

Device Bulletin

Guidance on the safe use of lasers, intense light source systems and LEDs in medical, surgical, dental and aesthetic practices

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Medicines and Healthcare products Regulatory Agency

An executive agency of the Department of Health

We enhance and safeguard the health of the public by ensuring that medicines and medical devices work, and are acceptably safe.

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1 Introduction

The Medicines and Healthcare products Regulatory Agency (MHRA) is the executive agency of the Department of Health charged with protecting and promoting public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and that they are used safely.

This guidance document relates to medical lasers and other types of optical radiation devices, including light emitting diodes (LEDs) and intense light/heat sources, referred to as intense pulsed light (IPL) (sources) systems in the text.

Equipment used in conjunction with the optical radiation equipment, such as optical fibres, contact tips, articulated arms etc. are also reviewed.

This document reflects the changes in equipment technology and technical and safety standards that have been initiated since the last edition. It updates and replaces DB 9602 'Guidance on the safe use of lasers in medical and dental practice'.

1.1 Document aim

The aim of this document is to provide sufficient guidance to the reader, in conjunction with relevant supplementary information, for the safe use of the laser systems, IPL equipment and LEDs.

This is a guidance document; it should not be regarded as an authoritative statement of law, nor having any legal status.

1.2 Document audience

This document is suitable for all personnel who are associated with the purchase, supply, installation, use and maintenance of medical, dental and cosmetic lasers, IPL systems and LEDs. Not all the content will be relevant to all readers.

The following may find this guidance document to be useful:

- healthcare professionals including registered doctors, surgeons, nurses and dentists who provide treatments using class 3B or 4 lasers, IPL and LEDs
- beauty therapy establishments where class 3B or 4 lasers, or IPL treatments are provided in a clinic/salon
- mobile laser and IPL services, where a beauty therapist undertakes treatments in various locations within the United Kingdom
- clinical scientists, engineers and other healthcare professionals, including laser protection advisers and supervisors.

1.3 New formatting



Cautions are formatted like this.



The MHRA's recommendations are formatted like this.

2 Nature of hazards

Optical radiation devices include lasers, intense pulsed light (IPL) systems and light emitting diodes (LEDs). Details of these devices and their applications are given in section 7. Section 8 reviews the optical radiation effects on the tissue.

The optical radiation emitted by lasers, IPLs and LEDs has potentially hazardous effects on patients, clients and equipment users. The effect can be direct such as damage to eyes or skin. There is also a potential risk of fires or explosions from lasers igniting gases or fabrics and the problem of inhalation of smoke given off when surgical lasers are used.

Hazards from lasers will depend on the type of laser (see Table 5 in section 9) but problems can include: eye injury; skin burns; fire/explosion; smoke inhalation.

2.1 Effects of exposure

Eyes

The eye is particularly susceptible to damage from optical radiation (see section 8.1) if focused onto the retina and can be sufficient to cause local heating; it may damage both the pigment epithelium and the adjacent light-sensitive rods and cones, resulting in temporary or permanent loss of vision.

There is the potential for a photochemically induced retinal injury (photoretinitis or blue-light injury) resulting from radiation exposure at wavelengths primarily between 400nm and 600nm. This damage mechanism dominates over thermal damage for exposure times exceeding 10 seconds. The photochemical effects may result from a single exposure. Multiple exposures over a period of time (hours) may be cumulative.

Tissue

Skin is susceptible to damage from optical radiation i.e. tissue burn. Large areas of skin may be protected by light-absorbing or light-scattering materials (e.g. regular clothing). Hazards to hands and face may require shielding. Section 8 has details of how optical radiation affects tissue.

Fire hazard

Class 4 lasers are potentially a fire hazard in certain clinical situations. Protective clothing may be necessary which must be flame or heat resistant. However, not all

such clothing provides the wearer with the fluidity of movement that the usual surgical clothing affords.

Smoke inhalation

Members of staff and patients or clients may suffer from inhalation effects of smoke and vapour (plume) following tissue destruction. The debris contained in the plume may produce airway irritation and nausea. There is some evidence that inhaled cellular and viral debris dispersed in the air have resulted in certain adverse effects [1]. Measures for dealing with the effects of smoke plume are discussed in section 5.13.

