Bwrdd Iechyd Prifysgol Hywel Dda University Health Board

# PWYLLGOR IECHYD A DIOGELWCH
# HEALTH & SAFETY COMMITTEE

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| **DYDDIAD Y CYFARFOD: DATE OF MEETING:** | 14 November 2022 |
| **TEITL YR ADRODDIAD: TITLE OF REPORT:** | Updated Procedure (770) – Medical Laser Safety Policy – V.2 |
| **CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:** | Mandy Rayani, Director of Nursing, Quality and Patient Experience |
| **SWYDDOG ADRODD: REPORTING OFFICER:** | Tim Harrison, Head of Health, Safety and Security<br>Adam Springthorpe, Health & Safety Manager |

**Pwrpas yr Adroddiad** (dewiswch fel yn addas)
**Purpose of the Report** (select as appropriate)

Ar Gyfer Penderfyniad/For Decision

## ADRODDIAD SCAA
## SBAR REPORT

### Sefyllfa / Situation

The Health and Safety Committee (HSC) is requested to approve the revised and updated 770 – Medical Laser Safety Policy – (Version 2). This report provides the required assurance that this Written Control Document has been developed in line with all relevant legislation / regulations and available evidence and can therefore be implemented within Hywel Dda University Health Board (HDdUHB).

### Cefndir / Background

Medical lasers are used by HDdUHB for the treatment and benefit of patients. They can be found within various departments in all the major hospital sites – such as dermatology, ophthalmology, surgical theatres and physiotherapy departments. Unfortunately, due to the nature of laser radiation, they also present a potential hazard to the eyes and skin of patients, staff and visitors.

The Health and Safety at Work Act etc. (1974) places a general duty on the health board to ensure, so far as is reasonably practicable, the health and safety of its employees. This duty includes in particular the provision of safe equipment, systems of work and a working environment.

Several pieces of legislation, guidance and standards are relevant to medical lasers, a full list of which are detailed in, as detailed in Section 11 of the Policy. The Health Board is fully committed to following and implementing all legislation and guidance relating to the safe use of medical lasers, thus ensuring that risks to its staff, patients and visitors arising from the use of medical lasers are eliminated or minimised so far as is reasonably practicable. This Policy describes the framework by which HDdUHB manages the safe use of medical lasers.

### Asesiad / Assessment

There have been no changes to the relevant legislation or guidance since the 2019 Version 1 of this Policy, therefore the only changes that have been made are to update the corporate

arrangements and some minor improvements / adjustments. In terms of changes made to the corporate arrangements, the lead Executive Director for the Policy is now the Director of Nursing, Quality and Patient Experience rather than the Director of Operations.
The only other changes were very minor amendments to the reference and guidance documents listed in Section 11 of the Policy. These changes were as a result of direct discussions with the Medical Physics Expert from Swansea Bay University Health Board (SBUHB) whose expertise is utilised by HDdUHB.

The reviewed and updated Policy was then circulated to the full membership of the Radiation Protection Group for comment and approval for a period of two weeks. No comments were received other than a confirmation from the Head of Radiation Physics in SBUHB that the Policy was satisfactory for approval.

As only minor amendments to the Policy have been made, there has been no requirement to undertake consultation via global email to staff.

The Policy will be available in all areas via the HDdUHB Policy Internet site. For the Medical Laser Safety Policy to be successful, all managers will need to ensure that all Laser users within their areas of responsibility comply with the requirements of the procedure.

The Radiation Protection Group will ensure that the Policy is implemented and monitored. This will be re-enforced within localities by local risk management and health and safety arrangements.

This document will be reviewed every three years or earlier should audit results or changes to legislation / practice within HDdUHB indicate otherwise.

**Argymhelliad / Recommendation**

For the Health and Safety Committee to approve the revised and updated 770 – Medical Laser Safety Policy (Version 2).

| **Amcanion: (rhaid cwblhau)**<br>**Objectives: (must be completed)** | |
|---|---|
| Committee ToR Reference:<br>Cyfeirnod Cylch Gorchwyl y Pwyllgor: | 3.16 Approve organisational Health and Safety Policies, Procedures, Guidelines and Codes of Practice (policies within the scope of the Committee). |
| Cyfeirnod Cofrestr Risg Datix a Sgôr Cyfredol:<br>Datix Risk Register Reference and Score: | Not applicable. |
| Safon(au) Gofal ac Iechyd:<br>Health and Care Standard(s): | 1. Staying Healthy<br>1.1 Health Promotion, Protection and Improvement<br>2.1 Managing Risk and Promoting Health and Safety<br>7. Staff and Resources |
| Amcanion Strategol y BIP:<br>UHB Strategic Objectives: | 1. Putting people at the heart of everything we do<br>4. The best health and wellbeing for our individuals, families and communities |

