Safeguarding public health

MHRA

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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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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Contents

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.

Anticipated knowledge level of an Authorised User:

- Understand the general nature of optical radiation.
- Be familiar with the intended purpose of the optical radiation equipment.
- Understand the meaning of the warning labels associated with optical radiation equipment.
- Understand the health hazards, including effects on tissue, which can arise from the use of laser, IPL or other optical radiation equipment.
- Understand the equipment-related hazards that arise from the use of optical radiation devices.
- Be familiar with hazard control procedures.
- 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 optical radiation local rules (section 4.1).
- Be familiar with the content of contingency plans within the local rules and other related emergency procedures.

The level of competency described is not a mandatory requirement, it is a guide. The level of competency is dependent on the requirements of the healthcare establishment.

3.7 Assisting staff

There will be occasions when the Authorised User requires help from assisting staff during a laser/IPL procedure. The assisting staff will need to be authorised by the LPS and/or LPA.

Assisting staff role

Assisting staff should be appropriately trained in the use of any equipment that they may use; they should adhere to all appropriate safety measures, including the local rules.

3.8 Training

In general, training will cover three areas; equipment-based training, safety training and procedural training.

3.8.1 Equipment training

The manufacturer or their supplier usually provides the equipment-based training to the Authorised User(s) at the time of installation. Thereafter, training may be provided to additional staff either by the LPS, manufacturer/supplier, or the individual who has been designated the training supervisor.

Equipment upgrade or replacement

If the equipment is upgraded or replaced, additional training may be required from the manufacturer/supplier.

3.8.2 Safety training

The ‘Core of Knowledge’ course will provide the basic knowledge component for staff that either work directly with lasers and/or IPL systems, or assist with such equipment.

Core of Knowledge courses may be specifically related to cosmetic or medical applications. However, in general they are broad-based courses.

In the United Kingdom, a number of organisations run Core of Knowledge courses on laser, IPL and optical radiation safety and applications.

Core of Knowledge course

The course should have a specific predetermined content, which includes optical radiation types and risk management. An example of the course content is given in Appendix C.

It may be considered good practice for staff to periodically re-attend a Core of Knowledge course in order to maintain their awareness levels.

3.8.3 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.

4 Safety administration

4.1 Local rules

The 'local rules' form part of an employer's means of complying with the Health and Safety at Work Act 1974, section 2(3) [2].

Local rules (or working procedures) should reflect safe working practices and relate to the day-to-day safety management of lasers, IPL systems and LEDs.

4.1.1 Laser and IPL local rules

The local rules should be specific to each optical radiation device and the clinical application. Consideration will need to be given in the local rules for lasers/IPL systems that are co-located.

The purpose of local rules is to ensure that all employees are working in a safe environment and that all patients are treated safely.

All staff who are involved with optical radiation equipment should read the document.

Introduction of local rules

The LPS or LPA should 'talk through' the content of the local rules with staff to ensure their understanding of the document. The staff should then sign a declaration, thereby acknowledging that they have read, understood and will adhere to the local rules.

The local rules should be easily available to staff in the treatment area. A copy of the local rules should also reside with the LPS and the LPA.

Local rules review

The local rules should be kept under regular review and should be updated when necessary. The LPA may defer the undertaking of the local rules review and updating to the LPS. However, such reviews should be undertaken with advice from the LPA.

A review of the local rules should reflect any changes to the working procedures associated with the particular device.

If the local rules are amended, staff will be required to re-read them and re-sign the declaration.

4.1.2 Local rules content

The local rules should either directly address the following issues or refer to any separate supporting documentation:

- Management safety structure (e.g. manager, consultant, LPA, LPS and users)
- Contact point for LPS and LPA
- A register of Authorised Users
- Arrangements for safe keeping and issue of laser/IPL keys

- Defined region and limits of the equipment Controlled Area
- Nature of hazard to persons (users and patients)
- Controlled and safe access to the equipment area
- Training requirements for persons assisting in or undertaking laser/IPL use
- Equipment user's responsibilities
- Methods of safe working, including layout of equipment
- Definition of simple pre-use safety checks and instructions
- Personal protective equipment, especially protective eyewear
- Prevention of use by unauthorised persons
- Adverse event and equipment fault procedures and logs
- Use of loan or demonstration equipment
- Temporary staff
- Visiting engineers.

Appendix A includes a specimen local rules document.

Any revised document should indicate the date it was reviewed, by whom and the new version number. Older versions of the document should be removed from circulation.

4.2 Risk assessment

The identification and categorisation of potential hazards in all aspects of optical radiation safety is extremely important.

Risk assessment is a legal requirement. 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 [3]. The law does not expect all risks to be eliminated, but rather to protect people as far as reasonably practicable.

The legal responsibility for the risk assessment process lies with the employer.

Risk assessment is a tool for assessing the effectiveness of existing controls and aids in the identification of shortfalls that need further control. The Health and Safety Executive has issued guidance on health and safety management [9].

The assessment will need to address routine aspects of work, as well as accident/incident situations. It should identify likely scenarios and contingency plans. However, do not over complicate the process.

The risk assessment may be drafted by the Laser Protection Adviser (LPA), Laser Protection Supervisor (LPS) and/or other appropriate staff. The Authorised User(s) should also provide input. The responsibility for the final version of the risk assessment (including the review process) lies with the employer.

The roles and responsibilities of the Laser Protection Adviser and Supervisor are detailed in sections 3.3 and 3.5.

Five steps to risk assessment
The Health and Safety Executive (HSE) has developed five steps to risk assessment (http://www.hse.gov.uk/risk/fivesteps.htm). These steps are:

- Identify the hazards
- Decide who may be harmed and how
- Evaluate the risks and decide on precautions
- Record your findings and implement them
- Review your assessment and update if necessary

This basic principle may be used when undertaking a laser or IPL risk assessment.

The risk assessment should include determining the hazards associated with these four areas:
1) equipment (purchased/loan/demonstration)
2) personnel who may be at risk
   - Authorised User
   - other staff who work in the area
   - cleaners
   - maintenance staff
   - contractors
   - visitors
   - patients
   - others
3) procedure(s)
4) location.

The risk assessment may be a summary of principal measures, which then refer to subsidiary documents that contain specific detail.

Fault/failure modes and effects analysis
A fault/failure modes and effects analysis (FMEA) may be used in identifying and categorising all possible faults and potential effects associated with the equipment, staff/patient etc, procedure and the location.

Risk assessment review
It is recommended that the LPA, in conjunction with the LPS and Authorised User should undertake an initial risk assessment review/audit of the Controlled Area which will review the potential hazards and control measures. The risk assessment may be undertaken by the LPA on behalf of the employer. **However, it is the employer's responsibility to ensure it is done.**

The LPS, in conjunction with the Authorised User(s), should review the risk assessment on a routine basis to assess the effectiveness of the control measures in place.

Risk assessment review
The LPS review should be conducted on an annual basis or earlier if there are any changes that impinge on the operating environment.

The LPA should undertake a risk assessment audit to review and re-assess the potential hazards at least every two years or earlier if any changes in procedures or equipment are introduced.

4.3 Ophthalmic surveillance

Ocular adverse incident

If there is a suspected or actual ocular injury, staff should report the incident to both their employer and LPA. An ophthalmologist should then perform a medical examination within 24 hours of the event, so that the extent of the injury can be identified.

It should be noted that some retinal injuries may be incorrectly attributed to damage from optical radiation treatment [10].

There are currently no UK regulations regarding ophthalmic surveillance of laser or IPL workers, although there are a number of recommendations contained in PD IEC TR 60825-14 [7], including the following:

> 'Pre, interim, and post-employment ophthalmic examinations of workers using Class 3B and Class 4 lasers have value for medical legal reasons only and are not a necessary part of a safety programme.'

At the time of writing the Health Protection Agency was drafting guidance on this subject.

4.4 Reporting adverse incidents

An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including patients) or other persons.

Appendix D has details of how to report incidents to the MHRA and to other authorities, including the devolved administrations.

Withdrawal of equipment from service

Following the adverse incident, it may be necessary to withdraw the equipment from service. The issue should be discussed with the LPS, LPA and any appropriate manager.

The event and fault should be recorded in the appropriate log book. A warning notice should be attached to the equipment, alerting all personnel to the fault.

5 Safety mechanisms and controlling hazards

5.1 Hierarchy for controlling safety

There is a hierarchy for controlling safety:

- equipment/engineering
- administration
- personal

To minimise risk, equipment/engineering and administration safety control measures should be established first, prior to introducing personal protective measures.

Equipment/engineering
Control measures will include the device interlocks, room interlocks (if appropriate), warning lights, barriers and laser-proof blinds etc.

Administration
Use of local rules, operating procedures, designated areas, user training and warning signs are all effective methods of controlling hazards. These practices, in conjunction with equipment/engineering safety measures should be the principal control mechanisms.

Personal
Eye protection and other patient/client/user protective clothing may be introduced as a safety control measure. However, personal protective equipment (PPE) should not be used as the primary method of controlling a hazard.

Safety review period
It is recommended that the safety measures should be reviewed annually or earlier if there is any change that impinges on the operating environment. This review should be undertaken by the LPS as part of the risk assessment review and be in conjunction with the LPA if there have been any changes in practice.

Laser and IPL equipment safety
Either at the end of the clinical session or working day, whichever is appropriate, the laser or IPL should be powered down. The key or smart card, where fitted, should be removed to an appropriate storage location. If the unit is password protected this should be initiated.

Contingency arrangements
The risk assessment should include contingency arrangements for different scenarios e.g. out of normal hours working; environment cleaning or equipment decontamination; service engineer visits. Additional contingency arrangements may be required if a service engineer is working alone.

The contingency arrangements and corresponding systems of work may be included in the local rules. If the contingency arrangements are not included in the local rules a reference should be made to the subsidiary document.

5.2 Controlled area

A laser 'Controlled Area' is the region around the laser where people may be present and in which specific protective control measures are required.

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 (see section 4.2).

A laser Controlled Area will usually be physically enclosed, either by the walls of a room or by the use of a dedicated enclosure in the form of curtains hung from the ceiling; these can be used to screen off the laser from the adjacent working area. However, the boundaries should take into account the nature of the work undertaken within the room. Depending on the nominal ocular hazard distance (NOHD section 5.4), the boundaries of the IPL or Class 3B laser Controlled Area may be defined through the use of a curtain.

The Controlled Area should include the region around the equipment where the maximum permissible exposure (MPE) level is exceeded (see section 5.3 below).

Controlling access

A number of methods can be employed to control access when the laser or IPL is in use. The mechanism most suitable to a particular environment should be employed. These may include the following:

- knock and wait to be admitted
- key pad lock
- interlocks (door or equipment).

5.3 Maximum permissible exposure

Maximum permissible exposure (MPE) is the highest level of laser exposure at the eye or skin that is generally considered safe.

Maximum permissible exposure calculations

The concept of exposure limits is generally defined in terms of health and safety; separating those exposure levels that are hazardous from those which are generally considered to be safe.

The exposure levels are related to the wavelength of the optical radiation, the pulse duration or exposure time, the tissue at risk and for radiation in the range 400 nm – 1400 nm, the size of the retinal image. The published MPE values are based on exposures causing the minimum injury that may be observed clinically.

Maximum permissible exposure limits

MPE will become legal limits by no later than April 2010, when the Artificial Optical Radiation Directive [11] is brought into UK law.

MPE calculations
Details of the method of calculation and recommendations for MPE levels are given in PD IEC TR 60825-14: 2004 Safety of laser products. A user's guide [7].
These levels should be used as guidance in the control of exposure and should not be regarded as precisely defined lines between safe and dangerous.

Practical use of MPE values

The MPE may be calculated prior to the installation of the equipment, as part of the preparatory risk assessment by the Laser Protection Adviser.

When a laser emits optical radiation as a series of pulses or in several spectral regions, or where pulses are superimposed upon a continuous wave background, calculation of the hazard may be complex. The calculations are equally complex for IPL systems since the device emits optical radiation as a series of pulses in a broad spectrum of wavelengths (non-coherent spectrum).

If within the equipment area the level of direct, reflected, or scattered optical radiation achieved during normal operation, exceeds the applicable MPE, the area will be subject to control and supervision for the purpose of protection from the radiation hazard.

If the MPE is not exceeded, it is unlikely that the environment would be designated as a Controlled Area.

