

American National Standard

ANSI Z136.3 – 2011

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



**Laser Institute
of America**
Laser Applications and Safety



ANSI®
Z136.3 – 2011
Revision of
ANSI Z136.3-2005

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

Secretariat
Laser Institute of America

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**American
National
Standard**

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Foreword (This introduction is not a normative part of ANSI Z136.3-2011, *American National Standard for Safe Use of Lasers in Health Care*.)

In 1968, the American National Standards Institute (ANSI) approved the initiation of the Safe Use of Lasers Standards Project under the sponsorship of the Telephone Group.

Prior to 1985, Z136 standards were developed by ANSI Committee Z136 and submitted for approval and issuance as ANSI Z136 standards. Since 1985, Z136 standards are developed by the ANSI Accredited Standards Committee (ASC) Z136 for Safe Use of Lasers. A copy of the procedures for development of these standards can be obtained from the secretariat, Laser Institute of America, 13501 Ingenuity Drive, Suite 128, Orlando, FL 32826 or viewed at www.z136.org.

The present scope of ASC Z136 is to protect against hazards associated with the use of lasers and optically radiating diodes.

ASC Z136 is responsible for the development and maintenance of this standard. In addition to the consensus body, ASC Z136 is composed of standards subcommittees (SSC) and technical subcommittees (TSC) involved in Z136 standards development and an editorial working group (EWG). At the time of this printing, the following standards and technical subcommittees were active:

SSC-1	Safe Use of Lasers (parent document)
SSC-2	Safe Use of Lasers and LEDs in Telecommunications Applications
SSC-3	Safe Use of Lasers in Health Care
SSC-4	Measurements and Instrumentation
SSC-5	Safe Use of Lasers in Educational Institutions
SSC-6	Safe Use of Lasers Outdoors
SSC-7	Eyewear and Protective Barriers
SSC-8	Safe Use of Lasers in Research, Development, and Testing
SSC-9	Safe Use of Lasers in Manufacturing Environments
SSC-10	Safe Use of Lasers in Entertainment, Displays, and Exhibitions
TSC-1	Biological Effects and Medical Surveillance
TSC-2	Hazard Evaluation and Classification
TSC-4	Control Measures and Training
TSC-5	Non-Beam Hazards
TSC-7	Analysis and Applications
EWG	Editorial Working Group

The six standards currently issued are:

ANSI Z136.1-2007, *American National Standard for Safe Use of Lasers* (replaces ANSI Z136.1-2000)

ANSI Z136.3-2011, *American National Standard for Safe Use of Lasers in Health Care* (replaces ANSI Z136.3-2005 *American National Standard for Safe Use of Lasers in Health Care Facilities*)

ANSI Z136.4-2010, *American National Standard Recommended Practice for Laser Safety Measurements for Hazard Evaluation* (replaces ANSI Z136.4-2005)

ANSI Z136.5-2009, *American National Standard for Safe Use of Lasers in Educational Institutions* (replaces ANSI Z136.5-2000)

ANSI Z136.6-2005, *American National Standard for Safe Use of Lasers Outdoors* (replaces ANSI Z136.6-2000)

ANSI Z136.7-2008, *American National Standard for Testing and Labeling of Laser Protective Equipment* (first edition)

This American National Standard is intended to ensure the safe use of lasers in health care, and has been published as part of the ANSI Z136 series of laser safety standards. The base document of the series is the *American National Standard for Safe Use of Lasers*, ANSI Z136.1. The procedures and methodologies described in this standard are based on requirements previously established in ANSI Z136.1 and are intended to give more specific processes for accomplishing laser safety in health care. The purpose of this standard is to provide more specific user processes for accomplishing laser safety protecting anyone who might become exposed during laser use for health care. It provides guidance to personnel who are using lasers and institutions where health care lasers are used. It should be recognized that the scope of ANSI Z136.3 includes all circumstances when people may be exposed to a laser when they are being used for health care applications, where laser systems as medical devices are used for diagnosis of disease, or for preventive, aesthetic, or therapeutic purpose, where bodily structure or function is altered, symptoms are relieved, or any health care application, where a laser is applied by people for health care purposes. This standard includes policies and procedures to ensure laser safety in any area where a health care laser system, as a medical device, is being used, including hospital facilities, non-hospital facilities, outpatient facilities, individual medical, dental and veterinarian offices, and non-medical locations, such as salons and spas.

In general, this standard may be used independently of ANSI Z136.1; however, instances where additional guidance contained in ANSI Z136.1 is required are noted in the text of this document. The body of this

standard is normative and applies to all health care laser use. The appendices are informative providing examples and discipline specific supplementary information.

It is expected that this standard will be periodically revised as new information and experience in the use of lasers are gained. Future revisions may have modified content and use of the most current document is highly recommended.

While there is considerable compatibility among existing laser safety standards, some requirements differ among federal, state and international standards and regulations. These differences may have an effect on the particulars of the applicable control measures.

Occasionally questions may arise regarding the meaning or intent of portions of this standard as it relates to specific applications. When the need for an interpretation is brought to the attention of the secretariat, the secretariat will initiate action to prepare an appropriate response. Since ANSI Z136 standards represent a consensus of concerned interests, it is important to ensure that any interpretation has also received the concurrence of a balance of interests. For this reason, the secretariat is not able to provide an instant response to interpretation requests except in those cases where the matter has previously received formal consideration. Requests for interpretations and suggestions for improvements of the standard are welcome. They should be sent to ASC Z136 Secretariat, Laser Institute of America, 13501 Ingenuity Drive, Suite 128, Orlando, FL 32826.

This standard was processed and approved for submittal to ANSI by ASC Z136. Committee approval of the standard does not necessarily imply that all members voted for its approval.

Robert Thomas, Committee Chair
Sheldon Zimmerman, Committee Vice-Chair
Ben Edwards, Committee Secretary

Notice

(This notice is not a normative part of ANSI Z136.3-2011, *American National Standard for Safe Use of Lasers in Health Care*.)

Z136 standards and recommended practices are developed through a consensus standards development process approved by the American National Standards Institute. The process brings together volunteers representing varied viewpoints and interests to achieve consensus on laser safety related issues. As secretariat to ASC Z136, the Laser Institute of America (LIA) administers the process and provides financial and clerical support to the committee.

