GIG CYMRU NHS WALES | Bwrdd Iechyd Prifysgol Caerdydd a'r Fro | Cardiff and Vale University Health Board

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THE LASER RISK MANAGEMENT PROCEDURE

Introduction and Aim

The optical radiation emitted by lasers has potentially hazardous effects on patients, equipment users and the public. Hazards from lasers will depend on the type of laser, but potential problems include eye injury, skin burns, fire or explosion and smoke inhalation.

The UHB has a Laser Risk Management Policy whose aim is to ensure that we manage the use of medical treatment lasers, to ensure the health and safety of all staff working with medical treatment lasers, and any person who may be affected by the work.

This Laser Risk Management Procedure supports the Policy and will provide a set of minimum service standards against which all Clinical Services which use medical treatment lasers will comply with, and outlines the identification of organisational and individual responsibilities.

This will ensure that risks to patients, staff and the UHB arising from the use of medical treatment laser equipment are minimised, and that the UHB consistently delivers the best health and financial outcomes from the use of medical laser equipment.

Objectives

The Laser Risk Management Procedure establishes a clear framework within which the UHB can:

- Effectively and actively manage its laser services, so as to reduce risk,
- Meet its legal obligations to comply with legislation,
- Meet its governance obligations, both clinical and financial,
- Adhere to the requirements of the relevant Health and Care Standards,
- Demonstrate that it is taking account of MHRA guidance.

The UHB will achieve these objectives by:

- Providing a framework for service managers to develop services that are safe, effective and compliant with current legislation in order to protect the UHB, the public and staff.
- Providing direction to service managers as regards to procedures, training, documentation and resources that must be in place.
- Outlining the responsibilities of staff working with medical treatment lasers.

- Ensuring that employees, contractors and others are adequately informed of the risk posed from laser use and, where appropriate, ensure they receive adequate training and supervision.
- Ensuring protection measures for all persons on Cardiff and Vale UHB premises from the associated risks of laser radiation are implemented and maintained.
- Ensuring all laser equipment is in good repair, operating correctly and safely, and regularly maintained.
- Appointing a Laser Safety Advisor(s).
- Appointing a Laser Safety Supervisor(s).
- Monitoring and reviewing the effectiveness of the laser policy and procedure and, if necessary, implement improvements.

Scope

This Procedure applies to all of Cardiff and Vale UHB staff in all locations including those with honorary contracts. It covers all Medical Treatment Lasers used by Cardiff and Vale UHB services, irrespective of whether the laser device is owned, loaned, leased or used by external service providers commissioned by the UHB.

Equality Impact Assessment	An Equality Impact Assessment (EqIA) has been completed and this found there to be a positive impact.
Documents to read alongside this Procedure	Cardiff and Vale UHB Policies: • The Medical Equipment Management Policy • Decontamination of Reusable Medical Devices Policy Regulations, Guidelines and Standards: • Provision and Use of Work Equipment Regulations (PUWER), 1998 • The EU regulation on Medical Devices, 2017 / 745 and The EU regulation on In Vitro Medical Devices, 2017 / 745 • Managing Medical Devices, Guidance for healthcare and social services organisations, MHRA, April 2014 • Lasers, intense light source systems and LEDs – guidance for the safe use in medical, surgical, dental and aesthetic practices. MHRA, Department of Health, September 2015 • The Control of Artificial Optical Radiation at Work Regulations 2010. Statutory Instruments 2010 No. 1140 • BS EN 207:2009 Personal eye-protection equipment. Filters and eye-protectors against laser radiation (laser eye-protectors) • BS EN 208:2009 Personal eye-protection. Eye-protectors for adjustment work on lasers and laser systems (laser adjustment eye-protectors) • BS EN 60825-1:2014 Safety of laser products. Equipment classification and requirements

	• BS EN 60601-1:2006+A12:2014 Medical electrical equipment. General requirements for basic safety and essential performance • BS EN 60601-2-22:2013 Medical electrical equipment. Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment • BS 5499-10:2014 Guidance for the selection and use of safety signs and fire safety notices • ICNIRP Guidelines on limits of exposure to laser radiation of wavelengths between 180 nm and 1,000 µm: Health Physics 105(3):271-295; 2013
Approved by	Quality, Safety and Experience Committee
Accountable Executive	Executive Director of Therapies and Health Science.
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Disclaimer

