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TECHNICAL REPORT

Safety of laser products –
Part 8: Guidelines for the safe use of lasers on humans

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Safety of laser products –
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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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SAFETY OF LASER PRODUCTS –

Part 8: Guidelines for the safe use of lasers on humans

FOREWORD

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IEC TR 60825-8 has been prepared by IEC technical committee 76: Optical radiation safety and laser equipment. It is a Technical Report.

This third edition cancels and replaces the second edition published in 2006. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition.

a) Recent medical laser equipment classified as laser class 1C is now included. Equipment of laser class 1C incorporates sensors which ensure good contact, so that laser emission into free space is inhibited.
b) More emphasis is given to protective eyewear of patients or clients, to the burning of materials close to the skin and to collateral hazards such as from internal or external fire and from noxious gases.
c) General technical update.

The text of this Technical Report is based on the following documents:

Draft	Report on voting
76/640/DTR	76/658/RVDTR

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this Technical Report is English.

Terms written in small capitals in this document are defined in Clause 3.

A list of all parts in the IEC 60825 series, published under the general title *Safety of laser products*, can be found on the IEC website.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

Lasers emit visible or invisible optical radiation or both. In some cases, this radiation is a parallel beam with almost no divergence. This means that the inherently high IRRADIANCE of the laser is maintained over considerable distances. Due to the laser irradiation properties, injuries to the eye and skin can occur. Annex A includes descriptions of laser systems and some medical applications.

Lasers present hazards to anyone present during the operation of the laser. Serious risks of injury, particularly to the eye, or undesired effects can result from lack of protective measures, the use of faulty laser equipment, misdirected beams or inappropriate laser controls or settings.

Lasers which are used in contact mode on the skin may be classified as laser class 1C. These laser systems incorporate safety means which ensure that laser radiation can only be emitted if the interlocks detect good contact with the skin so that free space emission above the AEL of class 1 is prohibited. When used correctly, class 1C laser systems are considered safe for the eyes.

This document is intended to give direction as to how aspects of laser safety are incorporated into medical laser practice. It is not intended to take precedence over existing or proposed national guidance. However, where none exists, this document is intended to provide helpful information.

Although the LASER USER has direct responsibility for safety during laser use, the employer, referred to in this document as RESPONSIBLE PERSON, bears the responsibility for the setting up of a framework for the safe use of the system. A LASER SAFETY OFFICER (LSO) can be appointed to provide expert advice to the RESPONSIBLE PERSON and all personnel concerned with the laser operation. This document emphasizes the need for appropriate laser safety training for all staff involved in providing practical guidance on installation, operation, maintenance and servicing.

SAFETY OF LASER PRODUCTS –

Part 8: Guidelines for the safe use of lasers on humans

1 Scope

This part of IEC 60825, which is a Technical Report, serves as a guide to the employer, the RESPONSIBLE PERSON, the LASER SAFETY OFFICER, the LASER USER and other persons involved, on the safe use of lasers and laser equipment classified as laser class 1C, 3B or 4 in interventional applications of laser beams on humans, excluding use of consumer products.

NOTE Premises where lasers are used include, but are not limited to, health-care facilities, dental-care practices, physiotherapy, beauty-care and cosmetic facilities.

This document explains the control measures recommended for the safety of the LASER USER, patients, clients, staff, maintenance personnel and others. Engineering controls which form part of the laser equipment or the installation are also briefly described to provide an understanding of the general principles of protection.

The subject areas covered in this document include

– BEAM DELIVERY SYSTEMS;
– biological effects of laser radiation;
– reporting of ACCIDENTS and dangerous situations, and
– checklists.

The object of this document is to enhance the protection of persons from laser radiation and other associated hazards by providing guidance on how to establish safety procedures, precautions and user control measures.

Medically relevant advice such as about treatment indications, counter-indications, patient or client condition, medical or beauty-care treatment procedures, patch testing, medication, adverse tissue or skin conditions and follow-up controls is beyond the scope of this document.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
accident
unforeseen situation which results in an injury to any individual

3.2
beam delivery system
mechanism or device which delivers the laser output to the target site

EXAMPLE fibre optics, handpiece, micromanipulator, scanning device

3.3
incident
potentially dangerous situation which could result in an injury to any individual

3.4
irradiance
RADIANT POWER per unit irradiated area

Note 1 to entry: IRRADIANCE is expressed in $W \cdot m^{-2}$.

3.5
laser controlled area
area where laser safety controls apply

3.6
laser user
user
person who controls the delivery of the laser radiation

Note 1 to entry: An assistant may control the settings such as output level, timing and stand-by or ready functions. The responsibility for the treatment is however with the USER. When in this document any action is attributed to the USER, it should also be understood that the action is performed by an assistant under the responsibility of the USER.

3.7
laser safety officer
LSO
person who is knowledgeable in the evaluation and control of laser hazards and has responsibility for oversight of the control of laser hazards

Note 1 to entry: Functions and responsibilities of the LSO are regulated differently in different countries.

3.8
maximum permissible exposure
MPE
maximum level of radiation to which, under normal circumstances, persons can be exposed without suffering permanent adverse effects

3.9
nominal ocular hazard area
NOHA
area within which the IRRADIANCE or RADIANT EXPOSURE can exceed the MPE

[SOURCE: IEC 60825-1:2014 [3], 3.64, modified – In the definition, "exceeds the appropriate corneal maximum permissible exposure (MPE), including the possibility of accidental misdirection of the laser beam" has been replaced by "can exceed the MPE".]

3.10
nominal ocular hazard distance
NOHD

distance from the output aperture beyond which the IRRADIANCE or RADIANT EXPOSURE remains below the MPE

[SOURCE: IEC 60825-1:2014 [3], 3.65, modified – In the definition, "beam" has been deleted and "appropriate corneal maximum permissible exposure (MPE)" has been replaced by "MPE".]

3.11
pulse duration
time increment measured between the half-peak power points at the leading and trailing edges of a pulse

[SOURCE: IEC 60825-1:2014 [3], 3.69]

3.12
radiant exposure
radiant energy per unit irradiated area

Note 1 to entry: For the purpose of this document, the area of the spot size on the target tissue is considered to be the irradiated area which receives the RADIANT ENERGY. A spatially uneven distribution of the RADIANT ENERGY across the spot is neglected. See also IEC 60826-1:2014, 3,73. RADIANT EXPOSURE is expressed in $J \cdot m^{-2}$.

3.13
radiant power
power emitted, transferred or received in the form of radiation

Note 1 to entry: RADIANT POWER is expressed in W.

[SOURCE: IEC 60825-1:2014 [3], 3.74]

3.14
remote interlock connector
connector which permits the connection of external controls placed apart from other components of the laser product

Note 1 to entry: Medical laser equipment usually has a REMOTE INTERLOCK CONNECTOR incorporated which is used to attach an external switch or door switch which interrupts the laser emission when activated.

[SOURCE: IEC 60825-1:2014 [3], 3.76]

3.15
responsible person
person legally responsible for assuring safe working conditions

Note 1 to entry: The RESPONSIBLE PERSON is usually the owner of the premises, the Chief Executive Officer (CEO) or a person in a leading position who is liable in case of an ACCIDENT in the premises.

4 Hazards and preventive measures

4.1 Risks to eyes

4.1.1 General

The eye is at risk of injury from laser radiation exceeding the MAXIMUM PERMISSIBLE EXPOSURE (MPE). Laser radiation at wavelengths between 400 nm and 1 400 nm is focused onto the retina resulting in permanent damage to vision. Refer to Annex A.

Any person who is present within the NOHA should be protected against unintended laser exposure above the MPE.

Laser equipment of laser class 1C is considered safe for the eyes, as the accessible emission is stopped or reduced to the accessible emission limits of class 1 when the laser applicator is removed from contact with the skin or tissue. Lasers of class 1C have no NOHA. However, the eye of the patient or client is at risk from the incorporated laser, when the laser is applied to an area which is close to the eye.

4.1.2 Laser protective eyewear of personnel

Unless there is no reasonably foreseeable risk (as assessed by the LSO) that any person can be exposed to laser radiation exceeding the MPE, eye protection specifically designed for the wavelength(s) and output in use should be worn in addition to any other controls that are in place. Eyewear should be selected and approved by the LSO. When the eyes of any person

including the treated individual are within the NOHA, then the appropriate eye protection should be selected.

Laser protective eyewear should conform with ISO 19818-1[1].

NOTE Information on safety eyewear can be found in the manufacturer's documentation.

In addition to the required marking according to eyewear standards and when different lasers are available, an unambiguous and robust method of marking the laser safety eyewear should be employed to ensure that there is a clear link to the laser in use and wavelength (if selectable) for which it has been specified. The type of marking should be sufficiently permanent.

