25 Texas Administrative Code

§289.301

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

(Effective December 17, 2024)
(Shaded text reflects added or significant changes to the October 2008 rule.)

# §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 the responsibilities of the registrant and the laser safety officer (LSO), laser and IPL device hazard control methods, training requirements, and notification of injuries.

(2) For the purpose of this section, any reference to a class of laser includes both International Electrotechnical Commission (IEC) and United States Food and Drug Administration (FDA) classifications, as appropriate.

(3) This section establishes requirements for the registration of a person who receives, possesses, acquires, uses, or transfers Class IIIb (3B), or Class IV (4) lasers in the healing arts, veterinary medicine, and industrial, academic, research and development institutions, and of a person in the business of providing laser services.

(A) A person must not use a Class 3B or Class 4 laser or perform laser services except as authorized in a certificate of registration issued by the Texas Department of State Health Services (department) as specified in this section.

(B) A person who receives, possesses, uses, owns, or acquires a Class 3B or Class 4 laser before receiving a certificate of registration is subject to the requirements of this chapter.

(4) Class I (1) lasers, Class II (2) lasers, FDA Class IIIa (3a) lasers, IEC Class 3R lasers, and IPL devices are not required to be registered. However, the use of Class 1, Class 2, Class 3a, Class 3R lasers, and IPL devices is subject to applicable requirements in this section.

(b) Scope.

(1) Except as otherwise provided, this section applies to a person who receives, possesses, acquires, transfers, or uses lasers that emit or may emit laser radiation. Lasers or IPL devices must not be used on humans or animals unless under the supervision of a licensed practitioner of the healing arts (practitioner) or veterinary medicine and unless the use of lasers or IPL devices is within the scope of their professional license. This section does not limit the intentional exposure of patients to laser or IPL device radiation for the purpose of diagnosis, therapy, or treatment by a practitioner of the healing arts or veterinary medicine within the scope of their professional license. This section does not apply to the manufacture of lasers or IPL devices.

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

(3) This section applies to IPL devices. These devices must be Class 2 or Class 3 surgical devices certified as complying with the designing, labeling, and manufacturing standards of the FDA.

(4) This section applies to lasers meeting the requirements of IEC standards 60825-1 and 60601-2-22 as allowed by the FDA Centers for Devices and Radiological Health in the current Laser Notice guidance document.

(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 chapter (relating to Notices, Instructions, and Reports to Workers; Inspections) except for 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 chapter (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services);

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

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

(c) Prohibitions.

(1) The department prohibits the use of lasers and IPL devices posing a significant threat or endangering occupational or public health and safety as specified in §289.205 and §289.231 of this chapter.

(2) An individual must not be intentionally exposed to laser or IPL radiation above the maximum permissible exposure (MPE) unless a practitioner has authorized such exposure.

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

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

(C) Research and development using radiation machines on humans is prohibited except for the following.

(i) Any research using radiation machines on humans must be approved by an Institutional Review Board (IRB) as required by 45 Code of Federal Regulations (CFR) Part 46, and 21 CFR Part 56. The IRB must include at least one physician to direct any laser radiation or IPL device use as specified in subsection (b)(1) of this section.

(ii) Facilities with radiation machines, with investigational device exemptions, involved in clinical studies must follow regulations governing the conduct of clinical studies and applying to the manufacturers, sponsors, clinical investigators, IRBs, and the medical device. These regulations include:

(I) 21 CFR Part 812, Investigational Device Exemptions;

(II) 21 CFR Part 50, Protection of Human Subjects;

(III) 21 CFR Part 56, Institutional Review Boards;

(IV) 21 CFR Part 54, Financial Disclosure by Clinical Investigators; and

(V) 21 CFR Part 820, Subpart C, Design Controls of the Quality System Regulation.

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

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

(4) American National Standards Institute (ANSI) standards--Specific standards for lasers and IPL devices published by the American National Standards Institute.

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

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

(7) Class 1 laser--Any laser not permitting human exposure during operation to levels of visible laser radiation more than the accessible emission limits contained in ANSI.

(8) Class 2 laser--Any laser permitting human exposure during operation to levels of visible laser radiation more than the accessible emission limits of Class 1 lasers contained in ANSI but does not permit human exposure during operation to levels of visible laser radiation more than the accessible emission limits of Class 2 lasers contained in ANSI.

