TECHNICAL REPORT

IEC TR 60825-8

Second edition
2006-12

Safety of laser products –

Part 8: Guidelines for the safe use of laser beams on humans

Reference number
IEC/TR 60825-8:2006(E)

Publication numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series. For example, IEC 34-1 is now referred to as IEC 60034-1.

Consolidated editions

The IEC is now publishing consolidated versions of its publications. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

Further information on IEC publications

The technical content of IEC publications is kept under constant review by the IEC, thus ensuring that the content reflects current technology. Information relating to this publication, including its validity, is available in the IEC Catalogue of publications (see below) in addition to new editions, amendments and corrigenda. Information on the subjects under consideration and work in progress undertaken by the technical committee which has prepared this publication, as well as the list of publications issued, is also available from the following:

- **IEC Web Site (www.iec.ch)**

- **Catalogue of IEC publications**

  The on-line catalogue on the IEC web site (www.iec.ch/searchpub) enables you to search by a variety of criteria including text searches, technical committees and date of publication. On-line information is also available on recently issued publications, withdrawn and replaced publications, as well as corrigenda.

- **IEC Just Published**

  This summary of recently issued publications (www.iec.ch/online_news/ justpub) is also available by email. Please contact the Customer Service Centre (see below) for further information.

- **Customer Service Centre**

  If you have any questions regarding this publication or need further assistance, please contact the Customer Service Centre:

  Email: custserv@iec.ch
  Tel: +41 22 919 02 11
  Fax: +41 22 919 03 00

TECHNICAL REPORT

IEC TR 60825-8

Second edition
2006-12

Safety of laser products –

Part 8: Guidelines for the safe use of laser beams on humans

International Electrotechnical Commission, 3, rue de Varembé, PO Box 131, CH-1211 Geneva 20, Switzerland
Telephone: +41 22 919 02 11 Telefax: +41 22 919 03 00 E-mail: inmail@iec.ch Web: www.iec.ch

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE W

For price, see current catalogue

CONTENTS

FOREWORD 3
INTRODUCTION 5

1 Scope and object 6
2 Normative references 6
3 Terms and definitions 6
4 Hazards, goals and control measures 9
4.1 Risks to eyes 9
4.2 Risks to skin 10
4.3 Fire and burn hazards 11
4.4 Fumes, plumes and vapours 12
4.5 Collateral hazards 13
5 Administrative procedures 13
5.1 LASER SAFETY OFFICER (LSO) 13
5.2 Medical supervision (ophthalmic surveillance) 15
5.3 INCIDENT and ACCIDENT reporting 15
5.4 Maintenance and inspection 16
6 Training recommendations 16
7 Laser environment 17
7.1 The LASER CONTROLLED AREA 17
7.2 Windows 18
7.3 Walls 18
7.4 Fire protection 18

Annex A (informative) Biological effects, hazards, laser equipment technology 19
Annex B (informative) Window shielding 26
Annex C (informative) Checklist for laser installation 27
Annex D (informative) Laser safety training 30
Annex E (informative) Inspection schedule 31
Annex F (informative) Safety issues in laser applications 36

Bibliography 40

Table A.1 – Summary of pathological effects associated with excessive exposure to light 20
Table E.1 – Inspection schedule 33

INTERNATIONAL ELECTROTECHNICAL COMMISSION

SAFETY OF LASER PRODUCTS –

Part 8: Guidelines for the safe use of laser beams on humans

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with an IEC Publication.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

The main task of IEC technical committees is to prepare International Standards. However, a technical committee may propose the publication of a technical report when it has collected data of a different kind from that which is normally published as an International Standard, for example "state of the art".

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

This second edition cancels and replaces the first edition published in 1999. It constitutes a technical revision. This second edition, which is the result of continued maintenance work on the previous edition, reflects more thorough consideration of the hazards involved. It also takes into account newer laser technology and laser radiation supply instrumentation, and addresses refined application procedures. Additionally, this second edition implements more recent information available from other standards relevant to safety procedures, which have been revised in recent years. Further technical developments in this area will be reflected on an ongoing basis in future amendments or editions of this technical report.

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

Enquiry draft	Report on voting
76/316/DTR	76/329/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 2.

Terms indicated in small capitals are defined in Clause 3.

A list of all parts of the IEC 60825-8 series, published under the general title *Safety of laser products,* can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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

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 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 or skin. Annex A includes descriptions of laser systems and some medical applications.

Lasers may present hazards to anyone present during the operation of the laser. 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 OPERATOR has direct responsibility for safety during laser use, 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, operation, maintenance and servicing.