Subclause 4.1.2 does not apply to lasers of class 1C.

4.1.3 Laser protective eyewear of patients or clients

Patient eye protection can include corneoscleral eye shields (see the manufacturer's instruction for use for possible risks), overlay external eye shields, moistened opaque cotton, pads or towels, eye protectors, and laser protective eyewear (glasses, spectacles or goggles). Protective eyewear should be chosen which reduces the radiant energy below the MPE.

More information can be found in ISO/TR 22463 [5][2].

Laser devices of class 1C incorporate engineering controls which prevent hazardous eye exposure to the USER and to personnel. However, the technical engineering controls possibly do not prevent eye damage to the patient when the laser is applied to a skin area close to the patient's or client's eye.

The extent of the NOHA will vary according to the type of laser used and the optical properties of the applicators used. Positioning of the treatment setting in a part of the treatment room can reduce the risk of exposure to errant beams.

4.1.4 Eye protection with viewing optics

When using viewing optics such as microscopes, colposcopes, slit lamps and other optical devices, the person(s) looking through the eyepiece(s) should be protected with a suitable filter or a shutter fitted to reduce the risk from radiation reflected through the vision channel. In case of monocular optics, consideration should be given to protecting the unshielded eye.

The use of a video endoscope can overcome the problems of reflected radiation in the viewing optics; however, it is still advisable for all persons present to wear eye protection when there is a risk of fibre breakage, or possible firing of the laser when the fibre is retracted from the endoscope. A risk assessment should be undertaken.

4.1.5 Eye protection of persons behind room windows

When the NOMINAL OCULAR HAZARD DISTANCE (NOHD) extends further than the nearest window, and the wavelength of the laser is less than 2 500 nm, protection should be provided to persons behind the window. Persons behind windows can be adequately protected by means of a window barrier which reduces transmission to a value below the MPE. Window barriers should meet infection control standards. For carbon dioxide lasers or other lasers which emit at wavelengths longer than approximately 2 500 nm, glass or plastics can provide sufficient absorption. Windows and shields should provide sufficient protection against the maximum IRRADIANCE for

[1] EN 207 [2] and ANSI Z136.7 [1] are current standards in use, although new safety eyewear conforms with ISO 19818-1 [9].

[2] Numbers in square brackets refer to the Bibliography.

the exposure duration likely to be encountered in normal use, as identified in the risk assessment carried out by the LSO.

For more information, see Annex B.

4.1.6 Reflecting surfaces

Reflections from glossy surfaces such as surgical instruments, mirrors, shiny jewellery, lubricating or cooling gels or tissue surfaces can be hazardous, particularly to the unprotected eyes. Depending on the wavelength and beam configuration, diffuse reflection of radiation from class 4 lasers from the irradiated tissue can also be hazardous. The probability for inadvertent exposure by reflected light should be assessed, for example in the case that eye protection is inadequate or is not worn or is temporarily put aside. Technical means for minimizing this probability may consist of the following:

d) Wall and ceiling surface or texture

   The surface of the wall and ceiling should be chosen such that specular reflections are minimized. A matt finish of any colour will minimize specular reflections.

e) Room equipment

   Glossy surfaces are found with windows, cupboards, vent frames, sterilization cases, X-ray viewing screens, video monitors, operating room lights, etc. Glossy surfaces reflect laser radiation unexpectedly and unpredictably. Unless concave in shape, glossy surfaces do not normally present a risk greater than that already present within the LASER CONTROLLED AREA. The checklist as described in Annex C may be used.

f) Instrumentation

   Care should be taken to prevent the unintentional reflection of the laser beam from an instrument. If the laser beam is likely to hit an instrument, for instance when it is placed in the beam path or adjacent to it, any such instruments should have a roughened surface to diffuse the beam. Instruments which have convex shape with radii in the millimetre range are suitable too as they also diverge the beam.

   The USER should be aware that a rough surface which does not specular reflect visible light reflects long-wavelength infra-red laser radiation such as that from a carbon dioxide laser. Black or dark-coloured instruments become hot when the absorbed radiant energy is sufficiently high, causing unintended patient burns. These instruments can also be significantly reflective at infra-red wavelengths. When working in the upper respiratory digestive tract, the USER should consider that a reflected beam or a hot instrument can perforate the endotracheal tube, possibly igniting it, with the risk of a severe endotracheal fire, see also 4.3.3 and Annex F.

Instruments with reflective surfaces are sometimes used to deflect the laser output onto an otherwise inaccessible operating site. Mirrors or other reflective devices should be checked for suitability at the laser wavelength and laser output employed.

When using laser equipment of laser class 1C, reflecting surfaces are of no concern.

4.2 Risks to skin

4.2.1 General

Depending on the radiation parameters of errant beam exposure, skin damage can occur such as erythema, burns, blistering, and scarring. Besides the fire hazard, a collateral skin burn of personnel, of the patient or the client can be caused by the ignition of material.

NOTE Risks to the skin of the patient or client due to unsuitable skin treatment parameters or other adverse treatment conditions are not covered in 4.2.

4.2.2 Skin protection against laser radiation

Treatment procedures should be determined which minimize the probability for unintended skin exposure of personnel to the treatment beam or errant or reflected radiation.

In cutaneous application, when manipulation of the tissue is necessary, protective measures should be considered such as tongue depressors, templates or wet gauze.

4.2.3 Protection against burning of materials close to the skin

The LSO should recommend or approve the use of appropriate non-flammable or fire-retardant materials as determined by the risk assessment. The LSO should consider using patient covers such as drapes which are claimed by the manufacturer to be laser resistant.

NOTE Laser-resistant drapes usually conform with ISO 11810 [7].

Lasers can produce sufficient energy to ignite flammable materials particularly in an oxygen-enriched environment. Oxygen can possibly accumulate under patient drapes or covers.

Any new agent used with a laser should be checked for flammability before use. The USER should consider the use of non-flammable agents (e.g. water-based). If the use of flammable agents cannot be avoided, the drying times determined by the manufacturer should be adhered to, allowing complete dispersal of the agent to take place.

Dry or flammable materials, including sponges, gauze pads and swabs, located near the operating field should be moistened and then kept moistened with saline or sterile water, throughout the use of class 4 laser equipment due to the risk of fire. Prior to releasing or placing the delivery systems (handpiece, fibre, etc.) on the instrumentation table, the laser should be set to stand-by mode, to avoid unintended irradiation and ignition. If available, the storage means, as provided by the manufacturer, should be used. The delivery system should always be under direct control of the USER. Placement of the unprotected delivery system directly on the patient should be avoided.

Protective measures may include

a) use of wet drapes and materials to protect tissues adjacent to the target site, or in the path of the beam;
b) if oxygen is likely to accumulate under covers or cloths, changing the location of oxygen exhaust or providing means for ventilation;
c) eliminating flammable solutions and preparations from the target site;
d) adherence to manufacturer's drying times of skin preparations and solutions;
e) all staff be knowledgeable of location and operation of fire extinguisher appropriate for electrical equipment and flammable materials;
f) availability of water or saline that is easily accessible to the LASER USER.

4.3 Risk of internal combustion

4.3.1 General

Fire hazards within the patient body cavities are associated with the presence of combustible material, oxygen and energy which is capable of ignition.

4.3.2 Protection against combustion of endogenous gases

To avoid combustion of endogenous gases like methane in the gastro-intestinal tract, localized ventilation and gas scavenging techniques should be employed.

4.3.3 Protection against airway fire

Airway fires are the most devastating and patient life-threatening events that can happen. Such events have been caused by lasers being focused or laser fibres being inserted.

For instance, materials which can burn include endotracheal tubes, flexible endoscopes, the laser fibre itself including tubular sheaths, inserted pads or sponges. Under increased oxygen concentration, the ignition takes place instantly and the flames are abundant even extending through the mouth of the patient to the exterior.

When, during airway laser surgery, oxygen concentrations higher than the normal 21 % are likely to be inhaled by the patient, a written medical airway management protocol should be followed. The USER, surgeon, and anaesthesia personnel should have received education and training.

Only endotracheal tubes specially specified for use with lasers should be used. The endotracheal tube chosen should be labelled for use with the intended wavelength and range of output parameters, in conformity with ISO 11990 [6]. If an adequate product is not available, the LASER USER together with the anaesthetist should consider other means to avoid airway fire and describe them in the written medical airway management protocol.

Since combustion can be initiated in the respiratory digestive tract in high oxygen concentrations, the lowest clinically acceptable concentration of oxygen should be chosen in laryngotracheal procedures. Jet ventilation should be considered.

4.3.4 Protection against burning of an endoscope

Care should be taken to avoid laser beam exposure of the sheaths of flexible fibre optic endoscopes since most of the sheaths are flammable.