5.4 Nominal ocular hazard distance

The distance at which the beam irradiance or radiant exposure equals the appropriate maximum permissible exposure (MPE – see section 5.3) is defined as the nominal ocular hazard distance (NOHD). The NOHD would be provided by the equipment manufacturer. It should be recognised that adding components to the laser beam delivery system may alter the NOHD.

The LPA will take into account the NOHD when specifying the boundaries of the Controlled Area.

5.5 Blinds and barriers

The principal mechanisms for controlling safety are through engineering means. However, even when this method is used in conjunction with good working practice it may not be sufficient in controlling a hazard and so laser-proof blinds or barriers may be required. Such barriers and blinds should be specifically designed to block optical radiation up to a Class 4 Laser.

Measure for controlling safety

The use of barriers and blinds should only be introduced with the LPA's agreement and should be based on the risk assessment**.**

5.6 Door interlocks

Depending on the orientation of the equipment within the room or type of laser being used, it may be appropriate to fit an entrance door interlock. Door interlocks should only be introduced with the agreement of the LPA and the decision will be based on the risk assessment.

Doors that are fitted with magnetic interlocks are generally powered up whenever the laser is enabled so preventing casual opening of doors. Only authorised personnel can enter the area by entering a code into the keypad; this type of door lock has been fitted to some operating theatres, thus enabling the laser to be used uninterrupted and without risk to staff.

Alternatively, some door interlocks disable the laser's power supply when the door is opened. This may lead to lengthy warm-up times for the equipment or may impinge on certain patient treatments.

It is unlikely that door interlocks would be necessary for IPLs. However, the LPA would make a decision following an assessment of risk of the particular operating environment.

Whatever mechanism is used to control access to the room while the laser is in use should be practical and realistic to the environment in which it is to be used.

5.7 Warning signs

Appropriate laser/IPL warning signs should be used. The signs will alert staff and patients/clients to the activity being undertaken in the area.

Signs should be compliant with the Health and Safety (Safety Signs and Signals) Regulations 1996 [12] and relevant standards such as BS EN 60825-1 [13].

Signs stating 'Eye protection must be worn' should be placed at the entrance(s) to each laser/IPL room. It may be appropriate to include 'No entry' signs on certain doors where unauthorised access could be gained to the laser/IPL room. It is recommended that all signage issues are discussed with the LPA.

Use of warning signs

When the laser or IPL is in use warning signs should be placed at each entrance to the Controlled Area.

It is advisable to include details of the type of laser or IPL in use so that prior to entering the room personnel are aware of what type of eye protection is required.

In some departments illuminated warning signs may be used. They should be sited at the entrance(s) to the room containing the laser.

Removal of warning signs

Signs should only be displayed or illuminated during the laser/IPL procedure. Wherever possible it is advised that the warning signs should be either removed, or reversed or switched off at the end of the laser/IPL procedure i.e. when the hazard is no longer present.

5.8 Beam hazards and reflections

Good practice dictates that the beam is directed only at the treatment site. However, the reflective properties of its surface are often unknown; there is also the possibility of the accidental introduction of highly reflecting surfaces into the beam.

Potential reflective surfaces

- Walls and ceilings. Ensure that reflections from surfaces are minimised.
- Room equipment. All reflective surfaces such as windows, video monitors, room lights etc. need to be identified and risk assessed.
- Instruments. Reflections from surgical instruments may focus the optical radiation towards the eye. Also, diffuse reflections from surgical instruments towards tissue may be hazardous. Mirrors or other reflective devices are sometimes used in laser and IPL procedures to deflect the optical radiation into inaccessible operating sites. These reflective devices should be suitable for relevant optical wavelengths. The use of mirrors in dentistry is often unavoidable.

All class 3B and 4 medical lasers will generally produce beams that can exceed the maximum permissible exposure (MPE) at some distance from the exit aperture of the device; the direction of the laser beam and the possibility of unwanted reflections will need to be considered and appropriate control measures taken.

Accidental exposure risk

Whenever there is any risk that an individual may be accidentally exposed to optical radiation, safety measures should be introduced to reduce that risk.

Eye exposure

For Class 2 and 2M lasers, which emit visible optical radiation, the natural aversion response to bright light (e.g. blink reflex) can generally prevent retinal injury. However, eye aversion should not be routinely relied upon.

It is possible that visible light laser beams can cause indirect harm (dazzle from laser beam) i.e. if the person is distracted, or the patient is sedated, or the aversion response is compromised. Under these conditions protective measures should be used.

Class 1 lasers are generally regarded as safe because of their low power, or because access to the beam was prevented and no radiation in excess of Class 1 is emitted.

Class 1M lasers can be hazardous if viewed via magnifying optics (see also Table 5 in section 9).

Ophthalmic hazard

In ophthalmic surgery, reflections from both corneal contact lenses and binocular indirect ophthalmoscope viewing lenses may constitute a hazard.

This hazard may be reduced by using anti-reflection coated lenses, which protect the user and also improve the visualisation of the target area.

Walls and surfaces

Reflections from walls or fittings in the treatment room should be considered in the risk assessment. Note: the reflectivity of surfaces is wavelength dependent.

The risk of the beam being directed or reflected towards a door or window can be minimised if the equipment is sited appropriately in the treatment room. Matt paint will normally be sufficient for walls.

Appropriate barriers (e.g. curtains, window covers) may be required to limit the extent of the controlled area.

5.9 Eye protection

Protective eyewear

The requirement for protective eyewear for the operator and patient/client and others is based on the hierarchy for controlling safety (see section 5.1).

Equipment/engineering and administrative safety control measures should be established first, prior to introducing personal protective measures. A risk assessment should then be conducted to consider when it is appropriate for eye protection to be used.

The advice of the Laser Protection Adviser should be sought on the use of appropriate protective eyewear to be employed.

Different styles of protective eyewear are available with different filters fitted for various wavelength ranges and for different types of lasers and IPLs. Protective eyewear is required under the Personal Protective Equipment regulations [14] to be clearly marked indicating whether they are suitable for use with a laser or IPL and for which wavelength range.

If appropriate to the local arrangements personal protective eyewear should either be stored with the laser or IPL, or be made available outside the laser/IPL room prior to personnel entering the room.

Eye protection risk assessment

The risk assessment should consider the need for eye protection and its use should be justified.

The main areas which should be reviewed in order to justify the use of eye protection are:

- the likelihood that the eyes will be exposed to optical radiation levels above the MPE
- there are no practical alternative options, through working practices, to provide protection
- visibility and colour perception issues will also need to be addressed.

The use and type of eye protection and when it is to be used should be included in the local rules.

Protective eyewear should fit the following criteria:

- Filters must correspond to the wavelength range for the particular device (laser or IPL) being used
- Be appropriately labelled with the wavelength range
- Be close fitting and have side protection
- Either have arms that rest on the ears or have an adjustable elasticated band that will fit securely around the head
- If necessary, can accommodate the individual wearing glasses
- Filters must not be cracked or have scratches
- Comply with the Personal Protective Equipment Regulations [14] and BS EN 207:1999 compliant laser safety eyewear [15].

Eyewear cautions

Protective eyewear (protective goggles) may not provide sufficient shielding for viewing the direct beam.

Lasers such as Class 1 devices, which are considered safe, can cause disturbing after-images in an individual's eye following an unexpected exposure.

If treating above the neck then use close fitting patient eye protectors; ordinary goggles should not be used. Alternatively the eyes may be covered with opaque material.

Reactive (shuttered) IPL eyewear should be tested before first use, then test prior to each subsequent use.

Caution should be exercised by users of therapy and diagnostic X-ray equipment, which incorporate Class 2 alignment lasers, when dealing with anaesthetised patients or others in whom the aversion response may be inhibited. Some form of eye protection may be required.

Allocation of eyewear
There should be a sufficient number of appropriate eye protectors available for use with each laser, or IPL i.e. a set of eyewear for each individual and patient/client in the controlled area.

Eyewear labelling
In addition to CE marking and indicators required by BS EN 207 the protective eyewear should be clearly marked for use with a particular laser or IPL system. For example, labelling may be achieved by placing colour stickers onto the protective eyewear which match a corresponding coloured sticker on the laser or IPL. In certain establishments it may be appropriate to have eyewear labelled with each individual user's name.

Protective eyewear should be disinfected between users. Refer to the manufacturer's instructions for use.

Wear and degradation issues
All eye protectors should be routinely checked for signs of wear and tear, especially any damage that may have occurred to the filters or frames. It is important that there is a record kept of these checks.

Any protective eyewear that shows signs of degradation should be immediately removed. The eyewear should be assessed by the LPS or LPA and replaced or repaired where appropriate.

Dual wavelength and multiple devices
Where different lasers, or dual wavelength laser devices, or laser and IPL combination systems are in use different eye protection may be required. Users will need to be clear which eye protectors are to be worn for each device/wavelength in use. There needs to be careful planning and good communication between all personnel to prevent incorrect eyewear being worn. Dual wavelength eye protection is available. If employed, the wearer should ensure that the eye protection covers the wavelengths to be used.

Eye protection with viewing optics
For certain laser and IPL procedures (e.g. endoscopes, laparoscopes or a slit lamp), it may be necessary for the Authorised User to utilise viewing optics e.g. eye piece. On these occasions protective eyewear may not be able to be used. The advice of the LPA should be sought in these circumstances.

Use of eyepieces
Eyepieces should have a suitable protective filter or shutter fitted to them to reduce the risk of harmful optical radiation being reflected back to the user's eyes.

It may be necessary for the Authorised User to continue to wear protective eyewear, especially if monocular optics are being used.

5.10 Hand and clothing protection

Surgical gloves should be worn by the user when they are operating the laser or IPL as a means of controlling infection.

Special clothing, including gloves may need to be worn in circumstances where personnel are required to have their hands in close proximity to the laser beam. These gloves will need to offer the wearer flexibility and freedom of movement, especially in terms of finger dexterity.

Hand and clothing cautions

If any special gloves or clothing are used they may only provide protection for certain wavelengths e.g. ultraviolet radiation.

Any protection of this type should only be used in certain circumstances and not as a substitute method for controlling hazards. The advice of the Laser Protection Adviser should be sought.

5.11 Surgical fires – causes and prevention

Surgical fires may occur on or in a patient during laser procedures. The fires can have serious consequences for the patient, the surgical staff and critical care equipment; any of which may be in close proximity to the fire.

The Emergency Care Research Institute (ECRI) has produced a fire prevention guide [16] which may be of interest to the reader.

5.4.1 Causes of fires

Surgical fires can occur when three critical elements are present. These three elements form the basis of the fire triangle: fuel, oxygen, heat.

The highest risk of fire is from class 4 lasers but lower classes of laser with focussed beams still have the potential to cause fire.

Fire triangle hazard

Fuel: Drapes, towels and gowns around the surgical area, as well as sponges, gauze and packing material should be kept moist if possible. Water soluble jelly may be used on the patient's hair or skin near the surgical site. If this is not appropriate, their hair (including eyebrows) may need to be shaved.

Flammable liquid (skin) preparations, oil based lubricants and volatile organic chemicals should be allowed to dry completely and any pooled liquid should be mopped up, prior to the start of the procedure.

Care should be taken to ensure wicking of flammable liquids does not take place on any material around the operating site.

Intestinal gases can also present a fire hazard.

Oxygen: An environment that is either oxygen enriched (greater than 21% oxygen concentration), or a nitrous oxide environment poses an increased risk of combustion.

Some methods of oxygen delivery are considered open sources because oxygen can easily escape, whereas an endotracheal tube connected to the breathing circuit is considered closed. Closed sources have been known to leak and should be monitored.

Special laser proof tubes are available which may be appropriate for use. However, they carry particular risks for certain endotracheal tube procedures. The LPA should assess the risks for each procedure with input from the surgeon, anaesthetist and theatre staff.

Oxygen tends to settle in low lying areas, such as beneath drapes or a chest cavity. Active gas scavenging of the space beneath the drapes should be considered.

Heat: Heat may be supplied by a variety of sources; a direct laser beam, an optical fibre, electrosurgical active electrode, argon beam coagulators. Incandescent sparks produced from the heat source, and ignitions from glowing residue of charred tissue are additional risks.

5.4.2 Prevention

In order to significantly reduce the potential for a fire all potential risks should be reviewed by the Laser Protection Adviser and Fire Officer, in conjunction with the LPS and Authorised User(s). A contingency plan should be drafted which details the action to be undertaken by staff in the event of a fire. Appropriate working practices and control mechanisms should be adopted to prevent such events.

