the MPE taking into

account relevant professional guidance.

5.6.6 Acceptance, commissioning and routine performance tests on radiotherapy treatment and associated imaging equipment will be carried out under advice by the MPE taking into account relevant professional guidance.

5.6.7 All ionising radiation and radioactivity measuring equipment must be subjected to tests before use, and periodic examination and testing normally once every 12 months and at least once every 14 months, in accordance with the guidance given in the Health and Safety Executive's booklet HS(G)49: "The Examination and Testing of Portable Radiation Instruments for External Radiations". Records will be maintained for a minimum period of 2 years for periodic tests and tests before use of all such measuring equipment.

5.6.8 Equipment which emits or detects radiation will not be modified without the written agreement of, or a contractual arrangement with the manufacturer or supplier.

5.7 Radioactive Substances

5.7.1 All sealed and unsealed radioactive sources will be kept in secure containers with the contents of the containers clearly marked. The security arrangements for the facilities housing these sources must comply with the requirements in SRRS and must be specified in a site security plan for radioactive substances which also complies with these requirements in SRRS. These sources will be stored, dispensed, handled and administered using appropriate methods outlined in the guidance material supporting the relevant statutory requirements.

5.7.2 A written record must be kept of the issue and return of each sealed source on every occasion that it is removed from its secure container, apart from gamma camera flood sources, calibrator check sources and patient markers which must be returned to their storage location immediately after use. The record must include the name of the member of staff involved with each movement as well as the date.

5.7.3 Practical arrangements for the transport of radioactive substances must satisfy the requirements of CDGR and TDGSAR99.

5.8 Contingency Planning

5.8.1 All practical steps must be taken to prevent incidents occurring and to minimise their consequences.

5.8.2 Contingency plans must be drawn up in the local rules to deal with such events, and they must include the posting of notices advising staff who to contact in the first instance, how to contact relevant emergency services, the location of emergency equipment, and the initial procedures to follow. Staff must be trained to implement these contingency plans and in emergency procedures.

5.8.3 Emergency equipment must be located as near as possible to the locations where accidents are most likely to occur, and in the case of an

accident involving an unsealed radioactive source; this equipment must include a decontamination kit whose contents must be regularly checked.

5.9 Incidents

5.9.1 All Business Units owning ionising radiation equipment must ensure:

- That all incidents resulting in, or with the potential to result in, additional or unintended radiation dose must be recorded on the Trust's DATIX system.
- Incidents must be reviewed by a staff member with sufficient knowledge of Radiation Protection to assess the risks and escalate the incident where appropriate.
- Dose estimates must be made by a Medical Physics Expert in consultation with a Radiation Protection Adviser when incidents are considered to have the potential to be externally reportable.

5.9.2 If there is an obvious or suspected equipment fault, the equipment must be immediately taken out of use; the fault must be investigated in consultation with the Radiation Protection Adviser and remedied. Procedural errors must also be investigated in consultation with the Radiation Protection Adviser, and appropriate remedial action taken.

5.9.3 Where a medical exposure is deemed 'a significant overexposure to a patient due to equipment malfunction, operator error or procedural error, such events will be notified to the Care Quality Commission's IRMER inspectorate where appropriate as per the Significant Accidental or Unintended Exposures (SAUE) Guidelines.

5.9.4 It is the responsibility of the Clinical Director of the Business Unit in which the incident occurred, to ensure that significant radiation incidents are managed appropriately.

- Where the incident concerns significant doses to staff, or the public, the RPA must be informed. They will make any required dose calculations and advise on reporting to the HSE. Where an incident is to be reported to the HSE, this will be done by the Trust Health and Safety Manager.

- Where the incident concerns significant doses to patients, the MPE must be informed. They will make any required dose calculation and advise on reporting to the CQC IRMER inspectorate; taking into account the criteria in the CQC guidance document Significant accidental and unintended exposures under IR(ME)R Guidance for employers and duty holders (June 2019). Where an incident is to be reported to the CQC this will normally be done by the relevant Clinical Manager / Head of Service.

- Where an incident concerns radioactive materials the RWA should also be informed and will advise on possible breaches of the EPR and actions required including reporting to the EA.