The USER should check the proper positioning of the laser delivery fibre within the endoscope prior to placing the laser in a READY mode. Means include

– checking the integrity of the aiming spot;
– introducing the fibre far enough so that the tip can be seen through the endoscope. It should be realized that the tip of the fibre possibly becomes excessively heated during laser transmission and can cause heat damage to the endoscope or (upon contact) to the tissue although the aiming spot looks normal.

Care should be taken when endoscopy is performed in an oxygen enriched atmosphere, see 4.3.3.

Cases have been reported that fibres or fibre tips have broken within body cavities and endoscopes. Therefore, upon removal, the USER should confirm that the BEAM DELIVERY SYSTEM is intact and not compromised or broken.

Inadvertent pulling on the fibre during a laser procedure can cause damage to endoscopes, loss of part of the fibre inside the body, breakage of the fibre outside of the body with risk of inadvertent emission of radiation including cause of fire. If the fibre bridges a gap between the laser system and the treatment area, nobody should be allowed to enter that gap.

4.4 Risks due to inhalation of noxious fumes and plumes

4.4.1 General

When lasers are used to disrupt cells through the process of vaporization, noxious airborne contaminants are produced which can enter the breathing zones of all personnel present in the operating and treatment rooms, as well as the patient. Surgical plume contains carbon, gases, bio-aerosols, cellular material, blood, viruses and ultrafine particles (UFP).

Electro-dissectors, electrocautery devices, ultrasound dissectors, mechanical abrasion systems and the like also cause micro-particulates to become airborne. The known means of dealing with them may also apply for laser-generated particulates.

The health hazard to patients who receive a one-time exposure may be regarded differently from the health hazard of personnel who are subjected to repeated or chronic exposure.

Laser generated fumes, plumes, vapours and UFP should be removed from the environment. Procedures should preferably be performed in a facility with adequate ventilation and an adequate number of air exchanges per hour.

The means of plume scavenging should primarily be achieved by using evacuators equipped with filters. Additional protection is achieved via means of room conditioning and personal face masks. The disposal of filters should be considered.

More information can be found in ISO 16571 [8].

4.4.2 Dedicated smoke evacuation systems

Airborne contaminants should be captured as close as possible but not further away than 5 cm from the point of plume generation and removed by local exhaust ventilation (LEV). Numerous portable, disposable and stationary LEV systems are available to meet the needs of multiple types of facilities. The plume evacuation system should be designed to ensure that any potentially infectious agents are sufficiently captured in the air handling or exhaust systems. This may be accomplished with a plume evacuation system using ultra low penetration air (ULPA) filters (at least 0,12 µm) with a filtration efficiency at this particle size of not less than 99,999 %. Local extraction of plume also eliminates cellular debris and vapours, thus providing greater visibility of the surgical site, for increased precision and safety.

4.4.3 Central vacuum suction systems

Central vacuum suction systems built in the hospital or the premises should not be used for the purpose of removal of surgical plume, unless an in-line filter is installed, positioned between the wall outlet and the floor canister. The filter should be rated at 0,12 µm and staff should be aware of the manufacturer's time limit for its use. Filters should be disposed of according to the facility's infection control policy. Wall suction with in-line filtration may be appropriate for procedures producing an only small amount of plume.

4.4.4 Face masks

Masks, including special laser surgical masks, are not recommended for use as the primary method of filtration. Standard surgical masks are designed to protect the USER from contact with particulates of greater than 5 µm. They are not protective from the inhalation hazards associated with laser generated plume. It has been reported that particulates less than 1 µm comprise 77 % of matter found in surgical laser plume. During high-risk or aerosol generating procedures with suspected transmitted diseases, respiratory protection of a surgical N95 respirator mask along with a local exhaust ventilation (LEV) is recommended. However, N95 masks should be regarded as disposable, single-use devices that only protect the USER as a secondary adjunct to the LEV.

NOTE An N95 respirator is a respiratory protective device designed to achieve a close facial fit and efficient filtration of airborne particles. The "N95" designation means that when subjected to testing, the respirator blocks at least 95 % of the 0,3 µm test particles.

4.4.5 Disposal of filters

Filters and absorbers should be monitored and replaced on a regular basis in accordance with the manufacturer's recommendations. All plume collection supplies including masks, filters, tubing, connectors, etc., should be disposed of according to blood borne pathogens standards due to the presence of airborne contaminants.

Additional information can be obtained from the manufacturer's instructions for use.

NOTE Health hazards due to laser generated plume, vapours and airborne particles are sometimes difficult to assess. The assessment usually covers the characteristics of the laser in use, the surgical procedures and the local situation. Protective measures could already have been established regarding electrocautery devices and the like and can be adopted for laser use. Odour following use of laser is a first indication for possible health-relevant airborne substances which need consideration. Specific information is provided by Bibliography references [10], [11], [12] and [13].

5 Administrative procedures

5.1 LASER SAFETY OFFICER (LSO)

5.1.1 General

For installations where lasers of class 1C, 3B or class 4 are in use, the RESPONSIBLE PERSON should appoint a LASER SAFETY OFFICER (LSO) and define the LSO's responsibilities. The LSO should be sufficiently knowledgeable to be able to advise the RESPONSIBLE PERSON on aspects of laser safety which relate to the lasers in use in that facility. The RESPONSIBLE PERSON may assume the role of the LSO. The LSO should cooperate directly with the USER of the equipment.

Locally, within the LASER CONTROLLED AREA, there should be a designated person, suitably trained, who ensures that on a day-to-day basis safety measures are obeyed. The USER may assume this role.

NOTE 1 Medical laser equipment is often used in small settings whose staff consists of a LASER USER and a receptionist. This situation is found in the offices of physicians, podiatrists, dentists, beauty care practitioners and others. The owner of the facility, referred to as RESPONSIBLE PERSON, the USER and the LSO can be the same person.

NOTE 2 The requirement for appointment of a LASER SAFETY OFFICER is regulated in different countries differently.

NOTE 3 Class 1C is included because the laser output incident on the tissue can be as high as from laser class 4 devices.

5.1.2 Duties and responsibilities of the LSO

5.1.2.1 Duties

The primary duty of the LSO should be to support and advise the RESPONSIBLE PERSON with respect to the safe use of lasers and protection measures.

5.1.2.2 Responsibilities

More specifically, the responsibilities of the LSO should include:

a) performing a hazard assessment of laser working areas, including the determination of the NOMINAL OCULAR HAZARD AREA (NOHA); a scheme of a risk assessment should be followed (see Annex C);

b) giving advice to the RESPONSIBLE PERSON about safety issues when purchasing and putting into operation the laser equipment as well as operational and occupational safety measures;

c) choosing personal protective equipment;

d) contributing to the education of employees who work with the lasers or are present in the NOHA, about the hazards and about the safety measures;

e) contributing to the checking and approval of laser equipment and verifying that the maintenance and service of the equipment are performed by persons who have been trained for that purpose or are otherwise qualified;

f) ensuring, by repeated auditing, that the prescribed control measures are effective, for example, checking that personal protective equipment, laser radiation barriers and laser signs are in place, verifying standard operating procedures, alignment procedures, laser operational checklists and reviewing documentation pertinent to the laser utilization site;

g) providing information to the RESPONSIBLE PERSON about shortcomings and failures of the laser equipment;

h) investigating all ACCIDENTS and INCIDENTS involving lasers, providing information (see 5.2) on preventive measures to those involved, including the dedicated safety specialists of the facility.

Additional responsibilities include:

i) recommending and approving technical and organizational safety measures;

j) advising employees working with lasers or in laser areas;

k) withdrawing laser equipment from use, if necessary;

l) initiating investigations, if a laser ACCIDENT is reported;

m) liaising with national authorities;

n) in the case that laser equipment is rented from a third party or the laser equipment is serviced by a third party, defining and allocating, in accordance with the third party, responsibilities regarding safe procedures.

5.2 INCIDENTS and ACCIDENTS

5.2.1 General

After receiving an initial event report, the LSO should carry out an investigation of any INCIDENT or ACCIDENT, develop recommendations to prevent recurrence and report the findings.

5.2.2 Initial reporting

Personnel should be encouraged to report INCIDENTS. INCIDENT reporting is part of modern management techniques in terms of quality assurance and ACCIDENT prevention.

Any INCIDENT or ACCIDENT arising from the use of the laser should be reported by the USER or any other person involved immediately to the LSO. Further use of the laser equipment should be suspended until the LSO allows it to be put again into service.

5.2.3 Medical examination

A medical examination should be considered, when personnel is suspected of having received excessive laser exposure to the eye. A medical examination by a qualified specialist should be carried out immediately, i.e. within 24 h, after an apparent or suspected injurious ocular exposure. Such an examination should be supplemented with a full biophysical investigation of the circumstances of exposure.