SAFETY OF LASER PRODUCTS –

Part 8: Guidelines for the safe use of laser beams on humans

1 Scope and object

This part of IEC 60825 serves as a guide to the employer, the RESPONSIBLE ORGANISATION, the LASER SAFETY OFFICER, the LASER OPERATOR and other persons involved, on the safe use of lasers and laser equipment classified as class 3B or class 4. It covers all applications of laser beams on humans in, but not limited to, health-care facilities, cosmetic and hair removal centres and dental practices, including applications in vehicles and domestic premises.

NOTE Although the scope excludes laser classes lower than class 3B and 4, it is appropriate to state, that particular care should be taken when levels of laser energy are used below the Class 3B and 4 limits when the individual's normal AVERSION RESPONSES are compromised or absent.

This technical 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.

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.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

None.

3 Terms and definitions

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

NOTE Reference is also made, as indicated, to individual terms and definitions in IEC 60825-1 and IEC 60601-2-22.

3.1
accident
unforeseen situation which results in an injury to the patient and/or other personnel

3.2
aversion response
movement of the eyelid or the head to avoid an exposure to a noxious stimulant or bright light

NOTE For visible lasers the AVERSION RESPONSE is assumed to occur within 0,25 s.

3.3
beam delivery system
optical system which delivers the laser beam to the target area, focuses or shapes the laser beam and makes it manoeuvrable

NOTE 1 Examples of a beam delivery system include fibre optic, handpiece, micromanipulator or scanning device.

NOTE 2 See also 2.1.106 of IEC 60601-2-22.

3.4
incident
potentially dangerous situation which could result in an injury to the patient and/or other personnel

3.5
irradiance
RADIANT POWER divided by the irradiated area

NOTE See also 3.39 of IEC 60825-1. IRRADIANCE is expressed in Wm^{-2}.

3.6
laser controlled area
area where laser safety controls apply

NOTE See also 3.41 of IEC 60825-1.

3.7
laser operator
person who handles the laser equipment and in general controls the application of the laser radiation at the working area

NOTE The LASER OPERATOR may appoint other person(s), who assist with the selection and/or setting of the parameters.

3.8
laser safety officer
LSO
one who is knowledgeable in the evaluation and control of laser hazards and has responsibility for oversight of the control of laser hazards

[IEC 60825-1, definition 3.47]

3.9
maximum permissible exposure
MPE
that level of radiation to which, in normal circumstances, the skin or eye may be exposed without suffering adverse effects

NOTE See also 3.55 and A.2 of IEC 60825-1.

3.10
nominal ocular hazard area
NOHA
area within which the IRRADIANCE or RADIANT EXPOSURE can exceed the MPE

NOTE See also 3.59 of IEC 60825-1.

3.11
nominal ocular hazard distance
NOHD
distance from the laser aperture within which the IRRADIANCE or RADIANT EXPOSURE can exceed the MPE

NOTE See also 3.60 of IEC 60825-1.

3.12
operator
See LASER OPERATOR.

3.13
optical density
OD
value that defines the attenuation property of a filter

NOTE For example, when the attenuation value is 1/100, the OD is 2; when the value is 100 000, the OD is 5. See 3.86 of IEC 60825-1.

3.14
pulse duration
time increment measured between the half peak power points at the leading and trailing edges of a pulse

[IEC 60825-1, definition 3.65]

3.15
radiant exposure
radiant energy divided by the irradiated area

NOTE See also 3.69 of IEC 60825-1. RADIANT EXPOSURE is expressed in Jm^{-2}.

3.16
radiant power
power emitted, transferred or received in the form of radiation

[IEC 60825-1, definition 3.70]

NOTE RADIANT POWER is expressed in watts.

3.17
remote interlock connector
socket or terminal on the laser equipment, allowing for connection of a remote interlock to make provisions to interrupt the laser's emission with a door interlock or other external safety switches

NOTE See also 3.72 of IEC 60825-1.

3.18
responsible organisation
individual or group responsible for the use and maintenance of equipment, and for assuring that LASER OPERATORS are adequately trained

3.19
ultra low penetration air filter
ULPA
porous filter normally used for removing particulate matter from the laser plume

4 Hazards, goals and control measures

4.1 Risks to eyes

The eye is at risk of injury from laser radiation in excess of the MAXIMUM PERMISSIBLE EXPOSURE (MPE). In particular, laser radiation at wavelengths between 400 nm and 1 400 nm may be focussed onto the retina resulting in permanent damage to vision. Refer to Annex A.

4.1.1 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.

