

# American National Standard

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

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

Secretariat  
Laser Institute of America

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American National Standards Institute, Inc.

**American  
National  
Standard**

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

## 1. General

### 1.1 Scope.

This standard provides guidance for the safe use of lasers in health care. As defined herein, laser radiation refers to the ultraviolet, visible, and infrared regions of the electromagnetic spectrum. Laser radiation should not be confused with ionizing radiation or light from other sources.

Specific processes are provided to protect anyone who might become exposed to laser radiation and to assist in establishing a program that promotes the safe use of health care laser systems (HCLS). The following guidelines for laser safety programs contain requirements (designated by *shall*) and recommendations (designated by *should*). The scope of this standard includes all circumstances when people may be exposed to a laser in health care applications where:

- a) Laser systems as medical devices are used for diagnosis of disease, or for preventive, aesthetic, or therapeutic purposes
- b) Bodily structure or function is altered, or symptoms are relieved
- c) Any application where a laser is applied for health or wellness purposes

This standard applies to any location where an HCLS is being used as a medical device, including hospital facilities, ambulatory surgery centers (ASC), individual medical, dental and veterinarian offices, and non-medical locations, such as salons and spas.

A laser used in these applications is incorporated into an entire apparatus, referred to as an HCLS, which includes:

- a) A delivery system to direct the output of the laser
- b) A power supply with laser control and calibration functions
- c) Protective housing, including mechanical housing with interlocks if required
- d) Associated liquids and gases if required for the operation of the laser

This standard pertains to the safe use of lasers and laser systems that operate at wavelengths between 180 nm and 1000  $\mu\text{m}$ . It is intended for use by all people associated with the application, installation, operation, calibration, maintenance and service of an HCLS and anyone who might be exposed to lasers being used as medical devices for health care applications.

This standard provides guidance to employers for establishing proper laser safety policies and procedures and training programs in safe laser use.

This standard includes engineering, procedural and administrative controls, and laser safety training. These controls are based upon the following: evaluation of potential hazards from laser radiation, unique problems related to hospitals and operating rooms (ORs) and non-hospital

**Table 1. Requirements by Laser Classification<sup>3</sup>**

<b>Class</b>	<b>Administrative Controls</b>	<b>Training</b>	<b>LSO</b>	<b>Engineering Controls</b>
<b>1</b>	Not Required	Not Required	Not Required	Not Required
<b>1C</b>	Not Required	Not Required	Not Required	Not Required
<b>1M</b>	Required	Application Dependent <sup>b</sup>	Application Dependent <sup>b</sup>	Application Dependent <sup>a</sup>
<b>2</b>	Not Required <sup>a</sup>	Not Required <sup>a</sup>	Not Required	Not Required <sup>b</sup>
<b>2M</b>	Required	Application Dependent <sup>b</sup>	Application Dependent <sup>b</sup>	Application Dependent <sup>a</sup>
<b>3R</b>	Not Required <sup>a</sup>	Not Required <sup>a</sup>	Not Required <sup>a</sup>	Not Required <sup>b</sup>
<b>3B</b>	Required	Required	Required	Required
<b>4</b>	Required	Required	Required	Required
NOTE—During maintenance and service, the classification associated with the maximum level of accessible laser radiation shall be used to determine the applicable control measures.				

<sup>a</sup> Certain uses of Class 1M or Class 2M lasers or laser systems that exceed Class 1 or Class 2 because they do not satisfy Measurement Condition 1 may require hazard evaluation and/or manufacturer’s information (see ANSI Z136.1-2014, Section 4.1).

<sup>b</sup> Not required except for conditions of intentional intrabeam exposure applications.

<sup>3</sup> Adapted from ANSI Z136.1-2014, Table 1

NOTE—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's (FDA) Center for Devices and Radiological Health (CDRH) has the responsibility for implementing and enforcing 21CFR1040.10 and the sections of the Food, Drug and Cosmetic Act applicable to medical devices. These regulations have an important bearing on the regulatory status of an HCLS (see Appendix H).

State and local requirements may also apply. Some states require personnel who use an HCLS to be licensed or to work under the supervision of licensed individuals who use lasers within their scope of practice, license, training and experience. Some states have specific registration, facility licensing, training and educational requirements for laser installations, users and operators. The LSO shall be responsible for obtaining and maintaining individual state requirements and licenses.

