25 TEXAS ADMINISTRATIVE CODE

§289.301

Registration and Radiation Safety Requirements for Lasers and Intense-Pulsed Light Devices

Texas Regulations for Control of Laser Radiation Hazards

(revisions effective October 12, 2008 are shown as shaded text)

25 TAC §289.301

Registration and Radiation Safety Requirements for Lasers and Intense-Pulsed Light Devices (Continued)

§289.301. Registration and Radiation Safety Requirements for Lasers and Intense-Pulsed Light Devices.

(a) Purpose.

(1) This section establishes requirements for protection against all classes of laser radiation and intense-pulsed light (IPL) device hazards. This section includes responsibilities of the registrant and the laser safety officer (LSO), laser and IPL device hazard control methods, training requirements, and notification of injuries.

(2) This section establishes requirements for the registration of persons who receive, possess, acquire, transfer, or use Class 3b (IIIb), International Electrotechnical Commission (IEC) Class 3B and Class 4 (IV), IEC 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 Class 3b (IIIb), IEC Class 3B or 4 (IV), IEC Class 4 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 section. Class 1 (I) lasers, IEC Class 1 and 1M, Class 2 (II) lasers, IEC Class 2 and 2M, and Class 3a (IIIa) lasers, IEC Class 3R and IPL devices are not required to be registered. However, use of Class 1 (I) lasers, IEC Class 1 and 1M, Class 2 (II) lasers, IEC Class 2 and 2M, and Class 3a (IIIa) lasers, IEC Class 3R and IPL devices are subject to other applicable requirements in this section.

(b) Scope.

(1) Except as otherwise specifically provided, this section applies to all persons who receive, possess, acquire, transfer, or use lasers that emit or may emit laser radiation. Individuals shall not use lasers or IPL devices on humans unless under the supervision of a licensed practitioner of the healing arts and unless the use of lasers or IPL devices is within the scope of practice of their professional license. Nothing in this section shall be interpreted as limiting the intentional exposure of patients to laser or IPL device 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. This section does not apply to the manufacture of lasers or IPL devices.

(2) This section applies to lasers that operate at wavelengths between 180 nanometers (nm) and 1 millimeter (mm).

(3) This section applies to IPL devices. These devices shall be 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).

(4) This section applies to lasers that meet the requirements of IEC standards 60825-1 and 60601-2-22 as allowed by the United States Food and Drug Administration Centers for Devices and Radiological Health in guidance document, Laser Notice No.50, dated July 26, 2001.

(5) In addition to the requirements of this section, all registrants authorized to use Class 3b and Class 4 lasers are subject to the following requirements:

(A) §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections) with the exception of subsection (d), "Notifications and reports to individuals" and information relating to ionizing radiation or exposure history contained in subsection (i),"Notice to employees."

(B) §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services);

(C) subsections (a), (b), and (h)-(n) of §289.205 of this title (relating to Hearing and Enforcement Procedures); and

(D) subsections (d), (f)-(j), (aa), (bb), (ff), (kk), and (ll)(1), (2), and (5) of §289.231 of this title (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation) and the applicable definitions in subsection (c) of §289.231 of this title.

(c) Prohibitions.

(1) The agency may prohibit the use of lasers and IPL devices that pose significant threat or endanger occupational or public health and safety, in accordance with §289.205 of this title and §289.231 of this title.

(2) 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.

(A) Exposure of an individual for training, demonstration, or other non-healing arts purposes is prohibited unless authorized by a licensed practitioner of the healing arts.

(B) Exposure of an individual for the purpose of healing arts screening is prohibited, except as specifically authorized by the agency.

(C) Exposure of an individual for the purpose of research is prohibited, 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 subsection (b)(1) of this section.

(d) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Access to laser radiation--Proximity to radiation that is not blocked by an intervening barrier or filter.

(2) Accessible emission limit (AEL)--The maximum accessible emission level permitted within a particular class.

(3) Accessible laser radiation--Proximity to radiation that is not blocked by an intervening barrier or filter.

(4) Aperture--An opening through which radiation can pass.

(5) Apparent visual angle--The angular subtense of the source as calculated from source size and distance from the eye. It is not the beam divergence of the source.

(6) Beam--A collection of rays characterized by direction, diameter (or dimensions), and divergence (or convergence).

(7) Class 1 (I) laser, IEC Class 1 and 1M--Any laser that does not permit access during the operation to levels of laser radiation in excess of the accessible emission limits contained in American National Standards Institute (ANSI) Z136.1-2000, Safe Use of Lasers.

(8) Class 2 (II) laser, IEC Class 2 and 2M--Any laser that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits of Class 1 lasers contained in ANSI Z136.1-2000, Safe Use of Lasers, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits of Class 2 lasers contained in ANSI Z136.1-2000, Safe Use of Lasers.

(9) Class 3a (IIIa) laser, IEC Class 3R--Any laser that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits of Class 2 lasers contained in ANSI Z136.1-2000, Safe Use of Lasers, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits of Class 3a lasers contained in ANSI Z136.1-2000, Safe Use of Lasers.

(10) Class 3b (IIIb) laser, IEC Class 3B--Any laser that permits human access during operation to levels of laser radiation in excess of the accessible emission limits of Class 3a lasers in ANSI Z136.1-2000, Safe Use of Lasers but does not permit human access during operation to levels of laser radiation in excess of the emission limits of Class 3b lasers contained in ANSI Z136.1-2000, Safe Use of Lasers.

(11) Class 4 (IV) laser, IEC Class 4--Any laser that permits human access during operation to levels of laser radiation in excess of the accessible emission limits of Class 3b lasers contained in the most recent edition of ANSI Z136.1-2000, Safe Use of Lasers.

(12) Coherent--A light beam is said to be coherent when the electric vector at any point in it is related to that at any other point by a definite, continuous function.

(13) Collateral radiation--Any electromagnetic radiation, except laser radiation, emitted by a laser that is physically necessary for its operation. The applicable, accessible emission limits for collateral radiation may be found in Title 21, CFR, Part 1040.10.

(14) Continuous wave--The output of a laser that is operated in a continuous rather than a pulsed mode. In this section, a laser operating with a continuous output for a period of ≥ 0.25 seconds is regarded as a continuous wave laser.

(15) Controlled area--An area where the occupancy and activity of those within is subject to control and supervision by the registrant for the purpose of protection from radiation hazards.

(16) Divergence--For the purposes of this section, divergence is taken as the plane angle projection of the cone that includes 1 - 1/e (for example 63.2%) of the total radiant energy or power. The value of the divergence is expressed in radians or milliradians.

(17) Electromagnetic radiation--The flow of energy consisting of orthogonally vibrating electric and magnetic fields lying transverse to the direction of propagation. X-ray, ultraviolet, visible, infrared, and radio waves occupy various portions of the electromagnetic spectrum and differ only in frequency, wavelength, or photon energy.

