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American National Standard for Safe Use of Lasers in Health Care

Secretariat
Laser Institute of America

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American National Standards Institute, Inc.

American National Standard

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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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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).