**1.2.3 Non-governmental Controls.** Organizations such as The Joint Commission, the Association of Surgical Technologists (AST), the Association of periOperative Registered Nurses (AORN), the American Society for Lasers in Medicine and Surgery (ASLMS), the American Veterinary Medical Association (AVMA), and the Academy of Laser Dentistry (ALD), have referenced ANSI Z136.1 and Z136.3 as guidelines.<sup>5</sup> These non-governmental organizations have recommended practices, guidelines, or position statements associated with their disciplines and laser uses.

### **1.3 Laser Safety Officer (LSO) and Other Personnel.**

The LSO is an individual designated by the employer with the authority and responsibility to effect the knowledgeable evaluation and control of laser hazards, and to monitor and enforce the control of such hazards. The LSO shall have authority to suspend, restrict, or terminate the operation of a laser system if he/she deems that laser hazard controls are inadequate. The LSO may be a part-time position when the workload for an LSO does not require a full-time effort.

If deemed necessary, additional personnel such as a Deputy LSO (DLSO) may be appointed by management or the LSO to perform the functions of the LSO when the latter is not available. For institutions with multiple divisions or plant locations, a system of DLSOs or other personnel such as a Laser Safety Site Contact (LSSC) or Laser Safety Specialist (LSS) may be appropriate. In smaller settings, like ambulatory surgery centers (ASC), other outpatient facilities, medical, dental and veterinary offices, salons and spas, the LSO can be the laser user, laser operator, or other trained person who is responsible for the laser safety program. Suggested responsibilities for the LSO, DLSO, and LSSC/LSS are provided in Appendix A. (See also ANSI Z136.1-2014, Appendix A3.)

**1.3.1 General.** The LSO is the person in each facility or organization responsible for the laser safety program. This individual has the training and experience to administer a laser safety program. The LSO is authorized by the health care facility (HCF) administration and is responsible for monitoring and overseeing the control of laser hazards. The LSO shall effect the knowledgeable

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<sup>5</sup> Reference to Z136 standards that do not include the year of publication means the latest revision thereof.

**1.4.3 Diagnostic Health Care Laser Systems.** HCLSs for diagnostic applications are also common. Although these HCLSs may incorporate embedded lasers of higher classes, some of these systems have low outputs that place them in Class 1, Class 2 or Class 2M. For those lasers in Class 1 and Class 2, neither control measures nor medical surveillance is required. Those lasers that are Class 2M require that applicable control measures are in place. All diagnostic HCLSs that have an output in Class 3B or Class 4 require control measures appropriate for Class 3B or Class 4 lasers. These controls are listed in Section 4.

The Laser Safety Officer (LSO) is responsible for overseeing and controlling the hazards of Class 3B or Class 4 lasers only. For clarification, embedded lasers are frequently found in medical diagnostic equipment, computers, printers, laser pointers, and other devices. The LSO is not responsible for oversight of these systems operating in accordance with manufacturer configuration and specifications that render them low output devices. Manufacturers and service agents assume responsibility for overseeing and controlling the hazards of these embedded laser systems including the removal of covers (i.e. protective housings) to service equipment that may increase the hazard class to that of the embedded laser. It may be determined by the LSO that the use of temporary control measures (e.g., walls, barriers, signs, beam stops) shall be utilized to define a laser controlled area (LCA) during time of service (see 4.2.4, 4.5.1.3, and 4.5.2). As indicated in 6.2, medical surveillance should be considered for those potentially exposed to a Class 3B or Class 4 laser emission.

## 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 appendices and are in no way intended to constitute a dictionary of terms used in the laser field as a whole.

**ablation.** Tissue removal (such as vaporization) by laser action.

**accessible emission limit (AEL).** The maximum accessible emission level permitted within a particular laser hazard class.

**accessible laser radiation.** Laser radiation to which it is possible for the human eye or skin to be exposed in normal usage. This is also described as laser radiation emitted from a laser, including accessible radiant energy and power, that is compared with the AEL to determine its hazard class.

**administrative control measure.** Control measures incorporating administrative means, e.g., training, safety approvals, LSO designation, and policies and procedures (P&Ps), to mitigate the potential hazards associated with laser use.

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

**aversion response.** Closure of the eyelid, eye movement, pupillary constriction, or movement of the head to avoid an exposure to a noxious or bright light stimulant. In this standard, the aversion response to an exposure from a bright, visible, laser source is assumed to limit the exposure of a specific retinal area to 0.25 s or less.