(18) Electronic product--Any product or article defined as follows:

(A) any manufactured or assembled product that, 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

(B) any manufactured or assembled article that is intended for use as a component, part, or accessory of a product described in subparagraph (A) of this paragraph and that when in operation emits, or in the absence of effective shielding or other controls would emit, such radiation.

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

(20) Healing arts--Any system, treatment, operation, diagnosis, prescription, or practice for the ascertainment, cure, relief, palliation, adjustment, or correction of any human disease, ailment, deformity, injury, or unhealthy or abnormal physical or mental condition.

(21) Infrared radiation--The region of the electromagnetic spectrum between the long-wavelength extreme of the visible spectrum (about 0.7 μm) and the shortest microwaves (about 1 mm).

(22) Inoperable--Incapable of operation by reason of damage, disassembly, removal, or inactivation of key components that cannot be restored without significant repair or renovation.

(23) Institutional Review Board (IRB)--Any board, committee, or other group formally designated by an institution to review, approve the initiation of, and conduct periodic review of biomedical research involving human subjects.

(24) Intense-pulsed light (IPL) device--A device that emits radiation to energy density levels that could reasonably cause bodily harm and that is used for photothermolysis. This device is a Class 2 or Class 3 surgical device certified as complying with the design, labeling, and manufacturing standards of the United States Food and Drug Administration (FDA).

(25) Invisible radiation--Laser or collateral radiation having wavelengths of equal to or greater than 180 nm but less than or equal to 400 nm or greater than 710 nm but less than or equal to 1.0×10^6 nm (1 millimeter).

(26) Irradiance--Radiant power incident per unit area upon a surface, expressed in watts-per-square-centimeter ($W\text{-}cm^{-2}$).

(27) Joule--A unit of energy. One joule is equal to one watt • second.

(28) Laser--An electronic device that emits stimulated radiation to energy density levels that could reasonably cause bodily harm. A laser may also produce an intense, coherent, directional beam of light by stimulating electronic or molecular transitions to lower energy levels. The term "laser" also includes the assembly of electrical, mechanical, and optical components associated with the laser. A laser can be a component of a product or system.

(29) Laser product--Any manufactured product or assemblage of components that constitutes, incorporates, or is intended to incorporate a laser and is classified as a Class 1 (I), IEC Class 1 and 1M, Class 2 (II), IEC Class 2 and 2M, Class 3a (IIIa), IEC Class 3R, Class 3b (IIIb), IEC Class 3B or Class 4 (IV), IEC Class 4 laser product according to the performance standards set by the United States Food and Drug Administration (FDA). A laser that is intended for use as a component of an electronic product shall itself be considered a laser product. A laser product can contain an enclosed laser with an assigned class number higher than the inherent capability of the laser product in which it is incorporated and where the product's lower classification is appropriate due to the engineering features limiting accessible emission.

(30) Laser safety officer (LSO)--An individual who has a knowledge of and the authority and responsibility to apply appropriate laser radiation protection rules, standards, and practices, and who must be specifically authorized on a certificate of laser registration.

(31) Maximum permissible exposure (MPE)--The level of laser radiation to which a person may be exposed without hazardous effect or adverse biological changes in the eye or skin. For the purposes of this section, maximum permissible exposures for laser radiation may be found in ANSI Z136.1-2000, Safe Use of Lasers.

(32) Medical event--Any adverse patient health effect that is a result of failure or misuse of laser safety equipment.

(33) Mobile service operation--The provision of lasers and personnel at temporary sites for limited time periods. The lasers may be fixed inside a motorized vehicle or may be a portable laser that may be removed from the vehicle and taken into a facility for use.

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

(35) Optical density (D_λ)--The logarithm to the base ten of the reciprocal of the transmittance. $D_\lambda = -\log_{10} \tau_\lambda$, where τ_λ is transmittance.

(36) Practitioner of the healing arts (practitioner)--For the purposes of this section, a person licensed to practice the healing arts by either the Texas Medical Board as a physician; the Texas State Board of Dental Examiners; the Texas Board of Chiropractic Examiners; or the Texas State Board of Podiatric Medicine. A practitioner's use of a laser is limited to his/her scope of professional practice as determined by the appropriate licensing agency.

(37) Protective housing--An enclosure surrounding the laser that prevents access to laser radiation above the applicable MPE level. The aperture through which the useful beam is emitted is not part of the protective housing. The protective housing may enclose associated optics and a work station and shall limit access to other associated radiant energy emissions and to electrical hazards associated with components and terminals.

(38) Provider of lasers--Provision of lasers on a routine basis to a facility for limited time periods.

(39) Pulse duration--The duration of a laser pulse. This is usually measured as the time interval between the half-power points on the leading and trailing edges of the laser pulse.

(40) Pulsed laser--A laser that delivers its energy in the form of a single pulse or a train of pulses. In this section, the duration of a pulse is <0.25 seconds.

(41) Reflection--The deviation of radiation following incidence on a surface.

(42) Source--A laser or a laser-illuminated reflecting surface.

(43) Transmission--Passage of radiation through a medium.

(44) Ultraviolet radiation--Electromagnetic radiation with wavelengths shorter than those of visible radiation; for the purposes of this section 0.18 to 0.4 μm.

(45) Visible radiation (light)--In this section, the term is used to describe electromagnetic radiation that can be detected by the human eye. This term is commonly used to describe wavelengths that lie in the range of 0.4 to 0.7 μm.

(46) Watt--The unit of power or radiant flux. 1 watt equals 1 joule per second.

(47) Wavelength (λ)-- The distance between two successive points on a periodic wave that have the same phase.

(e) Exemptions.

(1) Lasers in transit or in storage incident to transit are exempt from the requirements of this section. This exemption does not apply to the providers of lasers.

(2) Inoperable lasers are exempt from the requirements of this section.

(3) Class 1 (I), IEC Class 1 and 1M, Class 2 (II), IEC Class 2 and 2M, and Class 3a (IIIa), IEC Class 3R lasers or products and IPL devices are exempt from the registration requirements of subsections (f) and (g) of this section.

(4) Facilities, including academic institutions and research or development facilities, registered for the use of lasers are exempt from the registration requirements of subsections (f) of this section, regarding laser services, and the applicable paragraphs of subsection (g) of this section, to the extent that their personnel perform laser services only for the registrant by whom they are employed.

(f) Registration of use of Class 3b and 4 lasers and laser services.