(9) Class 3a laser, IEC Class 3R--Any laser permitting human exposure during operation to levels of laser radiation more than the accessible emission limits of Class 2 lasers contained in ANSI but does not permit human exposure during operation to levels of laser radiation more than the accessible emission limits of Class 3a lasers contained in ANSI.

(10) Class 3B laser--Any laser permitting human exposure during operation to levels of laser radiation more than the accessible emission limits of FDA Class 3a lasers in ANSI but does not permit human exposure during operation to levels of laser radiation in excess of the emission limits of Class 3B lasers contained in ANSI.

(11) Class 4 laser--Any laser permitting human exposure during operation to levels of laser radiation more than the accessible emission limits of Class 3B lasers contained in ANSI.

(12) Coherent--A light beam is coherent when the electric vector at any point in it is related to 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 are found in 21 CFR §1040.10.

(14) Continuous wave--A laser operating with a continuous output for greater than or equal to 0.25 seconds is regarded as a continuous wave laser.

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

(16) Divergence--The increase in the diameter of the laser beam with propagation distance from the exit aperture. This is also referred to as beam spread. The value of the divergence is expressed in radians or milliradians.

(17) Electromagnetic radiation--Radiation consisting of electromagnetic waves, including x-ray, ultraviolet, visible, infrared, and radio waves occupying various portions of the electromagnetic spectrum and differing only in frequency, wavelength, or photon energy.

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

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

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

(20) Engineering controls--Control measures designed or incorporated into the laser or laser system (e.g., interlocks, shutters, watchdog timer) or its application.

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

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

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

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

(25) Intense-pulsed light (IPL) device--A device that emits radiation to energy density levels that could cause bodily harm and used for photothermolysis. This device is a Class 2 or Class 3 surgical device certified as complying with FDA designing, labeling, and manufacturing standards.

(26) Invisible radiation--Laser or collateral radiation having wavelengths greater than or equal to 180 nm but less than or equal to 400 nm or greater than 710 nm but less than or equal to $1.0 \times 10^6$ nm (1 millimeter).

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

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

(29) Laser--An electronic device that emits stimulated radiation to energy density levels that could 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" includes the assembly of electrical, mechanical, and optical components associated with the laser. A laser can be a component of a product or system.

(30) Laser light show--Use of lasers for entertainment, advertising display, or artistic composition.

(31) Laser product--Any manufactured product or assemblage of components constituting, incorporating, or intending to incorporate a laser and is classified as a Class 1, Class 2, Class 3a, Class 3B, or Class 4 laser product according to the performance standards set by the FDA. A laser intended for use as a component of an electronic product must 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.

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

(33) Manufacturer--Any person who designs, manufactures, assembles, fabricates, or processes a finished laser device.

(34) Maximum permissible exposure (MPE)--The level of laser radiation a person may be exposed to without hazardous effects or adverse biological changes in the eye or skin. Maximum permissible exposures to laser radiation may be found in ANSI.

(35) Medical event--Any adverse patient health effect directly resulting from the use of laser equipment on an individual.

(36) 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 a portable laser that can be removed from the vehicle and taken into a facility for use.

(37) Nominal hazard zone (NHZ)--The space where 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.

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

(39) Personal protective equipment (PPE)--Device used to mitigate hazards associated with laser use, including laser eye protection (LEP), protective clothing, and gloves.

(40) Practitioner--A person licensed under Texas Occupations Code Title 3 Health Professions. A practitioner's use of a laser is limited to the person's scope of professional practice as determined by the appropriate licensing agency.

(41) Protective housing--An enclosure surrounding the laser preventing 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 workstation and must limit access to other associated radiant energy emissions and to electrical hazards associated with components and terminals.

(42) Provider of lasers--A person providing lasers on a routine basis to a facility for limited time periods.

(43) Pulse duration--The duration of a laser pulse. This is measured as the time interval between the half-power points on the leading and trailing edges of the laser pulse. (44) Pulsed laser--A laser delivering its energy in the form of a single pulse or a train of pulses. In this section, the duration of a pulse is less than 0.25 seconds.

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

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

(47) Supervision--Delegating to a person under the practitioner's authority, the task of applying laser radiation to persons or animals under this section. The practitioner assumes full responsibility for these tasks and must ensure the tasks are administered correctly.

(48) Transmission--Passage of laser radiation through a medium.

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

(50) Veterinarian--A person licensed as a veterinarian by the Texas Board of Veterinary Medical Examiners.

