

PART AA

Registration and Radiation Safety Requirements for Lasers

Sec. AA.1 - Purpose and Scope.

- a. This Part establishes requirements for the registration of persons who receive, possess, acquire, transfer, or use Class 3b and Class 4 lasers in the healing arts, veterinary medicine, industry, academic, research and development institutions, and of persons who are in the business of providing laser services. No person shall use lasers or perform laser services except as authorized in a certificate of laser registration issued by the Agency in accordance with the requirements of this Part.
- b. This Part establishes requirements for protection against laser radiation hazards, laser hazard control methods, training requirements, and notification of injuries. This Part includes responsibilities of the registrant and the laser safety officer (LSO).
- c. Except as otherwise specifically exempted, these regulations apply to all persons who receive, possess, acquire, transfer, own, or use lasers that emit or may emit laser radiation. [Individuals shall not use lasers on humans unless under the supervision of a licensed practitioner of the healing arts if use of lasers is within the scope of practice of their license.] Nothing in these regulations shall be interpreted as limiting the intentional exposure of patients to laser radiation for the purpose of diagnosis, therapy, or treatment by a licensed practitioner of the healing arts within the scope of practice of their professional license. [These regulations do not apply to the manufacture of lasers.]
- d. Laser products certified by a manufacturer to be compliant with the Federal laser product performance standard of Title 21, Code of Federal Regulations (21 CFR 1040) applicable at the date of manufacture shall be maintained in compliance with such requirements. Certified laser products that have been modified shall comply with these regulations or the Federal standard.
- e. If any conflict arises between the requirements of these regulations and the Federal laser product performance standard with respect to the same aspect of performance for laser products subject to the Federal standard, the requirements of the Federal standard shall apply.
- f. In addition to the requirements of this Part, all registrants authorized to use Class 3b and 4 lasers are subject to the following requirements:
 - i. Part A.3a, A.4, A.5, A.7, A.8, A.9, A.11, A.12 and the applicable definitions in A.2 of these regulations;
 - ii. Part D.1004a. of these regulations; and
 - iii. Part J of these regulations with the exception of J.13 - Notification and Reports to Individuals.

Sec. AA.2 - Definitions. As used in these regulations:

"Accessible emission level" means the magnitude of emission from laser or collateral radiation of a wavelength and emission duration to which human access is possible within a particular class in the Federal laser product performance standard or the most recent edition of the American National Standards Institute for Safe Use of Lasers, ANSI Z136.1, as measured under the conditions specified in AA.31.

"Accessible emission limit (AEL)" means the maximum accessible emission level permitted within a particular class in the most recent edition of the American National Standard for Safe Use of Lasers, American National Standards Institute (ANSI) Z136.1.

"Act" means [cite State Radiation Control Act or appropriate State statute].

"Agency" means [cite appropriate State Agency responsible for administration of the Act].

"Aperture" means an opening through which laser or collateral radiation can pass allowing human access to such radiation.

"Aperture stop" means an opening serving to limit the size and to define the shape of the area over which radiation is measured.

"Certified laser product" means that the product is certified by a manufacturer as required by Title 21, Code of Federal Regulations (CFR), Part 1040.

"Class 1 laser" means a laser or laser system that may produce visible or invisible laser radiation. Under all normal conditions of operation, a Class 1 laser is considered to be incapable of causing injury. For maximum permissible exposure limits, see the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1.

"Class 2 laser" means a laser or laser system that produces low-power visible laser radiation not exceeding 1 mW. Eye protection is normally afforded by the natural aversion response to viewing bright lights. The typical reaction time is less than 0.25 second. For maximum permissible exposure limits, see the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1.

"Class 2a laser products" means any laser product that permits human access to levels of visible laser radiation in excess of the Class 1 accessible emission limits, during its operation, but does not permit human access to levels of laser radiation in excess of the accessible Class 2a emission limits. For maximum permissible exposure limits, see the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1.

"Class 3a laser, International Electrotechnical Commission (IEC) Class 3R" means a laser or laser system that produces moderate levels of visible or invisible laser radiation of 1 to 5 mW and requires more stringent control than a Class 2 laser. For those Class 3a lasers whose output is visible, the transiency of most exposures and the aversion response are generally sufficient to prevent eye injury. For maximum permissible exposure limits, see the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1.

"Class 3b laser" means a laser or laser system that produces visible laser radiation of 5 to 500 mW of visible continuous wave output and 5 to 500 mW of invisible infrared laser radiation. A Class 3b laser is considered medium power laser and is capable of producing eye injury when viewed directly or with optics, even if viewed momentarily. For maximum permissible exposure limits, see the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1.

"Class 4 laser" means a laser or laser system that produces visible or invisible laser radiation capable of causing injury to the eye and skin, and dangerous specular and diffuse reflections. For maximum permissible exposure limits, see the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1.

"Collateral radiation" means any electronic product radiation, except laser radiation, emitted by a laser as a result of the operation of the laser(s) or any component of the laser product that is physically necessary for the operation of the laser(s). (The accessible emission and maximum permissible exposure limits for collateral radiation are specified in Title 21, CFR, Part 1040.10.)

"Continuous wave (CW)" means the output of a laser that is operated in a continuous rather than a pulsed mode. For purposes of these rules, a laser operating with a continuous output for a period greater than 0.25 second is regarded as a CW laser.

"Controlled area" means any area where the occupancy and activity of those within is subject to control and supervision for the purpose of protection from radiation hazards.

"Demonstration laser" means any laser manufactured, designed, intended, or used for purposes of demonstration, entertainment, advertising display, or artistic composition.

"Diffuse reflection" means the change of the spatial distribution of a beam of laser radiation when it is reflected in many directions by a surface or by a medium.

"Electronic product" means:

- (1) Any manufactured or assembled product which, when in operation,
 - (i) Contains or acts as part of an electronic circuit and
 - (ii) Emits, or in the absence of effective shielding or other controls would emit, electronic product radiation, or
- (2) Any manufactured or assembled article that is intended for use as a component, part, or accessory of a product described in (1) and which when in operation emits, or in the absence of effective shielding or other controls would emit, such radiation.

"Electronic product radiation" means radiation that is emitted from an electronic product as the result of the operation of an electronic circuit in such product, and includes:

- (1) Any ionizing or nonionizing electromagnetic or particulate radiation, or

- (2) Any sonic, infrasonic, or ultrasonic wave.

"Embedded laser" means an enclosed laser with an assigned class number higher than the inherent capability of the laser system in which it is incorporated, where the system's lower classification is appropriate due to the engineering features limiting accessible emission.

"Enclosed laser" means a laser that is contained within a protective housing of itself or of the laser or laser system in which it is incorporated. Opening or removing of the protective housing provides additional access to laser radiation above the applicable maximum permissible exposure (MPE) than possible with the protective housing in place. (An embedded laser is an example of one type of enclosed laser.)

"Energy" means the capacity for doing work. Energy content is commonly used to characterize the output from pulsed lasers and is generally expressed in joules (J).

"Facility" means any location where one or more lasers are used or operated. The confines of any facility shall be designated by the owner of such facility. A part of a building, an entire building, or other structure or plant or, where appropriate, a specified out-of-doors location may be designated as a facility.

"Human access" means access to laser or collateral radiation by any part of the human body.

"IEC Class 1M laser" means a laser or laser system that may produce visible or invisible laser radiation. Under all normal conditions of operation, a Class 1M laser is considered incapable of causing injury from direct unaided viewing. However, there can be a hazard if an optical aid, such as a telescope, binocular, loupe, or magnifier is used to directly view the laser radiation.

"IEC Class 2M laser" means a laser that is no more hazardous than a Class 2 laser for unaided viewing, but more hazardous if an optical aid is used to directly view the laser radiation.

"Incident" means an event or occurrence that result in a real or suspected accidental exposure to laser radiation that caused or is likely to cause biological damage.

"Individual" means any human being.

"Integrated radiance" means radiant energy per unit area of a radiating surface per unit solid angle of emission, expressed in joules per square centimeter per steradian ($\text{J cm}^{-2} \text{ sr}^{-1}$).

["Intense-pulsed light (IPL) device" means a non-laser device that emits radiation to energy density levels of optical radiation that could reasonably cause bodily harm and that is used for photothermolysis. This device is a Class I or Class II medical device. The United States Food and Drug Administration (FDA) regulations require pre-marketing clearance or approval and a quality system for manufacturing.]

"Irradiance" means an area, specified by laser safety standards, over which the irradiance is to be averaged. This area is given as the diameter of a circular aperture for measurement.

"Joule (J)" means a unit of energy: 1 joule = 1 watt second.

"Laser" means any device that can produce or amplify electromagnetic radiation with wave lengths in the range of 180 nanometers to 1 millimeter primarily by the process of controlled stimulated emission. Laser is an acronym for Light Amplification by Stimulated Emission of Radiation.

"Laser energy source" means any device intended for use in conjunction with a laser to supply energy for the operation of the laser. General energy sources such as electrical supply mains or batteries shall not be considered to constitute laser energy sources.

"Laser product" means any manufactured product or assemblage of components which constitutes, incorporates, or is intended to incorporate a laser or laser system. A laser or laser system which is intended for use as a component of an electronic product shall itself be considered a laser product (See AA.26a. for applicability requirements).

"Laser protective device" means any device used to reduce or prevent exposure of personnel to laser radiation. Such devices may include protective eyewear, garments, engineering controls, and operational controls.

"Laser radiation" means all electromagnetic radiation emitted by a laser product within the spectral range specified in the definition of "Laser" in Section AA.2 that is produced as a result of controlled stimulated emission or that is detectable with radiation so produced through the appropriate aperture stop having a diameter, a solid angle of acceptance, and collimating optics as specified in AA.31.

"Laser safety officer (LSO)" means any individual, qualified by training and experience in the evaluation and control of laser hazards, which is designated by the registrant and has the authority and responsibility to establish and administer the laser radiation protection program for a particular facility or a particular mobile laser.

"Laser system" means an assembly of electrical, mechanical, and optical components that includes a laser.

"Maintenance" means the performance of those adjustments or procedures by the user (specified in user information provided by the manufacturer with the laser or laser system) that are to be performed by the user to ensure the intended performance of the product.

"Maximum permissible exposure (MPE)" means that level of laser radiation to which persons may be exposed without hazardous effect or adverse biological changes in the eye or skin. (The criteria for the MPE for cornea (eye) and skin are detailed in the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1.)

"Mobile laser" means a laser which is used at temporary job sites.

"Operation" means performance of the laser or laser system over the full range of its intended functions (normal operation). It does not include maintenance or service tasks as defined in these regulations.

"Optical density (OD)" means a logarithmic expression of the optical attenuation afforded by a material:

$$OD = \log_{10} \frac{(\text{Incident power})}{(\text{Transmitted power})}$$

"Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Agency, political subdivision of this State, any other State or political subdivision or Agency thereof, and any legal successor, representative, agent, or Agency of the foregoing[, but shall not include federal government agencies].

["Photothermolysis" means the non-invasive aesthetic application of intense-pulsed light (IPL) energy to selective superficial features such as unwanted body hair or veins (also see definition for intense-pulsed light (IPL) device).]

"Practitioner of the healing arts (practitioner)" means, for the purposes of this Part, a person licensed to practice the healing arts by either the [state] Board of Medical Examiners as a physician; the [state] Board of Dental Examiners; the [state] Board of Chiropractic Examiners; or the [state] Board of Podiatry Examiners. A practitioner's use of a laser is limited to his/her scope of professional practice as determined by the appropriate licensing agency.

"Protective housing" means those portions of a laser product that are designed to prevent human access to laser or collateral radiation in excess of the prescribed accessible emission limit.

"Pulse duration" means the duration of a laser pulse, usually measured as the time interval between the half-power points on the leading and trailing edges of a pulse.

"Radiance" means time-averaged radiant power per unit area of a radiating surface per unit solid angle of emission, expressed in watts per square centimeter per steradian ($\text{W cm}^{-2} \text{ sr}^{-1}$).

"Radiant energy" means energy emitted, transferred or received in the form of radiation, expressed in joules (J).

"Radiant exposure" means the radiant energy incident on an element of a surface divided by the area of that element, expressed in joules per square centimeter (J cm^{-2}).

"Radiant power" means power emitted, transferred, or received in the form of radiation, expressed in watts (W).

"Registrant" means any person who registers a mobile laser, facility, or service organization with the Agency pursuant to these regulations.

"Safety interlock" means a device associated with the protective housing of a laser product, system or facility which prevents human access to laser and/or collateral radiation in excess of the prescribed accessible emission limit.

"Sampling interval" means the time interval during which the level of accessible laser or collateral radiation is sampled by a measurement process. The magnitude of the sampling interval in units of seconds is represented by the symbol (t).