(1) For purposes of this section, use of Class 3b or 4 lasers and laser services shall include, but may not be limited to:

(A) possession and use of lasers in the healing arts, veterinary medicine, industry, academic, and research and development institutions;

(B) demonstration and sales of lasers that require the individual to operate or cause a laser to be operated in order to demonstrate or sell;

(C) provision of lasers on a routine basis to a facility for limited time periods by a provider of lasers. For healing arts facilities, the use of lasers shall be directed by a practitioner employed by the contracting facility;

(D) alignment, calibration, and/or repair; or

(E) laser light shows.

(2) A person who has made application for registration in accordance with this section and is using a Class 3b or 4 laser prior to receiving a certificate of laser registration is subject to the requirements of this chapter.

(g) Application requirements.

(1) General application requirements.

(A) Application for certificate of laser registration shall be completed on forms prescribed by the agency and shall contain all the information required by the form and accompanying instructions.

(B) An 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 subsection (p) of this section and carry out the responsibilities of subsection (q) of this section.

(C) Each application shall be accompanied by a completed BRC Form 226-1 (Business Information Form).

(D) Each application for a certificate of laser registration shall be accompanied by the appropriate fee prescribed in §289.204 of this title.

(E) An application for a certificate of laser registration may include a request for authorization of one or more activities.

(F) The agency may, at any time after filing of the original application, require further statements in order to enable the agency to determine whether the certificate of laser registration should be granted or denied.

(G) Applications and documents submitted to the agency may be made available for public inspection except that the agency may withhold any document or part thereof from public inspection in accordance with §289.231(aa) of this title.

(2) Application for use of Class 3b or 4 lasers on humans or animals.

(A) In addition to the requirements of subsection (g)(1) of this section, each person having a Class 3b or 4 laser for use in the healing arts, or for use on animals, shall submit an application to the agency within 30 days after beginning operation of the laser.

(B) An application for healing arts shall be signed by a licensed practitioner of the healing arts. An application for veterinary medicine shall be signed by a licensed veterinarian. The signature of the administrator, president, or chief executive officer will be accepted in lieu of a licensed practitioner's signature if the facility is a licensed hospital or a medical facility. A signature by the administrator, president, or chief executive officer does not relieve the practitioner user or veterinarian user from complying with the requirements of this section.

(C) If a person is furnished a Class 3b or 4 laser by a provider of lasers, that person is responsible for ensuring that a licensed practitioner of the healing arts authorizes intentional exposure of laser radiation to humans.

(3) Application for use of Class 3b or 4 lasers in industrial, academic, and research and development institutions. In addition to the requirements of subsection (g)(1) of this section, each applicant having a laser(s) for use in industrial, academic, and research and development institutions shall submit an application to the agency within 30 days after beginning operation of the laser.

(4) Application for demonstration for the purpose of sales of Class 3b or 4 lasers. Each applicant shall apply for and receive a certificate of laser registration before the demonstration for purpose of selling laser(s) in accordance with paragraph (1) of this subsection.

(5) Application for providers of Class 3b or 4 lasers.

(A) Each applicant shall apply for and receive a certificate of laser registration before providing Class 3b or 4 lasers.

(B) In addition to the requirements of subsection (g)(1) of this section, the applicant shall submit the address of the established main location where the laser and records will be maintained for inspection. This shall be a physical street address, not a post office box number.

(6) Application for alignment, calibration, and/or repair of Class 3b or 4 lasers. In addition to the requirements of subsection (g)(1) of this section, each applicant shall apply for and receive a certificate of laser radiation for alignment, calibration, and/or repair before providing alignment, calibration, and/or repair of Class 3b or 4 lasers or other lasers that allow access, through alignment, calibration, and/or repair, to Class 3b or 4 lasers.

(7) Application for laser light show.

(A) Each applicant shall apply for and receive a certificate of laser registration for a laser light show before beginning any show.

(B) In accordance with subparagraph (A) of this paragraph and in addition to the requirements of subsection (g)(1) of this section, 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; and

(ii) a written notice of the laser light show to be performed in Texas. The information contained in BRC Form 301-3 shall be provided at least seven days prior to each show. If, in a specific case, the seven-day period would impose an undue hardship on the applicant, the applicant may, upon written request to the agency, obtain permission to proceed sooner.

(8) Application for mobile service operation for Class 3b or 4 lasers used in the healing arts and veterinary arts.

(A) Each applicant shall apply for and receive a certificate of laser registration for mobile service operation involving Class 3b or 4 lasers before beginning mobile service operation.

(B) In addition to the requirements of subsection (g)(1) of this section, 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.

(C) An application for mobile service operation for the 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.

(h) Issuance of certificate of laser registration.

(1) Upon determination that an application meets the requirements of the Texas Radiation Control Act (Act) and the rules of the agency, the agency may issue a certificate of laser registration authorizing the proposed activity in such form and containing such conditions and limitations as the agency deems appropriate or necessary.

(2) The agency may incorporate in the certificate 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 section as it deems appropriate or necessary in order to:

(A) minimize danger to occupational and public health and safety;

(B) require additional reports and the keeping of additional records as may be appropriate or necessary; and

(C) prevent loss or theft of lasers subject to this section.

(3) The agency may request, and the registrant shall provide, additional information after the certificate of laser registration has been issued to enable the agency to determine whether the certificate of laser registration should be modified in accordance with subsection (n) of this section.

(i) Specific terms and conditions of certificates of laser registration.

(1) Each certificate of laser registration issued in accordance with this section shall be subject to the applicable provisions of the Act, now or hereafter in effect, and to the applicable rules in this chapter and orders issued by the agency.

(2) Each person registered by the agency for laser use in accordance with this section shall confine use and possession of the laser registered to the locations and purposes authorized in the certificate.

(3) No certificate of laser registration issued or granted under this section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, to any person unless the agency authorizes the transfer in writing.

(4) In making a determination whether to grant, deny, amend, renew, revoke, suspend, or restrict a certificate of laser registration, the agency may consider the technical competence and compliance history of an applicant or holder of a certificate of laser registration. After an opportunity for a hearing, the agency shall deny an application for a certificate of laser registration, an amendment to a certificate of laser registration, or renewal of a certificate of laser registration if the applicant's compliance history reveals that at least three agency actions have been issued against the applicant, within the previous six years, that assess administrative or civil penalties against the applicant, or that revoke or suspend the certificate of laser registration.

(j) Responsibilities of registrant.

(1) The registrant shall notify the agency in writing within 30 days of a change in any of the following:

(A) business name and mailing address;

(B) street address where laser(s) will be used; or

(C) laser safety officer (LSO).

(2) No person shall make, sell, lease, transfer, or lend lasers unless such machines and equipment, when properly placed in operation and used, meet the applicable requirements of this section.

