



Conference of Radiation Control Program Directors, Inc.

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MEMORANDUM

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TO: CRCPD Board of Directors,
FROM: Bruce Hirschler
SSRCR Publication Manager
DATE: March 8, 2005
RE: Adoption of Revised Part AA (2005) into the SSRCR's

Please find enclosed **Part AA - Registration and Radiation Safety Requirements for Lasers** as submitted to the CRCPD board by the SR-AA working group, chaired by Cathy Fontaine. On draft displays full edit marks indicating what language has been added (double underline) or deleted (strikeout) from the currently published Part AA. In addition, I have included a draft free of edit marks for ease of reading, the 2005 Rationale for Part AA, the SR-AA working group's response to peer review comments, and Terry Devine's report.

Part AA will be presented to the Board by Kathleen McAllister (SR committee chair) at the Wednesday, May 18, 2005 conference call.

Should you have any questions or concerns regarding form or format of this package, please feel free to contact me.

Cc: Thom Kerr, Executive Director, CRCPD
Pat Gorman, Administrative Officer, CRCPD
Kathleen McAllister (MA) Chair, SR Committee
Cathy Fontaine (TX), Chair, SR-AA

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PART AA

General Provisions Registration and Radiation Safety Requirements for LasersSec. AA.1 - Purpose and Scope.

- a. This Part establishes requirements for the registration of persons-facilities (institutions) 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 which 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.] treatment or use commensurate with the licensed practitioners use of the healing arts.
- b.d. i. 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 thatwhich have been modified shall comply with these regulations or the Federal standard.
- ii. Uncertified lasers shall meet the requirements of these regulations.
- ee. 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 Section AA.32₁ of these regulations.

"Accessible emission limit (AEL)" means the maximum accessible emission level permitted within a particular class in the most recent edition of American National Standard for Safe Use of Lasers, American National Standards Institute (ANSI) Z136.1, as set forth in Tables I, II, IIa, IIIa, IIIb, and V.

"Accuracy" means the degree of conformity of a measure to a standard or a true value and not the degree of repeatability or precision with which a measurement is performed.

"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 the such radiation.

~~any opening in a protective housing through which radiation is emitted, thereby 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.

"Attenuation" means the decrease in the radiant flux of any optical beam as it passes through an absorbing and/or scattering medium.

"Certified laser product" means that the product is certified by a manufacturer as required by pursuant to the requirements of Title 21, Code of Federal Regulations (CFR), Part 1040.10.2, to comply with the applicable requirements of Part 1040, 21 CFR Chapter I Subchapter J.

~~"Class I dual limits" means, for classification purposes, laser and collateral radiation in the wavelength range of greater than 400 nanometers but less than or equal to 1400 nanometers exceeds the accessible emission limits of Class I if it exceeds both:~~

- (1) ~~The Class I accessible emission limits for radiant energy within any range of emission duration specified in Table I, and~~

emission duration specified in Table I.

"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 American National Standard for Safe Use of Lasers, ANSI Z136.1.

"Class 1 laser" means any laser which permits human access to laser radiation less than the accessible emission limits of Table I for any combination of emission duration and wavelength range.

"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 s. For maximum permissible exposure limits, see the most recent edition of 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 American National Standard for Safe Use of Lasers, ANSI Z136.1.

"Class II laser" means any laser which permits human access to laser radiation above the accessible emission limits of Table I up to the accessible emission limits of Table II and does not permit human access to laser radiation in excess of the accessible emission limits of Class I for any other emission duration or wavelength range. Class II lasers are separately designated as Class II or Class IIa. Class IIa lasers are those lasers which do not exceed the accessible emission limits of Class I for any emission duration less than or equal to 1×10^3 seconds. Class II laser designation is given to all other Class II lasers as defined above.

"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 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 American National Standard for Safe Use of Lasers, ANSI Z136.1.

"Class III laser" means any laser which permits human access to laser radiation above the accessible emission limits of Table I and, if applicable, Table II, but below the accessible emission limits of Table III. Class III lasers are separately designated as Class IIIa or Class IIIb. Class IIIa lasers are those lasers with an emission duration greater than 3.8×10^{-4} second and in the wavelength range greater than 400 nanometers but less than or equal to 710 nanometers with an irradiance of less than or equal to 2.5×10^{-3} watts/cm² and with a radiant power of less than or equal to 5×10^{-2} watts. Class IIIb laser designation is given to all other Class III lasers as defined above.

"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 American National Standard for Safe Use of Lasers, ANSI Z136.1.

~~"Class IV laser" means any laser which permits human access to laser radiation above the accessible emission limits of Table III.~~

~~"Class I, II, III, or IV facility" means a facility which has one or more Class I, II, III, or IV lasers, respectively. In case of facilities possessing more than one laser class, the assigned facility classification shall be determined by the most hazardous class of laser contained therein.~~

"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 Table V.)

"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 > 0.25 seconds 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 ~~which~~ 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 ~~which~~ 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).

"Energy density" (see "Radiant exposure").

"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 which results in a real or suspected accidental exposure to laser radiation that which 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 ($J\text{ cm}^{-2}\text{ sr}^{-1}$).

["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 premarketing 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, the radiant power incident on an element of a surface divided by the area of that element, expressed in watts per square centimeter ($W\text{-cm}^{-2}$).

"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, any device which can produce or amplify electromagnetic radiation of frequencies between 3×10^{14} and 1.67×10^{15} hertz (or wavelengths in air between 10^{-3} and 1.8×10^{-7} meter) by the process of controlled stimulated emission, including additional incorporated components providing for a total laser system.

"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 Paragraph AA.27a26a. 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.3231.

"Laser safety officer" (LSO) means any individual, qualified by training and experience in the evaluation and control of laser hazards, who 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,
~~a laser in combination with an appropriate laser energy source, with or without additional incorporated components.~~

"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, to keep equipment in its intended operating condition. Maintenance does not include operation or service as defined in these regulations.

"Maximum permissible exposure" (MPE) means that level of laser or collateral 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 American National Standard for Safe Use of Lasers, ANSI Z136.1, Tables IVa, IVb, IVc, and V.)

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

"Operable laser" means a laser system which can produce laser radiation.

"Operation" means the performance of the laser or laser system over the full range of its intended functions (normal operation), tasks required for the equipment to perform its intended. 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.

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

"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.

"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.

["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.)]

"Protective housing" means those portions of a laser product that are designed to prevent any panel, partition, dividing wall, or similar device which prevents human access to laser and/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 time increment measured between the half peak power points at the leading and trailing edges of a pulse.

~~"Pulse interval" means the time duration between identical points on two successive pulses.~~

"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, lock, by latch, or by screws.

"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, adjustments, repairs, or procedures required to return equipment to its intended state. ~~These adjustments and procedures usually require specialized training and/or tools. Service does not include operation or maintenance as defined in these regulations.~~

"Specular reflections" means mirror-like reflections.

"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}).

~~"Uncontrolled area" means any area to which access is not controlled by the registrant for purposes of protection from radiation hazards.~~

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;

- a. ~~All certified Class I, Class II, Class IIa, and Class IIIa laser products, except for those that allow access to Class IIIb or Class IV laser radiation during servicing, are exempted from these regulations, provided that the laser product is maintained as a certified Class I, Class II, Class IIa, or Class IIIa laser product throughout its useful life.~~
- b. Certified Class 3b visible (0.4 to 07 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 $5 \text{ W} \geq 0.25 \text{ s}$; or
 - ii. Cannot produce a radiant energy greater than 0.03125 within an exposure time less than 0.25 s. J per pulse.
- c. Mobile lasers that are certified Class 1, Class 2, Class 2a, and Class 3a;
- bd. Lasers that are in transit or in storage incident to transit or sale. These regulations do not apply to lasers in storage, during shipment or sale, provided such lasers are inoperable or not operated.; and

c. Facilities containing only IEC Class 1M, 2M, and 3R Lasers.

e. ~~The Agency may, upon application by persons or upon its own initiative, grant such exemptions or exceptions from the requirements of these regulations as it determines are authorized by law and will not result in undue hazard to occupational or public health and safety or to the environment.~~

~~Sec. AA.4—Additional Requirements. The Agency may, by rule, regulation, or order, impose upon any person such requirements in addition to those established in these regulations as it is authorized by law and as it determines to be appropriate or necessary to reduce or eliminate any hazard which causes or threatens to cause any danger to occupational or public health and safety or to the environment.~~

~~Sec. AA.5—Violations. [State to cite penalties used for enforcement of the Act.]~~

~~Sec. AA.6—Impounding. [Subject to provisions of State Law.] The [cite Agency] shall have the authority in the event of any emergency to impound or order the impounding of lasers in the possession of any person who is not equipped to observe or fails to observe the provisions of this Act or any rules or regulations issued thereunder [usually specified by State statute].~~

~~Sec. AA.7—Inspections.~~

- a. ~~Each person shall afford the Agency at all reasonable times opportunity to inspect the laser facility or mobile laser.~~
- b. ~~Each person shall make available to the Agency for inspection, upon reasonable notice,~~

~~records maintained pursuant to these regulations.~~

~~Sec. AA.8—Tests. Each person shall perform, upon instructions and reasonable notice from the Agency, or shall permit the Agency to perform, such reasonable tests as the Agency deems appropriate or necessary to assure compliance with these regulations.~~

~~Sec. AA.9—Administrative Review. [Cite Administrative Procedures of State enabling legislation.]~~

Sec. AA.10—1 - Prohibited Uses. (Reserved.)

- 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 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.11—Communications. All communications and reports concerning these regulations, and applications filed thereunder, shall be addressed to the Agency at its office located at {~~

~~Sec. AA.12— Severability. Insofar as the Agency may provide, each Section or Part thereof of these regulations shall be construed as separate, to the end that, if any Section, sentence, clause, or phrase, shall be held invalid for any reason, the remainder of these regulations shall continue in full force.~~

Registration

~~Sec. AA.13— Purpose. The purpose of this Part is to provide for the registration of facilities, mobile lasers, and persons servicing lasers.~~

~~Sec. AA.14— Scope.~~

- ~~a. Every person possessing a laser or laser system and persons providing laser and laser system installation, servicing, maintenance, and/or services involving the use of a laser or laser system shall register in accordance with this Part.~~
- ~~b. The registrant shall be subject to all applicable requirements of these regulations.~~

Sec. AA.15 - General Registration Requirements.

- a. All facilities using fixed lasers or mobile lasers, and persons servicing lasers or laser systems, except as exempted in Section AA.316, shall be registered 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 set forth all applicable information included in called for by 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 facility 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; and,

ii. A list of facilities where the laser will be provided.

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 radiation registration for alignment, calibration, and/or repair before providing alignment, calibration, and/or repair of lasers.

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

a. In addition to the requirements of Section AA-5, each applicant shall submit the following:

i. A valid 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];

ii. 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.

iii. Prior to the performance of an outdoor laser light show, the licensee shall notify 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.

Class 2 or Class 3 surgical devices certified as complying with the design, labeling, and manufacturing standards of the United States Food and Drug Administration (FDA).

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 laser. An application for healing arts facilities shall be signed by a licensed practitioner of the healing arts.]

Sec. AA.16—Exemptions from Registration Requirements:

a. The following are exempt from the registration requirements of this Part:

i. Facilities containing only;

(1) Certified Class I, Class II, Class IIa, or Class IIIa laser products, and/or

(2) Certified Class IIIb laser products in the wavelength range of 400 through 710 nanometers and having a peak radiant power of less than or equal to 5×10^{-3} watts; and

ii. Mobile lasers which are certified Class I, Class II, Class IIa, and Class IIIa.

b. Servicing of certified laser products with accessibility to Class IIIb or Class IV laser radiation is not exempt from the registration requirements of this Part.