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| Amcanion Cynllunio Planning Objectives | 2H Supporting talent, succession planning and leadership development |
| Amcanion Llesiant BIP: UHB Well-being Objectives: Hyperlink to HDdUHB Well-being Objectives Annual Report | 2. Develop a skilled and flexible workforce to meet the changing needs of the modern NHS |

| **Gwybodaeth Ychwanegol: Further Information:** | |
|---|---|
| Ar sail tystiolaeth: Evidence Base: | Directives<br>• The Medical Devices Directive. The European Commission. Council Directive 93/42/EEC concerning Medical Devices, OJ 169/ 12.7.93.<br>• Directive 2006/25/EC of the European Parliament and of the Council of 5 April 2006 on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation).<br><br>Acts<br>• Health and Safety at Work etc. Act 1974<br><br>Regulations<br>• The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013<br>• The Control of Artificial Optical Radiation at Work Regulations 2010<br>• The Personal Protective Equipment Regulations 2002<br>• The Control of Substances Hazardous to Health Regulations 2002<br>• The Management of Health and Safety at Work Regulations 1999<br>• The Provision and Use of Work Equipment Regulations 1998<br>• Health and Safety (Signs and Signals) Regulations 1996<br>• The Personal Protective Equipment at Work Regulations 1992<br><br>Guidance<br>• Lasers, intense light source systems and LEDs – guidance for safe use in medical, surgical, dental and aesthetic practices, MHRA, Sep 2015.<br>• ICNIRP Guidelines on limits of exposure to laser radiation of wavelengths between 180nm and 1,000µm; Health Physics 105 (3): 271 – 295; 2013. |

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| | • Non-binding guide to good practice for implementing Directive 2006/25/EC 'Artificial Optical Radiation' European Commission, Jun 2010.<br>• Laser radiation: Safety advice, Public Health England, updated 15th August 2017 (www.gov.uk/government/publications/laser-radiation-safety-advice/laser-radiation-safety-advice).<br><br><u>Standards</u><br>• BS EN 60825-1: 2014 Safety of Laser Products - Equipment Classification and Requirements.<br>• PD IEC/TR 60825-8: 2006 Safety of laser products - Guidelines for the safe use of laser beams on humans.<br>• PD IEC TR 60825-14: 2022 Safety of laser products - A user's guide.<br>• BS EN 207: 2017 Personal eye protection equipment – Filters and eye protectors against laser radiation.<br>• BS EN 60601-2-22: 2020 Medical electrical equipment - Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.<br>• PD CLC/TR 50448: 2005 Guide to Levels of Competence Required in Laser Safety.<br>• IEC EN 62471: 2008 Photo-biological Safety of Lamps and Lamp Systems.<br>• Health and Care Standards, Welsh Government, April 2015.<br><br><u>Other References</u><br>British Medical Laser Association Website: www.bmla.co.uk/ |
| Rhestr Termau:<br>Glossary of Terms: | As contained within the body of the report. |
| Partïon / Pwyllgorau â ymgynhorwyd ymlaen llaw y Pwyllgor Ansawdd lechyd a Diogelwch:<br>Parties / Committees consulted prior to Health and Safety Committee: | Radiation Protection Group<br>Health & Safety Advisory Group<br>Local consultation |

| **Effaith: (rhaid cwblhau)<br>Impact: (must be completed)** | |
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| **Ariannol / Gwerth am Arian:<br>Financial / Service:** | There are no direct costs associated with the policy. |
| **Ansawdd / Gofal Claf:<br>Quality / Patient Care:** | There is a positive impact on staff safety, health and wellbeing through compliance with this Procedure. |

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| **Gweithlu:**<br>**Workforce:** | There will be no adverse impact upon staff. |
| **Risg:**<br>**Risk:** | Not applicable. |
| **Cyfreithiol:**<br>**Legal:** | A breach of health and safety regulations can result in the issue of prohibition or improvement notices or criminal proceedings. |
| **Enw Da:**<br>**Reputational:** | Prosecutions and claims due to breaches in legislation or personal injury claims can lead to negative publicity. |
| **Gyfrinachedd:**<br>**Privacy:** | Not applicable. |
| **Cydraddoldeb:**<br>**Equality:** | The Equality Impact Assessment (EqIA) document from 2019 has been reviewed and updated.<br><br>No evidence gathered at this stage to indicate a negative impact on any protected group(s). |

# Medical Laser Safety Policy

DRAFT FOR HSC APPROVAL NOVEMBER 2022

## Policy information

**Policy number: 770**

**Classification:**
Corporate

**Supersedes:** Previous versions

**Version number: 2**

**Date of Equality Impact Assessment:**
*Detail date of EqIA*

## Approval information

**Approved by:**
Health Safety Committee

**Date of approval:**
*Enter approval date*

**Date made active:**
*Enter date made active (completion by policy team)*

**Review date:**
**Enter review date (normally three years from approval date)**

**Summary of document:**
This document describes the framework by which HDdUHB manages the safe use of medical lasers.

**Scope:**
This policy applies to all HDdUHB employees (including trainees, holders of honorary contracts and locum staff) who use or are involved in the use of medical lasers, ILS and LEDs.