A number of key areas for controlling potential fires

Laser equipment

- Never leave the optical fibre or tip on top of the drapes when it is not in active use. The tip can remain hot for some time after firing.
- Activate the optical fibre's output only when the tip is under the Authorised User's direct vision or under their control.

- The optical fibre should only be activated by the person holding it, or on their instruction.
- Deactivate the optical fibre prior to removing it from the surgical site.
- Fluid leakage from lasers that employ pumped water in their cooling system or with a liquid lasing medium can pose problems. Users should be aware of the hazard of toxic material (laser dye) and the hazard of water leakage (electrical safety, equipment overheating).
- In theatres, the spillage of fluids (saline, water) onto the laser can pose a problem. Any spillage should be mopped up immediately.

IPL equipment

- Never leave the IPL applicator on drapes, or on patient/client clothing when not in use.
- The IPL applicator should only be activated by the person holding it.
- Frequently wipe the IPL filter to remove hair and tissue debris build-up.

Laser and IPL equipment

IPL systems and medical lasers often employ high voltages which are safe in normal use but can be a hazard in the case of fluid leakage, or if inspection panels are removed. All electrical components and contacts should be enclosed and the equipment should be appropriately earthed in accordance with national regulations.

Oropharyngeal surgery and dentistry

- Use suction as near as possible to any potential breathing gas leak, to scavenge the gases from the oropharynx of an intubated patient.
- Verify that all oxygen and anaesthetic delivery circuits are leak free.
- Inflate the endotracheal tube cuff with methylene blue-tinted water or saline during airway procedures to aid in the detection of a compromised cuff and oxygen leak.
- Wet any gauze or sponges used with uncuffed tracheal tubes to minimise leakage of gases into the oropharynx, and keep them wet.
- Keep all moistened sponges, gauze etc and their strings moist throughout the procedure to render them ignition resistant.
- Avoid the use of plastic endotracheal tubes without cuffs.
- Prevent accumulation of oxygen and nitrous oxide in the oropharynx and beneath surgical drapes by venting to allow dissipation.
- Use pulse oximetry to determine oxygen saturation levels and the need for 100% oxygen supplementation.
- Avoid pooling or wicking of flammable liquid preparations; remove any excess as necessary.
- Ensure all areas treated with a flammable liquid preparation are completely dry before proceeding with the clinical procedure.
- Use a properly vented drape to help prevent a problem of oxygen and flammable vapour accumulation around head and neck examinations.

- If appropriate, use a laryngeal mask airway in order to minimise the build-up of oxygen or nitrous oxide beneath the drapes.

Responding to surgical fires

Small fires on a patient, which are the result of an optical fibre tip or hot metal surgical accessory igniting the drapes, may be extinguished by patting out the fire with a towel.

- Remove burning material from the patient and extinguish.
- Sterile saline or water should be kept in close proximity to the operating table for use in extinguishing flames. Care should be taken if electrosurgical equipment is being used.
- A fire blanket may be used to smother flames, albeit with extreme care in order to avoid injury to the patient.

5.12 Other thermal and operational issues

In addition to laser beam initiated fires there are other thermal hazards that can cause serious harm to an individual through a burn.

5.12.1 Laser thermal and operational issues

Optical fibres

- Prior to using the optical fibre, the operator should always check that the fibre is not damaged and is firmly attached to the laser output aperture.
- Prior to firing, the fibre's distal end should be located in its intended position, or inside a suitable beam absorbing device.
- When in position it may be appropriate to secure the optical fibre with tape or clips to prevent movement of the fibre during use.
- If a sapphire or other tip is to be used, ensure that the tip is securely attached to the fibre.
- Excessive overheating of the optical filter may arise if inadequate cleaning of the device occurs during the procedure.

Mirrors and beam stops

Objects, such as mirrors or beam stops that are in the path of a laser may become very hot; this can result in a burn to the user or patient/client.

Aiming beam

- If the aiming beam is adjustable set it to a low brightness initially and slowly increase the emitted power as required.
- Any minor knock or bump to the device could affect the coincidence of the aiming beam and the treatment laser; therefore, alignment of both the aiming beam and laser needs to be verified prior to use.

Endoscopic sheath

As the majority of sheaths are flammable, serious burns can occur if the endoscopic sheath of a flexible optical fibre is exposed to the laser beam.

Metallic tubing and instruments

Metallic tubing such as that used in laparoscopes, bronchoscopes, or other surgical instruments will get hot if the laser beam is misdirected onto their surface. This may result in thermal tissue damage in the patient and cause a burn to the user's fingers or hand.

5.12.2 IPL thermal and operational issues

Applicator cleaning and heat effects

- Excessive overheating of the applicator may arise and a build-up of tarnish can occur if inadequate cleaning of the device occurs during the procedure. The applicator head should be wiped frequently with a non-abrasive cloth.
- The manufacturer's cleaning instructions should be followed. Unless directed by the manufacturer, an abrasive tool should not be used; it is likely to leave small scratches on the applicator head/filter, which may lead to hot spots and may result in a patient/client burn.

5.13 Smoke plume issues

Whether a laser or IPL is being used in hair reduction, or a laser is being utilised in a surgical procedure, very small particles in the form of a bio-aerosol (smoke plume) can be released into the environment.

Smoke plume effects

The plume may contain hair, desiccated cells (viable and non-viable cellular material), prions, or other deleterious matter. In addition to the smoke plume, noxious gaseous fumes, or vapour, will be given off which may have toxic or carcinogenic constituents.

Chemicals, such as benzene and formaldehyde may be found in smoke plumes from a number of lasers [17,18]. Benzene can cause drowsiness or dizziness. The major effect of long-term exposure to high levels of benzene can result in anaemia or other blood disorders. Benzene is also a carcinogen. Formaldehyde can cause irritation to the eyes, nose, skin and respiratory tract.

The smoke plume may also cause acute inflammation and congestion in the alveolus of the lung, and irritation to the respiratory tract. However, of greater concern is the potential of harmful bacteria and viruses contained in viable particles, which opens the way for infections to be transferred between individuals [19,20].

Transportation of plume particles

The content of the smoke plume may also affect a patient's respiratory system. If jet ventilation is used during laser surgery, especially in the upper respiratory tract, the ventilation flow can transport particles within the plume into the patient's respiratory system.

Recent scientific evidence indicates that the smoke plume may be harmful to patients, clients and staff [21,22].

Smoke plume reduction

An approach based on precautionary action should be pursued, which aims to reduce, if not remove, the exposure to the plume.

5.13.1 Preventative measures

Masks

The Authorised User and patient/client should wear a face mask during aesthetic procedures e.g. hair reduction; this may reduce the inhalation of hair and cellular particulates and mitigate the odour. However, masks, including special laser surgical masks, are not recommended for use as the primary method of filtration; these masks may not be sufficiently effective as the primary method of smoke plume filtration; they may not create an effective seal around the face. It is recommended that a dedicated smoke evacuation system should be used.

When using a Q-switched laser during tattoo removal, tissue and blood may be ejected over some distance. The user should employ appropriate protection e.g. face mask or enclosure around the delivery piece.

Smoke evacuators

Smoke evacuation systems may be used to reduce the plume debris and limit the effect on staff and patients/clients. Smoke evacuators are vacuum pumps. The extractor nozzle inlet should be placed close to where the plume is generated as this will maximise smoke capture and enhance visibility at the surgical site. The evacuation system may either be built into the laser device or be a separate dedicated smoke evacuation system.

Smoke evacuator use

If a hazard remains from the effects of the smoke plume following the introduction of other preventative measures and appropriate working practices, it is recommended that smoke evacuators are used during the laser procedure.

The basic smoke evacuation system will generally have a primary and secondary filter although there are some evacuation systems that also contain an exhaust filter and a pump intake filter. These may be more suitable for the operating theatre environment. The purpose of the multi filter system is to ensure that the filtration efficiency is maximised during operation. Systems should be capable of removing

viable and non-viable cellular material contained in the plume including bacteria and virus particles down to about 0.01 µm. The systems should also effectively remove odours.

Operating theatre evacuation systems

Operating theatre evacuation systems are not suitable for smoke plume removal.

Operating theatre evacuation systems are designed to remove liquids and larger matter. The filters that are found in the operating theatre evacuation systems are not suitable to deal with the particles contained in the bio-aerosol.

Smoke plume regulation

The Control of Substances Hazardous to Health Regulations (COSHH) [23] require that exposure to substances hazardous to health are adequately controlled to prevent occurrence of ill-health.

Where there is likely to be an exposure to a substance hazardous to health an employer should carry out an assessment of the risks of any such exposure and ensure that steps are implemented to reduce the risks.

The primary duty on an employer is to apply the eight principles of good control practice, detailed in the COSHH regulations. If all the principles are being properly applied and maintained then any workplace exposure limit (WEL) will not be exceeded. Section 10 provides additional information on the COSHH regulations.

6 Equipment management

6.1 Equipment management

Equipment management
It is best practice to employ equipment management and quality control procedures at the healthcare facility.

Equipment management procedure example

- How to purchase the appropriate device
- Acceptance (pre-use checks)
- Provision of instructions
- Quality assurance (control) checks
- Equipment fault log
- Maintenance and servicing
- Equipment modifications
- Equipment disposal.

Advice on this can be found in the MHRA's guidance document DB 2006(05) Managing Medical Devices [24], which can be downloaded from the MHRA website (www.mhra.gov.uk).

6.2 Equipment purchasing, loan and demonstration

Introduction of new equipment
Individuals intending to purchase or loan/demonstrate equipment should liaise with the LPS and where necessary the LPA prior to proceeding. A suitable and sufficient risk assessment will need to be conducted prior to first use of the equipment.

Equipment purchase and installation requirements
The purchaser/prospective user(s) should obtain sufficient information from the manufacturer/supplier in order to ensure that the equipment meets the clinical and operational needs. The equipment may have specific installation requirements.

MEIGaN requirements
There are a number of electrical considerations that should be considered when permanently installing a laser. The MHRA's Medical Electrical Installation Guidance (MEIGaN) document [25] provides healthcare establishments with important information regarding the permanent installation of medical devices.

6.3 Pre-use equipment checks

Following the manufacturer/supplier's installation of the equipment, the healthcare facility should ensure that pre-use equipment checks (acceptance testing) are undertaken. The tests may be conducted by the LPA or LPS, the medical physics department or electrical and biomedical engineering unit. These checks may be undertaken at installation time, with the relevant hospital representative in attendance with the equipment installer.

The pre-use checks are performed in order to detect any faults and ensure that the equipment meets its specification. These tests may be in addition to any tests undertaken initially by the manufacturer. The tests should provide a baseline for future quality assurance checks.

Examples of pre-use equipment checks
Not all these checks are applicable to every device.

- Electrical safety
- Output measurements
- Beam alignment
- Beam stop, shutter or attenuator
- Aiming beam
- Accuracy of timer (if applicable)
- Interlock operation
- Filters
- Emergency cut-off
- Warning lights
- Footswitch operation
- Protective eye-wear assessment
- Equipment accessories assessment

6.4 Entry of equipment into service

Equipment records

Record keeping
Following the pre-use checks and once the LPA or LPS have agreed that the device can enter into clinical use, a record should be maintained of all planned and unplanned maintenance, including any problems or modifications. *This is not a mandatory requirement but it would constitute good practice.*

Any issue deemed as significant should be brought to the attention of the LPA, LPS and/or service engineer as soon as possible. The issue should be recorded in an appropriate log. The record should be readily available to all staff.

Laser / IPL equipment record details

- Date of pre-use equipment checks
- Date of last and next planned services
- Details of problems that have occurred with equipment
- Details of any authorised modifications
- Who to contact in case of problems and servicing

The LPA or a manager within the healthcare facility may recommend who should undertake this duty.

6.5 Quality assurance

Quality assurance programmes

In addition to regular equipment servicing by the manufacture/supplier, or other appropriately trained organisation, the hospital/clinic/salon should ensure that appropriate quality assurance checks are undertaken on the laser and IPL equipment.

The quality assurance programme may be divided into two specific components:

1. Routine quality assurance, undertaken by the Authorised User on a daily or weekly basis, or when appropriate.
2. Annual or bi-annual quality assurance undertaken by specialist hospital staff (e.g. physics, electro-biomedical engineering department etc.), or by the equipment manufacturer or their representative.

