Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Lasers, intense light source systems and LEDs – guidance for safe use in medical, surgical, dental and aesthetic practices

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Contents

Acknowledgements

Mr D Ferguson, Scottish Healthcare Supplies, NSS
Dr I Gillan, Northern Ireland Medical Physics Group
Dr A Manivannan, Aberdeen University and Grampian University Hospitals
Mr M Mayo, Derriford Hospital, Plymouth
Dr J O'Hagan, PHE
Dr S Parker, Dental Practitioner
Stephen Hanna, Northern Ireland DHSS&PH
Stuart Conney, DH Health Protection
Josette Galligan, St James' Hospital Dublin
Chris Edwards, Aneurin Bevan University Healthboard, Newport, South Wales
Tom Lister, Salisbury NHS Foundation Trust
Philip Loan, Northern Ireland Regional Medical Physics Services
Elizabeth Chaloner, IPEM UNIRSIG
Matt Williamson, Leeds Teaching hospital
Valerie Field, Catriona Blake, David Grainger, MHRA
Matthew Thomas, Healthcare Inspectorate, Wales
Raj Bunger, Society of Radiation Protection
Stan Batchelor and Julie Robinson, Guys and St Thomas's NHS Foundation Trust
Andy Bradley, Central Manchester University Hospitals
Sally Taber, Treatments You Can Trust

Authors: Mel King and Andy Marsden, MHRA

This document replaces DB2008(03) 'Guidance on the safe use of lasers, intense light source systems and LEDs in medical, surgical, dental and aesthetic practices'.

Revision history

Version	Date published	Changes
V1.0	September 2015	Minor text changes from DB2008(03). Update to list of standards and references.

1 Introduction

The Medicines and Healthcare products Regulatory Agency is the executive agency of the Department of Health that regulates medical devices and medicines in the UK.

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.

It includes equipment used in conjunction with the optical radiation equipment, such as optical fibres, contact tips, articulated arms etc. It excludes non-laser, non-IPL and UV treatment sources.

This edition reflects the changes in equipment technology and safety standards that have been made since the last version of this guidance. It updates and replaces DB 2008(03) 'Guidance on the safe use of lasers, intense light source systems and LEDs in medical, surgical, dental and aesthetic practices'.

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 laser systems, IPL equipment and LEDs.

This is a guidance document and so has no 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 people may find this guidance useful:

- healthcare professionals including doctors, surgeons, nurses and dentists registered to provide treatments using class 3B or 4 lasers, IPL and LEDs
- beauty therapists in clinics or salons that provide treatments using class 3B or 4 lasers, or IPL
- beauty therapists working with mobile laser and IPL services, in various locations in the UK
- clinical scientists, engineers and other healthcare professionals, including laser protection advisers and supervisors
- tattoo artists or assistants who use a laser to remove tattoos
- environmental health officers (EHOs) and other regulators who visit establishments where class 3B or 4 lasers or IPL / LED systems are being used for medical, dental or aesthetic purposes.

1.3 Formatting

⚠ Cautions are formatted like this.

✓ The MHRA's recommendations are formatted like this.

2 Nature of hazards

The optical radiation emitted by lasers, IPLs and LEDs has the potential to damage the eyes and skin of patients, clients and equipment users. There is also a 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.

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 and skin
Both are susceptible to damage from optical radiation i.e. burns. 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. This may require risk assessment. Section 8 has details of how optical radiation affects tissue and skin.

Fire hazard
Mechanical and administrative means of reducing risks of fire are usually adequate. However, class 4 lasers are potentially a fire hazard in certain clinical situations. Protective clothing may be necessary which must be flame or heat resistant. 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 irritate the airways and cause 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. Check fibres for damage and ensure the correct position, before beam delivery. Check the optical fibre and delivery device (i.e. handpiece) connectors for correct closure before using the laser. Record these checks to the fibre.

Eye injury

Treatments to the face pose a particular risk to patients' eyes due to the proximity of the direct beam and scattered light. Furthermore, an anaesthetised patient is particularly at risk because they can't react to any stimulus; it is therefore essential to suitably protect the patient's eyes in such circumstances.

Skin burn from damaged external filter (IPL)

Scratches on the external filter can cause a photochemical effect or burn on a patient/client's tissue or skin following an IPL treatment. This is because 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 developing on the filter 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.

Be careful when using optical fibres 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 that aren't laser safe, patient hair and clothing may be ignited by accidental exposure to laser/light energy.

Use laser-safe endotracheal tubes and laser-safe surgical drapes where possible.

It's useful to have a container of sterile water nearby to extinguish small non-equipment fires.

Risk of mistreatment

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

The aiming beam and the treatment beam follow the same path through the fibre. Inspect the quality of the aiming beam at the tip of the fibre by directing the aiming beam at a suitable non-reflective surface, clearly showing the aiming spot.

Many lasers incorporate a power meter at the user interface, allowing the output from the handpiece or disposable fibre to be verified before treatment.

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 4.1) should take into account the 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 can damage eyes and skin. Exposure can come from misdirected or unintentionally reflected beams, or from beams that escape from the protective housing. Wear appropriate eye protection if indicated by the risk assessment and agreed by the LPA.

Risk of fire

All surgical instruments, tubing and other associated equipment that are used close to the laser beam should be protected or be made of a suitable fire resistant material.

Laser plume emissions

These may pose a health risk to the surgeon and theatre staff.

You might need an evacuation system.

Section 5.13 contains more details on smoke plume emissions.

Unexpected adverse events

Do not have more than one laser or IPL switched on during a treatment session.

Switch off the laser or IPL before using a different optical radiation device.

This good working practice reduces 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 and implemented, as part of local management procedures. The employer may delegate the task(s), but they should not delegate their legal responsibility for ensuring all tasks are undertaken.

Effective instruction, training, maintenance 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, trust board or health authority, or 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 would define the aims of the senior management and should reflect the management's commitment to maintaining high standards of safety. The document should summarise the principal safety approaches.

It is important to tie the optical radiation safety policy 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, or health and safety committee.

Optical radiation safety policy
Although not mandatory, a healthcare establishment may wish to incorporate optical radiation safety into a specific policy, rather than being included in the radiation protection policy.

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 adviser' 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 the employer and have direct access to them. 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 an LPA for class 3B and class 4 lasers or IPL systems.

If you work in the NHS or private sector you might have to appoint or consult an LPA if your establishment uses:

- certain class 1 laser products that contain an embedded class 3B or class 4 laser which produces accessible emissions under certain conditions of use (e.g. servicing)
- an invisible-beam class 3R laser
- 1M or class 2M lasers which generate a well-collimated beam. The beam may present a hazard, if viewed through optical instruments.

For the private healthcare sector (hospitals, clinics and salons) there is specific guidance for the consultation or appointment of an LPA for each country in the UK:

England
MHRA considers that it is good practice to consult an LPA where class 3B or class 4 lasers and/or IPL systems are operated. However, this is currently not a mandatory

requirement for all areas of England. Some English local authorities require private healthcare establishments to consult with an LPA where class 3B or class 4 lasers and/or IPL systems are operated. Information on the requirements for each region should be obtained from an individual local authority (either licensing department or environmental health department).