4.1.2 Control measures

4.1.2.1 Laser protective eyewear (goggles or glasses)

Unless there is no reasonably foreseeable risk (as assessed by the LSO, see Clause C.4) 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, the LASER OPERATOR, the anaesthetist, assisting staff and others. It is one of the duties of the LSO to specify appropriate eyewear, resistant to the power or energy levels of the working beam expected during reasonably foreseeable hazard conditions. When the target area is close to the eye, the patient’s eye protection should be selected carefully, since the aiming beam as well as the working beam IRRADIANCE or RADIANT EXPOSURE may exceed the MPE. Additionally, the AVERSION RESPONSE may be altered due to anaesthesia or sedation.

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.

NOTE There is concern that eyewear with correct OPTICAL DENSITY may shatter, if subjected to laser radiation with very high IRRADIANCE or RADIANT EXPOSURE. The European Standard EN 207:2002 contains the requirement, that the eyewear has to withstand such high IRRADIANCE or RADIANT EXPOSURE as long as 10 s. In many EU member countries, laser eyewear has to comply with this standard, In other countries, laser eyewear may not necessarily comply.

4.1.2.2 Eye protection with viewing optics

When using viewing optics, e.g. endoscopes, 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 out of the endoscope. A risk assessment should be undertaken by the LSO.

4.1.2.3 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 or plastics 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.

4.1.2.4 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 from the irradiated tissue from class 4 lasers may also be hazardous. In order to reduce hazards due to reflected laser radiation the following should be considered:

NOTE Class 3B laser diffuse reflections are not normally considered 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 minimize the reflections.

b) Room equipment

   Glossy surfaces may be found with windows, cupboards, vent frames, 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.

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.

The OPERATOR 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 OPERATOR 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.

4.2 Risks to skin

Although an acute skin injury resulting from exposure to laser radiation is less likely to affect the individual's quality of life, it should be recognised that the skin presents a much larger target than the eye and therefore the probability of exposure may be higher. Of particular concern is exposure of the skin to laser radiation below 400 nm, which may increase the risk of skin cancer. Refer to Annex A.

4.2.1 Goal

All personnel including the patient/client should be sufficiently protected against unintended hazardous laser exposure.

4.2.2 Control measures

The LSO should recommend or approve the use of appropriate clothing or drapes of low flammability, as determined from the risk assessment, see Annex C. When working with lasers in the UV region, a protective skin cream should be considered to be used, in order to avoid an erythema.

4.3 Fire and burn hazards

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

4.3.1 Goal

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

4.3.2 Methods of compliance

4.3.2.1 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 to minimize flammability at the laser target site. Care should be taken to monitor $p(O_2)$.

NOTE The anaesthesiologist should be consulted. A typical rate is 250 cm^3 per minute.

4.3.2.2 Endogeneous combustion

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

4.3.2.3 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 of the wall should be avoided to minimize the risk of thermal damage to adjoining tissue.

The OPERATOR 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.

4.3.2.4 Cleaning, disinfecting and anaesthetic agents

Any new agent used with a laser should be checked for flammability before use. The OPERATOR 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.

4.3.2.5 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. However, it should be considered that the sterility can be compromised and that the hazard of leakage current can occur.

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 procedure 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. See ISO 11810-1 and ISO 11810-2[1)],

4.4 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.

4.4.1 Goal

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

4.4.2 Control measures

4.4.2.1 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. The evacuation system 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 smoke extractor using ULTRA LOW PENETRATION AIR FILTER (ULPA) filters (at least 0,1 μm) with a filtration efficiency at this particle size of not less than 99,999 %. Local extraction of fume also eliminates cellular debris and vapours, thus providing greater visibility for increased precision and safety.

---

1) ISO 11810-2, to be published.

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

4.4.2.2 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 target site. Laser safety eyewear, if worn, can be assumed to provide adequate protection for the eyes.

4.4.2.3 Laser plume in the patient's respiratory system

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

4.4.2.4 Surgical suction systems

If the amounts of plume are small, surgical suction equipped with a disposable in-line filter should be used to remove the plume from the operating site.

4.5 Collateral hazards

4.5.1 Noxious vapours

Presently, 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.

4.5.2 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 patient should therefore be equipped with an in-line filter to remove the contaminants.

4.5.3 Collateral radiation and high voltages

Many lasers employ high voltage, radio-frequency or 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 from collateral radiation and high voltage hazards. In order to ensure this, the manufacturer's instructions should be followed by all staff using or maintaining the laser.

4.5.4 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 small cavities.

5 Administrative procedures

5.1 LASER SAFETY OFFICER (LSO)

For installations where lasers of class 3B or class 4 are in use, the RESPONSIBLE ORGANISATION should appoint a LASER SAFETY OFFICER (LSO) and define his/her responsibilities. The LSO should be sufficiently knowledgeable to be able to advise the RESPONSIBLE ORGANISATION on

aspects of laser safety which relate to the lasers in use in that facility. A member of the RESPONSIBLE ORGANISATION may assume the role of the LSO. The LSO should cooperate directly with the operator 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 OPERATOR may assume this role.