(3) Each registrant shall inventory all Class 3B and 4 lasers in their possession at an interval not to exceed one year. The inventory record shall be maintained for inspection by the agency in accordance with subsection (ee) of this section and shall include:

(A) manufacturer's name;

(B) model and serial number of the laser(s);

(C) description of the laser(s) (for example, yag, silicon, CO_2, neon);

(D) location of laser(s) (for example, room number); and

(E) if using a provider of lasers as defined in subsection (d)(38) of this section, a statement with the inventory that the registrant is using lasers provided by a provider of lasers.

(4) Notification to the agency is required within 30 days of the following:

(A) any increase in the number of lasers authorized by the certificate of laser registration; or

(B) if the registrant begins or terminates the use of a provider of lasers as defined in subsection (d)(38) of this section.

(5) No registrant shall engage any person for services described in subsection (g)(6) of this section until such person provides to the registrant evidence of registration with the agency.

(6) The registrant is responsible for complying with this section and the conditions of the certificate of laser registration.

(7) Registrants with certificates of laser registration in accordance with subsection (g)(7) of this section shall have the following documents on site at each laser light show:

(A) certificate of laser registration;

(B) FDA variance with all applicable documents required by the variance; and

(C) instructions for the safe use of lasers in accordance with subsection (r)(2) of this section.

(8) Each registrant shall maintain records of receipt, transfer, and disposal of Class 3b or 4 lasers for inspection by the agency. The records shall include the following information and shall be kept until disposal is authorized by the agency:

(A) manufacturer's name;

(B) model and serial number from the laser;

(C) date of the receipt, transfer, and disposal;

(D) name and address of person laser(s) received from, transferred to, or disposed of; and

(E) name of the individual recording the information.

(k) Expiration of certificates of laser registration.

(1) Except as provided by subsection (m) of this section, each certificate of laser registration expires at the end of the day, in the month and year stated in the certificate of laser registration.

(2) If a registrant does not submit an application for renewal of the certificate of laser registration in accordance with subsection (m) of this section, as applicable, the registrant shall on or before the expiration date specified in the certificate of laser registration:

(A) terminate use of all lasers and/or terminate laser servicing or laser services authorized under the certificate of laser registration;

(B) submit to the agency a record of the disposition of the lasers, if applicable, and if transferred, to whom it was transferred within 30 days following the expiration date; and

(C) pay any outstanding fees in accordance with §289.204 of this title.

(3) Expiration of the certificate of laser registration does not relieve the registrant of the requirements of this chapter.

(l) Termination of certificates of laser registration. When a registrant decides to terminate all activities involving laser or laser services authorized under the certificate of laser registration, the registrant shall immediately do the following:

(1) request termination of the certificate of laser registration in writing;

(2) submit to the agency a record of the disposition of the radiation machines, if applicable; and if transferred, to whom it was transferred; and

(3) pay any outstanding fees in accordance with §289.204 of this title.

(m) Renewal of certificate of laser registration.

(1) An application for renewal of a certificate of laser registration shall be filed in accordance with subsection (g)(1)(A)-(B), and (E)-(G) of this section and applicable paragraphs of subsections (g)(2),(4), and (7) of this section.

(2) If a registrant files an application for a renewal in proper form before the existing certificate of laser registration expires, such existing certificate of laser registration shall not expire until the application status has been determined by the agency.

(n) Modification, suspension, and revocation of certificates of laser registration.

(1) The terms and conditions of all certificates of laser registration shall be subject to revision or modification.

(2) Any certificate of laser registration may be revoked, suspended, or modified, in whole or in part, for any of the following:

(A) any material false statement in the application or any statement of fact required under the provisions of the Act;

(B) conditions revealed by such application or statement of fact, or any report, record, or inspection, or other means that would warrant the agency to refuse to grant a certificate of laser registration on an original application;

(C) violation of, or failure to observe any of the terms and conditions of the Act, this chapter, or of the certificate of laser registration, or order of the agency; or

(D) existing conditions that constitute a substantial threat to the public health or safety or the environment.

(3) Each certificate of laser registration revoked by the agency ends at the end of the day on the date of the agency's final determination to revoke the certificate of laser registration, or on the revocation date stated in the determination, or as otherwise provided by the agency order.

(4) Except in cases in which the occupational and public health or safety requires otherwise, no certificate of laser registration shall be suspended or revoked unless, prior to the institution of proceedings therefore, facts or conduct that may warrant such action shall have been called to the attention of the registrant in writing and the registrant shall have been afforded an opportunity to demonstrate compliance with all lawful requirements.

(o) Notifications. The following applies to voluntary or involuntary petitions for bankruptcy.

(1) Each registrant shall notify the agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy by the registrant or its parent company. This notification shall include:

(A) the bankruptcy court in which the petition for bankruptcy was filed; and

(B) the date of the filing of the petition.

(2) A copy of the "petition for bankruptcy" shall be submitted to the agency along with the written notification.

(p) LSO qualifications. LSO qualifications shall be submitted to the agency and shall include the following:

(1) educational courses related to laser radiation safety or a laser safety officer course; or

(2) experience in the use and familiarity of the type of equipment or services registered for; and

(3) knowledge of potential laser radiation hazards and laser emergency situations.

(q) LSO duties. Specific duties of the LSO shall include, but not be limited to the following:

(1) ensuring that users of lasers are trained in laser safety, as applicable for the class and type of lasers the individual uses;

(2) assuming control and having the authority to institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions; and

(3) specifying whether any changes in control measures are required following:

(A) any service and maintenance of lasers that may affect the output power or operating characteristics; or

(B) whenever deliberate modifications are made that could change the laser class and affect the output power or operating characteristics.

(4) ensuring maintenance and other practices required for safe operation of the laser(s) are performed;

(5) ensuring the proper use of protective eyewear and other safety measures; and

(6) ensuring compliance with the requirements in this section and with any engineering or operational controls specified by the registrant.

(r) Requirements for protection against Class 3b or 4 lasers and IPL device radiation. These requirements are for Class 3b or 4 lasers and IPL devices in their intended mode of operation and include special requirements for service, testing, maintenance, and modification. During some operations, certain engineering controls may be inappropriate. In situations where an engineering control may be inappropriate, for example, during medical procedures or surgery, the LSO shall specify alternate controls to obtain equivalent safety protection.

(1) MPE. Each registrant or user of any laser shall not permit any individual to be exposed to levels of laser or collateral radiation higher than are specified in ANSI Z136.1-2000, Safe Use of Lasers and Title 21, CFR, §1040.10 respectively.

(2) Instructions to personnel. Personnel operating each laser presently being used or listed on the registrant's current inventory, shall be provided with written instructions for safe use, including clear warnings and precautions to avoid possible exposure to laser and collateral radiation in excess of the MPE, as delineated in ANSI Z136.1-2000, Safe Use of Lasers and the collateral limits listed in Title 21, CFR, §1040.10. The instructions to personnel shall be maintained in accordance with subsection (ee) of this section for inspection by the agency.

