



Loss Control TIPS

Technical Information Paper Series

Innovative Safety and Health SolutionsSM

Understanding Medical Lasers and Using Them Safely

What Are Medical Lasers? What Do They Do?

The word “laser” is an acronym for “*light amplification by stimulated emission of radiation.*” This phrase describes the process in which photons are emitted and amplified by atoms and molecules. This process creates laser light. The output of the laser process is a pure and powerful beam of light that has uses in many industrial, scientific, military, and medical (including dental) applications.

How Do Medical Lasers Work?

All types of lasers have three general components: an energizing source, an active medium, and a resonant cavity. The laser light is generated within the *active medium*, which may be solid, liquid, or gas. Laser action originates in the active medium bounded by two mirrors which reflect photons. The output mirror is semitransparent to allow laser light to leave the cavity.

The space formed by the optical medium bounded by the two mirrors is called a *resonant cavity*. Laser action occurs when the great majority of the atoms or molecules within the active medium are simultaneously brought to a higher energy state. Energizing the active medium is done by an *energy source*. Energy sources commonly used in medical laser systems include flash lamps similar to that used in a photographic flash, or electric currents similar to the electric current that lights a neon or fluorescent bulb. Other components that may be within the cavity include *apertures* to shape the beam and *shutters* to control laser action.

All medical lasers contain a *delivery system* that is responsible for directing the energy output of the laser to its site of action. A *fixed delivery system* is incorporated into another instrument. For example, a CO₂ laser beam directed by an operating microscope is fixed in space and directed by a joystick or similar control that allows very limited movement of the beam.

Fixed delivery systems are also found in ophthalmic lasers that are connected to a slit lamp, which allows the surgeon to view the operative site and deliver the laser energy to the treatment site in the eye. An *articulated delivery system* can be moved freely in space. For example, dermatologic lasers employ a freely movable hand piece so the surgeon can apply laser energy directly to the skin. The clinical requirements and design of a medical laser’s delivery system will largely determine its hazards.



How Are Medical Lasers Used?

Lasers are used routinely in many medical, dental, and surgical specialties. Many types of lasers are used in medical, dental, and surgical practice. The more common health care laser systems (HCLS) are Argon, Nd:YAG, and CO₂. The medical/surgical application of laser technology is based on the laser's ability to interact with, and create changes in, tissue. Depending on several factors, including the power of the laser, the duration of exposure and localization of the beam or lateral heat diffusion, both desired and deleterious effects on tissue can occur. Thermal, ionizing, or photochemical effects produce various results, including coagulation, sealing or cauterizing to control blood loss, cutting or removing tissue, and "welding" tissue (as in reconnecting blood vessels).

Medical lasers are being used in many medical/surgical specialties. Many of these specialties and the associated applications of laser technology are listed in Table 1 (at the end of this article).

Lasers have been found to be effective in a variety of applications, including corneal surgery, dermatology (including pigment/tattoo removal), angioplasty, tumor removal, and research. Lasers are used for diagnostic and therapeutic medical purposes as well as for surgical purposes. Lasers are in routine clinical use in many medical, dental, and surgical practices. Lasers interact with tissue to create a change in that tissue. Depending upon laser power, exposure duration, wavelength, energy and spot size of the incident beam, and absorption characteristics of the tissue, one of the following thermal, ionizing, or photochemical laser-tissue interactions may occur:

- photocoagulation (thermal): coagulation, sealing or cauterizing, with minimal tissue destruction
- photothermal ablation (vaporization) for incising or excising (cutting, tissue removal)
- photochemical ablation (photoablative decomposition)
- photodisruption
- photochemical interaction: nonablative

The most common surgical applications of medical lasers employ the process of *photocoagulation*. In this process, proteins, enzymes, and other critical biological molecules in tissue are heated to temperatures above 50° Centigrade, and up to 100° Centigrade, with a resultant tissue denaturation occurring almost immediately. Photocoagulation is used to prevent blood loss when surgically incising heavily vascularized tissue (e.g., the liver, the nasal mucosa, the larynx, etc.), to stop gastric bleeding, and, on an investigational basis, to anastomose (connect) severed vessels and weld tissues. Photocoagulation is also used in ophthalmology.

When a tissue temperature of 100° Centigrade is exceeded, *photovaporization* occurs. Photovaporization is used for incision and removal of diseased tissue. Delayed bleeding is a complication of vaporization; this occurs in 6 to 10 percent of cases, most frequently four to seven days after surgery. The bleeding resolves on its own 98 percent of the time. Stenosis (narrowing) and scarring is minimal.