NOTE Medical laser equipment is frequently used in small clinics whose staff may consist of a single LASER OPERATOR 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 OPERATOR who is using the laser to be aware of the requirements for safe use. In effect, the individual professional OPERATOR 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.

5.1.1 Duties and responsibilities of the LSO

5.1.1.1 Duties

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

5.1.1.2 Responsibilities

More specifically, the responsibilities of the LSO include:

a) performing a hazard assessment of laser working 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 5.3) 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.

5.2 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.

5.3 INCIDENT and ACCIDENT reporting

5.3.1 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 ORGANISATION. The latter, in consultation with the LSO, is strongly advised to circulate the recommendations resulting from the investigation at least to

– all other LSOs appointed by the RESPONSIBLE ORGANISATION;
– the biomedical engineering department, as appropriate.

The LSOs are advised to inform the OPERATORS 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 strongly recommended 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 severity and statistics of laser INCIDENTS and ACCIDENTS. However, knowledge of INCIDENTS and ACCIDENTS is the best basis for adequately aimed counter-measures. Therefore, a legalized standardized reporting system is worthwhile and established in some countries.

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 disseminating this information widely is emphasized.

5.3.2 ACCIDENT reporting

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

5.3.2.1 National ACCIDENT reporting procedure

Not defined in this report.

5.3.3 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 or ACCIDENT that led to an injury, which should specify
   1) the date, location and time,
   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,
   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 OPERATOR and/or assistants) 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, in particular, the condition of the equipment immediately after the INCIDENT;
e) listing of equipment in use during the procedure with appropriate identification information.

5.4 Maintenance and inspection

5.4.1 Acceptance testing

It is recommended that laser equipment which is obtained for use within the scope of this technical report comply with the safety standard IEC 60601-2-22, before being put into service. This applies to demonstration lasers as well as to purchased or leased laser equipment.

NOTE In some countries compliance with IEC 60601-2-22 is documented by the CE mark indicating conformity with the European Medical Device Directive.

5.4.2 Inspection schedule

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

6 Training recommendations

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

- **Laser safety training**

The RESPONSIBLE ORGANISATION 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 beam 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.

7 Laser environment

7.1 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 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 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.

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

7.1.1 Entry way controls

7.1.1.1 Warning signs

Every entrance to a LASER CONTROLLED AREA should be marked with a laser warning and other signs according to national requirements (see note). 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 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.

NOTE If there is doubt on the kind of laser warning to be used, the reader is advised to refer back to the national authorities, e.g. the national committee for standardisation. It may also be helpful to use the warning label, as shown in IEC 60825-1, Figure 14.

7.1.1.2 Illuminated warning indicators

In some circumstances, it may be useful to provide an illuminated warning in addition to the warning sign, as described in 7.1.1.1

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.

7.1.1.3 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 procedure (e.g. while using a laser to control bleeding).

NOTE If door locks are to be considered, the LSO should obtain fire and safety advice. It is usually better to adopt a safe working practice.

7.2 Windows

Refer to 4.1.2.3.

7.3 Walls

Refer to 4.1.2.4 a).

7.4 Fire protection

See 4.3. It is recommended that an open bowl of water (sterile or saline, as required) be placed in a convenient position near the operating instruments for use in extinguishing smoldering drapes or small fires. Some drape materials cannot be extinguished by water; in these or similar cases fire blankets may be considered as an additional safety measure.

Where laser procedures are likely to cause fires, consideration should be given to providing electrical equipment 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 to determine the necessary range of fire control measures.

It should be considered that the water used to extinguish fire should never get in contact with electrical equipment, because of the severe risk of causing electrical shock

Annex A
(informative)

Biological effects, hazards, laser equipment technology

A.1 Biological effects and hazards

The mechanism by which laser radiation induces damage is similar for all biological systems and may involve interactions of heat, thermo-acoustic 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 supra-threshold 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 and non-linear effects; from 1 ms to several seconds, thermal effects, and, in excess of 10 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, this energy is usually transformed into heat. 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 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 (continuous wave) 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. Heat is also removed by the blood flow through convection. 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 at a given wavelength of radiation. Rather than releasing the energy, however, the species undergoes a chemical reaction unique to its excited state.

