American National Standard

ANSI Z136.3 - 2024

American National Standard for Safe Use of Lasers in Health Care

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ANSI Z136.3 – 2024
Revision of
ANSI Z136.3-2018

American National Standard for Safe Use of Lasers in Health Care

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Secretariat
Laser Institute of America

Approved April 5, 2024
American National Standards Institute, Inc.

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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 (UV), visible, and infrared (IR) regions of the electromagnetic spectrum. Laser radiation should not be confused with ionizing radiation, or light from other sources.

Specific processes and control measures 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 could potentially be exposed to a laser used in health care applications where

a) laser systems as medical devices are used for diagnosis of disease, or for preventive, aesthetic, therapeutic, or regenerative therapy purposes,

b) bodily structure or function is altered, or symptoms are relieved, or

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 that 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, and

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 µm. 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, control measures, 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.

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Table 1. Requirements by Laser Classification[3]

Class	Administrative Controls	Training	Laser Safety Officer (LSO)	Engineering Controls
1	Not Required	Not Required	Not Required	Not Required
1C	Not Required	Not Required	Not Required	Not Required
1M	Required	Application Dependent [a]	Application Dependent [a]	Application Dependent [a]
2	Not Required [b]	Not Required [b]	Not Required	Not Required [b]
2M	Required	Application Dependent [a]	Application Dependent [a]	Application Dependent [a]
3R	Not Required [a]	Not Required [a]	Not Required [a]	Not Required [b]
3B	Required	Required	Required	Required
4	Required	Required	Required	Required
NOTE—During maintenance and service, the classification associated with the maximum level of accessible laser radiation is used to determine the applicable control measures.				

[a] Certain uses of Class 1M or 2M lasers or laser systems that exceed Class 1 or 2 because they do not satisfy Measurement Condition 1 may require hazard evaluation as well as manufacturer's information (see ANSI Z136.1-2022, Section 4.1). The design and inclusion of engineering controls are critical to implementation of this type of system and they must be demonstrated by original design.

[b] Not required except for conditions of intentional intrabeam exposure applications.

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[3] Adapted from ANSI Z136.1-2014, Table 1-1

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1.2.1.1 Procedure for Application of This Standard. The recommended stepwise procedure for using this standard is as follows.

a) Determine the hazard class of the HCLS as certified by the manufacturer in accordance with 21 CFR 1040.10 (see Section 1.2.2).

NOTE—The laser hazard classification does not completely indicate the type of eye hazard. HCLSs can be divided into two broad categories that are:

1. those in the retinal hazard region, roughly 400 nm to 1400 nm, in which a focal image on the retina presents the main hazard, and
2. those in the ultraviolet (UV) and far-infrared (IR) regions, in which the main hazard is to the cornea and skin (see Appendix B3, and Tables B1, B2, and B3).

b) Comply with the control measures recommended for the appropriate laser class (see Section 4.1).

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 21 CFR 1040.10 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 (TJC), Association of Surgical Technologists (AST), Association of periOperative Registered Nurses (AORN), American Society for Lasers in Medicine and Surgery (ASLMS), American Veterinary Medical Association (AVMA), and Academy of Laser Dentistry (ALD), have referenced ANSI Z136.1 and Z136.3 as guidelines.[5] These non-governmental organizations have recommended practices, guidelines, or position statements associated with their disciplines and laser uses.

1.3 Laser Safety Officer (LSO).

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 the authority to suspend, restrict, or terminate the operation

[5] Reference to Z136 standards that do not include the year of publication means the latest revision thereof.