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

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Appendices

1 Definition of terms

Laser
For the purposes of this policy the term laser is used for any piece of equipment that emits light at wavelengths between approximately 100nanometres and 1millimetre, and which is capable of producing accessible levels of harmful optical radiation through the physical mechanism of light amplification by stimulated emission of radiation

Medical Treatment Laser
All Medical Treatment lasers covered by this policy are Class 3B or 4.

Maximum Permissible Exposure (MPE)
The Maximum Permissible Exposure (W/m^2 or J/m^2) is the maximum exposure level for the eyes or skin considered safe

Nominal Ocular Hazard Distance (NOHD)
Distance over which the laser hazard extends.

Laser Controlled Area
A designated area around an item of laser equipment where the accessible level of laser radiation is considered potentially hazardous.

LPA
Laser Protection Adviser

LPS
Laser Protection Supervisor

RPG
Radiation Protection Group

SOP(s)
Standard Operating Procedure(s)

PPE
Personal Protective Equipment

2 Use and Classification of Medical Treatment Lasers

Lasers are classified according to their potential to cause injury. This classification is summarised below. Full classification has been given by the MHRA guidance document [1].

Class 1	Inherently safe – either completely enclosed or very low power.
Class 2	Low power visible.
Class 2M	Low power. Safe for brief exposure with naked eye. Potentially hazardous when exposure occurs with magnifiers for divergent beams or binoculars for large diameter collimated beams.
Class 3R	Low power. Accidental exposure usually not hazardous, but eye injury possible for intentional intra-beam viewing.
Class 3B	Medium power. Exposure of the eye to the direct beam may cause serious eye injuries. Limited skin hazard. Viewing of reflections normally safe.
Class 4	High power. Exposure of the eye to the direct beam and close viewing of reflected beam may lead to serious eye injuries. May cause serious skin hazard. Presents a fire hazard.

All medical treatment lasers covered by this policy are Class 3B or 4. Lower class laser devices e.g. positioning lasers are not covered by this policy.

3 Duties

Responsibility for implementing the Laser Risk management policy and its supporting procedures lies with the UHB as the employer, with the Executive Director of Therapies and Health Science being the responsible officer. This responsibility is fulfilled by assigning the duties described here.

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

- Taking overall responsibility for the management of Laser Safety on behalf of the UHB
- Providing assurance to the UHB Board that Laser safety is managed in compliance with the UHB's policies and procedures
- Informing the UHB about issues related to laser safety management.
- Appointing the UHB's Laser Protection Adviser(s) in writing.
- Delegating duties to other managers as appropriate

The duties of the Clinical Board Heads of Operations and Delivery include:

- Providing assurance to the Executive Director of Therapies and Health Science that laser safety is managed in compliance with the UHB's policies and procedures.
- Reporting instances of non-compliance and other concerns to the Executive Director of Therapies and Health Science.
- Communicating and liaising with relevant Directorate Managers about issues related to laser safety.

The duties of the Chair of the UHB Radiation Protection Group (RPG) include:

- Reviewing relevant UHB policies and procedures at least every three years, and ensuring that they are amended and updated as necessary.
- Reviewing reports from the Laser Protection Adviser and taking action as necessary.
- Reporting laser safety issues to the Quality and Safety Committee.
- Recommending relevant action to the Chief Executive via the approved route when necessary.

The duties of the Clinical Director of each directorate include:

- Ensuring compliance with this policy, and the requirements of legislation and guidance relevant to the use of medical treatment lasers.
- Authorising Authorised Users in writing.
- Ensuring that local Standard Operating Procedures (SOPs), Local Rules and risk assessments are written to implement the requirements of this UHB procedure.
- Appointing one or more Laser Protection Supervisor (LPS).
- Ensuing sufficient and suitable personal protective equipment (PPE) is provided for all staff.
- Ensuring that all relevant members of staff including the LPS, authorised users and assisting staff are adequately trained and have the resources to comply with the SOPs and Local Rules.

