TECHNICAL REPORT

IEC TR 60825-8

First edition
1999-11

Safety of laser products –

Part 8: Guidelines for the safe use of medical laser equipment

Sécurité des appareils à laser –

Partie 8:
Lignes directrices pour la sécurité d'utilisation des appareils à laser médicaux

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For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams*.

* See web site address on title page.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

SAFETY OF LASER PRODUCTS –

Part 8: Guidelines for the safe use of medical laser equipment

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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Technical reports do not necessarily have to be reviewed until the data they provide are considered to be no longer valid or useful by the maintenance team.

IEC 60825-8, which is a technical report, has been prepared by IEC technical committee 76: Optical radiation safety and laser equipment.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
76/180/CDV	76/194/RVC

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 3.

This document which is purely informative is not to be regarded as an International Standard.

Terms indicated in small capitals are defined in 1.3.

A bilingual version of this technical report may be issued at a later date.

INTRODUCTION

Lasers emit visible and/or invisible optical radiation. In some cases, this radiation is a parallel beam with almost no divergence. This means that the inherently high IRRADIANCE (power per unit of area irradiated) of the laser may be maintained over considerable distances. Because of this, the beam may be focused to a very small area, which may be hazardous to the eye. Annex A includes descriptions of laser systems and some medical applications.

Lasers may present hazards to patients and staff. Serious risks of injury, in particular to the eye, and/or undesired effects can result from lack of protective measures, the use of faulty laser equipment, misdirected beams or inappropriate laser control settings.

This guide is intended to give direction as to how aspects of laser safety may be incorporated into medical laser practice. Its publication as a technical report indicates that it is not intended to take precedence over existing or proposed national guidance. However, where none exists, this guide should prove helpful.

Although the LASER USER has direct responsibility for safety during treatment, the employer bears the responsibility for the setting up of a framework for the safe use of the system. This guide strongly advocates the appointment of a LASER SAFETY OFFICER to provide expert advice to the employer and all personnel concerned with the laser operation. This guide emphasizes the need for appropriate laser safety training for all staff involved in providing practical guidance on installation and maintenance.

SAFETY OF LASER PRODUCTS –

Part 8: Guidelines for the safe use of medical laser equipment

1 General

1.1 Scope and object

This technical report serves as a guide intended to give information to the employer and the USER on the safe use of lasers and laser equipment classified as class 3B or class 4, for diagnostic and therapeutic applications in healthcare facilities. However, particular care should be taken in the use of class 2 and class 3A lasers where the patient's normal aversion response is compromised or absent.

This report explains the control measures recommended for the safety of patients, 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. However, detailed specifications of laser equipment and installation controls are not included in this report, such requirements being separately specified in other standards, e.g. see 1.2.

The subject areas covered in this guide include

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

The object of this report 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.

1.2 Reference documents

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*
Amendment 1 (1991)
Amendment 2 (1995)

IEC 60601-1-1:1992, *Medical electrical equipment – Part 1: General requirements for safety – 1. Collateral standard: Safety requirements for medical electrical systems*

IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-2-22:1995, *Medical electrical equipment – Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment*

IEC 60825-1:1993, *Safety of laser products – Part 1: Equipment classification, requirements and user's guide*

ISO/TR 11991:1995, *Guidance on airway management during laser surgery of upper airway*

1.3 Terminology and definitions

For the purpose of this technical report, the following definitions apply. Reference is also made, as indicated, to IEC 60825-1 and IEC 60601-2-22.

1.3.1
accident
INCIDENT which results in an injury

1.3.2
beam delivery system
fibre optic, handpiece, micromanipulator, scanning device, etc.
See also 2.1.106 of IEC 60601-2-22.

1.3.3
healthcare facility
any hospital, outpatient treatment centre, clinic or the like, where a laser can be used for *in vivo* diagnosis, or surgical or therapeutic purposes on humans

1.3.4
high efficiency particulate-free air filter (HEPA)
porous filter normally used for removing particulate matter from air streams

1.3.5
incident
potentially dangerous situation which could result in an injury to the patient and/or other personnel

1.3.6
irradiance
radiant flux, in watts per unit irradiated area, W/m^2. See also 3.35 of IEC 60825-1.

1.3.7
laser controlled area
area where laser safety controls apply. See also 3.37 of IEC 60825-1.

1.3.8
laser operator
person who operates laser controls (e.g. parameter settings, actuation switch). The LASER OPERATOR may also be the LASER USER.

1.3.9
laser user
person who controls the delivery of the laser radiation to the working area

1.3.10
laser safety officer (LSO)
person who has the authority to monitor and enforce the control of laser safety hazards, and to effect knowledgeable evaluation and control of laser hazards. See also 3.43 of IEC 60825-1.

1.3.11
maximum permissible exposure (MPE)
that level of radiation to which, in normal circumstances, the skin or eye may be exposed without suffering adverse effects. See also A.2 of IEC 60825-1.

1.3.12
nominal ocular hazard area (NOHA)
area around the laser beam inside which the IRRADIANCE or RADIANT EXPOSURE is expected to exceed the MPE. See 3.55 of IEC 60825-1.

1.3.13
nominal ocular hazard distance (NOHD)
distance from the laser aperture below which the IRRADIANCE or RADIANT EXPOSURE is expected to exceed the MPE. See 3.56 of IEC 60825-1.

1.3.14
operator
See LASER OPERATOR.

1.3.15
optical density (OD)
negative of the logarithm to base ten of the factor related to the material's property to attenuate light during transmission, e.g. when the transmission factor is 0,01, the OD is 2; when the transmission factor is 0,00001, the OD is 5. See 3.78 of IEC 60825-1.

1.3.16
pulse duration
time increment measured between the half peak power points at the leading and trailing edges of a pulse. See 3.60 of IEC 60825-1.

1.3.17
radiance
radiant flux emitted by a unit area and propagating in a unit solid angle, expressed in W/m^2sr. See also 3.62 of IEC 60825-1.

1.3.18
radiant exposure
radiant energy per unit irradiated area, expressed in J/m^2. See 3.64 of IEC 60825-1.

1.3.19
radiant power (radiant flux)
power emitted, transferred or received in the form of radiation, expressed in watts. See 3.65 of IEC 60825-1.

1.3.20
remote interlock connector
socket on the laser equipment, allowing for a remotely connected emergency laser switch to make provisions to interrupt the laser's emission with a door interlock or other external safety interlock switches. See also 3.67 of IEC 60825-1.

1.3.21
responsible body
individual or group responsible for the use and maintenance of equipment, and for assuring that LASER OPERATORS and LASER USERS are adequately trained

1.3.22
user
See LASER USER.