2.2 Dangers to patients and clients

The hazards to patients and clients can stem from a number of areas including over-exposure due to elevated power or energy outputs, or misdirected laser beams.

Below we give some examples of dangers to patients/clients and how they may be controlled.

Stray optical radiation (laser/IPL)

Optical radiation that is misdirected, unintentionally reflected or escapes from the protective housing and optical fibres can cause damage to non-targeted tissue or organs. Ensure position prior to beam delivery.

Eye injury

An anaesthetised patient may be particularly at risk because they are not able to react to any stimulus; it is essential that the patient's eyes are suitably protected in such circumstances.

Skin burn from scratched external filter (IPL)

A photochemical effect or burn may result on a patient/client's tissue or skin following an IPL treatment, especially if there are scratches on the external filter. Scratches may result in lower wavelengths being transmitted by the filter.

Skin burn from hot spots on filter (IPL)

Ensure the IPL external optical filter is cleaned appropriately during the patient/client treatment. This should prevent hot spots on the filter occurring and burning the patient's skin.

Broken optical fibres – burn/infection risk

Optical fibre breakages, or tip detachments put the patient at risk of burns or infection if they become lodged in tissue. Optical fibres, though flexible, have not been designed to bend to acute degrees during procedural manipulations and are vulnerable to damage.

Caution should be observed to reduce the risk of damage to optical fibres when used with a rigid bronchoscope or similar device.

Risk of fire

External (endotracheal tube ignition) and internal (body cavity) patient fires may arise when there are high concentrations of flammable gas (oxygen or anaesthetic gas mixtures) or body gases.

Flammable materials such as surgical drapes and clothing may be ignited by accidental exposure to laser/light energy.

It may be appropriate to have a container of sterile water located nearby to extinguish any small non-equipment fires.

Risk of mistreatment

During treatments performed via an optical fibre delivery system, if no visible treatment beam or change in tissue is observed when the laser is operated, the laser should not be fired again until the fibre has been withdrawn and inspected.

See also section 5 'Safety mechanisms and controlling hazards'.

2.3 Dangers to staff

Many procedural and environmental risks are common to patients, clients and staff although the level of risk may be different. The risk assessment (section 4.2) should take into account the potential dangers from the perspective of the equipment user(s) and the associated staff.

Below we give some examples of dangers to staff and how they may be controlled.

Optical radiation risks

Optical radiation may cause damage to the eyes and skin of staff. Exposure may arise from misdirected, from unintentionally reflected, or from beams that escape from the protective housing. Appropriate eye protection should be worn.

Risk of fire

To mitigate this risk all surgical instruments, tubing and other associated equipment, used in close proximity to the laser beam should be made of a suitable fire resistant material. It may be appropriate to have a container of sterile water located nearby to extinguish any small non-equipment fires.

Laser plume emissions

These may pose a health risk to the surgeon and theatre staff. Precautionary measures may need to be put in place i.e. the use of an evacuation system. Section 5.13 contains more details on smoke plume emissions.

Unexpected adverse events

To reduce the likelihood of an adverse incident occurring, no more than one laser or IPL should be switched on during a single patient/client treatment. The laser or IPL should be switched off, prior to initiating use of a different optical radiation device. This good working practice would help to reduce the risk of an unanticipated adverse event.

See also section 5 'Safety mechanisms and controlling hazards'.

3 Safety management

3.1 Employer responsibilities

Health and safety at work legislation (see section 10) places a general duty on employers to ensure so far as is practicable, the health and safety of their employees. This duty includes in particular the provision of safe equipment, systems of work and working environment.

The employer is responsible for ensuring that the local rules and risk assessment(s) are drafted. The employer may delegate the task(s), but they cannot delegate their legal responsibility for ensuring all tasks are undertaken.

Effective instruction, training and supervision of staff are also the responsibility of the employer.