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<i>Organization Represented</i>	<i>Name of Representative</i>
Altos Photonics, Inc.	Lucian Hand
American Academy of Dermatology	Mark Nestor
American College of Obstetricians & Gynecologists	Ira Horowitz
American Dental Association	Joel White
American Glaucoma Society	Michael Berlin
American Industrial Hygiene Association	R. Timothy Hitchcock
American Society for Laser Medicine & Surgery	David Sliney
American Society of Safety Engineers	Jerome Garden (Alt)
	Thomas V. Fleming
	Walter Nickens (Alt)
American Veterinary Medical Association	Kenneth Bartels
American Welding Society	Mark McLearn
Association of periOperative Registered Nurses (AORN)	Evangeline Dennis
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Kentek Corporation	William Arthur
L*A*I International	Thomas Lieb
Laser Institute of America	Gus Anibarro
Laser Safety Consulting, LLC.	Darrell Seeley
LASERVISION USA	Richard Greene
LFI International	Roberta McHatton
Lawrence Berkeley National Laboratory	Ken Barat
Lawrence Livermore National Laboratory	Robert Ehrlich
Los Alamos National Laboratory	Connon Odom
National Aeronautics and Space Administration	Guy Camomilli
National Institute of Standards and Technology (NIST)	Randall Scott (Alt)
National Institute of Standards and Technology (NIST)	Shao Yang
North American Association for Laser Therapy (NAALT)	Raymond Lanzafame
Power Technology, Inc.	William Burgess
Rockwell Laser Industries	William Ertle

Solta Medical Inc.
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University of Texas,
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US Department of Health and Human
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Naval Air Systems Command
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Individual Members

David Dewey
Peter Boden
John Hoopman

Richard Felten

Jeffrey Lodwick

Benjamin Rockwell
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G. Scott Braley

Bruce Stuck

Jeffrey Pfoutz
Penelope Galoff (Alt)
James Sheehy

Sheldon Zimmerman
Mary Zimmerman (Alt)

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Prem Batra
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Antonio Triventi
Karl Umstadter
Robert Weiner
Anthony Zmorenski

Emeritus Members

Sidney Charschan
David Edmunds
James Smith
Myron Wolbarsht

The various subcommittees that participated in developing this standard had the following members:

Safe Use of Lasers in Health Care, SSC-3

Joel White, Chair	Gus Anibarro	Bill Janssen
John Hoopman, Vice-Chair	William Arthur	Raymond Lanza fame
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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. 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 lasers. The scope of this standard includes all circumstances when people may be exposed to a laser used in health care applications where:

- 1) Laser systems as medical devices are used for diagnosis of disease, or for preventive, aesthetic, or therapeutic purposes
- 2) Bodily structure or function is altered, or symptoms are relieved
- 3) Any application where a laser is applied by people for health care purposes

This standard applies to any location where a health care laser system (HCLS) is being used as a medical device, including hospital facilities, non-hospital facilities, outpatient facilities, individual medical, dental and veterinarian offices, and non-medical locations, such as salons and spas. 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.

A laser used in these applications is incorporated into an apparatus that 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
- 4) Associated liquids and gases if required for the operation of the laser

This standard pertains to the safe use of the entire apparatus, which is referred to as an HCLS. This standard is intended for use by all people associated with the application, installation, operation, calibration, and 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 recognizes the need for employers to provide proper laser safety policies and procedures and training in safe laser use for health care applications, in order for their personnel to be responsible in laser use. In this standard, the principal hazard control rests with the laser user whose responsibility is to know and follow the guidelines stated in this standard.

This standard includes engineering, procedural and administrative controls, and laser safety training necessary for the safety of people who may be exposed. These controls are based upon: evaluation of potential hazards from laser radiation; unique problems related to hospitals and operating rooms (ORs) and non-hospital settings such as outpatient clinics, mobile laser units,

individual medical, dental and veterinarian offices, and any location where an HCLS is being used such as salons and spas. The control measures of this standard apply to all locations where laser radiation is applied for health care applications.

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

The Federal Laser Product Performance Standard (FLPPS) for laser products, Code of Federal Regulations (CFR)¹, requires that the operating manuals for HCLSs contain adequate instructions for assembly, calibration (Class 3 and Class 4 laser products), operation and maintenance, including necessary 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 obtain written information from the manufacturer on suitable laser protective eyewear (LPE), the nominal hazard zone (NHZ), calibration procedures, or adequate instructions for safe use. If the 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 policies and procedures (P&Ps) for the HCLS and the LSO shall maintain a copy of these procedures on file. See 1.3 for LSO definition and responsibilities.

The guidelines 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 health care applications including diagnostic, aesthetic, preventative, therapeutic, or medical/dental research purposes, by or under the direction of qualified licensed professionals engaged in health care. The control measures are intended to give reasonable assurances of laser safety to the patient, public, employer and personnel engaged in use of lasers for health care applications.

1.2 Application: Hazard Classification Scheme.

Appropriate control measures are based on the relative hazards of the HCLS, as determined through risk assessment. 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. The laser hazard classification system is based entirely on laser radiation, to which human access is possible during operation of the laser. 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

¹ CFR 21, Code of Federal Regulations, Title 21, Chapter I, Subchapter J, Part 1040 (Performance standards for light-emitting products), Section 1040.10 (Laser products), Section 1040.11 (Specific purpose laser products).

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. A Class 2 laser system emits in the visible portion of the spectrum (400 to 700 nm) and eye protection is normally afforded by the aversion response. A Class 2M laser system emits in the visible portion of the spectrum (400 to 700 nm) 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 to the eye 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 or a significant hazard to the skin. Class 3R is a relatively low-risk subclass with reduced safety requirements. A Class 3R laser system is potentially hazardous under some direct and specular viewing conditions if the eye is appropriately focused and stable, but the probability of an actual injury is small. A Class 3B laser system may be hazardous under direct and specular viewing conditions, but is normally not a diffuse reflection or 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 that have been classified previously as Class IIa under the FLPPS should be treated the same as Class 1.

Table 1. Requirements by Laser Classification²

Class	Procedural & Administrative Controls	Training	LSO
1	Not Required	Not Required	Not Required
1M	Required	Application Dependent ^b	Application Dependent ^b
2	Not Required ^a	Not Required ^a	Not Required
2M	Required	Application Dependent ^b	Application Dependent ^b
3R	Not Required ^a	Not Required ^a	Not Required ^a
3B	Required	Required	Required

² Adapted from ANSI Z136.1-2007, Table 1

Class	Procedural & Administrative Controls	Training	LSO
4	Required	Required	Required

^a Not required except for conditions of intentional intrabeam exposure applications.

^b 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 Section 4.1.1.3 of ANSI Z136.1-2007).