Whenever an incident is reported to an external body The Divisional Governance Team must be informed and must escalate this within the Trust by informing the

Trust's Risk Management team, including the Trust Risk Manager and the Executive Medical Director as the designated Responsible Officer.

5.9.6 Externally reportable incidents are regarded as SI / HLI's under the Trust's Incident Reporting and Investigation Policy. Investigations must be led by the area where the root cause of the incident occurred, (e.g. an unintended exposure resulting from a referral error must be investigated by the area where the referral was made). A detailed investigation must be made following the Trust process and submitted for Divisional and Trust approval before being submitted to the CQC, via the Trust Risk Manager.

5.9.7 For externally notifiable incidents the Trust Duty of Candour process must be followed. Currently this is a 3 stage process:

1. The patient must be informed of the error / incident as soon as possible aster it occurred.

    a. When this is detected at the time, the staff involved should provide the patient / relatives with a brief verbal explanation and apology.
    b. When the incident is detected at a later date, the Referrer will be informed of the incident and must inform the patient, supported by the IRMER Practitioner if necessary.
    c. If the referrer is unable to inform the patient, the Referrer's Clinical Director must ensure the patient is informed by an appropriately senior member of the clinical team.
    d. If a decision is made not to inform the patient, or relative, then that decision together with the reasons should be clearly recorded in the patient's records. This decision must be discussed with the Divisional governance team at the earliest opportunity

2. Once an incident has been confirmed as externally reportable and a SI / HLI investigation has been initiated, the lead investigator will contact the patient using the DoC1 template letter

3. Once the SI / HLI investigation has been concluded and the report signed off, the relevant Divisional Nurse Director will contact the patient using the DoC2 template letter.

Records of all 3 stages of the Duty of Candour process must be added to the DATIX report.

5.10 Training

5.10.1 All staff who are involved with the use of ionising radiation must have received theoretical and practical training appropriate to their duties and to the hazard involved, and will be expected to undergo continuous education, training and development.

5.10.2 For staff with specific responsibilities defined by IRMER:-

- Medically qualified Referrers will be instructed in their statutory responsibilities on joining the Trust as part of their induction training.

- Non-medically qualified Referrers must have successfully completed a Trust approved course on radiation protection for Non-Medical Staff Referring Patients for Imaging or similar examination.

- Practitioners and Operators must have successfully completed theoretical and practical training in all areas relevant to their functions and to their safe use of radiation, as listed in Schedule 3 of IRMER.

- The Trust must keep, and have available for inspection by the relevant enforcing authority, an up-to-date record of all relevant training completed by its IRMER practitioners and operators in regard to their delivery of medical radiation exposures. Individual records should also be kept in staff personal files.

6. Monitoring Compliance and Effectiveness

This Policy will be monitored by:-

6.1.1 Line managers ensuring that radiation protection responsibilities are included in the appraisals and personal development plans of their staff

6.1.2 Business Units owning radiation equipment maintaining a comprehensive patient dose audit programme, undertaking appropriate reviews whenever local diagnostic reference levels are consistently exceeded, and carrying out quality assurance programmes which review all their written procedures, examination protocols, risk assessments, other statutory documentation, and radiation equipment usage

6.1.3 The annual programme of equipment performance and radiation protection surveys

6.1.4 The regular scrutiny of occupational dose records and the investigation of overexposure

6.1.5 The inclusion of relevant occupational and medical radiation protection considerations into clinical audit programmes.