5.2.4 Medical surveillance

Ophthalmic examinations of employees working with laser equipment have no value as part of a health surveillance programme and are not recommended. Ophthalmic examinations are sometimes carried out for other (e.g. medico-legal) reasons. Some of the investigative procedures used are themselves hazardous, and these should therefore only be carried out when medically advisable, and not used for routine screening.

SOURCE: IEC TR 60825-14:2022 [4], Clause 13.

5.2.5 Investigation of the circumstances of the event

Where an INCIDENT or ACCIDENT involving a laser is suspected, the LSO should prepare a report of the circumstances. The report should at minimum contain the following information:

a) a summary of the circumstances of the INCIDENT or ACCIDENT that led to an injury, which should specify

- the date, location and time;
- the names and designations of all staff and other persons involved;
- the details of the training and qualifications of the injured person other than the patient or client;
- the laser settings including RADIANT POWER or pulse energy;
- apparent contributing factors; and
- the obvious or suspected nature of any injury sustained by the person;

b) full written statements from all persons (including the LSO and, if practicable, the USER or assistants, as appropriate) who were engaged in the procedure in question and who can give any information relevant to the occurrence of the INCIDENT or ACCIDENT;

c) medical reports on any injured person;

d) full details of the type of laser product including the physical condition of the equipment immediately after the INCIDENT or ACCIDENT;

e) steps taken immediately following the INCIDENT or ACCIDENT;

f) listing of equipment in use during the procedure with appropriate identification information.

The report should be communicated to the RESPONSIBLE PERSON. The LSO should keep records of all such INCIDENTS.

ACCIDENTS involving lasers and serious defects in the equipment which could lead to injuries should be reported to the central health authority if a country-wide reporting system is in operation.

NOTE In large hospitals local rules can apply.

5.2.6 INCIDENT and ACCIDENT follow-up

Any INCIDENT should be followed by an appropriate action. Appropriate actions include the development of preventive strategies or recommendations and the distribution of information about the INCIDENT along with preventive recommendations to all persons who are likely to be subjected to the same kind of hazard.

The aim is preventing recurrence. Based on the circumstances of the event, the LSO should conclude safety measures to be implemented or the existing set of safety measures or rules of safe behaviour should be amended accordingly.

The RESPONSIBLE PERSON, in consultation with the LSO, should circulate the recommendations resulting from the investigation at least to

- any LSO appointed by the RESPONSIBLE PERSON, if more than one LSO is appointed;
- the biomedical engineering department, when in place and if concerned.

The LSO should inform the USERS and employees concerned.

5.3 Maintenance and inspection

5.3.1 Maintenance

The laser equipment should be maintained by a technically competent person only.

Maintenance comprises a range of activities including

a) preventive maintenance of the device and its accessories;

b) calibration of the output RADIANT POWER, energy and temporal characteristics according to the manufacturer's instructions;

c) user tasks associated with regular inspections prior to operation such as check of fibre integrity, interlocks working, function of gas flow.

The maintenance of the laser should be carried out in a LASER CONTROLLED AREA only. When maintenance procedures are performed in an area dedicated to maintenance purposes, this area should be prepared to temporarily function as a LASER CONTROLLED AREA.

5.3.2 Inspection schedule

The LSO should establish an inspection schedule, by reference to Annex E. Some inspections could be performed daily as a check of proper function of the equipment.

6 Laser safety training recommendations

The RESPONSIBLE PERSON should establish and maintain adequate training for the management of laser risks. Any person working within a LASER CONTROLLED AREA should receive laser safety training prior to commencing working with laser devices. The training should be updated regularly and if circumstances change. For a suggested syllabus of training, see Annex D.

All training activities should be documented and retained on file.

7 Laser environment

7.1 The LASER CONTROLLED AREA

Clause 7 does not apply to the use of laser devices classified as laser class 1C.

A LASER CONTROLLED AREA should be established around the laser in use and when there is a risk of the MPE levels being exceeded within that area. The access to laser radiation and activity of all persons within that area will be subject to control and supervision to prevent exposure to laser radiation exceeding the MPE. The boundaries of such areas should be decided by the LSO as part of the risk assessment but will commonly be the walls, floor and ceiling of the room in which the laser is to be used.

The LASER CONTROLLED AREA should be the same or greater than the NOHA.

In certain circumstances, a curtain may be an acceptable method of defining the boundaries of the area for use with lasers with sufficiently diverging beams.

Many medical or beauty-care lasers emit their beam focused or are guided through an optical fibre, resulting in a highly divergent propagation angle. The NOHD in these cases usually is much shorter than in the case of collimated beams. The NOHD should be assessed by the LSO or specified by the manufacturer. Unless the area of the NOHA is known, it is advisable to designate the entire room in which the laser is used as the LASER CONTROLLED AREA.

7.2 Access controls

7.2.1 General

The ways which provide access to the LASER CONTROLLED AREA should be marked by indicative means such as warnings and indicators.

7.2.2 Warning signs

Every entrance to a LASER CONTROLLED AREA should be marked with a laser warning and other signs according to national requirements. It is advisable to include information about the type of laser in use so that the person reading the signs is in no doubt as to what type of eye protection is required.

Warning signs should be displayed only when the laser equipment is connected to the mains or in use.

All warning signs should be placed at eye level to maximize their visibility.

If there is doubt on the kind of laser warning to be used, the reader is advised to refer to the national authorities, e.g. the national committee for standardization. Refer to the warning signs as shown in IEC TR 60825-14 [4].

7.2.3 Illuminated warning indicators

In some circumstances, it is useful to provide an illuminated warning in addition to the warning sign, as described in 7.2.2.

A typical illuminated warning has the form of a yellow lamp placed outside each entrance to the LASER CONTROLLED AREA. This lamp should be energized only when the laser is in use.

Alternatively, a light may be used to illuminate a translucent sign with wording such as "Caution – Laser in use", where the wording is not visible when the light is off.

7.2.4 Door switches and interlocks

Based on the risk assessment, a door switch in conjunction with the REMOTE INTERLOCK CONNECTOR may be considered to disable the laser if the door to the working area is opened. However, when such interruptions introduce an unnecessary and possibly serious hazard to the patient or client during a procedure, this risk should also be considered.

7.3 Fire protection policy

The USER and personnel present should be familiar with the location of fire protective and fire extinguishing equipment, which is in place due to national or local rules.

If the hazard assessment reveals that an elevated level of fire hazard exists, the LSO should consider the following.

In case of risk of smouldering drapes or small fires, an open container of water (sterile or saline, as required) should be placed in a convenient position near the operating instruments.

If drape material when ignited is difficult to extinguish, it should not be used and should be replaced by alternative drapes which are flame retardant.

Consideration should be given to providing carbon dioxide fire extinguishers in a readily accessible position near the LASER CONTROLLED AREA as determined by the local fire code regulations. The LSO should consult the fire control officer, if available, to determine the necessary range of fire control measures.

Annex A
(informative)

Biological effects, hazards, laser equipment technology

A.1 Biological effects and hazards

A.1.1 General

The mechanism by which laser radiation induces damage involves interactions of heat, thermomechanical transients and photo-chemical processes. The degree to which any of these mechanisms is responsible for damage is related to certain physical parameters of the irradiating source, the most important of which are wavelength, PULSE DURATION, spot size, IRRADIANCE and RADIANT EXPOSURE.

In general terms, in supra-threshold exposures, the predominating mechanism is broadly related to the PULSE DURATION of the exposure. Thus, in the order of increasing PULSE DURATION, the predominant effects in the following time domains are:

– at nanosecond and sub-nanosecond exposures, photo-acoustic and non-linear effects are generated;
– from 1 ms to several seconds, thermal effects are generated;
– for longer exposure durations, additional photochemical effects are generated.

Laser radiation is distinguished from most other known types of radiation by its beam directionality and wavelength specificity. This, together with the ability to produce lasers with an initial high IRRADIANCE, means that high instantaneous power densities can be transmitted to biological tissues. The primary event in any type of laser radiation damage to a biological system is the absorption of radiation by that system.

Absorption occurs at an atomic or molecular level and is usually a wavelength-specific process. Thus, it is the wavelength that determines which tissue a laser is liable to damage. Most laser damage is due to the heating of the absorbing tissue or tissues. This thermal damage is usually confined to a limited area surrounding the laser energy absorbing site and centred on the irradiating beam. Cells within this area show burn characteristics, and tissue damage primarily results from denaturation of proteins. As indicated above, the occurrence of secondary damage mechanisms from laser exposure can be related to the time course of the tissue heating reaction, which is directly related to the PULSE DURATION, IRRADIANCE, and wavelength of the laser. If a CW (continuous wave) or long pulse laser system is directed onto a tissue, then because of conduction, the volume of the tissue experiencing a raised temperature is progressively increased. This spreading thermal front results in an increasing damage zone as more and more cells are raised above their thermal tolerance. Heat is also removed by the blood flow through convection. The beam image size is also of importance, as the degree of peripheral spread due to conduction is a function of the size as well as the temperature of the initial area of tissue heating. This type of thermal lesion is commonly seen on exposure to CW or long pulsed lasers. On the other hand, damaging effects can be the direct result of specific molecular absorption at a given wavelength of radiation.