Photochemical ablation is a process in which surface tissue is removed through UV interaction with surface cells. Photoablation occurs when short-pulsed radiation photolytically disassociates and volatilizes tissue, producing a cut with no visible degradation (necrosis) of surrounding tissue and no hemostasis. This process makes unusually clean-cut incisions possible.

Ionizing effects of lasers produce an acoustic shock wave, ionizing molecules in the target tissue. This process, in which a small volume of tissue is instantly vaporized and atoms are ionized, has been of value in microsurgical applications. The resulting *photodisruption* is used in ophthalmological procedures.

Photochemistry, or *photochemical interaction*, occurs whenever visible or ultraviolet radiation interacts with molecules. There are beneficial photochemical interactions, such as vision and the production of vitamin D in the skin. There are also adverse photochemical effects, such as erythema (reddened skin) and photodermatoconjunctivitis (welder's flash). To induce a photochemical response, laser energy is delivered sufficiently slowly so that heat is conducted away from the interaction site, and normal temperatures are maintained. This process is the primary interaction in photochemotherapy, such as the use of the hematoporphyrin derivative (HpD) to treat tumors. A photosensitizing drug is introduced into biological tissue that is then exposed to the incident laser radiation. This exposure elicits the desired biological response (perhaps a toxic side effect), in the targeted tissues.

Medical lasers are usually categorized by their active medium and by their intended applications. The laser active medium may be either a solid, liquid, or gas. Table 2 (at the end of this article) summarizes typical medical laser systems and their applications.

The carbon-dioxide (CO₂) laser has enjoyed the widest use of any laser in general surgery. The CO₂ laser is used in almost every specialty as the most common laser source, except in photodynamic therapy and ophthalmic applications. It is used extensively for removing polyps, incising heavily vascularized tissue where coagulation is desired, and removing tumors in surface lesions. The CO₂ laser has been referred to as the "light knife" and the "bloodless scalpel." The other lasers (ruby argon and tunable dye for minor bleeding; YAG for major bleeding) are often referred to as "welders." The latter have also been referred to as "erasers" because of their use in removal of birthmarks and tattoos.

The benefits of the use of several types of lasers have been demonstrated in dentistry, particularly relative to procedures involving the soft tissues of the mouth, including the gums, ligaments and fibers that bind tooth to socket, and the tissue supporting the tongue. The FDA has cleared for marketing certain lasers for soft tissue use, such as gingivectomies (removing excess gum tissue). FDA approval of hard tissue (including tooth and root) laser applications is just beginning. Certain carbon dioxide, Nd:YAG, argon, Ho:YAG, Er:YAG, Er:YSGG and diode lasers have been cleared for intraoral soft tissue surgery; certain Nd:YAG lasers have been cleared for aphthous ulcer treatment and sulcular debridement (soft tissue curettage); certain argon lasers have been cleared for the curing of composite materials; certain carbon dioxide and argon lasers have been cleared for tooth whitening; and certain Er:YAG lasers have been cleared for caries removal, cavity preparation, and enamel roughening.

Potential Hazards and Control Measures

Lasers have been found to be effective in a variety of medical applications, including corneal surgery, dermatology, angioplasty, tumor removal, and research. However, the use of lasers for diagnostic and therapeutic medical purposes as well as for surgical purposes is not without risk. ANSI's laser standards and classification system, the FDA's laser regulations and classifications, and the FDA's classification of lasers as medical devices group lasers into classes according to levels of hazard and provide guidance with respect to necessary control measures. Engineering performance requirements and administrative control measures are required by either or both the FDA and ANSI Z-136.1 and Z-136.3 (discussed in detail in Part 3, below.)

Depending on the duration of exposure and the localization or lateral heat diffusion, both desired and damaging effects on tissue can occur. Laser injuries typically involve the eye or the skin.

Eye Hazards

The biological effects of laser light on the eye depend upon wavelength. Lasers operating between 400 and 1,400 nm are potentially dangerous to the retina; their use almost always requires protective eyewear. Damage to the retina can result in substantial loss of vision. The cornea and lens, which are in the front part of the eye, can be damaged by wavelengths outside of the retinal hazard region. The severity of injury, which depends on the wavelength, can range from a superficial corneal injury with spontaneous repair and recovery of vision, to permanent corneal scarring with vision loss. The latter may necessitate corneal transplantation. Lasers which are potentially hazardous to the retina are the argon, krypton, copper or gold-vapor, helium-neon, and neodymium:YAG lasers.