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c) data and elements of documentation collected by the third party are appropriate, meet the HCF policy, and can be verified by facility health care personnel (HCP),

d) all HCP expected to be in the room with the third party laser have completed safety control training on the laser and accessory equipment to ensure a laser safe environment for personnel and the patient during the device operation, and

e) assessment should be performed through a thorough intake procedure, exceeding biomedical testing for electrical leakage, and include the condition of the HCLS and all delivery systems and accessory devices to be used, credentials of the technician, credentials of the provider, inventory of accessories (for example, fibers, and filters) documentation forms, staffing requirements, and assignments for personnel to be present in the room.[7]

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, 2, or 2M. For those lasers and laser systems in Class 1 and 2, neither control measures nor medical surveillance is required. Lasers that are Class 2M require that applicable control measures are in place. All diagnostic HCLSs that have an output in Class 3B or 4 require control measures. These controls are listed in Section 4.

The LSO is responsible for overseeing and controlling the hazards of Class 3B or 4 lasers and laser systems 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, namely, 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, for example, walls, barriers, signs, and beam stops, shall be utilized to define a laser controlled area (LCA) during time of service (see Sections 4.2.4, 4.5.1.2, and 4.5.2). As indicated in Section 6.2, medical surveillance should be considered for those potentially exposed to a Class 3B or 4 laser emission.

2. Acronyms, Abbreviations, and Definitions

2.1 Acronyms and Abbreviations.

The following is a listing of the various acronyms and abbreviations used throughout this standard and its appendices.

ADA-CERP – American Dental Association – Continuing Education Recognized Provider

AEL – accessible emission limit

AGD-PACE – Academy of General Dentistry-Program Approval for Continuing Education

[7] See Appendix G, Example Intake Checklist for Third Party Rental of Health Care Laser System (HCLS).

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5.2 Training.

Detailed training in laser safety shall be provided for those HCP using or working in the presence of Class 3B and 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-related work experience. Laser safety training shall be required for the following HCP.

a) LSO, DLSO, if assigned, and LSSC or LSS, if assigned

b) Laser users

c) Laser operators

d) Technical support staff

e) Nurses

f) 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. Refresher training should be provided at intervals determined by the LSO in accordance with the facility P&Ps, and applicable regulations, but no less frequently than every five years for laser users, laser operators, LSOs, DLSOs (if assigned), LSSC or LSS (if assigned), and laser repair technicians. The level of periodic training necessary should be determined by the LSO (see Appendix G for sample laser training program).

5.2.3 Certification and Credentialing. Each discipline has evolved its own procedures for ensuring proper training for their health care applications. The laser user shall use the laser for its intended purpose within their 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.

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HCP should wear additional PPE such as splash guards, gloves, and appropriate clothing, during laser procedures when vaporized or ejected tissue plume is generated.

7.5 Collateral and Plasma Radiation.

UV 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, such as the use of flammable liquids and oxidizing gases. Drape fires can result from a broken laser fiber or inadvertent impact of the direct or reflected beam on non-targeted sites. 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, fires can be created in patients undergoing laser surgical procedures because of the laser beam interacting with some material, for example, methane gas in the bowels, foam positioning devices, and plastic tubing introduced into the airway. See NFPA 115-2016[11] 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. 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 and LGAC (see Section 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 because of 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

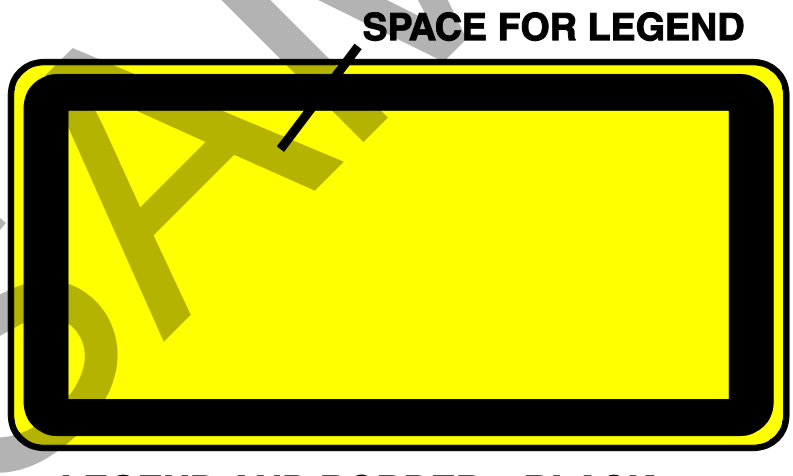
[11] NFPA 115, National Fire Protection Association Standard for Laser Fire Protection, 2016.