Employers and the self-employed also have a duty to ensure where reasonably practicable, the health and safety of people other than employees who may be affected by their work. This will include patients, clients and visitors.

Section 10 lists some of the legislation that an employer needs to be aware of.

3.2 Optical radiation safety policy

The overall responsibility for optical radiation equipment safety will lie with the employer, e.g. the NHS trust's chief executive, health board or authority, or the private healthcare establishment's chief executive or managing director.

The Health and Safety at Work etc Act 1974 [2] and the Management of Health and Safety at Work Regulations 1999 [3], require the employer and employee to undertake reasonable and practical health and safety measures.

The optical radiation safety policy should be separate from the local rules. It should define the aims of the senior management and reflect the management's commitment to maintaining high standards of safety. The document should summarise the principal safety approaches.

It is important that the optical radiation safety policy is tied into other management policies, so that it can be managed in the same way as other areas of activity. The policy may be led by the organisation's laser or optical radiation safety committee, or may be incorporated as part of the healthcare establishment's radiation safety committee.



Optical radiation safety policy

The healthcare establishment may wish to incorporate optical radiation safety into a specific policy, rather than being included in the radiation protection policy.

This is not a mandatory requirement, but may be appropriate to the healthcare establishment.

3.3 Laser Protection Adviser

The Laser Protection Adviser (LPA) is given responsibility by their employer to oversee laser safety. The LPA will be knowledgeable and have expertise in matters related to optical radiation equipment safety.

Note: The term 'Laser Protection Advisor' may also be used where only IPLs or LEDs 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.

The LPA will be responsible to and have direct access to the employer. However, they need not be an employee of the organisation concerned, but may be an external adviser.

LPA requirement

In the NHS, an employer should appoint or consult a LPA for Class 3B and Class 4 lasers or IPL systems.

In the private healthcare sector (hospitals, clinics and salons) where Class 3B or Class 4 lasers and/or IPL systems are operated, a LPA must be consulted; this is a requirement of the Department of Health's national minimum standards for independent healthcare [4].

A medical establishment employer may choose to consult or appoint a LPA if an invisible-beam Class 3R laser is operated.

For certain Class 1 laser products that contain an embedded Class 3B or Class 4 laser and that may produce accessible emissions under certain conditions of use (e.g. servicing), the appointment or consultation of a LPA may be necessary.

A LPA may be consulted or appointed for Class 1M or Class 2M lasers which can generate a well-collimated beam. The beam may present a hazard, if viewed through optical instruments.

3.3.1 LPA competency

The national minimum standards [4] do not define any criteria of LPA competence; it is for the LPA's employer to judge what level of competency they require.

In general terms, the LPA should be knowledgeable in the evaluation of laser hazards and should have responsibility for advising on their control (such a person may have responsibility for advising on other related hazards, e.g. ionising radiation hazards).

The duties of the LPA will be defined by their employer, though they should include undertaking hazard analysis and risk assessment for each laser and IPL installation and ensuring that suitable local rules are drawn up and implemented for each installation.

The employer has a legal responsibility for ensuring that the following duties are undertaken. The LPA assists their employer by undertaking these duties on their behalf. This is **not** an exhaustive scope of duties and should be used only as a guide.

- Undertake risk assessments before the laser or IPL is operated.
- Identification of the Laser Controlled Area.
- Oversee the commissioning* of the laser or IPL i.e. post installation testing.
- Ensure that suitable local rules and working practices are drafted.
- Liaise with all appropriate LPS personnel and Authorised Users.
- Undertake regular equipment and personnel safety reviews.
- Investigate any adverse events, including reporting the incident to their employer and if necessary, external body.

*The LPA may undertake the commissioning themselves or delegate to another member of staff, or the supplier may produce a report of checks and output calibrations that the LPA can inspect.

The role of the LPA may also include equipment purchase advice, installation planning, acceptance testing and regular safety audits.

The standard document PD CLC/TR 50448:2005 Guide to levels of competence required in laser safety [5] provides information and guidance to employers and employees in organisations in which lasers are used. The document outlines procedures for the management of laser hazards, including the employer's responsibilities and defines levels of competence for laser users, Laser Safety Officers and Laser Protection Advisers.