**To be read in conjunction with:**
010 – Health and Safety Policy - opens in a new tab
467 – Medical Device Management Policy– opens in a new tab

608 – Risk Management Framework – opens in a new tab
674 – Risk Assessment Procedure– opens in a new tab
982 – Incident, Near Miss and Hazard Reporting Procedure – opens in a new tab

**Patient information:**
Include links to Patient Information Library

**Owning group:**
Radiation Protection Group / Health and Safety Committee
07/10/2022

**Executive Director job title:**
Mandy Rayani, Director of Nursing, Quality and Patient Experience

**Reviews and updates:**
1.0 – new policy 5.11.2019
2.0 – revised

**Keywords**
Medical Laser, Lasers, Safety, Radiation

**Glossary of terms**
LASER – light amplification by stimulated emission of radiation
MPE – maximum permissible exposure
NOHD – nominal ocular hazard distance
ILS – intense light sources
LED – light emitting diodes
LPA – laser protection advisor
LPS – laser protection supervisor

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# INTRODUCTION AND POLICY STATEMENT

Medical lasers are used by Hywel Dda University Health Board (HDdUHB) for the treatment and benefit of patients. They can be found within various departments in all the major hospital sites – such as dermatology, ophthalmology, surgical theatres and physiotherapy departments.

Unfortunately, due to the nature of laser radiation, they also present a potential hazard to the eyes and skin of patients, staff and visitors.

The Health and Safety at Work Act etc. (1974) places a general duty on the health board to ensure, so far as is reasonably practicable, the health and safety of its employees, see 010 – Health and Safety Policy – opens in a new tab.  for further information. This duty includes in particular the provision of safe equipment, systems of work and a working environment (MHRA). Further duties and responsibilities, specific to medical lasers, are detailed in several pieces of legislation, guidance and standards (refer to section references and relevant legislation).

The Health Board is fully committed to following and implementing all legislation and guidance relating to the safe use of medical lasers, thus ensuring that risks to its staff, patients and visitors arising from the use of medical lasers are eliminated or minimised so far as is reasonably practicable.

This document describes the framework by which HDdUHB manages the safe use of medical lasers.

# SCOPE

Device Use

This policy applies to medical lasers (including ILS and LEDs) used by HDdUHB services, irrespective of whether the device is owned, loaned, leased, on trial, being demonstrated, brand new, second hand or transferred from another location within HDdUHB. This policy also applies to medical lasers (including ILS and LEDs) used by any external service providers commissioned by HDdUHB.

Staff

This policy applies to all HDdUHB employees (including trainees, holders of honorary contracts and locum staff) who use or are involved in the use of medical lasers, ILS and LEDs.

Location

This policy applies to all HDdUHB premises where medical lasers, ILS and LEDs are used.

Laser Classification

This policy applies to medical lasers that may produce harmful levels of accessible laser radiation under normal use, in particular Class 3R, Class 3B and Class 4 lasers.

Risk Group Classification

This policy applies to ILS and LEDs classified as 'Risk Group 3' as defined in standard IEC EN 62471.

Specific Exclusions

This policy does not apply to lasers with classifications: 1, 1M, 1C, 2, 2M. Such lasers are regarded as safe under normal viewing conditions (MHRA).

This policy does not apply to lasers used to aid positioning of the patient e.g. as found on CT scanners and Radiotherapy Treatment Machines. Such lasers are usually no higher than Class 2. However, caution should be exercised by the users of such equipment when dealing with anaesthetised patients or others in whom the aversion response may be inhibited; some form of eye protection may be required. The LPA should be consulted for advice in these circumstances.

This policy does not apply to ILS or LEDs in the Exempt Group or Risk Group 1. Devices in Risk Group 2 are safe if used appropriately, however, the LPA should be consulted. If there is concern regarding the safety of particular conditions of use.

## AIMS

- To help ensure the effective organisation and management of safety associated with medical lasers.
- To help ensure that the necessary standards for the protection all persons on Health Board premises from the associated risks of medical lasers are implemented and maintained.
- The assist with the dissemination of health and safety information related to medical lasers to all relevant parties to ensure awareness of contemporary safety issues.
- To assist in the production, maintenance and adherence to local documents relating to the safe use of medical lasers.

## Objectives

- To define the key terms with regards to medical lasers.
- To outline roles and responsibilities to ensure the safety of all parties associated with the use of medical lasers.

- To provide general arrangements for managing laser safety including risk assessment, local rules, Laser Controlled Areas, PPE, control and security of laser key, reporting of adverse incidents and equipment maintenance and repair.
- To outline the requirements in terms of information, instruction and training for staff that use medical lasers to ensure their competency.
- To provide information on who to contact for strategic and local advice to the Health Board on matters of Medical Laser safety.

## Definitions

**Laser**

Means any device which can be made to produce or amplify electromagnetic radiation in the wavelength range from 180nm to 1mm primarily by the process of controlled stimulated emission (60825-1, p.17).

'Laser' is an acronym for Light Amplification by Stimulated Emission of Radiation.

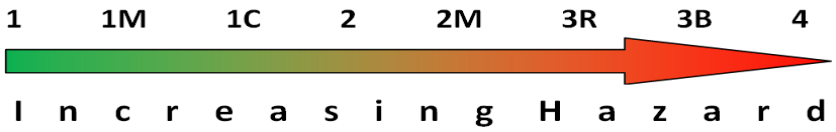
**Medical Laser**

Means any laser product designed, manufactured, intended or promoted for purposes of in vivo diagnostic, surgical, cosmetic or therapeutic laser irradiation of any part of the human body (60825-1, p.19).

**Laser Classification**

To help users select appropriate control measures to minimise the risk from laser radiation, a laser can be classified according to its potential to cause harm.