2 Hazards, goals and control measures

2.1 Eye hazards

The retina of the eye is particularly susceptible to injury from laser radiation at wavelengths in the visible and near-infrared regions (wavelengths between 400 nm and 1 400 nm). This is because these wavelengths are readily transmitted through the ocular media and focused onto the retina. Due to the focusing action of the eye, the retina may be exposed to an IRRADIANCE that is over 100 000 times the IRRADIANCE arriving at the cornea. Surgical lasers, e.g. Nd-YAG or argon-ion lasers, thus present a potential threat to the eyesight by direct exposure to the beam or by specular (mirror-like) reflections from flat surfaces. Furthermore, looking at diffuse reflections from rough surfaces can be hazardous with surgical lasers at all wavelengths.

The heat generated in retinal tissues exposed to laser radiation can cause rapid and irreversible damage. Injury is dependent on the total RADIANT POWER passing through the pupil, the laser wavelength and its transmission through the ocular media, the duration of the exposure and the size of the image formed. A precise injury threshold is therefore difficult to define. It should be emphasized that, in contrast to other tissues where tiny lesions may not cause significant loss of function, a retinal lesion can cause irreversible loss of central vision.

Wavelengths above 1 400 nm are absorbed in the anterior components of the eye (cornea and aqueous humour). Beyond 1 900 nm, the cornea is considered the sole absorber. Heat produced in the anterior part of the cornea from, for example, a surgical carbon dioxide (CO_2) laser may be conducted to adjacent tissues causing thermal damage. A surgical CO_2 laser may continuously vaporize surface tissue; the cornea of the eye can easily be injured if accidentally exposed to this laser beam.

Other parts of the eye can also sustain injury, depending on the wavelength of the laser radiation. The ultraviolet (UV) spectrum is divided into three specific regions which are related to different biological responses:

– UV-A (315 nm to 400 nm) is strongly absorbed by the lens of the adult eye. The harmful effects of exposure may not become apparent for many years (small lens opacities can form, which may become clinically significant);

– UV-B (280 nm to 315 nm) and UV-C (100 nm to 280 nm) are mainly absorbed by the cornea and conjunctiva and this can lead to inflammation of the cornea (photokeratitis) and conjunctivitis. Damage limited to the outer layer of the cornea may be temporary. Special considerations should be given to those persons who may be at particular risk from UV exposure, e.g. aphakes or photosensitized persons. Refer to annex A.

2.1.1 Goal

Any person who is present within the nominal ocular hazard area (NOHA) should be protected against unintended laser exposure above the maximum permissible exposure (MPE) for the cornea.

2.1.2 Control measures

2.1.2.1 Laser protective eyewear (goggles or glasses)

Unless there is no reasonably foreseeable risk (as assessed by the LSO) that personnel may be exposed to laser radiation in excess of the MPE, eye protection specifically designed for the wavelength(s) and output in use should be worn in addition to any other controls that may be in place. “Personnel” includes the patient, LASER USER, LASER OPERATOR, anaesthetists, assisting staff and spectators. It is one of the duties of the LSO to specify appropriate eyewear, resistant to the power or energy levels of the treatment beam expected during reasonably foreseeable hazard conditions. When the treatment region is close to the eye, the patient’s eye protection should be selected carefully, since the aiming beam as well as the treatment beam IRRADIANCE

or RADIANT EXPOSURE may exceed the MPE. Additionally, the blink reflex may be altered due to anaesthetic drugs.

Laser protective eyewear should be clearly marked with the wavelength(s) and corresponding OPTICAL DENSITY. Additionally, it is recommended that an unambiguous and robust method of marking the laser safety eyewear be employed to ensure that there is a clear link to the particular laser for which it has been specified.

The extent of the NOHA will vary according to the type of laser used and the optical properties of the applicators used. Placement of the laser equipment and the patient within the room can do much to control the direction and reduce the risk of exposure to errant beams.

As an alternative to having many people in the NOHA, which would require many pairs of goggles to be available, consideration should be given to installing a remote video monitor outside the NOHA.

2.1.2.2 Eye protection with viewing optics

When using viewing optics, e.g. endoscopes, microscopes, colposcopes, laparoscopes, 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 accidental firing of the laser when the fibre is out of the endoscope. A risk assessment should be undertaken by the LSO.

2.1.2.3 Windows

Persons behind windows can be adequately protected by means of an opaque material temporarily attached or unfolded at the window inside the room. For carbon dioxide lasers or other lasers which emit at wavelengths longer than approximately 4 000 nm, glass may provide sufficient absorption. Windows and shields should provide sufficient protection against IRRADIANCE for the exposure duration likely to be encountered in normal use, as identified in the risk assessment carried out by the LSO. For possible technical solutions, see annex B.

2.1.2.4 Reflecting surfaces

Reflections from shiny surfaces such as surgical instruments may focus the laser beam, which can be hazardous, particularly to the eyes. Depending on the wavelength and beam configuration, diffuse reflections like that from the irradiated tissue from class 4 lasers [1)] may also be hazardous.

a) Wall and ceiling surface or texture

   The surface of the wall and ceiling should be chosen such that reflections are minimized. The LSO should consider the risks due to possible reflections. A matt finish of any colour will normally meet this requirement.

b) Room equipment

   Glossy surfaces may be found with windows, cupboards, vent frames, fixation frames at tables, infusion stands, sterilization cases, X-ray viewing screens, video monitors, operating room lights, etc. Shiny surfaces may reflect laser radiation in an unpredictable way. The LSO should identify the hazards involved and decide on the appropriate measures to be taken. The checklist as described in annex C may be used.

[1)] Class 3B laser diffuse reflections are not normally considered hazardous.

c) 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, any such instruments which may be used with a laser should either be

– convex with small radii, if polished, or

– roughened, or

– anodized.

The USER should be aware that a surface which does not reflect visible light may reflect long-wavelength infra-red laser radiation such as that from a CO_2 laser. Black instruments may absorb sufficient energy to become hot, causing unintended patient burns. These instruments may 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 annex F.

Reflective surfaces are sometimes used to deflect the laser energy into an otherwise inaccessible operating site. Mirrors or other reflective devices should be suitable for the laser wavelengths and powers or energies employed.

NOTE Glass mirrors may shatter if used at high laser powers.

2.2 Skin hazards

In general terms, the skin can tolerate a great deal more 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 780 nm) and infra-red (780 nm to 1 mm) spectral regions may vary from a mild erythema to severe blisters. See annex A.

2.2.1 Goal

Every person should be protected against unintended hazardous laser exposure.