Table 2. Comparison of National and International Standards for Classification ³

Class	IEC 60825-1 (Ed. 2) ^a	U.S.: FDA/CDRH (FLPPS)	ANSI-Z136.1
Class 1	Any laser or laser system containing a laser that cannot emit laser radiation at levels that are known to cause eye or skin injury during normal operation. This does not apply to service requiring access to Class 1 enclosures containing higher-class lasers.		
Class 1M	Not known to cause eye or skin damage unless collecting optics are used.	N/A	Considered incapable of producing hazardous exposure unless viewed with collecting optics.
Class 2a	N/A	Visible lasers that are not intended for viewing and cannot produce any known eye or skin injury during operation based on a maximum exposure time of 1000 s	N/A
Class 2	Visible lasers considered incapable of emitting laser radiation at levels that are known to cause skin or eye injury within the time period of the human eye aversion response (0.25 s).		

³ Adapted From ANSI Z136.1-2007, Table H2a

Class	IEC 60825-1 (Ed. 2) ^a	U.S.: FDA/CDRH (FLPPS)	ANSI-Z136.1
Class 2M	Not known to cause eye or skin damage within the aversion response time unless collecting optics are used.	N/A	Emits in the visible portion of the spectrum, and is potentially hazardous if viewed with collecting optics.
Class 3a	N/A	Visible lasers less than 5 times the Class 2 limit.	N/A
Class 3R	Replaces Class 3a and has different limits. Up to 5 times the Class 2 limit for visible and 5 times the Class 1 limits for some invisible.	N/A	A laser system that is potentially hazardous under some direct and specular reflection viewing condition if the eye is appropriately focused and stable.
Class 3B	Medium-powered lasers (visible or invisible regions) that present a potential eye hazard for intrabeam (direct) viewing or for viewing specular (mirror-like) reflections. Class 3B lasers do not present a diffuse (scatter) reflection hazard or significant skin hazard except for higher powered Class 3B lasers operating in certain wavelength regions.		
Class 4	High-powered lasers (visible or invisible) that present a potential acute hazard to the eye and skin for both direct (intrabeam) exposure and for exposure to diffuse (scatter) reflections. Class 4 lasers also present a potential hazard for fire (ignition) and by-product emissions from target or process materials.		

^a IEC 60821-1 Ed 2, 2007, Safety of laser products - Part 1: Equipment classification and requirements

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 ensure proper operation of the safety program. An HCLS certified for a specific class by the manufacturer in accordance with the FLPPS may be considered as fulfilling all classification requirements of this standard.

1.2.1.1 Stepwise Procedure for Hazard Classification. The recommended stepwise procedure for using this standard is as follows:

- 1) Determine the hazard class of the HCLS as certified by the manufacturer in accordance with the FLPPS (see 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: 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).⁴

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

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 the FLPPS 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 G).

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. Non-governmental organizations such as The Joint Commission (TJC, formerly known as The Joint Commission on Accreditation of Healthcare Organizations, JCAHO), 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.⁵ These non-governmental organizations have recommended practices, guidelines, or position statements associated with their disciplines and laser uses.

⁴ NOTES in this standard are used as explanatory statements, for emphasis or to offer informative suggestions about technical content—NOTES are not normative.

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

1.3 Laser Safety Officer (LSO).

1.3.1 General. The LSO is the one 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 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 by qualified individual(s); and the LSO may, at times, delegate specific responsibilities. The LSO can be the laser user, laser operator, or other trained person responsible for the laser safety program (see ANSI Z136.1 2007, Appendix A).

1.3.1.1 Deputy Laser Safety Officer (DLSO). If deemed necessary, a DLSO should be appointed by management or the LSO to perform the duties and fulfill the responsibilities of the LSO when the LSO is not available, in large HCF. For facilities with multiple divisions or locations, a system of DLSOs may be deemed necessary. The DLSO can be the laser user, laser operator, or other trained person responsible for the laser safety program.

1.3.1.2 Laser Safety Site Contact (LSSC). If deemed necessary, in organizations with multiple divisions or locations, an LSSC should be appointed by management or the LSO to oversee all operational aspects of laser safety at each site where lasers are being used in health care (e.g., outlying clinical areas such as ophthalmology clinic, day surgery unit, neonatal intensive care unit, dermatology clinic, etc.). The LSSC can also be the laser user, laser operator, or other trained person responsible for the laser safety program. The duties of the LSSC may include but are not limited to:

- 1) Overseeing laser activities in an identified use area
- 2) Working as a liaison between clinical staff and the LSO regarding concerns or questions related to clinical practice
- 3) Troubleshooting equipment
- 4) Monitoring compliance with operational policies and procedures
- 5) Maintaining unit inventory, processing requests for new or additional equipment through to the LSO
- 6) Reviewing documentation pertinent to the use site
- 7) Assisting users and staff as needed during laser use
- 8) Assisting the LSO with auditing, assessing continuing education and training needs, monitoring of licensure, credentialing, and certification status of all staff in the area
- 9) Reporting to the LSO, other activities as assigned

1.3.1.3 LSO, DLSO and LSSC in Non-hospital HCF. In smaller settings, like outpatient facilities, medical, dental and veterinary offices, salons and spas, the LSO can be the laser user, laser operator, or other trained person responsible for the laser safety program. In addition a

DLSO and LSSC may not be needed as long as the LSO remains responsible for overall laser safety and is readily available on a day-to-day basis.

1.3.2 LSO Specific Responsibilities.

1.3.2.1 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. 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 Hazard Evaluation. The LSO shall ensure that a hazard evaluation of the laser treatment controlled areas (LTCA) has been performed prior to laser operation. This shall include evaluation of the potential hazards of the laser as used in the LTCA using the hazard and safety guidance as provided by the HCLS manufacturer and by 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.

1.3.2.3 Hazard Response. The LSO, or designee, 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 policies and procedures (P&Ps) for HCLS use. These P&Ps should include, for example, maintenance, service, and procedural checklists and any laser safety related items reflected in the Institutional P&Ps used by operating personnel (see Appendixes D, E, and G).

1.3.2.6 Protective Equipment. The LSO shall ensure that appropriate protective equipment is available, in good working order (see Section 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 ensure that it is consistent with the manufacturer's safety recommendations and labeling, contained in the user's manual. Modifications of existing facilities or HCLS equipment shall be reviewed by the LSO. Modifications to the equipment shall comply with FDA regulations⁶. 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

⁶ FDA Regulations: Federal Laser Product Performance Standard (21 CFR 1040) and the Medical Device Regulations

carried out by qualified personnel, and that records of this maintenance and service are maintained.

1.3.2.9 Training. The LSO shall ensure that appropriate laser safety education and training is provided to all people associated with lasers, such as providers, clinicians, 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.

