

American National Standard

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*American National Standard
for Safe Use of Lasers
in Health Care Facilities*



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**American National Standard
for Safe Use of Lasers
in Health Care Facilities**

Secretariat
The Laser Institute of America

Approved January 6, 2005
American National Standards Institute, Inc.

**American
National
Standard**

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American National Standard for Safe Use of Lasers in Health Care Facilities

1. General

1.1 Scope

This standard provides guidance for the safe use of lasers for diagnostic, cosmetic, preventive, and therapeutic applications in health care facilities (HCF) (see definition, page 5). Lasers used in these applications are incorporated into an apparatus, which includes:

- (1) a delivery system to direct the output of the laser,
- (2) a power supply with laser control and calibration functions,
- (3) mechanical housing with interlocks, and
- (4) associated liquids and gases if required for the operation of the laser.

This document pertains to the safe use of the entire apparatus, which is referred to as a health care laser system (HCLS). This standard is intended for use by all personnel associated with the installation, operation, calibration, and maintenance and service of HCLS.

This standard includes engineering, procedural and administrative controls, and laser safety training necessary for the safety of patients and health care professionals. These controls are based upon: evaluation of potential hazards from laser radiation; unique problems related to operating rooms, outpatient clinics, mobile laser units, and private medical and dental offices, or any HCF where the laser is being used to treat people. The control measures of this standard apply to all facilities where laser radiation is applied to individuals for recognized health care procedures or for claimed salutary or aesthetic beneficial effect.

Suggestions for safe use of specific types of HCLSs, as well as their use in various subspecialties are included in the Appendixes.

The Federal Laser Product Performance Standard (FLPPS) for laser products (21 CFR 1040.10 and 1040.11) requires that the operating manuals for HCLSs contain adequate instructions for assembly, calibration (Class 3 and Class 4 laser products), operation and maintenance, including clear warnings concerning precautions to avoid possible exposure to hazardous levels of laser and/or collateral radiation

(see Appendix G). Users of HCLSs should obtain information from the operator's manual or direct questions to the manufacturer on suitable eyewear, the nominal hazard zone (NHZ), calibration procedures, or adequate instructions for safe use. If manufacturer's labeling safety information does not exist and cannot be obtained from the manufacturer or the distributor of the laser system, the laser safety officer (LSO) shall provide safety instructions, which shall be incorporated into the standard operating procedure (SOP) for the HCLS, and the LSO shall maintain a copy on file. See Section 1.3 for LSO definition and responsibilities.

The control measures contained herein are not intended to restrict or limit in any way the use of laser radiation, of any type, which may be intentionally administered to an individual for diagnostic, cosmetic, preventative, therapeutic, or medical/dental research purposes, by or under the direction of qualified professionals engaged in health care.

1.2 Application: Hazard Classification Scheme

The practical means for classifying the HCLS should be according to its relative hazard and used for specifying appropriate controls for each classification. The hazard classification scheme detailed in Section 3 of this standard is based primarily on the ability of the beam to cause histological damage to the eye and skin. Although hazards to skin and other parts of the body are of importance, they are generally associated only with Class 3B and Class 4 lasers and occur at exposure levels equal to or greater than those producing eye damage. Laser radiation as defined herein refers to the ultraviolet, visible, and infrared regions of the electromagnetic spectrum and should not be confused with ionizing radiation.

The laser hazard classification system is based entirely on laser radiation, to which human access is possible during operation. Other non-beam hazards must be dealt with separately and are addressed in Section 7.

1.2.1 Laser Hazard Classification. The laser hazard classification system is based only on the accessible laser radiation. For example, a Class 1 laser system is considered to be incapable of producing damaging laser exposure during operation