- Implementing measures to monitor staff compliance with SOPs and Local Rules.
- Maintaining records of staff training.
- Liaising with, and seeking advice from the LPA.
- Making risk assessments and taking mitigating action as necessary.
- Reporting Laser safety issues to the Clinical Board Head of Operations and Delivery.
- Ensuring lasers are regularly serviced and maintained, and subject to adequate quality assurance and safety testing.
- Ensuring adequate records are kept of laser equipment, including servicing, maintenance, electrical safety and quality assurance testing.
- Delegating responsibilities to other managers where appropriate.

The duties of the Service Managers of each laser department include:

- The day-to-day delivery of safe laser services, supported by the LPS(s).

A Laser Protection Advisor (LPA) should be appointed who is knowledgeable in the evaluation of laser hazards. The role profile of the LPA is summarised in Appendix 1. The duties of the Laser Protection Advisor include:

- Advising on compliance with statutory requirements concerning the use of medical lasers.
- Reporting laser safety issues to the Radiation Protection Group.
- Identifying the Laser Controlled Area.
- Advising on the control of hazards.
- Assisting the Laser Protection Supervisor (LPS) in writing Local Rules and SOPs.
- Undertaking a risk assessment in conjunction with the LPS before the laser is brought into operation, and reviewing annually.
- Providing safety training in line with MHRA guidelines [1] for the LPS, laser operators and assistants, or identify relevant training courses for them to attend.
- Performing an annual inspection of all locations where laser equipment is being used in order to review compliance with legislation, guidance and Local Rules.
- Reporting the annual inspection results and recommendations to the LPS, and RPG as necessary.
- Liaising with all appropriate LPSs, laser operators and those who assist with medical procedures involving lasers to promote the safe operation of medical lasers.
- Investigating any adverse events, including reporting the incident to the employer.
- Providing advice on equipment purchase, installation planning, and acceptance testing.

A Laser Protection Supervisor (LPS) is an individual within the directorate where the laser is used. The role profile of the LPS is summarised in Appendix 2. The duties of the Laser Protection Supervisor include:

- Understanding the nature of the hazards involved.
- Ensuring they have up to date laser safety training.
- Producing the local rules, with assistance and advice from the LPA.
- Undertaking a risk assessment in conjunction with the LPA before the laser is brought into operation, and reviewing annually.
- Ensuring all Laser operators (authorised users) and those assisting with the procedures (including trainee doctors, registrars or visiting staff) sign statements to acknowledge they have read and understood the Local Rules, and agree to abide by them.
- Ensuring that the register and signed statements of those authorised to operate and assist with the laser are kept up to date.
- Implementing and ensuring compliance with the Local Rules on a day-to-day basis.
- Ensuring that only authorised operators use the laser.
- Ensuring that the key for each laser is clearly labelled and is kept in safe custody in a locked key cupboard when the laser is not in use. In addition, the LPS shall ensure that the key for each laser is issued only to a registered authorised operator or assistant.
- Holding an up to date copy of safety training records of all laser operators and those assisting with laser procedures.
- Informing the LPA as soon as possible of any matters which may require the Local Rules to be amended.
- Informing the LPA as soon as possible of any matters which give rise to a potential hazard.
- Informing the LPA as soon as possible of any hazardous event. Verbal communications must be confirmed in writing within 48 hours and include details of the date and time of the event, the nature of the event and a list of those present.
- Seeking assistance from the Laser Protection Adviser on the safety implications of any proposed changes in operating procedure.
- Keeping an inventory of all laser / IPL / optical radiation equipment kept in their department and provide a copy to the LPA.
- Reporting any changes in equipment or environment that may affect laser safety to the LPA.
- Ensuring loan or demonstration equipment complies with, and is covered by the local rules.
- Ensuring that service engineers have followed the correct equipment handover procedures.
- Regularly checking the condition of laser PPE, including protective eyewear (Laser goggles).
- Regularly checking the condition of warning signs, and equipment such as protective blinds and screens on a regular basis.
- Liaising with the LPA during LPA inspections, and acting on any recommendations.