Sec. AA.147 - Laser Safety Officer (LSO) Qualifications. The registrant shall designate a laser safety officer who is responsible for laser radiation protection. Such individual shall LSO

qualifications shall be submitted to the Agency and shall include the following:

- a. ~~Be designated from such personnel as the radiation protection officer, industrial hygiene officer, safety officer, laser specialist, or laser operator.~~
- b. ~~Be qualified by t[Training and experience in the following areas (seeas outlined in Appendix B.2.D):~~
- ~~i. Fundamentals of laser operation.~~
 - ~~ii. Biological effects of laser radiation on the eye and skin.~~
 - ~~iii. Relations of specular and diffuse reflections.~~
 - ~~iv. Laser and laser system classification.~~
 - ~~v. Control measures.~~
 - ~~vi. Nonradiation hazards of lasers.~~
 - ~~vii. Medical surveillance practices (if applicable).~~
 - ~~viii. Laser terminology.~~
 - ~~ix. Types of lasers, wavelengths, pulse shapes, modes, power, and energy.²²~~
 - ~~x. Basic radiometric units and measurement devices and techniques.~~
 - ~~xi. Maximum Permissible Exposure (MPE) levels for eye and skin under all conditions.²²~~
 - ~~xii. Laser hazard evaluations, range equations, and other calculations.~~
- h. 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.
- 2c. Establish and supervise a program of laser radiation safety for effective compliance with the applicable requirements of these regulations.
- 2d. Provide instructions concerning hazards and safety practices to individuals who may be exposed to laser radiation and to individuals who operate the lasers.

Sec. AA.18 Acceptance of Laser Safety Officer. When, in the opinion of the Agency, the individual designated to be the laser safety officer does not have qualifications sufficient to carry out the requirements of Section AA.26 of these regulations, the Agency may order the registrant to designate another individual.

Sec. AA.19 - Annual Report. ~~The registrant shall notify the Agency annually of changes, if any, in the information supplied on the registration application or in the previous annual reports.~~

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

- a. ~~e.~~ Establishing and supervising ~~Establish and supervise 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. ~~d.~~ Providing ~~Provide 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 sectionPart 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 and Sections AA.6 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 before making 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. ~~The Agency [may] [shall] terminate registration upon notification from the registrant that all lasers have been transferred to another person or are no longer operable.~~ 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; ~~(?)~~and.

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 ~~sueh~~the source of laser radiation into the State shall give written notice to the Agency [at least 7 working days] before ~~sueh~~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.

~~Requirements for Protection Against Laser Radiation~~

~~Sec. AA.24 Purpose and Scope. This Part establishes regulations for protection against laser radiation. 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.~~

Sec. AA.245 - - 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 American National Standard for Safe Use of Lasers, ANSI Z136.1, specified in Tables IVa, IVb, IVc, and V. 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.2526 - Implementation of Protective Measures. Protective measures used to avoid laser or collateral radiation shall be implemented by a laser safety officer (LSO), ~~or in the case of those lasers not registered,~~ an individual designated by management.

Sec. AA.2627 - 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 American National Standard for Safe Use of Lasers, ANSI Z136.1 and Title 21, CFR, Part 1040 respectively, I and Paragraphs A and B of Table V, 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 and Paragraphs A and B of

Table V in the most recent edition of 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 Subparagraph AA.267b.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 IIIb-3b and Class IV4 CW ~~continuous-wave (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) hHuman access to levels of laser radiation in excess of the radiant power accessible emission limit of Class IIIa-3a laser radiation, or
 - (b) laser radiation in excess of the accessible emission limits of Class II-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 American National Standard for Safe Use of Lasers, ANSI Z136.1 and collateral radiation limits in Title 21, CFR, Part 1040, and Table V limits 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 Class 2, or 3a, or 4II, III, or IV laser product shall provide visual or aural indication during the emission of accessible laser radiation in excess of the limits for Class I. 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, except that, in the case of Class 3bIIIb, except those which allow access only to less than 5 mW peak visible laser radiation, and Class 4IV lasers, this indication shall be sufficiently prior to emission of such radiation to allow appropriate action to avoid exposure. Any visual indicator shall be clearly visible through protective eyewear designed specifically for the wavelength(s) of the emitted laser radiation. If the laser and laser energy source are housed separately and can be operated at a separation distance of greater than two meters, both laser and laser energy source shall incorporate visual or aural indicators. The visual indicators shall be positioned so that viewing does not require human access to laser radiation in excess of the MPE.~~

v. Laser Controlled Area. ~~With a Class 3bIIIb, except those which that allow access only to less than 5 mW visible peak power, or Class 4IV laser, a laser controlled area shall be established when exposure to the laser radiation in excess of the MPE in the most recent edition American National Standard for Safe Use of Lasers, ANSI Z136.1 and collateral radiation limits in Title 21, CFR, Part 1040 or Table V limits is possible. The controlled area shall meet the requirements of Subdivisions AA.267b.v.(1) through (3) for Class 3IIb lasers and the requirements of Subdivisions AA.267b.v.(1) through (7) for Class 4IV lasers:~~

- (1) The area shall be the responsibility of the laser safety officer.
- (2) The area shall be posted as required by Section AA.2930.

- (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 4IV 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.

~~For such emergency conditions, a control disconnect switch or equivalent device (panic button) shall be available for deactivating the laser.~~

- (5) For Class 4IV 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 4IV 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 American National Standard for Safe Use of Lasers, ANSI Z136.1 and collateral radiation limits in Title 21, CFR, Part 1040, and Table V limits. 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 space² or controlled ground space when the beam irradiance or radiant exposure is above the appropriate MPE and collateral radiation ~~and Table V~~ 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 American National Standard for Safe Use of Lasers, ANSI Z136.1 and collateral radiation limits in Title 21, CFR, Part 1040 and Table V limits, 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 3HB and Class 4IV lasers.
- ii. Output Emission Limitations. The minimum laser radiant energy or laser power level required for the application shall be used.

²Contact FAA or other appropriate agencies, as necessary.

- iii. Education and Training. The degree and level of education and training on laser safety concepts and procedures shall be in accordance with Appendix ~~D-C~~, Table 1 of these regulations.
- iv. Operation and Maintenance. Class ~~3~~3Hb and Class ~~4~~4V lasers shall be operated and maintained only by qualified personnel.
- v. Alignment Procedures. Alignment of laser optical systems (e.g., mirrors, lenses, and 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 American National Standard for Safe Use of Lasers, ANSI Z136.1, Appendix A, and collateral radiation limits in Title 21, CFR, Part 1040 and Table V limits.
- vi. Eye Protection. Protective eyewear, as specified by the laser safety officer, shall be worn by all individuals with access to Class ~~4~~4V levels of laser radiation. Protective eyewear, when specified by the laser safety officer, shall be worn by all individuals with access to Class ~~3~~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.26-27 - Additional Requirements for Special Lasers and Applications.

- a. Infrared Laser - Greater than 710 Nanometers. The beam from a Class ~~3~~3Hb and Class ~~4~~4V laser shall be terminated in fire-resistant material where necessary. Periodic inspection of absorbent material shall be made since many materials degrade with use.²
- ~~b. Laser Light Shows. The requirements of Appendix B shall be met.~~
- eb. 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 or Table V limits 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 Subdivision AA.30e29c.i. ~~(Six).~~

² Many metal surfaces which appear "dull" visually can act as specular reflectors of infrared radiation.

Sec. AA.29-28 - 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.
- (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 to ensure the reliability of the protective filters and integrity of the protective filter frames. Eyewear with the integrity compromised or that is not serviceable as intended should be discarded, in suspicious condition shall be discarded or tested for acceptability.b. Skin Protection. When there is a possibility of exposure to laser radiation which ~~that~~ exceeds the MPE limits for skin as specified in the most recent edition American National Standard for Safe Use of Lasers, ANSI Z136.1 ^{Table IVc**} 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 ~~and~~ or maintenance of lasers which ~~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.30-29 - Caution Signs, Labels, and Posting.a. General.

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

- i. Except as otherwise authorized by the Agency, signs, symbols, and labels prescribed by this Section shall use the design and colors specified in Figures 1 and 2.
 - ii. In addition to the signs, symbols, and labels prescribed in this Section, 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. Posting and Instructions.~~i. The controlled area shall be conspicuously posted with an appropriate sign or signs as specified in Paragraph AA.230e. and Figures 1 and 2.~~
- ii. Operating personnel of each laser shall be provided with adequate written instructions 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 American National Standard for Safe Use of Lasers, ANSI Z136.1, or collateral radiation limits in Title 21, CFR, Part1040, and Table V limits.
 - iii. 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 ~~which 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 ~~which that~~ could allow access by personnel to laser and collateral radiation in excess of the MPE limits in the most recent edition American National Standard for Safe Use of Lasers, ANSI Z136.1, or collateral radiation limits in Title 21, CFR, Part1040, and Table V limits
- 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 I-1 lasers shall have a label including the following wording: "CLASS I1 LASER"; ~~Class I facilities need not be posted.~~
 - iii. Class 2 laser facilities need not be Class posted. Class 2aH lasers ~~which that~~ do not exceed accessible emission limits of Class 1H for any emission duration less than or equal to 1×10^3 seconds shall have a label with the following wording: "Class Ha-2a Laser (or Laser Product) - Avoid Long Term Viewing of Direct Laser Radiation";

^{1/} With respect to laser products only, the labeling requirements found in 21 CFR Part 1040 may be used in lieu of Paragraph AA.30e2)c.

~~Class IIa laser facilities need not be posted.~~

- iiiiv. Class 2H laser facilities need not be posted. Class 2H lasers other than those specified in Subdivision AA.30e29c.iii.(2) 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 H-2 LASER (OR LASER PRODUCT)"

- v.(4) ——— (a(1)) Each laser or facility classified in Class III-3a solely because of the emission of 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 IIIa-3a LASER (OR LASER PRODUCT)"

- (b2) Class III-3b lasers or facilities other than those specified in Subdivision AA.30e29c.i.(4)(a)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 IIIb-3b LASER (OR LASER PRODUCT)"

- vi.(5) Class IV-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 IV-4 LASER (OR LASER PRODUCT)"

vii.(6) Class II₂, III₃, or IV-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 Tables 1 and 5 the most recent edition of 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:

- (a₁) "AVOID EXPOSURE - Laser radiation is emitted from this aperture," if the radiation emitted through such aperture is laser radiation.
- (b₂) "AVOID EXPOSURE - Hazardous electromagnetic radiation is emitted from this aperture," if the radiation emitted through such aperture is collateral radiation.
- (c₃) "AVOID EXPOSURE - Hazardous x-rays are emitted from this aperture," if the radiation emitted through such aperture is collateral x-ray radiation.

viii.(7) Each Class II₂, III₃, and IV-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 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.
- (8) ~~Each noninterlocked or defeatably interlocked portion of the protective housing or enclosure which is designed to be displaced or removed during normal operation, maintenance, or servicing, and which thereby would permit human access to laser or collateral radiation, shall have labels as follows:~~
- (a) ~~For laser radiation in excess of the accessible emission limits of Class I but not in excess of the accessible emission limits of Class II, the wording: "CAUTION—Laser radiation when open. DO NOT STARE INTO BEAM."~~
- (b) ~~For laser radiation in excess of the accessible emission limits of Class I or Class II as applicable, but not in excess of the accessible emission limits of Class III, the wording: "DANGER—Laser radiation when open, AVOID DIRECT EXPOSURE TO BEAM."~~
- (c) ~~For laser radiation in excess of the accessible emission limits of Class III, the wording: "DANGER—Laser radiation when open. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION."~~
- (d) ~~For collateral radiation in excess of the emission limits of Table V.~~
- ~~(i) If the limits in paragraph A of Table V are exceeded, the wording: "CAUTION—Hazardous Electromagnetic Radiation when open"; and~~
- ~~(ii) If the limits in paragraph B of Table V are exceeded, the wording: "CAUTION—Hazardous X-Ray Radiation."~~
- (e) ~~For protective housing or enclosures which provide a defeatable interlock, the words "and interlock defeated" shall be included in the labels specified in Subdivisions AA.30e.i.(8)(a), (b), (c), and (d).~~
- xi.(9) (a1) The word "Invisible" shall immediately precede the word "radiation" on labels and signs required by Paragraph AA.30e29c. for wavelengths of laser and collateral radiation that are outside of the range of 400 to 710 nanometers.