There are currently eight classes: the higher the class, the greater the potential to cause harm. The laser classes are 1, 1M, 1C, 2, 2M, 3R, 3B and 4.




The laser classification scheme only considers the hazard from the laser beam itself and not other hazards presented by the laser (so called 'non beam hazards') (MHRA, p.52).

The classification relates only to the normal use of the laser - it might not be applicable if the laser is undergoing service, repair or is faulty.

It is the responsibility of the laser manufacturer to provide the correct classification of the laser (60825-1, p.24).

The manufacturer is also required to implement all appropriate safety and engineering controls that are applicable to each class of laser.

Note that in the previous laser classification scheme, lasers were grouped into four main classes and two sub-classes (i.e. 1, 2, 3A, 3B and 4). These classifications will still apply to older lasers that may still be currently in use (MHRA p.52).

**Laser Controlled Area**
Means an area where the occupancy and activity of those within is subject to control and supervision for the purpose of protection from laser radiation hazards (60825-1, p.17).

**Maximum Permissible Exposure (MPE)**
Means the maximum level of laser radiation to which, under normal circumstances, the eye or skin can be exposed without suffering injury or adverse effects (60825-1, p.19).

The MPE depends upon the wavelength of the laser radiation, the pulse duration or exposure duration, the tissue at risk and, for visible and near infra-red laser radiation in the range 400 nm to 1,400 nm, the size of the retinal image (60825-1, p.19).

**Nominal Ocular Hazard Distance (NOHD)**
Means the distance from the laser at which the level of laser radiation equals the appropriate MPE; hence, exposure of the eye or skin at this distance will not cause injury (MHRA, p.26).

**Intense Light Sources**
Intense Light Sources (ILS) are devices used in conjunction with application-based filters. They emit a broad spectrum of incoherent light and have a similar effect on the skin as lasers.

The devices are generally used in the cosmetic sector for aesthetic purposes, such as hair reduction. In recent years, the technology has been developed to include other procedures, including skin treatments such as photo-rejuvenation.

These devices are also marketed by some manufacturers as Intense Light Pulsed Sources (ILPS) or Intense Continuous Light Systems (ICLS).

**Light Emitting Diodes**
Light Emitting Diodes (LEDs) are semiconductors that emit, in general, incoherent light over a range of wavelengths: typically 260 – 2100nm. LEDs are often used in conjunction with optical fibres. Radiation is produced primarily by the process of spontaneous emission, although some stimulated emission may be present.

**Risk Group Classification**
To help users select appropriate control measures to minimise the risks from incoherent light sources, such devices are grouped according to their potential to cause harm (EN 62471).

There are currently four Risk Groups as indicated in the following table:

| Group | Risk | Hazard |
|---|---|---|
| Exempt | None | No photo-biological hazard |
| Group 1 | Low Risk | No photo-biological hazard under normal behavioural limitations |
| Group 2 | Moderate Risk | Does not pose a hazard due to aversion response to bright light or thermal discomfort |
| Group 3 | High Risk | Hazardous even for momentary exposure |

## Roles & Responsibilities

**Chief Executive**
The employer, as defined in the regulations, is HDdUHB with the Chief Executive taking overall responsibility for the safe use of medical lasers.

The Chief Executive will delegate tasks, but not responsibility, for medical laser safety appropriately through the following organisational arrangements in order to effectively manage and control the risk from the use of medical lasers.

**Medical Director**
The Medical Director should ensure that, where necessary, medical personnel receive appropriate training in the safe use of medical laser equipment.

**Chair of the Radiation Protection Group**
The Radiation Protection Group (RPG), chaired by the Executive Director of Therapies and Health Science (DOTH), oversees the implementation of radiation protection arrangements on behalf of the Chief Executive in relation to both ionising and non-ionising radiations (which includes lasers).

The DOTH should ensure that:

- The Radiation Protection Group is convened regularly with a remit to report to the Chief Executive on policy matters concerning medical lasers;
- Assurance is provided to the HDdUHB that laser safety is managed in compliance with HDdUHB's policies and procedures;
- A Laser Protection Adviser is appointed, in writing, to advise the Health Board on compliance with legislation relating to the safe use of medical lasers, and that the appointed LPA is appropriately consulted;
- Records of incidents and investigations are kept and identified corrective action is implemented;
- This policy is reviewed at least once every three years.

**Managers of Departments using Medical Lasers**
Managers of Departments using medical lasers should ensure that:

- All medical lasers within their department (over which they have control) have received a suitable and sufficient risk assessment. This requirement applies irrespective of whether the laser is owned, loaned, leased, on trial, being demonstrated, brand new, second hand or transferred from another location within HDdUHB;
- A Risk Assessment is carried in respect of any material changes (e.g. building, engineering) in or around a Laser Controlled Area;
- The LPA is consulted for advice in relation to risk assessments for medical lasers;
- A suitable number of Laser Protection Supervisors (LPS) are appointed to supervise all working practices using potentially hazardous medical lasers, within their defined area of responsibility, to ensure they are undertaken in accordance with the local rules and that the LPA is notified of this appointment;
- Staff within their department who have responsibilities under this policy are aware of the extent of those responsibilities and comply with the requirements of the policy and associated Departmental documents;
- An inventory is kept of each item of equipment and an appropriate maintenance and periodic calibration is performed in line with the equipment risk assessment;
- A list of all Authorised Users and Authorised Assistants is maintained;
- Training records are maintained for all Authorised Users and Authorised Assistants;
- Risk assessments are reviewed annually, and any subsequent actions implemented;
- Records of clinical use of medical lasers are maintained;
- There are written Departmental Clinical Protocols for the use of medical lasers.