6.5.1 Example of daily quality assurance programme

Daily quality assurance may include:

- Check the laser/IPL output terminates when the footswitch or finger-switch is released
- Check the device's alignment of the aiming beam with the therapeutic beam
- Check device's filters for scratches or tarnish build-up. Clean or replace if appropriate
- Check all system alarms and lights are operating appropriately
- If feasible, monitor the actual position of any beam stop, shutter or attenuator, rather than the position of the attenuating mechanism
- If multi-use optical fibres are used ensure; 1) they have been cleaned prior to use, as per the manufacturer's instructions; 2) are undamaged; 3) re-calibrated if required

- Assess all device accessories including cables and connectors. Ensure that they are clean, undamaged and fit for purpose.

6.5.2 Example of weekly quality assurance programme

Weekly quality assurance may include:

- Visually inspect protective eye wear for lens scratches or general damage
- Check all protective blinds, windows and doors are functioning correctly and are undamaged
- Check that warning lights are functioning correctly
- Ensure all warning signs are undamaged and illuminated signs function correctly
- Ensure interlock operations are functioning correctly.

6.5.3 Example of annual/bi-annual quality assurance programme

The checks will likely mirror the initial pre-use equipment tests (acceptance tests) and may include:

- Electrical safety
- Output measurements
- Beam alignment
- Shutter operation
- Accuracy of timer
- Filters
- Emergency cut-off
- Warning lights
- Device calibration checks

Note: Not all the listed checks are applicable for every device, nor are they an exhaustive list.

6.6 Equipment fault log

Equipment fault log

Logging equipment faults

It is recommended that an equipment fault log should be held for each laser, IPL and associated equipment. It may either be a separate document for each item of equipment or it may be a single departmental log.

The fault log may be located centrally within a department, or kept with each individual device. The fault log should be easily accessible for inspection by the LPA, service engineer or NHS/government inspector.

Details of the fault including error codes displayed, audible alarms alerts etc. should be noted. Each fault should be signed by the fault observer and countersigned by the LPS, departmental safety manager, or other designated signatory.

6.7 Equipment modifications

Any modification to equipment, or change in its operational usage may have safety implications associated with it. All potential equipment modifications/change of use should be discussed with the LPA and LPS. It is recommended that a review of the risk assessment is undertaken at the time of the equipment modification.

Any modification by third parties, including in-house changes may transfer the manufacturer's safety responsibilities to the person(s) or organisation carrying out the modification.

Equipment modifications should be documented and may have implications on working and safety procedures, which may need to be revised. The local rules may require modification to reflect any of the afore-mentioned equipment and procedural changes. Additional staff training may be required.

It is recommended that old/redundant equipment is not cannibalised to keep another unit in operation as there may be issues of product quality, liability and traceability.

Unauthorised modifications

Medical device equipment should not be modified without the prior written consent of the manufacturer.

If a fault or incident should occur following an unauthorised modification, liability may be devolved to the healthcare establishment rather than the manufacturer.

6.8 Equipment accessories

Most manufacturers of lasers or IPLs sell the accompanying accessories. However, there are a number of third-party companies who manufacture/supply accessories that may be suitable for name branded lasers and IPLs.

Purchasing equipment accessories

If an accessory is purchased for the laser or IPL, the purchaser should ascertain whether the equipment is suitable for both the make **and** model of optical radiation device.

Frequently accessories are purchased in bulk through a central authority. The central purchasing authority should be made aware of any compatibility issues between devices and accessories.

Accessory purchase issues

- Verify that the accessory is suitable for the specific manufacturer's make and model of laser or IPL
- Verify that the product, including accessory is CE marked as a medical device
- Verify that the accessory is suitable for the required procedure
- Ensure that the device has not passed its expiry date.

7 Optical radiation devices

7.1 Lasers

The word 'laser' is an acronym for 'light amplification by stimulated emission of radiation'. The first working laser, using ruby as the lasing material, was demonstrated in the early 1960s, when a laser was used for the treatment of retinal detachment.

Lasers concentrate their output over an extremely narrow portion of the spectrum, which for practical purposes is considered as a single wavelength. The type of active material determines the wavelength.

7.1.1 Lasing materials

The lasing medium may be solid, semiconductor, liquid or gas. Solid materials may be crystals, such as ruby or neodymium yttrium aluminium garnet (Nd:YAG); or in the form of a semiconductor diode, such as gallium arsenide (GaAs). Liquid mediums are generally organic dyes in a suitable solvent (e.g. rhodamine 6G in methanol). Gases such as argon, carbon dioxide, rare gas-halide mixtures and also metal vapours may be employed.

7.1.2 Laser properties

Laser optical radiation has some unique features in addition to that ordinarily possessed by optical radiation, which enables the beam to be focused to a very small spot size.

Laser optical radiation is:

Collimated

Most lasers (an exception being semiconductors) emit optical radiation from the laser aperture as a nearly parallel beam. This low divergence means that the inherently high irradiance (power per unit area irradiated) of the laser is maintained over large distances.

Monochromatic

A laser spectrum comprises one or more very narrow lines at characteristic wavelengths, in contrast to the broad spectrum produced by conventional light sources; this enables a particular laser wavelength to be chosen to affect certain body tissues selectively or activate specific types of chemical.

Spatially coherent
All components of the laser wavefront are exactly in step. This property may be reduced when laser light is transmitted down an optical fibre and is rapidly lost with penetration through tissue.

7.1.3 Laser output mechanisms

Continuous wave
The continuous wave (emission) of laser optical radiation is generally produced when the shutter is opened for as long as the operator depresses the footswitch or hand-switch, which is typically for a few seconds.

The output from a continuous wave laser is quantified in watts (joules per second).

Pulsed laser
The pulsed laser output is intermittent and generally relates to lasers whose individual pulses do not exceed 0.25 seconds. They can emit a single pulse, or the pulses may be grouped together to appear as a single long pulse (pulse train). The output pulses may range typically from microseconds to milliseconds.

The total energy of each pulse is usually given in joules, or for repeated pulses as the average power in watts.

Q-switched
Q-switched outputs are very short laser pulses of low energy, but very high peak power. Q-switching also increases spatial coherence and therefore the quality and usefulness of the laser emission.

7.1.4 Laser types

Table 1 gives examples of the type of laser generally used in a particular medical application.

Table 1: Examples of medical application for a variety of lasers

Laser type	Wavelength µm	Emission mode	Associated beam transport	Medical application examples
He-Ne	0.63 0.54	CW	Optical fibre Mirror	Aiming beam
Nd:YAG	1.06	CW Pulsed Q switched Free-running pulse (FRP)	Optical fibre Mirrors	Dentistry Ophthalmology Dermatology Gynaecology Urology Respiratory
Ho:YAG	2.1	CW Pulsed	Optical fibre Mirrors	Ophthalmology Urology
Er:YAG	2.94	Pulsed FRP	Waveguide Mirrors	Dermatology Plastic Surgery Dentistry
Diode	0.81-0.98	CW Gated CW Pulsed	Optical fibre	General Surgery Physiotherapy Ophthalmology Dentistry Gastroenterology
CO_2	10.6	CW Q switched	Mirrors Waveguide	General Surgery Neurosurgery Head & Neck Dentistry Gynaecology
Dye	0.4-0.7	Pulsed	Optical fibre	Dermatology Urology
Ruby	0.69	Pulsed Q switched	Optical fibre Mirror	Dermatology Plastic Surgery
Excimer	0.16-0.35	Pulsed	Optical fibre Direct Articulated arm	Cardiac Ophthalmology
Alexandrite	0.755	Q switched	Optical fibre	Dermatology
KTP	0.532	Q switched Gated CW	Optical fibre	Gynaecology Dentistry Dermatology Obstectrics Plastic Surgery

7.2 Laser delivery systems

A laser delivery system comprises a number of components: entrance optics, a beam guide and target optics.

The choice of delivery system will depend upon the characteristics of the laser and the medical, surgical, dental or aesthetic application.

7.2.1 Beam guides

Waveguide

Waveguides fall into two groups – leaky and guide-mode propagating. Both types of waveguide transmit the laser energy along the bore.

In general waveguides have limited flexibility. They are most often used in hand-pieces and connected to the articulated arm.

Articulated arm

When the wavelength or peak power does not permit transportation through a waveguide, the laser beam can be transported using reflecting surfaces of an articulated arm.

An articulated arm consists of between six and eight mirrors, which are mounted on rotating holders to provide steering in any direction. The holders are connected to each other by a set of rigid tubes. If the system is properly aligned, the laser beam will exit the arm at the same position and angle, independent from the position of the freely movable tubes; the alignment is very critical.

The articulated arm is the transportation system of choice for Q-switched laser systems which deliver high peak power pulses.

7.2.2 Beam delivery systems

Focusing and collimated hand-pieces

Focusing hand-pieces are coupled to the laser and are used for precise vaporisation of skin lesions, such as warts.

Microscope manipulators

A microscope may be connected to the distal end of the articulated arm. A joystick is used to guide the laser beam along the optical path of the microscope and through the field of view. The beam is then focused onto the target tissue using optics that have a focal length that is compatible with the microscope optics. The spot size will determine the resulting tissue effect. Microscope manipulators may be used in certain ear, nose and throat surgery, as well as some gynaecological procedures.

Endoscopic applicators

A rigid endoscope may be coupled to an articulated arm. This apparatus is used when laser tissue vaporisation is needed within body cavities.

Scanning heads

Scanners allow large areas of tissue to be treated from a distance. The tissue is irradiated more evenly and accurately than can be achieved manually. Treatment patterns may either be preset or tailored for specialised treatments.

Various scanners have been developed for selective vascular lesion treatments (e.g. port wine stains).

Diffusers

A diffuser may be attached to the probe. The diffuser is used to spread the laser light over a large treatment area. The shape of the diffuser will also control the energy spread to the treatment area.

7.2.3 Fibre delivery systems

Optical fibres

With some laser applications, the lasing output is not used directly, but is instead coupled to an optical fibre, which conveys the laser radiation. Optical fibres of different materials are available; each material will transmit light over different ranges of wavelength. The scattering and absorption properties will be different for each different type of optical fibre.

The side firing fibre directs the laser energy at an angle, typically 70º and may be used in a fluid environment. The side-firing fibre may be used in endoscopic urology and is compatible with rigid, semi-rigid and flexible endoscopes. The side-firing fibre is generally compatible with holmium and Nd:YAG wavelength systems.

For some applications, the fibre delivery system may be used in conjunction with a distal assembly which aids the delivery of laser energy to the target tissue. Examples may be a simple conduit hand-piece, or more complex flexible, or rigid endoscopes.

The delivery system may use a particular type of sheath with the fibre, which delivers irrigation fluids or gas to cool the tip, while simultaneously removing tissue debris.

Fibre (contact) tips

Optical fibres are often used in conjunction with various shaped contact tips. The tips have been developed to provide a more controlled application of the light beam to the target. Commonly, they are made of sapphire glass (or other similar material) and may be of varying size (e.g. 200-1500 µm diameter). The tips improve the cutting characteristics of the laser by shaping the beam, delineating a controlled spot size and minimising beam scatter. The purpose of the fibre tip is to improve cutting and coagulation processes, control more easily the depth of the cut and allow tissue contact.

The tips can be damaged if the maximum output through the device is greater than 20 watts. The tips are also susceptible to breakage, especially if too much pressure is applied to its end.

Contact tips, such as sapphire are commonly used in soft tissue procedures with Nd:YAG lasers and with Er:YAG lasers in hard tissue procedures.

7.3 Laser applications

Table 2 provides a few examples of typical applications and the type of laser that may be used.