and is, therefore, exempt from any control measures or other forms of surveillance. A Class 1M laser system is considered to be incapable of producing hazardous exposure conditions during normal operation unless the beam is viewed with an optical instrument such as eye-loupe (diverging beam) or telescope (collimated beam). It is, therefore, exempt from any control measures other than to prevent potentially hazardous optically aided viewing, and is exempt from other forms of control measures. A Class 2 laser system emits in the visible portion of the spectrum (0.4 to 0.7 μm) and eye protection is normally afforded by the aversion response. A Class 2M laser system emits in the visible portion of the spectrum (0.4 to 0.7 μm) and eye protection is normally afforded by the aversion response for unaided viewing, but is potentially hazardous if viewed with certain optical aids. Class 3 laser systems (medium-power) are divided into two subclasses, 3R and 3B. A Class 3 laser system may be hazardous under direct and specular reflection viewing conditions, but the diffuse reflection is usually not a hazard. A Class 3 laser system is normally not a fire hazard. A Class 4 laser system (high-power) is a hazard to the eye or skin from the direct beam, and sometimes from a diffuse reflection, and can also be a fire hazard. A Class 4 laser system may also produce laser generated air contaminants (LGAC) and hazardous plasma radiation (see Section 7). For the purposes of this standard, products which have been classified previously as Class IIa under the Federal Laser Product Performance Standard (FLPPS) should be treated the same as Class 1.

The manufacturer is required to supply the HCLS laser hazard classification. If this classification is not available or the system has been modified, the classification shall be determined by the LSO. Accurate classification is essential to assure proper operation of the safety program. HCLSs certified for a specific class by the manufacturer in accordance with the FLPPS may be considered as fulfilling all classification requirements of this standard.

The recommended stepwise procedure for using this standard is as follows:

- (1) Determine the Class of the HCLS as certified by the manufacturer in accordance with the FLPPS (see 1.2.2).
- (2) Comply with need for control measures (see 4.1) specified for the appropriate laser class.

Note 1 to (1) The laser hazard classification does not completely indicate the type of eye

hazard. HCLSs can be divided into two broad categories: those in the retinal hazard region, roughly 400 to 1400 nm, in which a focal image on the retina presents the main hazard; and those in the ultraviolet and far-infrared regions, in which the main hazard is to the cornea and skin (see Appendix A3, and Tables A1, A2, and A3).

Note 2 to (1) In general, Class 4 HCLSs present an eye, skin and fire hazard, and appropriate precautions should be taken. Surgical lasers and laser systems are mostly Class 4, with a few exceptions at the higher levels of Class 3B.

1.2.2 Federal, State and Local Regulations.

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) has the responsibility for implementing and enforcing the Federal Laser Product Performance Standard and the Medical Devices Amendment to the Food, Drug, and Cosmetic Act. These regulations have an important bearing on the regulatory status of HCLSs (see Appendix G).

The Occupational Safety and Health Administration (OSHA), from the Department of Labor, has developed Guidelines for Laser Safety and Hazard Assessment. OSHA is a governmental regulatory body for industry and will also be a regulatory body for the medical use of lasers. State and local requirements may also apply.

1.2.3 Non-governmental Controls. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has referenced the American National Standards (Z136.1 and Z136.3) as guidelines for hospital surveillance in laser audits and safety in Health Care Facilities (HCF).

1.3 Laser Safety Officer (LSO)

1.3.1 General. The laser safety officer (LSO) is the person responsible for the laser safety program in the health care facility. This individual has the training and experience to administer a laser safety program. The LSO is authorized by the HCF administration and is responsible for monitoring and overseeing the control of laser hazards. The LSO shall effect the knowledgeable evaluation and control of laser hazards by utilizing, when necessary, the most appropriate clinical and technical support staff and other resources. Throughout the body of this standard, it shall be understood that wherever duties

or responsibilities of the LSO are specified, it will mean that the LSO either performs the stated task or ensures that the task is performed.

1.3.2 LSO Specific Responsibilities.

1.3.2.1 Hazard Classification. The LSO shall assure that all lasers and laser systems in the HCF have been labeled by the manufacturer to indicate the appropriate hazard classification, in accordance with the Federal regulations. If a laser or laser system is not labeled by the manufacturer, the LSO shall ensure that the product is properly classified and that the correct classification label is affixed.

1.3.2.2 Hazards Evaluation. The LSO shall evaluate the potential hazards of the laser as used in the laser treatment controlled areas using the hazard and safety guidance as provided by the HCLS manufacturer and by taking into consideration the laser use environment and personnel using the laser. The LSO shall ensure that a hazard evaluation of the laser treatment controlled area has been performed prior to laser operation. The LSO may utilize the hazard and safety guidance as provided by the HCLS manufacturer. In some cases, the LSO may perform a hazard evaluation and determine the laser hazard.