Short-pulse high-peak power lasers such as Q-switched or mode-locked lasers can give rise to tissue damage with a different combination of induction mechanisms. Energy is delivered to the biological target in a very short time and hence a high IRRADIANCE is produced. The target tissues experience temperatures great enough to cause the liquid components of their cells to boil and blood vessels to rupture. Boiling of tissue results in the production of a plume at the tissue surface. Confined boiling can occur below the surface of tissue, leading to explosive effects. Pressure transients result from thermal expansion and from the production of gaseous products and both can also result in shearing damage to tissues remote from the absorbing layers and in disruption due to mechanical shock waves.

Some biological tissues such as the skin, the lens of the eye and the retina can show irreversible changes induced by prolonged exposure to moderate levels of light. The changes are the result of photochemical reactions arising from the activation of molecules induced by the capture of photons. Such photochemically induced changes can result in damage to a system if the duration of irradiation is excessive, or if shorter exposures are repeated over prolonged periods.

All of the above described damage mechanisms have been shown to operate in the retina and are reflected in the breakpoints or changes of slope in the safe exposure levels described in IEC 60825-1 [3].

The pathologies caused by excessive exposures are summarized in Table A.1.

Table A.1 – Summary of pathological effects associated with excessive exposure to light

CIE spectral region [a]	Eye	Skin
Ultra-violet C (180 nm to 280 nm)	Photokeratitis	Erythema (sunburn) Accelerated skin ageing process Increased pigmentation
Ultra-violet B (280 nm to 315 nm)		
Ultra-violet A (315 nm to 400 nm)	Photochemical cataract	Pigment darkening Photosensitive reactions Skin burn
Visible (400 nm to 780 nm) [b]	Photochemical and thermal retinal injury	
Infra-red A (780 nm to 1 400 nm)	Cataract, retinal burn	Skin burn
Infra-red B (1,4 µm to 3,0 µm)	Aqueous flare, cataract, corneal burn	
Infra-red C (3,0 µm to 1 mm)	Corneal burn only	

[a] The spectral regions defined by the CIE are short-hand notations useful in describing biological effects but do not necessarily match the spectral breakpoints in the MPE Tables A.1 to A.3 of IEC 60825-1:2014 [3].

[b] Photochemical reactions are known to occur at wavelengths below 600 nm.

SOURCE: IEC 60825-1:2014 [3], Table D.1.

A.1.2 Hazards to the eye

Visible and near infra-red lasers are particularly hazardous to the eye because the very properties necessary for the eye to be an effective transducer of light result in a high RADIANT EXPOSURE being presented to highly pigmented tissues. The increase in IRRADIANCE from the cornea to the retina is approximately equal to the ratio of the pupil area to that of the retinal image. This increase arises because the light which has entered the pupil is focused to a "point" on the retina. The pupil is a variable aperture, but the diameter can be as large as 7 mm when maximally dilated in the young eye. The retinal image corresponding to such a pupil is between 10 µm and 20 µm in diameter. With intra-ocular scattering and corneal aberrations considered, the increase in IRRADIANCE between the cornea and the retina is of the order of 2×10^5. If an increase of 2×10^5 is assumed, a 50 $W \cdot m^{-2}$ beam on the cornea becomes 1×10^7 $W \cdot m^{-2}$ on the retina. In this document, a 7-mm pupil is considered as a limiting aperture as this is a worst-case condition and is derived from figures obtained from the young eye where pupillary diameters of this order have been measured.

When an intense beam of laser light is brought to a focus on the retina, only a small fraction of the light (up to 5 %) will be absorbed by the visual pigments in the rods and cones. Most of the light will be absorbed by melanin pigments contained in the pigment epithelium. In the yellow macular region, some energy in the 400 nm to 500 nm range will be absorbed by the macular

pigment. The absorbed energy will cause local heating and burn both the pigment epithelium and the adjacent light sensitive rods and cones. Depending on the magnitude of the exposure, such a loss of vision can be permanent. The injured retina does not heal, unlike the anterior eye or the skin. A visual decrement will usually be noted subjectively by an exposed individual only when the central or foveal region of the macula is involved.

The fovea, a small pit in the centre of the macula is responsible for sharp central vision and is utilized during activities where detailed vision is required such as reading or driving. When this region is damaged, the decrement appears initially as a blurred white spot obscuring the central area of vision; however, within two or more weeks, it changes to a black spot. The loss of central vision is very serious. Peripheral lesions will only be registered subjectively when gross retinal damage has occurred. Small peripheral lesions will pass unnoticed and can escape detection during a systematic eye examination.

In the wavelength range from 400 nm to 1 400 nm, the greatest hazard is retinal damage. The cornea, aqueous humour, lens and vitreous humour are normally transparent for radiation of these wavelengths. However, there have been cases where high intensity laser beams have caused burns in the cornea and lens. In the case of a collimated beam, the hazard is virtually independent of the distance between the source of radiation and the eye, because the retinal image is assumed to be a diffraction-limited spot of around 10 µm to 20 µm in diameter.

In the case of an extended source, the hazard is again virtually independent of the distance between the source and the eye, because then the retinal IRRADIANCE depends only on the source's RADIANCE and on the lens characteristics of the eye.

In the case of a "point-type", diverging-beam source, the hazard increases with decreasing distance between the beam waist and the eye. The reason is that, with decreasing distance, the collected RADIANT POWER increases, while the size of the retinal image can be assumed to remain nearly diffraction-limited for true laser sources down to a distance as close as 100 mm (due to the accommodation capabilities of the eye). The greatest hazard occurs at the shortest accommodation distance. With further reduced distance, the hazard to the unaided eye is also reduced, as there is a rapid growth of the retinal image and a corresponding reduction of the IRRADIANCE, even though more RADIANT POWER can be collected.

For wavelengths of more than 1 400 nm, the hazard is thermal damage to the lens or the cornea. Optical radiation is absorbed by the cornea or the lens at variable depth, depending on the wavelength (see Table A.1). For extended or point-type diverging-beam sources of these wavelengths, short distances between the source and the eye should be avoided.

For wavelengths less than 400 nm extending into the UV, the lens or the cornea can develop photokeratitis or a photochemical cataract can be generated.

A.1.3 Hazards to the skin

A.1.3.1 General

MAXIMUM PERMISSIBLE EXPOSURE values for the skin apply to USERS and are set below known hazard levels. They are based on the best available information from experimental studies. The MPE values should be used as guides in the control of exposures and should not be regarded as precisely defined dividing lines between safe and dangerous levels. Safety means should be employed, which eliminate the possibility for any inadvertent exposure to laser radiation, if feasible. However, cases for skin injury of personnel, within the scope of this document, have not been reported.

A.1.3.2 Thermal effect

The skin can tolerate higher exposure to laser beam energy than the eye. The biological effect of irradiation of the skin by lasers operating in the visible (400 nm to 700 nm) and infra-red (greater than 700 nm) spectral regions can vary from burning trauma grade I to grade III.

A.1.3.3 UV-laser hazard

Exposure from UV-laser sources are potentially hazardous to the skin of personnel, for example during set-up of the equipment and measurement of the output.

A.1.4 Determination of NOHD

The distance at which the beam IRRADIANCE or RADIANT EXPOSURE equals the appropriate corneal MPE is defined as the NOMINAL OCULAR HAZARD DISTANCE (NOHD). The NOHD should be considered when specifying the boundaries of the LASER CONTROLLED AREA within which the access to laser radiation and activity of personnel is subject to control and supervision for protection from laser radiation hazards.

More information can be found in Clause B.6 of IEC TR 60825-14:2022 [4].

A.2 Laser applications

A.2.1 General

For risk assessment and INCIDENT or ACCIDENT analysis, a precise differentiation of laser applications is valuable.

A.2.2 Area of application

A.2.2.1 Body surface

Treatment of skin, skin adnexa and the visible mucosa in natural orifices (ear, nose, mouth, anus, exterior genitalia).

A.2.2.2 Open surgery

Intraoperative application of laser radiation after surgical opening of body cavities, organs, soft tissue, bone and joint system using free hand or directed application.

A.2.2.3 Intra-corporeal laser application

Any laser application using endoscopes or catheters where the treatment is within the body. This can be in body cavities, hollow or solid organs, vessels ("endovascular") and soft tissue ("interstitial") via natural orifices or punctures.