Northern Ireland

The Independent Health Care Regulations (Northern Ireland) 2005, which are enforced by the Regulation & Quality Improvement Authority, require the appointment of a certified LPA by private healthcare establishments which use class 3B or class 4 lasers and/or IPL systems.

Scotland

Under the provisions of the National Care Standards (Scotland) all private hospitals should consult with an LPA where class 3B or class 4 lasers and/or IPL systems are used. Social Care and Social Improvement Scotland has responsibility for all private hospitals.

There is no mandatory requirement for private salons and clinics to consult an LPA but it is considered good practice for those establishments to do so where a class 3B, class 4 lasers and/or IPL systems is used.

Wales

The National Minimum Standards for Independent Health Care Services in Wales (2011) specify that in private healthcare establishments a certificated laser protection adviser (LPA) is appointed to provide advice on the safety of the laser installation and operational use.

3.3.1 LPA competency

There are no defined criteria for LPA competence. However, in addition to the guidance in this document there are two other sources of information:

- Technical report PD CLC/TR 50448 Guide to levels of competence required in laser safety [4]
- RPA 2000 LPA certification scheme for laser protection advisers [5]

It is for the employer to judge what level of competency they require for an LPA. In order to ensure competency the prospective employer may also wish to review a candidate's references or LPA certificate if they are certificated (see section 3.3.2).

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. from ionising radiation).

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 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.

- Planning advice for new or refurbished laser and IPL rooms.
- Undertake risk assessments before the laser or IPL is operated.

- Identification of the laser controlled area.
- Provide advice on the level of protection and specification of what eyewear to provide or buy.
- Oversee the commissioning* of the laser or IPL i.e. post-installation and acceptance testing.
- Ensure appropriate safety training of relevant personnel.
- 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.

3.3.2 LPA certification

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

It is good practice for all private healthcare establishments and cosmetic clinics in England operating class 3B or 4 lasers and/or IPL systems to have access to safety advice from a certificated laser protection adviser; for some English local authorities this is a mandatory requirement.

In Scotland, Northern Ireland and Wales there are responsibilities for private healthcare establishments to consult or appoint a certificated LPA.

There are a number of organisations which run laser protection adviser certification schemes. The overall level of competence that is required in each of the schemes is broadly similar.

The following organisations run LPA certification schemes but it is not an exhaustive list. The MHRA does not endorse any of the schemes detailed.

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.

There is more information on this website: http://www.laserprotectionadviser.com/

RPA 2000 runs schemes to assess competency in ionising and non-ionising radiation protection practice. 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.

Due to the different regulatory frameworks, RPA 2000 awards LPA certificates for different applications:

- medical
- industry
- telecommunications
- entertainment
- research and teaching
- defence

Under RPA 2000 an individual who is working as a laser protection adviser is certificated for 5 years. At the end of this time period, they should seek re-certification from the awarding authority. Information on the scheme is on the website: http://www.rpa2000.org.uk/about-rpa-2000/

3.4 Laser safety officer

The role of the laser safety officer (LSO) is defined in the 2005 guidance document PD CLC/TR 50448 Guide to levels of competence required in laser safety [4].

The roles and responsibilities of an LSO are similar to those of a laser protection supervisor. However, depending on the requirements of the employer there may be some overlap in their duties with an LPA. The additional appointment of an LPA would likely reduce the level of detailed knowledge that the LSO needs to have.

The standard BS EN 60825-1 [6], recommends that ‘for installations where class 3B or 4 lasers are operated, a laser safety officer should be appointed’. The recommendation in BS EN 60825-1 does not make the appointment of an LSO a legal requirement, the Management of Health and Safety at Work Regulations [3] require employers to actively address safety matters, including laser safety.

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) or LSO 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 4.2) 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.

Note: Some healthcare establishments may use the term LSO instead of LPS. The roles and responsibilities outlined in this section are applicable to both LSO and LPS.

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.

As part of their role the LPS is expected to liaise with the LPA, equipment users and others.

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

The individual needs 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 having a certificate of attendance of an appropriate safety course.

LPS deputy

When the LPS is away, there needs to be an appointed deputy.
The LPA, in conjunction with the employer and LPS, should agree who this is.

LPS role
In some healthcare establishments the LPS’s role may be divided into 2 – 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. The title ‘operational laser protection supervisor’ may vary in different healthcare environments but the role will broadly be as described below.

Operational LPS role
The operational LPS would directly supervise all optical radiation protection on a day-to-day basis and make sure the local rules are followed. They would also ensure that other members of staff who work within the device’s controlled area are familiar with the local rules.

The operational LPS would 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 would be expected to maintain a register of approved laser and IPL authorised staff (authorised users). However, the employer should decide whether to add a person's name to the register, 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 / lead laser clinician / clinical laser protection supervisor would work in an advisory capacity. They would generally be the lead clinician (senior consultant), who is associated with the laser or IPL. The clinical laser expert / lead laser clinician / clinical LPS would be expected to work with the operational LPS. The title 'clinical laser expert' may vary in different healthcare environments but the role will broadly be as described below.

Clinical LPS role
The role of the clinical expert/LPS would relate to making clinical assessments of the suitability of junior clinicians or other authorised users who are to use the equipment for a particular procedure.

Note: The appointment of an individual who is acting as a lead laser clinician or as a clinical laser expert or solely as a clinical LPS may **not** be appropriate for every healthcare establishment.

3.5.3 LPS competency

PD CLC/TR 50448 'Guide to levels of competence required in laser safety' [4], 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 competencies and knowledge for a laser protection supervisor are:

- 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.
- Ensure quality assurance tests are performed (see section 6.5).
- 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.
- In conjunction with the LPA draft appropriate safe working procedures, including local rules (see section 4.2 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
The healthcare establishment should have a register of authorised users of class 3B or 4 lasers and IPL systems. An example of a register of authorised users is provided in Appendix B.

Authorised user equipment usage
The employer may specify which lasers or IPL systems the user is allowed to use or which procedures they can undertake.

3.6.1 Authorised user competency

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

They should also have attended an appropriate safety course, e.g. 'core of knowledge' (see section 3.9).

The authorised user must be knowledgeable in how to operate the particular device and how the controls will affect the treatment.

An authorised user should:

- 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 the safety precautions required when using optical radiation devices

- be familiar with hazard control procedures
- be aware of additional precautions that may be necessary when undertaking non-routine activities with the equipment
- be familiar with the optical radiation local rules (section 4.2)
- be familiar with the content of contingency plans within the local rules and other related emergency procedures.

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

3.7 Assisting staff

There will be times when the authorised user needs help from assisting staff (authorised laser assistants) during a laser/IPL procedure.

Assisting staff role

Assisting staff need to be trained to use the equipment that they will help with.