1.3.2.3 Hazard Response. The LSO shall immediately inform the user of imminent danger from a laser hazard.

1.3.2.4 Control Measures. The LSO shall ensure that control measures as prescribed by the HCLS manufacturer or as determined by the LSO are in effect; recommend or approve substitute or alternate control measures when the primary ones are not feasible or practical; and periodically evaluate the effectiveness of the selected controls.

1.3.2.5 Procedure Approvals. The LSO shall establish and enforce standard operating procedures (SOPs) for HCLS use. These procedures should include, for example, maintenance, service, and perioperative checklists and any laser safety related items reflected in the institutional Policies and Procedures Manual used by operating personnel (see Appendixes D, E, and G).

1.3.2.6 Protective Equipment. The LSO shall ensure that protective equipment is available, in good working order (see 4.6), and is used correctly.

1.3.2.7 Signs and Labels. The LSO shall ensure that the wording on area signs and equipment labels are in accordance with Section 4.7.

1.3.2.8 Facilities and Equipment. The LSO shall approve the HCLS installation and equipment prior to use to assure that it is consistent with the manufacturer's safety recommendations appearing in the manufacturer's labeling contained in the user's manual. Modifications of existing facilities or HCLS equipment shall be reviewed by the LSO. Modification to the equipment shall not cause the equipment to fail to comply with FDA standards¹. A hazard evaluation of modified equipment shall be prepared, and this shall be retained on file by the LSO. The LSO shall ensure that periodic maintenance and service is carried out by qualified personnel, and assure that records of this maintenance and service are maintained.

1.3.2.9 Training. The LSO shall ensure that appropriate safety education and training is provided to all personnel associated with lasers such as staff, technicians, students, and other health care personnel (HCP). The LSO shall ensure maintenance of records of laser safety education and training of those HCP as specified in Section 5.

1.3.2.10 Medical Surveillance. The LSO shall ensure that personnel categories for medical surveillance of individual staff members are established (see 6.2), if the HCF requires medical surveillance of health care personnel (HCP).

1.4 Non-Hospital Environment

Health Care Laser Systems (HCLSs) may be used in a variety of non-hospital environments. The requirements and principles of the safe use of HCLSs 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 user in the non-hospital environment to be aware of the requirements for safe use. The individual user shall be responsible for all the requirements of safe use contained in this document. This user shall assume the administrative responsibilities of the LSO, as well as ensuring that all Federal regulations are followed, and non-governmental controls are in place. This means that

¹ FDA Standards: Federal Laser Product Performance Standard (21 CFR 1040) and the Medical Device Regulations

the user shall be trained in laser safety, and be knowledgeable of local and Federal regulations, advisory standards, and professional recommended practices. The user is responsible for, among others, the physical facility and its signs, proper use of protective eyewear and other safety measures, both for protection of the patient, or others who may be potentially exposed to hazards associated with the laser use. This individual is also responsible for overseeing maintenance and other practices required for safe operation of the health care laser system or systems that the user employs. If needed, the user should consult a safety expert, a consultant, or other sources regarding safety related issues such as site assessment, hazard evaluation, problem solving, or compliance enforcement.

1.5 Diagnostic Health Care Laser Systems

HCLSs for diagnostic applications are also common. Although these HCLSs may incorporate embedded lasers of higher classes, these systems usually have low outputs, which place them in Class 1 or Class 2. For those lasers in Class 1, neither control measures nor medical surveillance is required. Those lasers that are Class 2 require that applicable control measures be in place. These controls are listed in Section 4. They are usually engineering control measures in nature, and require warning labels, proper maintenance, and periodic calibration.