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8. Appendices

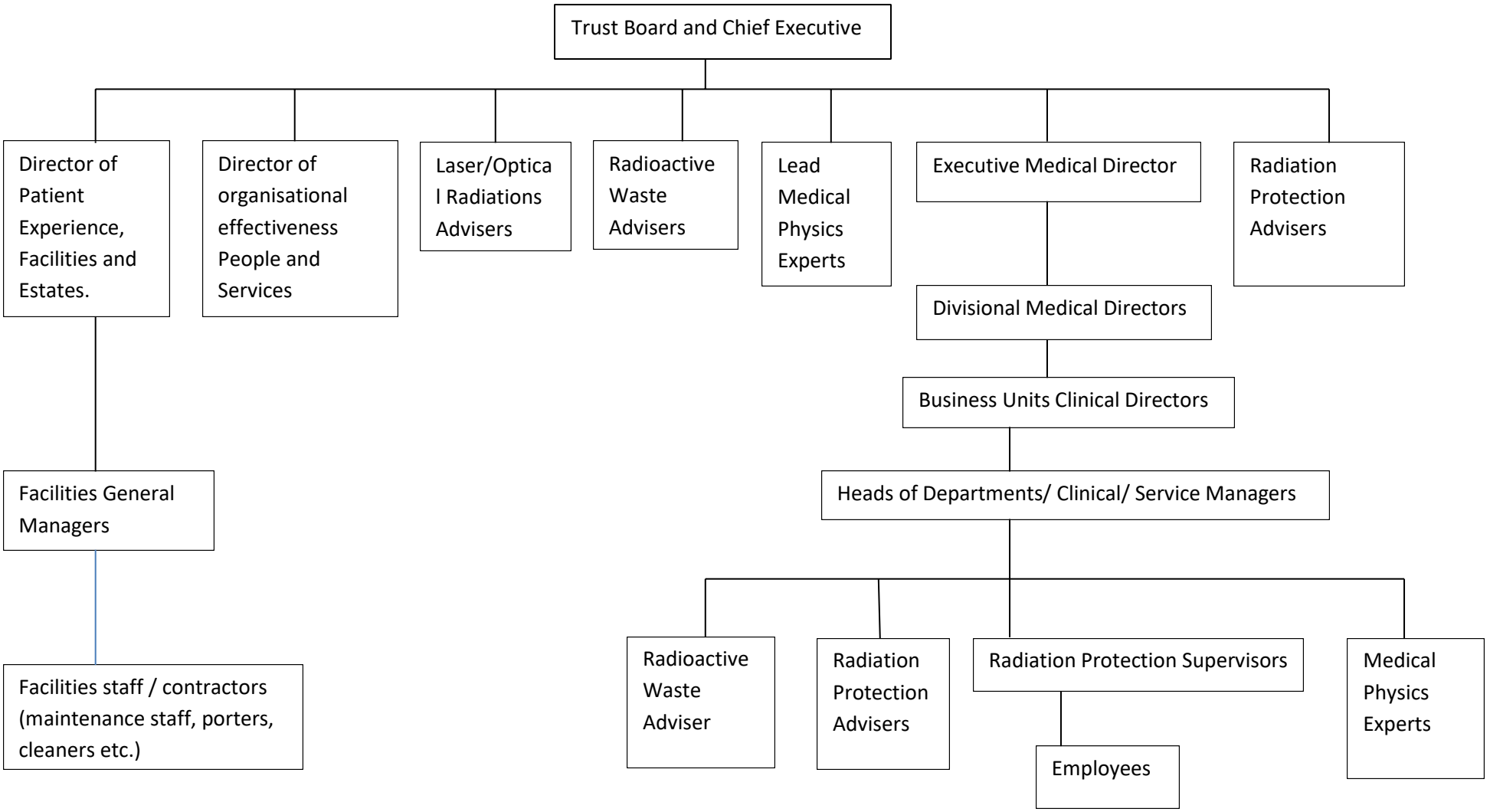
Appendix 1 – Lines of Responsibility

Appendix 2 – Reporting Structure

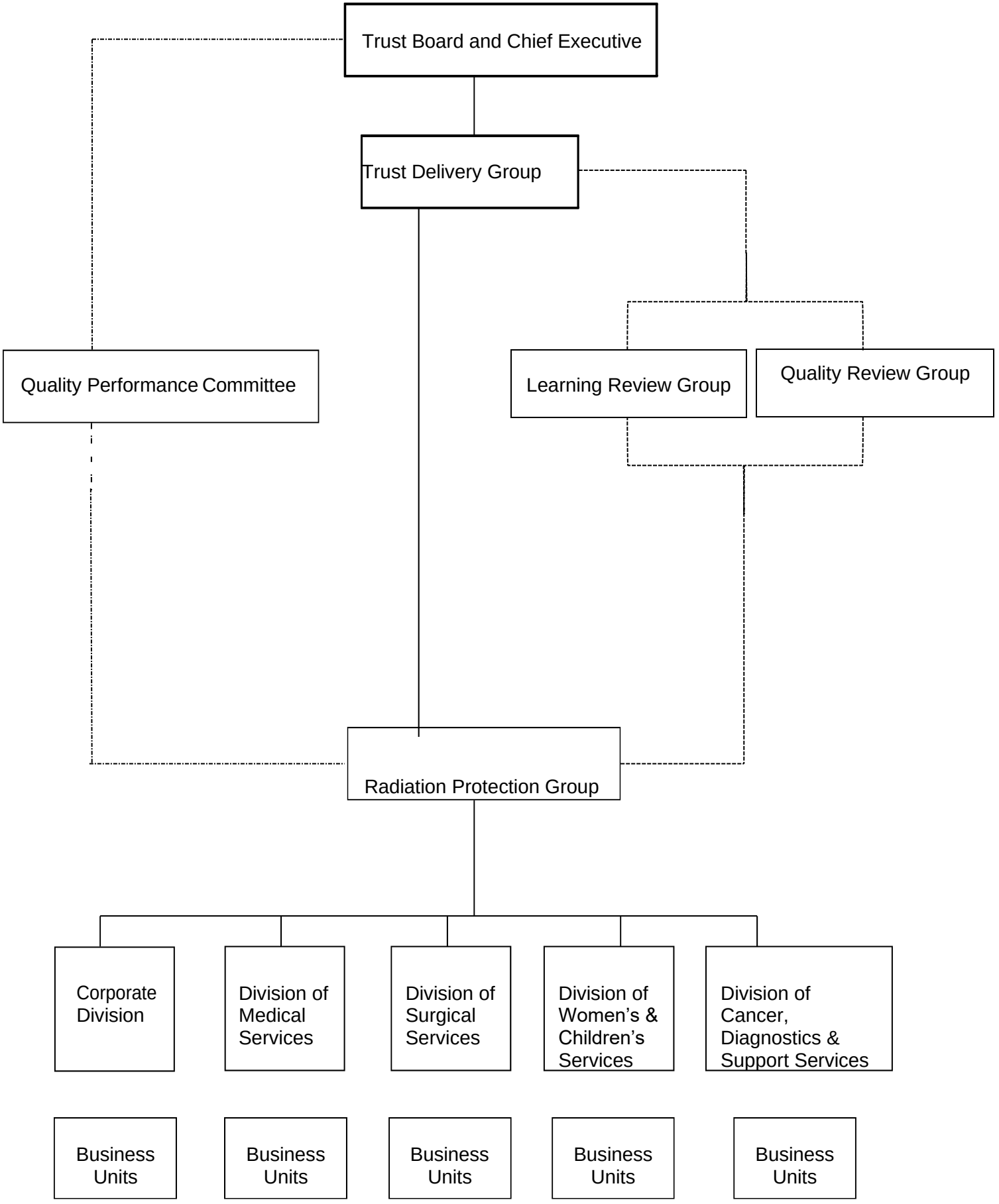
Appendix 3 - Environmental Impact Assessment

Appendix 4 – Equality Impact Assessment

Appendix 1 – Lines of Responsibility



Appendix 2 – Reporting Structure



Appendix 3 - Environmental Impact Assessment

The purpose of an environmental impact assessment is to identify the environmental impact of policies, assess the significance of the consequences and, if required, reduce and mitigate the effect by either, a) amend the policy b) implement mitigating actions.

Area of impact	**Environmental Risk/Impacts to consider**	**Action Taken (where necessary)**
Waste and materials	• Is the policy encouraging using more materials/supplies? • Is the policy likely to increase the waste produced? • Does the policy fail to utilise opportunities for introduction/replacement of materials that can be recycled?	No – the policy explicitly reduces amount of radioactive material usage and waste
Soil/Land	• Is the policy likely to promote the use of substances dangerous to the land if released (e.g. lubricants, liquid chemicals) • Does the policy fail to consider the need to provide adequate containment for these substances? (e.g. bunded containers, etc.)	No
Water	• Is the policy likely to result in an increase of water usage? (estimate quantities) • Is the policy likely to result in water being polluted? (e.g. dangerous chemicals being introduced in the water) • Does the policy fail to include a mitigating procedure? (e.g. modify procedure to prevent water from being polluted; polluted water containment for adequate disposal)	No
Air	• Is the policy likely to result in the introduction of procedures and equipment with resulting emissions to air? (e.g. use of a furnaces; combustion of fuels, emission or particles to the atmosphere, etc.) • Does the policy fail to include a procedure to mitigate the effects? • Does the policy fail to require compliance with the limits of emission imposed by the relevant regulations?	Not specifically