They will need to follow the appropriate safety measures, including the local rules.

The LPS or LPA will authorise the assisting staff.

Training for assisting staff will depend on their role. They might need to know:

- what the optical radiation equipment is for
- the meaning of the labels on the equipment
- the health hazards of the equipment, including effects on tissue
- the procedures to control the hazards
- the optical radiation local rules (section 4.2)
- contingency plans within the local rules and other related emergency procedures
- quality assurance tests (section 6.5).

3.8 Other healthcare staff

There may be occasions when a member of staff is present within the controlled area, but they may not be operating or assisting in the operation of optical radiation equipment. The LPS and/or LPA should ensure that these staff members are aware of optical radiation hazards and risks, and have a basic laser and/or IPL safety training.

Other healthcare staff

Basic laser and/or IPL safety training should be provided to all healthcare professionals who are present in a controlled area, even though they do not operate or assist with the optical radiation equipment. The staff should keep to all appropriate safety measures, including the local rules.

3.9 Training

In general staff training will cover 3 areas: equipment-based training, safety training and procedural training. However, depending on their role assisting staff should have at least 2 of the training levels: equipment-based training and safety training.

All staff should have the appropriate competency training to undertake their role. The employer should keep training records.

3.9.1 Equipment training

The manufacturer or their supplier usually provides the equipment-based training to the authorised user(s) at the time of installation. After this, 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.

3.9.2 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.

The core of knowledge course content may be tailored to suit the needs of the different staff groups and environments. Core of knowledge courses may also be specifically related to cosmetic or medical applications. However, in general they are broad-based courses.

In the UK, a number of organisations, including some local radiation physics departments, run core of knowledge courses on laser, IPL and optical radiation safety and applications.

There is no statutory approvals body for core of knowledge courses but there are organisations and professional bodies that have ‘approved’ courses. It is expected that the core of knowledge course follows, or is similar in terms of outcomes and participant understanding to, the content detailed in Appendix C.
The core of knowledge courses should be delivered by persons who have a high level of knowledge and understanding of different optical radiation devices systems, optical radiation safety and the risks and hazards associated to the equipment, for example a certified LPA.

Core of knowledge course
The course should have a specific, predetermined content, which includes optical radiation hazards and risk management.

An example of the course content is given in Appendix C.

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

3.9.3 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.

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

4 Safety administration

4.1 Risk assessment

The identification and categorisation of 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. Risk assessment is a tool for assessing the effectiveness of existing controls and helps identify shortfalls that need further control.

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

Five steps to risk assessment
The Health and Safety Executive (HSE) has developed 5 steps to risk assessment (http://www.hse.gov.uk/risk/fivesteps.htm). These steps are:

1 identify the hazards
2 decide who may be harmed and how
3 evaluate the risks and decide on precautions
4 record your findings and implement them
5 review your assessment and update if necessary.

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

The risk assessment should include determining the hazards associated with these 4 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.

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.

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

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 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 routinely to assess the effectiveness of the control measures in place.

Risk assessment review

The LPS should review the risk assessment every year or earlier if there are any changes that affect the operating environment.

The LPA should undertake a risk assessment audit to review and re-assess the hazards at least every 2 years or earlier if any changes in procedures or equipment are introduced.

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

4.2.1 Laser and IPL local rules

The local rules should be specific to each optical radiation device and the clinical application. Consider 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 and clients 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 follow the local rules.

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

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.

4.2.2 Local rules – what to include

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 controlled area
- nature of hazard to persons (users and patients)
- controlled and safe access to the treatment area
- training requirements for persons assisting in or undertaking laser/IPL use
- authorised 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, including an explanatory grab pack (to accompany the injured to A&E or eye clinic)
- use of loan or demonstration equipment
- temporary staff
- visiting engineers.

Appendix A has an example of local rules.

Any revised document should have on it the date when it was reviewed, the name of the person who revised it and the new version number. Older versions of the document should be removed from circulation.

4.3 Health surveillance

If there is a risk of adverse effect to an employee's eyes and skin as a result of exposure from a laser, IPL or LED, the employer must conduct health effect risk assessments of their staff. The risk of any adverse health effect must be documented in the risk assessments.

If any members of staff are identified as at risk of an adverse health effect, the employer must ensure access to medical examinations, and health surveillance. A suitably qualified doctor or occupational health professional must undertake the health surveillance. All findings from medical examination must be documented and recommendations acted upon if required.

Regulation 6 of The Control of Artificial Optical Radiation at Work Regulations 2010 (AOR) [7] details fully the employer's responsibility regarding health surveillance.

Regulation 3(5) c and d specifically highlights the requirements that the employer must undertake if any staff are identified as being particularly at risk from optical radiation exposure, or who are photosensitive. All health effect risks must be documented in the risk assessments, and, if required, actions taken to eliminate or reduce risks to staff.

4.4 Ophthalmic surveillance

Ocular adverse incident

If there is a suspected or actual eye injury, report it to both the employer and LPA. An ophthalmologist should then check the eye(s) within 24 hours of the event, to identify the extent of the injury.

Note that some retinal injuries may be incorrectly attributed to damage from optical radiation treatment [8].

There are requirements under The Control of Artificial Optical Radiation at Work Regulations 2010 (Regulation 3) [7] to conduct assessment of the risk of adverse health effects to an employee's eyes from workplace exposure to artificial optical radiation.

PD IEC TR 60825-14 [9] includes a number of recommendations regarding ophthalmic surveillance of laser or IPL workers including this statement:

> '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.'

4.5 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.

Taking equipment out of service

Following the adverse incident, discuss with the LPS, LPA and any appropriate manager whether the equipment needs to be taken out of service.

Record the event and fault in the appropriate log book.

Attach a warning notice 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:

1 equipment/engineering
2 administration
3 personal.

1 Equipment/engineering
Establish these controls first. They will include: device interlocks, enclosed light sources, room interlocks (if appropriate), warning lights, barriers and laser-proof blinds etc.

2 Administration
Use of local rules, operating procedures, designated controlled 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.

3 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
Review safety measures every year or earlier if there is any change that affects the operating environment. The LPS should include this as part of the risk assessment review 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 working hours; 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 4.1).

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). If appropriate, spare PPE should be kept outside the controlled area for emergency purposes.

Controlling access

A number of methods can be used to control access when the laser or IPL is in use. Use the mechanism most suitable to your workplace. 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 to the eye or skin that is generally considered safe and is a term specific to laser use.
The more general term ‘exposure limit value’ (ELV) is used in the Control of Artificial Optical Radiation at Work Regulations and has the same meaning as MPE. The Regulations refer to the ELVs in the Artificial Optical Radiation Directive [10].

MPEs 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 to 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, separating those exposure levels that are hazardous from those which, in normal circumstances, won’t harm people.

MPE calculations

Details of the method of calculation and recommendations for MPE levels are given in PD IEC TR 60825-14: Safety of laser products: a user’s guide [9]. 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 before the installation of the equipment, as part of the preparatory risk assessment by the laser protection adviser. The MPE is also sometimes specified by the manufacturer in the equipment manual or instructions for use (IFU).