Authorised users are individuals authorised in writing by the clinical director, and named within the local rules, who operates the laser. The duties of Authorised users include:

- The safety of all persons present, including the patient, visitors and themselves, during the operation of the laser.
- Using all personal protective equipment that has been provided.
- Reading, understanding and signing the Local Rules.
- Understanding the nature of the hazards involved.
- Ensuring that all staff present have been adequately instructed about laser hazards.
- Complying with local rules, SOPs, legislation and guidelines.
- Using the laser safely.
- Only using the laser for specific purposes authorised by the Cardiff and Vale UHB, in which they have been trained, in line with the SOPs.
- Using the laser only in compliance with the manufacturer's operating instructions.
- Ensuring they have up to date laser equipment training, including safety training, how to operate the equipment, and how the controls effect treatments.
- Keeping records of all training.
- Ensuring a record of each laser treatment is kept.

The duties of all staff assisting with, or present during laser procedures include:

- Attending laser safety training.
- Attending training in the use of any laser equipment they may use.
- Reading, understanding and signing the Local Rules.
- Understanding the nature of the hazard involved.
- Complying with local rules, SOPs, legislation and guidelines.
- Using all personal protective equipment that has been provided.
- Following instructions from the LPS and authorised user w.r.t laser safety.

The duties of the Head of Medical Physics and Clinical Engineering include:

- The provision of the Laser Protection Advice Service.
- Recommending suitable member(s) of staff to the Executive Director of Therapies and Health Science for appointment as LPA to the UHB.
- The provision of electrical safety testing of medical lasers by suitably trained Medical Physics staff.
- Delegating duties to other managers as appropriate.

4 General arrangements for the management of Laser Safety

4.1 Laser Controlled Areas

The Nominal Ocular Hazard Distance (NOHD) is the distance over which the laser hazard extends. A potential hazard exists where there is a possibility that the Maximum Permissible Exposure (MPE) levels might be exceeded. Any areas where this possibility exists shall be designated a Laser Controlled Area. The advice of the LPA shall be sought on the designation of areas.

All persons entering a Laser Controlled Area must be controlled under Local Rules. All entry points to the laser controlled area must be appropriately and adequately signed, and access restricted when the laser is in use.

4.2 Risk Assessment

For each activity involving a medical laser a suitable and sufficient risk assessment shall be carried out before first use, and subject to regular review.

4.3 Local Rules

Local Rules shall be issued for each locality where Class 3B or Class 4 medical lasers are to be used. The Local Rules shall be designed to prevent the unauthorised operation of the laser and to control the conditions under which they are used, to minimise the risk to patients, staff and any other persons.

The LPS is responsible for writing the local rules, with assistance from the LPA. Guidance for content of the local rules is given in the MHRA 2015 guidance document [1].

The Local Rules must be read and signed by all laser operators and assistants.

4.4 Laser Protection Supervisors

A Laser Protection Supervisor (LPS) shall be appointed for each locality where Class 3B or Class 4 medical lasers are to be used. The LPS must be appropriately trained and is responsible for ensuring compliance with the Local Rules. The LPS shall be named in the Local Rules. The advice of the LPA shall be sought on the appointment of a LPS and their training requirements.

The LPS is not responsible for the safe operation of the laser equipment – this lies with the operator. The role profile of the LPS is summarised in Appendix 2.

4.5 Clinical Protocols

All work involving medical lasers shall be carried out in accordance with written protocols and standard operating procedures.

4.6 Register of Authorised Operators and Assistants

For each Class 3B, and Class 4 medical laser, a register shall be kept of:
(a) persons authorised to operate that specific laser
(b) persons authorised to assist in the use of that laser

Operators and assistants must be appropriately trained and sign to indicate that they have read and understood the Local Rules and they agree to abide by them. The register and signed statements shall be appended to the Local Rules and the completed document kept by the LPS.

4.7 Personal Protective Equipment (PPE)

All personnel in the Laser Controlled Area shall wear protective eyewear of an approved type and appropriate for the laser in use. For certain medical lasers, the operator may be provided with adequate eye protection by means of a suitable viewing device in which case additional protective eyewear may not be necessary.