The amount of energy in the laser beam required to injure the cornea is much greater than that required to injure the retina. This is because laser light striking the cornea is not concentrated by the eye, as are wavelengths in the retinal hazard region. Lasers which are potentially hazardous to the cornea are the erbium:YAG, erbium:YLF, holmium:YAG, hydrogen-fluoride, carbon-monoxide, and carbon-dioxide, and the excimer lasers.

Skin Hazards

The skin is less vulnerable to laser injury than the eye because the skin's outer layer serves as a protective barrier to exposure of the living cells, whereas the living cells of the cornea are protected only by a thin film of tears. This is why more laser energy is required to injure the skin than the cornea. However, there is a greater probability of laser exposure to some part of the exposed skin from a direct or reflected laser beam than to the considerably smaller surface area of the eye.

Injury to the skin can be either *photochemical* or *thermal*. Photochemical injuries, commonly referred to as "sunburn," are predominant in the ultraviolet end of the spectrum. Higher levels of visible and infrared laser beam exposure can cause second- and third-degree thermal injuries (burns). The severity of injury depends upon the length of exposure and the penetration depth of the laser radiation. Generally, laser exposure to the skin for a second or more will elicit pain and a withdrawal response. However, this protective reaction is not available to a sedated or anesthetized patient who may be subject to inadvertent skin damage.

Skin injuries can also occur as a result of ignition of clothing by a direct or reflected laser beam.

Serious complications have occurred during head and neck surgical procedures as a result of endotracheal tube fires. The outcome can be as serious as death. Measures that can be used to reduce fire risk include the use of less flammable airways and reduction of oxygen in anesthetic gas mixtures.

Cloth drapes used in surgery lose their fire retardant qualities after frequent laundering, and can contribute to fire hazard in the surgical field. Injuries have occurred when drapes have burst into flames during laser procedures.

Who Is Susceptible To Injury?

Patients who are undergoing medical or surgical laser procedures, surgeons, other medical personnel, and bystanders are susceptible to laser hazards and potential injuries. Accidental exposure to the patient from misdirection of the laser beam is a concern, particularly when lasers are used near the eye and where exposure of the eye itself is not intended. Proper precautions must be followed to prevent injury of the patient's eye and skin. Shields placed over the eye or under the eyelid will reflect laser energy or absorb laser light and thermal energy, thus protecting the eye.

Surgeons, surgical assistants, nurses, and other bystanders who are present during laser procedures can be exposed to misdirected laser beams. The risk to the surgeon or laser operator is generally small, particularly when the target tissue is viewed through optics that have been properly designed for use with the laser instrument. However, the absence of a safety filter during some procedures could pose a risk to the surgeon's eye. Furthermore, with hand-held laser delivery systems, the surgeon's hand is the closest laser target of potentially hazardous reflections from adjacent surgical instruments.

Nurses, assistants, and other bystanders are potentially exposed to misdirected laser beams or to secondary reflections from surgical devices. A hazard exists when lasers are fired by accidental activation of a foot-switch. This can be avoided by placing the laser in "standby" mode when it is not in operation. Reflections from the cornea or the contact lens used in ophthalmic surgery may be hazardous to assistants or bystanders who are in line of view of the contact lens. The operating microscope used by a number of specialties in laser microsurgery will protect the eyes of the surgeon if it is properly designed, whereas assistants and bystanders may be exposed to potentially hazardous reflections from surgical implements if they are inserted into the beam. Fortunately, most reflected beams are highly divergent and therefore less hazardous than the collimated beam. Visitors to the operating room may be at greater risk because of their lack of training or knowledge about the laser surgical procedure.

Service personnel are particularly susceptible to laser injury, since they often have access to collimated laser beams. Service personnel have experienced serious eye injuries when they gain access to the laser cavity and are exposed to invisible secondary collimated laser beams.

Other Hazards

Other hazards associated with medical lasers include the potential for injury from electrical shock, airborne contaminants, compressed gases, incoherent light, as well as mechanical and chemical hazards. Electrical hazards arise from the high electric voltages and currents necessary to power the laser. These electrical hazards are not unique electrical safety problems, and are controlled through the facility's electrical safety program. To prevent the potential of electrical shock, appropriate grounding, electrical shielding of electrical equipment, and other electrical safety procedures are essential. The Joint Commission on Accreditation of Health Care Organizations (JCAHO) requires that only instruments that meet certain electrical safety standards be used.

Unlike conventional surgical techniques, a laser can produce fumes that are derived from vaporized tissue during incision, ablation, and coagulation. These fumes, or "plumes," are potentially hazardous, and, if sufficient quantities are produced, special attention is needed and local exhaust ventilation or respiratory support will be required. In applications where there is significant tissue ablation, the use of a fume evacuator will reduce atmospheric contamination of noxious fumes and potentially infectious particulate matter. Local exhaust ventilation is also necessary also to control levels of chemical contaminants like acetylene, ethene, ethane, propene, hydrogen-cyanide, acrolein, xylene, benzene, and formaldehyde.