When a laser or LED emits optical radiation as a series of pulses or in several spectral regions, or where pulses are superimposed on 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 treatment 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. Be aware that adding components to the laser beam delivery system may alter the NOHD, such as handpieces with different focal lengths and spot sizes.

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.

Measures 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, so that the laser can be used uninterrupted and without risk to staff. In the case of an emergency there should also be a means of unlocking doors from outside the theatre.

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 affect certain treatments. If door interlocks are used with doors that have an automatic opening door (AOD) function, then the AOD function must be disabled before locking the doors.

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 comply with the Health and Safety (Safety Signs and Signals) Regulations 1996 [11] and relevant standards such as BS EN 60825-1 [6]

If identified in the risk assessment, signs stating 'Eye protection must be worn' should be placed at the entrance(s) to each laser/IPL room with details of the correct type of eyewear to be worn. It may be appropriate to include 'No entry' and/or 'Laser in use' signs on certain doors, dependent on the restriction of access required, to the laser/IPL room. We recommended discussing signage 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 before entering the room personnel know what type of eye protection to use.

In some departments illuminated warning signs are used. They should be at the entrance(s) to the room containing the laser and ideally placed at eye level.

Removal of warning signs

Signs should only be displayed or illuminated during the laser/IPL procedure. Wherever possible the warning signs should be either removed, or reversed or switched off at the end of the 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 and 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, monitors, mirrors, 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, before introducing personal protective measures. A risk assessment should then be conducted to consider when it is appropriate for eye protection to be used.

Seek the LPA's advice on what protective eyewear to use.

Protective eyewear is 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 [12] 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 before personnel enter the room.

Eye protection risk assessment

The risk assessment should consider the need for eye protection and reasons why it should be used.

Points to consider:
- the likelihood that the eyes will be exposed to optical radiation levels above the MPE
- whether there are practical alternative options, through working practices, to provide protection
- visibility and colour perception issues.

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

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 fit over an individual's glasses
- filters must not be cracked or have scratches
- have a CE marking, indicating compliance to the Personal Protective Equipment Regulations [12] and BS EN 207: compliant laser safety eyewear [13].

Eyewear cautions

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

Class 1 lasers, 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 before 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. An inventory of eyewear should be maintained.

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. The consistency of the labelling within the organisation must be considered by the LPA. 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. Manufacturers' guidelines must be strictly followed, as incorrect methods using harsh chemicals can damage delicate coatings and compromise their effectiveness. If in doubt, ask the LPA.

Wear and degradation

Routinely check all eye protectors before use for signs of wear and tear, especially for any damage to the filters or frames. It is important to keep a record of these checks. They should be stored in individual cases to avoid damage, as they are delicate and often expensive

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, dual wavelength laser devices, or laser and IPL combination systems are used, different eye protection may be required. Users will need to be clear about which eye protectors are to be worn for each device or 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 you wear these, make sure 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 employ viewing optics e.g. eyepiece, loupes. On these occasions it might not be possible to wear the protective eyewear. Seek the LPA's advice 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.

5.10 Hand and clothing protection

If the laser or IPL user will wear surgical gloves for infection control, then they must also be suitable regarding PPE requirements.

Special clothing, including gloves may need to be worn if personnel need to have their hands close to the laser beam. The gloves need to allow 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. Seek the LPA's advice

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.

The Emergency Care Research Institute (ECRI) has produced a fire prevention guide [14] 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.

Higher powered laser beams are more likely to cause a fire. However, if a lower class laser has a focused beam, there is also a potential for a 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.

Allow flammable liquid preparations (for skin), oil based lubricants and volatile organic chemicals to dry completely and mop up any pooled liquid before starting the procedure.

Make sure that flammable liquids don't wick into any material around the operating site.

Other fire hazards: intestinal gases, tracheal tube emissions and anaesthetic gases.

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. Consider using active gas scavenging of the space beneath the drapes.

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 the laser protection adviser and fire officer, in conjunction with the LPS and authorised user(s) should review all risks. A contingency plan should be drafted with details of what to do in the event of a fire.

Key areas for preventing fires

Laser equipment

- Never leave the optical fibre or tip on top of the drapes when it is not in active use. The tip will remain hot for some time after firing.
- Activate the optical fibre's output (ready mode) 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 (standby mode) before removing it from the surgical site.
- Users should be aware of the leakage hazard of toxic material (laser dye) or 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.
- Only the person holding the IPL applicator should activate it.
- Frequently wipe the IPL filter to remove hair and tissue debris.

Electrical hazard
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 ingress 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 make 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 starting the 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.
- Keep some sterile saline or water near the operating table to put out flames but take care should if electrosurgical equipment is being used.
- A fire blanket may be used to smother flames but with extreme care to avoid injuring the patient.

5.12 Other thermal and operational issues

In addition to fires started by laser beams there are other thermal hazards that can cause serious burns to people.

5.12.1 Laser thermal and operational issues

Optical fibres

- Before using the optical fibre, always check that it is not damaged and is firmly attached to the laser output aperture.
- Before firing, put the fibre's distal end in its intended position, or inside a suitable beam absorbing device.
- Once in position it may be appropriate to secure the optical fibre with tape or clips to prevent it moving during use.
- If a sapphire or other tip is to be used, ensure that it is securely attached to the fibre.
- Inadequate cleaning of the optical filter during the procedure may cause it to overheat.

Mirrors and beam stops

Objects, such as mirrors or beam stops that are in the path of a laser may become very hot and subsequently burn 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 so check the alignment of both the aiming beam and laser before 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

- Frequently wipe the applicator head with a non-abrasive cloth otherwise it might over-heat because of a build-up of tarnish.
- Follow the manufacturer's cleaning instructions. Unless directed by the manufacturer, do not use an abrasive tool because this is likely to leave small scratches on the applicator head/filter. Such scratches may lead to hot spots and subsequently burn the patient/client.

5.13 Smoke plume issues

A bio-aerosol of very small particles (smoke plume) can be released into the environment by lasers or IPL used for hair reduction, or a laser used in surgical procedures.

Over the years, many studies [15,16,17,18] have shown that the smoke plume can be harmful to the healthcare worker and the patient. Concerns range from inflammation of the respiratory tract and lungs, harmful bacteria and viruses contained in viable particles and chemicals, such as benzene and formaldehyde, found in smoke plumes from a number of lasers.

Smoke plume effects

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

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.

Smoke plume reduction
If preventative measures aren't enough to reduce the risks from the smoke plume to acceptable levels, then we recommend using a smoke evacuator.

Smoke plume regulation
The Control of Substances Hazardous to Health Regulations (COSHH) [19] 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 smoke plumes, an employer should carry out an assessment of the risks of any such exposure and ensure that steps are implemented to reduce the risks.

