Royal Cornwall Hospitals
NHS Trust

Non-Ionising Radiation Safety Policy

V5.0

October 2023

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Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

1. Introduction

1.1. For the purpose of this policy, non-ionising radiation (NIR) is defined as static magnetic fields and electromagnetic radiations within the optical, radio wave and microwave regions.

1.2. Optical radiation includes laser radiation and incoherent (non-laser) ultraviolet, visible, and infra-red electromagnetic radiations.

1.3. A variety of sources of NIR are used within the Trust for the purposes of medical diagnosis and treatment, in support of the provision of healthcare and in the pursuance of medical research. Examples of such NIR devices include visible and non-visible lasers (including class 3 and 4 lasers), ultraviolet (UV) imaging and phototherapy equipment, photodynamic therapy equipment, neonatal therapy equipment, infra-red physiotherapy equipment and UV laboratory equipment, MRI scanners.

1.4. These sources are used to benefit patients directly through diagnostic and therapeutic procedures on the patient and indirectly through clinical tests, research, and routine operations of the Trust.

1.5. This policy addresses non-ionising radiation. Ionising radiation safety (for example x-ray and radioactive materials) is addressed in the Ionising Radiation Safety Policy, accessible via the document library.

1.6. This version supersedes any previous versions of this document.

2. Purpose of this Policy/Procedure

2.1. The aim of this policy is to ensure, as far as reasonably practical, the health, safety and welfare of staff, patients and members of the public who may be exposed to hazards arising from non-ionising radiation on the Trust's premises.

2.2. The objectives of this policy are to ensure devices are installed, maintained, and operated in an effective and safe manner and to ensure the Trust complies with current national or international guidance and legislation regarding non-ionising radiation use.

2.3. The intended outcome of this policy is to ensure the safe and effective use of non-ionising radiation devices all areas.

2.4. It is the policy of Royal Cornwall Hospitals NHS Trust to ensure, as far as reasonably practical, the health, safety and welfare of staff, patients and members of the public who may be exposed to hazards arising from NIR on the Trust's premises, in accordance with current national and international guidance and legislation.

2.5. Patients will undergo a technique utilising NIR only where the potential medical benefit outweighs the risk of harm from the exposure to NIR. The risk to staff, patients and visitors arising from NIR use shall be as low as reasonably practicable (ALARP), social and economic factors being taken into account.

2.6. The Trust will fully co-operate with any inspections by statutory bodies and furnish any information requested. The Trust will respond expeditiously to requirements and comments raised by an inspector.

2.7. Royal Cornwall Hospitals NHS Trust accepts its responsibility to comply with the requirements of the relevant UK legislation, including:

- The Control of Artificial Optical Radiation at Work Regulations 2010.
- The Health and Safety at Work Act 1974.
- The Management of Health and Safety at Work Regulations 1999.

2.8. Failure to comply with this policy may lead to capability or disciplinary action and/or prosecution of the Trust or individual.

3. Scope

3.1. This policy applies to all employees, contractors, voluntary workers, supernumerary staff, students, locum, and agency staff and to individuals holding honorary employment contracts.

3.2. This policy covers all sites owned by Royal Cornwall Hospitals NHS Trust and those areas on other Employer's sites where RCHT staff work with non-ionising radiation.