In some laser systems, chemical hazards exist with the use of toxic gases, toxic dyes, and solvents. There is particular concern with chemical and excimer lasers. Excimer lasers use canisters of toxic fluorine or hydrogen chloride which is mixed with a nontoxic inert gas such as argon, krypton, or xenon. These gases must be properly contained. Externally vented gas cabinets are recommended for storage of gas cylinders in research laboratories. Excimer laser gases such as F and HCL can be premixed with the inert gas and stored in smaller size bottles to minimize the potential amount of gas release in the event of a serious leak. Medical excimer laser systems use built-in gas cabinets and use special non-corrosive tubing and fittings.

Mechanical hazards exist with any movable equipment. Injuries have been caused by the rapid movement of an articulated arm into an individual, or the tipping over of a laser console. Users must be knowledgeable about the mechanical properties of any laser system in order to avoid injuries to themselves or others.

Controls

Laser hazard controls can be categorized as follows:

- administrative procedures (laser safety program)
- personnel protective equipment (eye protectors, respirators, gloves, etc.)
- engineering controls for the laser and environment

Engineering controls are typically more costly, but are considered more reliable. Examples of engineering controls are installation of baffles, laser protective filters installed in doors, shutters on windows, low-reflectance walls, and laser system safety features, such as protective housings for the laser, key-locked switches, and interlocks. (FDA-mandated laser system safety features are outlined in Table 3)

A laser safety program must be designed to suit the size of the facility. ANSI standards Z-136.1 (*Safe Use of Lasers*) and Z-136.3 (*Safe Use of Lasers in Health Care Facilities*) outline general precautions and requirements for the safe use of lasers. While most states, municipalities, and the federal government do not have specific regulatory requirements for medical laser safety programs, if an injury occurs or a complaint is filed, the Occupational Safety and Health Administration (OSHA) could investigate and find that the management of the facility is at fault if a laser safety program is not in place and if the general precautions outlined by the ANSI standards are not being followed. The JCAHO would also rely on ANSI Z-136.3 as the accepted guide for safe use of medical lasers. (Control measures for the health care laser systems are outlined in Table 4.)

Classification and Safety Standards

ANSI's Laser Standards and Classification

The principal laser safety standard in the United States is ANSI Z136.1-1993, *American National Standard for the Safe Use of Lasers*.¹ This is a consensus standard co-published by the American National Standards Institute (ANSI) and the Laser Institute of America (LIA). The ANSI Z136 committee has published two other standards addressing laser safety: ANSI Z136.2-1988, *Safe Use of Optical Fiber Communications Systems Utilizing Laser Diode and LED Sources*,² and ANSI Z136.3-1996, *Safe Use of Lasers in Health Care Facilities*.³

The ANSI laser safety standards use a Hazard Classification Scheme to group medical lasers into four major classes and two sub-classes, and describe *maximum permissible exposure limits* (MPEs) for laser users. As described in ANSI Z136.3-1996,⁴ the major classes range from Class 1, the least hazardous, to Class 4, the most hazardous:

- Class 1: A low-powered laser device that cannot, under normal circumstances, emit laser radiation that creates an optical hazard. These are sometimes called exempt lasers.
- Class 2: Low-powered laser devices operating in the visible spectrum that cannot injure a person accidentally, but which may injure the eye when viewed directly for an extended period of time.

- Class 3: Medium-powered laser devices that are capable of causing eye damage with short-duration exposures to the direct or specularly reflected beam.
- Class 4: Lasers that can injure if viewed directly or if reflections are viewed. These lasers can also cause severe skin damage and are to be considered a fire hazard.

This hazard classification system aids the user in determining what degree of hazard is posed by any specific laser, and it allows the user to select appropriate precautions that are increasingly stringent for each successively higher class laser. Each of the four classes is distinguished by a *maximum accessible radiation output level*, which is the amount of radiation to which the human eye or skin may normally be exposed.