5.13.1 Preventative measures

Masks
The authorised user and patient/client should wear a face mask during aesthetic procedures e.g. hair reduction as this helps 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 as they don't create an effective seal around the face. We recommend using a dedicated smoke evacuation system.

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 can 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.

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. They are designed to remove liquids and larger matter. The filters in these systems are not suitable to remove particles contained in the bio-aerosol.

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.

Examples of what to include in an equipment management policy

- 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 Managing Medical Devices.

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 before proceeding. A suitable and sufficient risk assessment will need to be done before first use of the equipment.

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

6.3 Pre-use equipment checks

After the manufacturer or supplier has installed the equipment, the healthcare facility should carry out pre-use equipment checks (acceptance testing). The tests can be done by the LPA or LPS, the medical physics department or electrical and biomedical engineering unit. These checks can be done at installation time, in the presence of the relevant hospital representative with the manufacturer or supplier.

The pre-use checks are done to detect any faults and ensure that the equipment meets its specification. 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 (energy, wavelength, beam profile, temporal pulse shape, etc).
- 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.
- Fibre connectors at each end.
- Records should be kept of the above checks.

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 mandatory but is 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. Record it in an appropriate log and make it easily 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. A detailed record of quality assurance checks should be kept.

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. Quality assurance undertaken once or twice a year 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 stops when the footswitch or finger-switch is released
- check the device's alignment of the aiming beam with the therapeutic beam
- check the device's filters / aperture for scratches or build-up of tarnish. 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 that: 1) they have been cleaned before 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.
- check that the output energy corresponds to the set energy, using a suitable power meter or the self-calibration function to check for power losses
- check the integrity of fibre connectors at each end.

6.5.2 Example of weekly quality assurance programme

Weekly quality assurance may include:

- check for scratches on the lenses or general damage of protective eye wear
- 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

- check wavelength(s) (specifically for tuneable lasers and IPLs).

6.5.3 Example of yearly or six monthly quality assurance programme

The checks will likely mirror the initial pre-use equipment tests (acceptance tests) and may include (in addition to the checks listed above):

- 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. Acceptance checks should be carried out by the LPA or their representative following maintenance, upgrades or repairs.

6.6 Equipment fault log

Logging equipment faults

We recommend having an equipment fault log for each laser, IPL and associated equipment. It may either be a separate document for each item of equipment or 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.

Make a note of details of the fault including error codes displayed, audible alarms alerts etc. Each fault should be signed by the person who saw it 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. We recommend reviewing the risk assessment 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) carrying out the modification.

The local rules may require modification to reflect any of the equipment and procedural changes already mentioned. Additional staff training may be required.

We don't recommend using parts of old or redundant equipment to keep another unit in operation as there may be issues with the quality, liability and traceability of the parts.

Unauthorised modifications

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

If a fault or incident occurs following an unauthorised modification, the healthcare establishment rather than the manufacturer may be liable.

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 or supply accessories that may be suitable for name branded lasers and IPLs.

Buying equipment accessories

If buying an accessory for the laser or IPL, check whether the equipment is suitable for both the make **and** model of optical radiation device.

Accessories are often bought in bulk through a central authority. The central purchasing authority needs to know about 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
- the product, including accessory is CE marked as a medical device
- the accessory is suitable for the required procedure
- 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 can be used.

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 handswitch, which is typically for a few seconds.

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

Gated or chopped CW mode
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
Excimer	0.16-0.35	Pulsed	Optical fibre Direct Articulated arm	Cardiac Ophthalmology
Dye	0.4-0.7	Pulsed	Optical fibre	Dermatology Urology
KTP	0.532	Q switched Gated CW	Optical fibre	Gynaecology Dentistry Dermatology Obstetrics Plastic surgery
He-Ne	0.63 0.54	CW	Optical fibre Mirror	Aiming beam
Ruby	0.69	Pulsed Q switched	Optical fibre Mirror	Dermatology Plastic surgery
Alexandrite	0.755	Q switched	Optical fibre	Dermatology
Diode	0.81-0.98	CW Gated CW Pulsed	Optical fibre	General surgery Physiotherapy Ophthalmology Dentistry Gastroenterology
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
CO_2	10.6	CW Q switched	Mirrors Waveguide	General surgery Neurosurgery Head & neck Dentistry Gynaecology

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 handpieces 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 typically 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 handpieces

Focusing handpieces 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. Some diffusers and scanning heads are used

to deliver ‘fractionated’ beams, an array of small treatment zones over a predetermined area.

7.2.3 Fibre delivery systems

Optical fibres

With some laser applications, e.g. slit lamps, laser indirect ophthalmoscopes and colposcopes, 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. Side firing tips are available for use with Er, Cr:YSGG lasers used in dentistry.

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 handpiece, 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 Diode and Nd:YAG lasers and with Er:YAG / Er:YSSG lasers in hard tissue procedures.

7.3 Laser applications

The following table 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, soft tissue, endodontics
	Er,Cr:YSGG Er:YAG	Soft tissue surgery, tooth cavity preparation, bone surgery
Dermatology	Dye	Port wine stain
	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
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	Ga Al As	Wound healing, pain control small joint inflammation, adhesive capsulitis, arthritis
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.

IPL 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.

7.4.1 IPL properties

The intense pulsed light system uses technology that is different from the one in lasers. Xenon or krypton gas is commonly 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 can be used to select wavelengths.

7.4.2 IPL delivery mechanisms

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

Some method of skin cooling should be used during IPL procedures to protect the patient’s skin from heat damage and to make the procedure more comfortable. 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 uses a refrigerated spray that is applied before, during, and after each light pulse.

7.4.2 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
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).

7.6.1 LED applications

Table 4 Examples of clinical applications for LEDs

Speciality	Application
Aesthetic	Spider veins, sunspots, broken capillaries
Dentistry	Dental composite curing
PDT	Cancer treatment
Physiotherapy	Wound healing

8 Optical radiation effects on tissue

8.1 Optical radiation

Electromagnetic radiation is 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).

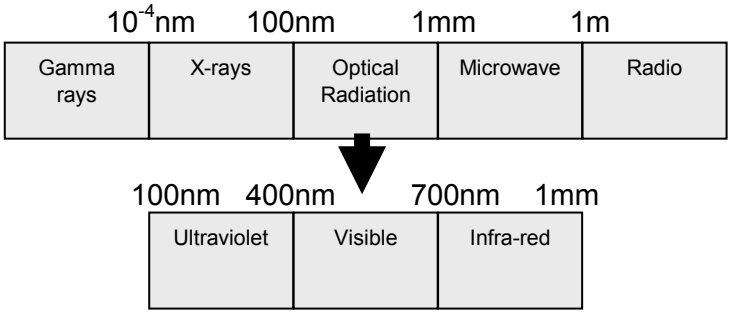

Figure 1: The electromagnetic radiation spectrum

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

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 exposure and the temperature reached in the tissue. Short exposures (less than 1 second) are less damaging than longer exposures.

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.