4. Definitions / Glossary

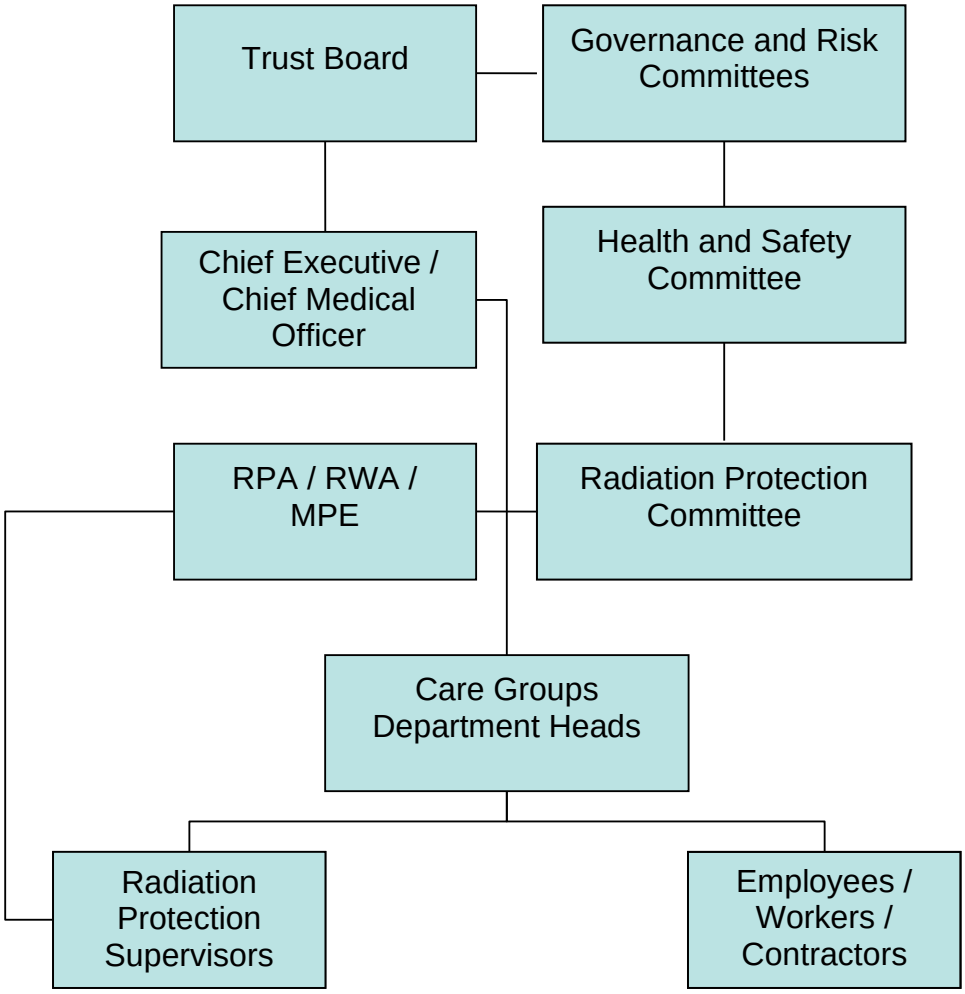
4.1. **Non-ionising radiation (NIR)** is defined (for the purposes of this policy) as static magnetic fields and electromagnetic radiations within the optical, radio wave and microwave regions.

4.2. **Optical radiation** is defined as laser radiation and incoherent (non-laser) ultraviolet, visible and infra-red electromagnetic radiations.

4.3. **Laser** is defined a device that emits intense optical radiation ('light') at one or more distinct wavelengths.

4.4. **Potentially hazardous non-ionising radiation** is defined as that which has the potential to produce transient or long term health effects – for example such as eye, skin or specialised hazards. See section 6.2/6.3.

5. Ownership and Responsibilities



5.1. The Trust Board

The Trust board retains overall responsibility for the health, safety, and welfare of employees and non-employees.

5.2. The Chief Executive

The Chief Executive as the 'Employer', is identified as the person having overall responsibility for ensuring that the Trust complies with the requirements of the relevant legislation. This responsibility cannot be delegated.

5.3. The Chief Medical Officer

The Chief medical Officer is identified as the Trust Board member tasked with operational management of radiation safety.

5.4. The Laser Protection Adviser (LPA)/MR Safety Adviser

The Laser Protection Adviser (LPA)/MR Safety Adviser formally appointed by the Employer, provides expert advice on the respective matters to ensure that the Employer is able to comply with the requirements of the relevant legislation.

They must be consulted on all matters required by legislation.

5.5. The Protection Supervisors

The Protection Supervisors, formally appointed by the Employer, will supervise all work practices using potentially hazardous non-ionising radiation, within their defined area of responsibility, to ensure that they are undertaken in accordance with the Local Rules.

5.6. The Service Manager / Head of Department,

The Service Manager / Head of Department, under advice from the respective Protection Adviser(s), are responsible within their area for:

5.6.1. Operational management of non-ionising radiation protection in the areas for which they are responsible.

5.6.2. Ensuring that the Protection Adviser(s) is fully aware of all existing and proposed uses of potentially hazardous non-ionising radiation within their area and for seeking advice from specialist advisers on safety and compliance, in particular risk management.