"Secured enclosure" means an enclosure to which casual access is impeded by appropriate means,

such as a door secured by a magnetically or electrically operated lock or latch or by fasteners that need a tool to remove.

"Service" means the performance of those procedures or adjustments described in the manufacturer's service instructions that may affect any aspect of the performance of the laser or laser system. Service does not include operation or maintenance as defined in these regulations.

"Specular reflection" means mirror-like reflection.

"These regulations" mean all Parts of [cite appropriate rules or regulations].

"Watt" (W) means the unit of power or radiant flux; 1 watt = 1 joule per second (J sec^{-1}).

Sec. AA.3 - Exemptions. The following are exempt from regulations in this Part:

- a. Facilities containing only certified Class 1, Class 2, Class 2a, and Class 3a lasers or laser products, provided that the laser product is maintained as a certified Class 1, Class 2, Class 2a, and Class 3a laser product throughout its useful life except for those that allow access to Class 3b or Class 4 laser radiation during servicing;
- b. Certified Class 3b visible (0.4 to 0.7 μm) or near-infrared (0.7 to 1.4 μm) lasers or laser systems that emit in excess of the AEL of Class 3a but which:
 - i. Cannot emit an average radiant power in excess of $5 \text{ W} \geq 0.25$ second; or
 - ii. Cannot produce a radiant energy greater than 0.125 within an exposure time less than 0.25 second J per pulse.
- c. Mobile lasers that are certified Class 1, Class 2, Class 2a, and Class 3a;
- d. Lasers that are in transit or in storage incident to transit or sale provided such lasers are inoperable or not operated; and
- e. Facilities containing only IEC Class 1M, 2M, and 3R Lasers.

Sec. AA.4 - Prohibited Uses.

- a. An individual shall not be permitted to look directly into a laser beam or at specular reflections of a laser beam, or align a laser by eye while looking along the axis of a beam when the intensity of the beams or reflections exceed the MPE limits.
- b. A registrant shall not permit any individual to enter a laser-controlled area if the skin exposure would be in excess of the MPE limits, unless the registrant provides and requires the use of protective clothing, gloves, and shields.
- c. Laser products emitting spatially scanned laser radiation shall not, as a result of scan failure or any other failure, causing a change in angular velocity or amplitude, permit human access to laser radiation in excess of the accessible emission limits applicable to the class of the

product.

- d. The Agency may prohibit the use of lasers and Intense-pulsed light (IPL) devices that pose significant threat or endanger occupational or public health and safety.
- e. Individuals shall not be intentionally exposed to laser and IPL radiation above the maximum permissible exposure (MPE) unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits intentional exposure for the following purposes:
 - i. Exposure of an individual for training, demonstration, or other non-healing arts purposes;
 - ii. Exposure of an individual for the purpose of healing arts screening, except as specifically authorized by the Agency; and
 - iii. Exposure of an individual for the purpose of research, except as authorized in research studies. Any research using radiation-producing devices on humans must be approved by an institutional review board (IRB) as required by Title 45, Code of Federal Regulations (CFR), Part 46 and Title 21, CFR, Part 56. The IRB must include at least one practitioner of the healing arts to direct use of laser and IPL device radiation in accordance with AA.1c.

Sec. AA.5 - General Registration Requirements.

- a. All facilities using fixed or mobile lasers, and persons servicing lasers or laser systems, except as exempted in Section AA.3, shall register with the Agency.
- b. Application for registration shall be made on forms furnished by the Agency or in a manner otherwise approved by the Agency. The application shall contain all applicable information included in Agency Form AA.
- c. The Agency may, at any time after filing of the original application and before issuance of the certificate of laser registration, require further statements in order to enable the Agency to determine whether the application should be granted or denied. The applicant or registrant shall furnish the Agency with such other information as the Agency may reasonably request.
- d. Information designated as proprietary by the applicant or registrant shall be treated as provided by law.
- e. A laser safety officer (LSO) shall be designated on each application form. The qualifications of that individual shall be submitted to the Agency with the application. The LSO shall meet the applicable requirements of Section AA.14 and carry out the responsibilities of Section AA.15.

Sec. AA.6 - Application for Registration of Healing Arts Laser Facilities and Veterinary Laser Facilities.

- a. In addition to the requirements of AA.5, each healing arts laser facility or veterinary laser facility shall submit an application to the Agency [within 30 days after beginning operation of the laser].
- b. An application for healing arts facilities shall be signed by a licensed practitioner of the healing arts. An application for veterinary medicine shall be signed by a licensed veterinarian. The signature of the administrator, president, or chief executive officer will be accepted in lieu of a licensed practitioner's signature if the facility is a licensed hospital or a medical facility. A signature by the administrator, president, or chief executive officer does not relieve the practitioner user or veterinarian user from complying with the requirements of this section.
- c. If a person is furnished a laser by a provider of lasers, that facility is responsible for ensuring that a licensed practitioner of the healing arts authorizes intentional exposure of laser radiation to humans.

Sec. AA.7 - Application for Industrial, Academic, and Research and Development Laser Facilities.

In addition to the requirements of AA.5, each applicant for use of lasers in industrial, academic, and research and development facilities shall submit an application to the Agency [within 30 days after beginning operation of the laser].

Sec. AA.8 - Application for Demonstration for the Purpose of Sales of Lasers.

- a. Each applicant shall apply for and receive a certificate of laser registration before the demonstration for purpose of selling laser(s), including demonstration for the selling of surplus lasers.
- b. In addition to the requirements of Section AA.5, the applicant shall submit a statement confirming that no demonstration will be performed on humans unless directed by a licensed practitioner of the healing arts.

Sec. AA.9 - Application for Providers of Lasers.

- a. Each applicant shall apply for and receive a certificate of laser registration before providing lasers.
- b. In addition to the requirements of AA.5, the applicant shall submit the address of the established main location where the laser and records will be maintained for inspection and the name of the on-site operator. This shall be a physical street address, not a post office box number.

Sec. AA.10 - Application for Alignment, Calibration, and/or Repair. In addition to the requirements of AA.5, each applicant shall apply for and receive a certificate of laser registration for alignment, calibration, and/or repair before providing alignment, calibration, and/or repair of lasers.

Sec. AA.11 - Application for Laser Light Show.

- a. Each applicant shall apply for and receive a certificate of laser registration for laser light

show before beginning any show and shall meet the requirements of Appendix A. In addition to the requirements of Section AA.5, each applicant shall submit a valid light show variance issued from the FDA for the laser intended to be used, with all applicable documents required by the variance [to include operating and safety procedures];

- b. Responsibilities of the registrant include the following:
 - i. Notification to the Agency in writing at least seven days in advance of the proposed laser show, including the following information:
 - (1) The location, time, and date of the light show;
 - (2) Sketches showing the location of the laser, operators, performers, laser beam path, viewing screens, walls, mirror balls, and other reflective or diffuse surfaces which may be struck by the laser beam (Examples of sketches may be found in the diagram portion of Appendix A);
 - (3) Scanning beam patterns, scan velocity, and frequency in occupied areas;
 - (4) Physical surveys and calculations made to ensure compliance with Part AA.
 - ii. Prior to the performance of an outdoor laser light show, the registrant shall notify and receive approval from the Federal Aviation Administration of the proposed show and provide documentation to the Agency.

[Sec. AA.12 - Application for Laser Mobile Services Used in the Healing Arts and Veterinary Arts. Each applicant shall apply for and receive a certificate of laser registration for mobile services before beginning to provide mobile services.

- a. In addition to the requirements of AA.5, each applicant shall submit the address of the established main location where the laser, records, etc. will be maintained for inspection. This shall be a physical street address, not a post office box number.
- b. An application for mobile services for healing arts shall be signed by a licensed practitioner of the healing arts and an application for mobile services for veterinary medicine shall be signed by a licensed veterinarian.]

[Sec. AA. 13 - Requirements for Intense-Pulsed Light Device (Photothermolysis) Facilities.

- a. Intense-pulsed light devices used for photothermolysis shall be Class II or Class III medical devices. FDA regulations require that these devices have premarketing clearance or approval and a quality system for manufacturing.
- b. An intense-pulsed light device used for medical purposes shall be used as directed by a licensed practitioner of the healing arts.
- c. Intense-pulsed light devices used for photothermolysis shall only be sold to licensed practitioners of the healing arts.

- d. Each registrant shall establish a safety training program that provides a thorough understanding of the medical procedures being performed and shall require each user demonstrate to the licensed practitioner the competence to use the intense pulsed light device safely. Documentation of the training shall be maintained for Agency review and as a minimum address the following:
 - i. Fundamentals of intense-pulsed light device operation;
 - ii. Bioeffects of intense-pulsed light device radiation on the skin and eye and contraindications for its use;
 - iii. Non-beam hazards of intense-pulsed light device operation;
 - iv. Responsibilities of management and employee as related to control measures and emergencies; and
 - v. Regulatory requirements.
- e. In addition to the requirements of Section AA.5, each photothermolysis facility shall submit an application to the Agency within 30 days after beginning operation of the IPL device. An application for healing arts facilities shall be signed by a licensed practitioner of the healing arts.]

Sec. AA.14 - Laser Safety Officer (LSO) Qualifications. The registrant shall designate a laser safety officer who is responsible for laser radiation protection. LSO qualifications shall be submitted to the Agency and shall include the following:

- a. Training and experience as outlined in Appendix B;
- b. Experience in the use and familiarity of the type of equipment or services registered for; and
- c. Knowledge of potential laser radiation hazards and laser emergency situations.

Sec. AA.15 - Duties of Laser Safety Officer. Specific duties of the LSO shall include, but not be limited to the following:

- a. Establishing and supervising a program of laser radiation safety for effective compliance with the applicable requirements of these regulations to ensure that users of lasers are trained in laser safety as applicable for the class and type of lasers used;
- b. Providing instructions concerning hazards and safety practices to individuals who may be exposed to laser radiation and to individuals who operate the lasers;
- c. Assuming control and having the authority to institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions;
- d. Specifying whether any changes in control measures are required:

- i. Following any service and maintenance of lasers that may affect the output power or operating characteristics; or
 - ii. Whenever deliberate modifications are made that could change the laser class and affect the output power or operating characteristics;
- e. Ensuring maintenance and other practices required for safe operation of the laser(s) are performed; and
- f. Ensuring the proper use of protective eyewear and other safety measures.

Sec. AA.16 - Issuance of Laser Registration.

- a. Upon determination that an application meets the requirements of the regulations, the Agency shall issue a notice of laser registration authorizing the proposed activity.
- b. The Agency may incorporate in the notice of laser registration at the time of issuance, or thereafter by amendment, additional requirements and conditions with respect to the registrant's receipt, possession, use, and transfer of lasers subject to this Part as it deems appropriate or necessary in order to:
 - i. Minimize danger to occupational and public health and safety;
 - ii. Require reports and the keeping of records for inspection by the Agency; and
 - iii. Prevent loss or theft of lasers subject to this section.

Sec. AA.17 - Expiration of Laser Registration. Except as provided by Sec. AA.18b., each notice of registration shall expire at the end of the specified day in the month and year stated on the notice.

Sec. AA.18 - Renewal of Laser Registration.

- a. Application for renewal of laser registration shall be filed in accordance with Section AA.5 through AA.12, as applicable.
- b. If a registrant files an application for a renewal in proper form before the existing laser registration expires, the existing laser registration shall not expire until the application status has been determined by the Agency.

Sec. AA.19 - Report of Change. The registrant shall notify the Agency in writing within thirty days of any change that would render the information contained in the application for registration and/or the notice of laser registration no longer accurate.

Sec. AA.20 - Termination of Registration. When a registrant decides to terminate all activities involving laser or laser services authorized under the laser registration, the registrant shall:

- a. Request termination of the laser registration in writing; and

- b. Submit a record of the disposition of the lasers to the Agency, if applicable.

Sec. AA.21 - Validity of Registration. Registration accepted by the Agency as properly executed shall remain valid until terminated or until declared invalid by the Agency.

Sec. AA.22 - Registration Shall Not Imply Approval. No person, in any advertisement, shall refer to the fact that a facility is registered with the Agency, and no person shall state or imply that any activity so registered has been approved by the Agency.

Sec. AA.23 - [Reciprocal] Out-of-State Laser Radiation Sources.

- a.
 - i. Whenever any source of laser radiation is to be brought into the State, for any temporary use, the person proposing to bring the source of laser radiation into the State shall give written notice to the Agency [at least 7 working days] before the source of laser radiation is to be used in the State. The notice shall include:
 - (1) The type of laser radiation source;
 - (2) The nature, duration, and scope of use; and
 - (3) The exact location(s) where the laser radiation source is to be used.
 - ii. If, for a specific case, the [7 working-day] period would impose an undue hardship on the person, upon application to the Agency, permission to proceed sooner may be granted.
- b. The person referred to in Paragraph AA.23a. shall:
 - i. Comply with all applicable regulations of the Agency;
 - ii. Supply the Agency with such other information as the Agency may reasonably request; and
 - iii. Not operate within the State on a temporary basis in excess of 180 calendar days per year.