The standard specifically applicable to medical lasers, ANSI Z136.3-1996, focuses primarily on the *use* of lasers; however, it does provide some product safety guidance for design, warning labels, quality control, and calibration. (Table 4 outlines control measures for health care laser systems as presented in ANSI Z136.3-1996.⁵)

The FDA's Laser Regulations and Classifications

Lasers are classified by the Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), which has the responsibility for implementing and enforcing the laws and regulations which apply to radiation-producing electronic products and medical devices. Manufacturers of laser products are required to certify that their products comply with the *Federal Laser Product Performance Standard* (21 CFR Part 1040)⁶, which is promulgated and enforced by CDRH. Under the provisions of the Radiation Control for Health and Safety Act (RCHSA), this standard is intended to prevent unnecessary access to laser and collateral radiation, and to ensure that each laser product provides adequate safety-related engineering control features, labeling, and instructions for use. A classification scheme (which is very similar, but not identical, to that used in ANSI Z136.1-1996) determines which performance features and labels must be provided by the manufacturer.⁷ (The tables referred to in these definitions specify wavelength and emission duration for the various classes of medical lasers.)

- *Class I laser product* means any laser product that does not permit access during the operation to levels of laser radiation in excess of the accessible emission limits contained in Table I of paragraph (d) of this section [of the regulation].
- *Class IIa laser product* means any laser product that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits contained in Table I, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in Table II-A of paragraph (d) of this section [of the regulation].
- *Class II laser product* means any laser product that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits contained in Table II-A, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in Table II of paragraph (s) of this section [of the regulation].
- *Class IIIa laser product* means any laser product that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits contained in Table II, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in Table III-A of paragraph (s) of this section [of the regulation].
- *Class IIIb laser product* means any laser product that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits contained in Table III-A, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in Table III-B of paragraph (s) of this section [of the regulation].

- *Class III laser product* means any Class IIIa or Class IIIb laser product.
- *Class IV laser product* means any laser that permits human access during operation to levels of laser radiation in excess of the accessible emission limits contained in Table III-B of paragraph (d) of this section [of the regulation].

A summary of the FDA/CDRH requirements for laser products (21 CFR 1040) is available on OSHA's World Wide Web site,⁸ and is included below as Table 3.

The FDA's Classification of Lasers as Medical Devices

The Medical Devices Amendment (MDA) to the Food, Drug and Cosmetic Act (FD&C Act) requires that the FDA regulate *all* medical devices. Therefore, all medical lasers are regulated by the FDA as medical devices. The FDA's *Medical Device Classification Procedures* are published in the *Code of Federal Regulations* at 21 CFR 860.⁹ The MDA places *all* medical devices in one of three classes: (I, II, or III), as follows:

- *FDA Medical Device Class I devices*, such as surgical scissors, retractors, or diagnostic lights, are subject to general controls only. These controls prohibit the adulteration or misbranding of devices, and require registration, listing, and labeling as well as adherence to Good Manufacturing Practices (GMPs). Medical lasers are not usually placed in FDA Medical Device Class I.
- *FDA Medical Device Class II devices*, such as cardiac pacemakers, are those which have been designated as requiring "special controls" or performance standards to ensure their safety and effectiveness. All controls applicable to FDA Medical Device Class I devices also apply to FDA Medical Device Class II. *Most medical lasers are placed in FDA Medical Device Class II.* Such lasers can be brought to market through submission of a pre-market notification (or "510K"), in which the manufacturer claims substantial equivalence to currently classified laser devices.¹⁰ The FDA may require that a study be done under an investigational device exemption (IDE) to demonstrate the equivalence. The FDA only recently published guidelines for design controls which specify the "special controls" for all Class II medical devices.¹¹ The regulation, which is promulgated in 21 CFR Parts 808, 812, and 820, is effective June 1, 1997 with a one year phase in period. (See Table 5 for an outline of 21 CFR 820 *Quality System Regulation*.) The concept of "good manufacturing practices" is replaced by "quality control system" which includes principles of good manufacturing practices and enhances, rather than replaces, this concept.
- *FDA Medical Device Class III devices*, such as prosthetic implants, infant radiant warmers, and extended wear contact lenses, require pre-market approval (PMA) by FDA before they can be marketed or promoted. *All new medical lasers and lasers promoted for new applications are in Class III and are investigational devices whose use is subject to federal regulation.* In order for a manufacturer to obtain a PMA, scientific, statistically valid evidence of safety and effectiveness must be determined through controlled clinical investigations performed under an IDE (as outlined in 21 CFR 812).¹² Sponsors and investigators involved in clinical studies are urged to carefully review the outline of the IDE.

These medical device classes are *not* equivalent or related to the laser hazard classification schemes of the *Federal Laser Product Performance Standard* (21 CFR 1040) or the *American National Standard for the Safe Use of Lasers in Health Care Facilities* (ANSI Z136.3-1996). Rather, they refer to the *degree of regulatory control* necessary to assure that each medical device is *safe* and *effective*.