1.4 Environment.

Before laser control measures are established, the environment where the device is being utilized must be considered. The recommended stepwise procedure for using this standard is as follows:

- 1) Determine the hazard class from the device warning label.
- 2) Determine the type of location. The type of location will determine the degree of controls required for each of the hazard classification or access levels. There are three location types applied in this standard:
 - a) Unrestricted location is where access to an open beam is unrestricted. Examples include home use and some office and spa premises and any other premises open to the public.
 - b) Restricted location is where access to an open beam is not accessible to the public. Examples include secured areas within hospitals, such as operating room areas that are not open to the public and entry is secured by physical means.
 - c) Controlled location is where access to any area where open beams are controlled and entry is limited to only authorized persons who have received adequate training in laser safety and proper use of the system.
- 3) Determine and apply the appropriate control measures. Apply the relevant control measures specified for the appropriate hazard level as described in Section 4.

1.4.1 Non-hospital Environment. An HCLS may be used in a variety of non-hospital environments including medical, dental and veterinarian offices, salons and spas. The requirements and principles of the safe use of an HCLS 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 laser user in the non-hospital environment to be aware of the requirements its 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, or ensure a qualified person is appointed in that role, as well as ensuring that all federal regulations are followed and non-governmental controls are in place. This requires that the user shall be trained in laser safety, and be knowledgeable of federal, state and local regulations, advisory standards, and professional recommended practices. The user is responsible for, among others, the physical area and its signs, proper use of LPE 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 HCLS(s) that the user employs. If needed, the user should

consult a safety expert, a local LSO, or other appropriate resource regarding safety related issues such as site assessment, hazard evaluation, problem solving, or compliance enforcement.

1.4.2 Third Party Laser Use. If the user employs a third party to provide an HCLS (often including an operator and all accessory equipment), the LSO or designee shall assess the rented or borrowed equipment for compliance with all federal, state and local requirements, as well as compliance with all requirements found in this document.

The LSO shall also ensure that the terms of agreement between the third party provider and the HCF include, but are not limited to:

- 1) The credentials of the third party laser operators meet the facility's policy
- 2) The HCF has received written validation of the maintenance, service, cleaning and condition of the equipment
- 3) Data and elements of documentation collected by the third party are appropriate, meet the HCF policy, and can be verified by facility HCP
- 4) All HCP expected to be in the room with the third party laser have had adequate training on all equipment, in order to safely operate the equipment in the absence of the third party employee, thereby ensuring safe patient care at all times

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.

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

administrative control measure. Control measures incorporating administrative means, e.g., training, safety approvals, LSO designation, and 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.

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**.

collateral radiation. Any electromagnetic radiation, except laser radiation, emitted by a laser or laser system, which is physically necessary for its operation.

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.

deputy laser safety officer (DLSO). The person authorized and responsible for managing the laser safety program, in the absence of the LSO.

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.

NOTE—Sometimes 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).

engineering control measure. Control measures designed or incorporated into the laser or laser system, e.g., interlocks, shutters, watch-dog timer circuits, etc., or its application.

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 that cannot be resolved into a geometrical image.⁷

failsafe interlock. An interlock where the failure of a single mechanical or electrical component of the interlock will cause the system to go into, or remain in, a safe mode.

fire retardant. A material that does not support combustion without an external source of heat such as a laser.

focal length. The distance from the secondary nodal point of a lens to the primary focal point. In a thin lens, the focal length is the distance between the lens and the focal point.

focal point. The point toward which radiation converges or from which radiation diverges or appears to diverge.

half-power point. The value on either the leading or trailing edge of a laser pulse at which the power is one-half of its maximum value.

health care application. Use of a laser device on a patient (human or animal) by or under the supervision of a licensed practitioner, physician, dentist, veterinarian, within their scope of practice for diagnostic, preventive, aesthetic, or therapeutic purposes, where bodily structure or function is altered or symptoms are relieved. These include prescription use of the medical laser device and over the counter indications for use.

health care facility (HCF). For the purpose of this standard, any location where a laser is applied for a health care application.

health care laser system (HCLS). A laser system used in health care applications. The HCLS includes the laser or lasers, a delivery system to direct the output of the laser, a power supply with control and calibration functions, mechanical housing with interlocks, and associated liquids and gases required for the operation of the laser.

health care personnel (HCP). An individual directly involved in application and use of a laser for health care applications.

hertz (Hz). The unit which expresses the frequency of a periodic oscillation in cycles or pulses per second. 1 Hz = 1 cycle per second.

infrared radiation. Electromagnetic radiation with wavelengths which lie within the range of 700 nm to 1 mm.

⁷ See ANSI Z136.1-2007, Section 8.1 for criteria.

installation. The procedure for supplying and connecting electrical power and other utilities to an HCLS.

intrabeam viewing. The viewing condition whereby the eye is exposed to all or part of a laser beam.⁸

ionizing radiation. Electromagnetic radiation having a sufficiently large photon energy to directly ionize atomic or molecular systems with a single quantum event.

irradiance. Radiant power incident per unit area upon a surface. The SI unit of irradiance is watts-per-square-meter ($\text{W}\cdot\text{m}^{-2}$), or for convenience, watts-per-square-centimeter ($\text{W}\cdot\text{cm}^{-2}$). Symbol: *E*.

NOTE—The terms *power density* and *fluence rate* are sometimes used as synonyms for irradiance, although these terms have slightly different technical meanings.

joule. A unit of energy. 1 joule = 1 watt · second.

label. For the purposes of this standard, a display of written, printed, or graphic matter upon the protective housing of a laser product. See: **medical device labeling**.

labeling. A term used in two senses in this standard. First, Medical Device Regulations, 21 CFR 801, use “labeling” to indicate the intended and approved use of the HCLS. Second, a term used to describe the physical label attached to the HCLS equipment. See: **medical device labeling and label**.

laser. A device which produces an intense, coherent, directional beam of light by stimulating electronic or molecular transitions to lower energy levels. An acronym for Light Amplification by Stimulated Emission of Radiation.

laser generated airborne contaminants (LGAC). Airborne contaminants generated when a laser beam interacts with target materials. The materials may include, but are not limited to, plastics, metals, ceramics, glasses, wood and tissue. LGAC may be in the form of gases, vapors, organic or inorganic particulates, or aerosols, and often are a complex mixture of substances in all three states. See also: **plume**.

laser operator. A person who handles the laser equipment and is responsible for setting up the laser prior to use or who operates the console to control the laser parameters under supervision of the user. The operator may also be the laser user.

laser protective eyewear (LPE). Equipment such as eyecups, face shields, goggles, eye shields, spectacles and visors, intended to protect the eyes from overexposure to laser radiation. LPE does not include laser protective windows.