Sec. AA.24 - Maximum Permissible Exposure (MPE).

- a. No individual shall be exposed to levels of laser or collateral radiation higher than are in the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1. It is good practice to maintain exposure levels as far below the MPE values as is practicable.
- b. In those cases where no MPE is shown for particular wavelengths and pulse durations, all exposure shall be prohibited.

Sec. AA.25 - Implementation of Protective Measures. Protective measures used to avoid laser or collateral radiation shall be implemented by a laser safety officer (LSO), or an individual designated

by management.

Sec. AA.26 - General Requirements for the Safe Operation of All Facilities.

- a. Applicability. These requirements are for laser products in their intended mode of operation and include special requirements for service, testing, maintenance, and modification. During manufacture and research and development activities, some engineering controls may be inappropriate; the LSO shall specify alternate requirements to obtain equivalent laser safety protection.
- b. Engineering Controls.
 - i. Protective Housing. Each laser product shall have a protective housing which prevents human access during operation to laser and collateral radiation that exceeds the limits of Class 1 in the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1 and Title 21, CFR, Part 1040 respectively, wherever and whenever such human access is not necessary in order for the product to perform its intended function. Wherever and whenever human access to laser radiation levels that exceed the limits of Class 1 in the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1 and Title 21, CFR, Part 1040 is necessary, these levels shall not exceed the limits of the lowest laser class necessary to perform the intended function(s).
 - ii. Safety Interlocks.
 - (1) A safety interlock, which shall ensure that radiation is not accessible above MPE limits, shall be provided for any portion of the protective housing which, by design, can be removed or displaced without the use of tools during normal operation or maintenance, and thereby allows access to radiation above MPE limits.
 - (2) Adjustment during operation, service, testing, or maintenance of a laser containing interlocks shall not cause the interlocks to become inoperative or the laser radiation to exceed MPE limits outside protective housing except where a laser controlled area as specified in AA.26b.v. is established.
 - (3) For pulsed lasers, interlocks shall be designed so as to prevent firing of the laser, e.g., by dumping the stored energy into a dummy load.
 - (4) For Class 3b and Class 4 CW lasers, the interlocks shall turn off the power supply or interrupt the beam, e.g., by means of shutters.
 - (5) An interlock shall not allow automatic accessibility of laser radiation emission above MPE limits when the interlock is closed.
 - (6) If failure of a single interlock would allow:
 - (a) Human access to levels of laser radiation in excess of the radiant

power accessible emission limit of Class 3a laser radiation, or

- (b) Laser radiation in excess of the accessible emission limits of Class 2 to be emitted directly through the opening created by removal or displacement of that portion of the protective housing; then, either multiple safety interlocks or a means to preclude removal or displacement of the interlocked portion of the protective housing upon such failure shall be provided.

iii. Viewing Optics and Windows.

- (1) All viewing ports, viewing optics or display screens included as an integral part of an enclosed laser or laser system shall incorporate suitable means to attenuate the laser and collateral radiation transmitted through the port to less than the MPE in the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1 and collateral radiation limits in Title 21, CFR, Part 1040, under any conditions of operation of the laser.
- (2) Since optical systems such as lenses, telescopes, and microscopes may increase the hazard to the eye or the skin, the laser safety officer shall determine the potential hazard and specify administrative procedures and the use of controls such as interlocks or filters.

iv. Warning Systems. Each laser system classified as a Class 3b or Class 4 laser product shall incorporate an emission indicator which provide a visible or audible signal during emission of accessible laser radiation in excess of the accessible emission limits of class 1, and sufficiently prior to emission of such radiation to allow appropriate action to avoid exposure to the laser radiation.

v. Laser Controlled Area. With a Class 3b, except those that allow access only to less than 5 mW visible peak power, or Class 4 laser, a laser controlled area shall be established when exposure to the laser radiation in excess of the MPE in the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1 and collateral radiation limits in Title 21, CFR, Part 1040 is possible. The controlled area shall meet the requirements of Subdivisions AA.26b.v.(1) through (3) for Class 3b lasers and the requirements of Subdivisions AA.26b.v.(1) through (7) for Class 4 lasers:

- (1) The area shall be the responsibility of the laser safety officer.
- (2) The area shall be posted as required by Section AA.29.
- (3) Access to the laser controlled area shall be only by permission of the laser safety officer or a trained designated representative.
- (4) For Class 4 indoor controlled areas, latches, interlocks, or other appropriate means, as defined in written policy and procedure of the registrant, shall be used to prevent unexpected entry into laser controlled areas. Such measures

shall be designed to allow both rapid egress by the laser personnel at all times and admittance to the laser controlled area in an emergency condition.

- (5) For Class 4 indoor controlled areas, during tests requiring continuous operation, the individual in charge of the controlled area shall be permitted to momentarily override the safety interlocks to allow access to other authorized personnel if it is clearly evident that there is no optical laser radiation hazard at the point of entry and if the necessary protective devices are being worn by the entering personnel.
- (6) For Class 4 indoor controlled areas, optical paths (e.g., windows) from an indoor facility shall be controlled in such a manner as to reduce the transmitted values of the laser radiation to levels at or below appropriate ocular MPE limits in the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1 and collateral radiation limits in Title 21, CFR, Part 1040. When the laser beam must exit the indoor controlled area (as in the case of exterior atmospheric beam paths), the operator shall be responsible for ensuring that the beam path is limited to controlled air space^{*/} or controlled ground space when the beam irradiance or radiant exposure is above the appropriate MPE and collateral radiation limits.
- (7) In the case of the removal of panels or protective covers and/or overriding of interlocks becomes necessary, such as for service, testing, or maintenance, and accessible laser radiation exceeds MPE limits in the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1 and collateral radiation limits in Title 21, CFR, Part 1040, a temporary laser controlled area shall be established. The laser safety officer or a designated representative shall ensure that the necessary laser safety requirements for all potentially exposed individuals shall be established.

c. Administrative and Procedural Controls.

- i. General. Unless otherwise specified, administrative and procedural controls shall apply only to Class 3b and Class 4 lasers.
- ii. Output Emission Limitations. The minimum laser radiant energy or laser power level required for the application shall be used.
- iii. Education and Training. The degree and level of education and training on laser safety concepts and procedures shall be in accordance with Appendix B, Table 1 of these regulations.
- iv. Operation and Maintenance. Class 3b and Class 4 lasers shall be operated and maintained only by qualified personnel.
- v. Alignment Procedures. Alignment of laser optical systems (e.g., mirrors, lenses, and

^{*/}Contact FAA or other appropriate agencies, as necessary.

beam deflectors) shall be performed in such manner that assures that no one is exposed to laser radiation above MPE limits in the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1, Appendix A. and collateral radiation limits in Title 21, CFR, Part1040.

- vi. Eye Protection. Protective eyewear, as specified by the laser safety officer, shall be worn by all individuals with access to Class 4 levels of laser radiation. Protective eyewear, when specified by the laser safety officer, shall be worn by all individuals with access to Class 3b levels of laser radiation.
- vii. Service Procedures. All service procedures shall be performed by qualified personnel who, when appropriate, are trained in laser radiation protection. The service personnel shall comply with applicable information supplied by the manufacturers and instructions provided by the laser safety officer.

Sec. AA.27 - Additional Requirements for Special Lasers and Applications.

- a. Infrared Laser - Greater than 710 Nanometers. The beam from a Class 3b and Class 4 laser shall be terminated in fire-resistant material where necessary. Periodic inspection of absorbent material shall be made since many materials degrade with use.**/
- b. Systems Utilizing Fiber Optics.
 - i. Laser transmission systems which employ optical cables shall be considered enclosed systems with the optical cable forming part of the protective housing.
 - ii. Disconnection of a connector resulting in access to laser radiation in excess of the applicable MPE limits in the most recent edition of the American National Standard for Safe Use of Optical Fiber Communication Systems Utilizing Laser Diode and LED Sources, ANSI Z136.2 shall take place in a controlled area. The use of a tool shall be required for the disconnection of a connector for service and maintenance purposes when the connector is not within a secured enclosure. All connectors shall bear the appropriate label or tag as specified in AA.29c.ix.

Sec. AA.28 - Additional Requirements for Safe Operation.

- a. Eye Protection.
 - i. Protective eyewear devices shall meet the following requirements:
 - (1) Provide a comfortable and appropriate fit all around the area of the eye.
 - (2) Be in proper condition to ensure the optical filter(s) and holder provide the required optical density or greater at the desired wavelengths, and retain all protective properties during its use.

**/ Many metal surfaces which appear "dull" visually can act as specular reflectors of infrared radiation.

- (3) The required optical density shall be determined based on the type of potential exposure requiring protection.
 - (4) Have the optical density or densities and associated wavelength(s) permanently labeled on the filters or otherwise permanently identified.
- ii. At intervals not to exceed 6 months, each registrant shall examine protective eyewear devices for scratches, nicks or other physical damage. Eyewear with the integrity compromised or that is not serviceable as intended should be discarded.
- b. Skin Protection. When there is a possibility of exposure to laser radiation that exceeds the MPE limits for skin as specified in the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1,^{***/} the registrant shall require the appropriate use of protective gloves, clothing, and shields.
- c. Other Personal Protective Equipment. Respirators and other personal protective equipment shall be required as a temporary control measure whenever engineering controls cannot provide protection from toxic air contaminants and other hazards.
- d. Service and Maintenance of Lasers. Following any service or maintenance of lasers that may affect the output power or operating characteristics, the laser safety officer shall specify whether any changes in control measures are required.
- e. Modification of Laser. Whenever deliberate modifications are made which could change the laser class and affect the output power or operating characteristics, the laser safety officer shall specify whether any changes in control measures are required.

Sec. AA.29 - Caution Signs, Labels, and Posting.

- a. General.
 - i. Except as otherwise authorized by the Agency, signs, symbols, and labels prescribed by AA.29 shall use the design and colors specified in Figures 1 and 2.
 - ii. In addition to the signs, symbols, and labels prescribed in AA.29, a registrant may provide near such signs, symbols, and labels any additional information which may be appropriate in aiding individuals to minimize exposure to laser or collateral radiation within a facility.
- b. Instructions.
 - i. Operating personnel of each laser shall be provided with adequate written instructions

^{***/} This need is particularly important in the ultraviolet region.

for safe use, including clear warnings and precautions to avoid possible exposure to laser and collateral radiation in excess of the MPE limits in the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1, or collateral radiation limits in Title 21, CFR, Part 1040.

- ii. Service personnel shall be provided with:
 - (1) Adequate training and instructions for service adjustments and procedures for each laser or facility, including clear warnings or precautions to be taken to avoid possible exposure to laser or collateral radiation.
 - (2) Service instructions which shall contain a listing of controls and procedures that can increase accessible emission levels of laser or collateral radiation, and a clear description of the location of displaceable portions of the protective housing or enclosure that could allow access by personnel to laser and collateral radiation in excess of the MPE limits in the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1, or collateral radiation limits in Title 21, CFR, Part 1040.
- c. Labeling and Posting.^{1/} Labeling laser products and posting laser facilities.
 - i. The controlled area shall be conspicuously posted with an appropriate sign or signs as specified in Figures 1 and 2.
 - ii. Class 1 facilities need not be posted. Uncertified Class 1 lasers shall have a label including the following wording: "CLASS 1 LASER";
 - iii. Class 2 laser facilities need not be posted. Class 2a lasers that do not exceed accessible emission limits of Class 1 for any emission duration less than or equal to 1×10^3 seconds shall have a label with the following wording: "Class 2a Laser (or Laser Product) - Avoid Long Term Viewing of Direct Laser Radiation";
 - iv. Class 2 laser facilities need not be posted. Class 2 lasers other than those specified in AA.29c.iii. shall have a label with the warning logotype A specified in Figure 1 and including the following wording:

(Position 1 on the logotype)

"LASER RADIATION - DO NOT STARE INTO BEAM"

(Position 3 on the logotype)

"CLASS 2 LASER (OR LASER PRODUCT)"

- v. (1) Each laser or facility classified in Class 3a solely because of the emission of

^{1/} With respect to laser products only, the labeling requirements found in 21 CFR Part 1040 may be used in lieu of Paragraph AA.29c.

accessible laser radiation in the wavelength range of greater than 400 but less than or equal to 710 nanometers, with an irradiance of less than or equal to 2.5×10^{-3} watts per square centimeter, and with a radiant power less than or equal to 5.0×10^{-3} watts, shall have a label and be posted with sign(s) with the warning specified in Figure 1 and including the following wording:

(Position 1 on the logotype)

"LASER RADIATION - DO NOT STARE INTO BEAM OR VIEW DIRECTLY
WITH OPTICAL INSTRUMENTS"

(Position 3 on the logotype)

"CLASS 3a LASER (OR LASER PRODUCT)"

- (2) Class 3b lasers or facilities other than those specified in AA.29c.v.(1) shall have a label and be posted with sign(s) with the warning specified in Figure 2 and including the following wording:

(Position 1 on the logotype)

"LASER RADIATION – AVOID DIRECT EXPOSURE TO BEAM"

(Position 3 on the logotype)

"CLASS 3b LASER (OR LASER PRODUCT)"

- vi. Class 4 lasers and facilities shall have affixed a label and be posted with sign(s) with the warning specified in Figure 2 and including the following wording:

(Position 1 on the logotype)

"LASER RADIATION - AVOID EYE OR SKIN EXPOSURE TO DIRECT
OR SCATTERED RADIATION"

(Position 3 on the logotype)

"CLASS 4 LASER (OR LASER PRODUCT)"

- vii. Class 2, 3, or 4 lasers, except lasers used in the practice of medicine, shall have a label(s) in close proximity to each aperture through which is emitted accessible laser or collateral radiation in excess of the limits specified in the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1 and the collateral radiation limits in Title 21, CFR, Part 1040 with the following wording as applicable:

- (1) "AVOID EXPOSURE - Laser radiation is emitted from this aperture," if the radiation emitted through such aperture is laser radiation.