The information presented in the RPA2000 LPA certification scheme for Laser Protection Advisers [6] provides details of the competency that an individual may be expected to achieve.

3.3.2 LPA certification

All private healthcare establishments operating Class 3B or 4 lasers and/or IPL systems should have access to safety advice from a certificated laser Protection Advisor.

In NHS healthcare facilities, there is no mandatory requirement for the LPA to be certificated, though the NHS employer may stipulate it.

Following the designation of a 'certificated Laser Protection Adviser' in the national minimum standards for private healthcare [4] a number of organisations now award such certification. The overall level of competence that is required in each of the schemes is broadly similar.

The following organisations run LPA certification schemes. However, this list of certificating bodies is not exhaustive. The MHRA does not endorse any of the schemes detailed.

- **RPA 2000** is a non-profit making organisation, which was set up by The Society for Radiological Protection, The Institute of Physics and Engineering in Medicine, the Institute of Radiation Protection and the Association of University Radiation Protection Officers, solely for the purpose of certifying competence in radiation protection practice and from 2005, laser protection. There is no requirement to join any of the aforementioned institutes or society in order to apply for certification.

The RPA 2000 certification scheme for Laser Protection Advisers requires individuals to provide an evidence based portfolio showing that they have sufficient education, training, knowledge and practical experience to meet the requirements of the scheme and thus demonstrate a sufficient level of competence.

Under RPA 2000 an individual who is operating as a Laser Protection Adviser is certificated for five years. At the end of this time period, they should seek re-certification from the awarding authority. Information related to the RPA 2000 scheme may be found at the following website: <http://www.srp-uk.org/rpa2000/>

- **Association of Laser Safety Professionals (ALSP)**. The ALSP is a members-based organisation. The aim of the association is to provide a focus within the UK for laser safety expertise and to promote high standards in the provision of laser safety services.

The Association's assessment procedure for LPA certification is a two stage process. First the candidate submits a curriculum vitae and any supporting documentation and is then interviewed by two ALSP assessors.

Due to the different regulatory frameworks, the ALSP awards LPA certificates in two areas:

- Medical and cosmetic laser applications
- Non-medical applications

More information can be found on this website: <http://www.laserprotectionadviser.org/>

- **Health Protection Agency (HPA)**. The HPA operates a certification scheme which is based on the RPA 2000 scheme. Staff are subject to peer review during their development, their portfolio of evidence is assessed internally and externally and finally they receive an interview by an external assessor. The director of the radiation protection division confirms the certification. Re-certification is every three years through continuing professional development and peer review of the individual while undertaking LPA work. More information can be found on this website: <http://www.hpa.org.uk/laser>

3.4 Laser Safety Officer

The role of the Laser Safety Officer (LSO) is defined in the 2005 standards document PD CLC/TR 50448 Guide to levels of competence required in laser safety [5].

The title Laser Safety Officer is usually found in universities, other academic institutions and some manufacturing establishments. The appointment requirement of a LSO comes from the standard PD IEC TR 60825-14 [7].

Note: The term 'Laser Safety Officer' may also be used where only IPLs or LEDs are used.

3.5 Laser Protection Supervisor

The Laser Protection Supervisor (LPS) is an individual within the department, clinic or healthcare establishment who is:

- responsible for supervising the work of personnel who operate optical radiation equipment
- responsible for supervising the optical radiation equipment
- responsible for supervising the local rules (section 4.1) and ensure that they are followed on a day-to-day basis.

Note: The term 'Laser Protection Supervisor' may also be used where only IPLs or LEDs are used.

The roles and responsibilities of the LPS within the healthcare establishment will need to be agreed by all parties (i.e. LPA and manager) and documented.

The LPS as part of their role would be expected to liaise with the LPA, equipment users and others.

The LPS would be expected to have achieved a certain level of equipment understanding, practical experience and knowledge of the optical radiation field that they are working in.

The individual must be able to satisfy the requirements of the healthcare establishment to prove that they have the relevant expertise to fulfil the role; this may be achieved through an interview, documentary evidence, and an appropriate safety course attendance certificate.