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 [a]</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 rowspan="2">Erythema
(sunburn)
Accelerated skin ageing process
Increased pigmentation</td><td rowspan="2">Accelerated skin ageing process</td></tr>
<tr><td>Ultra-violet B
(280 nm to 315 nm)</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><td rowspan="5">Skin burn</td></tr>
<tr><td>Visible
(400 nm to 780 nm)</td><td>Photochemical and thermal retinal injury</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">[a] The spectral regions defined by the CIE are short-hand notations 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. 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 Wm^{-2} beam on the cornea becomes 1×10^7 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 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 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 to 20 μm diameter. In this case, assuming thermal equilibrium, the retinal zone of hazard is determined by the limiting angular subtense α_{min}, which generally corresponds to retinal spot of approximately 25 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 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 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 a few young people and very few myopes 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 can 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 may vary from burning trauma grade I to grade III.

- MAXIMUM PERMISSIBLE EXPOSURE (MPE)

Maximum permissible exposure values are for users and are set below known hazard levels, and 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. In any case, exposure to laser radiation should be as low as possible.

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 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.

Recommendations for MPE levels are given in IEC 60825-1. These levels should be used as guidance in the control of exposure. 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 access to laser radiation and activity of personnel is subject to control and supervision for the purpose of protection from laser radiation hazards

NOTE See Clause 13 of IEC 60825-1.

A.2 Laser equipment technology

A.2.1 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. 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 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. 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 like the following:

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

The coherence property of laser radiation is important only for OCT (optical coherence tomography), e.g. in the eye, but in tissues coherence is soon lost on penetrating tissues where scattering predominates.

A.2.2 Laser radiation delivery systems

A.2.2.1 General

All lasers require a means of transmitting the radiation to the target 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.

One of a number of applicators may be attached to the delivery system, such as:

– lenses;
– side fire tips;
– shaped or sculpted fibres;
– bare fibres;
– diffusers;
– micromanipulators;
– scanners.

A.2.2.2 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 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.2.2.3 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.2.2.4 Hollow waveguide

Some of the limitations of articulated arms may 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.2.2.5 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 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 working 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.

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.

- *Limitations of fibre delivery systems*

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) heated up fittings, particularly metal fittings, at either end of the fibre delivery system following laser use, have resulted in cases of tissue burns on patients and OPERATORS. Instrument damage has also occurred. Adequate cooling time should be allowed;

g) the diameter of the working beam from an invisible laser can be larger than that of the aiming beam;

h) beam leakage at locations of small radius bends in fibres.

A.2.2.6 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 focus.

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 for obtaining the required power density;

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

b) 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.2.2.7 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.2.2.8 Scanners

Scanners use devices such as moveable mirrors to deflect the beam across a predefined area in a well-controlled manner.

Annex B
(informative)

Window shielding

B.1 Overview

Many medical laser applications take place in rooms, such as operating rooms, which have windows. Window shieldings restrict the NOHA 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.2 Laser wavelength

Generally, glass windows are assumed to transmit laser radiation efficiently. At wavelengths beyond 2 500 nm glass windows absorb laser radiation and can be regarded as an adequate barrier.

B.3 Fire/heat resistance

The IRRADIANCE or RADIANT EXPOSURE which could be reached at the window is 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 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, focused or diverging laser beam delivery is not necessarily considered to be critical in that respect.

B.4 Attachment/detachment

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:

– opaque plastic sheets hung on hooks;
– opaque cloth fixed by hook-and-loop closure (e.g.Velcro®) strips;
– shutters;
– blinds;
– curtains.

Some shieldings have 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

This annex 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

– 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 relevant 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

Procedures to be undertaken.

C.3.4 Life cycle

Parts of the life cycle for the laser installation to be considered, e.g.:

– delivery;
– installation;

– commissioning;
– training on use (for each application);
– normal use (for each application);
– maintenance;
– servicing;
– modification;
– decommissioning;
– disposal.

NOTE 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 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:

– 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. There are risks from hazards during the different 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.

C.4.2.3 Specification of appropriate protective clothing for each application with specific consideration to potential skin exposure to ultraviolet radiation.

C.4.3 Other hazards

C.4.3.1 Control measures for relevant section of life cycle of the laser installation.

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 Authorization and training of personnel

As applies to safety training, consider clinical requirements to be met by OPERATORS:

– clinical OPERATORS (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 Operating procedures

C.7.1 Operating procedure

Synopsis of the safety requirements of the installation and the operating instructions for the laser.

C.7.2 Pre-use testing

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

C.7.3 INCIDENT procedure

INCIDENT procedure documented for OPERATORS to implement when necessary.

C.8 Audit annually

C.8.1 Installation

Arrangements to audit the installation annually and to train other persons to audit it periodically. Maintain 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. The risk assessments may also include regular review, in particular when new applications are to be carried out.

Annex D
(informative)

Laser safety training

The following syllabus may be part of a laser safety training. It may be adapted in length and content 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
– Relevant symbols used on the equipment, as described by the manufacturer of the laser equipment in the accompanying documents.