5.6.3. Risk management surrounding the use of potentially hazardous non-ionising radiations, including ensuring that Risk Assessments are performed when introducing new or modified equipment and techniques, and that these are subject to review.

5.6.4. Ensuring that the Protection Adviser(s) is involved in the planning and purchase of all new and replacement facilities and equipment that utilise potentially hazardous non-ionising radiation – see Appendix 2.

5.6.5. Identifying suitably trained candidates to be formally appointed by the Employer as Protection Supervisors for each area where work with potentially hazardous non-ionising radiation is undertaken.

5.6.6. Ensuring that equipment is added to the Trust's equipment replacement programme where there are safety concerns.

5.6.7. Ensuring that all staff working with potentially hazardous non-ionising radiation devices receive appropriate training in the nature of risks to which they may be exposed and the necessary measures which they must take to ensure their safety and the safety of others.

5.6.8. Ensuring that all staff comply with Trust procedures and SOPs relating to radiation.

5.6.9. Undertaking audits to demonstrate compliance of clinical governance standards to support Trust assurance under that framework.

5.7. **The Radiation Protection Committee**

The Role of the Radiation Protection Committee reviews and advises on the implementation of the relevant radiation protection legislation and on other Health and Safety matters in connection with both ionising and non-ionising radiations. The Committee will inform the Trust, via the governance structure, of the state of protection arrangements in force. The full responsibilities of the committee are detailed in the terms of reference contained within the Ionising Radiation Safety Policy.

5.8. **Role of All Employees**

All Employees have a duty to take reasonable care, when carrying out their work, to protect themselves, their colleagues, and any other person. They must:

5.8.1. Exercise reasonable care in carrying out their duties and work in accordance with Standard Operating Procedures.

5.8.2. Attend training programmes as required by the Trust and undertake continuing education, if required.

5.8.3. Only undertake work for which they have been authorised and adequately trained.

5.8.4. Use as instructed any protective equipment provided by the employer.

5.8.5. Report any faults in equipment, facilities or procedures that may adversely affect the health and safety of any person, or cause untoward exposure of an individual.

5.8.6. Report any incident in which a patient or member of staff may have received a radiation exposure much greater than intended, to include incidents where a radiation exposure was not intended.

6. Standards and Practice

6.1. Overview

6.1.1. The Trust is committed to minimising risks arising from the Trust's use of non-ionising radiations.

6.1.2. The Trust will ensure that structures and systems are in place and reviewed in order to ensure that:

6.1.2.1. A non-ionising radiation protection management structure is developed and maintained to ensure that the Trust complies with current legislation.

6.1.2.2. Any new practice involving the use of potentially hazardous sources of non-ionising radiation shall undergo prior risk assessment.

6.1.2.3. The risk resulting from any exposure to non-ionising radiation shall be exceeded by the individual or societal benefit it produces, i.e. practices shall only be undertaken where they are justified.

6.1.2.4. The Trust shall ensure that it is not reasonably foreseeable for an individual exposure limit to be exceeded.

6.1.2.5. Employees are appropriately trained and undergo relevant continuous training and development.

6.2. Identification of Potentially Hazardous Devices – Laser and Optical

6.2.1. Potentially hazardous devices are defined as those that **have the potential to** present eye, skin, or specialised hazards.

6.2.2. Such devices may be identified by the manufacturer's documentation, hazard markings and other restrictions or recommendations regarding use. Where uncertainty exists the Protection Adviser(s) must be consulted. Examples include:

- Lasers marked Class 3R, 3B or 4 in accordance with the BS EN 60825-1 scheme.
- Apparatus described as UV, infra-red, blue or other light therapy.
- Infra-red warming devices.
- UV sterilisation equipment.
- UV laboratory equipment.

6.3. Identification of Potentially Hazardous Devices – Electromagnetic Fields

6.3.1. Potentially hazardous devices are defined as those that have the potential to present health hazards, such as tissue heating, peripheral nerve stimulation, interference with implanted devices, projectile hazard et cetera.

6.3.2. Such devices may be identified by the manufacturer's documentation, hazard markings and other restrictions or recommendations regarding use. Where uncertainty exists the Protection Adviser(s) must be consulted. Examples include:

- MRI scanners.
- Radio transmission dishes and masts.
- Surgical diathermy apparatus.