Table 2 Examples of clinical applications of lasers

Speciality	Laser type	Application
Dentistry	Nd: YAG	Soft tissue and periodontal surgery, root canal treatment, desensitisation, analgesia
	CO_2	Major & minor oral soft tissue and periodontal surgery
	Diode	Diagnostics, PAD, tooth bleaching, periodontal surgery, endodontics
	KTP	Tooth bleaching [26], soft tissue, endodontics
	Er,Cr:YSGG Er:YAG	Soft tissue surgery, tooth cavity preparation, bone surgery
Dermatology	Dye	Port wine stain [27]
	Alexandrite	Hair reduction
	Ruby	Tattoo removal
	Diode	Hair reduction
	Nd:YAG	Leg veins, vascular lesions
	CO_2	Ablation of skin / mucosa lesions, skin resurfacing, plastic surgical procedures
ENT Otorhinolaryngology	CO_2	Laryngeal papillomata, laryngology, webs, dysplasia, carcinoma-in-situ, vocal cord nodules, pharyngeal diverticula
	Ho:YAG	Endo-nasal surgery, tonsillectomy
Gastroenterology (see also PDT)	Nd:YAG	Tumour ablation. Bleeding from GI tract
General surgery (see also PDT, interstitial)	CO_2	Soft surgery
	GaAs	Laparoscopic surgery
	Ho/ Nd:YAG	Endoscopic surgery, laparoscopic surgery
Gynaecology	Nd:YAG	Endometrial ablation for menorrhagia
	CO_2	Cervical, vaginal and vulvar pre-cancer
	KTP	Laparoscopic, hysteroscopic surgery
Interstitial	Nd:YAG	Liver and breast cancer
Neurosurgery (see also PDT)	CO_2	Neuraxis neoplasia
Ophthalmology	Argon	Diabetic retinopathy, other retinal vascular abnormalities
	Nd:YAG	Posterior lens capsulotomy
	Excimer	Photorefractive keratectomy [28, 29]
Orthopaedics	Ho:YAG	Lateral retinacula release, osteoarthritic lesion removal, contouring and sculpting of articular surfaces
PDT (photodynamic therapy)	Dye	Bladder, GI tract, respiratory tract and other body site cancers
Physiotherapy	GaA/As	Wound healing, pain control [30] small joint inflammation [31, 32, 33], adhesive capsulitis [34], arthritis [35, 36]
Respiratory	Nd:YAG	Intraluminal lesions
Urology	CO_2	Ablative re-surfacing
	Dye	Lithotripsy
	Ho:YAG	Urinary stones, prostatic hyperplasia, bladder tumours
	Ho / Nd:YAG	Bladder, urethral and kidney stones

7.4 Intense pulsed light systems

Intense pulsed light (IPL) systems have been in use since the late 1990s. These systems are also marketed by some manufacturers as intense light source (ILS), or intense continuous light system (ICL system). Manufacturers may also describe the device as a light based or heat based system. All these types of devices are used similarly and have the same hazards associated with them.

Intense pulsed light and other forms of intense light source devices are used in conjunction with application based filters and will have similar effects 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.

A recent development is the combination IPL-laser system. The combination system is a single device; it allows the user to 'switch' from the IPL system to the laser. The output may be from a single hand-piece, or from a number of hand-pieces on the same piece of equipment. These types of system are more commonly used in clinics that offer cosmetic type procedures.

The effects of optical radiation on tissue are discussed in section 8.

7.4.1 IPL properties

The intense pulsed light system utilises technology that is different from that used in lasers. Xenon or krypton gas may be used as the filling for the quartz tube which forms the flash-lamp. IPL systems emit a broad spectrum of non-coherent light (400 nm to 1400 nm), which is filtered into wavelengths that are appropriate to the procedure being undertaken.

Filtering is achieved by a number of mechanisms:

- **Water path filtering**. The flash-lamps may be water-cooled, or a water based gel may be used, which will remove the majority of infra-red light.
- **Dichroic filtering**. Mirrors which are termed as being either 'hot' or 'cold' reflect unwanted wavelengths to a heat sink.
- **Longpass glass filtering**. Coloured glass filters may be employed for wavelength selection.

7.4.2 IPL delivery mechanisms

Typically the components of the IPL system will comprise a main unit and a hand-piece. The main unit has a control computer, a pulse-generating network and an ancillary cooling system. The hand-piece comprises a flash-lamp, filter and a lens or waveguide. The filtered light is delivered to the skin via the hand-piece. Other beam delivery systems may be used with IPL systems, including optical fibres, micromanipulators and scanners.

Some method of skin cooling should be employed during IPL procedures to protect the patient's skin from heat damage and aid patient comfort during the procedure. A gel may be applied to the skin creating a cold layer through which the light pulses pass.

Cooling mechanisms are also integrated into some IPL systems. Some of the more typical methods employed are:

- Forced air cooling uses high-flow, sub-zero (°C) air to the treatment area.
- Cryogen cooling utilises a refrigerated spray that is applied before, during, and after each light pulse.

7.5 IPL applications

The following table provides a number of examples of IPL applications.

Table 3 Examples of clinical and aesthetic applications of IPL systems

Speciality	Application
Aesthetic	Spider veins, sunspots, broken capillaries
Dermatology	Hair reduction, wrinkles, inflammatory acne [37]
Physiotherapy	Acute and chronic musculoskeletal aches and pains

7.6 Light emitting diodes

Light emitting diodes (LEDs) are semiconductor devices that emit in general incoherent light over a range of wavelengths, typically from 260 nm to 2100 nm. LEDs are often used in conjunction with optical fibres.

Since the latter part of the 1990s LEDs have provided medicine with a useful tool. Small LEDs can be placed anywhere in the body thus delivering light deep into tissues. The wavelengths have been biologically optimised in photodynamic therapy (PDT) for the treatment of cancer, wound healing and in a number of physiotherapy applications. LEDs are also used as the light source in the treatment of seasonal affective disorder (SAD).

LEDs have some advantages over lasers and IPL light sources:

- small in size
- low power consumption
- a negligible heat output.

Broad-band exposure limits for LEDs have been recommended by the International Commission on Non-Ionising Radiation (ICNIRP) and device emission limits for different risk groups have been published by the International Commission on Illumination (CIE).

7.7 LED applications

The following table provides a number of examples of LED applications.

Table 4 Examples of clinical applications for LEDs

Speciality	Application
Aesthetic	Spider veins, sunspots, broken capillaries
Dentistry	Dental composite curing [38]
PDT	Cancer treatment [39]
Physiotherapy	Wound healing [40]

8 Optical radiation effects on tissue

8.1 Optical radiation

Electromagnetic radiation may be defined as a form of energy that can propagate (radiate) through space. It is characterised by wavelength and extends from X-rays (short wavelengths) to radio (long wavelengths). Optical radiation has intermediate wavelength ranges. The optical spectrum is defined as electromagnetic radiation in the wavelength range 100nm to 1mm.

The optical radiation spectrum is divided into ultraviolet, visible and infra-red radiations. The ultraviolet (UV) and infra-red (IR) regions are subdivided into A, B, C (i.e UV-A, IR-A etc).

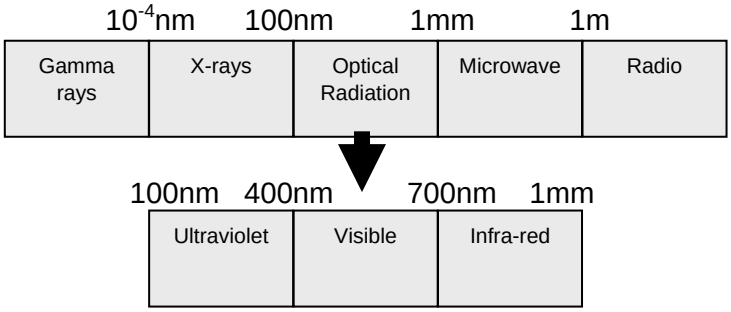

Figure 1: The electromagnetic radiation spectrum

The mechanisms by which optical radiation induces damage are similar for all biological systems and may involve thermal, mechanical, chemical and ablative processes.

The location and absorption of laser optical radiation in tissue, especially in the eye is strongly dependent on the wavelength.

8.2 Photo-thermal effect

The depth of penetration and absorption of optical radiation will depend primarily on its wavelength. Tissue damage from thermal effects is also related to the duration of the optical radiation exposure and the temperature reached in the tissue. If the optical radiation exposure to the tissue is for a short duration (less than 1 second) the tissue will suffer a lesser degree of damage, than if a longer exposure time is used.

For most surgical continuous wave (CW) lasers, damage is due to the heating of the absorbing tissue. If the duration is short and the tissue temperature is below 42 ºC then little or no permanent damage will occur. If this condition is exceeded, coagulation occurs. The proteins start to denature, which is evidenced by a whitening of tissue. Further heating above 100 ºC will cause evaporation of water and associated vaporisation of tissue. Continued irradiation heats the debris until the tissue blackens and carbonises at about 350 ºC. At temperatures above approximately 500 ºC carbonised tissue will burn.
Photocoagulation employs continuous wave laser light applied to absorbing material targets with effects mediated by primary and secondary effects of thermal damage. This technique is most widely used in the eye to treat retinal diseases e.g. diabetic retinopathy and macular degeneration.

Optical radiation exposure to the eye, especially focused on the retina, will cause local heating and can cause damage to both the pigment epithelium and the adjacent light-sensitive rods and cones; such damage can result in temporary or permanent loss of sight.

Intense pulsed light systems remove unwanted hair based on the principle of selective photo-thermal effect. The filtered light causes thermal injury to the hair follicle. The light penetrates the skin and is absorbed in the target pigment (melanin) found in the hair shaft. The energy absorbed in the shaft causes the temperature to reach a sufficiently high level in the hair follicle so that the targeted hair structures are destroyed and hair re-growth is inhibited.

8.3 Photo-mechanical effect

Photo-mechanical effects may occur when the tissue is exposed to pulses of radiation that last for a few nanoseconds. The tissue is heated up very quickly, which causes thermal expansion of the tissue and thermo-acoustic shock waves, which propagate through the tissue. This process is generally referred to as photo-disruption; it is used for removing fibrous tissue growths which may form in the eye following cataract surgery.

Thermo-acoustic shock waves are also produced by high power pulsed systems which may not be of sufficient intensity to create a plasma but may nevertheless cause very rapid heating. An example of this is seen with the use of erbium lasers in tooth cavity preparation, where interstitial water is rapidly vaporised causing explosive dislocation of enamel and dentine mineral components.

8.4 Photo-chemical effect

The cornea and the lens can be injured through ultraviolet radiation photo-chemical effects. The retina is particularly sensitive to damage from blue light. This sensitivity is the result of a photo-chemical reaction within pigments contained in the eye.

The occurrence of a photo-chemically induced injury depends on the number of absorbed photons per unit area on the tissue surface. It does not normally depend on the time taken to deliver the photons. A short exposure time to a high level of optical radiation will have the same effect as a long exposure period with a correspondingly reduced level of optical radiation. Photo-chemical damage has a cumulative effect.

However, the use of photo-chemical effects with tissue is used for positive benefits in medicine. An example of this in photodynamic therapy, where light therapy is used in combination with a photoactive drug.

8.5 Photo-ablative effect

Photo-ablation takes place when short duration laser pulses are focused onto a small area, rapid heating follows and results in the vaporisation of tissue and bone. Effective photo-ablation and precise depth control can be achieved by selecting the appropriate laser wavelength in a region where the absorbance of the tissue or bone to be treated is very high.

In excimer photo-ablation, strongly absorbing ultraviolet optical radiation is used to vaporize superficial tissues. It is primarily for surface etching, reshaping and refractive surgical applications in the cornea.

Tissue may be ablated by the beam from an excimer laser, which emits short wavelength ultraviolet optical radiation that breaks molecular bonds directly. The effect is to remove a localised volume, precisely defined by the physical extent of the beam.

The mid-infrared wavelength of an erbium laser may be used for bone ablation. An erbium laser coupled to a sapphire-tipped fibre may be used in photo-ablation orthopaedic surgery applications and dental and oral surgical applications.

9 Classification of lasers and IPLs

9.1 Laser classification scheme

In 2001, the Safety of Laser Products standard was revised.The revision to the laser classification system has resulted in the introduction of three new laser classifications – 1M, 2M and 3R – and the abolition of Class 3A.

The 2001 revised standard included a letter appended to a number of the laser classifications. The laser classification scheme only deals with the laser beam hazard.

The letter ‘M’ in Class 1M and Class 2M is derived from ‘magnifying’: optical viewing instruments.

The letter ‘R’ in Class 3R, is derived from ‘reduced’ or ‘relaxed’ requirements. The ‘R’ requirement relates to certain equipment and user specifics e.g. manufacturer: no key switch and interlock connector required; user: no eye protection is usually required.

The letter ‘B’ in Class 3B is historical.

It should be noted 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 are currently in use.

The 2001 edition has been revised as BS EN 60825-1:2007 Safety of laser products. Equipment classification and requirements [13].

The laser classification is determined by the equipment manufacturer. The manufacturer follows the specification laid out in the standard BS EN 60825-1:2007 [13]; details of the laser safety classes are given in Table 5. Additional equipment requirements are detailed in BS EN 60601-2-22 Medical electrical equipment. Particular requirements for safety. Specification for diagnostic and therapeutic laser equipment [41].