2.2.2 Control measures (protective clothing)

The LSO should recommend or approve the use of appropriate clothing or covers, as determined from the risk assessment, see annex C.

2.3 Fire and burn hazards

Lasers of class 4 may produce sufficient energy to ignite flammable materials particularly in oxygen enriched atmospheres.

2.3.1 Goal

All personnel including the patient should be sufficiently protected against burns.

2.3.2 Methods of compliance

2.3.2.1 Endotracheal fires

When performing airway laser surgery in the presence of endotracheal tubes, the tube should have adequate protection or be specially designed to reduce the likelihood of fire. For more detailed information on this subject, reference is made to ISO/TR 11991. Fire hazards related to endotracheal tubes, plastics, adhesive tapes, ointment and surgical preparatory solutions can be controlled by various methods. These include (but are not confined to) the use of non-combustible surgical instrumentation, Venturi (jet) ventilation techniques, shielding with wet substances and the use of low-combustion gas mixtures. Anaesthetics personnel should use non-flammable, specially manufactured or adequately protected laser resistant tubes.

Standard plastic and rubber tubes are particularly hazardous and should be avoided, unless there is no practical alternative. There have been ACCIDENTS involving spirally wound metal tapes and these should be avoided. If there is no medical contra-indication, the endotracheal tube cuffs should be inflated with liquid and externally protected with wet swabs.

Since combustion may be initiated in the respiratory/digestive tract in high oxygen concentrations, or in the presence of oxidizing gases (nitrous oxide), the lowest possible concentration of oxygen should be used in laryngo-tracheal procedures. In some cases where co-axial fibres are used, CO_2 can be passed down the fibre at a low rate [2)] to minimize flammability at the laser target site. Care should be taken to monitor $p(O_2)$.

2.3.2.2 Endogeneous combustion

In order to avoid combustion of endogeneous gases like methane in the gastro-intestinal tract, localized ventilation techniques should be employed.

2.3.2.3 Endoscope burns

Care should be taken to avoid laser beam exposure of the sheaths of flexible fibre optic endoscopes since most of the sheaths are flammable. For metallic tubular delivery systems (i.e. bronchoscopes, laparoscopes, laryngoscopes), heating the wall should be avoided to minimize the risk of thermal damage to adjoining tissue.

The USER should check the proper positioning of the laser delivery fibre (or waveguide) within the endoscope prior to releasing the beam. 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 may become excessively heated during laser transmission and may 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.

2.3.2.4 Cleaning, disinfecting and anaesthetic agents

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, time should be allowed for complete dispersal of the agent to take place.

2.3.2.5 Drapes and covers

Sponges, gauze pads and swabs located near the operating field should be moistened with saline or sterile water. If class 4 laser equipment is used, surgical drapes may catch fire. The region of the drape near the operating field should be kept moistened with saline or sterile water.

If the laser handpiece is placed on a dry region of the sterile drape, the drape may be ignited if the laser is accidentally operated, or if the handpiece is hot following use. This may go unnoticed. It should, therefore, become a matter of routine either to cover the aperture with a laser-resistant cap or to put the laser handpiece in a safe holder during a treatment pause and/or to set the laser equipment to stand-by. The laser transmission system should never be left lying on the patient or under uncontrolled conditions.

[2)] The anaesthesiologist should be consulted. A typical rate is 250 cm^3 per minute.

2.4 Fumes, plumes and vapours

In most class 4 laser operations, the vaporization of target tissue produces noxious airborne contaminants. The smoke plume may contain viral particles having a respiratory size of the order of 0,1 µm.

2.4.1 Goal

Laser generated fumes, plumes and vapours should be removed from the operating environment to produce a level which is considered acceptable.

2.4.2 Control measures

2.4.2.1 Dedicated smoke evacuation systems

Masks, including special laser surgical masks, are not recommended for use as the primary method of filtration.

Airborne contaminants should be captured as near as practicable to the source and removed by local exhaust ventilation. This should be designed to ensure that any potentially infectious agents are not passed downstream in the air handling/exhaust system. This may be accomplished with a portable smoke extractor using charcoal or HEPA filters (at least 0,1 µm) with an extraction efficiency at this particle size of more than 99 %. Local extraction of fume also eliminates cellular debris and vapours, thus providing greater visibility for increased precision and safety.

Replaceable filters should be monitored and replaced on a regular basis in accordance with the manufacturer's recommendations.

2.4.2.2 High speed particles

Consideration should be given to protecting the eyes and the respiratory tract from particles which may be ejected at high speed from the treatment site. Laser safety eyewear, if worn, should provide adequate protection for the eyes.

2.4.2.3 Laser plume in the patient's respiratory system

When jet ventilation is applied during laser treatment in the upper respiratory tract, the ventilation flow may transport plume particles and gases into the patient's respiratory system.

2.4.2.4 Surgical suction systems

If the amounts of fume are small, surgical suction may be used to clean the operating site.

2.4.2.5 Scavenging system for anaesthetic gases

The scavenging system for anaesthetic gases may also be used for the removal of fumes from the use of laser systems. Disposable in-line filters may need to be included.

2.5 Collateral hazards

2.5.1 Noxious vapours

Presently, many hazardous gases such as chlorine, fluorine, hydrogen chloride and hydrogen fluoride are used in some laser systems. Care should be taken with their storage and to ensure adequate removal of noxious vapours in the event of failure. Dyes and associated solvents are often toxic. The manufacturer's handling recommendations should be rigorously observed when draining or filling dye lasers. Skin contact with the fluid used and inhalation of its vapour should be avoided. Waste material should be disposed of in an approved manner.

2.5.2 Contaminants from gas containers used in endoscopy

Bacterial contaminants and metallic residues have been found in gas cylinders and pressure regulators. Fibre delivery systems, as well as Venturi ventilation systems, that deliver gas from gas containers to the lumen should therefore be equipped with an in-line filter to remove the contaminants.

2.5.3 Collateral radiation

Many lasers employ high voltage, radio-frequency and intense optical sources for excitation. These high-energy sources can be hazardous both to personnel and other equipment, if not shielded. Under normal conditions, modern laser systems are safe. In order to ensure this, the manufacturer's instructions should be followed by all staff using or maintaining the laser.

2.5.4 Gas embolism

The use of gases in laser surgery in closed body cavities can lead to a risk of gas embolism in the patient. This risk can be minimized by using carbon dioxide, if a gas is required, or by using a fluid. In particular, it is recommended that no gas be used in the uterus.