6.4. Introduction of Potentially Hazardous Devices

6.4.1. Any Trust employee intending to purchase or use such a device (including all Class 3R, 3B or 4 lasers) must consult the Protection Adviser(s). Approval must also be sought within each department at both professional and management level.

6.4.2. No such device may be purchased or brought onto (nor used within) the sites identified within the scope of this policy for the purposes of hire, lease, loan, or demonstration without the prior approval of the Protection Adviser(s).

6.5. Operational Arrangements For Potentially Hazardous Devices

6.5.1. The equipment shall only be operated within a designated 'Controlled Area'.

6.5.2. The equipment shall only be operated by Authorised Operators in accordance with written Local Rules and Standard Operating Procedures which are applicable to the Controlled Area specified. These are to be produced in consultation with the Protection Adviser.

6.5.3. The Head of Department shall ensure that device safety testing, hazard calculation, risk assessment, engineered control measures, Local Rules, personal protective equipment, Departmental Operating Procedures, Protection Supervisor and Operator (and for lasers, Keyholder) training as recommended by the Protection Adviser are in place prior to device use.

6.5.4. Each Controlled Area shall have an appointed Protection Supervisor.

6.5.5. Staff working within Controlled Areas shall exercise reasonable care, use personal protective equipment where provide, report any defect in such equipment to the Protection Supervisor and undertake any training deemed necessary by the Protection Supervisor or Protection Adviser.

6.5.6. The device shall be maintained under servicing/maintenance agreements to a level as specified by the Protection Adviser. This may include provision of regular preventative maintenance and also arrangements for emergency cover.

6.6. Additional Measures for Class 3R, 3B and 4 Medical Lasers

6.6.1. Wherever a medical laser is operated, suitably trained Keyholders must be appointed. The role of the Keyholder is to ensure that the laser is operated safely in accordance with the Local Rules. The Keyholder would usually be a nurse, Operating Department Practitioner (ODP) or support worker. In certain areas, where agreed by the LPA, the Keyholder may be the clinical operator of the laser; in particular, this applies to the use of ophthalmic lasers in ward locations or outpatient departments.

6.6.2. A medical laser shall only be used:

6.6.2.1. By an Operator authorised by the Protection Supervisor or the LPA. Medical staff who are not authorised Operators may operate a laser only if they are working under the direct supervision of a clinician who is an authorised Operator of that equipment.

6.6.2.2. In the presence of an authorised Keyholder.

6.6.2.3. In accordance with the Local Rules for use of that laser.

6.6.2.4. Within the Controlled Area defined within those Local Rules.

6.6.3. The Clinical LPS may be authorised to act on behalf of the LPA to approve new Operators and Keyholders, but approval shall only be granted where there is satisfactory evidence of clinical competence and safety training.

6.7. Adverse Event Reporting

6.7.1. All adverse events shall be recorded in accordance with standard Trust procedures (DATIX). This shall include breaches of the local rules, events in which a patient or member of staff may have received an unintended exposure.

6.7.2. An investigation shall be undertaken by the Head of Department in conjunction with the Protection Adviser.

6.7.3. The Protection Adviser shall report the event as may be required to the appropriate external regulatory agencies.

6.7.4. Should any employee experience any problems resulting from work with non-ionising radiation, they must inform their line manager immediately who with assistance and advice from the LPA will take action. If necessary, the Trust will investigate the circumstances and take remedial action.

6.8. Co-operation Between Employers

6.8.1. The Trust will establish good communication and co-operation with those employers whose staff may be occupationally exposed by the Trust's radiation work.

6.8.2. Where services are provided by a third party provider (e.g. MRI vans), the Trust and the provider shall co-operate with that provider to ensure responsibilities with regard to measures to ensure patient safety are defined.

6.9. Reporting Pathways

6.9.1. The Trust Radiation Protection Committee will report to the Trust Board through the organisational governance committees.

6.9.2. The Protection Adviser(s) will produce an annual report in consultation with the Chairman to the above Committee.

6.9.3. The Protection Adviser(s) will report to the Chairman of the Radiation Protection Committee and to the Chief Executive of the Trust.