LPS deputy

When the LPS is not present in the department/clinic/salon (i.e. on leave) an appointed deputy should be in attendance. The LPA in conjunction with the employer and LPS should agree who is the appointed deputy.

LPS role

In some healthcare establishments the LPS's role may be divided into two – the operational LPS and the clinical laser expert / clinical LPS.

This division of roles will **not** be suitable for every establishment. The LPA will advise on the LPS arrangement and scope of duties.

If this mechanism is adopted the individual roles may be defined as detailed in the next sections.

3.5.1 Operational Laser Protection Supervisor

The Operational Laser Protection Supervisor may be an ophthalmology nurse, theatre sister, operating department assistant, beauty therapist, or similar individual who is closely associated with the use of the laser or IPL.

Operational LPS role

The Operational LPS will directly supervise all optical radiation protection on a day-to-day basis.

The Operational LPS will be expected to ensure that the local rules are adhered to. They would also ensure that other staff who work within the device's Controlled Area are familiar with the local rules.

The Operational LPS will ensure that the Authorised Users were appropriately trained to operate each laser or IPL and that they were familiar with all appropriate procedures.

The Operational LPS will be expected to maintain a register of approved laser and IPL authorised staff (Authorised Users). However, the decision to add a person's name to the register should be undertaken by the employer, with advice from the LPA.

Note: The appointment of an Operational LPS may **not** be appropriate for every healthcare establishment.

3.5.2 Clinical Laser Expert

The Clinical Laser Expert / Clinical Laser Protection Supervisor would work in an advisory capacity. They are generally the lead clinician (senior consultant), who is associated with the laser or IPL. The Clinical Laser Expert / Clinical LPS is expected to work with the Operational LPS.

Clinical LPS role

The Clinical Expert/LPS would be expected to assess the competency of junior clinicians or other Authorised Users who are to use the equipment for a particular procedure.

Note: The appointment of an individual who is acting solely as a Clinical LPS may **not** be appropriate for every healthcare establishment.

3.5.3 LPS competency

The standard PD CLC/TR 50448 'Guide to levels of competence required in laser safety', section 4.2 (laser users) and section 4.3 (awareness for other persons) contain details of the expected levels of proficiency for individuals who use laser equipment.

The recommended level of knowledge that a Laser Protection Supervisor may be expected to have achieved when they commence their duties is detailed as follows:

Anticipated LPS competency level

- Understand the general nature of optical radiation.
- Understand the laser classification scheme.

- Understand the meaning of warning labels associated with optical radiation equipment.
- Know about the health hazards, including effects on tissue that can arise from the use of laser, IPL or other optical radiation equipment.
- Be familiar with the principles of evaluating optical radiation equipment related risks.
- Understand hazard control procedures, including the use of personal protection.
- Be familiar with the intended purpose of the optical radiation equipment.
- Be aware of the need for any additional precautions that may be necessary when undertaking non-routine activities with the equipment.
- Be familiar with the organisation's procedures and policies governing optical radiation equipment use, including emergency action and accident reporting procedures.
- Ensure appropriate safety training of relevant personnel.
- Oversee training, equipment and safety documentary records.
- Draft appropriate safe working procedures, including local rules (see section 4.1 and [Appendix A](#)).

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.

3.6 Authorised user

The Authorised User is the individual who operates the laser or IPL.



Authorised User register

A register of Authorised Users of Class 3B or 4 lasers and IPL systems should be held. This is mandatory for establishments that fall under the Care Standards Act [8]. An example of a register of Authorised Users is provided in [Appendix B](#).

Authorised user equipment usage

The employer may specify those lasers or IPL systems and/or procedures that each user is permitted to undertake.

3.6.1 Authorised user competency

The Authorised User's manager, LPS or LPA will specify and assess the level of competence required.

The Authorised User will have received suitable laser/IPL equipment training. They should also have attended an appropriate safety course.

The Authorised User must be knowledgeable in how to operate the particular device and how the controls will effect the treatment.