⁸ See ANSI Z136.1-2007, Appendix B, Figures B1 and B2.

laser radiation. Coherent optical (non-ionizing) radiation emitted by a laser. This should not be confused with ionizing radiation.

laser safety officer (LSO). The LSO is the person authorized and responsible for the laser safety program. This individual has the training and experience to administer a laser safety program and has responsibility for oversight and control of laser hazards. The LSO is authorized by the administration and is responsible for monitoring and overseeing the control of laser hazards (see Section 1.3).

laser safety site contact (LSSC). In diverse practice areas, such as large facilities or corporations, a LSSC serves under the supervision of the LSO, and is the person responsible for all aspects of laser safety in each site where lasers are used.

laser system. An assembly of electrical, mechanical and optical components that includes a laser.

laser treatment controlled area (LTCA). The room within which the HCLS is used, and the occupancy and activity of those within this area are subject to supervision for the purpose of protection against all hazards associated with the use of the HCLS. In a large room, a limited LTCA can be designated if clearly marked and controlled.

laser user. A person who controls the application of the laser radiation at the working area and is applying the laser energy of the HCLS for its intended purpose within their scope of practice, license, training and experience.

NOTE—Laser user is the same person as defined in IEC TR 60825-8 as “Laser Operator” and “Laser Operator” in many user manuals provided by manufacturers.

limiting aperture. The maximum diameter of a circle over which irradiance and radiant exposure can be averaged.

limiting exposure duration. An exposure duration which is specifically limited by the design or intended use(s).

maintenance. Performance of those adjustments or procedures specified in user information provided by the manufacturer with the laser or laser system, which is to be performed by the user to ensure the intended performance of the product. It does not include *operation* or *service* as defined in this section.

maximum permissible exposure (MPE). The level of laser radiation to which a person, under normal circumstances, may be exposed without hazardous effects or adverse biological changes in the eye or skin. The criteria for MPE for the eye and skin are presented in ANSI Z136.1-2007, Section 8.

medical device labeling. A term defined in the FDA Medical Device Regulations, 21 CFR 801, which includes all of the information required to appear in the device labeling including the intended use. Labeling, for example in a user's manual, is required to supply adequate directions

for use, which is defined to mean directions under which the layman can use a device safely and for the purposes for which it is intended. Exemptions from adequate directions for use may apply under specific circumstances for prescription devices. *See also: labeling.*

NOTE—The reader is cautioned to avoid confusion between physical labels required to provide cautionary warnings and the medical device labeling definition.

nominal hazard zone (NHZ). The space within which the level of the direct, reflected or scattered radiation during normal operation exceeds the applicable MPE. Exposure levels beyond the boundary of the NHZ are below the appropriate MPE level.

NOTE—Also referred to as the *nominal ocular hazard area* (NOHA).

nominal ocular hazard distance (NOHD). The distance along the axis of the unobstructed beam from the laser to the human eye beyond which the irradiance or radiant exposure during normal operation is not expected to exceed the appropriate MPE.

non-beam hazard. A class of hazards that result from factors other than direct exposure to a laser beam.

note. Additional information to expand or clarify the meaning of a normative section of the standard. Notes do not include the term “shall.”

operation. The performance of the laser or laser system over the full range of its intended functions (normal operation). It does not include *maintenance* or *service* as defined in this section.

optical density [$D(\lambda)$ or OD]. A value that defines the attenuation property of a filter and is equal to the logarithm to the base ten of the reciprocal of the transmittance at a particular wavelength, i.e., $D(\lambda) = \log_{10} [1/\tau(\lambda)]$, where $\tau(\lambda)$, is transmittance at wavelength λ .

NOTE—For example, when the attenuation is 1/100, the OD = 2; when the attenuation 1/100,000, the OD = 5.

patient. For purposes of this standard a patient is the recipient of the laser health care application.

perioperative. The period of time that extends from the setup to the completion of a surgical procedure, including the setup, testing and use of the health care laser system.

personnel. Those persons who are engaged in laser use for health care applications.

personal protective equipment (PPE). Personal safety protective devices used to mitigate hazards associated with laser use, e.g., laser eye protection (LEP), and biologic hazards for infection control, e.g., protective gowns, clothing, masks and gloves.

plasma radiation. Black-body radiation generated by luminescence of matter in a laser generated plume.

plume. Gases, vapors and aerosol created by vaporization of tissue or other materials and may contain viable bacteria, viruses, cellular debris or noxious fumes.

point source. For purposes of this standard, a source with an angular subtense at the cornea equal to or less than alpha-min ($\alpha_{\min}$), i.e., ≤ 1.5 mrad.

policies and procedures (P&Ps). Written policies and procedures that list administrative and procedural control safety measures.

power. The rate at which energy is emitted, transferred, or received. Power is expressed in watts (W). $1\text{ W} = 1\text{ Joule per second}$.

pulse-repetition frequency (PRF). The number of pulses occurring per second, expressed in hertz. Symbol: F .

procedural control measure. See: **administrative control measure**.

protective housing. An enclosure that surrounds a laser or laser system that prevents access to laser radiation above the applicable MPE. The aperture through which the useful beam is emitted is not part of the protective housing. The protective housing may enclose associated optics and a work station and limits access to other associated radiant energy emissions and to electrical hazards associated with components and terminals.

pulse duration. The duration of a laser pulse; usually measured as the time interval between the half-power points on the leading and trailing edges of the pulse.

pulsed laser. A laser that delivers its energy in the form of a single pulse or a train of pulses. In this standard, the duration of a pulse < 0.25 s.

radian (rad). A unit of angular measure equal to the angle subtended at the center of a circle by an arc whose length is equal to the radius of the circle. $1\text{ radian} \approx 57.3\text{ degrees}$; $2\pi\text{ radians} = 360\text{ degrees}$.

radiance. Radiant flux or power output per unit solid angle per unit area expressed in units of watts per steradian per meter squared ($\text{W} \cdot \text{sr}^{-1} \cdot \text{m}^{-2}$).

radiant energy. Energy emitted, transferred, or received in the form of radiation expressed in units of joules (J).

radiant exposure. Surface density of the radiant energy received. The SI unit of radiant exposure is joules per meter squared ($\text{J} \cdot \text{m}^{-2}$), or for convenience, joules per centimeter squared ($\text{J} \cdot \text{cm}^{-2}$). Symbol: H .

NOTE—The terms *energy density* and *fluence* are sometimes used as synonyms for radiant exposure, although these terms have slightly different technical meanings.

radiant flux. Power emitted, transferred, or received in the form of radiation expressed in units of watts (W).