- (2) "AVOID EXPOSURE - Hazardous electromagnetic radiation is emitted from this aperture," if the radiation emitted through such aperture is collateral radiation.
 - (3) "AVOID EXPOSURE - Hazardous x-rays are emitted from this aperture," if the radiation emitted through such aperture is collateral x-ray radiation.
- viii. Each Class 2, 3, and 4 laser shall state, at position 2 on the required warning logotype, the maximum output of laser radiation, the pulse duration when appropriate, and the laser medium or emitted wavelength(s).
- ix. For each laser product, labels shall be provided for each portion of the protective housing that has no safety interlock and that is designed to be displaced or removed during operation, maintenance, or service, and thereby could permit human access to laser or collateral radiation in excess of the limits of Class 1 in the Federal laser product performance standard or the most recent edition of the American National Standards Institute for Safe Use of Lasers, ANSI Z136.1. Such labels shall be visible on the protective housing prior to displacement or removal of such portion of the protective housing and visible on the product in close proximity to the opening created by removal or displacement of such portion of the protective housing, and shall include the wording:
- (1) "CAUTION--Laser radiation when open. DO NOT STARE INTO BEAM" for Class 2 accessible laser radiation.
 - (2) "CAUTION--Laser radiation when open. DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS" for Class 3a accessible laser radiation with an irradiance less than or equal to $2.5 \times 10^{-3} \text{ W cm}^{-2}$.
 - (3) "DANGER--Laser radiation when open. AVOID DIRECT EYE EXPOSURE" for Class 3a accessible laser radiation with an irradiance greater than $2.5 \times 10^{-3} \text{ W cm}^{-2}$.
 - (4) "DANGER--Laser radiation when open. AVOID DIRECT EXPOSURE TO BEAM" for Class 3b accessible laser radiation.
 - (5) "DANGER--Laser radiation when open. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION" for Class 4 accessible laser radiation.
 - (6) "CAUTION--Hazardous electromagnetic radiation when open" for collateral radiation in excess of the accessible emission limits in the Federal laser product performance standard or the most recent edition of the American National Standards Institute for Safe Use of Lasers, ANSI Z136.1.
 - (7) "CAUTION--Hazardous x-rays when open" for collateral radiation in excess of the accessible emission limits in the Federal laser product performance

standard or the most recent edition of the American National Standards Institute for Safe Use of Lasers, ANSI Z136.1.

- x. For each laser product, labels shall be provided for each defeatably interlocked portion of the protective housing which is designed to be displaced or removed during operation, maintenance, or service, and which upon interlock defeat could permit human access to laser or collateral radiation in excess of the limits of Class 1 in the Federal laser product performance standard or the most recent edition of the American National Standards Institute for Safe Use of Lasers, ANSI Z136.1. Such labels shall be visible on the product prior to and during interlock defeat and in close proximity to the opening created by the removal or displacement of such portion of the protective housing, and shall include the wording:
 - (1) "CAUTION--Laser radiation when open and interlock defeated. DO NOT STARE INTO BEAM" for Class 2 accessible laser radiation.
 - (2) "CAUTION--Laser radiation when open and interlock defeated. DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS" for Class 3a accessible laser radiation with an irradiance less than or equal to $2.5 \times 10^{-3} \text{ W cm}^{-2}$.
 - (3) "DANGER--Laser radiation when open and interlock defeated. AVOID DIRECT EYE EXPOSURE" for Class 3a accessible laser radiation when an irradiance greater than $2.5 \times 10^{-3} \text{ W cm}^{-2}$.
 - (4) "DANGER--Laser radiation when open and interlock defeated. AVOID DIRECT EXPOSURE TO BEAM" for Class 3b accessible laser radiation.
 - (5) "DANGER--Laser radiation when open and interlock defeated. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION" for Class 4 accessible laser radiation.
 - (6) "CAUTION--Hazardous electromagnetic radiation when open and interlock defeated" for collateral radiation in excess of the accessible emission limits in the Federal laser product performance standard or the most recent edition of the American National Standards Institute for Safe Use of Lasers, ANSI Z136.1.
 - (7) "CAUTION--Hazardous x-rays when open and interlock defeated" for collateral radiation in excess of the accessible emission limits in the Federal laser product performance standard or the most recent edition of the American National Standards Institute Safe Use of Lasers Z136.1.
- xi.
 - (1) The word "Invisible" shall immediately precede the word "radiation" on labels and signs required by AA.29c. for wavelengths of laser and collateral radiation that are outside of the range of 400 to 710 nanometers.
 - (2) The words "Visible and Invisible" shall immediately precede the word

"radiation" on labels and signs required by AA.29c. for wavelengths of laser and collateral radiation that are both within and outside the range of 400 to 710 nanometers.

- xii. All labels placed on lasers or signs posted to laser facilities shall be positioned so as to make unnecessary, during reading, human exposure to laser or collateral radiation in excess of the MPE limits in the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1 and the collateral radiation limits in Title 21, CFR, Part 1040.
- xiii. Labels and signs required by AA.29c. shall be clearly visible, legible, and permanently attached to the laser or facility.

WARNING LOGOTYPE A

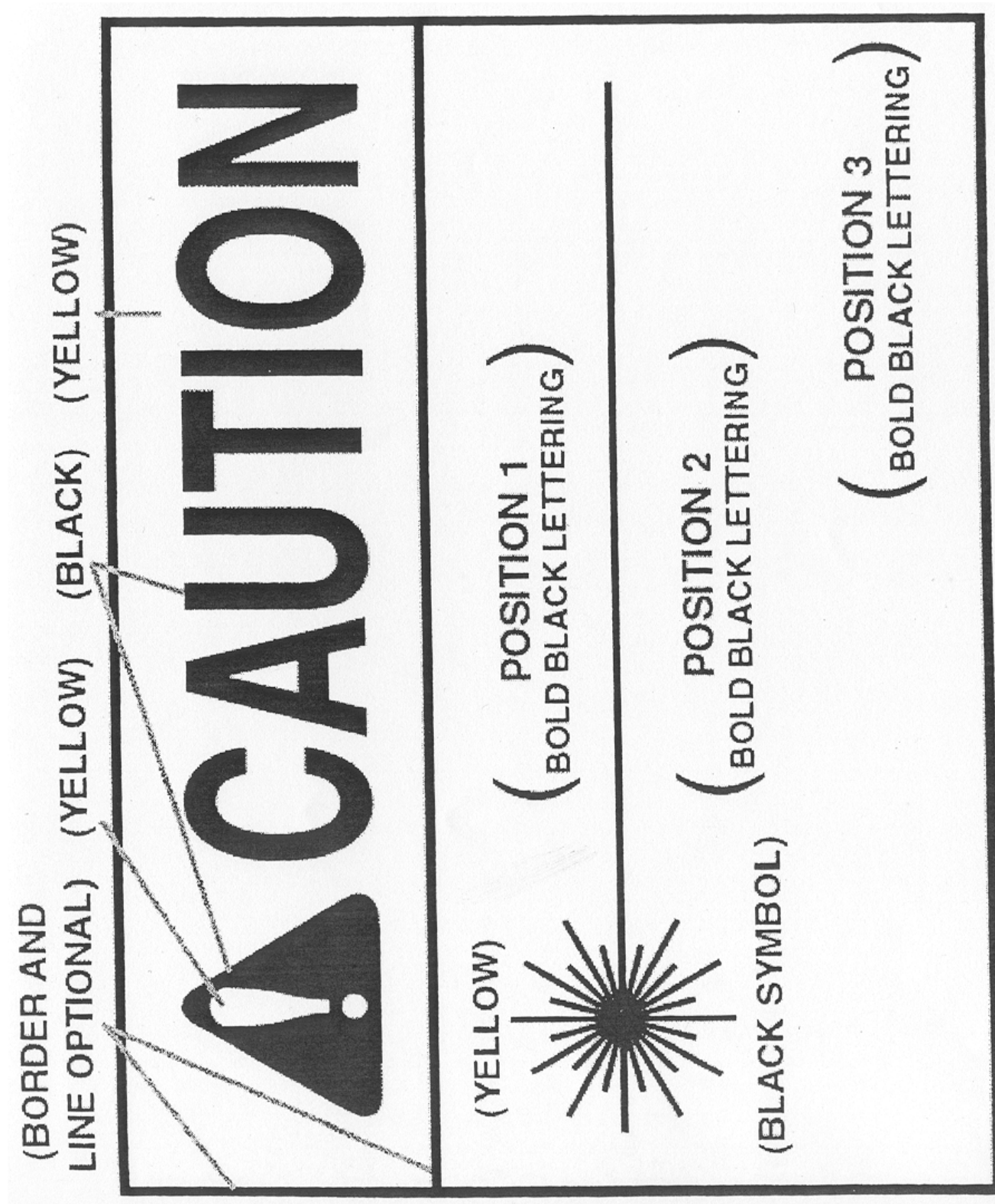


Figure 1

WARNING LOGOTYPE B

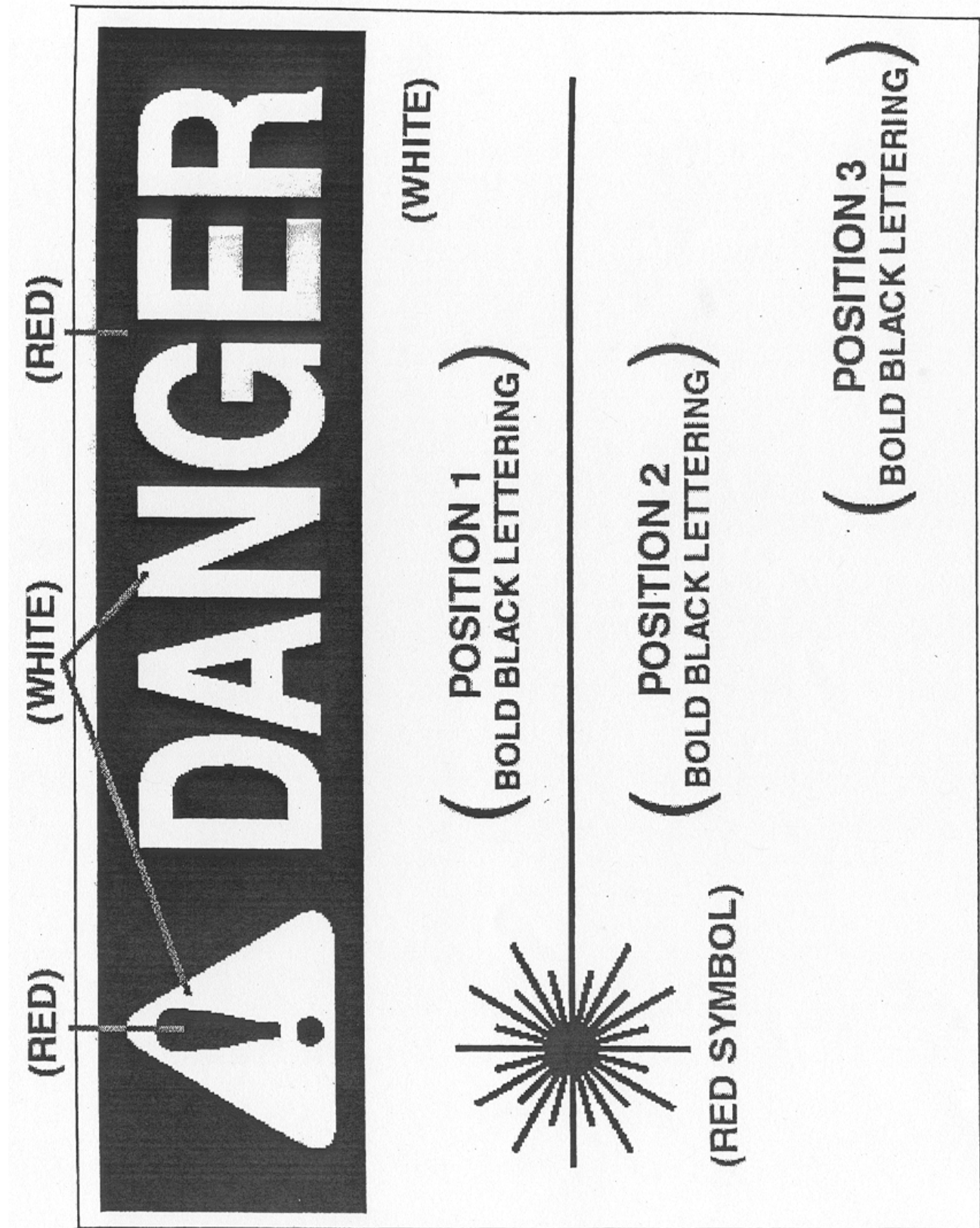


Figure 2

Sec. AA.30 - Surveys. Each registrant shall make or cause to be made such radiation protection surveys as may be necessary to comply with AA.30. At intervals not to exceed 6 months, surveys shall be performed which include but are not limited to:

- a. A determination that all laser protective devices are labeled correctly and functioning within the design specifications and are properly chosen for lasers in use.
- b. A determination that all warning devices are functioning within their design specifications.
- c. A determination that the laser controlled area is properly controlled and posted with accurate warning signs in accordance with AA.29.
- d. A re-evaluation of potential hazards from surfaces which may be associated with Class 3 and Class 4 beam paths.
- e. Additional surveys required to evaluate the laser and collateral radiation hazard incident to the use of lasers.

[Sec. AA.31 - Measurement and Instrumentation. Each determination requiring a measurement for compliance with these regulations shall use instrumentation which is calibrated and designed for use with the laser that is to be tested. The date of calibration, accuracy of calibration, wavelength range, and power/energy of calibration shall be specified on a legible, clearly visible label attached to the instrument.

- a. Measurement of accessible emission(s) for classification shall be made:
 - i. Under those operational conditions and procedures which maximize the accessible emission levels including startup, stabilized operation, and shutdown of the laser or facility;
 - ii. With all controls and adjustments listed in the operating and service instructions adjusted for the appropriate maximum accessible emission level of laser radiation which is not expected to be detrimental to the functional integrity of the laser or enclosure;
 - iii. At points in space to which human access is possible for a given laser configuration, e.g., if operation may include removal of portions of the protective housing or enclosure and defeat of safety interlocks, measurements shall be made at points accessible in that laser configuration;
 - iv. With the measuring instrument detector so positioned and so oriented with respect to the laser as to result in the maximum detection of radiation by the instrument; and
 - v. For a laser other than a laser system, with the laser coupled to that type of laser energy source specified as compatible by the laser fabricator, and that produces the maximum emission of accessible laser radiation from that laser.
- b. Compliance with the requirements of the regulations shall be determined by measurements or

their equivalent that account for all errors and statistical uncertainties in the measurement process.

- c. Accessible emission levels of laser and collateral radiation shall be based upon the following measurements as appropriate, or their equivalent:
 - (1) For laser products intended to be used in a locale where the emitted laser radiation is unlikely to be viewed with optical instruments, the radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 7 millimeters and within a circular solid angle of acceptance of 1×10^{-3} steradian with collimating optics of 5 diopters or less. For scanned laser radiation, the direction of the solid angle of acceptance shall change as needed to maximize detectable radiation, with an angular speed of up to 5 radians/second. A 50 millimeter diameter aperture stop with the same collimating optics and acceptance angle stated above shall be used for all other laser products (except that a 7 millimeter diameter aperture stop shall be used in the measurement of scanned laser radiation emitted by laser products manufactured on or before August 20, 1986).
 - (2) The irradiance (W cm^{-2}) or radiant exposure (J cm^{-2}) equivalent to the radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 7 millimeters and, for irradiance, within a circular solid angle of acceptance of 1×10^{-3} steradian with collimating optics of 5 diopters or less, divided by the area of the aperture stop (cm^2).
 - (3) The radiance ($\text{W cm}^{-2} \text{ sr}^{-1}$) or integrated radiance ($\text{J cm}^{-2} \text{ sr}^{-1}$) equivalent to the radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 7 millimeters and within a circular solid angle of acceptance of 1×10^{-5} steradian with collimating optics of 5 diopters or less, divided by that solid angle (sr) and by the area of the aperture stop (cm^2).
- d. Measurements for maximum permissible exposure shall be measured as specified in the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1.]

Sec. AA.32 - Medical Surveillance. The Agency may require the registrant to provide such medical examination procedures as it considers necessary to protect the health and safety of personnel who may be exposed to radiation within the nominal hazard zone (NHZ). Appendix C provides recommended procedures that apply primarily to users of Class 3b or 4 lasers.

Sec. AA.33 - Twenty-four hour Notification.

- a. Twenty-four hour Notification. Each registrant shall notify the Agency within 24 hours of discovery by telephone, fax or email of any incident involving any source of laser or collateral radiation possessed by the registrant and that has or may have caused:
 - i. An exposure to an individual of greater than 100 times the MPE limits in the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1, or the collateral radiation limits in Title 21, CFR, Part 1040.; or

- ii. An exposure to an individual that involves the partial or total loss of sight in either eye; or
 - iii. An exposure to an individual that involves perforation of the skin or other serious injury exclusive of eye injury; or
 - iv. A loss of one working week or more of operation of any facility affected.
- b. Five Working Days Notification. Each registrant shall notify the Agency by telephone, fax or email within five working days of any incident involving any source of laser or collateral radiation possessed by the registrant and that has or may have caused:
- i. An exposure to an individual of greater than 5 times the MPE limits in the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1, or collateral radiation limits in Title 21, CFR, Part 1040.; or
 - ii. An exposure to an individual with second- or third-degree burns to the skin or potential injury and partial loss of sight.

Sec. AA.34 - Reports of Overexposures and Excessive Levels.

- a. Each registrant shall make a report in writing within 30 days after a 24-hour notification has been made to the Agency of:
 - i. Each exposure of an individual to laser and collateral radiation in excess of the MPE limits in the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1, or collateral radiation limits in Title 21, CFR, Part 1040; or
 - ii. Any incident for which notification is required by AA.33.
- b. Each report shall describe the extent of exposure of individuals to laser and/or collateral radiation, including estimates of each individual's exposure; levels of laser and/or collateral radiation involved; the cause of the exposure; and corrective steps taken or planned to be taken to assure against a recurrence.
- c. Any report filed with the Agency pursuant to AA.34 shall include the full name of each individual exposed, an estimate of each individual's exposure, and a description of any injuries. The report shall be prepared so that this information is stated in a separate part of the report.****/

Sec. AA.35 - Notifications and Reports to Individuals. When a registrant is required pursuant to AA.34 to report to the Agency any exposure of an individual to laser and/or collateral radiation, the registrant shall also provide to the individual a report on the exposure data included therein. Such reports shall be transmitted at a time not later than the date of transmittal to the Agency.

****/ This paragraph is suggested for use by States which have the authority to maintain the names of individuals as confidential information

Sec. AA.36 - Records.

- a. Each registrant shall maintain current records, which shall be kept available for inspection by the Agency, showing:
 - i. The results of all surveys required under AA.28a.ii. and AA.30.
 - ii. The results of all instrument calibrations under AA.31.
 - iii. The results of medical surveillance performed under AA.32.
 - iv. The reports of incidents as described under AA.35.
- b. The registrant shall maintain such records required by AA.36 until the Agency authorizes disposition.

Part AA

APPENDIX AREQUIREMENTS FOR LASER LIGHT SHOWS

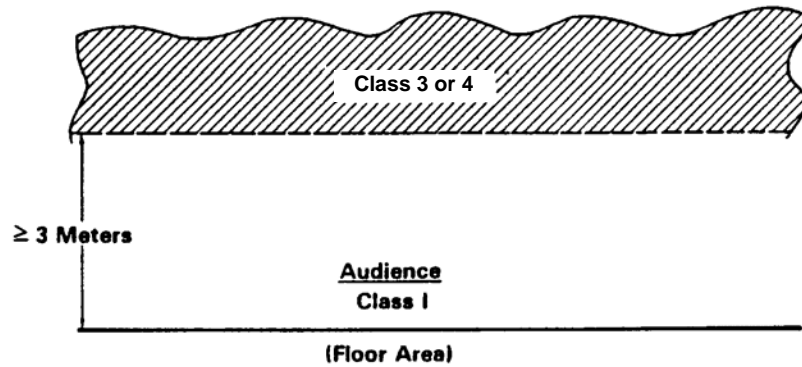
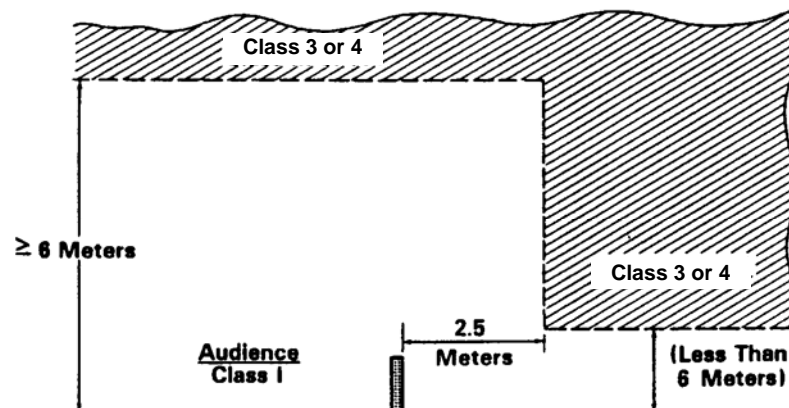
1. Each laser facility and mobile laser shall be registered in accordance with the provisions of these regulations.
2. The laser operator shall demonstrate his competency to operate the laser safely.
[Demonstration of competency may include, but is not limited to, proof of having taken and passed an acceptable laser training course such as given at several universities or sponsored by technical organizations.]
3. Laser radiation outside the spectral range 400 to 710 nanometers shall be as low as practicable but shall not, in any case, exceed the Class 1 limits under any possible conditions of operation.
4. Levels of laser and collateral radiation, measured where the audience is normally located, and laser and collateral radiation measured where the operators, performers, and employees are located if the radiation is intended to be viewed by them, shall not exceed the limits of Class 1 during operation. Measured radiation shall include reflections from targets and scattering materials. For example:
 - (a) If the average laser power collectable with appropriate apertures is below 0.39 microwatts, then the limits of Class 1 will not be exceeded.
 - (b) For pulsed radiation and scanning radiation treated as pulsed radiation, if the energy in a pulse or series of pulses is less than 0.2 microjoule collectable with appropriate apertures, the limits of Class 1 will not be exceeded.
5. Operators, performers, and employees shall be able to perform their functions without the need for exposure to laser and collateral radiation in excess of the limits of Class 2 when the radiation is not intended to be viewed by them. Areas where levels of laser radiation in excess of the limits of Class 2 exist shall be clearly identified by posting and/or through use of barriers or guards to prevent entry of operators or performers into these areas.
6. Scanning devices shall incorporate a means to turn off the beam or to prevent laser emission in case the beam stops scanning or slows down significantly. In cases where a mirror ball is used with a scanning beam, the limits of item 4 shall be met with the mirror ball stationary; or the mirror ball shall incorporate a means to turn off the beam or to prevent laser emission if the mirror ball stops rotating or slows down significantly such that the limits of item 4 or 5 are exceeded. Any such scan failure safe-guard system must have a reaction time fast enough to preclude audience access to levels in excess of Class 1.
7. Except as noted below, laser light shows shall be under the direct and personal supervision of a competent laser operator, as specified in item 2, and the laser beam to which human access

can be gained shall not exceed the limits of Class 2 at any point less than (a) 3.0 meters above any surface upon which the audience or general public is permitted to stand, and (b) 2.5 meters in lateral separation from any position where a person in the audience or general public is permitted during the performance or display, unless physical barriers are present which obstruct access by the audience or general public to such levels.