A.2.2.4 Guidance system

In the case of endoscopy, the position and laser application can be performed by direct or video visualization. In catheter applications, the positioning is normally controlled by an imaging system. The positioning can be automatically controlled by means of the system.

A.2.3 Types of application

A.2.3.1 Free hand application

Treatment with a delivery and application system which allows guidance in any direction.

A.2.3.2 Directed beam

Treatment with a mounted delivery and application system which allows application only in a limited direction, for example operating microscope with micromanipulator or ophthalmoscope or slit-lamp, colposcope, or laryngoscope.

A.2.3.3 Non-contact method

Application of laser radiation in conjunction with a gas or liquid. The beam can be collimated, divergent or focused. The laser delivery system has no direct contact with the tissue.

A.2.3.4 Contact method

Application of laser radiation where the delivery probe is in direct contact with the target. This can be performed directly with a fibre ("bare fibre"), sculpted fibres, diffusers, and special attachments such as sapphire tips or diamond knives.

A.3 Laser equipment technology

A.3.1 Laser radiation sources

Lasers typically operate at specific wavelengths which depend primarily on the lasing media and secondly on the engineering design of the optical cavity. Some lasers allow different output wavelengths to be selected. Lasers in common use range from the CO_2 laser (10 600 nm) with its output in the IR-C to excimer lasers (for example, the argon-fluoride laser operates at 193,1 nm) in the ultra-violet. Power output ranges from a few milliwatts to many tens of watts in continuous wave lasers. Pulsed lasers have energies from a few millijoules to many joules per pulse, giving instantaneous power outputs up to several megawatts. The laser-tissue interaction depends on a range of parameters, for example:

– output wavelength(s) (some lasers have more than one output wavelength);
– continuous or pulsed output, output power or pulse energy;
– pulse width;
– duration of pulse train;
– pulse repetition rate;
– tissue type.

The coherence property of laser radiation is important only for special diagnostic imaging applications, but plays no role when tissue is treated by the laser radiation.

A.3.2 Laser radiation delivery systems

A.3.2.1 General

All lasers require a means of transmitting the radiation to the target site. The means of transmission is known as a delivery system. The laser wavelength determines the type of delivery system. Besides direct delivery three types of delivery system are in common use:

– articulated arm;
– hollow flexible waveguide;
– optical fibre.

Usually, applicators are fitted to the delivery system, such as:

a) lenses;
b) side fire tips;
c) shaped or sculpted fibres;
d) bare fibres;
e) diffusers;
f) micromanipulators;
g) scanners.

A.3.2.2 Direct delivery

Laser pointers, patient positioning lasers and hand-held lasers are examples of direct delivery systems. The laser energy is delivered directly from the emitting aperture to the tissue (with or without focusing lenses). The output is controlled by switching the machine on or off, either by manually pressing a button or by a timer. The beam can be "steered" by hand or by mechanical means.

A.3.2.3 Articulated arm

A.3.2.3.1 General

Since some wavelengths (e.g. those from a CO_2 laser) are absorbed by glass, they cannot be delivered through conventional glass fibres or lenses. An articulated arm has been developed which allows the laser radiation to travel through a hollow arm using a system of joints and mirrors.

Because radiation from ultra-violet or infra-red lasers like the CO_2 laser is invisible, a low power visible laser, typically a green or red diode laser, is used to designate the target tissue. The beams of the invisible treatment laser and of the visible aiming laser are optically combined to coincide at the applicator or handpiece treatment plane.

The articulated arm is usually fitted with applicators such as a handpiece, a micromanipulator (microscope attachment), a rigid fibre delivery system, a waveguide or rigid endoscope. The applicator can include a lens to focus the beam.

A.3.2.3.2 Limitations of an articulated arm

There are inherent limitations in the use of an articulated arm, such as below.

a) The laser energy delivery is restricted to the "line of sight" or along straight segments of a delivery path.

b) The arm is liable to be bumped, which can result in optical misalignment. The aiming beam and treatment beam should be regularly checked for coincidence and spot shape. To avoid damage or misalignment, the articulated arm should be safely secured for transport and when not in use.

c) The sterilization procedures specified by the manufacturer should be observed, otherwise lens or mirror coatings can be damaged.

d) Dust and grease from hands can adversely affect the optics of mirrors or lenses.

The articulated arm transmits a collimated beam which is potentially hazardous, particularly if a handpiece or lens is not fitted. The collimated beam maintains its diameter over distances of some metres, so the IRRADIANCE can be high enough to cause injury, fire or physical damage at a far distance from the laser aperture.

A.3.2.4 Hollow waveguide

Some of the limitations of articulated arms can be avoided by using flexible hollow waveguides. These devices consist of a reflective coated hollow tube through which the laser energy can be delivered.

A.3.2.5 Optical fibre

A.3.2.5.1 General

The laser energy can be delivered through an optical fibre to emerge as a divergent beam at the fibre tip.

In the case where the treatment beam is invisible, a visible aiming beam is usually combined with the working beam before the fibre to produce a coincident beam at the treatment plane.

Where the treatment beam is visible, the RADIANT POWER can initially be reduced and used as an aiming beam. The beam power is then increased for treatment, and a shutter or filter will limit exposure to the USER's eyes.

Frequently, the fibre delivery system is used in conjunction with a rigid or flexible endoscope. According to the type of fibre utilized, the system is used in either a contact or non-contact mode.

Fibre optic delivery systems are often used via special sheaths which deliver gas or fluid to cool the tip and remove debris. This system can be used only in a non-contact mode. The addition of a separate tip will allow the system to operate in a contact mode.

A.3.2.5.2 Limitations of fibre delivery systems

The likely causes and effects of altered laser performance are:

a) damage to the fibre tip such as damage caused by excessive heating if debris is not removed from it;

b) severe damage to the endoscope up to the endoscope burning, due to firing of the laser while the fibre tip is inside the endoscope;

c) fibre breakage, due to use in unsuitable types of endoscopes;

d) fibre breakage, due to excessive bending (see manufacturer's specifications), dropping or "nicking" by a sharp object;

e) heating up of fittings, particularly metal fittings, at either end of the fibre delivery system following laser use, which has resulted in cases of tissue burns on patients and USERS. Damage to the equipment has also occurred. Adequate cooling time should be allowed;

f) the spot diameter of an invisible working beam being larger than the spot of the aiming beam up to a factor of two;

g) laser power leaking from locations of narrow bends in fibres, producing leakage intensities outside of the fibre which are high enough to potentially burn tissue and cause eye damage.

A.3.2.6 Handpieces and applicators

A.3.2.6.1 Applicators with focusing lenses

A.3.2.6.1.1 General

Focusing lenses are frequently used in applicators to increase or decrease IRRADIANCE or reduce the diameter of the beam at the target tissue. Where a laser is focused by a lens, the shorter the focal length, the smaller the focal spot size. The focal length of an applicator lens determines the diameter of the focal spot and the depth of focus.

A.3.2.6.1.2 Limitations of lens systems

The limitations of using focusing lenses are as follows.

a) Applicators using short focal length lenses require precise positioning with respect to the target.

b) Applicators using long focal length lenses usually produce a large focal spot size which can be too large for obtaining the required IRRADIANCE.

c) Depending on the design of the optical system, misalignment can be a problem in lens applicator systems, particularly among those employing interchangeable lenses, where loose or worn lens couplings allow the lens to move.

d) The aiming and working beams could possibly not coincide in space. This problem can be accentuated when the beams pass through a lens.

e) The need for placing focusing lenses close to the operating site can lead to damage through accumulation of debris if they are not adequately protected.

A.3.2.6.2 Diffuser probes

These probes incorporate a diffuser which spreads the laser light over a relatively large treatment area and are used in photodynamic therapy (PDT) as well as in laser-induced interstitial thermo-therapy (LITT). The diffuser shape determines the energy distribution to the target tissue.

A.3.2.6.3 Contact applicators

Special optical fibres are designed to be applied in contact with the target tissue, such as "bare fibres", "sculpted fibres" or fibres which have applicators mounted on the fibre tips. Lasers with applicators attached like bare fibres with or without contact tips generally are class 3B or 4 lasers, since laser radiation can potentially be emitted in free air.

Laser systems of laser class 1C which are usually applied on the skin have lasers of class 3B or 4 incorporated. Leakage of hazardous radiation is prevented by interlocks which allow laser emission only when placed in good contact with the skin. The window, through which the radiation is emitted, and which is in contact with the skin, occasionally is equipped with cooling devices. The skin is then cooled to below body temperature to minimize bulk tissue damage which can occur upon absorption of the radiation of the incorporated high output laser.

A.3.2.7 Micromanipulators

Micromanipulators on endoscopes and microscopes including ophthalmic slit lamp microscopes use a joystick which controls a mirror and directs laser energy to the tissue to be treated.