7. Dissemination and Implementation

7.1. Dissemination

7.1.1. This policy shall be disseminated by storage on the electronic document library.

7.1.2. For significant revisions, staff will be notified via the daily email bulletin and notification cascaded to radiation users via RPAC.

7.1.3. The Trust shall maintain an archive of previous document versions.

7.2. Training

7.1.1. The Trust will ensure that staff working with non-ionising radiation will be trained to a level commensurate with the work being performed and the degree of hazard involved.

7.1.2. The Training Needs Analysis for Radiation Protection is contained within the Trust Core Training Policy. This specifies the training needs of various staff groups and the training routes available to them.

7.1.3. For staff whose regular duties involve work with potentially hazardous sources of non-ionising radiation, role specific training shall be provided at local departmental induction.

7.1.4. It is the responsibility of the local Head of Department to liaise with the Protection Adviser(s) regarding the scope, content and suitability of the training programme provided.

7.1.5. Heads of Departments that use potentially hazardous sources of non-ionising radiation shall audit compliance with training requirements.

7.1.6. For staff whose role requires professional registration, they shall undertake suitable CPD activities and maintain that registration.

7.1.7. Trust-wide standards of radiation protection training shall be monitored by the Radiation Protection Advisory Committee.

7.1.8. Training routes and materials shall be reviewed at least 3 yearly.

7.1.9. The Protection Adviser(s) shall continuously monitor for changes in legislation or best practice standards or guidance that may present a further training need.

8. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Compliance.
Lead	Heads of Department in conjunction with Protection Advisers.
Tool	As applicable: • Periodic Audits. • Audit of reported adverse events. • Individual departmental inspection.
Frequency	Annually or sooner if indicated by Protection Adviser.
Reporting arrangements	Report to Radiation Protection Committee.
Acting on recommendations and Lead(s)	Actions identified by RPC to be acted upon by Head of Department.
Change in practice and lessons to be shared	Changes in practice will be fed back to RPC.

9. Updating and Review

9.1. The Radiation Protection Committee shall review this policy at least once every three years.

9.2. Heads of Departments shall provide feedback to the RPC Chair any arising need for changes to this policy.

9.3. The Protection Adviser(s) shall continuously monitor for changes in legislation or current best practice standards and guidance. Upon their recommendation a full review of this policy shall be commenced.

9.4. Any revision activity is to be recorded in the Version Control Table as part of the document control process.

10. Equality and Diversity

10.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

10.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Non-Ionising Radiation Safety Policy V5.0
This document replaces (exact title of previous version):	19 October 2023
Date Issued / Approved:	October 2023
Date Valid From:	October 2026
Date Valid To:	Trevelyan Foy (Principal Clinical Scientist/ Laser Protection Adviser/MR Safety Adviser)
Author / Owner:	01872 252495
Contact details:	Policy and procedures to ensure the health, safety and welfare of staff, patients and members of public who may be exposed to hazards arising from the use of non-ionising radiations on the Trust's premises and areas on other sites where Trust staff work.
Brief summary of contents:	Radiation, laser, UV, ultraviolet, magnetic resonance, safety.
Suggested Keywords:	RCHT Non-Ionising Radiation Safety Policy
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Radiation Protection Advisory Committee
Manager confirming approval processes:	Richard Andrzejak
Name of Governance Lead confirming consultation and ratification:	Kevin Wright
Links to key external standards:	The Control of Artificial Optical Radiation at Work Regulations 2010
Related Documents:	The Health and Safety at Work Act, 1974

Information Category	Detailed Information
Training Need Identified:	Yes, in conjunction with Learning and Development
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Medical Physics

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
01/06/ 2009	V1.0	Original.	Nick Powell (Laser Protection Adviser), Trevelyan Foy (deputy)
03/02/ 2012	V2.0	Substantial amendments, adoption of Trust policy template, change of policy title.	Trevelyan Foy (Laser Protection Adviser) (MR Safety Adviser)
14/01/2015	V3.0	Updating in accordance with Trust policy template.	Trevelyan Foy (Laser Protection Adviser) (MR Safety Adviser)
April 2019	V4.0	Updates to reflect new Trust structure.	Trevelyan Foy (Laser Protection Adviser) (MR Safety Adviser)
October 2023	V5.0	Full review and updated to latest Trust template.	Trevelyan Foy (Principal Clinical Scientist/ Laser Protection Adviser/MR Safety Adviser)