Exception: In cases where the maximum laser output power level is less than 5 milliwatts including all wavelengths and the laser beam path is located at least 6 meters above any surface upon which a person in the audience or general public is permitted to stand and at any point less than 2.5 meters in lateral separation from any position where a person in the audience or general public is permitted during the performance or display, then a laser operator need not be continuously present if other provisions of these regulations are met. In other cases, upon application to the Agency, appropriate arrangements may be made for unattended operation.

8. All laser light shows shall be provided with a key operated "on-off" switch. In the case of the exception of item 7, there shall be a designated individual present who can turn off and secure the laser in case of unsafe operating conditions.
9. The maximum laser output power shall be limited to a level required to obtain the intended effect.
10. The laser system, including projector, shall be rigidly mounted to prevent unintended movement or accidental misalignment.
11. The laser operator(s) shall be situated in a position such that performers, audience, beam path(s), and laser display can be viewed at all times during laser operation.
12. Where laser output power must be limited to less than the maximum power available in order to comply with criteria 3 through 9, the laser output power shall be measured, adjusted, and recorded before it is operated at each light show. All safety devices necessary to meet criteria 3 through 9, such as scanning-beam power interlock, shall be functionally tested and recorded before each light show.
13. The laser system shall be secured against unauthorized operation.
14. The following precautions shall be taken during alignment procedures:
 - (a) Alignment shall be performed by a competent and qualified individual and with the laser radiation emission reduced to lowest practicable level;
 - (b) Only persons required to perform alignment shall be in or near the beam path(s); and
 - (c) Protective eyewear shall be worn where necessary to prevent hazardous exposure.
15. In addition to the requirements of AA.11, before the laser light show is permitted to operate either at a permanent or temporary job site, the laser light show operator or an authorized representative shall provide the Agency with sufficient information, data, and measurements

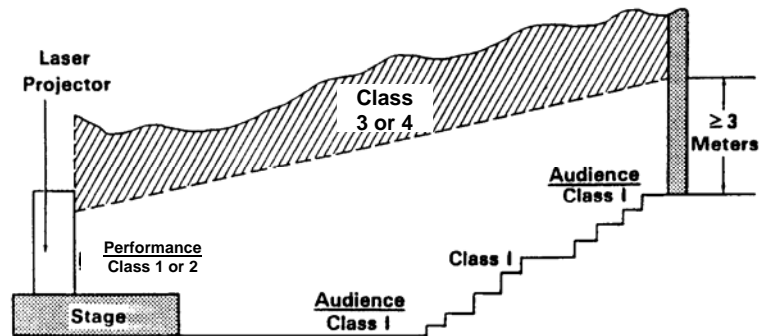
to establish that the above criteria will be met during use. [This shall include sketches showing the location of laser(s), operator(s), performer(s), viewers, beam paths, viewing screens, walls, mirror balls, and other reflective or diffuse surfaces which may be struck by laser beam, scanning beam patterns, scanning velocity and frequency in occupied areas and where beam strikes wall or other structure, radiometric measurement data including output power and location of all measurements. In the case of open air shows where a laser beam is projected into the sky, the information submitted shall also include beam spot size, beam divergence, and beam power measured at the projector, and a copy of the notification provided to the Federal Aviation Administration.]

LASER LIGHT SHOWS**Application of Safety Criteria****OPERATOR IN CONTROL****NO OPERATOR IN CONTROL**
(Side View)

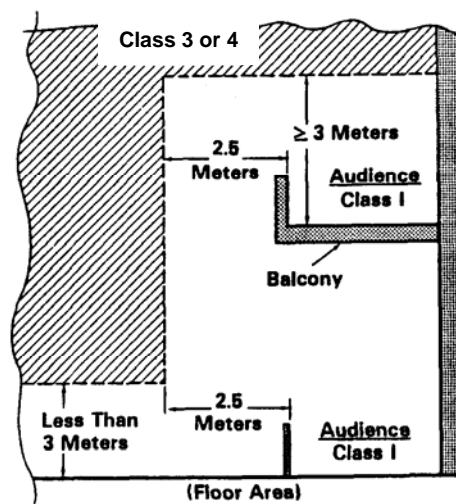
LASER LIGHT SHOWS

Application of Safety Criteria

OPERATOR IN CONTROL (Rising Floor Level)

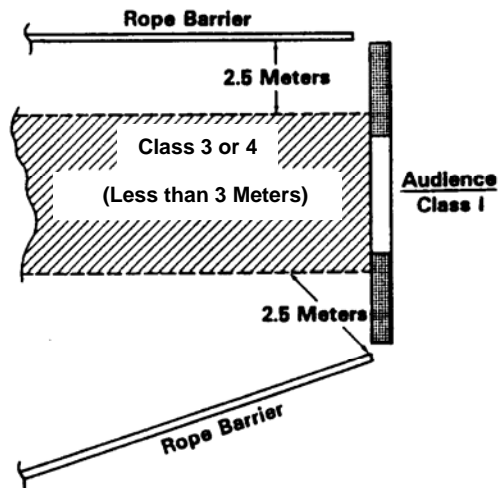
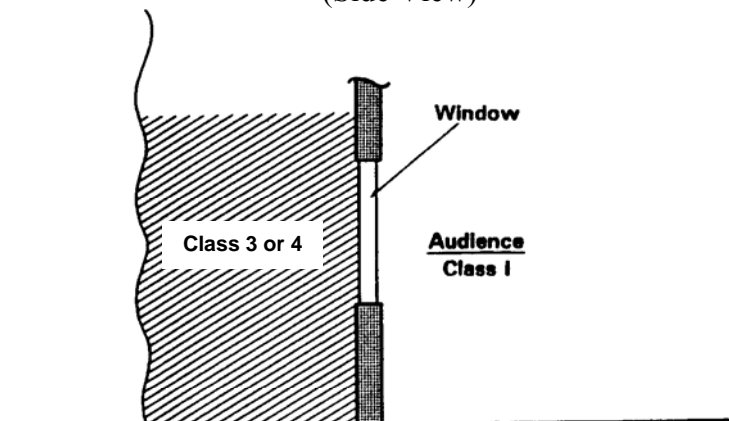


OPERATOR IN CONTROL (Side View)



LASER LIGHT SHOWS

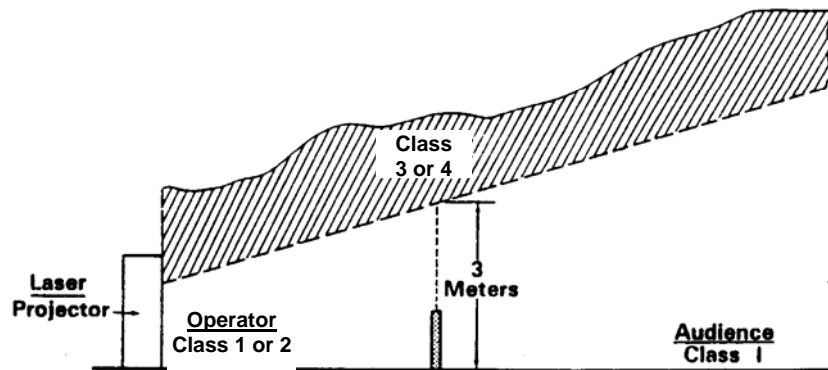
Application of Safety Criteria

**OPERATOR IN CONTROL
PHYSICAL OBSTRUCTION
(Top View)****OPERATOR IN CONTROL
PHYSICAL OBSTRUCTION
(Side View)**

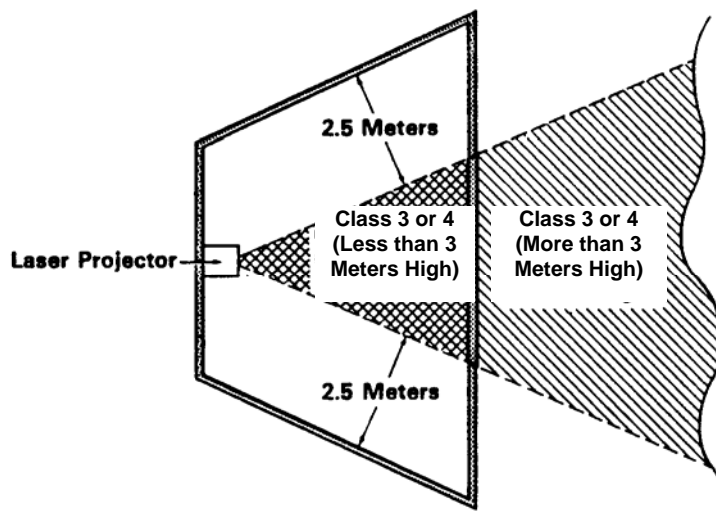
LASER LIGHT SHOWS

Application of Safety Criteria

OPERATOR IN CONTROL INCLINED LASER RADIATION FIELD (Side View)



OPERATOR IN CONTROL INCLINED LASER RADIATION FIELD (Top View)



[APPLICATION FOR REGISTRATION OF LASER FACILITY,
MOBILE LASER, OR SERVICE ORGANIZATION]

Registration is required for all uncertified laser products and for certified Class 3b (other than those exempted by AA.3b.) and Class 4 laser products.

1. Applicant's Name: _____ Telephone No.: _____

Address: _____

2. Location of use (if different from Number 1): _____

3. Type of registration: Laser Facility (), Mobile Laser (), Service Organization ().

4. Prior Laser Registration Number, if any: _____

5. Sources of laser radiation (Class 3b and Class 4 only):

a	b	c
---	---	---

	Number of Sources of Laser Radiation		Range of Average Power or Energy
Wavelength Range	In Facility	Mobile	
UV (< 0.4 μm)			
Visible (0.4 - 0.71 μm)			
Near IR (> 0.71 - 1.4 μm)			
Far IR (> 1.4 μm)			

6. Name of Laser Safety Officer: _____

7. Qualifications of Laser Safety Officer (use additional sheet if required): _____

8. Authorized Agent of Applicant: _____
(Print Name) (Title)

9. Signatures: _____
Laser Safety Officer Application Date

 Authorized Agent

See associated instruction sheet before completing this application.]

(For exemptions to registration requirement see AA.3)

PLEASE PRINT OR TYPE ALL INFORMATION

1. Applicant - The name, address, and telephone number of the person or facility in whose name the registration is to be made.
2. Location of Use - Addressor location where laser sources are operated, serviced, or manufactured. If lasers are serviced exclusively on customers' premises, so state.
3. Self-explanatory.
4. Self-explanatory.
5. Sources of Laser Radiation - Include data for certified Class 3b laser sources and for certified Class 4 laser sources. For each wavelength range, enter in column b the number of laser sources and in column c, the average power or energy of the minimum and maximum output source.

Service organizations should omit column b. In column c enter data describing lasers anticipated to be serviced during twelve-month period beginning with registration date. Laser source manufacturing facilities, enter words "Manufacturing Facility" in column b; do not enter numbers. In column c enter data describing lasers anticipated to be manufactured during twelve-month period beginning with registration date.

6. Name of Laser Safety Officer - Name of person appointed by applicant to serve as Laser Safety Officer in compliance with AA.5e.
7. Qualifications of Laser Safety Officer - Briefly describe the Laser Safety Officer's training and experience which qualify him/her in the areas listed in AA.14.
8. Self-explanatory.
9. Self-explanatory.

Mail [TWO] copies of your application for registration with [TWO] copies of your laser safety procedures to: [Name and address of Agency].]

Part AA

APPENDIX BTRAINING1. General

Training shall be provided in laser safety and laser health physics to all laser safety officers (LSO's) responsible for Class 3b and Class 4 Lasers. Training of LSO's responsible for Class 1, Class 2, and Class 3a lasers should be provided as needed. The degree and type of training shall be appropriate for the degree of potential laser and associated hazards. The LSO is responsible for ensuring that users of laser products are trained at a level commensurate with the users duties and the degree of hazard.