**Laser Protection Adviser**
The Laser Protection Adviser (LPA) has responsibility for advising service managers, departmental managers, members of staff and others on compliance with legislation relating to the safe use of Medical Lasers associated with practices carried out by the Health Board.

In the NHS, an employer should appoint or consult an LPA where Class 3B and/or Class 4 lasers are used. The employer should give the LPA adequate information, including a statement of the scope of advice required, and facilities to perform the work effectively (MHRA).

The LPA will be knowledgeable and have expertise in matters related to medical laser equipment safety. There is currently no defined criteria for determining LPA competence. It is for the employer to judge what level of competency they require for an LPA.

The following is an example of the *typical* duties expected of an LPA:

- Advising on compliance with statutory requirements concerning the use of medical lasers;
- Undertaking a risk assessment in conjunction with the LPS before the laser is brought into operation, and reviewing annually;
- Confirming the NOHD, MPE and the protective eyewear recommended by a laser manufacturer;
- Determining the extent of the Laser Controlled Area;
- Advising on the control of hazards arising from the use of medical lasers;
- Assisting the Laser Protection Supervisor in writing Local Rules;
- Providing safety training in line with MHRA guidelines for the LPS, laser users and assistants, or identify relevant training courses for them to attend;
- Performing a periodic audit of all locations where medical lasers are being used in order to review compliance with legislation, guidance and Local Rules;
- Liaising with all appropriate LPSs, laser users and those who assist with medical procedures involving lasers to promote the safe operation of medical lasers;
- Assisting with the investigation of any adverse events, including reporting the incident to the employer;
- Providing advice on equipment purchase, installation planning, and acceptance testing
- Reporting laser safety issues to the Radiation Protection Group.

**Laser Protection Supervisor**
A Laser Protection Supervisor (LPS) shall be appointed for each locality where Class 3B or Class 4 medical lasers are in use. The LPS acts as a focal point for all laser safety matters on a day-to-day basis and must be available (or a suitably nominated deputy) whenever a laser is to be used to ensure that all laser safety procedures are followed.

The LPS must be appropriately trained and is responsible for ensuring compliance with the Local Rules (and will be named in the Local Rules).

The manager of the locality will nominate an LPS and will seek the advice of the LPA on the appointment and training requirements of the nominated LPS.

The LPS is not responsible for the safe operation of the laser equipment – this lies with the authorised laser user.

### Competence

The LPS is expected to have a certain level of equipment understanding, practical experience and knowledge of the clinical application that they are working in. This may be achieved through an interview, documentary evidence, and having a certificate of attendance of an appropriate safety course.

PD CLC/TR 50448: 2005 contains details of the expected levels of proficiency for individuals who use laser equipment. The level of competency described is not a mandatory requirement. It is dependent on the specific LPS duties and the requirements of the healthcare establishment.

The LPS will have received instructions from the LPA as to what their duties involve and will have received safety training from either the laser manufacturer, the laser supplier or the LPA.

### LPS Responsibilities

The exact responsibilities of the LPS will need to be agreed by all parties (i.e. LPA and departmental manager) and documented. The following is an example of the *typical* duties expected of an LPS:

- Risk Assessment
  - The LPS should undertake a risk assessment, in conjunction with the LPA, before a laser is brought into clinical operation. The LPS should review this assessment on a regular basis as advised by the LPA.

- Local rules
  - With assistance and advice from the LPA, the LPS should write the Local Rules. This document details the appropriate safe working practices and procedures that should be followed by all staff within the Laser Controlled Area;
  - The LPS should ensure that all staff who enter or work within the Laser Controlled Area sign statements to acknowledge that they have read and understood the Local Rules and agree to abide by them. Copies of these signed statements should be kept by the LPS;

- The LPS should ensure that the Local Rules are followed and should monitor their adherence.

- Key Control
  - The LPS should ensure that the key for each laser is clearly labelled and is kept in safe custody (e.g. such as in a locked drawer) when the laser is not in use;
  - The LPS shall ensure that the key for each laser is issued only to a registered authorised user or assistant.

- PPE and Warning Signs
  - The LPS should ensure that laser protective eyewear is made available and checked prior to treatment with a medical laser;
  - The LPS will ensure that any staff (and patients) who are required to wear protective eyewear do so;
  - The LPS should regularly check the condition of any laser PPE;
  - The LPS should ensure that all laser-specific protective eyewear is kept separately from other safety eyewear;
  - The LPS should ensure that safety signs are placed at all entrance sites, at eye level, before treatment commences, and removed promptly after treatment;
  - The LPS should check the condition of warning signs, any protective blinds and any screens on a regular basis.

- Authorised Users & Assistants
  - The LPS should maintain an up-to-date register of authorised users and authorised assistants: only the personnel on this list are permitted to use, or assist with, the laser. However, the employer should decide whether to add a person's name to the register, with advice from the LPA.