- (b~~2~~) The words "Visible and Invisible" shall immediately precede the word "radiation" on labels and signs required by Paragraph AA.30e~~29c~~. for wavelengths of laser and collateral radiation that are both within and outside the range of 400 to 710 nanometers.

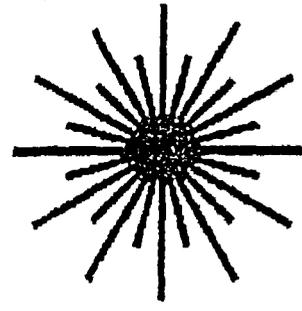
~~xii.(10)~~ All labels placed on lasers or signs posted to laser facilities shall be positioned so as to make unnecessary, during reading, human exposure to laser or collateral radiation in excess of the MPE and Table V limits in the most recent edition of American National Standard for Safe Use of Lasers, ANSI Z136.1 and the collateral radiation limits in Title 21, CFR, Part 1040.

~~xiii.(11)~~ Labels and signs required by Paragraph AA.30e~~29c~~. shall be clearly visible, legible, and permanently attached to the laser or facility.

(BORDER AND LINE OPTIONAL) (YELLOW) (BLACK) (YELLOW)



(YELLOW)



(BLACK SYMBOL)

(POSITION 1
BOLD BLACK LETTERING)

(POSITION 2
BOLD BLACK LETTERING)

(POSITION 3
BOLD BLACK LETTERING)

Figure 1

AA30

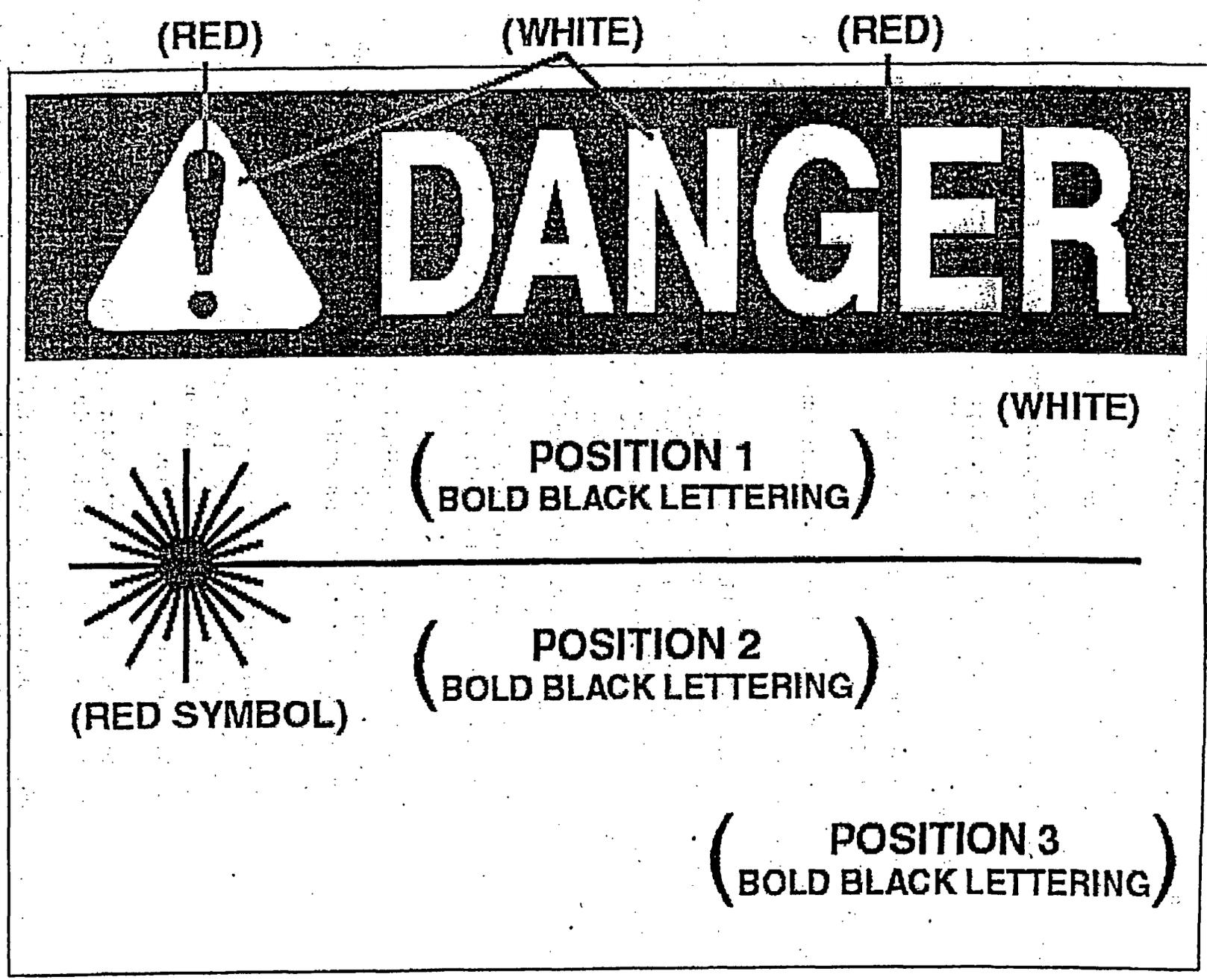


Figure 2

Sec. AA.302931 - Surveys. Each registrant shall make or cause to be made such radiation

AA31

protection surveys as may be necessary to comply with this Section AA.31. 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 ~~Section AA.3029~~.
- d. A re-evaluation of potential hazards from surfaces which may be associated with Class III-3 and Class IV-4 beam paths.
- e. Additional surveys required to evaluate the laser and collateral radiation hazard incident to the use of lasers.

[Sec. AA.32-31 - 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. ~~u~~Under those operational conditions and procedures which maximize the accessible emission levels including startup, stabilized operation, and shutdown of the laser or facility,
 - ii. ~~w~~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. ~~a~~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. ~~w~~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. ~~f~~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 ~~which 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 which ~~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 ($W \text{ cm}^{-2}$) or radiant exposure ($J \text{ cm}^{-2}$) 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 ($W \text{ cm}^{-2} \text{ sr}^{-1}$) or integrated radiance ($J \text{ cm}^{-2} \text{ sr}^{-1}$) 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). Accessible emission levels for classification of laser and collateral radiation shall be based upon the following measurements:
 - i. The radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 80 millimeters, except for scanned laser radiation, and within a circular solid angle of acceptance of 1×10^{-3} steradian with collimating optics of 5 diopters or less.
 - ii. The irradiance ($W \text{ cm}^{-2}$) or radiant exposure ($J \text{ cm}^{-2}$) 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).
 - iii. The radiance ($W \text{ cm}^{-2} \text{ sr}^{-1}$) or integrated radiance ($J \text{ cm}^{-2} \text{ sr}^{-1}$) 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 (cm²).

- ~~iv. Accessible emission levels of scanned laser radiation shall be based upon the measurement of radiation detectable through a stationary circular aperture stop having a 7 millimeter diameter and within the circular solid angle of acceptance with collimating optics applicable under Subparagraphs AA.32e.31e.i., ii., and iii. 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 per second.~~
- d. Measurements for maximum permissible exposure shall be measured as specified in Appendix E and MPE limits in the most recent edition American National Standard for Safe Use of Lasers, ANSI Z136.1, Tables IVa, IVb, and IVe.

Sec. AA.33-32 - 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 NHZ. Appendix A-C provides recommended procedures which that apply primarily to users of Class 3b or 4IV lasers.

Sec. AA.34-33 - Notification of Incidents Twenty-four hour Notification.

- a. Immediate Notification Twenty-four hour Notification. Each registrant shall notify the Agency immediately within 24 hours of discovery by telephone, fax or email or telegraph of any incident involving any source of laser or collateral radiation possessed by the registrant and which that has or may have caused:
- i. a 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 Table V limits of laser or collateral radiation; or
 - ii. a An exposure to an individual which that involves the partial or total loss of sight in either eye; or
 - iii. a An exposure to an individual which that involves perforation of the skin or other serious injury exclusive of eye injury; or
 - iv. a A loss of one working week or more of operation of any facility affected.
- b. Twenty-four Hour Five Working Days Notification. Each registrant shall notify the Agency by telephone, fax or email or telegraph within five working days 24 hours of any incident involving any source of laser or collateral radiation possessed by the registrant and which that has or may have caused:
- i. a An exposure to an individual of greater than 5 times the MPE limits in the most recent edition American National Standard for Safe Use of Lasers, ANSI Z136.1, or collateral radiation limits in Title 21, CFR, Part 1040, or Table V limits of laser or collateral radiation; or

- ii. ~~a~~An exposure to an individual with second- or third-degree burns to the skin or potential injury and partial loss of sight.

Sec. AA.35-34 - 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. ~~e~~Each exposure of an individual to laser and collateral radiation in excess of the MPE limits in the most recent edition American National Standard for Safe Use of Lasers, ANSI Z136.1, or collateral radiation limits in Title 21, CFR, Part 1040.5; or
 - ii. ~~a~~Any incident for which notification is required by ~~Section AA.3433.~~
- 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 ~~Section AA.3435~~ 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.^{2/}

Sec. AA.36-35 - Notifications and Reports to Individuals. When a registrant is required pursuant to ~~Section AA.35-34~~ 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.

Sec. AA.37-36 - 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 ~~Subparagraph AA.29a28a.ii.~~ and ~~Section AA.3430.~~
 - ii. The results of all instrument calibrations under ~~Section AA.3231.~~
 - iii. The results of medical surveillance performed under ~~Section AA.3332.~~
 - iv. The reports of incidents as described under ~~Section AA.3635.~~

^{2/} This paragraph is suggested for use by States which have the authority to maintain the names of individuals as confidential information

- b. The registrant shall maintain such records required by this Section AA.37 until the Agency authorizes disposition.

Part AA

APPENDIX AA

MEDICAL SURVEILLANCE

AA.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, per se. Specific information on medical surveillance requirements that might exist because of other potential exposures such as toxic gases, noise, ionizing radiation, etc., are 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 subacute 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.

AA.2 Medical Examinations:

AA.2.1 Rationale for Examinations:

AA.2.1.1 Preassignment Medical Examinations. Except for examination following suspected injury, these are the only examinations required. 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 AA. 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 tonometrygoniometry, 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 epidemiologic study indicates whether they are needed or not.

AA.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.

AA.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.

AA.2.2 Examination Protocols

AA.2.2.1 — Medical History. The following protocols are required for preplacement examinations of all laser workers:

- The patient's past eye history and family eye history are reviewed.
- Any current complaints which he now has about his 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.