3 Administrative procedures

3.1 Laser safety officer (LSO)

For installations where lasers of class 3B or class 4 are in use, the RESPONSIBLE BODY should appoint a LASER SAFETY OFFICER (LSO) and define his/her responsibilities. More than one LSO may be appointed where multiple lasers are used. The LSO should be sufficiently knowledgeable to be able to advise the RESPONSIBLE BODY of the healthcare facility on aspects of laser safety which relate to the lasers in use in that facility. In small healthcare facilities, the head or a member of the RESPONSIBLE BODY may assume the role of the LSO, provided the appropriate knowledge is possessed. The LSO should cooperate directly with the USERS 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 Medical laser equipment is frequently used in small clinics whose staff may consist of a single LASER USER and a receptionist. This situation is found in the offices of physicians, podiatrists, dentists and others. The requirements and principles of the safe use of such equipment in these settings are no less stringent than when the same systems are used in large institutional settings such as hospitals. It is the responsibility of the healthcare professional who is using the laser to be aware of the requirements for safe use. In effect, the individual professional USER becomes responsible for consideration of the recommendations for safe use outlined in this report. The professional should assume the administrative responsibilities of the LSO, as well as seeing that all national regulations are met and non-governmental controls are in place. This means that he or she should be trained in laser safety issues, and be responsible for, among others, the LASER CONTROLLED AREA and its warning signs, proper use of protective eyewear and other safety measures both for protection of the patient and other personnel who may be potentially exposed to hazards associated with laser use. The individual should also be responsible for maintenance and other practices required for the safe operation of the healthcare laser equipment he or she is using.

3.1.1 Duties and responsibilities of the LSO

3.1.1.1 Duties

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

3.1.1.2 Responsibilities

More specifically, the responsibilities of the LSO include:

a) performing a hazard assessment of laser treatment areas, including the determination of the nominal hazard area; a scheme of a risk assessment should be followed (see annex C);

b) giving advice to the administrative head and to the responsible person in the area 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 or close to lasers about the hazards and about the safety measures;

e) contributing to the checking and approval of laser equipment according to national regulations 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, e.g. checking that personal protective equipment, laser radiation barriers and laser signs are in place, verifying standard operating procedures, alignment procedures, peri-operative checklists;

g) providing information to the administrative head and to the responsible person in the area about shortcomings and failures of the laser equipment;

h) investigating all ACCIDENTS and INCIDENTS involving lasers, providing information (see 3.3) on preventive measures to those involved, including the dedicated safety specialists of the facility.

Additional responsibilities may include

i) deciding about 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 medical investigations, if a laser ACCIDENT is reported;

m) liaising with national authorities.

3.2 Medical supervision (ophthalmic surveillance)

In the absence of national regulations, the following recommendations should be taken into consideration:

a) the value of medical surveillance of laser workers is a fundamental problem as yet unresolved by the medical profession. If ophthalmic examinations are undertaken, they should be carried out by a qualified specialist and should be confined to workers using class 3B and class 4 lasers;

b) 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 under which the ACCIDENT occurred;

NOTE Specialists performing ophthalmic examinations should be aware that many retinal lesions can be incorrectly attributed to laser damage (see Mainster MA, Sliney DH, Marshall J., Warren KA, Timberlake GT, Trokel SL, *But is it really light damage?*, Ophthalmology, Vol. 104, Nr. 2, February 1997, Guest Editorial).

c) pre-, interim- and post-employment ophthalmic examinations of workers using class 3B and class 4 lasers have value for medico-legal reasons only and are not a necessary part of a safety programme.

3.3 INCIDENT and ACCIDENT reporting

3.3.1 INCIDENT reporting

Any INCIDENT or ACCIDENT arising from the use of the laser should be reported immediately to the LSO. Further use of the laser should be suspended until the LSO has made an investigation and taken steps to ensure that the INCIDENT or ACCIDENT cannot recur.

The LSO should carry out an investigation of any INCIDENT, develop recommendations to prevent recurrence and supply a report to the RESPONSIBLE BODY. The latter, in consultation with the LSO, is strongly advised to circulate the recommendations resulting from the investigation at least to

– all other LSOs of the healthcare facility;
– the biomedical engineering department, as appropriate.

The LSOs are advised to inform the USERS and employees concerned, as appropriate. The LSOs are also advised to keep records of all such INCIDENTS.

NOTE It is understood that any INCIDENT needs an action. Actions include the development of preventive strategies (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 danger. It is therefore mandatory that INCIDENTS which have happened are not allowed to be kept secret, in order to motivate people to freely report the situation, they should not be subjected to sanctions. INCIDENT reporting will more and more become part of modern management techniques, e.g. in terms of quality assurance and ACCIDENT prevention. It appears that, besides the United States FDA activity about collecting and reporting of laser INCIDENTS, very little is known about the severeness and statistics of laser INCIDENTS and ACCIDENTS. Some case reports are rumoured, most of them 'mouth to mouth', but solid facts are rare. However, knowledge of INCIDENTS and ACCIDENTS is the best basis for adequately aimed counter-measures. Therefore, a legalized standardized reporting system would seem worthwhile.

Any INCIDENT, whether an injury occurs or not, provides valuable information from which lessons can be learnt. This is an important part of safety management. The value of exchanging information between healthcare facilities is emphasized.

3.3.2 ACCIDENT reporting

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

3.3.2.1 National ACCIDENT reporting procedure

Not defined in this report.

3.3.3 Reporting scheme

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

a) a summary of the circumstances of the INCIDENT that led to an injury, which should specify
   1) the date, location and time of the INCIDENT,
   2) the names and designations of all staff and other persons involved,
   3) the details of the experience of the injured person,
   4) apparent contributing factors to the INCIDENT,
   5) the LSO's recommendations to prevent a recurrence, and
   6) 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 and/or OPERATOR) who were engaged in the procedure in question and who can give any information relevant to the occurrence of the INCIDENT;

c) medical reports on any injured person;

d) full details of the type of laser product including, in particular, the condition of the equipment immediately after the INCIDENT;

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

3.4 Maintenance and inspection

3.4.1 Acceptance testing

It is recommended that medical laser equipment which is obtained for use in a healthcare facility comply with the safety standards IEC 60601-1 and IEC 60601-2-22, before being put into service. This applies to demonstration as well as to purchased or leased equipment. It is recommended that the LSO participate in the usual procedures which take place when medical equipment of a similar usage or hazard potential is put to use (for example by checking laser-related functions like alignment and power transmission through the optical components, according to the manufacturer's recommendations).

NOTE In some countries compliance with IEC 60601-2-22 is mandatory, before the laser equipment is allowed to be put on the market. In the EU member countries, the legislation (i.e. The Medical Devices Directive) allows marketing of laser equipment which carries the "CE" mark within the EU and no further compliance testing is needed.