- Training
  - The LPS should ensure that those who work in the Laser Controlled Area have received appropriate training commensurate with their level of involvement with the laser. However, it is not the duty of the LPS to deliver this training.

- Maintenance, Loan, Demonstration
  - The LPS should co-ordinate with service engineers to ensure that laser equipment is made available for maintenance on a regular basis;
  - The LPS should ensure that service engineers have followed the correct equipment handover procedures and satisfy themselves that the laser equipment has undergone any appropriate quality assurance checks prior to returning to clinical use;
  - The LPS must ensure that loan or demonstration equipment complies with, and is covered by, the local rules;
  - The LPS must inform the LPA of any loan equipment as this will require a risk assessment prior to clinical use.
- Record Keeping
  - The LPS should ensure that records of training, servicing and other laser safety matters are kept filed;

- This file should be kept up-to-date and in an organised format that will allow audit by a suitable external body (such as HSE or HIW);
- The LPS should maintain an inventory of all medical laser equipment in their department and provide a copy to the LPA.

- Liaising with LPA
  - The LPS should inform the LPA of any matters which might give rise to a potential hazard;
  - The LPS should inform the LPA, without any delay, of any hazardous event occurring. The LPS should record as much information as possible concerning the circumstances and make this available to the LPA;
  - The LPS should inform the LPA of any changes in laser related equipment, changes to the controlled area, or changes in operating procedure, as soon as possible;
  - The LPS should inform the LPA of any matters which require the Local Rules to be amended;
  - The LPS should liaise with the LPA during laser audits and act upon any recommendations.

**Clinical Laser Expert**
The clinical laser expert works in an advisory capacity. They are generally the lead clinician (senior consultant), who is associated with the laser. The role of the clinical expert would relate to making clinical assessments of the suitability of junior clinicians or other authorised users who are to use the equipment for a particular procedure.

**Authorised Laser User**
The authorised user is the individual who physically operates the laser.

The authorised user's clinical laser expert, LPS or LPA will specify and assess the level of competence required. They will also determine when the authorised user is sufficiently competent to start using the equipment after suitable training.

They should also have attended an appropriate safety course, e.g. 'core of knowledge'. The authorised user must be knowledgeable in how to operate the particular laser and how the controls will affect the treatment.

The following is an example of the *typical* duties expected of an Authorised User:

- Ensuring 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;
- Using the laser safely;
- Only using the laser for specific purposes for which they have been trained;

- Using the laser only in compliance with the manufacturer's operating instructions;
- Keeping records of all training.

**Authorised Laser Assistant**
There will be times when the authorised user needs help from assisting staff (authorised laser assistants) during a laser procedure. Assisting staff need to be trained to use the equipment that they will help with. They will need to follow the appropriate safety measures, including the local rules.

The LPS or LPA will authorise the assisting staff.

The following is an example of the *typical* duties expected of an Authorised Assistant:

- 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.
- Using all personal protective equipment that has been provided.
- Following instructions from the LPS and authorised user regarding laser safety.

**Other members of staff**
There may be occasions when a member of staff is present within the controlled area, but they may not be operating or assisting in the operation of laser equipment.

The LPS and/or LPA should ensure that these staff members are aware of laser radiation hazards and risks and have received basic laser safety training.

## General Arrangements for Managing Laser Safety

**Risk Assessment**
Before first clinical use of a medical laser of Class 3R, Class 3B or Class 4; the employer should undertake a 'suitable and sufficient' risk assessment in order to comply with regulation 3 of the Management of Health and Safety at Work Regulations 1999.

Risk assessment is a tool for assessing the effectiveness of existing controls and helps identify shortfalls that need further control. The law does not expect all risks to be eliminated, but rather to protect people as far as is reasonably practicable. For further information on risk assessment and management refer to 608 – Risk Management Framework – opens in a new tab - and 674 – Risk Assessment Procedure – opens in a new tab.

The legal responsibility for the risk assessment process lies with the employer. In practice, the LPA usually undertakes the risk assessment along with the LPS with additional assistance from the laser manufacturer or supplier.

The assessment involves assessing the laser's technical suitability (which requires the provision of information from the supplier/manufacturer), an assessment of the intended treatment room, an assessment of the suitability of any personal protective equipment, making sure that any users of the lasers have had equipment and/or procedural training (usually provided by the supplier/manufacturer) and identifying the updates required to the Local Rules.

**Local Rules**

The purpose of Local Rules is to ensure that all employees are working in a safe environment and that all patients are treated safely. Local Rules form part of an employer's means of complying with the Health and Safety at Work Act 1974.

Local Rules shall be issued for each locality where Class 3B or Class 4 medical lasers are used. This may also extend to Class 3R lasers (the LPS should consult with the LPA regarding Class 3R lasers).

It is the responsibility of the LPS to ensure that all staff who have any involvement with a particular laser have read and signed the relevant Local Rules.

**Laser-Controlled Area**

The intention of a laser-controlled area is to establish a zone around the laser equipment within which hazards could arise and over which there is some element of control or restriction. The need for control measures should be decided on the basis of a risk assessment.

For practicable purposes, a laser-controlled area will usually be physically defined by the walls of a room even where the NOHD is smaller than the room dimensions.

Advice should be sought from the LPA on the designation of the controlled area.