~~AA.2.2.2 — See ANSI Z136.1, American National Standard for Safe Use of Lasers 6.3 and Appendix E for additional exam protocols. Visual Acuity. Required for preplacement examinations for all incidental and laser workers. Distance visual acuity should be tested both with and without corrective lenses to 20/15. Results should be recorded in Snellen figures. The visual acuity at near is tested at 35 cm and recorded in Jaeger-tested figures or Snellen figures with and without lenses, if any. Visual acuity screening instruments may be used.~~

~~AA.2.2.3 — Manifest Refraction. Required for preplacement examinations of all laser workers when indicated. This is to measure the patient's refractive error, and the new visual acuity of the patient must be noted if the visual acuity is improved over that achieved with the patient's old lens prescription, or if he has no lenses at the time of the examination. This examination shall be carried out in all personnel whose best corrected distance visual acuity in either eye is less than 20/20.~~

~~AA.2.2.4 — External Ocular Examination. Required for preplacement examinations for laser workers using laser systems producing radiation below 350 nm or above 1400 nm. This includes examination of brows, lids, lashes, conjunctiva, sclera, cornea, iris and pupillary size, equality, reactivity, and regularity.~~

~~AA.2.2.5 — Examination by Slit Lamp. Required for preplacement examinations of laser workers using laser systems producing radiation below 420 nm or above 750 nm. The cornea, iris, and lens are examined with a biomicroscope and described.~~

~~AA.2.2.6 — Examination of the Ocular Fundus with an Ophthalmoscope. Required for preplacement examinations of laser workers using laser systems producing radiation between 390 nm and 1400 nm and any aphakic worker. In the recording of this portion of the examination the points to be covered are: the presence or absence of opacities in the media; the sharpness of outline of the optic nerve; the size of the physiological cup, if present; the ratio of the size of the retinal veins to that of the retinal arteries; the presence or absence of a well-defined macula and the presence or absence of a foveolar reflex; and any retinal pathology that can be seen with a direct ophthalmoscope. Even small deviations from normal should be described and carefully localized.~~

~~AA.2.2.7 — Skin Examination. Not required for preplacement examinations of laser workers; however, suggested for employees with history of photo-sensitivity or those working with ultraviolet lasers. Examination of the skin for presence of abnormal pigmentation or depigmentation, keratoses, malignancies, etc.~~

~~AA.2.2.8 — Amsler Grid. Not required. The Amsler grid sheet is presented to each eye separately and any distortion of the grid is noted by the patient and drawn by him; may be part of a thorough ophthalmologic examination.~~

~~AA.2.2.9 — Tonometry. Not required. This is the measurement of intraocular pressure; should be~~

part of a thorough ophthalmologic examination.

AA.2.2.10 — Photograph of the Posterior Pole of the Fundus. Not required. This includes the area of the macula and head of the optic nerve and should be taken in color; may be obtained by the examining physician to more fully describe retinal abnormalities. Appropriate techniques to reduce the patient's exposure to optical radiation should be employed.

AA.2.2.11 — Other Examinations. Further examinations should be done as deemed necessary by the examiner.

AA.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.

AA.4 — Epidemiologic Studies. Past use of laser systems has generally been stringently controlled. Actual exposure to laser workers has been minimal or even nonexistent. It is not surprising that acute accidental injury has been rare and that the few reports of repeated eye examinations have not noted any chronic eye changes. For these reasons, examination requirements are minimal. However, animal experiments with both laser and narrow band radiation indicate the potential for chronic damage from both subacute or chronic exposure to certain wavelengths of radiation. Lens opacities have been produced by radiation in the 295-450 nm range and are also theoretically possible from 750-1400 nm.

Photochemical retinitis appears to be possible to induce by exposure to 350-500 nm radiation. If laser systems are developed that require chronic exposure of laser workers to even low levels of radiation in these wave length regions, it is recommended that such workers be included in the long-term epidemiologic studies and have periodic examinations of the appropriate eye structures.

Epidemiologic studies of workers with chronic skin exposure to laser radiation (particularly ultraviolet) are suggested.

AA.5 — References

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

AA.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.

AA.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.

Part AA

APPENDIX AAAGUIDELINES-REQUIREMENTS 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 I-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 I-1 during operation. ~~Radiation which shall be measured~~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 I-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 I-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 H-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 H-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 I-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 II-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 Guidelines Requirements and Regulations are met. In other cases, upon application to the Agency, appropriate arrangements may be made for unattended operation.

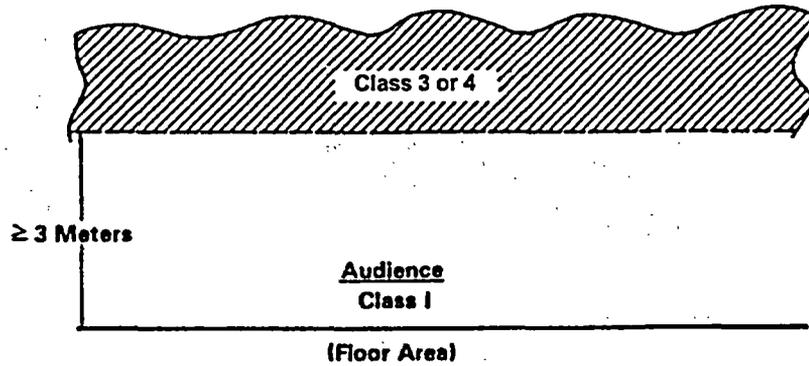
8. All laser light shows shall be provided with a key operated "on-off" switch. In the case of the exception of item 7, there shall be a designated individual present who can turn off and secure the laser in case of unsafe operating conditions.
9. The maximum laser output power shall be limited to a 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).
 - (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, 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.]

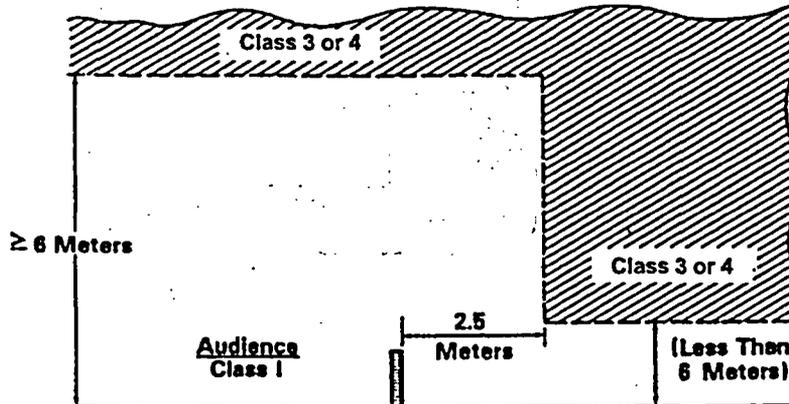
LASER LIGHT SHOWS

Application of Safety Criteria

OPERATOR IN CONTROL



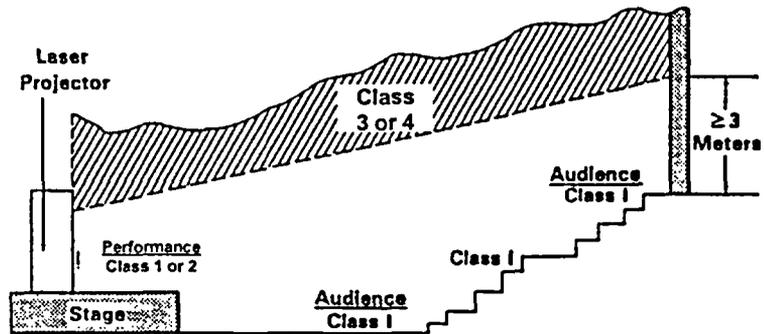
NO OPERATOR IN CONTROL (Side View)



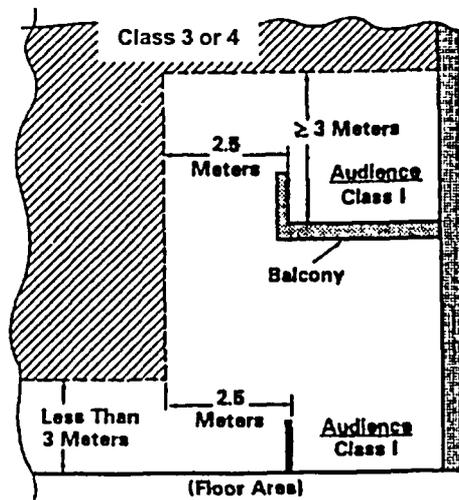
LASER LIGHT SHOWS

Application of Safety Criteria

OPERATOR IN CONTROL (Rising Floor Level)



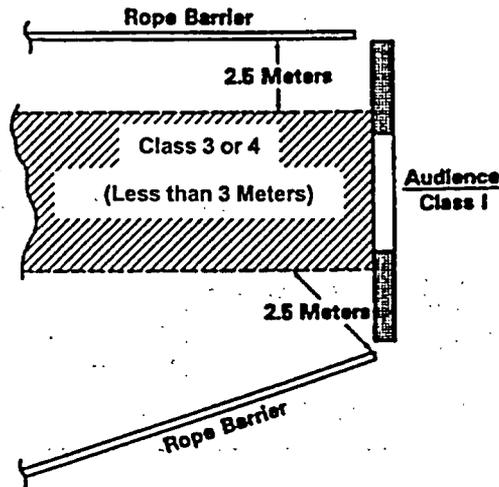
OPERATOR IN CONTROL (Side View)



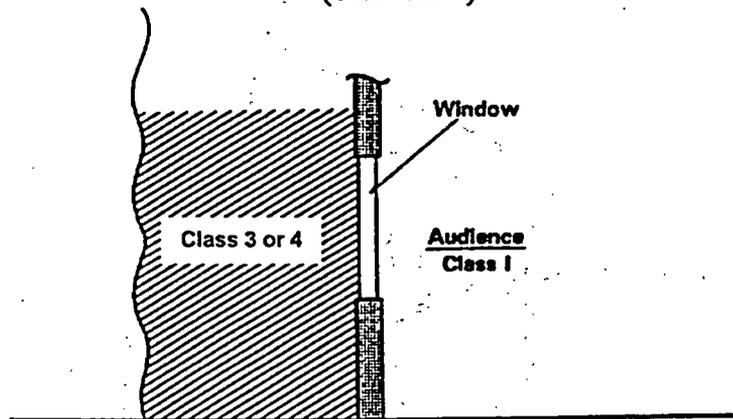
LASER LIGHT SHOWS

Application of Safety Criteria

OPERATOR IN CONTROL PHYSICAL OBSTRUCTION (Top View)



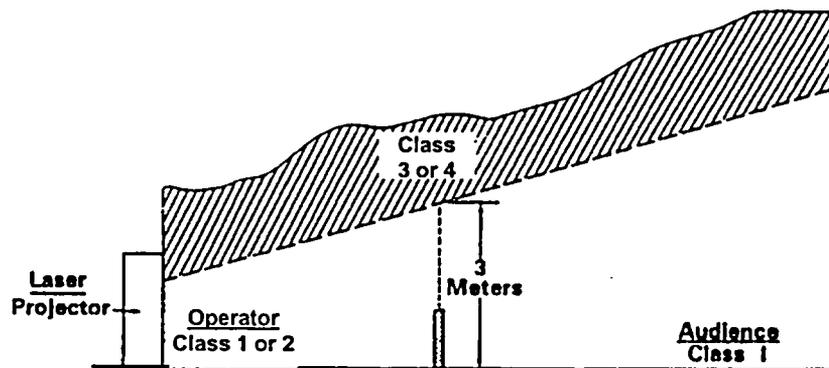
OPERATOR IN CONTROL PHYSICAL OBSTRUCTION (Side View)



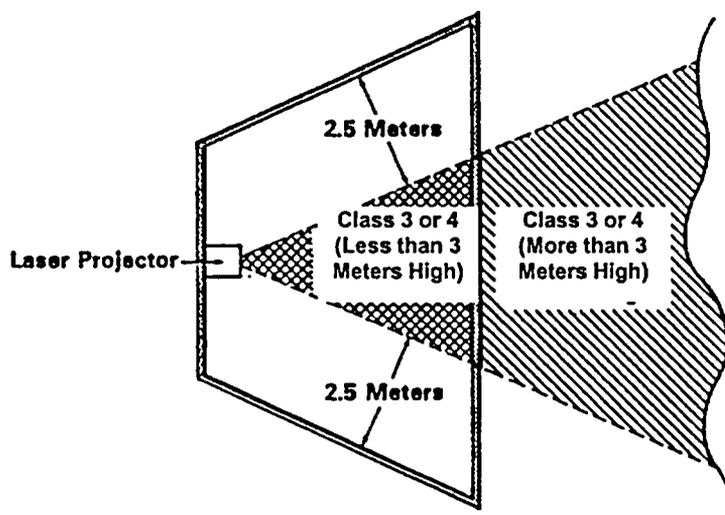
LASER LIGHT SHOWS

Application of Safety Criteria

OPERATOR IN CONTROL INCLINED LASER RADIATION FIELD (Side View)



OPERATOR IN CONTROL INCLINED LASER RADIATION FIELD (Top View)



APPENDIX AA

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

Registration is required for all uncertified laser products and for certified Class IIIb-3b (other than those exempted by Subparagraph AA.3b.16a.ii.) and Class IV-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 IIIb-3b and Class IV-4 only): _____

Wavelength Range	Number of Sources of Laser Radiation		Range of Average Power or Energy
	In Facility	Mobile	
UV (< 0.4 μm)	a	b	c
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.]