A.3.2.8 Scanners

Scanners use devices such as motorized moveable mirrors to deflect the beam across a predefined area in a programmed manner.

A.3.2.9 Interlocks of laser equipment of class 1C

Manufacturers need to conform with the relevant technical standard. The interlocks need to prevent any hazardous leakage of radiation. The surface curvature does play a role. The interlocks may allow a bit of tolerance in order not to slow down the availability of the laser system in an overly restrictive manner. Interlocks may include mechanical or optical sensors.

Although the class 1C laser equipment is considered inherently safe to the eyes of personnel, it should be used with caution. It cannot be regarded as safe to the eye of a patient or client when it is applied on the face close to an eye. Radiation can scatter through the close periorbital tissue and reach the bulb of the eye.

If the applicator is put on top of the closed eyelid and the laser is actuated, the iris is at risk to be burned causing irreversible damage and functional disability.

For details of patient eye protection, see 4.1.3.

Annex B
(informative)

Window shielding

B.1 General

Many medical laser applications take place in rooms, such as operating rooms, which have windows. Window shielding restricts the NOHA to the room boundaries (walls, ceiling, floor). Consideration of whether shielding is required and what type of shielding is appropriate depends on

a) the laser wavelength(s);
b) the irradiance and radiant exposure at the window;
c) the need to use the window when the laser is not in operation;
d) the fire or heat resistance of shielding materials;
e) the ease of attaching or detaching the shielding;
f) infection control;
g) the conditions of human access to the space behind the windows.

Window shielding is not relevant for laser equipment of laser class 1C.

B.2 Laser wavelength

Generally, glass windows are assumed to transmit laser radiation efficiently. At wavelengths beyond 2 500 nm, glass windows absorb laser radiation. Window glass is claimed to fully absorb UV-C and be partially protective for UV-B, but will transmit UV-A. However, different formulations of window glass can have different spectral transmission properties. If in doubt seek specialist advice or apply window covering.

B.3 Resistance to fire and heat

The IRRADIANCE and RADIANT EXPOSURE which could be reached at the window are important in determining the type of shielding.

Under exceptional circumstances, glass can shatter due to thermal stress under high IRRADIANCE. The flammability of materials is important if the IRRADIANCE or RADIANT EXPOSURE is sufficiently high. For most medical laser equipment, these kinds of problems occur only when the beam is almost parallel (of low divergence). Normally, if the laser beam is focused or diverging, this is less critical.

B.4 Removable attachments

Detachable shielding can easily and quickly be attached and removed and be accessible only to persons in the LASER CONTROLLED AREA.

Examples of shielding and attachment are:

a) opaque plastic sheets hung on hooks;
b) opaque cloth fixed by hook-and-loop closure (e.g. Velcro®[3]) strips;

[3] Velcro® is an example of suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of this product.

c) shutters;

d) blinds;

e) curtains.

Some shielding has gaps. Gaps are most likely to occur at the edges, for example a curtain being moved by air currents or by staff brushing against it.

Annex C
(informative)

Checklist for laser installation

C.1 General

Annex C gives guidance on the steps to be taken during the installation of a laser. It is assumed that a LASER SAFETY OFFICER has been appointed to oversee the process. The following steps may prove helpful in assessing the risk(s) of any laser installation.

C.2 Identify

a) employer of authorized personnel;

b) LASER SAFETY OFFICER;

c) safety organization, this could be a safety committee established by the RESPONSIBLE PERSON;

d) INCIDENT and ACCIDENT reporting procedure (to take note of local, national and statutory requirements).

C.3 Determine relevant information

C.3.1 Details of laser

a) type (make, model, manufacturer, supplier, etc.);

b) wavelength(s);

c) temporal characteristics of RADIANT POWER or pulse energy;

d) classification (determines level of protection required for the laser beam only);

e) type approved (local or national);

f) BEAM DELIVERY SYSTEM(S) (all options);

g) gas supplies (cylinders, piped gases, sealed);

h) dyes (risk assessment needed: solvents, additives, mixing, etc.);

i) laser gas exhaust(s);

j) preparation of the treatment room and the type of necessary supply connections.

C.3.2 Other hazards

a) operating equipment;

b) plume extraction;

c) drapes.

C.3.3 Application

Procedures to be undertaken.

C.3.4 Life cycle

Parts of the life cycle for the laser installation to be considered, for example:

a) delivery;

b) installation;

c) commissioning;

d) training on use (for each application);

e) normal use (for each application);

f) maintenance;

g) servicing;

h) modification;

i) decommissioning;

j) disposal.

C.4 Risk assessment

C.4.1 General

It is possible to divide the laser installation into a series of modules and to identify the hazards (and therefore the risks) associated with each module. The modules may comprise:

a) the laser process, for example what is the laser beam being used for?

b) the BEAM DELIVERY SYSTEM – how does it get there?

c) the laser assembly – where does it come from?

d) the room and other equipment;

e) human factors.

Hazards can be split into two categories: the laser beam and others. There are risks from hazards during the different sections of the life cycle of the laser equipment.

C.4.2 Laser beam

a) nominal ocular hazard distance or the nominal ocular hazard area for each application;

b) specification of appropriate protective eyewear;

c) specification of appropriate protective clothing for each application with specific consideration to potential skin exposure to ultraviolet radiation.

C.4.3 Non-laser hazards

a) fire hazards;

b) plume and fume hazards.

More information about risk assessment can be found in Clause 7 of IEC TR 60825-14:2022. National or local rules can apply.

C.5 Treatment unit

Determination and preparation of the LASER CONTROLLED AREA:

a) walls (reflections);

b) windows (locations, transmission, blinds, etc.);

c) doors (positions, viewing panels, etc.);

d) ceilings;

e) warning signs (positions);

f) REMOTE INTERLOCK CONNECTOR (whether used or not);

g) utilities (water, air, gases, electricity);

h) fire precautions (extinguishers, blankets, etc.).

More information can be found in 9.4.2 of IEC TR 60825-14:2022 [4].

C.6 Authorization and training of personnel

Safety training for personnel:

a) clinical USERS (including paramedical staff);

b) technical USERS (engineers, bio-engineers, etc.);

c) other non-medical USERS;

d) record keeping of training measures, formal and on-the-job.

C.7 Operating procedures

C.7.1 Pre-use testing

Pre-use testing according to the laser type, BEAM DELIVERY SYSTEMS, RADIANT POWER, shutter, control mechanisms, automatic scanning, gas supply, cooling devices and other accessories, as appropriate. See also the manufacturer's instructions.

C.7.2 INCIDENT procedure

INCIDENT procedure documented for USERS to implement when necessary.

C.8 Annual audit

C.8.1 Installation

Arrangements to audit the installation annually and to train other persons to audit it periodically. Records of periodic audits.

C.8.2 Risk assessment

Record of the significant findings of the risk assessment to satisfy local, national or statutory requirements. Schedule for regular checks.

Annex D
(informative)

Laser safety training

The syllabus as listed in Table D.1 should be considered to be part of the laser safety training. It should be adapted in length and content to suit the laser equipment to be used and take the role of the persons involved into account, including LASER SAFETY OFFICERS, USERS and staff.

NOTE In some countries, the syllabus for LSOs and for USERS are regulated.

Table D.1 – List of training items and allocation to persons involved (arbitrary order)

Training item	LSO	USER	Other staff
Characteristic features of laser radiation emitted from various types of laser	x	x	x
Generation of laser radiation and hazards	x	x	x
Principles of quality assurance	x		
Equipment management		x	x
Laser–tissue interactions	x	x	x
Effects of exposure of eye and skin to laser radiation	x	x	x
Laser safety management, role of the LSO and investigation of suspected cases of accidental exposure	x	x	
LASER CONTROLLED AREAS – boundaries – warning signs – access control	x	x	x
Selection and approval of personal protective equipment (PPE)	x		
Handling of PPE	x	x	x
Cleaning and disinfection of PPE		x	x
Hazards from reflection or absorption of the laser beam with respect to instruments and other substances, and hazards associated with anaesthetic mixtures		x	x
Developing the local hazard assessment	x	x	
Hazards to the patient associated with laser treatment procedures, and methods of minimizing risks	x	x	
Incidental hazards, such as electrical hazards, fire and explosion risks, cryogenic liquids, atmospheric contamination, smoke and tissue debris	x	x	x
Relevant IEC standards and guidelines (plus national regulations, as appropriate)	x	x	x
Meaning of symbols used on the equipment, as described by the manufacturer of the laser equipment in the accompanying documents	x	x	x
General understanding of facility-based policies, procedures and documentation	x	x	x
Response and procedures following INCIDENTS or ACCIDENTS	x	x	x

Annex E
(informative)

Inspection schedule

E.1 General

During testing and maintenance of a laser and its accessories, there are some important items to be checked prior to use of a laser. The design and applicability of individual tests will depend on the type of laser. Checklists supplied by the manufacturer should be observed.