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Area Warning Signs



SYMBOL AND BORDER: BLACK
BACKGROUND: YELLOW



LEGEND AND BORDER: BLACK
BACKGROUND: YELLOW

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

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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 management 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 Z136.1-2022, 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 HCLSs 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 hazards.

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.

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Appendix D
Use of Lasers in Specialties

D1. General

Guidance information is provided in each specialty. However, this Appendix does not serve as a substitute for either didactic or hands-on (practicum) laser training (see Section 1.1).

D2. Gynecology

The types of lasers as are presently utilized in obstetrics and gynecology include CO2, Ho:YAG, Nd:YAG, argon, KTP, tunable dye and diode lasers for PDT.

D2.1 Laser Characteristics.

Lasers are presently utilized for a multitude of clinical indications. One of the initial uses was for the treatment of pre-neoplastic lesions in the lower and upper genital tract. This was followed by endoscopic utilization via laparoscopy and most recently hysteroscopy.

CO_2 lasers for these procedures emit in the far IR with wavelengths at 9,600 nm to 10,600 nm. A helium-neon (HeNe) laser or visible diode is used for aiming the beam. Depending on the indication various pulse modes or CW mode is chosen.

Ho:YAG at 2,100 nm is in the IR range. The pulsed laser prevents heat build up and excessive charring when irradiating non-aqueous tissue where it has superficial penetration depth (0.3 mm to 0.5 mm). The Ho:YAG wavelength is highly absorbed by water and functions well in the vaporization, ablation, cutting, and coagulation of all soft tissues. The increased depth of penetration ranges only 0.1-0.2 mm greater than that of CO_2.

Nd:YAG lasers are solid state lasers that produce an invisible wavelength of 1,064 nm that requires a visible aiming beam during use. The typical output power ranges from 1 to 120 watts; the tissue penetration depth is 5 to 6 mm with the laser energy absorbed by the pigmented layers within the skin. Unlike the 10,600 nm CO_2 laser delivery systems that require articulated arms, the energy from a 1,064 nm Nd:YAG laser can be delivered through a fiber optic system, gas, air, or fluid cooled fibers, either direct or non-contact. Non-contact systems permit more coagulation and reduce the power administered. Contact tips are usually man-made sapphire that reduce the scatter effect that is seen with the non-contact approach. The contact tips are also reusable.

The Nd:YAG laser can be frequency-doubled using a KTP crystal to produce green light at 532 nm. Such lasers are usually referred to as KTP lasers. The shorter wavelength results in a decreased depth of penetration of 0.5-1 mm when there is an optical chromophore of either hemoglobin or oxyhemoglobin present. The KTP laser is used for incising, coagulating and vaporizing tissues, including tissues cooled with saline.

Argon lasers emit at several wavelengths between 450 nm and 530 nm with two prominent wavelengths at 488 nm and 514.5 nm. Both of these wavelengths are within the blue and green

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The LIA is the secretariat to Z136 SDC and publisher of the American National Standards Institute approved Z136 series of laser safety standards. These documents provide a thorough set of guidelines for implementing a safe laser program. The ANSI 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 and labels, laser safety officer training and conferences. LIA members receive substantial discounts on all LIA courses, publications, and conferences. We invite you to become a member and be part of the LIA experience.

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CONTACT INFORMATION

Standards: z136@lia.org
Membership: membership@lia.org
Conferences: conferences@lia.org
Education/Training: courses@lia.org
Journal of Laser Applications: jla@lia.org
General: lia@lia.org

LIA
12001 Research Parkway, Suite 210
Orlando, FL 32826
Phone:+1.407.380.1553 • Fax: +1.407.380.5588
email: lia@lia.org • www.lia.org

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