[Instruction Sheet for Registration of Sources of Laser Radiation
(For exemptions to registration requirement see Section AA.163.)

PLEASE PRINT OR TYPE ALL INFORMATION

~~Note: Care in compiling and entering all required information in the application will help to prevent undue delay and to reduce the amount of correspondence necessary. Your cooperation is earnestly solicited.~~

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 only for uncertified Class IIIb 3b and Class IV 4 laser sources, for certified Class IIIb 3b laser sources not exempted by Subdivision AA.3b16a.i.(2), and for certified Class IV 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 Section AA.5e.17.
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 Paragraph AA.17.b14.
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 AABTRAINING1. General

Training shall be provided in laser safety and laser health physics to all laser safety officers (LSO's) responsible for Class ~~IIIb-3b~~ and Class ~~IV-4~~ Lasers. Training of LSO's responsible for Class ~~I1~~, Class ~~H2~~, Class ~~Ha~~ and Class ~~IIIa-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 ew 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

3. ~~Training Guide for Laser Safety Officers Responsible for Various Laser Classifications~~

Table 1

Suggest Training for LSO's and Employees

<u>Training Vehicles</u>	<u>HIGHEST CLASS LASER</u>				
	<u>1/</u>	<u>H,IIa2</u>	<u>IIIa3a</u>	<u>IIIb3b</u>	<u>IV-4</u>
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: 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 IIIb-3b and IV-4 Lasers, duration of course would be several days. This training may be done by outside specialists if not available internally.

[Part AAAPPENDIX 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., are 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 subacute 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 Preassignment (Pre-employment) Medical Examinations. Preassignment (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 gonioscopy, 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 preplacement (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.

AA.5 References.

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

AA.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.

AA.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.

AA.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.]

Part AA

APPENDIX AA

MEASUREMENTS FOR MAXIMUM PERMISSIBLE EXPOSURE[#]

1. Limiting Aperture. The limiting aperture specified in Table VIII shall be the maximum circular area over which irradiance and radiant exposure can be averaged for measurements and calculations of all MPE values.

2. Intrabeam or Extended-Source Ocular Exposures

(a) For the purpose of these regulations:

(i) Sources such as laser arrays, diodes, and diffuse reflecting surfaces shall be considered extended sources if their angular subtense,* i.e., apparent visual angle, is equal to or greater than α_{\min} as specified in Figure 3. An extended source subtends an angle at the observer's eye equal to or greater than the angular subtense; α_{\min} as specified in Figure 3, across the greatest angular dimension of the source as viewed by the observer.

(ii) All other lasers, such as those

with collimated beams which produce a small, i.e., nearly diffraction-limited, retinal image and also point sources, shall be considered intrabeam viewing cases and shall have an angular subtense, i.e., apparent viewing angle, less than α_{\min} as specified in Figure 3. Sources such as laser arrays, multiple diodes, or multiple diffuse reflecting surfaces shall be considered intrabeam viewing cases for any of the separate images whose angular subtense is less than α_{\min} . Any sources whose centers are separated by an angle less than α_{\min} are treated as extended sources.

(iii) If measurements or calculations are required, distinction shall first be made between intrabeam viewing and extended source viewing in the 0.4 to 1.4 micrometer wavelength region.

† When a laser emits radiation at several widely different wavelengths, or where pulses are superimposed on a continuous wave (cw) background, computation of the MPE is complex. Exposures from several wavelengths in the same time domain are additive on a proportional basis of spectral effectiveness with due allowance for all correction factors. The simultaneous exposure to pulses and cw radiation is not strictly additive (there may be synergism) and caution should be used in these situations until more data are available.

** The angular subtense is not the beam divergence of the source. It is the apparent visual angle as calculated from the source size and distance from the eye. The limiting angular subtense is that apparent visual angle which divides intrabeam viewing from extended source viewing.*

(b) MPE values for direct ocular exposure to single pulses or exposures in intrabeam viewing are specified in Table IVa. Special qualifications and use requirements are provided in Appendix AA Measurements for Maximum Permissible Exposure 4 and 5 and Figures 4, 5, 6, and 10.

(c) MPE values for ocular exposure to extended sources for single pulses or exposures are specified in Table IVb for the cornea. Special qualifications and use requirements are provided in Appendix AA Measurements for Maximum Permissible Exposure 4 and 5 and Figures 5, 6, and 7.

(d) MPE values for broad-band collateral radiation shall be weighted with regard to spectral content in 50 nanometer increments using Tables IVa or IVb, as appropriate.

3. MPE for Skin Exposure to a Laser Beam. MPE values for skin exposure to a laser beam are specified in Table IVc. These levels are for worst case conditions and are based on the best available information. For repetitive pulsed lasers, the MPE's for skin exposure are applied as follows: Exposure of the skin shall not exceed the MPE based upon a single pulse exposure, and the average irradiance of the pulse train shall not exceed the MPE applicable for the total exposure train length.

4. Special Qualifications—Visible and Near-Infrared Multiple Pulses

(a) Multiple Pulse Trains, Pulsed and Scanning Lasers with Multiple Exposures. The MPE for energy or power in multiple pulse or multiple exposure trains where the instantaneous pulse repetition frequency of any pulses within a

train exceeds 1 per second has the limits specified in Appendix AA Measurements for Maximum Permissible Exposure 4.(a)(i) through (v).

(i) The irradiance of radiant exposure (radiance or integrated radiance) in any individual pulse in a train is limited to the MPE for a comparable pulse, as specified in Appendix AA Measurements for Maximum Permissible Exposure 2.(b), (c), and (3).

(ii) The average irradiance or radiant exposure (radiance or integrated radiance) for the pulse train is limited to the MPE as specified in Appendix AA Measurements for Maximum Permissible Exposure 2.(b), (c), and (3) for one pulse of this irradiance or radiant exposure (radiance or integrated radiance) whose duration is the same as that of the pulse train.

(iii) Any and all groups of pulses within the train are limited to the MPE of one pulse with the same duration as the group in the manner specified in Appendix AA Measurements for Maximum Permissible Exposure 4.(a)(ii).

(iv) For individual pulses with duration less than 10 microseconds, the MPE of Appendix AA Measurements for Maximum Permissible Exposure 4.(a)(i) is reduced as specified in Figure 12. In no case shall this reduction be less than the reciprocal of the number of pulses within 0.25 second when the pulse train duration is less than 0.25 second.

(v) When the individual pulse duration is 10 microseconds or greater, the MPE for an individual pulse in a train shall be calculated from the MPE for the total "on time" pulse (TOTP), which has a duration equal to the sum of all the individual pulse durations in the train, as follows: The MPE irradiance of an individual pulse within the train shall be reduced to the MPE for the TOTP. The MPE radiant exposure or integrated radiance of an individual pulse within the train shall be reduced to the MPE for the TOTP divided by the number of pulses within the train. The following formula shall be used to evaluate the MPE applicable to each pulse:

$$MPE_{\text{single}} = \frac{MPE_{nt}}{n}$$

where n = number of pulses in the train; t = individual pulse width; and MPE_{nt} = MPE applicable to a pulse of width nt, in seconds. An additional limitation is that the average irradiance in the pulse train shall not exceed the MPE as specified in Appendix AA Measurements for Maximum Permissible Exposure 4.(a)(ii) and the MPE's for the individual pulses or pulsed repetition frequency shall be reduced to keep within this limitation.

(b) Repetitive pulses at repetition rates of less than 1 hertz (Hz) shall be considered additive over a 24 hour period.

(c) Pulse trains whose duration is 18 microseconds or less shall have their pulses summed into a single pulse with the applicable MPE.

~~(d) Pulse trains whose duration is less than 0.25 second and whose instantaneous pulse repetition frequency is 10 Hz or less shall not have their MPE's reduced by the limitations of Appendix AA Measurements for Maximum Permissible Exposure 4.(a)(iv).~~

~~5. Special Qualifications—Infrared. Available data are not sufficient to define wavelength corrections relative to 1.06 micrometers (μm), over the entire infrared range (1.4 μm —1 mm). At 1.54 μm , the MPE given in Tables IVa and IVb is increased by a factor of 10^2 for time periods shorter than 1 microsecond. However, no extrapolation to other wavelengths is justified on the basis of present information.~~

PART AA**Registration and Radiation Safety Requirements for Lasers****Sec. AA.1 - Purpose and Scope.**

- a. This Part establishes requirements for the registration of facilities (institutions) 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 Section AA.31 of these regulations.

"Accessible emission limit (AEL)" means the maximum accessible emission level permitted within a particular class in the most recent edition of 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 1010.2, to comply with the applicable requirements of

"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 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 s. For maximum permissible exposure limits, see the most recent edition of 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 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 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 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 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 > 0.25 seconds 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 results 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 ($J\text{ cm}^{-2}\text{ sr}^{-1}$).

["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 premarketing 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, who 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 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].

"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.

["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.)]

"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 ($W \text{ cm}^{-2} \text{ sr}^{-1}$).

"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 ($J \text{ cm}^{-2}$).

"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 ($J \text{ sec}^{-1}$).

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 $5 \text{ W} \geq 0.25 \text{ s}$; or
 - ii. Cannot produce a radiant energy greater than 0.125 within an exposure time less than 0.25 s. 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 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 facility 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. 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.

- a. In addition to the requirements of Section AA.5, each applicant shall submit the following:
 - i. A valid 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];
 - ii. 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.
 - iii. Prior to the performance of an outdoor laser light show, the licensee shall notify 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 laser. 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 and Sections AA.6 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 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 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 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 Subparagraph 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 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 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 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^{2/} 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 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.

^{2/}Contact FAA or other appropriate agencies, as necessary.

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 C, 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 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 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.^{2/}
- 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

^{2/} Many metal surfaces which appear "dull" visually can act as specular reflectors of infrared radiation.

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 Subdivision 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.
 - (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 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.

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

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

- i. Except as otherwise authorized by the Agency, signs, symbols, and labels prescribed by this Section shall use the design and colors specified in Figures 1 and 2.
- ii. In addition to the signs, symbols, and labels prescribed in this Section, 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 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 American National Standard for Safe Use of Lasers, ANSI Z136.1, or collateral radiation limits in Title 21, CFR, Part1040.
- 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 American National Standard for Safe Use of Lasers, ANSI Z136.1, or collateral radiation limits in Title 21, CFR, Part1040.

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

^{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.

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 Subdivision 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 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 Subdivision 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 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 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 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.