Summary

The medical application of laser technology has grown considerably since the first laser was developed in 1960 by Theodore Maiman. Depending on the duration of exposure and localization or lateral heat diffusion, both desired and deleterious/damaging effects on tissue can occur. Deleterious results of laser tissue interactions may always be a factor that requires the utmost attention by practitioners.

Each type of laser has advantages, with regard to the amount of energy that can be stored, ease of handling and storage, secondary safety hazards, cooling properties, and physical characteristics of the laser output. Similarly, there are advantages and disadvantages associated with applications of various types of lasers, based on factors like efficiency, cost effectiveness, visibility of emission lines, bulk, fragility, precision of surgical cutting, and maintenance requirements.

Diagnostic lasers incorporated into health care laser systems usually have low outputs of energy and power, and are thus placed in ANSI Class 1 or Class 2. Most medical lasers fall into the ANSI Class 3 or 4 categories. Most surgical lasers fall into ANSI Class 4. Most medical/surgical lasers are classified by the FDA as Class II or Class III medical devices. Laser manufacturers and users must follow appropriate control measures.

There are differences among specific performance standards and other requirements applicable to medical lasers. From a product liability perspective, medical manufacturers should be knowledgeable about *all* applicable standards and guidelines, and should meet, or preferably *exceed*, them. It should be noted that, as non-governmental consensus standards, ANSI standards are *voluntary*. Federal regulations established by FDA are *mandatory*.

Laser performance features, such as remote interlock connectors, key switch master controls, and emission indicators, are installed by laser manufacturers. However, it is up to the user to actually *use* the safety features and to be in compliance with the ANSI standard for safe use of medical lasers. It is up to the facility to develop and enforce a program for safe use of medical lasers.

For more information, contact your local Hartford agent or your Hartford Loss Control Consultant. Visit The Hartford's Loss Control web site at <http://www.thehartford.com/corporate/losscontrol/>

This document is provided for information purposes only. It is not intended to be a substitute for individual legal counsel or advice on issues discussed within. Readers seeking resolution of specific legal issues or business concerns related to the captioned topic should consult their attorneys and/or insurance representatives.

Notes

1. *American National Standard for Safe Use of Lasers* (ANSI Z136.1-1993). Orlando, FL: Laser Institute of America, c1993.
2. *American National Standard for the Safe Use of Optical Fiber Communications Systems Utilizing Laser Diode and LED Sources* (ANSI Z136.2-1988) Orlando, FL: Laser Institute of America, c1988.
3. *American National Standard for the Safe Use of Lasers in Health Care Facilities*. (ANSI Z136.3-1996). Orlando, FL: Laser Institute of America, c1996.
4. *Ibid.*, pages 6-7.
5. *Ibid.*, page 20.
6. *Medical Device Classification Procedures*. (21 *Code of Federal Regulations* Part 860). Washington, DC: U.S. Dept. of Health and Human Services, Food and Drug Administration, 1996.
7. *Ibid.*, page 547.
8. "FDA/CDRH Requirements for Laser Products," from the *OSHA Technical Manual*, Section II, Chapter 6 Appendix II:6. U.S. Dept. of Labor, Occupational Safety and Health Administration (www.osha-slc.gov/TechMan_data/TM31.html) (as of March 6, 1997.)
9. *Performance Standards for Light-Emitting Products*. (21 *Code of Federal Regulations* Part 1040). Washington, DC: U.S. Dept. of Health and Human Services, Food and Drug Administration, 1996.
10. *Medical Devices; Current Good Manufacturing Practices (CGMP) Final Rule; Quality System Regulation*. Washington, DC: U.S. Dept. of Health and Human Services, Food and Drug Administration. *Federal Register* (vol. 61, no. 195), October 7, 1996, pp. 52602-52662.
11. *Pre-market Notification 510(k): Regulatory Requirements for Medical Devices*. Washington, DC: U.S. Dept. of Health and Human Services, Food and Drug Administration, 1995.
12. *Investigational Device Exemptions*. (21 *Code of Federal Regulations* Part 812). Washington, DC: U.S. Dept. of Health and Human Services, Food and Drug Administration, 1996.

Additional References

1. Gilcrease, Judith B. "Guidelines for Personnel in Avoiding Hazards." *The Cancer Bulletin*, Vol. 41, No. 4, 1989, pp. 224-226.
2. Lewis, Rich. "Lasers in Dentistry." *FDA Consumer*, January-February 1995, pp. 15-18.
3. Sliney, David H. and Trokel, Stephen L. *Medical Lasers and Their Safe Use*. New York: Springer-Verlag, 1993.
4. United States. Occupational Safety and Health Administration. "Guidelines for Laser Safety and Hazard Assessment." Instruction Publication 8-1.7. Washington, DC: Occupational Safety and Health Administration, August 1991.
5. Young, Paul. "Shedding Light on Lasers." *Perspective*, Fall, 1984, pp. 9-15.