NOTE—Also called *radiant power*.

radiant intensity (of a source in a given direction). Quotient of the radiant flux leaving a source and propagated in an element of solid angle containing the given direction, by the element of solid angle expressed in units of watts per steradian ($\text{W}\cdot\text{sr}^{-1}$).

radiant power. Power emitted, transferred or received in the form of radiation. *See:* **radiant flux.**

reflectance. The ratio of total reflected radiant power to total incident power. Also called *reflectivity*.

repetitive pulse laser. A laser with multiple pulses of radiant energy occurring in a sequence.

service. The performance of those procedures or adjustments described in the manufacturer's service instructions which may affect any aspect of the performance of the laser or laser system. These are usually performed by qualified technical personnel provided by the manufacturer or other service companies. It does not include *maintenance* or *operation* as defined in this section.

shall. The word "shall" is to be understood as mandatory.

should. The word "should" is to be understood as advisory.

specular reflection. A mirror-like reflection.

transmission. Passage of radiation through a medium.

transmittance. The ratio of total transmitted radiant power to total incident radiant power.

ultraviolet (UV) radiation. Electromagnetic radiation with wavelengths shorter than those of visible radiation; for the purpose of this standard, 180 to 400 nm.

visible radiation (light). Electromagnetic radiation which can be detected by the human eye. This term is commonly used to describe wavelengths which lie in the range 400 to 700 nm.

watt. The unit of power or radiant flux. 1 watt = 1 joule per second.

wavelength. The distance between two successive points on a periodic wave which have the same phase.

3. Hazard Evaluation and Classification

3.1 General.

Various aspects of the HCLS influence the total hazard evaluation and thereby affect selection of the control measures to be applied:

- 1) The capability of the radiant energy of the HCLS to injure HCP or the intended patient

- 2) The environment in which the HCLS is used (hospitals, outpatient facilities, doctors, dentist, chiropractic and veterinarian offices, salons, spas or other location where an HCLS is used)
- 3) The HCP who may use or be exposed to laser radiation
- 4) The delivery system which is important to defining the extent of the NHZ
- 5) The non-beam hazards associated with the HCLS (see Section 7)

Aspects (2), (3), (4) and (5) vary with each laser application and cannot be readily standardized. Normally, laser beam hazards exist only within the NHZ. The total hazard evaluation procedure shall consider all aspects.

The HCLS laser hazard classification scheme is based upon aspect (1). In this scheme a Class 1 laser is considered to be incapable of producing damaging levels of laser emission. Class 2 (low power) applies only to visible laser emissions which may be viewed directly for time periods less than or equal to 0.25 s, the aversion response time. Class 1M and 2M pose the same risk to the unaided eye as do Class 1 and Class 2 (respectively), but may pose an increased ocular hazard from intra-beam viewing with certain optical instruments.

Class 3 lasers may be hazardous for direct exposure or exposure to specular reflection and are divided into two subclasses, 3R and 3B. Class 3R is a transitional, lower-risk group of lasers with reduced requirements (Class 3R – formerly Class 3a). A Class 3B laser system may be hazardous under direct and specular reflection viewing conditions, but is normally not a diffuse reflection or fire hazard.

Class 4 lasers present significant eye, skin and fire hazards and may pose hazardous diffuse reflections. Most surgical lasers, and all lasers emitting in excess of 0.5 W average radiant power, are Class 4 (see ANSI Z136.1-2007).

An HCLS shall be labeled with the appropriate hazard classification (see Section 4.7). An HCLS certified for a specific class by a manufacturer in accordance with the FLPPS fulfills all classification requirements of this standard (see Section 1.2.2). It should be noted that in some cases there may be differences between this standard and the FLPPS (see ANSI Z136.1-2007, Appendix C and Table H2a for references). The responsible laser user shall arrange for a hazard evaluation and possible reclassification of an HCLS when it has been modified for use in a manner other than originally intended. This analysis may be performed by the LSO or the manufacturer. A written analysis, which is kept as part of the HCLS service record, shall be maintained on file and a copy supplied to the LSO.

3.2 Laser Considerations.

To apply appropriate control measures, the characteristics of the HCLS must be known. The laser output characteristics will define the NHZ (see 3.4.1). The wavelength of the laser determines whether retinal, corneal or skin hazards are the main safety consideration. In the event that multiple-wavelength or tunable lasers, (e.g., tunable dye lasers, krypton and mixed gas lasers) are available, the LSO shall determine that appropriate safety measures are employed for all emitted wavelengths.

3.3 Laser and Laser Systems Hazard Classification.

The manufacturer is required to supply the HCLS laser hazard classification in accordance with the FLPPS (see Appendix G). If this classification is not available, or the system has been modified, the classification shall be determined by the LSO.

3.4 Laser Use Environment: Operating or Treatment Rooms.

The importance of environmental factors depends on the HCLS classification.

3.4.1 Nominal Hazard Zone. The NHZ of the HCLS, or the technical information for its calculation, should be provided by the HCLS manufacturer. An HCLS may be equipped by the manufacturer with alternative delivery systems, each of which will have its own NHZ. The LSO shall determine the NHZ for each and every alternative delivery system based on information provided by the manufacturer, from measurements, calculations, or by designating the entire room as the LTCA.

3.4.2 Laser Treatment Controlled Area. The LTCA is the location in which the HCLS is used and which contains the NHZ. The LTCA shall be established wherever a Class 3B or Class 4 HCLS is used. This requirement applies to laser use in any location. The extent of the NHZ shall be indicated by the LSO if the entire LTCA is not declared as the NHZ. The design and placement of windows and viewing ports may extend the NHZ beyond the LTCA if the laser wavelength is between 310 nm to 2800 nm (where glass transmits optical radiation). If the NHZ is very small, it may be possible to define the LTCA as a region of a large room, but if this is done, the LTCA must clearly be identified and controlled.

3.5 People Who May be Exposed.

Potentially exposed people include all who may be in the vicinity of an HCLS and its emitted beam(s) including the patient, laser operator and HCP. The presence of such people can influence the total hazard evaluation and, hence, the decision to adopt additional control measures not specifically required for the class of HCLS being employed.

4. Control Measures

4.1 General Considerations.

Control measures are procedures or methods by which hazards associated with the safe use of lasers are minimized. Control measures are divided into administrative, engineering, and procedural controls (Table 3).

Administrative controls are those control measures that form the infrastructure of the laser safety program and may include, but not be limited to, the appointment and performance criteria for the LSO, policies and other relevant documentation, audit, reporting, and educational requirements.

Engineering controls are safety features incorporated into the HCLS, or designed into the installation of the HCLS and require verification by the LSO. Engineering control measures,

which are incorporated into the HCLS itself or added to the installation by the user, are almost always the preferred method for controlling access to laser radiation. If engineering controls are impractical or inadequate, administrative and procedural controls, which may include the use of personnel protective equipment (PPE), shall be used. Many engineering controls are mandated by the FLPPS, FDA/CDRH. Engineering control measures shall be used. This includes those implemented by both the manufacturer and the user.