Table 5 Laser safety classes

Laser safety class	Laser type	Potential eye or skin hazard
Class 1 (embedded)	Laser completely enclosed	Generally safe during use. Hazards according to power of enclosed laser when interlocks are overridden.
Class 1	Very low power level	Emitted power generally safe for long-term intrabeam viewing, even with optical instruments such as magnifying glasses.
Class 1M	Low power level. Collimated large beam diameter or divergent	Safe for long-term intrabeam viewing, but potentially hazardous with magnifyers (divergent beams) or binoculars (large diameter collimated beams).
Class 2	Low power level Visible wavelengths only	Safe for brief (accidental) direct exposure with naked eye and optical instruments. Prolonged staring may injure eye, especially blue wavelengths.
Class 2M	Low power visible Collimated large beam diameter or divergent	Safe for brief exposure with the naked eye, but potentially hazardous when exposure occurs with magnifiers (divergent beams) or binoculars (large diameter collimated beams).
Class 3R (visible)	Low power Typically alignment lasers	Accidental exposure usually not hazardous, but eye injury possible for intentional intrabeam viewing
Class 3R (non-visible)	Low power	Accidental exposure usually not hazardous, but eye injury possible for intentional intrabeam viewing.
Class 3B	Medium power	Exposure (including brief accidental exposure) of the eye to the direct beam may cause serious eye injuries. Very limited skin hazard. Viewing of diffuse reflections are normally safe.
Class 4	High power	Exposure (including brief accidental exposure) of the eye to the direct beam and close viewing of diffuse reflections may lead to serious eye injuries. May cause serious skin hazard. Presents fire hazard.

The manufacturer is required to implement all appropriate safety and engineering controls that are applicable to each class of laser; for example, with Class 3B and Class 4 lasers, remote interlocks, a key switch, a beam stop and an emission warning will be required.

Any laser equipment of a given class may contain an embedded laser, which is greater than the class assigned to the device. In these cases safety and engineering controls

are required to ensure that access to the optical radiation in excess of the device class is not possible.

Labelling on laser equipment is required for all classifications of device.

9.2 IPL classification scheme

The standard IEC 62471 Photobiological safety of lamps and lamp systems [42] provides details of lamp classification, which include IPL systems.

The lamp classification scheme indicates only the potential risk. Depending upon the use factors, time of exposure and luminaire effects these potential hazards may or may not become actual hazards.

The pulsed lamp criteria, including IPL, apply to a single pulse and to any group of pulses within 0.25 seconds. The hazard values are at a distance of 200 mm.

The risk group determination of the lamp being tested is detailed in the standard.

10 Legislation

There is no single item of UK legislation that deals with the use of non-ionising radiation devices in the work place. General health and safety legislation applies as well as certain other regulations that cover non-ionising (optical) radiation equipment use. There is specific legislation which controls aspects of Class 3B and 4 medical lasers usage in private healthcare.

The legislation given below is **not an exhaustive list** of requirements. The employer will have to consider their legal responsibilities in more detail before they proceed.

Artificial Optical Radiation Directive [11]
This directive is otherwise known as the Physical Agents Directive (Artificial Optical Radiation). It has to be implemented by 27 April 2010. It will include all optical radiation devices, including lasers and intense pulsed light systems, LEDs and other diagnostic and therapeutic light sources used in medical, surgical, dental or aesthetic practices.

Care Standards Act 2000 [8]
This act, and equivalent devolved administration legislation, covers all aspects of healthcare and social care, including the private and voluntary sectors. It includes definitions of independent hospitals and clinics.

In England, the Healthcare Commission is responsible for the enforcement of the Care Standards Act 2000. In Wales, the Healthcare Inspectorate Wales regulates under the Care Standards Act 2000. In Scotland, the Care Commission regulates under the Regulation of Care Scotland Act 2001. In Northern Ireland, regulation is encompassed under The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003.

Control of Substances Hazardous to Health Regulations 2002 (COSHH) [23]
These regulate chemical, biological and microbiological hazards. They are applicable to the dyes used in some lasers, the gas used as laser coolants, and the material contained in the laser/IPL generated smoke plume.

Electricity at Work Regulations 1989 [43]
These cover the electrical safety testing of new equipment, and periodic electrical safety testing programmes.

Health and Safety at Work etc Act 1974 [2]
This act provides the legal UK framework for the management of health, safety and welfare of all people within the work place including, for example, visitors. In the context of this guidance document visitors include patients and clients. The act imposes responsibilities on the employer and employees. In context of this guidance document the employer will be the healthcare establishment and the employees will be the staff employed by the healthcare establishment.
Note: in Northern Ireland the legislation is known as the Health and Safety at Work (Northern Ireland) Order 1978.

Health and Safety (Safety Signs and Signals) Regulations 1996 [12]
These require employers to provide specific safety signs whenever there is a risk that cannot be avoided or controlled by any other means, such as the adoption of particular systems of work or through equipment engineering controls.

Management of Health and Safety at Work Regulations 1999 [3]
The regulations require an employer to make an assessment of the risk to the health and safety of their employees at work and the risk to others not in their employment arising from the work undertaken. The employer should act upon the findings from the risk assessment i.e. need for a controlled area, local rules and working procedures.

The employer is required to appoint one or more competent persons to assist in the compliance with the statutory requirements. Healthcare establishments will appoint health and safety officers to assist with the compliance where there are specialised risks; this may include the appointment of the Laser Protection Adviser and Supervisor.

Medical devices directives
There are three directives regulating the safety and marketing of medical devices throughout the European Union. They are:

The Active Implantable Medical Devices Directive [44]
Covers all powered implants or partial implants that are left in the human body. Heart pacemakers are the most common example of powered implants.

The Medical Devices Directive [45]
Includes most other medical devices, ranging from first aid bandages to X-ray equipment. Lasers, IPLs and LEDs are covered by this Directive.

The In Vitro Diagnostic Medical Devices Directive [46]
Addresses any medical device which is a reagent, reagent product, calibrator, equipment or system intended for use in vitro for the examination of specimens,

including blood and tissue donations derived from the human body. Blood grouping reagents and pregnancy test kits are examples of in vitro diagnostic devices.

The directives set out the essential requirements that products must meet. These make it clear that devices must not compromise the health or safety of the patient, user or any other person, and that any risks associated with the device are compatible with patient health and protection.

National Minimum Standards [4]
These were issued by the Department of Health. They set out a minimum level of service for each element of the care service provided in England and Wales. Standards with a similar scope have been drafted by the Scottish and Northern Ireland authorities.

Personal Protective Equipment at Work Regulations 1992 [**47**]
These regulations require the employer to provide appropriate and adequate protective equipment to their employees where the risk to the employee cannot be adequately controlled by other means (e.g. protective eyewear).

Personal Protective Equipment Regulations 2002 [14]
These cover CE marking and supply issues. Compliance with BS EN 207 [15] and BS EN 208 [**48**] are a requirement under these regulations.

Private and Voluntary Healthcare Regulations (England) 2001 [**49**]
These cover a number of issues including the regulation of Class 3B and 4 lasers as well as IPL systems that may be used in the private healthcare sector. Regulations with a similar scope have been drafted by the Welsh, Scottish and Northern Ireland Authorities. These regulations require the healthcare establishment to be registered with The Healthcare Commission or the respective devolved authority organisation.
Note: These regulations apply to therapeutic, diagnostic and cosmetic procedures. However, there are a number of exceptions, including treatment of the patient in their own home.

Provision and Use of Work Equipment Regulations 1998 [**50**]
The employer should ensure that the equipment (e.g. optical radiation devices) and all ancillary systems are fit for purpose. All equipment maintenance should only be undertaken by appropriately qualified and trained personnel. Maintenance logs for all equipment should be held and kept up to date.

Instructions on the safe operation, hazard assessment and contingency plans should be adopted. In the case of this guidance document, this would be undertaken by the Laser Protection Supervisor.

Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 [**51**]
These regulations (also known as RIDDOR) require employers and others to report accidents and some diseases that arise out of or in connection with work.
Further information is given on the website: www.riddor.gov.uk

11 Equipment standards

11.1 Overview

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 [45] does not require them, although compliance with a harmonised standard (e.g. EN 60601-1) is accepted as evidence that a product meets the Directive's Essential Requirements.

BS EN 60601-1:2001, Medical electrical equipment: part 1: general requirements for safety [**52**], is the primary product safety standard.

In addition to the 60601-1 there are medical laser specific standards, including:

- BS EN 60601-2-22: Medical electrical equipment. Particular requirements for safety. Specification for diagnostic and therapeutic laser equipment [41].
- BS EN 60825-1:2007 Safety of laser products. Equipment classification and requirements [13].

At the time of writing there are no standards which specifically address the safety of IPL equipment. A standard is currently in development.

There are other standards that are relevant to certain aspects or features of lasers, IPL systems and LEDs; these are detailed below.

11.2 Standards

Current standards

BS EN 60601-2-22, Medical electrical equipment: particular requirements for safety: part 2.22. Specification for diagnostic and therapeutic laser equipment [41].

BS EN 60825-1 Safety of laser products. Equipment classification and requirements [13].

BS EN 60825-4:2006 Safety of laser products: part 4: laser guards [**53**].

PD IEC/TR 60825-8:2006 Safety of laser products — Part 8: Guidelines for the safe use of laser beams on humans [**54**].

PD IEC TR 60825-14 Safety of laser products. A user's guide [7].

BS EN 207 Personal eye protection: filters and eye protectors against laser radiation (laser eye protectors) [15].

BS EN 208 Personal eye-protection. Eye-protectors for adjustment work on lasers and laser systems (laser adjustment eye-protectors) [48].

PD CLC/TR 50448:2005 Guide to levels of competence required in laser safety [5].

BS EN 11810-1 Lasers and laser related equipment. Test method and classification for the laser resistance of surgical drapes and/or patient protective covers. Primary ignition and penetration [55].

BS EN 11810-2 Lasers and laser related equipment. Test methods and classification for the laser resistance of surgical drapes and/or patient protective covers. Secondary ignition [56].

BS EN 11990 Optics and optical instruments. Lasers and laser related equipment. Determination of laser resistance of tracheal tube shafts [57].

BS EN 14408 Tracheal tubes designed for laser surgery. Requirements for marking and accompanying information [58].

Draft standards (IPL)

IEC 60825-16, Safety of intense light source equipment: Guidelines for the safe use of IPL beams on humans.

IEC 60601-2-57, Medical electrical equipment: part 2-57: particular requirements for the safety and essential performance of therapeutic, diagnostic and cosmetic/aesthetic intense light source equipment.

BS 8497-1, Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications: Part 1: Specification.

BS 8497-2, Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications: Part 2: User Guide.

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Appendix A – Example of local rules for the safe use of lasers, IPL equipment and LEDs

Local rules (or working procedures) should reflect safe working practices and relate to the day-to-day safety management of laser, IPL systems and LEDs.

Local rules (see section 4.1) should be appropriate to the particular type of optical radiation device, the intended application, the hazards and local circumstances.

The local rules should either directly address the issues below or refer, within the local rules, to the supporting documentation:

- Nature of hazard to persons (users and patients)
- Defined region and limits of the equipment Controlled Area
- A register of authorised users
- Contact point for Laser Protection Supervisor and Laser Protection Adviser
- Controlled and safe access to the equipment area
- Authorised Users and associated responsibilities, including any restrictions of use
- Training requirements for persons assisting in or undertaking laser/IPL use
- Personal protective equipment, especially eyewear
- Methods of safe working, including layout of equipment
- Normal operating procedures
- Definition of simple pre-use safety checks and instructions
- Adverse incident and equipment fault procedures and logs
- Management safety structure (e.g. manager, consultant, LPA, LPS and users)

The local rules should be prominently displayed in the laser/IPL room or the theatre office.

All Authorised Users, assisting staff, or other individuals who work in the laser/IPL room should read the local rules then sign the associated form indicating that they have understood them and agree to work to them.

The following example is presented as a **guide to format only**; it is not presented as model rules. Local rules should be appropriate to the particular type of optical radiation device, the intended application, the associated risks and local circumstances.

Local rules for the safe use of laser and IPL equipment

Local rules for the use of the ‘type’ laser (or ‘type’ IPL) in the Eye Department, Hospital ‘name’.