(51) Veterinary medicine--When used in this chapter, has the same meaning as found in Texas Occupations Code Chapter 801.

(52) Visible radiation (light)--Electromagnetic radiation that can be detected by the human eye. This term is commonly used to describe wavelengths in the range of 0.4 to 0.7 μm.

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

(54) Wavelength (λ)--The distance between two successive points on a periodic wave having the same phase.

(e) Exemptions.

(1) Lasers in storage or 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, Class 2, and Class 3a lasers, 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 subsection (f) of this section, regarding laser services, and the applicable paragraphs of subsection (g) of this section, to the extent their personnel perform laser services only for the registrant by whom they are employed.

(f) Registration for the use of Class 3B and Class 4 lasers and laser services.

(1) For purposes of this section, use of Class 3B or Class 4 lasers and laser services includes:

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

(B) demonstration or sale of lasers requiring the person to operate or cause a laser to be operated 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 must be directed by a practitioner employed by the contracting facility;

(D) alignment, calibration, installation, or repair; or

(E) laser light shows.

(2) A person who applies for registration as specified in this section and uses a Class 3B or Class 4 laser before 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 must be completed on forms prescribed by the department and must contain all the information required by the form and accompanying instructions.

(B) An LSO must be designated on each application form. The qualifications of that individual must be submitted to the department with the application. The LSO must meet the applicable requirements of subsection (o) of this section and carry out the responsibilities of subsection (p) of this section.

(C) Each application must be accompanied by a completed RC Form 226-01 (Business Information Form), which must contain the legal name of the entity or business. Unless exempt under Texas Business and Commerce Code Chapter 71, the applicant must:

(i) be authorized to conduct business in the State of Texas as listed on the Texas Secretary of State (SOS) website; and

(ii) file an assumed name certificate with the Texas SOS if using an assumed name in their application.

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

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

(F) At any time after filing the original application, the department may require further information to determine whether the certificate of laser registration will be issued or denied.

(G) Applications and documents submitted to the department may be made available for public inspection, except the department may withhold any document or part of a document from public inspection as specified in §289.231(aa) of this chapter.

(2) Application for the use of Class 3B or Class 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 Class 4 laser for use in the healing arts or for use on animals must submit an application to the department within 30 days after beginning operation of the laser.

(B) Application signatures.

(i) An application for healing arts use must be signed by a practitioner.

(ii) An application for veterinary medicine use must be signed by a licensed veterinarian.

(iii) The signature of the administrator, president, or chief executive officer will be accepted instead of the practitioner's signature if the facility is a licensed hospital or a medical facility.

(iv) A signature by the administrator, president, or chief executive officer does not relieve the practitioner or veterinarian from following the requirements of this section. The LSO must also sign the application.

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

(D) The applicant must ensure a laser machine is operated by a person qualified by training and experience to use the laser machine for the purpose requested, and in a manner minimizing danger to occupational and public health and safety.

(3) Application for the use of Class 3B or Class 4 lasers in industrial, academic, and research and development institutions.

(A) In addition to the requirements of subsection (g)(1) of this section, each person having a laser for use in industrial, academic, and research and development institutions must apply to the department within 30 days after beginning operation of the laser.

(B) An application for the use of Class 3B or Class 4 lasers in industrial, academic, and research and development institutions must be signed by the applicant or registrant or a person duly authorized to act on behalf of the applicant or registrant. The LSO must also sign the application.

(4) Application for registration of laser services.

(A) In addition to the requirements of subsection (g)(1) of this section, an applicant who intends to provide laser services described in subsection (f)(1) of this section must apply and receive a certificate of registration from the department before providing the services.

(B) An application for laser services must be signed by the applicant, registrant, or a person duly authorized to act on behalf of the applicant or registrant. The LSO must also sign the application.

(C) Providing services specified in subsection (f)(1) of this section, not specifically authorized by the department, is prohibited.

(D) A service provider must not provide laser machine services for a person who cannot produce evidence of a completed registration application or a valid certificate of registration issued by the department, except for the initial installation of the first machine for a new certificate of registration.

(5) Application for laser light show.

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

(B) An application to use Class 3B or Class 4 lasers in a laser light show must be signed by the applicant, registrant, or a person duly authorized to act on behalf of the applicant or registrant. The LSO must also sign the application.