Table 1. Medical/Surgical Specialties And Laser Applications

General Surgery

- Tissue interactions: incision, ablation, coagulation
- Endoscopic laser surgery
- Tumor surgery (excision, ablation, photodynamic therapy)

Dermatology

- Surface vascular lesions (e.g., port wine stains)
- Pigment and tattoo removal
- Epithelial (superficial skin) lesions (e.g., removing warts, overgrowth, and calloused tissue)

Ophthalmology

- Ophthalmic photocoagulators (e.g., sealing retinal tears, other retinal procedures, treatment of glaucoma)
- Photodisruptors (controlled incising in any transparent or semitransparent membranes inside the eye)
- Ophthalmic diagnostic lasers (e.g., scanning laser ophthalmoscope to image the retina, corneal surface analyzer)
- Laser corneal surgery (e.g., keratorefractive and therapeutic surgery)

Cardiovascular and chest surgery

- Tissue welding and vessel anastomosis (replacement for suturing)
- Laser angioplasty and endarterectomy

Otolaryngology and head and neck surgery

- Removal tumors and other tissue in the nasal and oral cavities
- Biopsy or excision of tumors of vocal cord

Neurosurgery

- Microsurgery
- Removing tumor tissue close to critical neural tissue,

Gynecology

- Endometrial lesions
- Fertility surgery
- Removal of polyps

Urology

- Removal of tumors of bladder, urethra, and external genitalia

Podiatry

Dentistry

- Gingivectomies (Removing excess gum tissue)
- Soft tissue surgery, including ulcer treatment and sulcular debridement
- Curing of composite materials
- Tooth whitening
- Caries removal

Table 2. Typical Medical Laser Systems

Laser Type	Active medium	Application
Argon Fluoride excimer	ArF	Corneal surgery, plastic surgery, dentistry
Xenon chloride excimer	XeCl	angioplasty
Argon	Ionized Ar gas	Multispecialty surgical Dentistry
KTP (Nd:YAG)	Nd:YAG KTP crystals	Multispecialty surgical
Krypton	Ionized Kr gas	Retinal coagulation
Copper Vapor	Cu ions	Dermatology
Dye	Organic dyes	Ophthalmology (retinal coagulation), dermatology (tumors), plastic surgery
Gold Vapor	Au ions	Tumors
Helium-neon	Neon gas	Aiming, “biostimulation”
Ruby	Cr ³⁺ :Al ₂ O ₃	Dermatology, plastic surgery (noted advantage for tattoo removal)
Diode	Ga-As family	Diverse; Used for pain relief outside the U.S. (controversial)
Alexandrite	Crystal	Research
Neodymium	Nd:YAG crystal	Diverse Dentistry
Thulium	Th:YAG crystal	Developmental
Holmium	ThHoCr:YAG crystal	Developmental Dentistry
Erbium:YAG	Er:YAG crystal	Developmental Dentistry
CO ₂	CO ₂ gas	Diverse Dentistry

(Adapted from Sliney and Trokel, p. 24, and ANSI Z136.3)

Table 3. FDA/CDRH Requirements for Laser Products

Requirements	FDA/CDRH Class(1)					
	I	IIA	II	IIIA	IIIB	IV
Performance (all laser products)						
Protective housing	R(2)	R(2)	R(2)	R(2)	R(2)	R(2)
Safety interlock	R(3,4)	R(3,4)	R(3,4)	R(3,4)	R(3,4)	R(3,4)
Location of controls	--	R	R	--	R	R
Viewing optics	R	R	R	R	R	R
Scanning safeguard	R	R	R	R	R	R
Performance (laser systems)						
Remote interlock connector	--	--	--	--	R	R
Key control connector	--	--	--	--	R	R
Emission indicator	--	--	R	R	R(10)	R(10)
Beam attenuator	--	--	R	R	R	R
Reset	--	--	--	--	--	R(13)
Performance (specific purpose products)						
Medical	S	S	S	S(8)	S(8)	S(8)
Surveying, leveling, alignment	S	S	S	S	NP	NP
Demonstration	S	S	S	S	S(11)	S(11)
Labeling (all laser products)						
Certification and identification	R	R	R	R	R	R
Protective housing	D(5)	R(5)	R(5)	R(5)	R(5)	R(5)
Aperture	--	--	R	R	R	R
Class Warning	--	R(6)	R(7)	R(9)	R(12)	R(12)
Information (all lasers)						
User information	R	R	R	R	R	R
Product literature	--	R	R	R	R	R
Service information	R	R	R	R	R	R