3.4.2 Inspection schedule

The LSO should establish an inspection schedule, by reference to annex F. Some inspections may be necessary on a daily basis to check whether or not the equipment functions properly.

4 Training recommendations

The education of staff in medical procedures is not considered in this report.

Laser safety training

The RESPONSIBLE BODY 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 being potentially exposed to the laser and the training should be updated regularly and if circumstances change. For a suggested list of subjects, see annex D.

All training activities should be documented and retained on file.

5 Laser environment

5.1 The laser controlled area

A LASER CONTROLLED AREA should be established around the laser whilst it is in use and when there is a risk of the MPE levels being exceeded within that area. The occupancy and activity of all persons within that area will be subject to control and supervision to prevent exposure to laser radiation in excess of the MPE levels. 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.

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.

5.1.1 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 often 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 are more effective if they are 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.

5.1.2 Illuminated warning indicators

In some circumstances, it may be useful to add an illuminated warning. If used, these warnings must not replace the warning signs required in 5.1.1.

A typical illuminated warning may be in 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”, as long as the wording is not visible when the light is off.

Illuminated warning indicators are more effective when placed at eye level.

5.2 Windows

Refer to 2.1.2.3.

5.3 Walls

Refer to 2.1.2.4 a).

5.4 Door switches and locks

In very exceptional circumstances, it may be necessary to fit a door switch in conjunction with the REMOTE INTERLOCK CONNECTOR to disable the laser if the door to the working area is opened. However, such interruptions may introduce unnecessary and possibly serious delays to a treatment (e.g. while using a laser to control bleeding). If door locks are to be considered, the LSO should consult the fire and safety adviser at the HEALTHCARE FACILITY.

It is usually better to adopt a safe working practice.

5.5 Fire protection

It is recommended that a syringe containing at least 500 ml of sterile water or saline be placed in a convenient position near the operating instruments for use in extinguishing smoldering drapes or small fires.

Where laser procedures are likely to cause fires, consideration may be given to providing CO_2 fire extinguishers in a readily accessible position near or inside the operating theatre. The LSO should be consulted on the desirability of providing fire extinguishers.

5.6 Fume extraction

Refer to 2.4.

Annex A

Biological effects, hazards, laser equipment technology

A.1 Biological effects and hazards

This clause is taken from annex B of IEC 60825-1.

The mechanism by which laser radiation induces damage is similar for all biological systems and may involve interactions of heat, thermoacoustic transients and photo-chemical processes. The degree to which any of these mechanisms is responsible for damage may be related to certain physical parameters of the irradiating source, the most important of which are wavelength, PULSE DURATION, image size, IRRADIANCE and RADIANT EXPOSURE.

In general terms, in suprathreshold exposures, the predominating mechanism is broadly related to the PULSE DURATION of the exposure. Thus, in order of increasing PULSE DURATION, the predominant effects in the following time domains are: nanosecond and sub-nanosecond exposures, acoustic transients; from 100 ms to several seconds, thermal effects, and, in excess of 100 s, photochemical effects.

Laser radiation is distinguished from most other known types of radiation by its beam collimation. This, together with an initial high energy content, results in excessive amounts of energy being 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 a wavelength specific process. Thus, it is the wavelength that determines which tissue a particular laser is liable to damage. When sufficient radiation energy has been absorbed by a system, its component molecules experience an increased vibration, and this is an increase in heat content. Most laser damage is due to the heating of the absorbing tissue or tissues. This thermal damage is usually confined to a limited area extending either side of 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 protein. As indicated above, the occurrence of secondary damage mechanisms in laser impacts can be related to the time course of the tissue heating reaction which is directly related to the PULSE DURATION of the laser. If a CW or long pulse laser system is directed onto a tissue, then because of conduction, the area of the system 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. The beam image size is also of great 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 of a given light. This process is created by absorption of given light energy. Rather than releasing the energy, however, the species undergoes a chemical reaction unique to its excited state. This reaction is believed to be responsible for damage at low levels of exposure.

Short-pulse high-peak power (i.e. Q-switched or mode-locked) lasers may 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 such a rapid rise in temperature that the liquid components of their cells are converted to gas. In most cases, these phase changes are so rapid that they are explosive and the cells rupture. The pressure transients may result from thermal expansion and both may also result in shearing damage to tissues remote from the absorbing layers by bulk physical displacement.

Some biological tissues such as the skin, the lens of the eye and, in particular, the retina may 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 may result in damage to a system if the duration of irradiation is excessive, or if shorter exposures are repeated over prolonged periods. Some of the photochemical reactions initiated by laser exposure may be abnormal, or exaggerations of normal processes.

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.

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

<table>
<tr><th>CIE spectral region *</th><th>Eye</th><th colspan="2">Skin</th></tr>
<tr><td>Ultra-violet C
(180 nm to 280 nm)</td><td rowspan="2">Photokeratitis</td><td>Erythema (sunburn)</td><td rowspan="3">Accelerated skin ageing process</td></tr>
<tr><td>Ultra-violet B
(280 nm to 315 nm)</td><td>Increased pigmentation</td></tr>
<tr><td>Ultra-violet A
(315 nm to 400 nm)</td><td>Photochemical cataract</td><td rowspan="2">Pigment darkening, photosensitive reactions</td></tr>
<tr><td>Visible
(400 nm to 780 nm)</td><td>Photochemical and thermal retinal injury</td><td rowspan="4">Skin burn</td></tr>
<tr><td>Infra-red A
(780 nm to 1 400 nm)</td><td>Cataract, retinal burn</td><td rowspan="3"></td></tr>
<tr><td>Infra-red B
(1 400 nm to 3 000 nm)</td><td>Aqueous flare, cataract, corneal burn</td></tr>
<tr><td>Infra-red C
(3 000 nm to 1 mm)</td><td>Corneal burn only</td></tr>
<tr><td colspan="4">* The spectral regions defined by the CIE are useful in describing biological effects and may not agree perfectly with spectral breakpoints in the MPE tables.</td></tr>
</table>

A.1.1 Hazards to the eye

Visible and near infra-red lasers are a special hazard to the eye because the very properties necessary for the eye to be an effective transducer of light result in high RADIANT EXPOSURE being presented to highly pigmented tissues. The increase in IRRADIANCE from the cornea to the retina is approximately 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 may be as large as 7 mm when maximally dilated in the young eye. The retinal image corresponding to such a pupil may be between 10 µm and 20 µm in diameter. The increase in IRRADIANCE between the cornea and the retina is between 2×10^5 and 5×10^5. If an increase of 5×10^5 is assumed, a 50 Wm^{-2} beam on the cornea becomes $2{,}5 \times 10^7$ Wm^{-2} on the retina. In this guide, 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.