- f) Education and training of authorized personnel in the assessment and control of laser hazards in accordance with defined standards as well as federal, state and local requirements.
- g) Audits (see 4.3.6)

Any HCP violating safety regulations shall be reported to the LSO and the incident reviewed by the HCF safety committee.

## 5.2 Training.

Detailed training in laser safety shall be provided for those HCP using or working in the presence of Class 3B and Class 4 HCLSs. Personnel shall have sufficient knowledge, training and experience to ensure that laser health care applications are performed safely. All training activities shall be documented and the documentation retained on file. Additional required criteria for credentialing, (hospital privileges and accreditation standards), and certification (discipline, specialty and organization recognition programs) shall include all applicable aspects of safety.

**5.2.1 Personnel.** LSO education and preparation should include, but not be limited to, completion of a formal medical laser safety course, completion of a formal medical LSO course, certification as a medical LSO, and previous laser operator work experience. Laser safety training shall be required for the following HCP:

- a) LSO, DLSO, if assigned, LSSC/LSS, if assigned
- b) Laser users
- c) Laser operators
- d) Technical support staff
- e) Nurses and allied health personnel

**5.2.2 Training Programs.** Laser safety training programs shall provide a thorough understanding of all procedures required for establishing and maintaining a safe environment during the use of an HCLS. Training programs shall be specific to the HCLS in use, and to the procedures to be performed. Program criteria and content shall be in accordance with facility P&Ps, applicable standards, and federal, state and local regulations. Retraining programs should be provided at intervals determined by the LSO in accordance with facility P&Ps and applicable regulations, but not less frequently than every five years for laser users, laser operators, LSSC/LSS (if assigned), DLSOs (if assigned) and LSOs (see Appendix G for sample laser training program).

**5.2.3 Certification and Credentialing.** Each discipline has evolved its own procedures for assuring proper training for their health care applications. The laser user shall use the laser for its intended purpose within his or her scope of practice, training and experience. All certification and credentialing processes at the facility or point of laser use shall require training in the safe use of lasers, as well as the maintenance of a safe environment in compliance with defined standards, and federal, state and local requirements. Refer to the appropriate sections in the appendixes of this document for suggested recommendations for training, certification, and credentialing for the various disciplines of healthcare.

## 7.5 Collateral and Plasma Radiation.

Ultraviolet radiation emitted from laser discharge tubes and pumping lamps that are not part of the primary laser beam shall be suitably shielded. In addition, laser beam interactions with tough, dense tissues and bone can generate intense plasma emissions and bright light, thus requiring suitable optical filtering or goggles for direct viewing.

## 7.6 Fire and Explosion Hazards.

Fire hazards associated with an HCLS take many forms. The most obvious is the use of flammable liquids. Oxidizing gases can also pose significant fire hazards. Drape fires can result from a broken laser fiber or inadvertent impact of the direct or reflected beam on non-targeted sites. Not so obvious are the materials used in constructing the HCLS such as plastic parts and tubing that can enhance the spread of fire. Failure of electrical equipment is always a hazard as a potential source of ignition. While these forms of fire occur outside of the patient, it also has to be realized that fires can be created in patients undergoing laser surgical procedures due to the laser beam interacting with some material, (e.g., methane gas in bowels, foam positioning devices, plastic tubing introduced into the airway). See NFPA 115-2016<sup>12</sup> for further information.

**7.6.1 General.** When a Class 4 laser is used with drying agents, certain anesthetic preparation solutions, ointments, and plastic resins, there is a potential for fire. Potentially flammable items, such as sponges, gauze pads, foam positioning devices, and swabs located in or near the operating field should be eliminated or, if used, should be kept wet. Surgical preps that contain alcohol shall be allowed to dry completely according to the manufacturer's written instructions before a drape is applied. Analysis of laser accidents has shown that two key considerations in the selection of a surgical drape for use with HCLSs, especially with Class 4 systems, are the flammability rating and the ability to produce PAC (LGAC) (see 4.6.3).

Fire codes generally require a secured operational portable fire extinguisher that is prominently located. The LSO shall verify local rules for placement and periodic inspection of portable fire extinguishers. All HCP shall annually demonstrate competency on the operation of all fire extinguishers present in the laser use area.

Water for quenching non-electrical flames shall also be immediately available when using laser energy capable of causing ignition.