(C) According to subparagraph (A) of this paragraph and in addition to the requirements of subsection (g)(1) of this section, each applicant must submit:

(i) a valid variance issued by the FDA, or evidence of an Annual Report on Radiation Safety Testing of Laser and Laser Light Show Products meeting FDA variance requirements, 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 RC Form 301-05 must be provided at least seven days before 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 department, obtain permission to proceed sooner.

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

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

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

(C) An application for mobile service operation for the healing arts must be signed by a practitioner and an application for mobile services for veterinary medicine must be signed by a licensed veterinarian. The LSO must also sign the application.

(h) Issuance of certificate of laser registration.

(1) A certificate of registration application will be approved if the department determines an application meets the Texas Radiation Control Act (Act) requirements and the requirements of this chapter. The certificate of registration authorizes the proposed activity and contains the conditions and limitations the department requires. The certificate of laser registration must be maintained as specified in subsection (cc) of this section.

(2) The department may incorporate in the certificate of laser registration at the time of issuance, or by amendment, additional requirements and conditions concerning the registrant's receipt, possession, acquisition, use, and transfer of lasers subject to this section, as it deems appropriate or necessary to:

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

(B) prevent loss or theft of lasers; or

(C) require additional reports and maintenance records as may be appropriate or necessary.

(3) At the request of the department the registrant must provide additional information after the certificate of laser registration has been issued for the department to determine whether the certificate of laser registration will 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 as specified in this section is subject to the applicable provisions of the Act and the applicable rules in this chapter and orders issued by the department.

(2) Each person registered by the department for laser use as specified in this section must confine use and possession of the laser registered to the locations and purposes authorized in the certificate.

(3) A certificate of laser registration issued under this section must not be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, to any person unless the department authorizes the transfer, in writing.

(4) In determining whether to issue, deny, amend, renew, revoke, suspend, or restrict a certificate of laser registration, the department may consider the technical competence and compliance history of an applicant or holder of a certificate of laser registration.

(5) After an opportunity for a hearing, the department will deny an application, amendment, or renewal of a certificate of laser registration if the applicant's compliance history reveals, within the previous six years, three or more actions have been issued against the applicant assessing administrative or civil penalties, or revoking or suspending a certificate of laser registration.

(j) Registrant responsibilities.

(1) The registrant is responsible for complying with this section and the conditions listed on the certificate of registration.

(2) The registrant must designate a qualified individual as the LSO as specified in subsection (o) of this section and ensure the individual continually performs the responsibilities of the LSO as identified in subsection (p) of this section.

(3) A person must not make, sell, lease, transfer, or lend lasers unless the machine and equipment, when properly placed in operation and used, meet the applicable requirements of this section.

(4) The registrant must notify the department in writing within 30 days of a change in any of the following:

(A) name and mailing address;

(B) street address where laser will be used;

(C) LSO; or

(D) additional use location.

(5) Each registrant must inventory all Class 3B and Class 4 lasers in their possession at an interval not to exceed 12 months. The inventory record must be maintained for inspection by the department as specified in subsection (cc) of this section and must include:

(A) the manufacturer's name;

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

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

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

(E) a complete inventory of equipment supplied by a provider of lasers as defined in subsection (d)(42) of this section.

(6) Notification to the department is required within 30 days of:

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

(B) any change in the category of the machine type or type of use as specified in §289.231(ll) or as authorized on the certificate of registration.

(7) The registrant, or the parent company, must notify the department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy. The notification must include:

(A) the name of the bankruptcy court; and

(B) the case name, and number, when known, and the date the petition was filed.

(8) A registrant must not engage a person for services described in subsection (f)(1) of this section until the service provider demonstrates current registration with the department.

(9) Registrants with certificates of laser registration as specified in subsection (g)(5) of this section must have the following documents on site at each laser light show:

(A) certificate of laser registration;

(B) FDA variance, or evidence of Annual Report on Radiation Safety Testing of Laser and Laser Light Show Products meeting FDA variance requirements, with all applicable documents required by the variance; and

(C) instructions for the safe use of lasers as specified in subsection (q)(2) of this section.

(10) Each registrant must maintain records of receipt, transfer, and disposal of Class 3B or Class 4 lasers for inspection by the department. The records must include the following information and be maintained as specified in subsection (cc) of this section:

(A) manufacturer's name;

(B) model and serial number of the laser;

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

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

(E) name of the person recording the information.