Nature of hazards to persons

The laser can cause injury to the skin and eyes from both the direct and scattered beams. The aiming beam may also be hazardous. Safe use of the laser (or IPL) depends upon strict adherence to the following rules:

Controlled Area designation and access

1. The room in which the laser (or IPL) is used is designated a ‘Controlled Area’ and the laser should only be used in this area. Approved warning signs should be fitted to the door (see Annex 1).

2. A notice should be fixed to the laser (or IPL) indicating that its use is subject to the Local rules (see Annex 2).

Register of Authorised Users

3. A register should be kept of personnel authorised to operate the equipment (see Annex 3).

Laser Protection Supervisor

4. One Authorised User should be nominated Laser Protection Supervisor to ensure that the register is maintained and the local rules are adhered to (Annex 4).

Restriction of use to Authorised Persons

5. The equipment should only be used by an Authorised User.

6. If another person is judged by the Laser Protection Supervisor, in consultation with the Laser Protection Adviser, to be suitable to use the equipment, the name may be added to the register, provided the person has signed a statement that they have read and understood the local rules. A copy of the signed statement should be sent to the Laser Protection Adviser.

7. A copy of the register will be kept with the key and the Laser Protection Supervisor will instruct the key holder to issue the key to the Authorised Users only.

Need for training of all persons

8. Authorised Persons using the laser (or IPL, or LED) or assisting in the procedures should be sufficiently trained in the safe performance of their duties.

Operator responsibility

9. It is the responsibility of the equipment Authorised User to be aware of the nature of the hazard involved and to be familiar with the manufacturer's operating instructions.

10. During the operation of the laser (or IPL or LED) the Authorised User is responsible for the safety of all persons present, including the patient and themselves.

Protective eyewear

11. Protective eyewear should be provided and clearly marked for the laser. It is important that the correct goggles are used e.g. the use of a coloured sticker or other identifier on the goggles matches a similar identifier on the laser of IPL. The Authorised User should instruct all personnel in the Controlled Area to wear goggles suitable for the laser being used, unless they are viewing the treatment site through protective microscope optics.

Methods of safe working

12. Other procedures should not be undertaken in the Controlled Area while the laser is in use. No more than one laser or IPL should be switched on during the 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.

13. When the laser is in operation the number of persons in the room should be kept to a minimum.

14. The laser should not be enabled to fire unless it is directed towards the treatment site or a beam stop.

15. The Authorised User should be careful to avoid reflections of the beam from instruments in close proximity to the beam path and pay particular attention to the possibility of exposure of their own skin. Instruments with diffusely reflecting surfaces should be used when available, rather than those which give rise to specular reflections.

16. The risk of shattering a glass intra-ocular lens implant should be noted.

17. Whenever the device is unattended by an Authorised User, the laser should be switched off and the key withdrawn and placed in safe custody by the Authorised User.

Normal operating procedures

18. The operating procedure detailed in Annex 5 should be observed.

Adverse incident procedures

19. If an actual or suspected incident occurs, an eye examination should be carried out within 24 hours, and the Laser Protection Adviser contacted as soon as possible.

Laser Protection Adviser

20. For further information, please contact the Laser Protection Adviser.

    Laser Protection Adviser:
    Telephone Number (Office):
    Telephone Number (Home):

Application of local rules

21. The laser should only be used in accordance with these local rules.

22. Authorised Persons should sign statements that they have read and understood these local rules.

Annex 1

Signs should be fitted at each entrance to the Controlled Areas:

1. For all optical radiation equipment in use a sign stating:

EYE PROTECTION MUST BE WORN

2. A sign should contain the BS laser symbol and wording:

CONTROLLED AREA
Laser

3. If an illuminated sign is used it should contain wording which is only visible when sign is lit:

CAUTION LASER IN USE

Power to the sign should be provided such that the light is illuminated when the laser is connected to the electrical mains.

When an IPL system is in use a sign should be fitted at each entrance to the Controlled Areas:

4. Sign should contain IPL symbol and wording:

CONTROLLED AREA
Intense pulsed light

5. It may be appropriate to include '**No entry'** signs on doors where unauthorised access could be gained to the IPL/laser room.

Annex 2

Sign to be permanently displayed on laser (and IPL) with the wording:

This device should only be used by an Authorised User in accordance with the approved local rules.

Laser Protection Supervisor is: ……

Annex 3

Register of Authorised Users

'Name' (Laser Protection Supervisor)
'Named persons'
'Name' (Laser Protection Adviser)

Custody of the key
When not in use the key will be kept in the custody of 'named person'. The key will be clearly labelled with the words *LASER – To be used by Authorised User only*.

Annex 4

Responsibilities and duties of Laser Protection Supervisors

1. To ensure that the local rules are adhered to.
2. To inform the Laser Protection Adviser if they consider that the existing rules require amending.
3. To ensure that the register of Authorised Users is maintained and that the correct procedure for authorisation has been undertaken.
4. To obtain written statements from each Authorised User that they have read and understood the local rules and send copies of statements to the Laser Protection Adviser.
5. To ensure that only Authorised Users operate the laser (or IPL).
6. To inform the Laser Protection Adviser as soon as possible in the event of an incident occurring.
7. To seek assistance from the Laser Protection Adviser on the safety implication when a change in operating procedure is envisaged.

Annex 5

Operating procedure
The specific operating procedures to be undertaken with this laser should be described here.

Appendix B – Example of register of Authorised Users

The Authorised User is the individual who operates the laser, IPL system or LEDs. They may be a doctor, dentist, ophthalmology nurse, theatre sister, physiotherapist, beauty therapist or other appropriately trained person. All Authorised Users should be held on the healthcare facilities register of authorised equipment users. Dental practices and beauty salons will also have a register of authorised equipment users. Section 3.6 discusses the role of the Authorised User.

The example below indicates how the register may be set out. It may be appropriate to distinguish in the register between those permitted to use the laser for clinical purposes (healthcare professionals) and those permitted to only use the laser for testing and QA purposes (engineers and others).

Register of Authorised Users

Department: *Ophthalmology*
Room: *Room 2*
Laser Make and Model: *Laser Type II*

The following personnel are authorised by the head of department to operate the *Laser Type II***.**

In signing below, all signatories to this register acknowledge that they have read and understood the relevant local rules and agree to work to them. The signatory acknowledges that they have also received appropriate equipment training.

Name	Designation	Signed	Date
Mr S Surgeon	Head of Ophthalmology	*S Surgeon*	30/09/07
Dr A Laser	Laser Protection Adviser	*A Laser*	30/09/07
Ms LP Supervisor	Laser Protection Supervisor	*LP Supervisor*	30/09/07
Mrs A Nurse1	Ophthalmology Nurse	*A Nurse1*	30/09/07
Mr B Nurse 2	Ophthalmology Nurse	*B Nurse2*	30/09/07
Dr S Registrar 1	Ophthalmology Specialist Doctor	*S Registrar1*	30/09/07
Dr T Registrar 2	Ophthalmology Specialist Doctor	*T Registrar2*	30/09/07
Dr C Scientist 1	Clinical Scientist	*C Scientist1*	30/09/07
Mr S Engineer 1	Laser Service Engineer	*S Engineer1*	30/09/07

Appendix C – Core of Knowledge syllabus

Section 3 of this document details the anticipated minimum competency level of Laser Protection Supervisors and all Authorised Users of laser (Class 3B and 4) and IPL equipment.

In order to achieve the minimum competency level and as part of their initial safety training, staff will need to attend a Core of Knowledge course. This topic is discussed in section 3.8.2.

Ideally the Core of Knowledge course should include practical exercises on undertaking risk assessments, administration of safety and equipment management. The aim of the practical or interactive sessions is to aid and re-enforce learning.

If a Core of Knowledge course is tailored to professionals who work in a medical setting, cosmetic environment, or general healthcare area, the course certificate should clearly indicate which speciality has been covered.

Core of Knowledge requirements

The Core of Knowledge syllabus detailed below (for Class 3R, 3B and 4 lasers, IPL systems and/or LEDs) indicates the minimum course content that may be covered by training centres. Course lectures should total at least 3 hours.

Example of a Core of Knowledge course syllabus

The exact content may differ slightly from the example given, due to the needs of the participants.

- Understand the characteristics of optical radiation emitted from different types of equipment.
- Familiar with the intended purpose of the optical radiation equipment.
- Aware of the meaning of the warning labels associated with optical radiation equipment.
- The effects of exposure and health hazards, including eye, skin and tissue, which can arise from the use of laser, IPL or other optical radiation equipment.
- Equipment related hazards, which can arise from the use of laser, IPL or other optical radiation devices, including equipment malfunctions.
- Management of equipment and the role of personnel, including Controlled Areas and the role of the Laser Protection Adviser and Supervisor.
- The principles and requirements of equipment quality assurance processes and procedures.
- Hazards related to individuals through use of optical radiation equipment, including electrical hazards, fire risks and smoke plume effects.
- Hazards to patients associated with optical radiation treatment procedures and methods of minimising risks.
- Hazard control procedures, including the use of personal protection.

- Hazards from reflections or absorption of the optical radiation beam with respect to instruments or surfaces or other equipment.
- General principles of how to deal with a suspected accidental exposure to optical radiation.
- Aware of the basic principles of the maximum permissible exposure levels and the precautions required to ensure that exposure of unprotected skin and eyes of those present is less than the maximum permissible levels.
- Additional precautions that may be necessary when undertaking non-routine activities with the equipment.
- The safety procedures and policies governing optical radiation equipment use, including the local rules, Controlled Area, emergency action and accident reporting procedures.
- Understand the role of the Laser Protection Advisor and Laser Protection Supervisor.
- Be aware of the relevant legislation and standards that pertain to lasers and IPLs.
- Principles of risk assessment.
- Be familiar with the basic principles of the administration of safety.

Appendix D – Reporting adverse incidents

Reporting to the MHRA

Any incident should be reported to both the LPA and LPS as soon as possible. The local rules should detail the appropriate mechanism for reporting an event.

It is recommended that the event details are accompanied by the signature of the recorder and be counter-signed by the LPS, LPA, or departmental safety manager. The log should also document any post event corrective action.

Prior to reporting the adverse incident to the MHRA or appropriate devolved authority, the LPA and/or healthcare facility may in certain circumstances undertake an initial investigation into the event.

Adverse incidents should be reported at the earliest opportunity, following any local incident reporting policies.

We prefer you to use the online reporting system via our website: **www.mhra.gov.uk** The online reporting system can be used to send e-mail copies of a report to others at the same time as it is submitted to the MHRA.

However, if necessary you can download a form from our website and e-mail or fax it to us: e-mail: aic@mhra.gsi.gov.uk fax: 020 7084 3109

Adverse Incident hotline: 020 7084 3080

Details of reporting adverse incidents are given in the MHRA's first Device Bulletin of the year (for example DB 2008(01) 'Reporting adverse incidents and disseminating medical device alerts'), available on our website www.mhra.gov.uk.

Adverse incident details

- Equipment type and location
- Serial number or batch number
- Power setting of the laser or IPL
- Exposure time duration
- Optical radiation distance between source and target
- Clinical procedure being undertaken
- Details of the event, including contributory factors
- Nature of injury, if applicable
- Names and designations of all staff and other persons involved.

Following the LPA's investigation, corrective action may be initiated or recommendations made to the healthcare facility to prevent recurrence.

All medical device related adverse incidents should be reported to the MHRA. The LPA may also recommend further action, such as informing the Health and Safety Executive (HSE), the National Patient Safety Agency (NPSA), and/or the Healthcare Commission (or relevant devolved body).

Withdrawal of equipment from service

Following the adverse incident, it may be necessary to withdraw the equipment from service. The issue should be discussed with the LPS, LPA and any appropriate manager.

The event and fault should be recorded in the appropriate log book. A warning notice should be attached to the equipment, alerting all personnel to the fault.

Reporting to the devolved administrations

The MHRA works with its respective counterparts in the devolved administrations of Northern Ireland, Scotland and Wales to ensure all adverse events are investigated and where appropriate, initiates corrective action to reduce the risk of recurrence.