Procedural controls are those measures employed by HCP in the performance of their duties, operation and use of an HCLS during patient care, and during service and maintenance that include, but are not limited to, examination and use of LPE, posting of appropriate signage at LTCA entryways, use of local exhaust ventilation (LEV) during plume producing treatments, and assigning a dedicated laser operator to the control panel of the HCLS when appropriate to ensure safety to patients and HCP.

It is important to understand that regardless of the setting, the presence of the patient as recipient of the laser energy, creates the need for a set of unique control measures. These control measures recognize the potential for unintended hazards to the patient who is in a passive role. Special measures are required to protect the patient throughout the procedure. Hazards, pertinent to specific types of lasers, are covered in Appendixes A and B.

The ancillary hazards associated with the use of an HCLS can be significant. Severe injury and loss of life has occurred during electrical servicing and testing of laser equipment from endotracheal tube fires, explosions, and gas embolisms. In addition, LGCA and intense incandescent radiation (which can present additional eye hazards) may be produced during the interaction of laser energy with materials, e.g., bone and carbonized tissue. Controls for non-beam hazards are covered in Section 7.

Control measures in this section apply when the equipment is in its intended operational mode. Control measures applicable to maintenance and service are discussed separately (see 4.2.4). The limits of any type of control measures, e.g., failure modes of enclosures and LPE, or the inability of some people to understand written warnings, shall be considered in developing a laser hazard protection program.

4.1.1 HCLSs Used in Research. In non-clinical research laboratories the LSO shall establish control measures that comply with the requirements set forth in ANSI Z136.1. Any research involving people who might be exposed to laser radiation shall comply with this standard (ANSI Z136.3). Also see Appendixes C15.6 and G.

4.2 Administrative Controls.

Experience has shown the necessity for a clear line of administrative control in safety matters. Thus, an LSO shall be appointed to effect administrative controls (see Section 1.3). If deemed necessary in large HCF, a DLSO should be appointed to assume the responsibilities of managing the laser safety program in the absence of the LSO. The LSO may, at times, delegate specific responsibilities (see Sections 1, 3, 5, and Appendix F). Administrative controls are methods and/or instructions that regulate work practices to implement or supplement engineering controls and may specify criteria for personnel protection. The HCF shall establish P&Ps (see sample P&P in Appendix H). The

procedures should include, for example, perioperative checklists for use by operating personnel (see Appendix B, Form B1).

4.2.1 Policies and Procedures (Class 3B and Class 4). The HCF shall establish P&Ps (see sample P&P in Appendix H). The P&Ps should include, for example, perioperative checklists for use by operating personnel (see Appendix B, Form B1). The LSO shall require approved written operating and maintenance P&Ps for Class 3B and Class 4 HCLSs. These operating and maintenance P&Ps shall be maintained and readily available. The LSO shall require that safety P&Ps exist for servicing of the HCLS. See sample P&P in Appendix H.

4.2.2 Manufacturers' Procedures (Class 3B and Class 4). The LSO shall ensure that all safety items specified for the safe use of an HCLS, e.g., LPE, warning signs and adapters, have been received and have been delivered to the laser use site. The LSO shall obtain approved written operating, maintenance and calibration procedures from the manufacturer or distributor of the HCLS. The LSO shall periodically update the HCF procedures based upon the latest safety information supplied by the manufacturer.

4.2.3 Authorized Personnel—Laser Users. Class 3B and Class 4 HCLSs shall be operated by facility-authorized personnel appropriately trained in the safe use of the HCLS (see Section 5 and Appendix F).

4.2.4 Maintenance and Service (Class 3B and Class 4). The LSO is responsible for ensuring that service of Class 3B and Class 4 HCLSs, (or other HCLSs with embedded Class 3B and Class 4 lasers) shall be performed only by technicians trained in laser service. All aspects of maintenance and service of HCLSs shall follow the requirements of this standard and ANSI Z136.1.

4.2.5 Procedural Controls. Procedural controls, as determined by the LSO, shall be used to avoid potential hazards associated with Class 3B and Class 4 HCLSs. These include:

- 1) Adhering to written P&Ps.
- 2) Assigning a dedicated person to operate the controls, if applicable, when appropriate for the procedure and practice setting.
- 3) Maintaining a list of authorized laser users and HCP.
- 4) Requiring storage or disabling (removal of key) of the HCLS where unauthorized operation is of concern.
- 5) Assuring that operators know the location and operation of the emergency stop control provided with each HCLS.
- 6) Assuring that the ready function is enabled only when the user is ready to treat the target tissue.
- 7) Using only diffuse reflective materials or instruments with low reflectance in or near the beam path, where feasible.
- 8) Taking steps to avoid confusion encountered during surgical procedures when operating with more than one floor pedal.

4.3 Equipment Controls.

Engineering controls as an integral part of the laser or laser system shall be used as supplied by the manufacturer. In addition, the following additional equipment controls apply:

4.3.1 Guarded Switch (Class 3B and Class 4). For Class 3B and Class 4 HCLSs, the switch that controls patient exposure shall be guarded, e.g., a guarded pedal switch or guarded finger-trigger switch. In environments with multiple-guarded foot pedal switches for different HCLSs or other operating room instruments, precautions shall be taken to prevent inadvertent activation.

4.3.2 Accessory Equipment (Class 3B and Class 4). Accessory attachments to HCLSs, e.g., handpieces, endoscopes (including laparoscopes), fibers, remote controls and scanners, shall be compatible with and provide prerequisite laser safety. Laser filters placed on or used with operating microscopes shall protect the laser user at the main binocular viewing tube, and a label shall state clearly whether or not accessory viewing ports are protected in order to alert assistants or observers of the need to wear LPE.

4.3.3 HCLS Equipment Labels (All Classes except Class 1). Labeling in accordance with ANSI Z136.1 or the FLPPS shall satisfy the labeling requirements of this standard if it is visible during normal operation. Any required labeling shall not be covered or removed from the HCLS (see ANSI Z136.1- 2007).

4.3.4 Service and Repair of Laser Systems (All Classes). The LSO shall ascertain whether any changes in control measures are required following any service or repair procedure.

4.3.5 Equipment Modifications (All Classes). Manufacturers' recommended upgrades (including software) may require changes in safe operating procedures as well as recertification and reporting to the FDA. Modification of the HCLS, including the delivery system, that affect labeled claims require an updated hazard evaluation. The modification may introduce the need for changes in safe operating procedures that may be difficult to anticipate. Thus, any modifications should be undertaken with caution. The LSO shall ensure that locally instituted changes in laser system design or function shall be accompanied by a hazard evaluation (see Section 1.3.2.2). The safety P&Ps shall be revised if required by the hazard evaluation.