(BORDER AND LINE OPTIONAL) (YELLOW) (BLACK) (YELLOW)

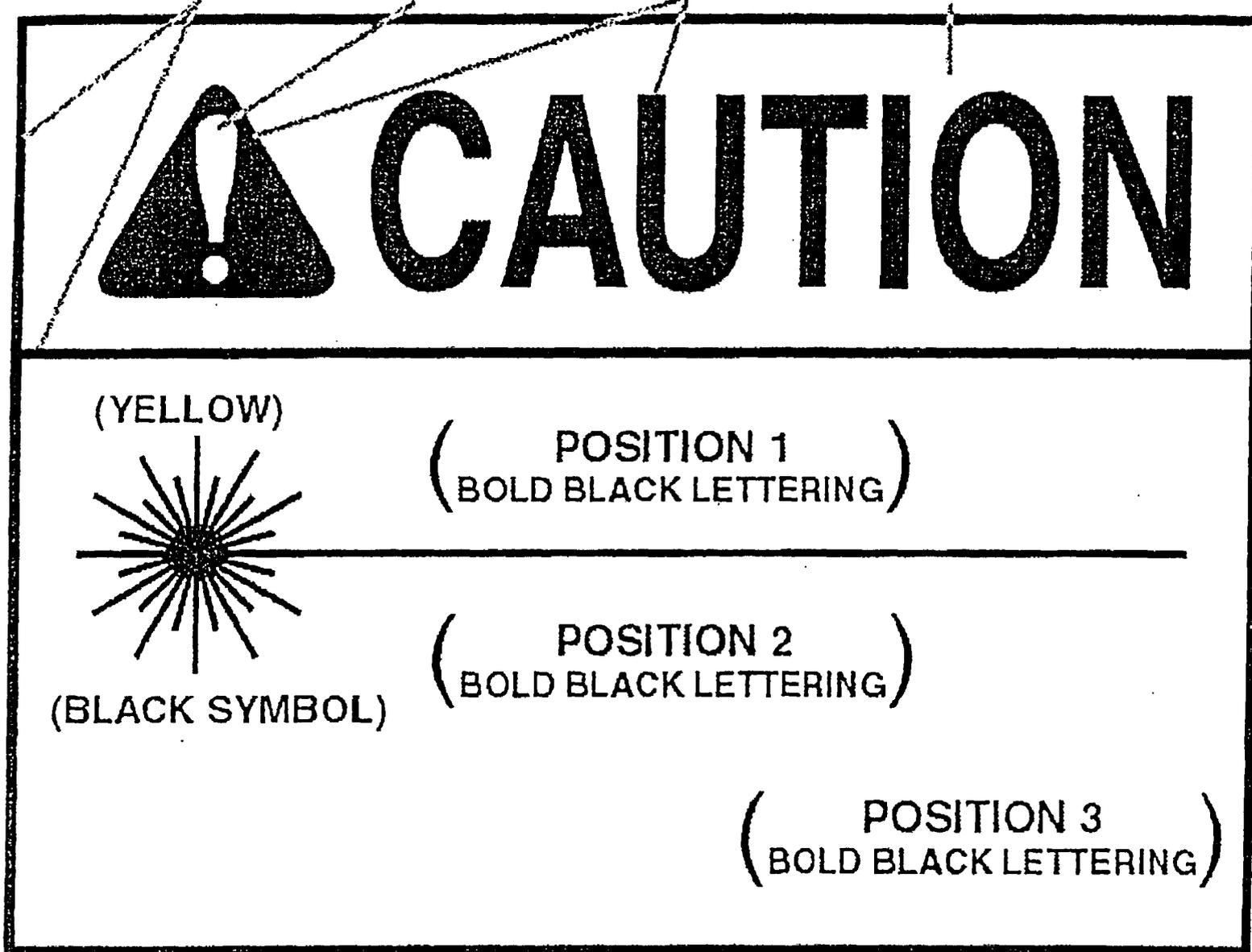


Figure 1

AA24

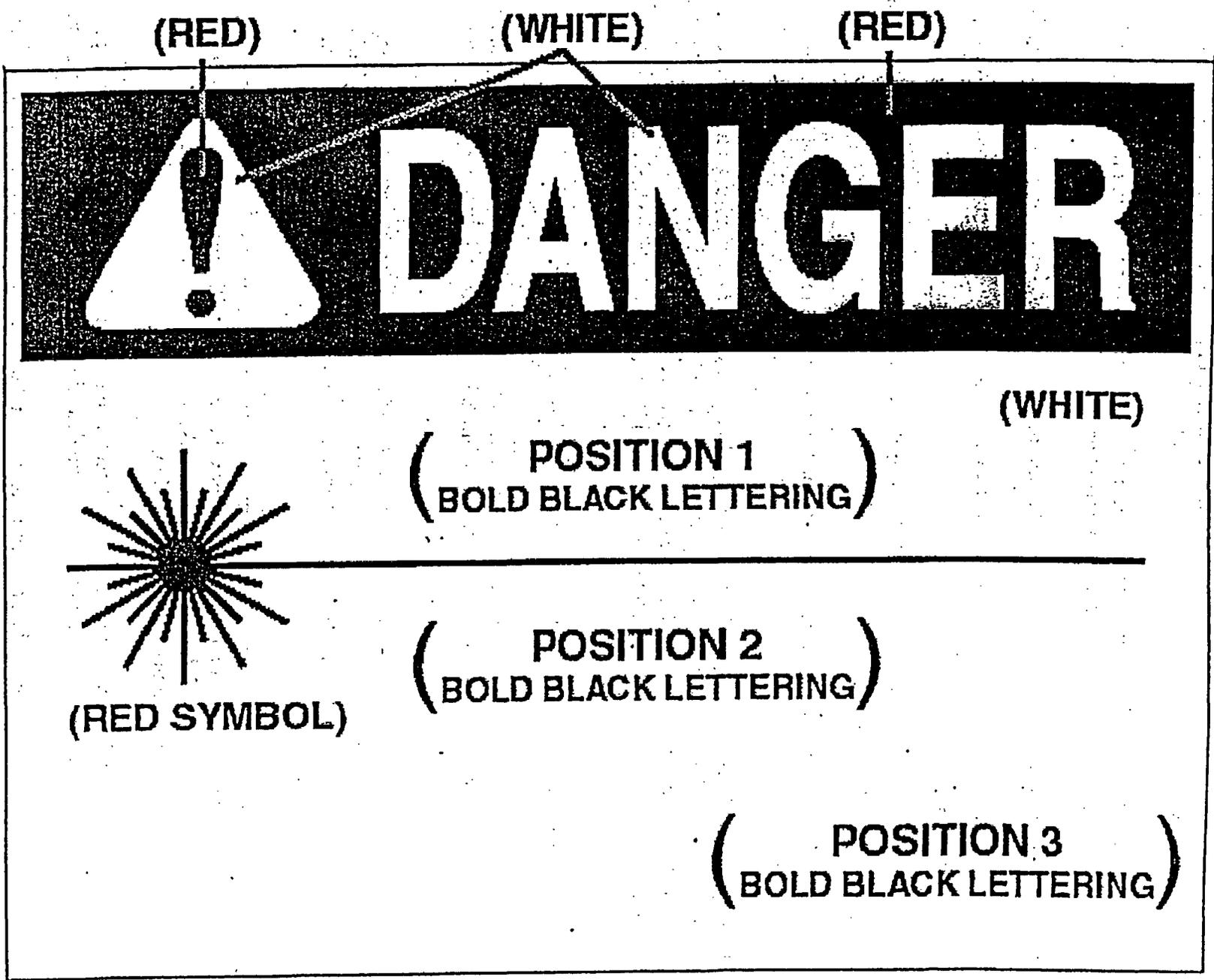


Figure 2

Sec. AA.30 - Surveys. Each registrant shall make or cause to be made such radiation protection

AA25

surveys as may be necessary to comply with this Section. 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 ($W \cdot cm^{-2}$) or radiant exposure ($J \cdot cm^{-2}$) 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 ($W \cdot cm^{-2} \cdot sr^{-1}$) or integrated radiance ($J \cdot cm^{-2} \cdot sr^{-1}$) 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 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 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 American National Standard for Safe Use of Lasers, ANSI Z136.1, or collateral radiation limits in Title 21, CFR, Part1040.; 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 American National Standard for Safe Use of Lasers, ANSI Z136.1, or collateral radiation limits in Title 21, CFR, Part1040; 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

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

reports shall be transmitted at a time not later than the date of transmittal to the Agency.

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 this Section 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 Requirements and Regulations are met. In other cases, upon application to the Agency, appropriate arrangements may be made for unattended operation.

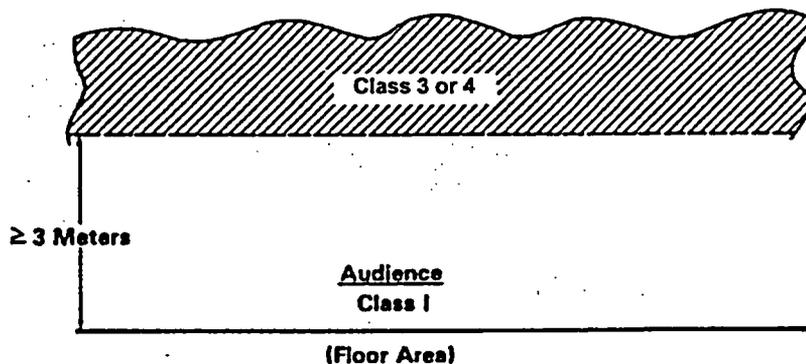
8. All laser light shows shall be provided with a key operated "on-off" switch. In the case of the exception of item 7, there shall be a designated individual present who can turn off and secure the laser in case of unsafe operating conditions.
9. The maximum laser output power shall be limited to a 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).
 - (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, 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.]

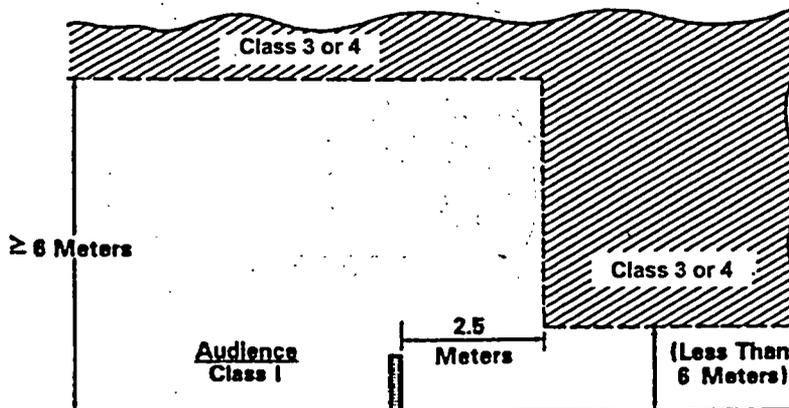
LASER LIGHT SHOWS

Application of Safety Criteria

OPERATOR IN CONTROL



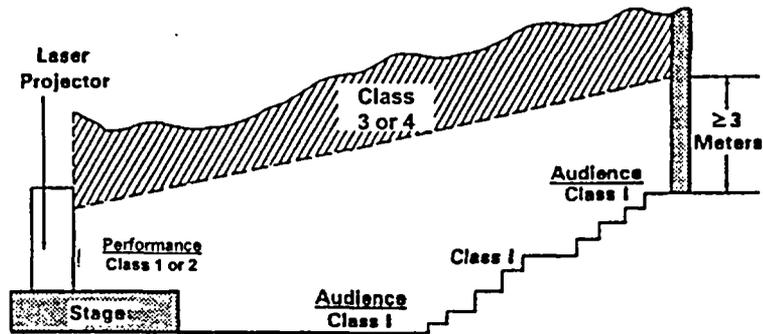
NO OPERATOR IN CONTROL (Side View)