All persons within the controlled area must obey the Local Rules.

All entry points to the laser-controlled area must be appropriately and adequately signed and access controlled when the laser is in use.

**Personal Protective Equipment (PPE)**
The requirement for PPE, such as protective eyewear, should be based upon the risk assessment. If deemed necessary, all personnel within the controlled area must wear protective eyewear appropriate for the laser being used.

The appropriate eyewear to be used is usually stated by the laser manufacturer or laser supplier – regardless of their advice, the LPA should always be consulted to ensure the eyewear is suitable.

Some types of lasers have special filters built into the viewing optics to protect the operator's eyes from laser radiation. For practicable reasons, wearing protective eyewear in this circumstance is not required – but the LPA should be consulted for advice.

Only eyewear having a CE marking [indicating compliance to the Personal Protective Equipment Regulations (2002) and BS EN 207] are permitted to be used.

**Control and Security of Laser Key**
For all lasers that are classified as 3R, 3B or 4 the system should incorporate a key-operated master control. The 'key' may be a software password incorporated into the laser's operating system or may be an actual physical key.

Either at the end of the clinical session or working day, whichever is appropriate, the laser should be powered down and the key removed to an appropriate safe store. If the unit is password protected this should be initiated. *The key should not be left in the proximity of an unattended laser*.

**Reporting of Adverse Incidents**
Adverse incidents involving medical lasers should be reported immediately to the departmental manager, the LPS and the LPA.

Adverse incidents should also be reported via the Datix incident reporting system and investigated accordingly in line with 982 – Incident, Near Miss and Hazard Reporting Procedure – opens in a new tab.

**Equipment Maintenance & Repair**
Equipment Standards

- All medical equipment, which has an electrical component associated with it, should meet the appropriate safety requirements for that product;

- Although equipment standards are widely used, they are not mandatory. The Medical Devices Directive does not require them, although compliance with a harmonised standard is accepted as evidence that a product meets the directive's essential requirements;
- The primary product safety standard is BS EN 60601-1 Medical electrical equipment - part 1: general requirements for safety;
- In addition, there are standards specific to medical lasers, such as BS EN 60601-2-22 and BS EN 60825-1.

Equipment Maintenance

- The employer shall ensure that work equipment is maintained in an efficient state, in efficient working order and in good repair (PUWER);
- Only appropriately qualified and trained personnel should carry out equipment maintenance. Maintenance logs for all equipment should be held and kept up to date;
- Standard 2.9 of the Health & Care Standards requires employers to have processes to ensure that equipment and devices are maintained, cleaned and calibrated in accordance with manufacturer's guidelines, ensuring they are appropriate for their intended use and for the environment in which they are used.

For further information refer to 467 – Medical Device Management Policy – opens in a new tab.

## Implementation / Policy Compliance

**Implementation**

This policy applies at all sites within the Health Board where Medical Laser equipment falling within the scope of this policy is in use.

**Policy Compliance**

Compliance with this policy will be assessed and enforced through a combination of internal audits and external inspection by regulatory agencies.

The policy will be reviewed three yearly at the Radiation Protection Group or following new/amended legislation and guidance governing the safe use of medical lasers.

## Information, Instruction and Training

In general, employee training will cover 3 areas: *equipment-based* training, *safety* training and *procedural* training. All staff should have the appropriate competency training to undertake their role. The employer should keep training records.

**Equipment Based Training**
The laser manufacturer or their supplier usually provides the equipment-based training to the authorised user(s) and authorised assistants at the time of installation. After this, training may be provided to additional staff members either by the LPS, manufacturer / supplier, or the individual who has been designated the training supervisor.

**Safety Training – Core of Knowledge**
All laser operators and those assisting with laser procedures, should attend a 'Core of Knowledge' course as outlined in Appendix C of MHRA document 'Lasers, intense light source systems and LEDs – guidance for safe use in medical, surgical, dental and aesthetic practices'.

There is no statutory approvals body for core of knowledge courses but there are organisations and professional bodies, such as the British Medical Laser Association, that have 'approved' courses (MHRA, p.67).

The core of knowledge courses should be delivered by persons who have a high level of knowledge and understanding of different optical radiation devices, optical radiation safety and the risks and hazards associated to the equipment: for example a certified LPA.

It is good practice for staff to periodically re-attend a core of knowledge course (e.g. at least every 5 years) in order to maintain their awareness levels (MHRA, p.19).

**Safety Training – Laser Awareness**
Other staff members, who do not use medical lasers, but may be present during laser use (e.g. nursing staff, theatre assistants, and trainees) should have a basic understanding of the risks they may face and how they can be prevented.

As for Core of Knowledge courses, there is no statutory approvals body for Laser Awareness Training, but the British Medical Laser Association (BMLA) has a list of approved courses and a typical syllabus.

Laser Safety Awareness training may be provided by the LPA.

It is good practice for staff to periodically re-attend a Laser Awareness course (e.g. at least every 5 years).

**Procedural Training**
Procedural based training may be provided by the equipment manufacturer or their supplier and is frequently supported by an appropriate training course. The clinician who oversees the procedures may provide the clinical based training to specific staff.

Changes to procedures or the introduction of new treatments to a department or healthcare facility may require additional training from clinical experts, the manufacturer/supplier or other healthcare related personnel.