To reduce the danger of burns or drape fires due to broken fibers, care should be taken to avoid leaning against a fiber, or clamping or otherwise stressing or bending a fiber beyond the manufacturer's recommended bend radius. The ability to visualize the entire fiber including the tip is important for fire prevention in the event of fiber breakage. Laser users can often see the breakage or observe the loss of energy at the tip. The tip of the fiber should be covered with a wet substrate when the fiber is not in use and outside the treatment area.

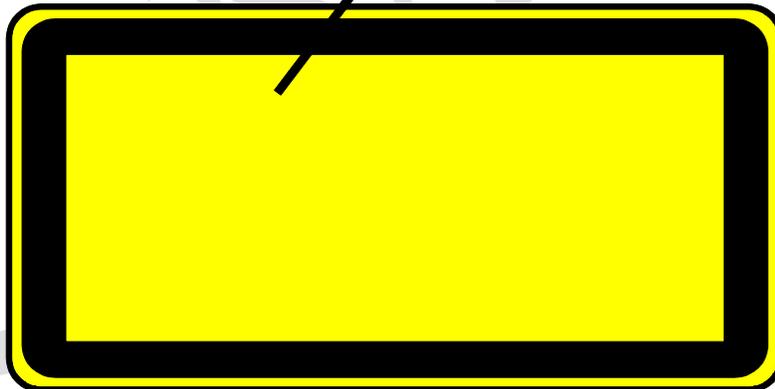
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<sup>12</sup> NFPA 115, National Fire Protection Association Standard for Laser Fire Protection, 2016.



**SYMBOL AND BORDER: BLACK**  
**BACKGROUND: YELLOW**

**SPACE FOR LEGEND**



**LEGEND AND BORDER: BLACK**  
**BACKGROUND: YELLOW**

**Figure 1c. IEC 60825-1 Warning Label - Hazard Symbol and Explanatory Label**

## **Appendix A**

### **Supplement to Section 1**

NOTE—The following material is an extension of 1.3 and, as a normative Appendix, is an integral part of the standard.

#### **A1. Laser Safety Officer (LSO) and Other Personnel**

**A1.1. General.** All facilities and practice scenarios shall designate an LSO who has the authority and responsibility to effect the knowledgeable evaluation and control of laser hazards, and to monitor and enforce the control of such hazards. This individual has the training and experience to administer a laser safety program. The LSO shall have the authority to suspend, restrict, or terminate the operation of a laser system if he/she deems that laser hazard controls are inadequate. The LSO may be a part-time position when the workload for an LSO does not require a full-time effort.

#### **A1.2 LSO Specific Duties and Responsibilities.**

- a) **Safety Program.** The LSO is the person in each facility or organization responsible for and administers the laser safety program. The LSO is authorized by 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, qualified clinical and technical support staff and other resources. The LSO either performs the stated task or may delegate the task to be performed by qualified individual(s). The LSO can be the laser user, laser operator, or other trained person responsible for the laser safety program. (See ANSI Z136.1-2014, Appendix A3)
- b) **Hazard Classification.** The LSO shall ensure 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. The LSO shall ensure that the products are properly classified and that the correct classification label is affixed. A hazard evaluation of modified equipment shall be prepared and retained on file by the LSO.
- c) **Hazard Evaluation.** The LSO shall ensure that a hazard evaluation of the LTCA has been performed prior to laser operation. This shall include evaluation of the potential hazards of the laser taking into consideration the laser use environment and people using the laser. 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.
- d) **Hazard Response.** The LSO, or designee, shall immediately inform the user of imminent danger from a laser hazard. The LSO shall have authority to suspend, restrict, or terminate the operation of a laser system if he/she deems that laser hazard controls are inadequate.
- e) **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



LIA is The Institute for Photonic Materials Processing Innovation. Our vision is helping to make the world a better place through safe, optimal and novel use of lasers, optics and photonics, including quantum science and technology, and their application to advanced materials. Our mission is delivering value to our members by developing and sharing knowledge, catalyzing innovation, stimulating access to capital, facilitating networking and professional development, and helping to integrate all the above across lasers, optics and photonics to advanced materials.

Additionally, LIA is secretariat to the American National Standards Institute (ANSI) Accredited Standards Committee Z136 for safe use of lasers, and publisher of the ANSI-approved Z136 series of the laser safety standards. These documents provide a thorough set of guidelines for implementing a safe laser program. The Z136 series is recognized by OSHA, and is the authoritative series of laser safety documents in the United States. LIA also offers a wide array of products and services including safety and application publications, training videos, signs, laser safety officer training, and conferences.

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