The recommendations in Annex E are not exhaustive or universally applicable. They outline general inspection and testing procedures.

E.2 Quality assurance (QA) tests

E.2.1 General

The equipment parts discussed in E.2.2 to E.2.13 should be tested regularly at the frequency given in Table E.1.

Table E.1 – Inspection schedule

Subclause number	Equipment part	Recommended frequency of test
E.2.2	Power and footswitch cables	Prior to each use or daily, whichever is the less frequent
E.2.3	Emergency switches	Monthly
E.2.4	USER accessible interlocks	Monthly
E.2.5	Laser emission indicator(s)	Prior to each use or daily, whichever is the less frequent
E.2.6	Beam power or pulse energy	Prior to each use or daily, whichever is the less frequent
E.2.7	Articulated arm movement and physical checks	Prior to commencement of each procedure
E.2.8	Convergence of aiming and main beam	Prior to commencement of each procedure
E.2.9	Fibre (physical check)	Each change of fibre
E.2.10	Aiming beam quality	Prior to each procedure or change of fibre delivery system accessory
E.2.11	Fibre (calibration)	Prior to each use or daily, whichever is the less frequent
E.2.12	Specialized accessories	As appropriate (see text)
E.2.13	Protective eyewear	Monthly

E.2.2 Cables

The mains supply cord and the footswitch cable should be checked for damage, particularly where they join to a plug or socket, before the laser is connected to mains supply. It is also appropriate to check for damage again at the end of a procedure, as cables can be run over or damaged during use.

E.2.3 Emergency switches

Any emergency switches on the laser should be checked at regular intervals to ensure that they function correctly.

E.2.4 Interlocks

Any interlocks (e.g. door, water flow, presence of fibre) should be checked at regular intervals to ensure that they function correctly.

E.2.5 Indicators

Visible and audible laser emission indicators should be checked for correct function at the beginning of each procedure.

E.2.6 Beam RADIANT POWER or pulse energy

There are two main causes of loss of power or energy at the distal end of a transmission system: optical misalignment at any stage or contamination of any of the mirrors, lenses or fibres which form the transmission system. As a result, distal beam power or, alternatively, distal power as a percentage of cavity output (which is measured in many lasers) should be determined regularly. Most manufacturers have built-in or external systems to accomplish this. Even insignificant amounts of contamination on any of the optical components will cause not only loss of power or energy but also absorption of energy, with potential thermal damage to that component. Contaminations on the detectors of internal power meters can result in a false display of the output power. This applies to both pulsed and continuous wave lasers. Distal pulse energy should also be checked (see also E.2.11).

E.2.7 Articulated arm

Before use, any laser using an articulated arm or micromanipulator should be checked for each movement over its full range. The articulated arm should be checked for physical damage and the correct positioning of the lens.

E.2.8 Beam coincidence

For lasers using articulated arms, the coincidence of aiming and working beams should be tested before each use of the laser, and possibly during use, especially if it is suspected that the alignment is disturbed. This can easily be performed with a marked wooden tongue depressor as a target. The aiming beam is used to align the working beam to the marked target. Firing the working beam should eliminate the mark. Coincidence of the aiming beam and the working beam should be calibrated to be within the tolerance specified by the manufacturer. After firing, the burn should be checked for symmetry and uniform depth.

Lenses and mirrors should not be touched as grease from the fingers can result in damage. The manufacturer usually recommends appropriate sterilization and cleaning methods.

E.2.9 Optical fibres

Optical fibres used with lasers should be checked for contamination at both ends and for damage along the entire fibre length prior to connection. A magnifying glass of 10× to 14× magnification and good illumination will prove helpful for this examination.

WARNING: It is hazardous when the inspection is carried out with the fibre connected to the laser and the laser equipment being switched on.

Both ends of the fibre should be clean and free of chips, i.e. damage to the edge or face of the fibre (see E.2.10). Coaxial fibres (those in which a fluid or gas is carried in the fibre) should be checked to ensure that the outlets are open and that the coolant flows freely. There should be

no residuals or fluids trapped in the coaxial fibre. Special accessories such as sapphire tips and other diffusing devices should be checked for cleanliness.

E.2.10 Aiming beam

The quality of the aiming beam at the distal end of the delivery system should be examined prior to use, and occasionally during use. The beam should then be directed at a clean, light coloured surface from a distance of approximately 5 cm to 10 cm. The image should be uniform and circular. Although a small amount of mottling is acceptable, there should be no smears, blotches, scattered light or dark shadows. The presence of these indicates damage or contamination of the delivery system. If the aiming beam is clearly defined and of normal brightness, then the fibre tip is probably in good condition.

E.2.11 Calibration of the RADIANT POWER (see also E.2.6)

There are two main reasons for a variation in the power output of a laser. First, the laser can change its output by several processes such as misalignment of the mirrors. Secondly, the delivery system can cause excessive power loss because of misalignment, contamination or damage. As a result, all lasers should be regularly calibrated, and many have built-in devices to measure RADIANT POWER at the distal end of the delivery system.

Such checks should be regularly performed, usually before each use, and possibly during a procedure if it is suspected that the delivered power has increased or decreased.

The method of calibration can vary according to the laser type and manufacturer. For example, either the actual power delivered or the delivery system transmission can be measured. Most lasers have built-in means of measuring power at the laser cavity. It is important to consider the loss of RADIANT POWER through the delivery system.

The RADIANT POWER delivered by lasers in clinical use possibly does not correspond to the power indicated on the meter of the laser; therefore, the output should be calibrated periodically according to manufacturer's instructions.

Adjustment of the laser and its calibration usually is a matter for the supplier or trained technical specialist.

E.2.12 Specialized accessories

Any accessories designed for laser use (such as laser instruments, smoke evacuators, etc.) should be examined and tested for damage or correct function. This should be performed in accordance with the manufacturer's instructions, or to any requirements set by the LSO.

E.2.13 Protective eyewear

Protective eyewear such as goggles or glasses, as well as special filters used in endoscopes and other devices, should be regularly checked and cleaned. Scratches, cracks, damage to frames, etc. reduce the protective efficiency. The required labelling should also be legible.

E.3 Preventive maintenance

E.3.1 General

All medical laser equipment should be appropriately maintained by a technically competent person.

Maintenance comprises a range of activities including

a) preventive maintenance of the laser and accessories;

b) calibration of the output power, energy and temporal characteristics;

c) tasks of dedicated staff members associated with clinical use.

In order that these activities do not compromise the safety of the staff, they should be carried out in a LASER CONTROLLED AREA, either one already designated or a temporary facility.

Corridors or other *ad hoc* rooms where restriction of access is difficult are not recommended as places to maintain laser equipment.

In addition to the optical radiation safety issues, there are problems associated with collateral radiation and electrical supplies.

E.3.2 Cleaning and disinfection

Prior to the equipment being serviced or repaired, the equipment should be cleaned or disinfected and be free from any contamination that might harm the person carrying out the work.

Appropriate disinfectants that do not damage the laser equipment will normally be recommended by the supplier. The local disinfection policy can provide information about the efficacy of the disinfecting agent against the specific pathogen(s) concerned.

E.3.3 Preventive maintenance checklist

This checklist will usually be specified by the manufacturer and undertaken by the supplier or by suitably qualified staff.

NOTE These staff members will usually be trained by the supplier.

a) Inspect and clean optical components.

b) Check and replace or replenish consumables such as dyes, coolants, filters.

c) Verify the output, aligning the optical cavity as necessary.

d) Verify the correct operation of the shutter, fail-safe interlocks, emergency switches and foot-switches.

e) Verify that all displayed modes of power, energy, pulse values are within the manufacturer's specification.

f) Check that all optical BEAM DELIVERY SYSTEMS are functioning correctly.

g) Check the alignment between the therapy and aiming beams.

h) Verify that the equipment is electrically safe.

E.3.4 Checks prior to use

These are checks prior to each clinical laser session, by the LASER USER. They should include (user's instructions should be observed):

a) checking the condition of the foot-switch cables and power cables for obvious signs of wear;

b) inspecting the laser handpiece including the output lens for signs of damage or contamination;

c) checking fibre optics for damage to the cladding (where applicable), cracking or contamination at the end of the fibre. A 10× magnifier may be used;

WARNING: Do not inspect the end of the fibre while the laser is switched on. Ensure that the laser is disconnected from the mains or the fibre is disconnected from the laser aperture.

d) checking the alignment of the aiming beam and the working beam;

e) checking the laser radiation output at the distal end of the delivery system if a built-in power or energy meter is available;