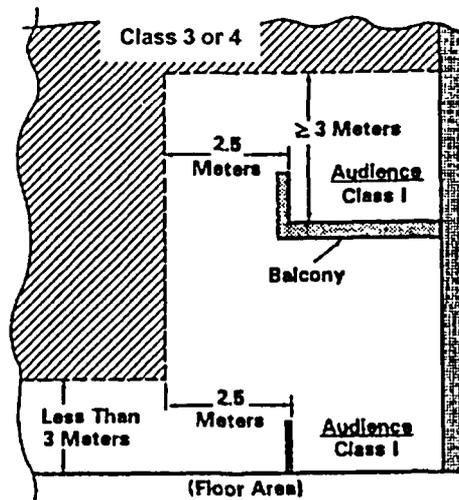
LASER LIGHT SHOWS

Application of Safety Criteria

OPERATOR IN CONTROL (Rising Floor Level)



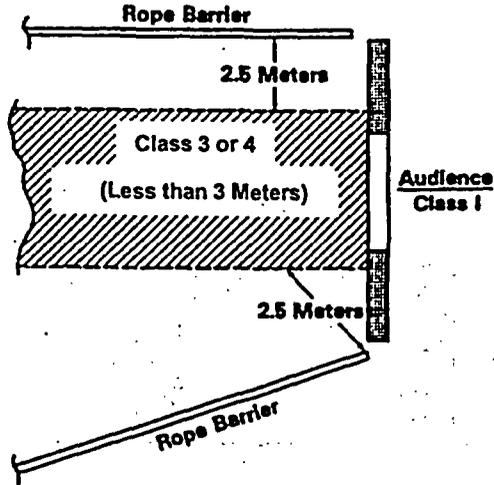
OPERATOR IN CONTROL (Side View)



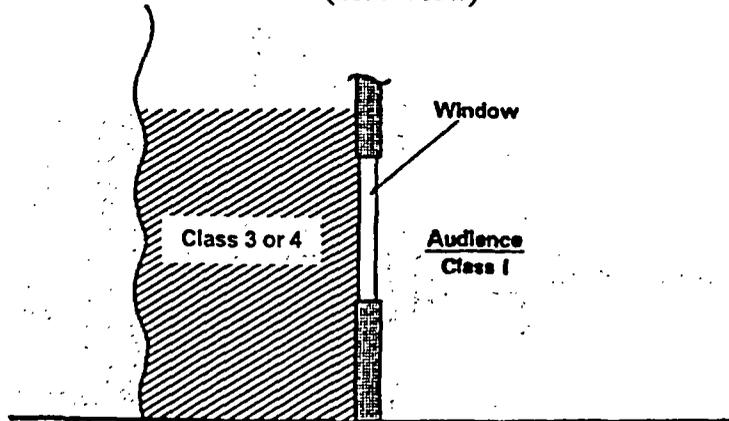
LASER LIGHT SHOWS

Application of Safety Criteria

OPERATOR IN CONTROL
PHYSICAL OBSTRUCTION
(Top View)



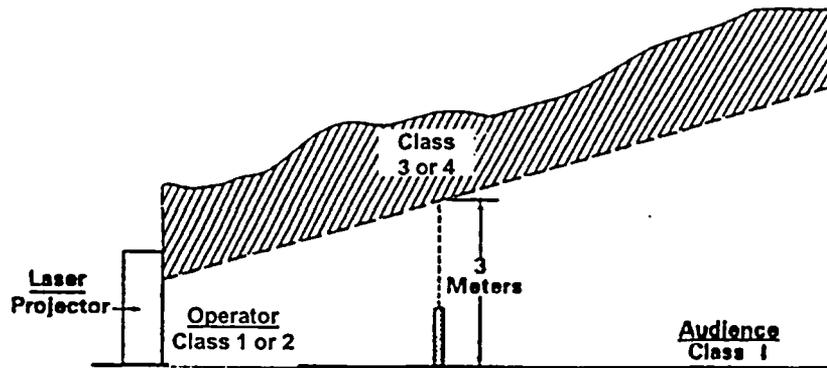
OPERATOR IN CONTROL
PHYSICAL OBSTRUCTION
(Side View)



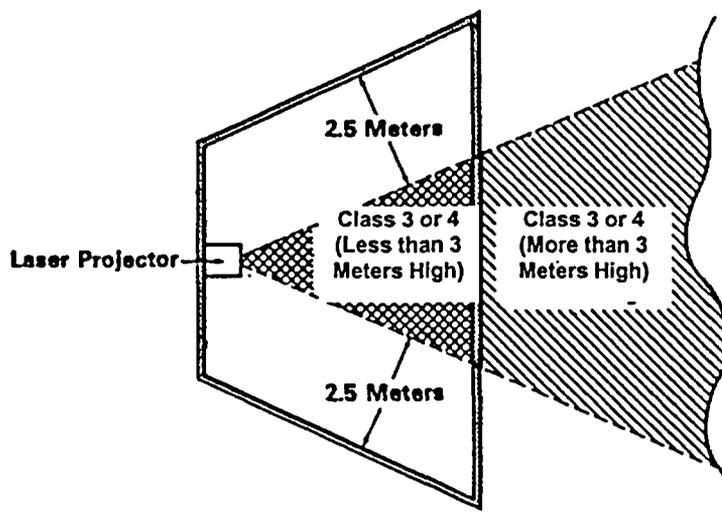
LASER LIGHT SHOWS

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):

Wavelength Range	Number of Sources of Laser Radiation		Range of Average Power or Energy
	a	b	
	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.]

[Instruction Sheet for Registration of Sources of Laser Radiation
(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 Section 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 Paragraph 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
Suggest Training for LSO's and Employees

Training Vehicles	<u>HIGHEST CLASS LASER</u>				
	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: 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 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., are 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 subacute 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 Preassignment (Pre-employment) Medical Examinations. Preassignment (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 preplacement (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.

AA.5 References.

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

AA.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.

AA.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.

AA.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.]

2004

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 repetitive. 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.

Analysis of Comments - Part AA

Part Number	Comments	Committee Action
Section AA 1	One commenter stated that there should be mention that there are some minimal requirements for Class 1, 2, and 3a lasers (e.g., labels) specified in other sections.	The committee acknowledges the comment. There are some labeling requirements included in the rule and required by the United States Food and Drug Administration. In addition, definitions of Class 1, 2, 2a, and 3a lasers and the International Electrotechnical Commission's Class 1M, 2M, and 3R lasers are included in the rule, primarily as information. Many of the lasers in the Class 1 - 3 range are laser pointers, printers, bar code readers, etc. and it would be extremely difficult for states to attempt to enforce requirements on these items. Therefore Class 1, 2, and 3a lasers and Class 1M, 2M, and 3R lasers are not required to be registered. No change was made as a result of the comment.
Section AA.1a	One commenter suggested adding facility (institution) to the first sentence (institution) ...that receive, possess, etc. The commenter further questioned if the intent was for each user at a University to register separately rather than the Institution? The same question applies for a commercial firm or each supervisor of laser equipment? The person who receives may be fine for some medical applications, but the majority of times it will be a company or institution.	The committee agrees and deleted the word "persons" and added the words "facilities (institutions)" in the first sentence. The intent is for the "facility" as a whole to receive, possess, etc. and not individuals

Part Number	Comments	Committee Action
Section AA 1.e.	One commenter stated that "uncertified laser shall meet the requirement of these regulations" is an odd statement. The commenter further stated if the intent is for uncertified lasers to be registered etc that is fine; however, if the intent is to meet product standard requirements, that violates the definition or option of being an uncertified laser.	The committee agrees and deleted the paragraph.
Section AA1.g	One commenter questioned what was applicable in the General Provisions Part that was not repeated in Part AA? Another commenter questioned which of these applied to lasers since they apply to ionizing radiation.	The committee agrees and revised the paragraph to specify the sections of Parts A, D, and J that are applicable to laser registrants.
Section AA.2 - "Accessible emission level"	One commenter suggested revising the definition of "accessible emission level" to include "...within a particular class in the Federal laser product performance standard or the most recent edition of the American National..."	The committee agrees and revised the definition.
Section AA.2 - "Certified laser product"	One commenter stated that the reference in the definition of "Certified laser product" is not quite correct and should be changed to 21 Code of Federal Regulations, Part 1010.2, to comply with the applicable requirements of Part 1040.	The committee agrees and revised the definition.
Section AA.2	Two commenters suggested adding definitions for Class 1M, 2M, and 3R lasers.	The committee agrees and added the definitions.

Part Number	Comments	Committee Action
Section AA.2 - "Intense-pulsed light (IPL) device"	One commenter suggested revising "Intense-pulsed light (IPL) device" to read: ["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 II or Class III medical device. The United States Food and Drug Administration (FDA) regulations require premarketing clearance or approval, and a quality system for manufacturing."	The committee agrees and revised the definition.
Section AA.2 - "Irradiance"	One commenter suggested revising "Irradiance" to read: "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.	The committee agrees and revised the definition.
Section AA.2 - "Joule"	One commenter suggested adding "or 10E7 ergs".	The committee disagrees, as the definition in the draft is consistent with the most recent edition of the American National Standards Institute for Safe Use of Lasers, ANSI Z136.1. No change was made as a result of the comment.
Section AA.2 - "Watt"	One commenter suggested adding "or 10E7 ergs per second".	The committee disagrees, as the definition in the draft is consistent with the most recent edition of the American National Standards Institute for Safe Use of Lasers, ANSI Z136.1. No change was made as a result of the comment.
Section AA.2 - "Photothermolysis"	One commenter suggested revising "Photothermolysis" by replacing the word "lesions" with the word "features".	The committee agrees and revised the definition.

Part Number	Comments	Committee Action
Section AA.3	Two commenters suggested adding Classes 1M, 2M and 3R lasers to the exemptions.	The committee agrees and added this to Section AA3e
Section AA.3b.i and ii	One commenter questioned that this statement did not read correctly.	<p>The committee reviewed the statement and agrees and made the following changes consistent with language in the most recent edition of the American National Standard for Safe Use of Lasers, ANSI Z136.1</p> <ul style="list-style-type: none"> i. Cannot emit an average radiant power in excess of 0.5 W for ≥ 0.25 s; or ii. Cannot produce a radiation energy greater than 0.125 J within an exposure time less than 0.25 s.
Section AA.4b. - Prohibited uses	One commenter indicated that since laser radiation is not supposed to be directed at an individual (excluding medical procedures), it is really diffuse reflection you are concerned about and should be stated here. The commenter indicates the statement is too open ended and almost all class 4 lasers can cause skin injury. The commenter questions what if the beams are contained and is that is what is meant by shields. The commenter further states that this is why you require an LSO to evaluate the hazard and set controls.	The committee disagrees with the comment. The intent of the prohibition is for a registrant to prohibit an individual from entering a laser-controlled area if the skin exposure would be in excess of the maximum permissible exposure limits, unless the registrant provides and requires the use of protective clothing, gloves, and shields. No change was made as a result of the comment.