If 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 the pigment called melanin contained in the pigment epithelium. (In the 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 will burn both the pigment epithelium and the adjacent light sensitive rods and cones. This burn or lesion may result in a loss of vision.

Depending on the magnitude of the exposure, such a loss of vision may or may not be permanent. 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, the pit in the centre of the macula, is the most important part of the retina as it is responsible for sharpest vision. It is the portion of the retina that is used "to look right at something". If this region is damaged, the decrement may appear initially as a blurred white spot obscuring the central area of vision; however, within two or more weeks, it may change 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 may not even be detected 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 transparent for radiation of these wavelengths.

In the case of a well-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 diameter. In this case, assuming thermal equilibrium, the retinal zone of hazard is 25 µm minimum in size.

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 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 power increases, while the size of the retinal image can be assumed to remain diffraction-limited (due to the accommodation capabilities of the eye). The greatest hazard occurs at the shortest accommodation distance. With further reduced distance, the hazard is also reduced, as there is a rapid growth of the retinal image and a corresponding reduction of the IRRADIANCE, even though more power may be collected.

For the purpose of this report, the shortest accommodation distance of the human eye is set to 100 mm at all wavelengths from 400 nm to 1 400 nm. This distance was chosen as a compromise, because all but young people and very few myopics cannot accommodate their eyes to distances of less than 100 mm. This distance may be used for the measurement of IRRADIANCE in the case of intrabeam viewing.

For wavelengths of less than 400 nm or more than 1 400 nm, the greatest hazard is damage to the lens or the cornea. Depending on the wavelength, optical radiation is absorbed preferentially or exclusively by the cornea or the lens (see table A.1). For diverging-beam sources (extended or point-type) of these wavelengths, short distances between the source and the eye should be avoided.

A.1.2 Skin hazards

In general terms, the skin can tolerate a great deal more 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 780 nm) and infra-red (780 nm to 1 mm) spectral regions may vary from mild erythema to severe blisters. An ashen charring is prevalent in tissues of high surface absorption following exposure to very short-pulse, high-peak power lasers. This may not be followed by erythema.

Pigmentation, ulceration and scarring of the skin, and damage of underlying organs may occur from extremely high IRRADIANCE. Latent or cumulative effects of laser radiation have not been found prevalent. However, some limited research has suggested that, under special conditions, small regions of human tissue may be sensitized by repeated local exposure, with the result that the exposure level for minimal reaction is changed and the reactions in the tissues are more severe for such low level exposure.

A.2 Maximum permissible exposure (MPE)

The maximum permissible exposure (MPE) is that level of laser radiation to which, in normal circumstances, the eye or the skin may be exposed without suffering adverse effects. These levels are related to the wavelength of the radiation, the PULSE DURATION or exposure time, the tissue at risk and, for radiation in the range of 400 nm to 1 400 nm, the size of the retinal image. The published MPEs are based on exposures causing the minimum injury that can be observed clinically. They vary considerably with the duration of the exposure and the wavelength of the laser radiation, and are lowest in the visible and near infra-red wavelength ranges where the lens, aqueous and vitreous humours are reasonably transparent. The power per unit area INCIDENT on the retina can be of the order of 10^5 times greater than that INCIDENT on the cornea when radiation in this range is focused onto the retina. In this wavelength range, the MPEs are generally a factor of 10 or more below the levels of exposure for which there is a 50 % probability of detecting a retinal injury. The important factor causing injury is the energy density in the absorbing tissue. Recommendations for MPE levels are given in IEC 60825-1. 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 levels. When a laser emits radiation as a series of pulses or in several spectral regions, or where pulses are superimposed upon a continuous wave background, calculation of the hazard may be complex. Details of the method of calculation are given in IEC 60825-1. 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 taken into account when specifying the boundaries of the LASER CONTROLLED AREA within which the occupancy and activity of personnel is subject to control and supervision for the purpose of protection from laser radiation hazards (see clause 13 of IEC 60825-1).

A.3 Laser equipment technology

A.3.1 Laser radiation sources

Most types of laser operate at specific wavelengths which depend primarily on the lasing media and secondly on the engineering design of the optical cavity. To change the wavelength normally involves a change to another system, although dye lasers and some solid state lasers allow different output wavelengths to be selected. At present, this is the exception rather than the rule, but research systems with a wide output range do exist. Lasers in common use range from the CO_2 laser (10,600 nm) with its output in the far infra-red to the Excimer laser (less than 200 nm) in the ultra-violet. Power output ranges from a few milliwatts to many tens of watts in continuous wave lasers. Pulse 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. It is therefore essential to note the following:

– output wavelength(s) (some lasers have more than one output wavelength);
– continuous or pulse output;
– pulse length;
– pulse repetition rate;
– tissue type.

The coherence property of laser radiation is important only for external purposes, as coherence is soon lost on penetrating tissues where absorption and scatter predominate.

A.3.2 Laser radiation delivery systems

A.3.2.1 General

All lasers require a means of transmitting the radiation or light to the treatment site: this is known as a delivery system. The laser wavelength determines the type of delivery system. The four types in common use are:

a) direct delivery;

b) articulated arm;

c) hollow flexible waveguide;

d) fibre optic.

At the treatment site, one of a number of applicators may be attached to the delivery system. Common applicators are:

1) lenses;

2) sapphire contact tips;

3) shaped or sculpted fibres;

4) metallic or ceramic tips;

5) diffusers;

6) micromanipulators;

7) scanners.

A.3.2.2 Direct delivery

Laser pointers, patient positioning lasers and ophthalmic 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 may be controlled by switching the machine on or off, either by a press button or a timer. The beam may be 'steered' by hand or by mechanical means.

A.3.2.3 Articulated arm

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 reflecting mirrors.

Because radiation from ultra-violet or infra-red lasers like the CO_2 laser is invisible, a low power visible laser, typically helium neon (HeNe) or diode laser, is used to designate the target tissue. The invisible and aiming lasers are optically combined to coincide at the applicator or handpiece. They are reflected from special mirrors placed at the front of each joint of the arm and emerge as a coincident, collimated beam.

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

Limitations of an articulated arm

Restrictions have been made because

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 CO_2 beam should be regularly checked for coincidence and spot shape, before and during use. 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 rigorously observed, otherwise expensive lens/mirror coatings may 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 diameter changes very little over distances of some metres, so the IRRADIANCE can be high enough to cause injury, fire or physical damage at a distance from the laser aperture.