(11) A laser must not be used unless an application for registration is filed with the department, as specified in subsection (g) of this section, within the first 30 days of use. This section does not apply to operation of a laser for installation and calibration.

(12) A service provider must not provide laser services for a person who cannot produce evidence of a completed application for registration or a valid certificate of registration issued by the department, except for:

(A) the initial installation of the first machine for a new certificate of registration; and

(B) the registrant authorized for demonstration and sale, demonstrates a laser machine as specified in paragraph (15) of this subsection.

(13) A person authorized to perform alignment, calibration, installation, and repair of lasers in Texas must maintain:

(A) a daily log including:

(i) date of service;

(ii) name and address of the customer; and

(iii) customer's certificate of registration number, unless the service provided is an initial installation as described in paragraph (12)(A) of this subsection; and

(B) records of all services for inspection by the department as specified in subsection (cc) of this section.

(14) A person authorized to provide lasers must comply with the following.

(A) Providers of equipment must:

(i) ensure all lasers used on humans meet the requirements of this chapter;

(ii) provide lasers only to facilities holding a valid certificate of registration; and

(iii) keep a log of lasers provided in Texas, and record the following information:

(I) date machine provided;

(II) name of customer; and

(III) customer's certificate of registration number.

(B) Records of machines provided must be made and maintained for inspection by the department as specified in subsection (cc) of this section.

(15) A person authorized to demonstrate and sell lasers in Texas must comply with the following.

(A) Maintain a log including:

(i) date of all demonstrations and sales of lasers performed in Texas;

(ii) name and address of the customer; and

(iii) customer's certificate of registration number unless the service provided is an initial demonstration as described in paragraph (12)(B) of this subsection.

(B) Prevent exposure of individuals to a laser except for healing arts purposes and unless a licensed practitioner of the healing arts has authorized such exposure. This provision specifically prohibits the deliberate exposure of an individual for training, demonstrating, or other non-healing arts purposes.

(C) Demonstrate lasers on phantoms only.

(D) Document all tests required by this section when a demonstration of a laser involves exposure specifically and individually ordered by a practitioner.

(E) Records of demonstrations and sales must be made and maintained for inspection by the department as specified in subsection (cc) of this section.

(16) A person using loaner laser machines must comply with the following.

(A) For a person having a valid certificate of registration, loaner radiation machines may be used for up to 30 days. Within 30 days, the registrant must:

(i) notify the department of a change in the category of the machine type or type of use as specified in §289.231(ll) of this title and as authorized in the certificate of registration; or

(ii) notify the department of any increase in the number of machines beyond those authorized by the certificate of registration in any machine type or type of use category.

(B) For a person who does not hold a valid certificate of registration, a loaner laser may be used for human use for up to 30 days, by or under the direction of a practitioner, before applying for a certificate of registration as specified in subsection (g) of this section. This does not include mobile services.

(k) Expiration of certificates of laser registration.

(1) Except as provided by subsection (m) of this section, a certificate of laser registration expires at 11:59 p.m. Central Time 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 as specified in subsection (m) of this section, as applicable, the registrant must, before the expiration date specified in the certificate of laser registration, terminate use of all lasers and laser services as specified in subsection (l) of this section.

(3) The 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.

(1) When a registrant decides to terminate all activities involving laser or laser services authorized under the certificate of laser registration, the registrant must immediately:

(A) request termination of the certificate of laser registration in writing, signed by the LSO, owner, or a person authorized to act on behalf of the registrant; and

(B) submit to the department a record of the disposition of the laser, and, if applicable, include if the laser was transferred and to whom it was transferred.

(2) The registrant must pay any outstanding fees as specified in §289.204 of this chapter.

(m) Renewal of certificate of laser registration.

(1) An application for renewal of a certificate of laser registration must be filed as specified in subsection (g)(1)(A) – (G) and (g)(2) of this section.

(2) If a registrant applies for a renewal before the existing certificate of laser registration expires, the existing certificate of laser registration does not expire until the application status has been determined by the department.

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

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

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

(A) any materially false statement in the application or any false statement of fact required by the Act;

(B) information received by the department indicating a certificate of laser registration should not be issued;

(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 department or a court; or

(D) existing conditions threatening occupational safety, public health and safety, or the environment.

(3) Except in cases in which occupational and public health or safety requires otherwise, a registrant will be notified, in writing, of the department's intent to suspend or revoke a certificate of registration and be provided an opportunity to demonstrate compliance before proceedings to suspend or revoke begin.