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

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 may be informative, highlighting important items to be checked.

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

E.2 Quality assurance (QA) tests

E.2.1 General

The following equipment parts may be tested regularly at the frequency given in Table E.1.

E.2.2 Cables

Power and footswitch cables may 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 may 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) may be checked at regular intervals to ensure that they function correctly.

E.2.5 Indicators

Visible and audible laser emission indicators may 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) may 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. Contaminations on the detectors of internal power meters may result in a false display of the output power. This applies to both pulse lasers and continuous wave lasers. Distal pulse energy may also be checked (see also E.2.11).

E.2.7 Articulated arm

Before use, any laser using an articulated arm or micromanipulator may be checked for each movement over its full range. The articulated arm may 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 may 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 working beam to the marked target. Firing the working beam should eliminate the mark. Coincidence of the aiming beam and the working beam may be calibrated to be within the tolerance specified by the manufacturer. After firing, the burn may be checked for symmetry and uniform depth.

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

E.2.9 Optical fibres

Optical fibres used with lasers may 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 may be hazardous to carry out the inspection with the fibre connected to the laser and the laser power 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) may 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 may also be checked for cleanliness.

E.2.10 Aiming beam

The quality of the aiming beam at the distal end of the delivery system may be examined prior to use, and occasionally during use. The beam should then 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 may 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.

The RADIANT POWER delivered by lasers in clinical use may not correspond to the power indicated on the meter of the laser; therefore, the output should be measured periodically with a calibrated power meter to ensure the accuracy of meters incorporated in the laser system.

Adjustment of the laser and its calibration may be 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.) may be examined and/or tested for damage and/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, may be regularly checked and cleaned. Scratches, cracks, damage to frames, etc. reduce the protective efficiency. The required labelling should also be legible.

Table E.1 – Inspection schedule

Clause 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	OPERATOR 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/pulse energy	Prior to each use or daily, whichever is the less frequent
E.2.7	Articulated arm movement and physical checks	Commencement of each procedure
E.2.8	Convergence of aiming and main beam	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.3 Preventive maintenance

E.3.1 General

It is recommended that 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) OPERATOR tasks associated with clinical use.

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

NOTE Corridors or other *ad hoc* rooms where restriction of access is difficult are not recommended as places to maintain laser equipment. It should be noted that, 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, it is recommended that the equipment be cleaned and/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 may be consulted to assess the efficacy of the disinfecting agent against the specific pathogen(s) concerned.

E.3.3 Preventive maintenance check list

This check list will normally be specified by the manufacturer and undertaken by the supplier or by suitably qualified staff.

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

a) Inspect and clean optical components.

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

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 OPERATOR checks

OPERATORS are advised to carry out a number of simple but useful checks prior to each clinical laser session. These may include

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

b) inspecting the laser handpiece for signs of damage and/or contamination. In particular look for contamination on the output lens;

c) checking fibre optics for damage to the cladding (where applicable), cracking or contamination at the end of the fibre. A 10× magnifier is suitable for this purpose;

   WARNING: Do not inspect the end of the fibre while the laser is in 'ready' mode. Ensure that the laser is in stand-by or the fibre 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/energy meter is available;

f) checking the emergency off-switch operation;

g) checking the protective eyewear for availability and integrity.

Annex F
(informative)

Safety issues in laser applications

NOTE This annex is intended to provide information about laser safety issues in common application areas. It is *not* concerned with medical procedure details or issues related to manufacturers' requirements, which are covered by IEC 60601-2-22.

F.1 General

In order to improve good safe practices in any of the following application areas, it is recommended that the LASER OPERATOR should enable the laser only if the BEAM DELIVERY SYSTEM is under direct control of the OPERATOR. If not, the laser should either be switched off or put into the stand-by mode.

F.2 Use of optical fibres

F.2.1 Hazard summary

– Fire
– Breakage
– Contamination
– Deterioration

F.2.2 Precautions

F.2.2.1 The fibre tip may heat up and glow due to laser power being absorbed by tissue contaminants. Ignition of flammable material can occur, particularly with an oxygen enriched environment (e.g. within the bronchial tree). Ensure that the fibre tip is clean before firing the laser beam.

F.2.2.2 Although laser fibres are known to be rugged, breakage can occur. A considerable hazard occurs if the fibre is pulled or pushed out of or into the instrumentation channel of an endoscope, especially where the opening is located close to the endoscopist's eye. In addition, sharp bending of the fibre will increase both the angle of divergence of the laser beam and the risk of breaking the fibre. It is possible that the critical angle of total reflection could be exceeded, resulting in a considerable part of the incident laser power escaping from the fibre where it is bent. This could produce heat damage and/or eye injury. A fibre should not be bent to a radius less than that stipulated by the fibre manufacturer.