2. Definitions

The definitions of the terms listed below are based on a pragmatic rather than a basic approach. The terms defined are therefore limited to those actually used in this standard and its appendixes and are in no way intended to constitute a dictionary of terms used in the laser field as a whole.

ablation. Tissue removal by laser action.

accessible radiation. Radiation to which it is possible for the human eye or skin to be exposed in normal usage.

average power. The total energy imparted during exposure divided by the exposure duration.

aversion response. Movement of the eye, eyelid, or the head to avoid an exposure to a noxious stimulant or bright light. It can occur within 0.25 s, including the blink reflex time.

blink reflex. The blink reflex is lid closure associated with the involuntary upward movement of the eye, triggered by an external event such as an irritation of the cornea or conjunctiva, a bright flash, the rapid approach of an object, an auditory stimulus, or with facial movements. The ocular aversion response may include a blink reflex. See *aversion response*.

collimated beam. Effectively, a “parallel” beam of light with very low divergence or convergence.

continuous wave (CW). The output of a laser which is operated in a continuous rather than a pulsed mode. In this standard, a laser operating with a continuous output for a period ≥ 0.25 s is regarded as a CW laser.

cryogenic. Related to the production of low temperatures.

diffraction. Deviation of part of a beam, determined by the wave nature of radiation and occurring when the radiation passes the edge of an opaque obstacle.

diffuse reflection. Change of the spatial distribution of a beam of radiation when it is reflected in many directions by a surface or by a medium.

divergence. The increase in the diameter of the laser beam with propagation distance from the exit aperture. Sometimes this is also referred to as beam spread.

embedded laser. A laser with an assigned hazard classification higher than the classification of the laser system in which it is incorporated, where the system's lower classification is the result of engineering features which limit the accessible emission.

energy. The capacity for doing work. Energy content is commonly used to characterize the output from pulsed lasers, and is generally expressed in joules (J).

extended source. A source of radiation that can be resolved by the eye into a geometrical image, in contrast to a point source of radiation, which cannot be resolved into a geometrical image (see ANSI Z136.1-2000, Section 8.1 for criteria).

failsafe interlock. An interlock where the failure of a single mechanical or electrical component of the

Table 1

Control Measures for the HCLS

| Classification | 1 | 1M | 2 | 2M | 3R | 3B | 4 |
|--|----|----|----|----|----|-------|-------|
| Research (4.1.1) | | | | | | X | X |
| Administrative Controls (4.2) | | | | | | X | X |
| Standard Operating Procedures (4.2.1) | | | | | | X | X |
| Authorized Personnel, Laser Users and Laser Assistants (4.2.3) | | | | | | X | X |
| Maintenance and Service (4.2.4 and 4.3.4) | X | X | X | X | X | X | X |
| Equipment Controls (4.3) | | | | | | X | X |
| Guarded Switch (4.3.1) | | | | | | X | X |
| Accessory Equipment (4.3.2) | | | | | | X | X |
| HCLS Warning Labels (4.3.3) | | X | X | X | X | X | X |
| Modification of HCLSs (4.3.5) | X | X | X | X | X | X | X |
| Facility and Equipment Safety Audits (4.3.6) | | | | | | X | X |
| Nominal Hazard Zone (4.4.1) | ** | ** | ** | ** | ** | ** | ** |
| Laser Treatment Controlled Area (4.4.2) | | | | | | X | X |
| Area Posting Sign (4.4.2.1) | | | ● | ● | ● | X | X |
| Surgical Probes and Optical Fibers (4.4.3) | ** | ** | ** | ** | ** | ** | ** |
| Patient Eye Protection (4.4.4) | | | | | | X-NHZ | X-NHZ |
| Alignment Procedures (4.5.1) | | | X | X | X | X | X |
| Operational Alignment and Calibration Procedures (4.5.1.1) | | | ● | ● | ● | X | X |
| Service Personnel (4.5.2) | X | X | X | X | X | X | X |
| Protective Eyewear (4.6.2) | | # | # | # | | X-NHZ | X-NHZ |
| Skin Protection (4.6.4) | ** | ** | ** | ** | ** | ** | ** |
| Warning Signs (4.7) | | ● | ● | ● | ● | ● | ● |
| Warning Labels (4.7) | | X | X | X | X | X | X |
| Laser Safety Committee (5.1(2)) | | | | | | ● | ● |
| Fire and Explosion Hazards (7.6) | | | | | | | X |

- Legend:
- X – Shall
 - X-NHZ – Shall within the NHZ
 - – Should
 - ** - LSO shall establish alternate controls
 - # - If Class 1M or 2M, see section 4.6.2.1.3 if optical instruments are used



Laser Institute of America

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American National Standard

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