(3) Engineering controls.

(A) Protective housing.

(i) Each laser shall have a protective housing that prevents human access during the operation to laser and to collateral radiation that exceeds the limits of Class 1 lasers as delineated in ANSI Z136.1-2000, Safe Use of Lasers and Title 21, CFR, Part 1040.10, respectively, wherever and whenever such human access is not necessary in order for the laser to perform its intended function.

(ii) Wherever and whenever human access to laser radiation levels that exceed the limits of Class 1 is necessary, these levels shall not exceed the limits of the lowest laser class necessary to perform the intended function(s).

(B) Safety interlocks.

(i) A safety interlock, that shall ensure that radiation is not accessible above MPE limits as delineated in ANSI Z136.1-2000, Safe Use of Lasers, shall be provided for any portion of the protective housing that by design can be removed or displaced during normal operation or maintenance, and thereby allows access to radiation above the MPE limits.

(ii) Adjustment during operation, service, testing, or maintenance of a laser containing interlocks shall not cause the interlocks to become inoperative or the radiation to exceed MPE limits outside protective housing except where a laser controlled area as specified in subparagraph (E) of this paragraph is established.

(iii) For pulsed lasers, interlocks shall be designed so as to prevent firing of the laser; for example, by dumping the stored energy into a dummy load.

(iv) For continuous wave lasers, the interlocks shall turn off the power supply or interrupt the beam; for example, by means of shutters.

(v) An interlock shall not allow automatic accessibility of radiation emission above MPE limits when the interlock is closed.

(vi) Either multiple safety interlocks or a means to preclude removal or displacement of the interlocked portion of the protective housing upon interlock failure shall be provided, if failure of a single interlock would allow the following:

(I) human access to levels of laser radiation in excess of the accessible emission limit of Class 3a laser radiation; or

(II) 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.

(C) Viewing optics and windows.

(i) All viewing ports, viewing optics, or display screens included as an integral part of an enclosed laser or laser product shall incorporate suitable means, (such as interlocks, filters, or attenuators, to maintain the laser radiation at the viewing position at or below the applicable MPE as delineated in ANSI Z136.1-2000, Safe Use of Lasers and the collateral limits listed in Title 21, CFR, §1040.10, under any conditions of operation of the laser.

(ii) All collecting optics, such as lenses, telescopes, microscopes, endoscopes, etc., intended for viewing use with a laser shall incorporate suitable means, such as interlocks, filters, or attenuators, to maintain the laser radiation transmitted through the collecting optics to levels at or below the appropriate MPE, as delineated in ANSI Z136.1-2000, Safe Use of Lasers. Normal or prescription eyewear is not considered collecting optics.

(D) Warning systems. Each Class 3b or 4 laser or laser product shall provide visual or audible indication during the emission of accessible laser radiation. In the case of Class 3b lasers, except those that allow access only to less than 5 milliwatt (mW) peak visible laser radiation, and Class 4 lasers, this indication shall be sufficient 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 audible indicators. The visual indicators shall be positioned so that viewing does not require human access to laser radiation in excess of the MPE, as delineated in ANSI Z136.1-2000, Safe Use of Lasers.

(E) Controlled area. With a Class 3b laser, except those that allow access only to less than 5 mW visible peak power, or Class 4 laser, a controlled area shall be established when exposure to the laser radiation in excess of the MPE, as delineated in ANSI Z136.1-2000, Safe Use of Lasers or the collateral limits listed in Title 21, CFR, §1040.10 is possible. The controlled area shall meet the following requirements, as applicable.

(i) The area shall be posted as required by subsection (v) of this section.

(ii) Access to the controlled area shall be restricted.

(iii) For Class 4 indoor controlled areas, latches, interlocks, or other appropriate means shall be used to prevent unauthorized entry into controlled areas.

(I) Such measures shall be designed to allow rapid egress by the laser personnel at all times and admittance to the 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.

(II) Where safety latches or interlocks are not feasible or are inappropriate, for example during medical procedures, such as surgery, the following shall apply.

(-a-) All authorized personnel shall be trained in laser safety and appropriate personal protective equipment shall be provided upon entry.

(-b-) A door, blocking barrier, screen, or curtains shall be used to block, screen, or attenuate the laser radiation at the entryway. The level at the exterior of these devices shall not exceed the applicable MPE, as delineated in ANSI Z136.1-2000, Safe Use of Lasers, nor shall personnel experience any exposure above the MPE immediately upon entry.

(-c-) At the entryway there shall be a visible or audible signal indicating that the laser is energized and operating at Class 4 levels. A lighted laser warning sign, flashing light (visible through laser protective eyewear), and other appropriate signage are some of the methods to accomplish this requirement. Alternatively, an entryway warning light assembly may be interfaced to the laser in such a manner that one light will indicate when the laser is not operational (high voltage off) and by an additional light when the laser is powered up (high voltage applied, but no laser emission) and by an additional (flashing optional) light that activates when the laser is operating.

(iv) 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 radiation hazard at the point of entry, and if the necessary protective devices are being worn by the entering personnel.

(v) For Class 4 indoor controlled areas, optical paths (for example, 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 the appropriate ocular MPE, as delineated in ANSI Z136.1-2000, Safe Use of Lasers and the collateral limits listed in Title 21, CFR, §1040.10. 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 air traffic is protected from any laser projecting into navigable air space (contact Federal Aviation Administration (FAA) or other appropriate agencies, as necessary) or controlled ground space when the beam irradiance or radiant exposure is above the appropriate MPE, as delineated in ANSI Z136.1-2000, Safe Use of Lasers.

(vi) When the removal of panels or protective covers and/or overriding of interlocks becomes necessary, such as for servicing, testing, or maintenance, and accessible laser radiation exceeds the MPE, as delineated in ANSI Z136.1-2000, Safe Use of Lasers and the collateral limits listed in Title 21, CFR, §1040.10, a temporary controlled area shall be established and posted**.**

(4) Key control. Each Class 3b or 4 laser and IPL device shall incorporate a key-actuated or computer-actuated master control. The key shall be removable and the Class 3b or 4 laser or IPL device shall not be operable when the key is removed. When not being prepared for operation or is unattended, the key will be removed from the device and stored in a location away from the machine.

(s) Additional requirements for special lasers and applications.

(1) Infrared laser. The beam from a laser shall be terminated in fire-resistant material where necessary. Inspection intervals of absorbent material and actions to be taken in the event or evidence of degradation shall be specified in the operating and safety procedures.

(2) Laser optical fiber transmission system.

(A) Laser transmission systems that employ optical cables shall be considered enclosed systems with the optical cable forming part of the protective housing.