Energy	• Does the policy result in an increase in energy consumption levels in the Trust? (estimate quantities)	No
Nuisances	• Would the policy result in the creation of nuisances such as noise or odour (for staff, patients, visitors, neighbours and other relevant stakeholders)?	No

Appendix 4 – Equality Impact Assessment

Equality Impact Risk Assessment (EIRA) Cover Sheet

Name of policy: Trust Ionising Radiation Safety Policy

Policy /process/ service/function reference no: RMK/2014/039

Person responsible for document:

Penny Owens: Director of Allied Health Professions and Chair of the Trust Radiation Protection Group

Process being assessed is a:

Guideline	
Written Policy	✓
Function or Strategy	
Service or Practice	
Informal policy	
Informal procedure	
Other (please state)	

New		Existing		Revised	✓

Lead person responsible for conducting the EIRA:

Mike Barnard: Clinical Manager - Compliance (Imaging Business Unit) & Chair of Trust IRMER Sub-Group

Partners / Stakeholders (Internal and External) involved in the assessment:

Trust Appointed Experts / Advisers (Radiation Protection Advisers, Medical Physics Experts, Radioactive Waste Advisers, etc.)

Business Units owning X-ray Equipment

Trust Radiation Protection Groups and its Subgroups

To be completed on completion of the assessment if no relevance to inequality found

Date screening completed:01/04/2020	Date for screening review:01/04/2023

To be completed if relevance found and full assessment undertaken

Date screening completed
Date full assessment completed
Date for review

Stage 1 – Screening the process

Q1. What is the aim and what are the key objectives of the Document?

To ensure that the use of ionising radiations within the Trust is as safe as possible for staff, patients and visitors.

To ensure the Trust's use of such radiations is compliant with legislative and regulatory requirements and in accordance with best practice guidelines

Q2. What outcomes or benefits is the document attempting to achieve, why and for whom? *(e.g. What do you want to be providing, how well, changes, improvements; what benefits will there be?)*

To bring together the 3 existing policies

Derby Sites:

- Compliance with Ionising Radiation (Medical Exposures) Regulations – IRMER (RMK/2014/038)
- Radiation Protection (RMK/2014/039)

Burton Sites:

- Radiation Protection (119)

into a single trust-wide policy and procedure:

To minimise the risks from ionising radiation to staff, patients and visitors.

That the Trust uses ionising radiations in a way which is compliant with relevant regulations.

Q3. What other key process/organisational documents does this link with? *(Consider documents that will affect access to your Process and outcomes. Consider a joint EIRA if there are interlinking issues)*

The Policy aims to replace 3 existing Policies:

- Compliance with Ionising Radiation (Medical Exposures) Regulations – IRMER (Derby - RMK/2014/038)
- Radiation Protection (Derby - RMK/2014/039)
- Radiation Protection (Burton - 119)

Trust Policy and Procedures for:

- Incident and Serious Incident Management (Burton only)
- Incident Reporting , Analysis, Investigating and Learning Including Serious Incidents (Derby Only)

- Health and Safety
- Investigations (ordering, requesting and the management of results) (Derby Only)

Clinical Guidelines:

- Nuclear Medicine – Information for Requesting Doctors (Derby)
- Radiological Imaging – Requesting – Clinical Guideline

The regulations relating to the use of ionising radiations (IRR, IRMER, EPA, etc.) require a wide range of specific procedures to be in place, covering various aspects relevant to the safe use of ionising radiation.

Q4. Do you believe the document being assessed is relevant to the public sector equality duty in:

Please tick all that apply:

Eliminating Discrimination	
Promoting Equal Opportunities	
Promoting good relations between different groups identified in Q5	

If you ticked any of the above the process will require a full assessment

What do you/we already know?