2. Laser Safety Training Topics

Topics for inclusion in a laser safety training program should include all or part of the following, as appropriate, for the class of lasers in use:

- a. Description of Lasers
 - i. Definitions
 - ii. Lasing fundamentals
 - iii. Lasing medium and types of lasers - solid, liquid, and gas
 - iv. Pumping methods
 - v. Optical cavities
- b. Characteristics of Laser Light
 - i. Directionality
 - ii. Single color (monochromaticity)
 - iii. Coherence
 - iv. Intensity
 - v. Divergency
 - vi. Relations of specular and diffuse reflections
- c. Biological Effects of Laser Light
 - i. Damage mechanisms: thermal and non-thermal effects from pulsed and CW lasers
 - ii. Eye hazard
 - iii. Skin hazard
 - iv. Criteria for setting Maximum Permissible Exposure (MPE) levels for eye and skin
- d. Associated Hazard
 - i. Electrical hazards
 - ii. Explosion hazards
 - iii. Chemical hazards

- iv. Fire, ionizing radiation, cryogenic hazards, and others, as applicable
- e. Laser Safety
 - i. Laser classifications
 - ii. Control measures including personnel protective equipment
 - iii. Management and user responsibilities
 - iv. Medical surveillance practices (if applicable)
 - v. Governmental regulatory requirements
- f. Laser Health Physics
 - i. Calculation of MPE limits for eye and skin under various conditions of laser use
 - ii. Basic radiometric units, measurement devices and measurement techniques
 - iii. Laser hazard evaluations and range equations

Table 1
Suggested Training for LSO's and Employees

Training Vehicles	HIGHEST CLASS LASER				
	1	2	3a	3b	4
Manufacturer's Guides & Operating Manuals	M	M	M	M	M
Safety Guide Literature ^{1/}	N/R	N/R	R	M	M
Review of Applicable Standards (ANSI, Federal, State, etc.)	N/R	N/R	R	M	M
Laser Safety Orientation Course ^{2/}	N/R	N/R	R	M	M
N/R - Not Required, R - Recommended, M - Mandatory					

^{1/} Such as: *The American National Standard for the Safe Use of Lasers, ANSI Z136.1*; *Laser Institute of America Laser Safety Guide*; *American Conference of Governmental Industrial Hygienists - A Guide for Control of Laser Hazards*; or any other similar literature the Agency considers adequate.

^{2/} Because of the greater potential hazards from Class 3b and 4 Lasers, duration of the course would be several days. This training may be done by outside specialists if not available internally.

[Part AA

APPENDIX CMEDICAL SURVEILLANCE

1. Purpose of Medical Surveillance. The basic reasons for performing medical surveillance of personnel working in a laser environment are the same as for other potential health hazards. Medical surveillance examinations may include assessment of physical fitness to safely perform assigned duties, biological monitoring of exposure to a specific agent, and early detection of biologic damage or effect.

Physical fitness assessments are used to determine whether an employee would be at increased or unusual risk in a particular environment. For workers using laser devices, the need for this type of assessment is most likely to be determined by factors other than laser radiation. Specific information on medical surveillance requirements that might exist because of other potential exposures such as toxic gases, noise, ionizing radiation, etc., is outside the scope of this Appendix.

Direct biological monitoring of laser radiation is impossible, and practical indirect monitoring through the use of personal dosimeters is not available.

Early detection of biologic change or damage presupposes that chronic or sub-acute effects may result from exposure to a particular agent at levels below that required to produce acute injury. Active intervention must then be possible to arrest further biological damage or to allow recovery from biological effects. Although chronic injury from laser radiation in the ultraviolet, near-ultraviolet, blue portion of the visible, and near-red regions appears to be theoretically possible, risks to workers using laser devices are primarily from accidental acute injuries. Based upon risks involved with current uses of laser devices, medical surveillance requirements that should be incorporated into a formal standard appear to be minimal.

Other arguments in favor of performing extensive medical surveillance have been based on the fear that repeated accidents might occur and that workers would not report minimal acute injuries. The very small number of laser injuries that have been reported in the past 15 years and the excellent safety records with laser devices does not provide support to this argument.

2. Medical Examinations.

2.1 Rationale for Examinations.

2.1.1 Pre-assignment (Pre-employment) Medical Examinations. Pre-assignment (Pre-employment) medical examinations may be considered for users of Class 3b or 4 lasers who may be exposed to radiation within the NHZ. One purpose is to establish a baseline against which damage (primarily ocular) can be measured in event of an accidental injury. A second purpose is to identify certain workers who might be at special risk from chronic exposure to selected wavelength lasers. For incidental workers, only visual acuity measurement is required. For laser workers, medical histories, visual acuity measurement and selected examination protocols are required. The

wavelength of laser radiation is the determinant for which specific protocols are required (see Paragraph 2.2). Examinations should be performed by or under the supervision of an ophthalmologist or other qualified physician. Certain of the examination protocols may be performed by other qualified practitioners or technicians, under the supervision of a physician. Many ophthalmologists may prefer to perform more thorough eye examinations to assess total visual function as opposed to limiting examination to those areas that might be damaged by particular laser radiation. Some employers may find it advantageous to offer these more thorough examinations to their workers as a health benefit. For example, certain of the additional examinations, such as gonimetry, may be of value in detecting unknown disease conditions; in this case glaucoma. Even though this type of problem is unrelated to work with lasers, appropriate medical intervention will promote a healthier work force. Although chronic skin damage from laser radiation has not been reported, and indeed seems unlikely, this area has not been adequately studied. Limited skin examinations are suggested to serve as a baseline until future epidemiological study indicates whether they are needed or not.

2.1.2 Periodic Medical Examinations. Periodic examinations are not required. At the present time no chronic health problems have been linked to work with laser radiation. Also, most uses of lasers do not result in chronic exposure of employees even to low levels of radiation. A large number of these examinations have been performed in the past and no indication of any detectable biologic change was noted. Employers may wish to offer their employees periodic eye examinations or other medical examinations as a health benefit; however, there does not appear to be any valid reason to require such examinations as part of a medical surveillance program.

2.1.3 Termination Medical Examinations. The primary purpose of termination examinations is for the legal protection of the employer against unwarranted claims for damage that might occur after an employee leaves a particular job. The decision on whether to offer or require such examinations is left to individual employers.

2.2 Examination Protocols.

2.2.1 Medical History. The following protocols may be considered for pre-placement (pre-employment) examinations of all laser workers:

- The patient's past eye history and family eye history are reviewed.
- Any current complaints about the worker's eyes are noted.
- Any history of skin problems is reviewed.
- Current and past medication use is reviewed.
- The patient's general health status should be inquired about with special emphasis upon diseases which can give ocular or skin problems.
- Certain medical conditions may cause the laser worker to be at increased risk if chronic exposure to ultraviolet or blue spectrum laser radiation is possible.
- Use of photosensitizing medications, such as phenothiazines and psoralens, lower the threshold for biologic effects in the cornea, lens, and retina of experimental animals.
- Aphakic individuals would be subject to additional retinal exposure from near-ultraviolet radiation.

Unless chronic viewing of lower levels of laser radiation in these wavelengths is required, there should be no reason to deny employment to these individuals. With current laser systems, chronic

exposure even to low levels of blue laser radiation is very unusual.

2.2.2 See ANSI Z136.1, American National Standard for Safe Use of Lasers 6.3 and Appendix E for additional exam protocols.

3. Medical Referral Following Suspected or Known Laser Injury. Any employee with a suspected eye injury should be referred to an ophthalmologist. Persons with skin injuries should be seen by a physician.

5.c References.

5.1 Friedmann, A.I., The Ophthalmic Screening of Laser Workers, Ann Occup Hyg, 21:277-279, 1978.

5.2 Hathaway, J.A., Stern, N., Soles, E.M., and Leighton, E., Ocular Medical Surveillance on Microwave and Laser Workers, J Occup Med, 19:683-688, 1977.

5.3 Hathaway, J.A., The Needs for Medical Surveillance of Laser and Microwave Workers, Current Concepts in Ergophthalmology, Societas Ergophthalmologica Internationalis, Stockholm, Sweden, 1978, pp. 139-160.

5.4 Wolbarscht, M.L., and Landers, M.B., Testing visual capabilities for medical surveillance or to ensure job fitness. J Occup Med, 27:897-901, 1985.]

Rationale for Revisions

Part AA General Provisions

AA.1 Scope. All laser products manufactured on and after August 2, 1976, and any previously certified laser products, used in the State shall conform to Title 21, Part 1040 of the Code of Federal Regulations (21 CFR 1040). Existing Federal OSHA standard for the construction industry is also applicable as a minimum requirement in the States. Concern was expressed by physicians that regulations would limit the use of laser radiation as a diagnostic or therapeutic tool. These regulations will not prevent such usage. The regulations will apply to the user. These regulations have been developed recognizing compatibility with existing Federal standards.

Because the Suggested State Regulations for Lasers (SSRL) are oriented toward the user, situations will arise where certified laser products are modified. Such modified and non-certified laser products must conform to the requirements specified in the SSRL for that particular laser class.

AA.2 Definitions. Where applicable, the definitions are consistent with the American National Standard for the Safe Use of Lasers, ANSI Z136.1-1980; Performance Standard for Laser Products (21 CFR 1040); and Federal OSHA Standard for Construction (29 CFR 1926.54).

The terms, exposure and emission, are used throughout the SSRL. The exposure term is applicable to users and the emission term is applicable to lasers. This has become necessary because a user may modify or assemble his own laser not subject to 21 CFR 1040. These regulations provide for the classification of such lasers.

To avoid confusion with the Federal "Certified laser product," these suggested regulations reference lasers which may or may not be a certified product.

"Class I, II, III, and IV lasers." These classes are consistent with 21 CFR 1040.

"Laser." Although these broad frequency limits go beyond available instrumentation for evaluation under present technology, there are lasers that can operate in this range and the regulations shall apply.

To avoid confusion, these regulations reference lasers, laser systems, and laser products. A laser located in a room or a building is defined as a laser facility.

AA.3 Exemptions. Certified Class I, Class II, Class IIa, and Class IIIa laser products manufactured in accordance with the Federal Performance Standard for Laser Products are exempt from these regulations.

AA.4 Additional Requirements. This Section is consistent with the Ionizing Radiation Category of the Suggested State Regulations for Control of Radiation and is needed to cover new development uses and situations which may require additional precautions to protect the individual using the laser or the public exposed to radiation from the laser.

AA.5 Violations. No wording is suggested for enforcement of violations because this will vary from State to State.

AA.6 Impounding. Lasers can cause severe damage if they are used incorrectly. This provision is included in the SSRL to permit the Agency to take this severe step to ensure public health and safety. Some States may want to use other administrative or legal means to achieve the same end.

AA.8 Tests. These may be tests of safety interlocks, safety eyewear, measurements of the power or energy output of the laser, and other such tests necessary to evaluate the hazard of a laser.

AA.9 Administrative Review. No wording is suggested for administrative procedures as this may vary from State to State.

Registration

AA.13 Purpose. Alternate wording for those States who wish to register the laser and not the facility is "...and use of laser systems." There are cases where there is no permanent facility where the laser is used in which case the State may wish to register the mobile laser.

AA.15 Registration Requirements. Registration is mandatory for those facilities using lasers which could blind or burn a person using them incorrectly. Registration is also required for non-certified lasers of any class because of the need to assure adequate controls and safeguards in their use. This will assist the Agency in their laser inspection program.

AA.16 Exemptions from Registration Requirements. This Section provides exemptions from certain classes of certified lasers. Such certified lasers have a lower probability of causing laser radiation injuries and will permit the agency to concentrate its efforts on higher risk installations and mobile laser users.

AA.17 Laser Safety Officer (LSO). The most effective means of minimizing the hazards associated with lasers is by the instruction of personnel and the establishment of a laser safety program. The laser safety officer provides a mechanism for the accomplishment of this.

AA.18 Acceptance of Laser Safety Officer. Cases may arise where the designated laser safety officer is not qualified in the opinion of the Agency to assume such a position. In such cases, Section AA.18 grants authority to the Agency to require the registrant to designate a new LSO.

AA.19 Annual Report. The annual report will assure that the Agency has up-to-date

information on lasers in possession of registrant and the information will allow the Agency to set realistic inspection schedules.

AA.20 Termination of Registration. This Section provides for termination of registration if certain conditions are met.

AA.21 Validity of Registration. This Section provides for validation of registration and specifies that registration will remain valid until terminated or declared invalid. Some States may want to specify a certain time limit on registration.

AA.22 Registration Shall Not Imply Approval. This Section assures that no commercial advantage is taken of registration by registrant.

AA.23 Out-of-State Laser Radiation Sources. The requirements for temporary use by out-of-state laser firms are specified. This Section provides for free flow of commerce but it assures that the Agency will be notified and that laser safety requirements will be met.

Requirements for Protection Against Laser Radiation

AA.25 Maximum Permissible Exposure (MPE). The MPE limits for laser radiation are the same as specified in the American National Standard for the Safe Use of Lasers, ANSI Z136.1-1980. The limits are based on the recommendations of ANSI Subcommittee "Biological Effects of Lasers on the Eye," Dr. M.L. Wolbarsht, Chairman, and ANSI Subcommittee "Biological Effects of Lasers on the Skin," Dr. W.H. Parr, Chairman.

AA.26 Implementation of Protective Measures. This includes such things as establishing the standard operating procedures to be followed for the safe operation of the laser and instructing personnel in laser radiation safety.

In the case of mobile lasers a State may want to place additional requirements on the user, such as, obtaining certification through demonstration of ability to safely use the laser by written or practical exam.