IPL 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 will 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 the photo-chemical effects of ultraviolet radiation. 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. Photo-chemical damage has a cumulative effect; 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.

However, the use of photo-chemical effects with tissue is used for positive benefits in medicine. An example of this is 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 can 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

The laser classification scheme only considers the laser beam hazard. Under normal viewing conditions (e.g. without the use of magnifying optics or anaesthetics), only class 3B and 4 lasers pose a 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. For example to the manufacturer it means no key switch and interlock connector required; to the user it means no eye protection is usually required.

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

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

The classification system is included in BS EN 60825-1 Safety of laser products. Equipment classification and requirements [6]. Class 1C is a new class, attributed to lasers which pose a risk to the skin (e.g. are designed for skin treatments) but pose no risk to the eye. Examples of such lasers include ‘home use’ devices which employ sophisticated interlocks restricting the user from activating the device unless a good contact is made with the skin.

The laser classification is determined by the equipment manufacturer. The manufacturer follows the specification laid out in the standard BS EN 60825-1 [6]; 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’ [20].

Table 5 Laser safety classes

Laser safety class	Laser type	Hazards to eye or skin
Class 1 (embedded)	Laser completely enclosed	Generally safe during use. Hazards according to power of enclosed laser when interlocks are overridden.
Class 1 Class 1C	Very low power level	Emitted power generally safe for long-term intrabeam viewing, even with optical instruments such as magnifying glasses. Eye safe
Class 1M	Low power level. Collimated large beam diameter or divergent	Safe for long-term intrabeam viewing, but potentially hazardous with magnifiers (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 (invisible)	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 diffuse reflections is 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, class 3B and class 4 lasers need to have remote interlocks, a key switch, a beam stop and an emission warning.
All lasers must be labelled, including the class.

9.2 IPL classification scheme

The standard IEC 62471 Photobiological safety of lamps and lamp systems [21] provides details of lamp classification, which includes IPL systems.

The lamp classification scheme indicates only the risk. Depending on the time of exposure and luminaire effects there may be a hazard.

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

Apart from the Artificial Optical Radiations at work Regulations, 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, however, specific legislation which controls aspects of class 3B and 4 lasers, IPL or LEDs for use 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.

The Control of Artificial Optical Radiation at Work Regulations [7]

The aim of these regulations is to improve the health and safety of workers by ensuring that a risk assessment performed by an appropriately qualified person has been made and also laying down limit values for exposures of workers to artificial optical radiation to eyes and skin.

These regulations 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. The Health and Safety Executive and Borough Councils are responsible for enforcing this legislation.

Care Quality Commission (Registration) Regulations [22]
The Regulations are applicable to England and apply to all regulated activities, and state the requirements about people or organisations, who wish to provide or manage a regulated activity in England, can become registered.

Independent Health Care (Wales) Regulations [23]
These regulations apply to independent health care services in Wales. They set out what services need to register with Healthcare Inspectorate Wales (HIW) and what they need to have in place at registration and for the longer term. HIW is also responsible for enforcing these regulations.

Control of Substances Hazardous to Health Regulations (COSHH) [15]
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 [24]
These cover the electrical safety testing of new equipment, and periodic electrical safety testing programmes. The Health and Safety Executive is responsible for enforcing this legislation.

Health and Safety at Work etc Act [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. The Health and Safety Executive is responsible for enforcing this legislation.
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 [11]
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. The Health and Safety Executive are responsible for this legislation.

Health and Social Care Act 2008 (Regulated Activities) Regulations [25]
There are a number of health and social care services and activities that are regulated in England. This act lists a number of ‘fundamental standards’. Providers and managers should be aware of these as they specify the standard of care which must never fall. The Care Quality Commission responsible for enforcing the Regulations.

The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order [26]
The order allows for the regulation of a range of health and social care services, and for the development of minimum standards for these services. Standards are in development for regulated services across the statutory, voluntary and private sectors.

Independent Health Care Regulations (Northern Ireland) [27]
These cover the registration of private clinics which use specially controlled techniques including the use of class 3B and 4 lasers. They are enforced by the Regulation & Quality Improvement Authority. The regulations detail the minimum standards expected by the private healthcare facility.

Management of Health and Safety at Work Regulations [3]
The regulations require an employer with more than five employees to make and record 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 Health and Safety Executive is responsible for enforcing this legislation.

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.

Council licencing
In England councils can control the use of non-surgical lasers & IPLs. Some councils can ask salons and private clinics to apply for a special treatment license (examples being London, Nottingham and south Essex). Councils may use the legislative powers for example under The Control of Artificial Optical Radiation at Work Regulations where they may take enforcement action if they feel treatments pose an unacceptable risk to the public or the worker.

The Medical Devices Directive [28]
Applies to lasers, IPLs and LEDs. Sets 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. The Medicines and Healthcare products Regulatory Agency is responsible for seeing that medical device manufacturers follow to this legislation.

Personal Protective Equipment at Work Regulations [29]
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). The Health and Safety Executive is responsible for enforcing this legislation.

Personal Protective Equipment Regulations [12]
This regulation covers CE marking and supply issues. Compliance with BS EN 207 [13], BS EN 208 [30] are a requirement under these regulations. The Health and Safety Executive is responsible for enforcing this legislation.

Provision and Use of Work Equipment Regulations [31]
The employer should ensure that the equipment (e.g. optical radiation devices) and all ancillary systems are fit for purpose. Only appropriately qualified and trained personnel should carry out equipment maintenance. Maintenance logs for all equipment should be held and kept up to date. The Health and Safety Executive is responsible for enforcing this legislation.

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.

Regulation of Care (Scotland) Act [32]
The legislation covers the regulation of all adult, child and independent healthcare services in Scotland. The Care Commission of Scotland ensures that care service providers meet the Scottish National Care Standard.

Reporting of Injuries, Diseases and Dangerous Occurrences Regulations [33]
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 . The Health and Safety Executive is responsible for enforcing this legislation.

11 Equipment standards

11.1 General requirements for basic safety and essential performance

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 [28] 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, Medical electrical equipment: part 1: general requirements for safety [34] 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 [20].
BS EN 60825-1, Safety of laser products. Equipment classification and requirements [6].

At the time of writing IPL systems need only comply with the general medical electrical standard 60601-1 [34]. However, a specific 'Safety of IPL Products' standard is currently in draft.

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

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Appendix A – Example of local rules

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 4.2) should be related to a risk assessment. They should contain the working practices, procedures and information required to address the hazards and risks identified in that assessment

The local rules should either directly address the issues below or refer to the supporting documentation.

- Nature of hazard to persons (users and patients).
- Defined region and limits of the treatment area.
- A register of authorised users and associated responsibilities, including any restrictions of use.
- Contact point for laser protection supervisor and laser protection adviser.
- Controlled and safe access to the treatment area.
- Training needed by the people using or helping to use the laser/IPL.
- Personal protective equipment, especially eyewear.
- Methods of safe working, including layout of equipment.
- Normal operating procedures.
- Explanations and instructions on pre-use safety checks.
- Adverse incident and equipment faults – how to report and where to log them.
- 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 to show that they have understood them and agree to follow them.