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity, and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Non-Ionising Radiation Safety Policy V5.0
Department and Service Area:	Medical Physics, Clinical Support Care Group.
Is this a new or existing document?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Trevelyan Foy (Principal Clinical Scientist/ Laser Protection Adviser/MR Safety Adviser)
Contact details:	01872 252495

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	Minimise the risks to health posed by exposure to non-ionising radiations
2. Policy Objectives	Ensure risks arising from non-ionising radiation exposure are maintained as low as reasonably practicable, social and economic factors being taken into account.
3. Policy Intended Outcomes	Excellence in the delivery of clinical treatments and techniques utilising non-ionising radiation and the safe and effective use of non-ionising radiation devices all areas.
4. How will you measure each outcome?	Monitoring of compliance through audit, monitoring of adverse events (DATIX), review by Radiation Protection Advisory Committee.
5. Who is intended to benefit from the policy?	Staff, patients, visitors, volunteers, contractors and the environment.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Radiation Protection Advisory Committee (RPAC).
6c. What was the outcome of the consultation?	Approved.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** No.

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	
Marriage and civil partnership	No	

Protected Characteristic	(Yes or No)	Rationale
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Trevelyan Foy, Director of Medical Physics and Clinical Technology.

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

Appendix 3. Procedure for the use of Medical Lasers that are on Hire, Lease, Loan or Demonstration

1. Introduction

1.1. This procedure lists and explains the measures that must be taken to provide and maintain a safe and protective environment for staff, patients and others when using lasers that are not directly owned by the Trust, i.e. are on hire, lease, loan or demonstration.

1.2. This procedure refers to any laser used for clinical examination or treatment for the first time in the Trust and which has not been purchased by the Trust. This includes lasers which are owned by a clinician, another hospital/clinic or a company and are brought into the Trust for clinical use, trial, demonstration, evaluation, testing or investigation. This applies whether the equipment is hired by or loaned to the Trust.

1.3. The written agreement of the LPA is required before each laser may be used for the first time.

2. Detailed Procedure

2.1. Any clinician proposing to use a laser within the Trust shall inform the LPA in writing at least 2 weeks before the planned use.

2.2. The clinician shall provide written evidence that the planned treatment falls within her/his sphere of clinical competence.

2.3. The LPS (where appointed) must liaise with the clinician, the Laser Protection Adviser (LPA) and a representative of the company supplying the laser as necessary, to ensure that all required details are established.

2.4. The LPS (where appointed) and LPA shall ensure that the necessary facilities, authorisations, device safety testing, hazard calculation, risk assessment, engineered control measures, Temporary Local Rules, personal protective equipment, Departmental Operating Procedures and LPS/Operator/Keyholder training are all in place for the safe use of the laser.

2.5. The LPS is responsible for ensuring that a representative of the supplier of the laser completes and signs an NHS Indemnity Form or that there is a current master indemnity agreement for the supplier before the laser may be put into use.

2.6. If the laser is to be used on an ongoing basis it shall be used in a room or theatre already equipped for laser use. If the laser is to be used for demonstration or trial prior to a decision to use the laser on an ongoing basis, then a clinic room or theatre not so equipped may be used temporarily for the purpose, provided that this has been agreed with the LPA in advance and that a risk assessment has been undertaken.

2.7. The first time the laser is brought onto the premises adequate time should be allowed before the planned time of use for the LPA to inspect the device.

3. Duties of the Supplier

3.1. The supplier is responsible for fitting the laser with a compatible electrical plug as necessary.

3.2. The supplier is responsible for ensuring that the laser complies with all relevant safety standards and that it is regularly serviced in accordance with the manufacturer's maintenance schedule. The service shall include:

3.2.1. An annual electrical safety test.

3.2.2. Power and energy checks using an external power/energy meter to ensure that the output of the delivery system is consistent with the displayed settings on the control panel.

3.3. The supplier shall provide documentary evidence of ownership, training, and competency to use the laser, maintenance contract and regular service records, electrical safety test and calibration.