Abbreviations: R (required) NP (not permitted)
 -- (not applicable) D (depends on level of interior radiation)
 S (same as other products of class)

(OSHA Technical Manual, Section II, Chapter 6, Appendix II:6-1)

Notes:

1. Based on highest level accessible during operation.
2. Required wherever and whenever human access to laser radiation above Class I limits is not needed for product to perform its functions.
3. Required for protective housings opened during operation or maintenance, if human access thus gained is not always necessary when housing is opened.
4. Interlock requirements vary according to Class of internal radiation.
5. Wording depends on level and wavelength of laser radiation with protective housing.
6. Warning statement label.
7. CAUTION logotype.
8. Requires means to measure level of radiation intended to irradiate the body.
9. CAUTION if 2.5m Wcm(2) or less, DANGER is greater than 2.5 mWcm(2).
10. Delay required between indication and emission.
11. Variance required for Class IIIB or IV demonstration laser products and light shows.
12. DANGER logotype.
13. Required after August 20, 1986.



Table 4. Control Measures for the Health Care Laser System

Classification	1	2a	2	3a	3b	4
Research (4.1.1)					X	X
Administrative Controls (4.2)					X	X
Laser Use Committee (5.1)					X	X
Maintenance and Service (4.2.1)					X	X
Standard Operating Procedures (4.2.2)					X	X
Authorized Personnel (4.2.3)					X	X
Equipment Controls (4.3)					X	X
Guarded Switch (4.3.1)					X	X
Beam Delivery Disconnect Safety Features (4.3.2)					X	X
HCLS Warning Labels (4.3.3)		X	X	X	X	X
Service and Repair of HCLS (4.3.4)	X	X	X	X	X	X
Modification of HCLS (4.3.5)	X	X	X	X	X	X
Quality Control and Safety Audits (4.3.6)					X	X
HCLS Output Calibration (4.5.1.1)		•	•	•	X	X
Area Posting Sign (4.4.2.1)			•	•	X	X
Environment in which Laser is Used (4.4.1)	**	**	**	**	**	**
Laser Treatment Controlled Area (4.4.2)					X	X
Optical Fiber Surgical Probes (4.4.3)	**	**	**	**	**	**
Alignment Procedures (4.5.1)			X	X	X	X
Patient Eye Protection (4.4.4)					X-NHZ	X-NHZ
Service Personnel (4.5.2)	X	X	X	X	X	X
Protective Eyewear (4.6.2)					X-NHZ	X-NHZ
Protective Clothing (4.6.4)	**	**	**	**	**	**
Warning Signs/ Labels (4.7)		•/X	•/X	•/X	•/X	•/X
Explosion and Fire Hazards (7.5)						X

(from ANSI Z-136.3-1996, page 20)

Legend:

- X** Shall
- X-NHZ** Shall within the NHZ (Nominal Hazard Zone)
- Should
- **** Laser Safety Officer (LSO) shall establish alternate controls

Numbers in parentheses refer to ANSI Z136.3-1996 paragraph numbers.



Table 5. Medical Devices; Current Good Manufacturing Practices (CGMP) Final Rule; Quality System Regulation. (from 21 CFR 820)

Subpart A General Provisions 820.1 Scope 820.3 Definitions 820.5 Quality System
Subpart B Quality System Requirements 820.20 Management responsibility 820.22 Quality audit 820.25 Personnel
Subpart C Design Controls (820.30)
Subpart D Document Controls (820.40)
Subpart E Purchasing Controls (820.50)
Subpart F Identification and Traceability (820.60 and 820.65)
Subpart G Production and Process Controls 820.70 Production and process controls 820.72 Inspection, measuring, and test equipment
Subpart H Acceptance Activities 820.80 Receiving, in-process, and finished device acceptance 820.86 Acceptance status
Subpart I Nonconforming Product (820.90)
Subpart J Corrective and Preventive Action (820.100)
Subpart K Labeling and Packaging Control 820.120 Device labeling 820.130 Device packaging
Subpart L Handling, Storage, Distribution, and Installation (820.140, 820.150, 820.160, 820.170)
Subpart M Records 820.180 General requirements 820.181 Device master record 820.184 Device history record 820.186 Quality system record 820.198 Complaint files
Subpart N Servicing (820.200)
Subpart O Statistical Techniques (820.250)