## Getting Help

The following persons should be available to provide strategic and local advice to the Health Board on matters of Medical Laser safety:

Laser Protection Advisor (LPA)

The Laser Protection Adviser is identified in the locality's Local Rules for Medical Laser Safety. The role of the LPA is defined in the LPA responsibilities section.

Laser Protection Supervisor (LPS)

The Laser Protection Supervisor is identified in the locality's Local Rules for Medical Laser Safety. The role of the LPS is defined in the LPS responsibilities section.

## References & Relevant Legislation

**Directives**

- The Medical Devices Directive. The European Commission. Council Directive 93/42/EEC concerning Medical Devices, OJ 169/ 12.7.93.
- Directive 2006/25/EC of the European Parliament and of the Council of 5 April 2006 on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation).

**Acts**

- Health and Safety at Work etc. Act 1974

**Regulations**

- The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013
- The Control of Artificial Optical Radiation at Work Regulations 2010
- The Personal Protective Equipment Regulations 2002
- The Control of Substances Hazardous to Health Regulations 2002
- The Management of Health and Safety at Work Regulations 1999
- The Provision and Use of Work Equipment Regulations 1998
- Health and Safety (Signs and Signals) Regulations 1996

- The Personal Protective Equipment at Work Regulations 1992

**Guidance**

- Lasers, intense light source systems and LEDs – guidance for safe use in medical, surgical, dental and aesthetic practices, MHRA, Sep 2015.
- ICNIRP Guidelines on limits of exposure to laser radiation of wavelengths between 180nm and 1,000µm; Health Physics 105 (3): 271 – 295; 2013.
- Non-binding guide to good practice for implementing Directive 2006/25/EC 'Artificial Optical Radiation' European Commission, Jun 2010.
- Laser radiation: Safety advice, Public Health England, updated 15th August 2017 (www.gov.uk/government/publications/laser-radiation-safety-advice/laser-radiation-safety-advice).

**Standards**

- BS EN 60825-1: 2014 Safety of Laser Products - Equipment Classification and Requirements.
- PD IEC/TR 60825-8: 2006 Safety of laser products - Guidelines for the safe use of laser beams on humans.
- PD IEC TR 60825-14: 2022 Safety of laser products - A user's guide.
- BS EN 207: 2017 Personal eye protection equipment – Filters and eye protectors against laser radiation.
- BS EN 60601-2-22: 2020 Medical electrical equipment - Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.
- PD CLC/TR 50448: 2005 Guide to Levels of Competence Required in Laser Safety.
- IEC EN 62471: 2008 Photo-biological Safety of Lamps and Lamp Systems.
- Health and Care Standards, Welsh Government, April 2015.

**Other References**

British Medical Laser Association Website: www.bmla.co.uk/

Checklist for Board and Committee SBARs and accompanying reports

| | Yes<br>**√** | No<br>X |
|---|---|---|
| Does each Board & Committee submission have an accompanying relevant standard SBAR template completed appropriately? | √ | |
| Has the submission been approved/signed-off by the named Executive Lead? | √ | |
| Are Board and Committee papers clearly marked “for decision”, “for assurance”, “for discussion”, or “for information” and does this align to the Recommendation section? | √ | |
| Does the SBAR answer the purpose stated (or implied) behind it being put on the agenda? | √ | |
| Does the SBAR fall within the remit of the committee’s Terms of Reference and answer the needs of the committee? | √ | |
| Has the information been placed in the appropriate sections of the SBAR and is it complete? | √ | |
| Does the SBAR make sense and cover all the issues? | √ | |
| Are there any sensitive, political or contentious information or statements within the SBAR? Have these been corroborated with evidence? | | √ |
| If the proposal in the SBAR is contentious, does it include more than one source of data? | Not Applicable | |
| Is the SBAR requesting a financial commitment? Not the role of an assurance committee. For Board , check that the right assurance process has been followed and the Board is not being asked to approve anything outside of its remit | | √ |
| Is there any sensitive or personal identifiable information contained with the SBAR and accompanying report? This may include data in very low numbers which could potentially allow identification of individuals | | √ |
| Does the report relate any security issues that may expose weaknesses in our control framework? Eg Cyber security, physical security, points of ligature/references to self-harm | | √ |
| Are attachments/appendices clearly numbered and cross-referenced? | √ | |
| Are graphs and/or tables carefully and correctly labelled? | Not Applicable | |
| Is data in graphs or tables also explained in words and analysed? | Not Applicable | |
| Does the SBAR or any of its attachments include embedded documents? If so, these will need to be extracted and attached separately | | √ |
| Is it jargon-free and clearly written? Are acronyms explained in full, either within the body of the report or in the glossary? | √ | |
| Have academic sources in the SBAR referenced appropriately and illustrations/figures cited correctly? | √ | |

| | | |
|---|---|---|
| If there are risks set out in the paper, are these referenced in the Risk section? | Not Applicable | |
| Does the Recommendation section relate to the objectives set out in the Situation? | √ | |
| Does the Committee have the authority (set out in TORs) to make the decision set out in the SBAR? | √ | |
| Does the SBAR give rise to likely queries which could be avoided by inclusion of more detail in the paper (eg reporting lines, dates for completion of actions). | | √ |