F.2.2.3 Either end of the fibre is susceptible to contamination. The fibre coupling system may be improperly aligned. In both cases, there will be a reduced power at the distal end. The coupling efficiency of the fibre should be checked at low laser power before delivering a high power beam.

F.3 Use of lasers with flexible endoscopes

F.3.1 Hazard summary

– Damage to endoscope
– Fire
– Beam misdirection
– Gas embolism

F.3.2 Precautions

F.3.2.1 The laser beam should not be activated when the fibre tip is still in the endoscope working channel. Catastrophic damage to the endoscope and/or fibre may result, with possible subsequent patient injury. When using an optical fibre in an endoscope, the laser should be kept at stand-by until the fibre has been passed through the biopsy channel and its tip can be seen protruding from the distal end, thus appearing in the visual field provided by the endoscope. This prevents damage to the fibre tip and other equipment that may be involved, i.e. video equipment, and the enclosure in case of accidental firing. To prevent damage to the endoscope, the fibre tip should be observed by the OPERATOR whenever the laser is activated.

F.3.2.2 In non-contact applications the fibre tip should be kept clean and free from tissue debris, to avoid the tip from being damaged. If bare fibres were used in the contact mode, a thin carbon layer at the tip is essential to achieve an efficient cutting effect.

F.3.2.3 If co-axial fibres are used, the only gas which should be used inside the body is carbon dioxide to minimize the risk of a gas embolism.

F.3.2.4 Although the laser is operated only when the fibre is inside the patient, there is still a small risk of fibre breakage in that part of the fibre outside the endoscope. For this reason, it is still advisable for the staff to wear safety eyewear.

F.3.2.5 In the lower gastro-intestinal tract, there is a possibility of ignition of bowel gas. Use of carbon dioxide in the co-axial fibre will reduce this risk.

F.4 Use of lasers with rigid endoscopes, microscopes and colposcopes

F.4.1 Hazard summary

– Fire
– Beam misdirection
– Laser smoke plume (in natural or insufflated cavities)

F.4.2 Precautions

F.4.2.1 If a microscope or a colposcope is used, both the focal length of the microscope or the colposcope and the focal length of the laser attachment should be the same.

F.4.2.2 If an endoscope (e.g. laryngoscope) is used, care should be taken that the diameter of the laser beam can be larger than the aperture of the endoscope, which could result in burns or hazardous reflections.

F.4.2.3 The articulated arm should be connected to the micro-manipulator before activating the laser beam.

F.4.2.4 A copious lavage of ringers or other solutions can be used during procedures to remove excess carbon and potentially decrease foreign body giant-cell reaction. This may also help prevent adhesions.

F.4.2.5 Wet pads should be packed, whenever possible, over organs adjacent to the tissue to be treated in order to protect them from an unintentional damage inflicted by a reflected laser beam.

F.4.2.6 The laser beam should be in the visual field of the microscope or endoscope and the laser effect on the tissue should always be visible. Care should be taken to ensure that the laser beam is contained within the confines of the instrument. Unwanted damage to sur-

rounding tissue or personnel may occur if the beam is incorrectly positioned. In paraxial micromanipulators, the beam position within the endoscope should be checked carefully.

F.5 Use of lasers with free hand manipulation capability

F.5.1 Hazard summary

– Fire
– Beam misdirection
– Skin burns
– Eye damage
– Laser smoke plume

F.5.2 Precautions

F.5.2.1 The beam guiding device, such as an articulated arm or fibre, should be connected to the handpiece before activating the laser beam.

F.5.2.2 Wet pads should be packed, whenever possible, over organs adjacent to the tissue to be treated in order to protect them from an unintentional damage inflicted by a laser beam reflected by an instrument.

F.5.2.3 A common ACCIDENT occurs when the laser is not being used but is accidentally fired with the beam aimed at a flammable material. This often causes burns to the patient. It is advisable to keep a supply of a suitable fluid, such as saline, at hand, for irrigation to extinguish such fires immediately.

F.5.2.4 If metal objects are used to protect the patient's eyes, the OPERATOR should be aware that the laser beam may heat the metal, thus causing thermal damage to the patient.

F.6 Use of lasers in eye surgery

F.6.1 Hazard summary

– Beam misdirection
– Eye damage
– Skin burn

F.6.2 Precautions

F.6.2.1 The contact lens used during the laser procedure should have an anti-reflection coating to reduce the reflection and thus limit the hazard area. Ensure that the contact lens has no damage to the anti-reflection coating.