A.3.2.4 Hollow waveguide

Many of the limitations of articulated arms have been overcome, in part by the development of hollow waveguides which may be flexible. These devices consist of a hollow tube with a reflective internal coating through which the laser energy can be delivered.

A.3.2.5 Fibre optic

Laser energy can be focused by a lens into a glass fibre and transmitted to emerge as a divergent beam at the fibre tip.

In medicine, the flexible endoscope makes use of fibre optic technology for vision and for light source input. Similar fibres can also be used to deliver a number of different laser wavelengths. Argon and neodymium-yttrium-aluminium-garnet crystal (Nd-YAG) lasers commonly use this technology in their delivery systems.

In the case of invisible near infra-red wavelengths, e.g. a Nd-YAG laser at 1,064 nm, a visible aiming beam is usually combined with the treatment beam at the source to produce a coincident beam. The power of a visible laser beam can be reduced to a safe level to provide the surgeon with a visible aiming beam. The beam power is then increased for surgery, the safety shutter limiting exposure to the surgeon' s eyes.

Typically, 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.

Extreme caution should be exercised when using gas cooling of fibre optic delivery systems in confined body cavities or vascular areas; in some instances, this practice has resulted in fatal gas embolisms.

Limitations of fibre delivery systems

To obtain optimum performance, it is necessary to understand the limitations of the fibre laser delivery system.

For a given power output, any observed change of laser effect on the tissue should be investigated for potential or actual hazards. The likely causes and effects of altered laser performance are as follows:

a) potential separation of the ferrule from the fibre, due to excessive heating from contamination of the non-contact fibre;

b) fibre breakage caused by undetected crimps in the fibre;

c) severe damage to endoscopes, due to firing of the laser while the fibre is inside the endoscope;

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

e) fibre breakage, due to harsh bending, dropping or 'nicking' by a sharp object;

f) failure to allow adequate cooling time for fittings, particularly metal fittings, at either end of the fibre delivery system following laser use, has resulted in cases of tissue burns on patients and OPERATORS. Instrument damage has also occurred;

g) USERS should be aware that the diameter of the treatment beam from an invisible laser can be larger than that of the aiming beam.

A.3.2.6 Handpieces and applicators

a) Applicators with focusing lenses

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 the field (i.e. the region in which the beam remains relatively small).

Limitations of lens systems

The use of lens systems has been limited because:

– applicators using short focal length lenses require precise positioning with respect to the target;

– applicators using long focal length lenses may have a focal spot size which is too large;

– 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 may allow the lens to move;

– the aiming and treatment beams may not coincide in space and this problem may be accentuated after the beams pass through a lens.

b) Sapphire or similar contact tips

Artificial sapphire tips have been developed for medical lasers, predominantly for the Nd-YAG system, in an attempt to improve cutting and coagulation characteristics, limit the treatment area, control the depth of penetration and allow tissue contact. These tips come in a variety of shapes (e.g. conical, cylindrical and spherical) and sizes, and are tailored for different applications. The tip acts as a lens on the end of the fibre delivery system, allowing a reduction in the laser energy required to produce the desired effect. The maximum laser energy typically recommended is up to 20 W, otherwise tip damage may result.

The tips improve the cutting characteristics of the laser by shaping the beam and modifying the energy distribution to the tissue, and allowing greater control of the depth of penetration of the Nd-YAG laser. They also enhance coagulation by permitting direct contact with the tissue. Sapphire tips concentrate the laser light and are a thermal source. Simple coupling can be used to screw on the various types of sapphire tips.

c) Shaped fibres

In another approach to contact laser surgery, the tips of the fibres can be sculpted to conical or hemispherical shapes. The advantages claimed include avoidance of the need for a tip coolant and less susceptibility to breakage than a sapphire tip. The resultant shapes are usually smaller and narrower than sapphire tips, and are generally not suitable for re-use.

d) Metallic or ceramic tips

Laser energy can be used to heat a metallic or ceramic tip to a temperature where the tip can be used as a recanalization probe. A guide wire allowing the tip to track the lumen of a blood vessel is sometimes provided. The metal tips are sometimes provided with a small sapphire 'window' which allows transmission of part of the beam to treat obstructions.

e) Diffusers and photodynamic therapy probes

These probes incorporate a diffuser which spreads the laser light over a relatively large treatment area. To take advantage of the photochemical properties of certain laser wavelengths, a fibre optic delivery system with a diffusing applicator attached has been developed. The diffuser shape determines the energy distribution to the target tissue.

A.3.2.7 Micromanipulators

Micromanipulators and endoscopes 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 moveable mirrors to deflect the beam across a predefined area in a well-controlled manner.

Annex B

Window shielding

Many medical laser applications take place in rooms, such as operating rooms, which have windows. In these cases, it may be necessary to provide window shielding so that the NOHA is restricted to the room boundaries (walls, ceiling, floor). Consideration of whether shielding is required and what type of shielding is appropriate depends on:

– the laser wavelength(s);
– the IRRADIANCE and RADIANT EXPOSURE at the window;
– the need to use the window when the laser is not in operation;
– the fire and/or heat resistance of shielding materials;
– the ease of attachment/detachment of shielding;
– the infection control.

B.1 Laser wavelength

B.1.1 Greater than 4 000 nm

Generally, normal window materials are an adequate barrier.

B.1.2 Less than 4 000 nm

All wavelengths less than 4 000 nm should be assumed to be transmitted efficiently by window materials.

B.2 IRRADIANCE or RADIANT EXPOSURE

In some applications, the IRRADIANCE or RADIANT EXPOSURE at the window may be so low that the MPE is not exceeded. If, however, there is any doubt, the radiation transmitted by the window should be assumed to be hazardous.

B.3 Fire/heat resistance

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

For wavelengths greater than 4 000 nm, under exceptional circumstances, glass may shatter due to thermal stress under high IRRADIANCE. The flammability of materials needs consideration if the IRRADIANCE or RADIANT EXPOSURE are sufficiently high. For most medical laser equipment, these kinds of problems occur only when the beam is almost parallel (of low divergence). Normal, focused laser beam delivery is not necessarily considered to be critical in that respect.

B.4 Attachment/detachment

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

Examples of shielding and attachment are:

– opaque plastic sheets hung on hooks;
– opaque cloth fixed by Velcro-type strips;
– shutters;
– blinds;
– curtains.