Part Number	Comments	Committee Action
Section AA.7 Applications for Industrial, Academic, and Research & Development Laser Facilities	One commenter indicated that once again it should be the facility and questions what happens when a registered laser application changes and will they need to re-register. The commenter questions the statement that each applicant for use of lasers shall submit an application and also questions can a laser acquired by one researcher be used by another after they leave it behind.	The committee disagrees with the comment. The term "applicant" means the facility applying for the certificate of registration to use the laser. It does not apply to an individual working for a facility. No change was made as a result of the comment.
Section AA.10 - Application for alignment.	One commenter questioned if this means the agency will develop a list of approved calibration, repair firms etc?	The committee acknowledges the comment. This section is a requirement for individuals or repair firms to apply for registration with the agency for authorization to perform calibrations or repairs at laser facilities within the state. It does not require the agency to develop a list of approved calibration or repair firms but that is an option that a state may consider. No change was made as a result of the comment.
Part Number	Comments	Committee Action
Section AA.11 - Application for Laser Light Show	One commenter questioned if the section on "Application for laser light show" is a permit, or notification and questioned if this could be tied into the reciprocity concept?	This is a certificate of registration, i.e. permit to operate in the state and would be used for laser light shows at permanent facilities, such as a "Six Flags" or "Disney World" operation. Out-of-state or reciprocal recognition is separate and is addressed in Section AA.23. No change was made as a result of the comment.
Section AA.11a.ii. Application for	One commenter suggesting revising the statement to read: "Notification to the Agency in writing at least seven days in	The committee agrees and revised the statement

Laser Light Show -	advance of the proposed laser show, including the following information:	
Section AA.13.a. - Requirements for Intense-Pulsed Light Device (Photothermolysis) Facilities	One commenter stated that the FDA has classified IPL devices as Class II or Class III medical devices and regulations require premarketing clearance or approval and a quality system for manufacturing. The commenter suggests that the paragraph be revised to reflect this language.	The committee agrees and revised the language.
Section AA.15d. and d.i.	<p>Duties of Laser Safety Officer - One commenter suggested changing this to read: "Specifying whether any changes in control measures are required:</p> <p style="padding-left: 40px;">i. Following any service and maintenance of lasers..."</p>	The committee agrees and revised the statement.

Part Number	Comments	Committee Action
Section AA.16 - Registrations	One commenter indicated that many firms have hundreds of laser diodes ready to be placed in applications and questions if they need to be registered before use or upon acquiring?	The committee acknowledges the comment. This section addresses issuing a certificate of laser registration after an applicant has made application and met the requirements of the regulations. Section AA.8, "Application for Demonstration for the Purpose of Sales of Lasers" addresses a company selling lasers. There is no requirement to register individual laser diodes or individual lasers that are available for sale. No change was made as a result of the comment.
Section AA.20 Termination of Registration	One commenter suggested adding a part to cover placing laser equipment in storage.	There is a provision for exempting lasers in storage or transit in Section AA.3.d., Exemptions. No change was made as a result of the comment.
Section AA.24 - Maximum permissible exposure	One commenter questioned if the ALARA principle could be applied here? The commenter further stated that the laser risks are non-stochastic, but it seems like time near the laser can be minimized, distance increased, or shielding added when it is reasonable.	The committee acknowledges the comment. While in principle ALARA could be applied, the practice of ALARA is more applicable to ionizing radiation. No change was made as a result of the comment.
Section AA.24a.	One commenter indicated that the Federal laser product performance standard does not prescribe MPE levels and that the reference to the Federal standard should be deleted.	The committee agrees and deleted the reference.

Part Number	Comments	Committee Action
Section AA.26b.iii.(2)	One commenter suggested beginning the sentence with the word "Because" instead of the word "Since".	The committee acknowledges the comment but does not feel the change adds clarification to the statement. No change was made as a result of the comment.
Section AA.26b.iv. - Warning system	One commenter indicated that the statement "Each Class 2 or 3a laser product shall incorporate an emission indicator..." is unnecessary as no laser pointer or alignment 2 or 3a has an emission indicator and its hazard level is so low it should not.	The committee agrees and eliminated the first sentence.
Section AA.26b.v.(4). - Laser Controlled Area	One commenter indicated that very few research facilities or other class 4 laser use areas have a panic button or need one.	The committee agrees and deleted this language.
Section AA.27.a.	One commenter suggested substituting the word "because" in place of the word "since" in the second sentence	The committee acknowledges the comment but does not feel the change adds clarification to the statement. No change was made as a result of the comment.
Section AA.27b. - Laser Optical Fiber Transmission System.	One commenter suggests that this section should clearly state it applies to more than optical communication systems. Since many industrial and research and development applications use fiber optics to transmit laser radiation even at Class 3B & 4 levels.	The committee agrees and has changed the title to "Systems Utilizing Fiber Optics."
Section AA.27b.ii.	One commenter indicated that ANSI Z136.2 is the appropriate standard for the safe use of optical fiber communications rather than ANSI Z136.1	The committee agrees and has changed the reference.
Part Number	Comments	Committee Action
Section AA.28a.ii.	One commenter suggests that if you mean visual check for scratches, nicks or other physical damage, it should be clearly stated to avoid confusion. But if you mean the user should	The intent is to perform a visual inspection. The committee agrees with the commenter and has revised the first

	confirm the optical density of the laser protective eyewear has not degraded from UV or other mechanism, almost no laser use facility has the testing equipment to do such an evaluation. In that case you have set up all registrants for failure. I only know of 1-2 test houses that offer the service.	sentence to read: "At intervals not to exceed 6 months, each registrant shall examine protective eyewear devices for scratches, nicks or other physical damage."
Section AA.29c.iii.	One commenter indicated that the warning specified here is that required for Class 2a, not Class 2 as indicated in the draft.	The committee agrees and has changed the wording to Class 2a.
Section AA.29c.vii.3.	One commenter indicated that there appears to be language missing from this statement.	The committee agrees and added the word "x-rays" to read: "AVOID EXPOSURE - Hazardous x-rays are emitted from this aperture," if the radiation emitted through such aperture is collateral x-ray radiation.
Section AA.29c.ix.	One commenter indicated that the wording of the warning labels for protective housings specified in the draft are at variance with the Federal standard in that they fail to distinguish between noninterlocked and defeatably interlocked protective housings.	The committee acknowledges the comment and separated the language for noninterlocked and defeatably interlocked protective housings consistent with the Federal standard.
Section AA.29c.ix.(4)(b)	One commenter suggested adding the words, "When Open" to the statement.	The committee acknowledges the comment. All of Section AA.29.c.ix. was deleted and replaced with language consistent with the Federal standard. No change was made as a result of the comment.
Part Number	Comments	Committee Action
Section AA.31c.	One commenter indicated that the Federal standard specifies that both unscanned and scanned laser radiation measurement of radiant energy and power is made with a 7 mm aperture only for products unlikely to be used in locales where the use of optical	The committee acknowledges the comment and included language consistent with the Federal standard.

	<p>instruments is unlikely. Otherwise, a 50 mm aperture is used. The requirement for the 50 mm aperture for scanned radiation was introduced to recognize that the use of binoculars is not uncommon at sporting events or in arenas where laser light shows are presented. A collecting optic can certainly increase the amount of exposure for scanned laser radiation.</p>	
<p>Section AA.32</p>	<p>One commenter indicated that the ANSI Laser Committee is moving away from requiring a baseline eye examination prior to working with lasers. The requirement is going from a SHALL to a SHOULD. The commenter further indicates that it will first be seen in Z136.3 Medical Laser Standard and then in the new Z136.1 when it comes out (projection date mid 2005)</p>	<p>The committee agrees and revised the language in Appendix C, Medical Surveillance. The language in this section reads: "The Agency may require the registrant..." and does not include the word "shall"; therefore no change was made to this section as a result of the comment.</p>

Part Number	Comments	Committee Action
Section AA.33. - Accident notification	<p>One commenter indicates that having experience leading the Arizona Radiation Regulatory Agency laser group and as a user LSO, there is no useful information or rationale for immediate notification of a regulatory agency of a laser injury. The commenter further indicated that for that matter, some suspected injuries can take 2 days to be visual on examination and some never show clinical signs and some incidents turn out to be only perception and not a real injury, flash lamp light or another optical source in the laser use area. The commenter states that while it is unfortunate, many times the LSO may not be notified till several days post incident and strongly believes it is sufficient to notify the regulatory agency within the first 72 hours. The commenter suggests a need to give the facility sometime to establish what happened and plan corrective actions.</p>	<p>The committee agrees and has made the following changes: AA.33.a. - Change the title and first sentence of AA.33a. to read: "Twenty-four hour-notification. Each registrant shall notify the Agency within 24 hours of discovery by telephone... AA.33.b. - Change the title and first sentence of AA.33b. to read: "Five Working Days Notification. Each registrant shall notify the Agency by telephone, fax or email within five working days after discovery of any incident involving any source of laser or collateral radiation possessed by the registrant and that has or may have caused: AA.34.a. - Reports of Overexposures and Excessive Levels. Change to read: "Each registrant shall make a report in writing within 30 days after a 24-hour notification has been made to the Agency of..."</p>
Section AA34a.i.	<p>One commenter indicated that there should be a semi-colon and "or" at the end of this statement.</p>	<p>The committee agrees and made this change.</p>
Table 1 page AA38	<p>One commenter suggested adding the new classification of 1M, 2M, 3R and also missing any reference to Awareness training for employees working around lasers to this table.</p>	<p>This table has been deleted. No change was made as a result of the comment.</p>
Part Number	Comments	Committee Action
Figure 1 Caution sign	<p>One commenter indicates that this is not compliant with American National Standards Institute (ANSI) Z535 (sign</p>	<p>The committee agrees and has added the figure from ANSI Z136.1</p>

	Standard) or ANSI Z136.1 for Safe Use of Lasers.	
Figure 2 Danger sign	One commenter indicates that this is not compliant with American National Standards Institute (ANSI) Z535 (sign Standard) or ANSI Z136.1 for Safe Use of Lasers.	The committee agrees and has added the figure from ANSI Z136.1 for Safe Use of Lasers.
Appendix B, Table 1 - Training	One commenter questions if this covers the proper use of personal protective devices? For example, proper kinds and use of goggles.	The committee acknowledges the comment. Laser safety is included in Item 2.e.ii. No change was made as a result of the comment.
Appendix C 2.1.1.	One commenter indicated that the ANSI Laser Committee is moving away from requiring a baseline eye examination prior to working with lasers and the requirement is going from a SHALL to a SHOULD. The commenter states that it will first be seen in Z136.3 Medical Laser Standard and then in the new Z136.1 when it comes out (projection date mid 2005)	<p>The committee agrees and revised the title, deleted the first sentence and replaced it with the following: Preassignment (Pre-employment) Medical Examinations. Preassignment (Pre-employment) medical examinations may be considered for users of Class 3b or 4 lasers who may be exposed to radiation within the NHZ.</p> <p>The committee also changed Appendix C - 2.2.1 Medical History and revised the first sentence to read: "The following protocols may be considered for preplacement (pre-employment) examinations of all laser workers.</p>

Part Number	Comments	Committee Action
Appendix C, Medical Surveillance - 2.2.1 Medical History	One commenter suggested this bullet should read: "Any current complaints about the worker's eyes are noted."	The committee agrees and revised the language. '

TELEFAX

Date: 10 March 2005
To: CRCPD Board of Directors
cc: Catherine Fontaine
From: Terry Devine
Re: current draft Part AA and comments & responses received Mar. 7 '05 for review.

Catherine and Bruce repaired several glitches. I have the following few comments, otherwise it seems to me that the committee responded to the comments received, and appropriately.

- 1. Agency Form AA section 5, the table needs work, e.g.

Sources of Laser Radiation (Class 3b and Class 4 only)

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

- 2. The point of AA.13b, it seems to me, is that IPL devices be used only as directed, i.e. I'd add the word 'only.'
- 3. In response to a comment, the definitions for Class 1M, 2M and 3R lasers were to be added. I found the "IEC Class 1M" and "IEC Class 2M" but where is the definition for Class 3R laser?
- 4. In response to a comment, the committee changed the definition of irradiance from what seemed to me scientifically correct to what seems to me misdirected and cyclic. Irradiance does not mean an area... And irradiance ... over which irradiance is averaged doesn't serve. It was much better as, "Irradiance means the radiant power incident on an element of surface divided by the area of that element, expressed in watts per square centimeter (W cm⁻²)" except that in SI units it would be watts per square meter.
- 5. Re AA.10, after reading the comment I'd suggest adding 'service providers' in the title, i.e. "Application for Providers of Services,' or 'Applications for ...Service Providers.'