4.8 Laser Security Key Protocol

Class 3B and Class 4 medical lasers must incorporate a key-operated master control. The key must be removed by an authorised operator or assistant whenever the laser is unattended. The key must be kept in safe custody by the LPS in a locked cupboard.

A log shall be kept by the LPS of authorised operator /assistants to whom the key can be issued with the date and time of issue and return.

4.9 Adverse Incidents

All adverse incidents including near misses shall be reported and investigated in accordance with the Health Board Incident Reporting and Investigation Procedure.

5 Equipment Management

5.1 Purchase of New or Replaced Equipment

The Health Board policy on the Management of Medical Equipment applies to the purchase of this type of equipment and must be followed.

Prior to the purchase of new or replacement medical laser equipment, the prospective purchaser shall consult with the LPA and LPS to gain advice on matters including the following:

- Equipment safety and suitability
- The proposed location of the equipment
- The necessary amendments to the Local Rules
- The requirements for additional training of professional users and assistants
- The provision of commissioning tests
- The provision of regular maintenance, output testing and safety testing

5.2 Equipment Maintenance, Repair and Quality Assurance (QA)

All medical laser equipment shall be kept in good repair and regularly maintained and safety tested, including electrical safety testing, by authorised personnel, technically competent in the field of work. Arrangements for repair, maintenance and safety testing shall be made in consultation with the LPA.

Procedures and schedule for QA tests shall be established at the time of commissioning, and this information specified in the Local Rules.

All Class 3B and Class 4 medical lasers equipment shall be regularly tested to monitor power/energy output and alignment of main beam and aiming system. All quality assurance and safety tests must be carried out by an authorised person technically competent in the field of work.

5.3 Equipment on Loan, Trial or Hire

Any medical laser equipment received on loan, trial or hire must be assessed for safety before clinical use and the appropriate indemnity arrangements put in place. All loan, hire or trial lasers must comply with this procedure, and be covered by the local rules, and risk assessments.

5.4 Equipment Modification

Modification, maintenance or repair of medical laser equipment other than by the manufacturer or his appointed agent is not permitted.

Modification of any medical laser equipment should not be carried out, unless by the manufacturer or his appointed agent. If these modifications affect its performance the laser must be examined and, if necessary, reclassified before use. Adequate notification of such modifications must be given to the LPA.

Modification of equipment other than by the manufacturer or his appointed agent will transfer the manufacturer's liability to the person carrying out the

modification. The Health Boards insurers (the Welsh Risk Pool) will only provide cover for modifications carried out by the Health Board if a full risk assessment has been carried out.

5.5 Infection Control and Decontamination

There is a risk of cross infection from laser equipment that comes into contact with many staff and patients. All laser equipment, including, laser beam applicators and manipulators, and auxiliary equipment must be cleaned and decontaminated according to the UHB's Infection control and reusable medical equipment decontamination policies.

6 Resources

In order for this policy to be implemented the following resources will be required:

- Applications training provided by the manufacturer or laser supplier is to be included in purchase arrangements for new Lasers.
- Regular Maintenance and servicing arrangements are to be included in purchase arrangements for new Lasers.
- The appointment of local LPS will impact upon their existing role within respective departments if they are to discharge their duties effectively and therefore arrangements must be put in place.
- Appointment of a LPA.
- Procurement of sufficient PPE and engineering controls

7 Training Requirements

7.1 Equipment Based Training

The manufacturer or laser supplier should provide equipment based training at the time of installation.

Further equipment based training may be provided by the LPS, manufacturer/supplier or another designated trainer.

7.2 Safety Training

The LPA should have received advanced, documented training.

All laser operators and those assisting with laser procedures, should attend a 'Core of Knowledge' course as outlined in the MHRA guidance [1], and re-attend a Core of Knowledge Course or receive update training every 5 years. The LPS will require additional training as advised by the LPA.

Training will be documented and records held by the LPS. The training will form part of the individual's Knowledge and Skills profile and will be reflected in the individual's personal development plan.

Laser Safety Awareness training may be provided by the LPA.