(B) Disconnection of a connector resulting in access to radiation in excess of the applicable MPE limits, as delineated in ANSI Z136.1-2000, Safe Use of Lasers and the collateral limits listed in Title 21, CFR, §1040.10, shall take place in a controlled area. Except for medical lasers whose manufacture has been approved by the FDA, 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 specified in subsection (v)(3) of this section.

(t) Additional requirements for safe operation.

(1) Eye protection. Protective eyewear shall be worn by all individuals with access to Class 3b and/or Class 4 levels of laser radiation. Protective eyewear devices shall meet the following requirements:

(A) provide a comfortable and appropriate fit all around the area of the eye;

(B) 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;

(C) be suitable for the specific wavelength of the laser and be of optical density adequate for the energy involved;

(D) have the optical density or densities and associated wavelength(s) permanently labeled on the filters or eyewear; and

(E) be examined, at intervals not to exceed 12 months, to ensure the reliability of the protective filters and integrity of the protective filter frames. Unreliable eyewear shall be discarded. Documentation of the examination shall be made and maintained in accordance with subsection (ee) of this section for inspection by the agency.

(2) Skin protection. When there is a possibility of exposure to laser radiation that exceeds the MPE limits for skin as specified in ANSI Z136.1-2000 Safe Use of Lasers, the registrant shall require the appropriate use of protective gloves, clothing, or shields.

(u) NHZ. Where applicable, in the presence of unenclosed Class 3b and Class 4 laser beam paths, an NHZ shall be established. If the beam of an unenclosed Class 3b and Class 4 laser is contained within a region by adequate control measures to protect personnel from exposure to levels of radiation above the appropriate MPE, as delineated in ANSI Z136.1-2000, Safe Use of Lasers, that region may be considered to be the NHZ. The NHZ may be determined by information supplied by the laser manufacturer, by measurement, or by using the appropriate laser range equation or other equivalent assessment.

(v) Caution signs, labels, and posting for lasers and IPL devices.

(1) General requirements. Except as otherwise authorized by the agency, signs, symbols, and labels prescribed by this section shall use the design and colors specified in subsection (dd) of this section.

(2) Posting. The laser controlled area shall be conspicuously posted with a sign or signs as specified in paragraph (3) of this subsection and subsection (dd) of this section.

(3) Labeling lasers and posting laser facilities. All signs and labels associated with Class 2, 3a, 3b, and 4 lasers shall contain the following wording.

(A) The signal word "CAUTION" shall be used with all signs and labels associated with all Class 2 lasers and all Class 3a lasers that do not exceed the appropriate MPE, as designated in ANSI Z136.1-2000, Safe Use of Lasers. This signal word is used in accordance with the sign in subsection (dd)(1) of this section.

(B) The signal word "DANGER" shall be used with all Class 3a lasers that exceed the appropriate MPE, as designated in ANSI Z136.1-2000, Safe Use of Lasers, and all Class 3b and 4 lasers. This signal word is used in accordance with the sign in subsection (dd)(2) of this section.

(C) Position 1 in the signs in subsection (dd)(1) and (dd)(2) of this section shall contain the following information, as applicable:

(i) for all Class 2 lasers, the words "LASER RADIATION - DO NOT STARE INTO BEAM";

(ii) for Class 3a lasers that do not exceed the appropriate MPE, as designated in ANSI Z136.1-2000, Safe Use of Lasers, the words "LASER RADIATION - DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS";

(iii) for all other Class 3a lasers, the words "LASER RADIATION - AVOID DIRECT EYE EXPOSURE";

(iv) for all Class 3b lasers, the words "LASER RADIATION - AVOID DIRECT EYE EXPOSURE"; or

(v) for Class 4 lasers, the words "LASER RADIATION - AVOID EYE or SKIN EXPOSURE to DIRECT or SCATTERED RADIATION".

(D) Positions 2 and 3 in the signs in subsections (dd)(1) and (2) of this section shall contain the following information, as applicable.

(i) Position 2 shall contain the type of laser or the emitted wavelength, pulse duration (if appropriate), or maximum output.

(ii) Position 3 shall contain the class of laser.

(E) 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 ANSI Z136.1-2000, Safe Use of Lasers and the collateral limits listed in Title 21, CFR, §1040.10, with the following wording as applicable.

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

(ii) "AVOID EXPOSURE - Hazardous electromagnetic radiation is emitted from this aperture," if the radiation emitted through such aperture is collateral radiation.

(iii) "AVOID EXPOSURE - Hazardous x-rays are emitted from this aperture," if the radiation emitted through such aperture is collateral x-ray radiation.

(F) Each noninterlocked or defeatably interlocked portion of the protective housing or enclosure that is designed to be displaced or removed during normal operation or servicing, and that would permit human access to laser or collateral radiation, shall have labels as follows:

(i) for Class 3b accessible laser radiation the wording, "DANGER - LASER RADIATION WHEN OPEN. AVOID DIRECT EXPOSURE TO BEAM";

(ii) for Class 4 accessible laser radiation the wording, "DANGER - LASER RADIATION WHEN OPEN. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION"; or

(iii) for collateral radiation in excess of the emission limits as described in Title 21, CFR, §1040.10, “CAUTION - HAZARDOUS ELECTROMAGNETIC RADIATION WHEN OPEN” and “CAUTION - HAZARDOUS X-RAY RADIATION” as applicable.

(G) For protective housing or enclosures that provide a defeatable interlock, the words "and interlock defeated" shall be included in the labels specified in subparagraph (F)(i) and (ii) of this paragraph.

(H) Other required information.

(i) The word "invisible" shall immediately precede the word "radiation" on labels and signs required by this subparagraph for wavelengths of laser and collateral radiation that are outside of the range of 400 to 700 nm.

(ii) The words "visible and invisible" shall immediately precede the word "radiation" on labels and signs required by this subparagraph for wavelengths of laser and collateral radiation that are both within and outside the range of 400 to 700 nm.

(I) Labels required by this subparagraph shall be clearly visible, legible, and permanently attached to the laser or facility. Signs required by this subparagraph shall be clearly visible, legible, and securely attached to the facility.

(4) In lieu of the requirements in paragraphs (1)-(3) of this subsection and subsection (dd) of this section, the agency will accept labeling and signage designated by the following:

(A) Title 21, CFR, §1040.10;

(B) ANSI Z136.1-2000, Safe Use of Lasers; and

(C) IEC standards 60825-1 and 60601-2-22.