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

Local rules for the safe use of laser and IPL equipment

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

Nature of hazards to persons

The laser can injure 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 on people strictly following the 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 the laser protection supervisor to ensure that the register is maintained and the local rules are followed (Annex 4).

Restriction of use to authorised persons

5. The equipment should only be used by an authorised user.

6. The laser protection supervisor, in consultation with the laser protection adviser, can decide if another person is suitable to use the equipment. Their name can 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 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 in terms of wavelength range, pulse length designation and L number. A coloured sticker or other identifier on the goggles could be used to match a similar identifier on the laser of IPL. The LPA should provide guidance on appropriate eyewear for each type of equipment. 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, before using a different optical radiation device. This good working practice helps reduce the risk of an 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 close 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 laser is unattended by an authorised user, it should be switched off and the key put in a safe place by the authorised user.

Normal operating procedures

18. Follow the operating procedure detailed in Annex 5.

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

This sign should be 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. The 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 operated by an authorised user in accordance with the approved local rules.

Laser protection supervisor is: …….

Annex 3

Register of authorised users

'X' (laser protection supervisor)
'X'
'X'
'X' (laser protection adviser)

Custody of the key
When not in use the key will be kept in the custody of [name of 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. ensure that the local rules are followed.
2. inform the laser protection adviser if they consider that the existing rules require amending.
3. ensure that the register of authorised users is maintained and that the correct procedure for authorisation has been undertaken.
4. 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. ensure that only authorised users operate the laser (or IPL).
6. inform the laser protection adviser as soon as possible in the event of an incident occurring.
7. 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 named on the register of authorised equipment users kept by the healthcare facility. Section 3.6 discusses the role of the authorised user.

The example below shows one way of setting out the register. It may be appropriate to make a distinction between who can use the laser for clinical purposes (healthcare professionals) and who can 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***.**

When you sign this register you acknowledge that you have read and understood the relevant local rules and agree to follow them. You also acknowledge that you have received the appropriate training to use the equipment.

Name	Designation	Signed	Date
Mr S Surgeon	Head of ophthalmology	*S Surgeon*	30/09/15
Dr A Laser	Laser protection adviser	*A Laser*	30/09/15
Ms LP Supervisor	Laser protection supervisor	*LP Supervisor*	30/09/15
Mrs A Nurse1	Ophthalmology nurse	*A Nurse1*	30/09/15
Mr B Nurse 2	Ophthalmology nurse	*B Nurse2*	30/09/15
Dr S Registrar 1	Ophthalmology specialist doctor	*S Registrar1*	30/09/15
Dr T Registrar 2	Ophthalmology specialist doctor	*T Registrar2*	30/09/15
Dr C Scientist 1	Clinical scientist	*C Scientist1*	30/09/15
Mr S Engineer 1	Laser service engineer	*S Engineer1*	30/09/15

Appendix C – Core of knowledge

Section 3 of this document details the anticipated minimum competency level for laser protection supervisors, authorised users and assisting staff of laser (class 3R, 3B and 4) and IPL equipment. In order to achieve the minimum competency level and as part of their safety training, staff should attend an initial and refresher 'core of knowledge' courses.

The core of knowledge course should be delivered by persons (e.g. a certified LPA) who have a high level of knowledge and understanding of: different optical radiation devices systems, optical radiation safety and the hazards associated with the equipment.

There is no statutory approvals body for core of knowledge courses but some organisations and bodies 'approve' courses to ensure course consistency. The content and depth covered in core of knowledge courses may be tailored to healthcare professionals who work in a medical setting, and/or general healthcare area, and/or cosmetic environment. The course certificate should clearly indicate which speciality has been covered.

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

Core of knowledge requirements

The core of knowledge syllabus indicates the content that should be covered by training centres. The content depth will depend on the differing needs of the healthcare professionals. Course lectures should generally total between 2 and 3 hours depending on course and content depth.

Example of a core of knowledge syllabus

Fundamentals of optical radiation devices and their interaction with tissue

- Understand how the different types of optical radiation are produced, what types of active media are used, and emission modes and delivery systems.
- Understand the characteristics of optical radiation emitted from different types of equipment.
- Be familiar with the intended purpose of the optical radiation equipment.
- Understand the effects of optical radiation exposure to eyes, skin and other tissue.

Hazards and how to control them

- Understand the principles of risk assessment.
- Be aware of 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.
- Be aware of the basic principles of the maximum permissible exposure levels and how to keep exposure of unprotected skin and eyes below these levels.
- Understand the hazards from optical radiation equipment, including optical beams, electrical hazards, equipment malfunctions, fire risks and smoke plume effects.
- Understand the hazards to patients and clients and the methods of minimising risks.
- Understand the hazards associated to the different staff groups and methods for minimising risks.
- Understand the hazards from reflections or absorption of the optical radiation beam with respect to instruments, or reflective surfaces, or other equipment.
- Understand the hazard control procedures, including the use of personal protection.
- Be familiar with the additional precautions that may be necessary when undertaking non-routine activities with the equipment.

Safety management

- Be familiar with the basic principles of the administration of safety.
- Be aware of the relevant legislation, standards and hazard classifications relevant to lasers, IPLs and LEDs.
- Understand the safety procedures and policies governing optical radiation equipment use, including the local rules, and controlled area.
- Understand the role of the laser protection adviser, laser protection supervisor, authorised users and assisting staff.
- Be aware of the principles and requirements of equipment quality assurance processes and procedures.
- Be aware of the meaning of the warning labels and signs associated with optical radiation equipment.
- Understand the general principles of emergency action and how to report accidents.

Appendix D – Reporting incidents

Reporting to the MHRA

Report any incident involving a laser, IPL or LED to both the LPA and LPS as soon as possible. The local rules should describe how to do this.

We recommend that the person recording the incident signs the form and that the LPS, LPA, or departmental safety manager counter-signs it.
The log should also record any corrective action taken after the event.

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

All adverse incidents involving medical devices should be reported to the MHRA. The LPA may also recommend informing other organisations such as the Health and Safety Executive (HSE), the National Patient Safety Agency (NPSA), and/or the Care Quality Commission (CQC) or the relevant devolved administration.

Report to us online via the Yellow Card scheme: https://yellowcard.mhra.gov.uk/

For general enquiries about adverse incidents involving medical devices contact the Adverse Incident Centre on 020 3080 7080 or aic@mhra.gsi.gov.uk

Details to include in your report

- Equipment type and location.
- Serial number or batch number.
- Power setting of the laser or IPL.
- Exposure 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.

After the LPA has investigated, they might put in place corrective actions or make recommendations to the healthcare facility to prevent recurrence of the incident.

Withdrawal of equipment from service

Following the adverse incident, it may be necessary to take the equipment out of service. Discuss this with the LPS, LPA and any appropriate manager.