Northern Ireland

Adverse events may be reported to the Northern Ireland Adverse Incident Centre. Details of how to report an adverse event may be obtained from their website: www.dhsspsni.gov.uk/niaic

Scotland

Details of how to report an event to the investigation centre in Scotland may be obtained from the Scottish Healthcare Supplies website: www.show.scot.nhs.uk/shs/hazards_safety/hazardsp3.htm

Wales

Currently all hazardous medical device related incidents occurring in Wales are to be reported directly to the MHRA with a copy of the report being sent to the Surgical Material Testing Laboratory (SMTL). The MHRA will undertake all necessary adverse event investigations and advise the Welsh Assembly Executive where appropriate. All non-hazardous reports/defects should be reported directly to SMTL. Details of how to report an adverse event may be obtained from the Welsh Assembly website: www.wales.gov.uk

Health and Safety Executive (HSE) incident reporting

The Health and Safety Commission is responsible for health and safety regulation in the UK. The Health and Safety Executive and local government are the enforcing authorities who work in support of the Health and Safety Commission.

The HSE requires certain injuries arising from incidents at work to be reported to them:

- temporary or permanent loss of sight
- electrical shock leading to unconsciousness
- injury requiring hospitalisation for more than 24 hours.

A full list of the type of injury that is reportable to the HSE may be found in: The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1995 [51]. Section 10 of this guidance provides further details of RIDDOR.

NPSA incident reporting

The National Patient Safety Agency's Reporting and Learning System has been implemented nationally across the NHS. This system allows the reporting of all mistakes, errors and near misses, with the aim of ensuring that lessons are both learned and shared throughout the health service. Although incidents and learning, involving the use of a medical devices are reported to the NPSA they are shared with the MHRA. The confidential reporting allowed under the NPSA system prevents the MHRA from investigating those incidents in full. The NPSA actively encourages reporting of all medical device failures directly to the MHRA.

Details of how to report an incident to the NPSA may be found on their website: www.npsa.nhs.uk/health/

Healthcare Commission and the devolved administrations

England and the devolved authorities each have their own independent inspection bodies for the NHS and independent healthcare establishments. The regulations that each of the inspection bodies adhere to will be different in terms of scope and detail. Information on the individual regulations may be obtained from the respective devolved authority organisations.

Each organisation has inspectors who routinely assess private healthcare establishments. The inspectors will review safety and treatment procedures, assess equipment modifications and review fault and incident logs.

Healthcare Commission

The Healthcare Commission's role is to promote improvement in the quality of NHS and independent healthcare across England. Information on the Healthcare Commission may be found on their website: www.healthcarecommission.org.uk

Healthcare Inspectorate

The Healthcare Inspectorate is a division of the National Assembly for Wales. The Healthcare Inspectorate is responsible for inspecting and investigating the provision of healthcare by and for Welsh NHS bodies. The Inspectorate also regulates all Independent Healthcare in Wales. Information on the Healthcare Inspectorate may be found on their website: www.hiw.org.uk

NHS Quality Improvement Scotland

The role of NHS Quality Improvement Scotland (NHS QIS) is to lead on improving quality of care and treatment delivered by the health service. NHS QIS is a special health board and is responsible for improving patient care across NHS Scotland. Information on NHS QIS may be found on their website: www.nhshealthquality.org/

Care Commission

The Care Commission regulates all independent healthcare in Scotland. Information on the work of the Commission may be found on their website: www.carecommission.com

The Regulation and Quality Improvement Authority

The Regulation and Quality Improvement Authority (RQIA) is the independent health and social care regulatory body for Northern Ireland, and forms an integral part of the new health and social care structures. In its work RQIA encourages continuous

improvement in the quality of these services through a programme of inspections and reviews. Information on the RQIA may be found on their website: www.rqia.org.uk

Northern Ireland Social Care Council

Northern Ireland Social Care Council is the regulatory body for the social care workforce in Northern Ireland. Information on the Northern Ireland Social Care Council may be found on their website: www.niscc.info

Appendix E – Laser equipment features and terminology

Aiming beam
An aiming beam may be used with an articulated arm or other type of delivery system, where the treatment laser emits optical radiation at invisible wavelengths. The aiming beam indicates the intended spot where the treatment beam should be directed.

The aiming beam should be concentric with the therapeutic beam; ideally the centre of both beams should lie on the same spot. The maximum allowable lateral displacement between the two centres should not exceed 50% of the diameter of the larger of the two spots. Additionally, the aiming beam spot diameter should not exceed 1.5 times the therapeutic beam's diameter.

Due to concern over the blue light component of the ophthalmic argon laser aiming beam, the fitting of a 'green only' filter to the aiming beam should be considered in systems which use an attenuated portion of the main argon beam as an aiming beam.

Some systems have a separate aiming beam. It should not be possible to operate the treatment laser without the aiming beam first being present.

Failure of the aiming beam during the treatment laser's operation should prevent further output of the treatment laser after the current exposure.

Aperture
The aperture is the optical system exit window through which optical radiation passes.

Aversion response
An aversion response, may include closure of the eyelid, eye movement, papillary constriction, or movement of the head to avoid exposure to a harmful stimulant

Beam stop (shutter)
Laser devices should be equipped with this safety mechanism. The beam stop or shutter allows or prevents optical radiation being emitted from the aperture.

The beam stop or shutter may be electronic, opto-electronic or mechanical. The actual position of the beam stop or shutter should be monitored during use, rather than the position of the actuating mechanism.

If the beam stop or shutter fails during use, the laser should not be used until the failure is rectified.

Beam transmission systems
Where a laser employs an external beam transmission system, such as an articulated arm or optical fibre, and on disconnection the AEL for Class 3R is exceeded, the connection should be interlocked to prevent laser emission or disconnection should require the use of a tool

The safety interlocking of interchangeable applicators is desirable in order to minimise the risk of accidental exposure.

Electrical safety
Electrical safety checks should be carried out on a planned and regular basis according to the documented procedure. If such electrical safety checks are undertaken by the healthcare establishment; this should be undertaken with the agreement of the manufacturer and should take into account all relevant reference material, including the manufacturer's instructions and relevant electrical safety tests.

Emergency stop
The emergency stop button is generally located on the front of the laser control panel, so that it can be activated to shut the system down should an emergency arise. The button should be labelled.

The emergency button must be red and must be located in a prominent and accessible place on the laser system. The emergency stop button should be periodically tested.

Emission control switch
The laser emission control switch, which may be finger or foot activated is intended to initiate and terminate the treatment beam.

Emission indicator
The laser emission indicator should be a visual and/or audible signal which will alert all personnel in the vicinity that the treatment beam is being emitted through the aperture.

An emission alert mechanism is required for all lasers classified as 3R, 3B or 4. For Continuous wave or repetitively pulsed lasers emitting non-visible radiation systems an audible warning should be provided.

Enable switch
Lasers that are classified as 3R, 3B or 4 may incorporate a hardware switch, which has to be depressed in order to put the laser into 'ready to fire' state. Releasing this control or reactivating it should immediately terminate the main laser output. Some systems have a software controlled enable switch.

Exposure termination system
In lasers that are classified as 3R, 3B and 4 an exposure termination system should be incorporated into the system. The exposure termination system may be an electronic timer, pulse counter or energy monitor. There should be some means of ensuring its correct operation. A test mechanism should be incorporated into the pre-procedure system safety checks.

Possible examples are fail-safe monitoring of components or an independent backup timer.

Footswitch
The footswitch is used to initiate beam delivery to the treatment area while leaving the Authorised User's hands free. All foot operated exposure control switches should be shrouded to prevent accidental operation. However this does not apply to foot operated emergency shut-off switches

Footswitches should be waterproof and comply with the requirements of BS 60601-2-22: Medical electrical equipment Part 2: Particular requirements for the safety of

diagnostic and therapeutic laser equipment. The footswitch should be checked prior to clinical use for correct operation. As part of a planned quality assurance programme the footswitch should be assessed for signs of wear and tear. The footswitch cable should similarly be checked.

Hand-switch
The hand-switch is used to initiate beam delivery to the treatment area. The hand-switch should comply with the requirements of BS 60601-2-22: Medical electrical equipment Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment.

The hand-switch should be checked prior to clinical use for correct operation. As part of a planned quality assurance programme the hand-switch switch should be assessed for signs of wear and tear. The hand-switch cable and connector should similarly be checked.

Key control
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 key.

If the latter is used, the key should be removable to a safe store at the end of the working day, or if appropriate the end of the session. The laser should not be operable when the key has been removed.

Labelling
All lasers must carry labels indicating: the laser classification; the precautions required; the maximum laser output; the wavelength of the radiation; and warnings of invisible radiation (if appropriate). The labels should be accessible and easy to read i.e. not stuck on the back of the laser.

Class 3R, 3B and 4 lasers should have an aperture label indicating the output aperture.

The standards document BS EN 60825-1:2007 Safety of laser products. Equipment classification and requirements [13] provides examples of the label descriptions for each Laser Classification.

Laser ready indicator
The ready indicator shows that the laser is in a state where a treatment beam can be produced. This should be clearly visible.

Any visible warning device should be clearly identifiable through protective eyewear.

Output measuring system
All Class 3R, 3B and 4 lasers which are intended for the irradiation of the human body should incorporate a means for monitoring the output power or energy of the optical radiation being emitted.

Protective filters
A protective filter is either a movable or fixed device which is used to protect the Authorised User's sight when they are using optical viewing instruments, such as a slit lamp or endoscope.

They should be interlocked such that failure in their operating system (manual or automatic) will prevent laser emission.

Stand-by
The stand-by condition is when the laser is connected to the mains power supply and the mains switch has been activated into the on position.

The laser is not capable of emitting any optical radiation, even if the laser emission control switch is depressed.

Target indicating device
The target indicating device is an aiming system which indicates the position of the treatment beam.

Class 3B and 4 lasers should incorporate a target indicating or aiming device unless the output aperture of the beam transmission is intended to be in contact (or virtually so) with the treatment area. This may take the form of an attenuation of the main laser beam (where visible laser beams are employed), a separate Class 1 or Class 2 laser, or non-collimated light source.

Lasers should not be operated if any target indicating or aiming device is faulty (e.g. aiming system misaligned or aiming beam not present). The alignment between the main laser beam and any aiming system must be checked prior to use.

Appendix F – IPL equipment features and terminology

Beam delivery system
Beam delivered is via the hand-piece. Typically the components of the IPL system will comprise a main unit and a hand-piece. The hand-piece comprises a flashlamp, filter and a lens, or waveguide.

Other IPL beam delivery systems may include optical fibres, micromanipulators and scanning devices.

Electrical safety
Electrical safety checks must be carried out on a planned and regular basis according to the documented procedure. If electrical safety checks are undertaken by the healthcare establishment this should be done with the agreement of the manufacturer and must take into account all relevant reference material, including the manufacturer's testing instructions and relevant electrical safety procedures.

Emergency stop
The emergency stop button is generally located on the front of the IPL control panel so that it can be enabled to shut the system down should an emergency arise. The button should be labelled 'emergency stop'.

The emergency button must be red and must be located in a prominent and accessible place on the IPL system. The emergency stop button should be periodically tested.

Emission control switch
The IPL emission control switch, which may be finger or foot activated, is intended to initiate and terminate the treatment beam.

Emission indicator
The IPL emission indicator should be a visual and/or audible signal, which will alert all personnel in the vicinity that the treatment beam is being emitted through the aperture.

Enable switch
IPL systems may incorporate a switch which has to be depressed in order to put the device into the 'ready to fire' state. Releasing this control or reactivating it should immediately terminate the IPL output.

Exposure termination system
An IPL exposure termination system should be incorporated into the system. The exposure termination system may be an electronic timer, pulse counter or energy monitor. There should be some means of ensuring its correct operation. A test mechanism should be incorporated into the pre-procedure system safety checks.

Possible examples are fail-safe monitoring of components or an independent backup timer.

Key control
The IPL system should incorporate a key-operated master control. The ‘key’ may be a software password incorporated into the IPL’s operating system or may be an actual key.

If the latter is used, the key should be removable at the end of the working day or when appropriate. The IPL should not be operable when the key has been removed.

IPL ready indicator
The IPL Ready Indicator is the condition where the optical radiation beam is ready to be exposed.

Any visible warning device should be clearly identifiable through protective eyewear specifically designed for the wavelength(s) of the emitted optical radiation.

Output measuring system
IPL systems should incorporate a means for monitoring the output power or energy of the optical radiation being emitted. This enables the user to ensure that the output is equal to the set value within allowable tolerances.

Pulse duration
The light is delivered in pulses. The width of the pulse or the lengths of time light pulses are emitted are important factors in the delivery mechanism.

Stand-by
The stand-by condition is when the IPL is connected to the mains power supply and the mains switch has been activated into the on position.

The IPL is not capable of emitting any optical radiation, even if the emission control switch is depressed.

The stand-by condition should not be confused with the IPL ready indicator.

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