Whatever the material and method used, the LSO should evaluate the chosen solution to ensure that there are no gaps in the shielding. 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

Checklist for laser installation

C.1 General

This annex gives guidance on the steps to be taken during the installation of a laser in a HEALTHCARE FACILITY. 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

– employer of authorized personnel;
– LASER SAFETY OFFICER;
– safety organization (could be safety committee and/or responsible person);
– INCIDENT and ACCIDENT reporting procedure (to take note of local, national and statutory requirements).

C.3 Determine background information

C.3.1 Details of laser

– type (make, model, manufacturer, supplier, etc.);
– wavelength(s);
– power/energy/temporal characteristics;
– classification (determines level of protection required for the laser beam only);
– type approved (local or national);
– beam transmission system(s) (all options);
– gas supplies (cylinders, piped gases, sealed);
– dyes (risk assessment needed: solvents, additives, mixing, etc.);
– laser gas exhaust(s).

C.3.2 Other hazards

– operating equipment;
– smoke extraction;
– drapes.

C.3.3 Application

Medical procedures to be undertaken.

C.3.4 Life cycle

Identify the parts of the life cycle for the laser installation to be considered by the healthcare facility, e.g.:

– delivery to the healthcare facility;
– installation;

– commissioning;
– training on use (for each application);
– normal use (for each application);
– maintenance;
– servicing;
– modification;
– decommissioning;
– removal from healthcare facility.

NOTE It is important to recognize that some hazards not specified in C.3.1 and C.3.2 may be accessible during some sections of the life cycle and that each section of the life cycle may put different people at risk.

C.4 Assess risks

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 will, at a minimum, be:

– the laser process, e.g. what is the beam being used for?
– the beam delivery system – how does it get there?
– the laser assembly – where does it come from?
– the room and other equipment;
– the people.

Hazards can be split into two categories: the laser beam and others. Identify risks from hazards during the appropriate sections of the life cycle.

C.4.2 Laser beam

C.4.2.1 Nominal ocular hazard distance (area) for each application.

C.4.2.2 Specification of appropriate protective eyewear needed to reduce reasonably foreseeable exposures to levels below the MPE for the eye for each application.

C.4.2.3 Specification of appropriate protective clothing for each application.

C.4.3 Other hazards

C.4.3.1 Identify control measures for relevant section of life cycle.

C.4.3.2 Assess adequacy, i.e. whether risk is acceptable.

C.5 Define

C.5.1 Laser controlled area

C.5.1.1 Boundaries

– walls (reflections);
– windows (locations, transmission, blinds etc.);
– doors (positions, viewing panels, etc.);
– ceilings.

C.5.1.2 Installation

– warning signs (positions);
– remote interlock(s) (use or not);
– utilities (water, air, gases, power);
– fire precautions (extinguishers, blankets, etc.).

C.6 Authorize and train personnel

This applies to safety training. Each organization should set clinical requirements which should be met by USERS:

– clinical USERS (including paramedical staff);
– technical USERS (manufacturers, engineers, bio-engineers, etc.);
– other USERS;
– maintain training records (may be formal training and on-the-job training).

C.7 Write operating procedures

C.7.1 Operating procedure

The operating procedure should contain a synopsis of the safety requirements of the installation and the operating instructions for the laser.

C.7.2 Pre-use testing

Pre-use testing should be specified according to the laser type, particularly testing power, shutter, control mechanisms and automatic scanning, if appropriate.

C.7.3 INCIDENT procedure

INCIDENT procedure should be documented for USERS to implement when necessary.

C.8 Audit annually

C.8.1 Installation

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

C.8.2 Risk assessment

It may be necessary to formally record the significant findings of the risk assessment to satisfy local, national or statutory requirements. The risk assessments may also need regular review, in particular when new applications are to be carried out.

Annex D

Laser safety training

The following syllabus is recommended for laser safety training. It should be adapted in length and content by the LASER SAFETY OFFICER to suit the laser equipment to be used and the role of the persons involved.

The syllabus is *not* sufficiently detailed for the training of the LASER SAFETY OFFICER.

– Characteristic features of laser radiation emitted from different types of laser
– Generation of laser radiation and hazards
– Principles of quality assurance
– Equipment management
– Laser-tissue interactions
– Effects of exposure of eye and skin to laser radiation
– Laser safety management, role of the LSO and investigation of suspected cases of accidental exposure
– LASER CONTROLLED AREAS, – boundaries, – warning signs, – access control
– Personal protective equipment
– Hazards from reflection or absorption of the laser beam with respect to instruments and other substances, and hazards associated with anaesthetic mixtures
– Precautions to ensure that exposure of unprotected skin and eyes of those present is less than the maximum permissible levels
– Hazards to the patient associated with laser treatment procedures, and methods of minimising risks
– Incidental hazards, such as electrical hazards, fire and explosion risks, cryogenic liquids, atmospheric contamination, smoke and tissue debris
– Relevant IEC standards and guidelines (plus national regulations, as appropriate)
– Principles of risk assessment and management

This material may normally be covered in lectures totalling approximately 4 h. This gives an indication of the depth of knowledge required.

Annex E

Inspection schedule

E.1 General

Although the USER cannot undertake the complete testing and maintenance of a laser and its accessories, there are some important items that should be checked prior to commissioning and during the service life 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 this annex should not be considered as exhaustive or universally applicable. They outline general inspection and testing procedures.

The LSO should be responsible for either carrying out these tests or arranging for a qualified person to do so.

E.2 Quality assurance (QA) tests

E.2.1 General

Regular testing of the following equipment parts is recommended at the frequency given in table E.1.

E.2.2 Cables

Power and footswitch cables should be checked for damage, particularly where they join to a plug or socket, before the laser is connected to the power. 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 power

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 may 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 small amounts of contamination on any of the optical components will cause not only loss of power/energy but also absorption of energy, with potential thermal damage to that component. This applies to both pulse lasers 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 treatment beams should be tested before each use of the laser, and possibly during use, especially if it is suspected that the alignment may have been disturbed. This can easily be performed with a marked wooden tongue depressor as a target. The aiming beam is used to align the treatment laser to the marked target. Firing the treatment beam should eliminate the mark. Coincidence of the aiming beam and the treatment beam should always 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 hands may result in damage. Only the sterilization and cleaning methods recommended by the manufacturer should be used.

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 be required for this examination.

WARNING: Do not use a magnifying glass if the fibre is connected to the laser.

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 exit holes 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 also 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 be directed at a clean, white surface from a distance of some 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 Delivery power calibration (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 a number of 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 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 may vary according to the laser type and manufacturer. For example, either the actual power delivered or the delivery system transmission may be measured. Most lasers have built-in means of measuring power at the laser cavity. It is important to consider the loss of power through the delivery system.