(w) Surveys. Each registrant shall make or cause to be made such surveys as may be necessary to comply with this section and maintain records of the surveys in accordance with subsection (ee) of this section for inspection by the agency. Surveys shall be performed at intervals not to exceed 12 months, to include but not be limited to the following:

(1) a determination that all laser and IPL protective devices are labeled correctly, functioning within the design specifications, and properly chosen for lasers and IPL devices in use;

(2) a determination that all warning devices are functioning within their design specifications;

(3) a determination that the controlled area is properly controlled and posted with accurate warning signs in accordance with subsection (v) of this section;

(4) a re-evaluation of potential hazards from surfaces that may be associated with beam paths; and

(5) additional surveys that may be required to evaluate the primary and collateral radiation hazard incident to the use of lasers and IPL devices.

(x) Records/documents. Each registrant shall maintain current records/documents required by this subsection in accordance with subsection (ee) of this section for inspection by the agency.

(y) Measurements and instrumentation. Each determination requiring a measurement for compliance with this section shall use instrumentation that is calibrated and designed for use with the laser or IPL device that is to be tested.

(z) Notification of injury other than a medical event.

(1) Each registrant of Class 3b or 4 lasers or user of an IPL device shall immediately seek appropriate medical attention for the individual and notify the agency by telephone of any injury involving a laser possessed by the registrant or an IPL device, other than intentional exposure of patients for medical purposes, that has or may have caused:

(A) an injury to an individual that involves the partial or total loss of sight in either eye; or

(B) an injury to an individual that involves intentional perforation of the skin or other serious injury exclusive of eye injury.

(2) Each registrant of Class 3b or 4 lasers or user of an IPL device shall, within 24 hours of discovery of an injury, report to the agency each injury involving any laser possessed by the registrant or IPL device possessed by a user, as applicable, other than intentional exposure of patients for medical purposes, that may have caused, or threatens to cause, an exposure to an individual with second or third-degree burns to the skin or potential injury and partial loss of sight.

(aa) Reports of injuries.

(1) Each registrant of Class 3b or 4 lasers or user of an IPL device shall make a report in writing, or by electronic transmittal, within 30 days to the agency of any injury required to be reported in accordance with subsection (z) of this section.

(2) Each report shall describe the following:

(A) the extent of injury to individuals from radiation from lasers or IPL devices;

(B) power output of laser or IPL device involved;

(C) the cause of the injury; and

(D) corrective steps taken or planned to be taken to prevent a recurrence.

(3) Any report filed with the agency in accordance with this subsection shall include the full name of each individual injured and a description of the injury. The report shall be prepared so that this information is stated in a separate part of the report.

(4) When a registrant or user of an IPL device is required in accordance with paragraphs (1)-(3) of this subsection to report to the agency any injury of an individual from radiation from lasers or IPL devices, the registrant or user of an IPL device shall also notify the individual. Such notice shall be transmitted to the individual at a time not later than the transmittal to the agency.

(bb) Medical event.

(1) The registrant of Class 3b or 4 lasers or user of an IPL device shall notify the agency, by telephone or electronic transmittal, within 24 hours of discovery of a medical event or of any injury to or death of a patient. Within 30 days after a 24 hour notification is made, the registrant of Class 3b or 4 lasers or user of an IPL device shall submit a written report to the agency of the event.

(2) The written report shall include the following:

(A) the registrant's or user's name;

(B) a brief description of the event;

(C) the effect on the patient;

(D) the action taken to prevent recurrence; and

(E) whether the registrant or user informed the patient or the patient's responsible relative or guardian.

(3) When a medical event occurs, the registrant or user shall promptly investigate its cause, make a record for agency review, and retain the records as stated in subsection (ee) of this section.

(cc) Reports of stolen, lost, or missing Class 3b or 4 lasers and IPL devices.

(1) Each registrant of Class 3b or 4 lasers or user of an IPL device shall report to the agency by telephone a stolen, lost, or missing laser or IPL device within 24 hours after its occurrence becomes known to the registrant or IPL device user.

(2) Each person required to make a report in accordance with paragraph (1) of this subsection shall, within 30 days after making the telephone report, make a written report to the agency that includes the following information:

(A) a description of the laser or IPL device involved, including the manufacturer, model, serial number, and class;

(B) a description of the circumstances under which the loss or theft occurred;

(C) a statement of disposition, or probable disposition, of the laser or IPL device involved;

(D) actions that have been taken, or will be taken, to recover the laser or IPL device; and

(E) procedures or measures that have been taken to prevent a recurrence of the loss or theft of lasers or IPL devices.

(dd) Caution and danger signs. The following contains signs required in accordance with subsection (v)(3) of this section.