F.6.2.2 Check that the optical fibre that connects the laser system to the microscope is not damaged.

F.6.2.3 For delivery systems (e.g. a slit lamp coupled photocoagulator), attention should be given to ensuring that the laser beam does not target objects which may cause a hazard (e.g. metal tools, watch glasses, gauzes moistened with flammable solvents, etc.).

F.6.2.4 For delivery systems employing a dynamic safety filter coupled to an optical magnifier, proper mechanical insertion of the safety filter should be checked prior to each laser application (i.e., the filter is fully inserted during and only during the period of laser beam emission).

F.6.2.5 For delivery systems working at tiny depth of focus and mechanically fixed in the magnifier assembly (e.g. slit-lamp mounted photocoagulator and photodisruptor), the eyepiece should be adjusted to compensate for any refractive error in the OPERATOR's eyes.

F.7 Use of lasers in conjunction with anaesthesia

F.7.1 Hazard summary

– Fire

F.7.2 Precautions

F.7.2.1 When an endotracheal tube is used, there is a risk of the beam striking the tube, with subsequent ignition of the oxygen in the anaesthetic gas mixture, when the target area is in the upper airway. The fire is not only a direct hazard, but the decomposition products from the tube may also be toxic. Endotracheal tubes specifically manufactured to be used in laser surgery should be employed. Jet ventilation may be an alternative.

Bibliography

IEC 60601-2-22, *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*
Amendment 1 (1997)
Amendment 2 (2001)

ISO 11810-1:2005, *Lasers and laser-related equipment – Test method and classification for the laser resistance of surgical drapes and/or patient protective covers – Part 1: Primary ignition and penetration*

ISO 11810-2, *Lasers and laser-related equipment – Test method and classification for the laser-resistance of surgical drapes and/or patient-protective covers – Part 2: Secondary ignition* [2)]

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

EN 207:1998, *Personal eye-protection – Filters and eye-protectors against laser radiation (laser-eye protectors)*

———————

2) To be published.

Standards Survey

The IEC would like to offer you the best quality standards possible. To make sure that we continue to meet your needs, your feedback is essential. Would you please take a minute to answer the questions overleaf and fax them to us at +41 22 919 03 00 or mail them to the address below. Thank you!

Customer Service Centre (CSC)

International Electrotechnical Commission
3, rue de Varembé
1211 Genève 20
Switzerland

or

Fax to: **IEC**/CSC at +41 22 919 03 00

Thank you for your contribution to the standards-making process.

Nicht frankieren
Ne pas affranchir

Non affrancare
No stamp required

A Prioritaire

RÉPONSE PAYÉE

SUISSE

Customer Service Centre (CSC)
International Electrotechnical Commission
3, rue de Varembé
1211 GENEVA 20
Switzerland

Q1 Please report on **ONE STANDARD** and **ONE STANDARD ONLY**. Enter the exact number of the standard: *(e.g. 60601-1-1)*

.....

Q2 Please tell us in what capacity(ies) you bought the standard *(tick all that apply).* I am the/a:

purchasing agent ❑
librarian ❑
researcher ❑
design engineer ❑
safety engineer ❑
testing engineer ❑
marketing specialist ❑
other.....

Q3 I work for/in/as a: *(tick all that apply)*

manufacturing ❑
consultant ❑
government ❑
test/certification facility ❑
public utility ❑
education ❑
military ❑
other.....

Q4 This standard will be used for: *(tick all that apply)*

general reference ❑
product research ❑
product design/development ❑
specifications ❑
tenders ❑
quality assessment ❑
certification ❑
technical documentation ❑
thesis ❑
manufacturing ❑
other.....

Q5 This standard meets my needs: *(tick one)*

not at all ❑
nearly ❑
fairly well ❑
exactly ❑

Q6 If you ticked NOT AT ALL in Question 5 the reason is: *(tick all that apply)*

standard is out of date ❑
standard is incomplete ❑
standard is too academic ❑
standard is too superficial ❑
title is misleading ❑
I made the wrong choice ❑
other .....

Q7 Please assess the standard in the following categories, using the numbers:
(1) unacceptable,
(2) below average,
(3) average,
(4) above average,
(5) exceptional,
(6) not applicable

timeliness.....
quality of writing.....
technical contents.....
logic of arrangement of contents .....
tables, charts, graphs, figures.....
other .....

Q8 I read/use the: *(tick one)*

French text only ❑
English text only ❑
both English and French texts ❑

Q9 Please share any comment on any aspect of the IEC that you would like us to know:

.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....

ISBN 2-8318-8935-9

ICS 31.260; 11.040.99

Typeset and printed by the IEC Central Office
GENEVA, SWITZERLAND