3.4. After the laser is delivered and before clinical use, the supplier shall undertake, and record quality assurance checks as follows:

3.4.1. A check that the aiming beam and the treatment beam are coincident.

3.4.2. A full functionality check.

3.5. The supplier is responsible for ensuring that adequate numbers of safety goggles/glasses, meeting the protection requirements specified by the Trust LPA, are available for use with the laser. The protective eyewear must be marked with the wavelength for the laser being used and must conform to the relevant standards on personal eye-protection against laser radiation.

3.6. If the clinician and assisting staff have not received practical training in the operation of the laser, then the supplier or his appointed representative shall supervise the safe use of the laser in accordance with the Trust's Local Rules.

Appendix 4. Procedure for the Procurement of Potentially Hazardous Non-Ionising Radiation Devices

1. Introduction

1.1. This procedure lists and explains the measures that must be taken to ensure that equipment is selected, purchased, and maintained in order to ensure a safe and protective environment for staff, patients, and others.

1.2. Any Trust employee intending to purchase or use a potentially hazardous non-ionising radiation device shall complete a prior risk assessment, as required by the Trust Medical Device and Equipment Management Policy. This includes all Class 3R, 3B or 4 lasers.

1.3. Procurement must be undertaken in accordance with the Trust's Standing Orders and Standing Financial Instructions and Public Procurement Regulations. The purchaser shall contact the Procurement and Supplies Contracts Manager to discuss the procurement process as, if the item is not covered by an existing contract, competitive tenders will need to be sought, which Procurement and Supplies will assist with.

2. Identification of Potentially Hazardous Devices

2.1. Potentially hazardous non-ionising radiation devices may be identified by the manufacturer's documentation, hazard markings and other restrictions or recommendations regarding use. Where uncertainty exists the Protection Adviser(s) must be consulted. Examples of such devices include, but are not limited to:

- Lasers marked Class 3R, 3B or 4 in accordance with the BS EN 60825-1:2007 scheme.
- Apparatus described as UV phototherapy, blue light phototherapy, infra-red phototherapy, or other light therapy.
- Infra-red warming devices.
- UV or light sterilisation equipment.
- UV laboratory equipment.
- Equipment with which protective eyewear will be supplied, for reasons other than chemical/projectile hazard.

3. Process For The Procurement of Potentially Hazardous Devices

3.1. No potentially hazardous non-ionising radiation device (including all Class 3R, 3B or 4 lasers) may be purchased without the written prior authorisation of the Protection Adviser(s). Approval must also be sought within each department at both professional and management level.

3.2. The purchaser shall supply to the Protection Adviser the following information for consideration:

3.2.1. Equipment details, such as brochures and technical specifications.

3.2.2. The proposed location(s) of use.

3.2.3. A description of the proposed application(s).

3.2.4. The contact details of the department manager and, where appropriate, lead clinician.

3.2.5. Details regarding any personal protective equipment (PPE) supplied with the device. For laser eyewear this shall include the protection specification marked in accordance with BS EN 207.

3.2.6. Details of any new or existing accessories/equipment to be used with the device.

3.2.7. Proposed equipment servicing arrangements, to include preventative maintenance and emergency repair. Quotations/contracts are to be enclosed where available.

3.2.8. Proposed staff training arrangements.

3.2.9. Details of potential suppliers and quotations where available.

3.2.10. The completed Pre-Purchase Questionnaire (PPQ).

3.3. The Protection Adviser shall assess the device and request further information from the purchaser/supplier/manufacturer as required.

3.4. Where further measures or organisational/operational arrangements are required for safe use, these shall be reported to the purchaser by the Protection Adviser. Such measures may include but are not limited to:

- Eye/Skin/other hazard calculation by the Protection Adviser.
- Formal risk assessment.
- Engineered control measures.
- Local Rules and Departmental Operating Procedures. This may include patient record keeping and safety screening measures.
- The provision of personal protective equipment (PPE).
- The appointment of a Protection Supervisor and provision of training.
- The provision of Operator and other staff training.
- Fire safety provision.
- Advice regarding the selection of alternative equipment or techniques.

3.5. Upon the satisfaction of the Protection Adviser that sufficient safety measures are in place, or it is has been formally agreed these measures will be established in an appropriate timeframe, approval by the Protection Adviser will be granted.

3.6. The Protection Adviser shall inspect the installation prior to use.