AA.27 General Requirements for the Safe Operation of all Facilities

AA.27.c.vi. Laser safety eyewear should be used as a last resort for laser safety. The primary emphasis should be placed on the design, installation, and utilization of the laser equipment to eliminate the exposure of personnel. For additional information on use of laser safety eyewear, see DHEW Publication (FDA) 79-8086 "Evaluation of Commercially Available Laser Protective Eyewear."

AA.28 Additional Requirements for Special Lasers and Applications. It is believed that special precautions are required for such facilities because of the high energy/power outputs of the lasers. Energy or power outputs at this level may also be capable of producing scattered

radiation which exceeds the MPE and therefore represents a far greater ocular exposure hazard than if only the direct beam is hazardous.

AA.29 Additional Requirements for Safe Operation

AA.29.a. This will eliminate the possibility of a laser beam entering the safety goggles from behind and being reflected from the inside surface of the filter into the eye.

Some laser safety eyewear now being manufactured only has the optical density(s) and wavelength(s) specified on the case or on a tag which can easily be lost. If the optical density and wavelength are not labeled on the eyewear, this may lead to the misuse of eyewear intended for protection against one type of laser radiation being used for protection against another.

AA.30 Caution Signs, Labels, and Posting. These signs, labels, and symbols are compatible with the ANSI and CDRH standards.

AA.31 Surveys. Surveys are required to provide evidence to the laser safety officer and the Agency that control measures are operational and are utilized. Surveys also provide a basis for the establishment or deletion of additional control measures in the judgement of the laser safety officer and the Agency.

AA.32 Measurement and Instrumentation. When all control measures are used with a particular laser class, and there is not any additional human access to laser or collateral radiation, then measurements are not required. However, for classification purposes (no Federal Classification label) and for human access conditions, measurements (or their equivalent) are required to indicate that levels normally encountered are below the MPE's. Measurements should only be attempted by persons trained or experienced in laser technology and radiometry.

AA.32.c.i, ii, iii, and iv. These measurement criteria affect product performance features and labeling requirements and are identical to the Federal laser products performance standard, as amended.

AA.32.d. MPEs are a user control concept and this paragraph is identical to the user standard, ANSI Z136.1-1980.

AA.34 Notification of Incidents. A requirement for reporting incidents is common in State and local agency health and safety codes. The working group urges State and local officials to report all laser injuries to the National Center for Devices and Radiological Health (CDRH) for tabulation and inclusion in the Radiation Incidents Registry.

AA.37 Records. The preservation period for records has not been designated. This should be determined by individual states.

Tables

Section 360F, EFFECT ON STATE STANDARDS, of the Public Health Service Act as added by Public Law 90-602, Radiation Control for Health and Safety Act of 1968, states "Whenever any standard prescribed pursuant to section 358 with respect to an aspect of performance of an electronic product is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, any standard which is applicable to the same aspect of performance of such product and which is not identical to the Federal standard..." (42 USC 263h). It is primarily because of this statute that the product classification levels found in the tables are compatible with those levels found in the Federal Laser Product Performance Standard and not those found in the ANSI Z136.1-1980 laser standard.

Based on comments received during the review of previous drafts of the Suggested State Regulations for Lasers (SSRL), it was agreed that the use of the Federal laser products performance standard's Class I Accessible Emission Limit (AEL) as a Maximum Permissible Exposure (MPE) limit was not appropriate. Therefore, the American National Standard Z136.1-1980 MPE's are used.

Collateral radiation from laser products includes non-coherent optical and x-radiation. An example of a laser product where both collateral radiations could be present is an actively mode-locked solid state laser. Optical radiation could radiate from the pump lamp, and x-radiation could radiate from the high-voltage power supply. The concept of collateral radiation is found in the Federal Performance Standard for Laser Products and this approach ensures consistency.

Table V. Since this is a performance requirement, it must be identical to the Federal laser products performance standard, as amended.

Appendix A - Medical Surveillance. This is included as a guide to States for information on medical examinations, frequency of examination, eye effects and surveillance, skin effects, and other medical evaluations for laser users.

Appendix B - Guidelines for Laser Light Shows. Because of the increasing number and current popularity of laser light shows, the pertinent requirements for such shows based on CDRH safety criteria are summarized herein.

Appendix C - Application for Registration of Laser Facility, Mobile Laser, or Service Organization. To aid in the promulgation and implementation by individual States of the registration requirement of the Suggested State Regulations for Lasers, a suggested format for the registration form is included.

Appendix D - Training. The material on training is included, due to the importance placed on training in the SSRL to achieve laser health and safety. In addition, the material is consistent

with similar material in the ANSI Z136.1-1980 standard on the Safe Use of Lasers.

Appendix E - Measurements for Maximum Permissible Exposure. Since there is a wide range of spectral, time duration, and geometric distribution of laser sources to which an individual might be exposed, the MPE measurement criteria as specified in ANSI Z136.1 guide are included to ensure a consistent interpretation of the limits.

Matters for Future Consideration

The Suggested State Regulations for Lasers is complete and up-to-date as of this writing (October 1982). It is anticipated, due to the pace of developments in several laser areas, that revisions will be necessary. In addition, it is expected that users of the SSRL will feed back their experiences and ideas for improvement in its content.

One area that may need future elaboration is "associated hazards" since, in some instances, these hazards are specific to lasers.

2005 Rationale for Revisions

Part AA Registration and Radiation Safety Requirements for Lasers

Introduction.

The current Part AA is divided into six major sections that include General Provisions, Registration, Requirements for Protection Against Laser Radiation, Tables, Figures, and Appendices. Part AA has been revised and the title of this Part was changed to more accurately reflect the contents. Sections AA.3(c) addressing general exemptions, AA.4 - Additional Requirements, AA.5 - Violations, AA.7 - Inspections, AA.8 - Tests, AA.9 - Administrative Review, AA.11 - Communications and AA.12 - Severability have been deleted from Part AA as they are addressed in Part A, General Provisions. and Part J, Notices, Instructions, and Reports. Laser registrants will be required to comply with Parts A and J under Section AA.1 Purpose and Scope instead of delineating separate sections within Part AA.

Because the American National Standards Institute (ANSI) Z136.1, Safe Use of Lasers is widely used in the laser industry, Part AA was revised and updated using ANSI Z136-1, Safe Use of Lasers as a basis for the changes. Outdated tables and graphs have been deleted. References to tables and graphs in ANSI Z136.1, Safe Use of Lasers and to Title 21, Code of Federal Regulations (CFR), Part 1040.10 are inserted.

Optional language is shown as bracketed language.

Section AA.1 - Purpose and Scope.

This section has been reformatted and revised to combine several sections in the Part and to more accurately describe the purpose and scope.

Section AA.2 - Definitions.

The definitions of Continuous wave, Embedded laser, Enclosed laser, Limiting duration, and Practitioner of the healing arts were added to define language in the section and to be consistent with language in ANSI Z-136.1, Safe Use of Lasers. The definition of photothermolysis was added as a section on the registration and use of intense-pulsed light devices (IPL) is now included in Part AA. The definitions of Accuracy, Attenuation, Class I, II, III, or IV facility, Operable laser, and Uncontrolled area were deleted as they are not used in the final version of Part SR-AA. Many of the other definitions were changed to clarify the meaning and to be consistent with ANSI Z-136.1. The definitions for Class 1, 2, and 3a lasers are revised to also include the current numbering system utilized by the International Electrotechnical Commission as well as references to the applicable, accessible emission limits in ANSI Z136.1-2000, Safe Use of Lasers.

Section AA.3 - Exemptions

Exemptions from Section AA.16 and AA.3 were combined into Section AA.3 for clarification.

Old Section AA.4 - Additional Requirements. - This was deleted as it was repetitive of language in Part A, General Provisions.

Old Section AA.5 - Violations. - This was deleted as it was repetitive of language in Part A, General Provisions.

Old Section AA.6 - Impounding. - This was deleted as it was repetitive of language in Part A, General Provisions.

Old Section AA.7 - Inspections. - This was deleted as it was repetitive of language in Part A, General Provisions.

Old Section AA.8 - Tests. - This was deleted as it was repetitive of language in Part A, General Provisions.

Old Section AA.9 - Administrative Review. - This was deleted as it was repetitive of language in Part A, General Provisions.

New Section AA.4 - (Old AA.10 - Reserved) - Prohibited Uses.

Because of the potential for misuse and possible injury, prohibitions were added to Part AA.

Old Section AA.11 - Communications. - This was deleted as it was repetitive of language in Part A, General Provisions.

Old Section AA.12 - Severability. - This was deleted as it was repetitive of language in Part A, General Provisions.

Old Section AA.13 - Purpose. - This was combined with Purpose and Scope in Section AA.1 for clarification.

Old Section AA.14 - Scope. - This was combined with Purpose and Scope in Section AA.1 for clarification.

New Section AA.5 - Old Section AA.15 - General Registration Requirements. - The title of this section was revised to indicate general registration requirements that apply to all applicants for registration of lasers. The requirement that a laser safety officer be designated on each application and his/her qualifications be submitted to the agency was added to ensure that qualified individuals serve in this capacity.

New Sections AA.6 - AA.12 - These sections contain specific requirements for registration applications for different uses of lasers including healing arts and veterinary facilities, industrial, academic, and research and development facilities, demonstration for the purpose of sales, providers of lasers, alignment, calibration, and repair of lasers, laser light shows, and laser mobile services. Applicants for laser registration would be required to submit documentation or

comply with items specific to the type of registration in question in addition to the general requirements.

New Section AA.13 - Requirements for Intense-Pulsed Light Device (Photothermolysis) Facilities. - This new section contains requirements for intense-pulsed light devices that are commonly used for hair removal. Since not all states regulate these devices, the language was added as bracketed optional language

New Section AA.14 - (Old Section AA.17) - Laser Safety Officer Qualifications. - This section was revised and language that was also referenced in the Training and Experience Appendix for Radiation Safety Officers was deleted as it was repetitious. The duties of the Laser Safety Officer were moved to new Section AA.15.

(Old Section AA. 18 - Acceptance of Laser Safety Officer). - When an application is submitted for registration that includes the qualifications for laser safety officer, the agency makes a decision on the application as a whole including the laser safety officer. This language is unnecessary and was deleted.

(Old Section AA. 19 - Annual Report.) - A registrant is required to report changes throughout the year as they occur as delineated in new Section AA.19. An annual report is unnecessary and this section was deleted.

New AA.15 - Duties of Laser Safety Officer. - The requirements were moved from the old Section AA.17 and were expanded to more accurately reflect the duties of this individual.

New AA.16 - Issuance of Laser Registration. - This section was added to delineate that a laser registration will be issued if the applicant has met the requirements. It also allows the agency to amend the registration as necessary when circumstances so dictate.

New Section AA.17 - Expiration of Laser Registration. - This section provides a time frame for expiration of the laser registration.

New Section AA.18 - Renewal of Laser Registration. - This section contains requirements for renewal of laser registrations.

New Section AA.19 - Report of Change. - This section contains requirements for reporting any changes to the application.

New Section AA.20 - Termination of Registration. - This section contains requirements for terminating a laser registration.

(Old Section AA.24 - Purpose and Scope.) - This section was combined with Section AA.1, Purpose and Scope.

New Section AA.26b.iv. - (Old Section AA.27(b)iv.) - Warning Systems - This section was revised to be more consistent with ANSI Z-136.1, Safe Use of Lasers.

New Section AA.31 (Old Section AA.32) - Measurement and Instrumentation. - This section has been bracketed as optional language. ANSI Z-136.1, Safe Use of Lasers indicates that measurements should be attempted only by personnel trained or experienced in laser technology and radiometry. Routine survey measurements of lasers or laser systems are neither required nor advisable when the laser classifications are known and the appropriate control measures implemented. Generally this would apply to research and development facility registrants.

Tables I, IIa, IIIa, IVa, IVb, IVc, V, VI, VII, and VIII have been deleted and reference made to ANSI Z-136.1, Safe Use of Lasers and Title 21, Code of Federal Regulations (CFR), Part 1040.

Figures 3, 4, 5, 6, 7, 8, 9, 10, 11, and 12 have been deleted and reference made to ANSI Z-136.1, Safe Use of Lasers and Title 21, Code of Federal Regulations (CFR), Part 1040.

Appendix AA, Medical Surveillance has been revised to be less prescriptive and to be more consistent with language in ANSI Z-136.1, Safe Use of Lasers. It is shown as bracketed optional language and renumbered to Appendix C.

Appendix AA, Guidelines for Laser Light Shows has been renumbered to Appendix A.

Appendix AA, Training has been renumbered to Appendix B.

Appendix AA, Measurements for Maximum Permissible Exposure has been deleted. See the rationale in Section AA.31.