The policy applies equally to all persons acting in the same capacity (Staff / Patient / Visitor).

Where issues which predominantly affect a particular group, the policy is written using neural language. For example sections relating to pregnancy or breast feeding now apply to patients of childbearing potential, not female patients, to reflect the changes made to IRMER in 2017.

Q5. Is there any EVIDENCE or CONCERN from staff, users or communities that any of the following groups have been or could in any way be differentially impacted by the aims, objectives or implementation of the process? Is that differential impact positive or negative? *N.B. A broad interpretation should be taken of the work 'evidence'. It should include anecdotal evidence and evidence derived from qualitative or quantitative analysis where available).*

Group	Yes	No	Positive	Negative
Age		✓		
Gender (Male, Female and Transsexual)?	✓		✓	
Learning Difficulties / Disability or Cognitive Impairment?		✓		
Mental Health Need?		✓		
Sensory Impairment?		✓		
Physical Disability?		✓		
Race or Ethnicity? (Including cultural beliefs and norms)		✓		
Religious, Spiritual belief		✓		
Sexual Orientation?		✓		
Homeless?		✓		
Others — Please state		✓		

Please give details of the evidence you have:

Where issues which predominantly affect a particular group, the policy is written using neural language. For example sections relating to pregnancy or breast feeding now apply to patients of childbearing potential, not female patients, to reflect the changes made to IRMER in 2017.

Q6. If you do not have any evidence for Q5 can you show that you have enough evidence to either demonstrate that the process will/ has not differentially impacted the groups or that the process is not applicable to differential impact assessment for these groups.

Yes	✓	**No**	

If you answered **No** the process is likely to require a full assessment (please go to Q7)

If you have tick **Yes** please detail what evidence you have:

The policy applies equally to all persons acting in the same capacity (Staff / Patient / Visitor).

Q7. Does this document need to go onto full assessment?

To decide whether your document needs a full assessment consider – does your evidence indicate possible negative impact, how clear is the evidence you already have, are you confident in your evidence of no negative impact?

Yes		If you have ticked yes please go to **Q9**
No	✓	If you have ticked no please go to **Q8**

Q8. Briefly state your reasons for this Process not going onto a full assessment.

The policy applies equally to all persons acting in the same capacity (Staff / Patient / Visitor).

Where issues which predominantly affect a particular group, the policy is written using neural language.

Q9. If full Risk Assessment required use the EIRA prioritisation guide on page 19 please indicate if you feel the Process has a possible:

Not Applicable

High Risk of Impact	
Medium Risk of Impact	
Low Risk of Impact	

Please state the date you are going to begin the full assessment:

Please now file a copy of your screening and send a copy to the Chair of the Equality and Human Rights Steering Group
Please also connect your results / findings with whatever procedures or process for policy development that is relevant to your work or Directorate)

Level of Impact	Criteria	Characteristics	Actions
HIGH The function is relevant to **all** parts of the duty There is **substantial** evidence of groups being adversely affected There is **substantial** public concern	Potential for significant negative outcomes on different groups Potential for significant concern about how different groups are treated	frontline services with high scope for, or evidence of, unequal access or outcomes Strategic planning functions with direct impact on how services that have an equality dimension are organised Typically **ACCESS** to service /proposal by either Employees or Service Users may be raised at this level	Proposal needs to be reviewed and amended as soon as possible and within **1 year**
MEDIUM The function is relevant to **most** parts of the duty There is **some** evidence of groups being adversely affected There is **some** public concern	Potential for different groups to be inappropriately treated differently Potential for concern about how different groups are treated or that services are delivered differently	Frontline services with less scope for, or evidence of, unequal access or outcomes Strategic functions that could nfluence how different groups are reated Typically **EXPERIENCE** of service / proposal by either Employees or Service Users may be raised at this level	Proposal needs to be reviewed and amended within **2 years**
LOW All other functions (even ones with very little relevance).	Little or no potential for unequal access or impacts between different groups	Back office support functions Direct service delivery where scope for different access or outcomes is limited	Proposal needs to be reviewed and amended within **3 years**