Record the event and fault in the appropriate log book.

Put a notice on the equipment to warn all personnel of 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

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.

Under the Independent Health Care Regulations (Northern Ireland) 2005 all private healthcare establishments, which use of class 3B or class 4 lasers and/or IPLs, are required to be registered with the Regulation & Quality Improvement Authority. The Independent Health Care Regulations (Northern Ireland) 2005 set out minimum standards for private healthcare establishments, expectations during inspections. The legislation does exempt health care professionals such as physiotherapists from the requirement to register provided that the laser is only class 3B**.**
Information on the RQIA may be found on their website:
www.rqia.org.uk/what_we_do/registration__inspection_

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

Scotland

Details of how to report an adverse event to the investigation centre in Scotland may be obtained from the Health Facilities Scotland website:
http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/how-to-report-an-adverse-incident/

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:
http://www.wales.nhs.uk/sites3/page.cfm?orgid=465&pid=56203

Health and Safety Executive (HSE) incident reporting

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

You need to report certain injuries arising from incidents at work to HSE:

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

There is a full list of reportable injuries in: The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) [33].

Reporting patient safety issues

In England

NHS England's National Reporting and Learning System accepts reports of all patient safety incidents concerning the use of medical devices, e.g. mistakes, errors and near misses. The aim is to ensure that lessons are both learned and shared throughout the health service.

Details of how to report an incident to NHS England are on their website: http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/

In Northern Ireland

In Northern Ireland there is no separate patient safety agency. Currently any issues relating to patient safety, incidents and near misses are reported within each NHS trust, and then referred to Regional Medical Physics Services who undertake an investigation. Outcome recommendations are circulated within the NHS Trust (usually via the medical director or deputy medical director), the report is then usually disseminated to the appropriate managers.

Within the private sector (hospitals, clinics and salons) patient safety, incidents and near misses should be reported to the relevant internal manager, following local policy and the LPA.

In Scotland

NHS Scotland has a national adverse event framework which ensures a standardised approach to adverse event management and to enable healthcare professionals to learn from each other in order to put improvements into practice.

Details of NHS Scotland's framework and adverse event management can be found at the following website:

http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/management_of_adverse_events/national_framework.aspx

In Wales

Clinical risk management and the safety of patients is a key process for NHS Wales. Hazards are identified and assessed through clinical risk assessments and are aimed

at ensuring clinical staff learn from adverse events.Further information is on the NHS Wales website: http://www.wales.nhs.uk/

Registration and inspection bodies

England and the devolved authorities each have their own independent inspection bodies for the NHS and independent healthcare establishments.

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

England

Care Quality Commission (CQC)

The Care Quality Commission's role is to promote improvement in the quality of NHS and independent healthcare across England.

The Care Quality Commission (CQC) registration system for independent healthcare organisations, salons and clinics came into force on 1 October 2010 under the Health and Social Care Act 2008. In the registration system the non-surgical use of lasers and Intense Light Systems is not regulated, as it is not defined as a regulated activity according to the Registration Regulations. To determine which services are required to be registered with the CQC, the healthcare organisation should refer to the CQC web site guidance.

Local authority Special Treatment Licence

The local authority Special Treatment Licence is required by private clinics and salons which use class 3B lasers, class 4 lasers and/or IPLs. The licence is applicable to clinics and salons that operate within London boroughs and some cities in England. In general the licencing conditions refer to the Treatments That You Can Trust standards, or use them when setting their conditions and inspection criteria.

Treatments You Can Trust

Treatments You Can Trust is an independent organisation which ensures best clinical practice and robust standards of patient and client care within the private cosmetic sector. The organisation has a Quality Assurance Mark registration scheme for private cosmetic clinics and salons, which ensures patients and clients are treated by suitably qualified personnel within a safe environment.

Treatments You Can Trust has developed some good practice essential standards for class 3B and class 4 and IPL systems, which are aimed at private establishments. 'Essential Standards for Class 3B and Class 4 Lasers and Intense Light Sources in non-surgical applications' is available on this webpage.

Northern Ireland

The Regulation and Quality Improvement Authority (RQIA)

The RQIA is the independent health and social care regulatory body for Northern Ireland, and has a programme of inspections and reviews.

The Independent Health Care Regulations (Northern Ireland) 2005 sate that all private healthcare establishments that use class 3B or class 4 lasers and/or IPLs

must be registered with the QIA. The regulations set out minimum standards for private healthcare establishments, expectations during inspections. The legislation does exempt health care professionals such as physiotherapists from the requirement to register provided that the laser is only class 3B**.**

Northern Ireland Social Care Council
Northern Ireland Social Care Council is the regulatory body for the social care workforce in Northern Ireland.

Scotland
Healthcare Improvement Scotland
The role of Healthcare Improvement Scotland is to lead on improving quality of patient care and treatment delivered by the Scottish health service. Healthcare Improvement Scotland has responsibility for the regulation of independent healthcare services.

Wales
Healthcare Inspectorate Wales (HIW)
Healthcare Inspectorate Wales is the independent regulator of all health care in Wales. It is responsible for inspecting NHS services and registering certain independent health care services, including class 3B & 4 laser and IPL services.

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 they should be done 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 in case of an emergency. 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 hand or foot activated, starts and stops the treatment beam.

Emission indicator
The laser emission indicator is a visual and/or audible signal that alerts 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 [20]. The footswitch should be checked before use for correct operation. As part of a planned quality assurance programme the footswitch and its cable should be assessed for signs of wear and tear.

Handswitch
The handswitch is used to initiate beam delivery to the treatment area. The handswitch 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 handswitch should be checked prior to use for correct operation. As part of a planned quality assurance programme the handswitch switch should be assessed for signs of wear and tear. The handswitch 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 Safety of laser products. Equipment classification and requirements [6] provides examples of the label descriptions for each laser classification.

Laser power and energy

The output from a continuous wave laser is quantified in watts. The output from a pulsed laser is measured as energy and is quantified in joules.

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.

Pulse width
Tissue interaction depends on the pulse width of the laser. One of the deciding parameters for eyewear is the pulse width of the laser. When the laser pulse width is longer than 0.25s, they are considered as continuous wave (D). When the pulse width is from a fraction of a second to tens of milliseconds, they are known as 'pulsed' lasers (I). From microseconds to few nanoseconds pulse width, the laser is termed to produce 'giant pulse' (R). Lasers that produce very short pulses of less than a nanosecond are called 'mode locked pulsed' (M)

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. However, the laser cannot emit 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 a 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 before use.

Appendix F – IPL equipment features and terminology

Beam delivery system
Beam delivered is via the handpiece. An IPL system is typically made up of a main unit and a handpiece. The handpiece 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 on the front of the IPL control panel. 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, starts and stops the treatment beam.

Emission indicator
The IPL emission indicator is a visual and/or audible signal, which alerts 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. 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 in this mode, even if the emission control switch is depressed.

Do not confuse the stand-by condition with the IPL ready indicator.