4.3.6 Health Care Facility and Equipment Safety Audits (Class 3B and Class 4). A laser safety audit of the facility and safety features (e.g., LPE, barriers, area controls, plume removal, warning signs, etc.) and equipment safety features (labels, electrical components, inspection stickers, fiber cables, etc.) shall be conducted and documented under the supervision of the LSO. The frequency of such audits shall be determined by the LSO, but should be no less than once per year. The audit should include examination of all equipment associated with the use of the laser, examination of the physical plant and use areas, assessment of staff knowledge of laser safety, and observation of procedures to determine deficits in compliance with policy and standards. A written audit report shall be required by the LSO, deficits remedied, and follow-up actions documented.

4.3.7 Lasers or Laser Systems for Home Health Care Use (Class 3B and Class 4). Class 3B and Class 4 laser products to be used in home healthcare applications can present atypical situations requiring unique control measures. When practicable, the laser products should be designed to preclude ocular exposure above the MPE during operation and maintenance, and also

under reasonably foreseeable misuse. If the laser products cannot be designed to preclude such exposure, the manufacturer or dispenser of the laser product shall provide the user with training and/or clear, plainly written procedures for safe use. In this case, the user/patient shall assume full responsibility for personal safety, as well as the safety of any other person or persons in the vicinity of the laser product.

4.4 Laser Use Environment (Class 3B and Class 4).

The Class 3B and Class 4 HCLS operating environment influences the choice of the most appropriate control measures. The LSO has the option to require additional control measures that are not specifically required in this section. Similarly, in rare circumstances, the LSO may determine that some control measures in this section are not required (see Section 1.3.2.4). The NHZ and the LTCA are defined to assist in the selection of the required safety procedures. Design considerations of the LTCA should include illumination appropriate to the laser application. The use of highly reflective specular surfaces, such as mirrors and glass should be avoided where possible. The design and placement of windows and viewing ports may extend the NHZ beyond the LTCA and controls shall be implemented in accordance with Section 3.4.2.

4.4.1 NHZ. The NHZ describes the space within which the level of direct, reflected or scattered radiation, during normal operation, exceeds the applicable MPE. The LSO determines the NHZ from safety information supplied in the manufacturer's labeling, by measurement, by using an appropriate analysis or other equivalent assessment, or by designating the entire room in which the laser is used, as the NHZ. The LSO shall ensure that suitable safety practices and procedures are maintained within the NHZ. Under some conditions, the LSO may determine that control measures are required within the entire LTCA defined in 4.4.2. Such situations may arise when movement of people in and out of the NHZ may be anticipated (see Table A3, and ANSI Z136.1-2007, Appendix B6.6).

In establishing the NHZ, the LSO shall ensure that consideration is given to direct, reflected and scattered radiation transmission through open doors or transparent windows, as well as the possibility of equipment malfunction (e.g., fiber breakage), or the intrusion of unauthorized unprotected people. No additional controls are required outside the NHZ.

Viewing the main beam or a specular laser target in the wavelength range of 310 nm to 2800 nm (or even to 4000 nm in rare cases) with an optical instrument (or magnification eyewear, endoscope, colposcope or microscope) is potentially hazardous due to the instrument's light-gathering and transmission capability. Use of such optical systems without laser-safety filters may therefore effectively increase the NHZ boundaries and shall be considered in the overall hazard analysis.

Service personnel and others involved in alignment, calibration or servicing of the HCLS should recognize that these activities may create a larger NHZ. The NHZ may be small when interlocks and delivery systems are in place. When interlocks are defeated, or the delivery system has been modified, the NHZ may change (see 4.2.4).

4.4.2 Laser Treatment Controlled Area (Class 3B and Class 4). The LTCA is the location where the HCLS is used, and which contains the NHZ. In those rare instances where the LTCA is a very limited area of a much larger space, the LSO shall carefully define the border of the

LTCA. The LTCA shall be established wherever a Class 3B or Class 4 HCLS is used. This requirement applies to laser use within all facilities. The extent of the NHZ shall be indicated by the LSO if the entire LTCA is not declared as the NHZ. The need to describe the location of the NHZ will generally arise from the use of lasers with very small NHZs, such as an ophthalmic laser with a 40 cm NHZ. By contrast, the much larger NHZ associated with some high-output surgical lasers will fill the LTCA. The LTCA shall be clearly delineated and shall:

- 1) Be posted with the appropriate area warning sign(s) (see 4.7) and LPE at the entry and if deemed necessary by the LSO, should be posted within the LTCA.
- 2) Be supervised by HCP trained in laser safety.
- 3) Be occupied only by patients and appropriately trained HCP or other authorized persons who shall be provided upon entry the appropriate personal protective equipment for use within the NHZ, as described in 4.6.

NOTE—The above provision is not intended to restrict or limit in any way the use of laser radiation which may be intentionally administered to a patient for cosmetic, preventive or therapeutic applications or clinical investigative purposes by, or under the direction of, a qualified professional engaged in health care.

- 4) All windows, doorways, open portals, within, or allowing access into, the NHZ, shall be either covered or restricted in such a manner as to reduce the transmitted laser radiation to levels at or below the appropriate ocular MPE for any laser radiation transmitted from the laser treatment area. Window barriers should be non-flammable, and should meet the facility's infection control policies for maintenance and cleaning.

NOTE—Typical window glass (3 mm or greater minimum thickness) has an optical density (OD) in excess of 5.0 for lasers operating in the spectral range of 180 – 300 nm and greater than 2,800nm. Only in these spectral regions will the facility windows not require additional covering or filtering.

- 5) Use a door, blocking barrier, screen, or curtains to attenuate laser radiation in the entryway. The level of laser radiation at the exterior of these devices shall not exceed the applicable MPE, nor shall people experience any exposure above the MPE immediately upon entry.

NOTE—These measures are needed since the more traditional entryway safety interlocks used in some Class 4 laser areas are usually not appropriate during medical and surgical procedures.

- 6) Have any area/entry safety controls designed to allow both rapid egress and admittance to the LTCA under emergency conditions.

4.4.3 Surgical Probes and Optical Fibers. The LSO shall evaluate the components, assembly procedures, maintenance procedures, and application of fiberoptic delivery systems and shall implement procedural and administrative controls commensurate with the potential hazards.

4.4.4 Patient Eye Protection. When the patient's eyes are potentially within the NHZ, they shall be protected from inadvertent exposure by a method approved by the LSO. The suitability of patient eye protection methods and equipment shall be determined based on the intended