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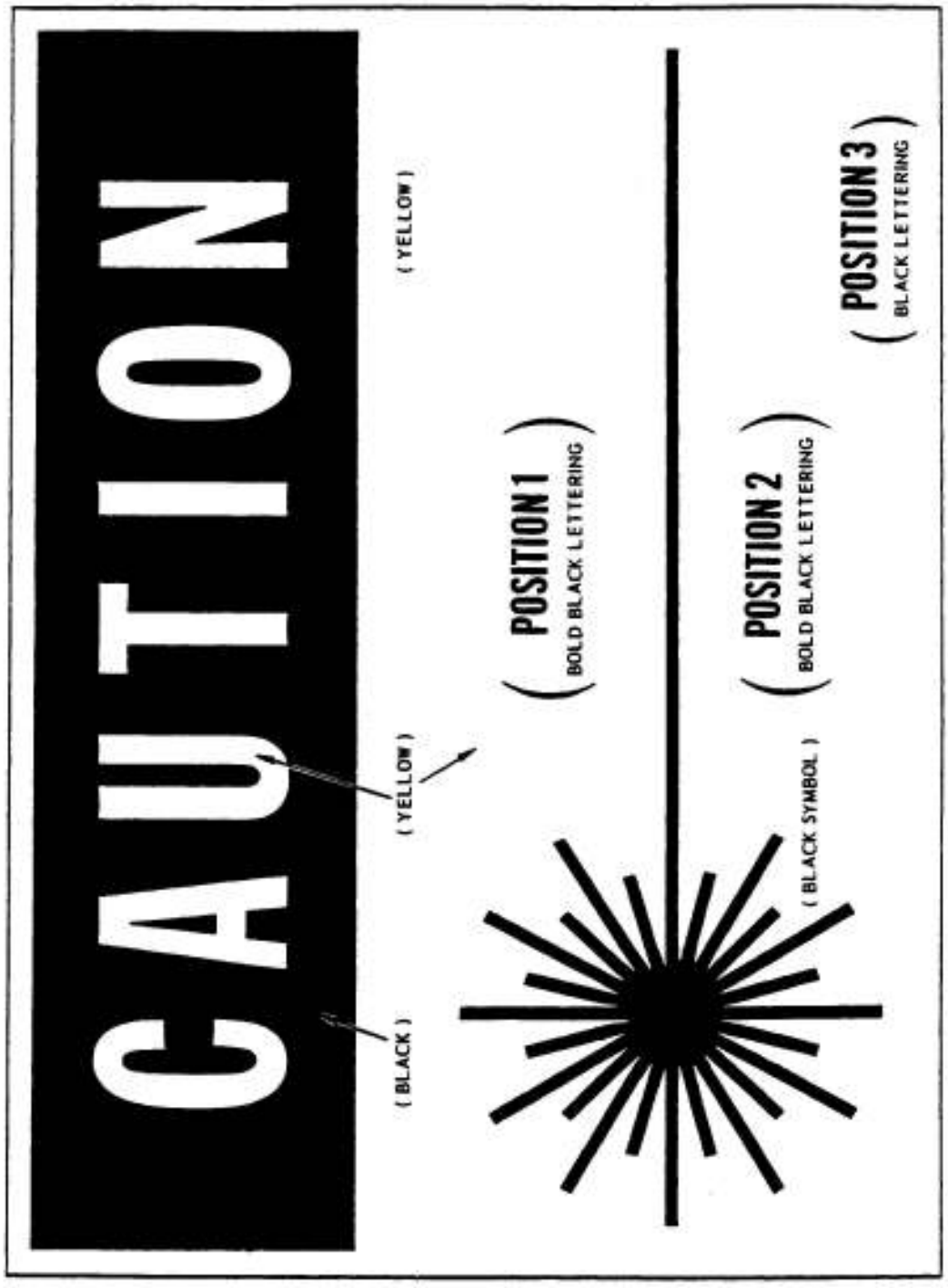
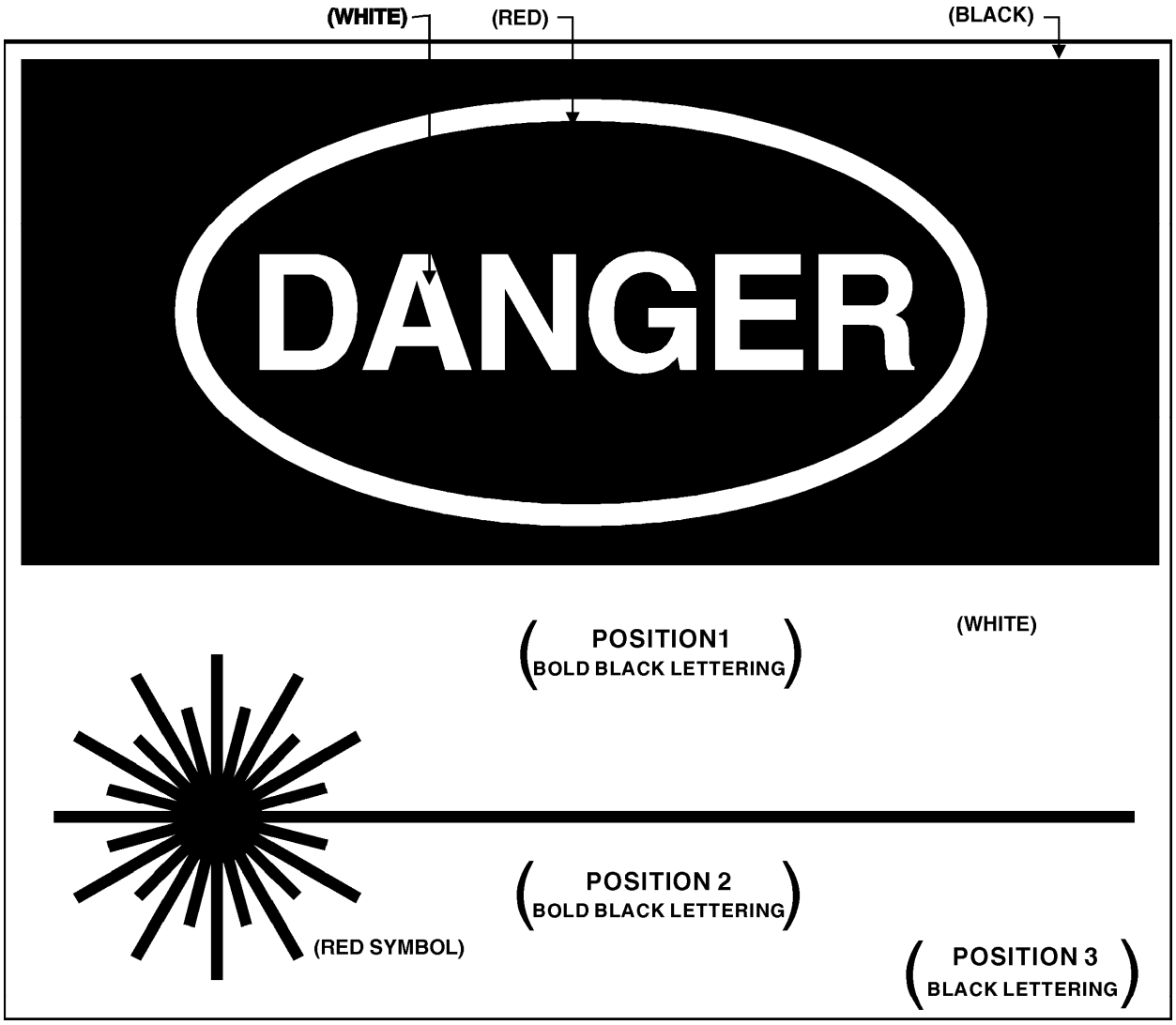
(1) This sign shall be used with all Class 2 lasers and Class 3a lasers that do not exceed the appropriate MPE, as designated in ANSI Z.136-2000, Safe Use of Lasers.



(2) This sign shall be used with all Class 3a lasers that exceed the appropriate MPE, as designated in ANSI Z.136-2000, Safe Use of Lasers, and all Class 3b and Class 4 lasers.



(ee) Keeping records/documents. The following chart contains time requirements for keeping records/documents:

Specific Subsection	Name of Record	Time Interval Required for Record Keeping
(a)(1)	Current Certificate of Laser Registration	Until termination of Certificate of Laser Registration
(b)(5)	Current 25 TAC §§289.203, 289.204, 289.205, 289.231, 289.301	Until termination of Certificate of Laser Registration
(j)(8)	Receipt, transfer, and disposal	Until termination of Certificate of Laser Registration
(r)(2)	Operator instructions for safe use for laser machines being used at present time	Until termination of Certificate of Laser Registration
(t)(1)(E)	Eye protection	5 years
(y)	Measurements and instrumentation	5 years
(z)	Notification of injury other than a medical event	5 years
(aa)	Reports of injuries	5 years
(bb)	Medical event	5 years
(cc)	Reports of stolen, lost, or missing lasers or IPL devices	Until termination of Certificate of Laser Registration or 5 years for IPL devices