7.3 Procedural Training

- Procedural based training may be provided by the laser manufacturer/supplier.
- The clinician who oversees the procedures may provide the clinical based training to specific staff.

8 Review

The effectiveness of this policy will be reviewed post implementation. The indicators used to monitor the effectiveness of this policy are:

- LPA inspection visits and audits
- Reported incidents involving laser use
- Reports of inspections by HSE.

This policy will be reviewed every three years in collaboration with the RPG. The policy will also be reviewed when there is a significant change in relevant legislation or national guidance for the use on Medical Lasers.

9 Further Information

9.1 Legislation

The legislation controlling the use of medical lasers includes:

- The Health and Safety at Work etc. Act 1974
- The Electricity at Work Regulations 1989
- The Management of Health and Safety at Work Regulations 1999
- The Personal Protective Equipment Regulations 1992 (2002)
- The Provision and User of Work Equipment Regulations 1998
- The Workplace (Health, safety and Welfare) Regulations 1992
- The Control of Artificial Optical Radiation at work Regulations 2010
- The Health and Safety (Safety Signs and Signals) Regulations 1996

9.2 Guidance and standards

Guidance and standards for Safety is given by:

- Lasers, intense light source systems and LEDs – guidance for safe use in medical, surgical, dental and aesthetic practices. MHRA September 2015
- Non-binding guide to good practice for implementing Directive 2006/25/EC ‘Artificial Optical Radiation’.

- BS EN 207:2009 Personal eye-protection equipment. Filters and eye-protectors against laser radiation (laser eye-protectors)
- BS EN 208:2009 Personal eye-protection. Eye-protectors for adjustment work on lasers and laser systems (laser adjustment eye-protectors)
- BS EN 60825-1:2014 Safety of laser products. Equipment classification and requirements
- BS EN 60601-1:2006+A12:2014 Medical electrical equipment. General requirements for basic safety and essential performance
- BS EN 60601-2-22:2013 Medical electrical equipment. Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- BS 5499-10:2014 Guidance for the selection and use of safety signs and fire safety notices
- ICNIRP Guidelines on limits of exposure to laser radiation of wavelengths between 180 nm and 1,000 µm: Health Physics 105(3):271-295; 2013

10 References

[1] Lasers, intense light source systems and LEDs – guidance for safe use in medical, surgical, dental and aesthetic practices. MHRA September 2015.

Appendix 1

Role profile for Laser Protection Advisor (LPA)

- HCPC Registered Clinical Scientist (Medical Physics)
- Ideally Certificated LPA (RPA 2000)
- Highly knowledgeable and competent on laser safety (documented training)
- Appointed in writing by the Chief Executive / Employer.

Appendix 2

Role profile for Laser Protection Supervisor (LPS)

A Laser Protection Supervisor (LPS) is an individual within the directorate where the laser is used who is responsible for implementing the Local Rules and ensuring that they are adhered to on a day-to-day basis. The duties and responsibilities of the LPS include the following.

1. The LPS should be knowledgeable in laser safety, and maintain up to date, documented laser safety training.
2. To ensure compliance with the Local Rules.
3. To inform the Laser Protection Adviser (LPA) as soon as possible of any matters which may require the Local Rules to be amended.
4. To ensure that the register and signed statements of those authorised to assist with and operate the laser are kept up to date.
5. To ensure that the key for each laser is clearly labelled and is kept in safe custody in a locked key cupboard when the laser is not in use. In addition, the LPS shall ensure that the key for each laser is issued only to a registered operator or assistant.
6. To ensure that only authorised operators use the laser.
7. To bring to the attention of the LPA as soon as possible any matters which give rise to a potential hazard.
8. To inform the LPA as soon as possible of any hazardous event. Verbal communications must be confirmed in writing within 48 hours and include details of the date and time of the event, the nature of the event and a list of those present.
9. To seek assistance from the Laser Protection Adviser on the safety implications of any proposed changes in operating procedure.
10. The LPS should regularly check the condition of laser PPE, including protective eyewear (Laser goggles).
11. The LPS should check the condition of warning signs, protective blinds and screens on a regular basis.
12. Liaise with the LPA during laser inspection audits, and act upon any recommendations.