(o) LSO qualifications. LSO qualifications must be submitted to the department and include:

(1) education 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; and

(3) knowledge of potential laser radiation hazards, laser emergency situations, and the appropriate response to an injury.

(p) LSO duties. The LSO must:

(1) ensure users of lasers are trained in laser safety, as applicable for the class and type of lasers used;

(2) assume control and have the authority to institute corrective actions to include the shutdown of operations, when necessary, in emergencies or unsafe conditions;

(3) specify whether any changes in control measures are required after:

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

(B) a deliberate modification is made that could change the laser class and affect the output power or operating characteristics;

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

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

(6) ensure compliance with the requirements in this section, the conditions of the certificate of laser registration, and any engineering or operational controls specified by the registrant.

(q) Requirements for protection against Class 3B or Class 4 lasers and IPL device radiation. These requirements are for Class 3B or Class 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. When an engineering control may be inappropriate, for example, during medical procedures or surgery, the LSO must specify alternate controls to obtain equivalent safety protection.

(1) MPE. A registrant or user of any laser may not permit any individual to be exposed to levels of laser or collateral radiation higher than are specified in ANSI and 21 CFR §1040.10, respectively.

(2) Instructions to personnel. Personnel using a laser must be provided with written instructions for safe use, including clear warnings and precautions to avoid possible exposure to laser and collateral radiation more than the MPE, as specified in ANSI and the collateral limits listed in 21 CFR §1040.10. The instructions to personnel must be maintained as specified in subsection (cc) of this section for inspection by the department.

(3) Engineering controls.

(A) Protective housing.

(i) Each laser must have a protective housing preventing human exposure during the operation to laser and collateral radiation that exceeds the limits of Class 1 lasers as specified in ANSI and 21 CFR §1040.10, if human exposure is not necessary for the laser to perform its intended function.

(ii) If human exposure to laser radiation levels more than the limits of Class 1 is necessary, these levels must not exceed the limits of the lowest laser class required to perform the intended function.

(B) Safety interlocks.

(i) A safety interlock ensuring radiation is not accessible above MPE limits as specified in ANSI must 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 exposure to radiation above the MPE limits.

(ii) Adjustment during operation, service, testing, or maintenance of a laser containing interlocks must 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 must be designed to prevent the firing of the laser; for example, by dumping the stored energy into a dummy load.

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

(v) An interlock must 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 must be provided if failure of a single interlock would allow the following:

(I) human exposure to levels of laser radiation more than the accessible emission limit of FDA Class 3a laser radiation; or

(II) laser radiation more than the accessible emission limits of Class 2 emitted directly through the opening created by removing or displacing 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 must 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 specified in ANSI and the collateral limits listed in 21 CFR §1040.10, under any conditions of operation or use of the laser.

(ii) All collecting optics, such as lenses, telescopes, microscopes, or endoscopes, intended for viewing use with a laser must 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 specified in ANSI. Normal or prescription eyewear is not considered collecting optics.

(D) Warning systems. Each Class 3B or Class 4 laser or laser product must provide visual or audible indication during the emission of accessible laser radiation. In the case of Class 3B lasers, except those only allowing access to less than 5 milliwatt (mW) peak visible laser radiation, and Class 4 lasers, the indication must be sufficient before emission of such radiation to allow appropriate action to avoid exposure. Any visual indicator must be visible through protective eyewear designed specifically for the wavelength 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 must incorporate visual or audible indicators. The visual indicators must be positioned so viewing does not require human exposure to laser radiation more than the MPE, as specified in ANSI.

(E) Controlled area. With a Class 3B laser, except those only allowing access to less than 5 mW visible peak power, or Class 4 laser, a controlled area must be established when exposure to the laser radiation more than the MPE, as specified in ANSI or the collateral limits listed in 21 CFR §1040.10, is possible. The controlled area must meet the following requirements, as applicable.

(i) The area is posted with hazard signs as required by subsection (u) of this section.

(ii) Access to the controlled area is restricted.

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

(I) Such measures are designed to allow rapid exit by laser personnel and allow admittance to the controlled area for emergency personnel. For such emergency conditions, a control-disconnect switch or equivalent device (panic button) must 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 applies.

(-a-) All authorized personnel are trained in laser safety, and appropriate PPE is provided upon entry.

(-b-) A door, blocking barrier, screen, or curtains is used to block, screen, or attenuate the laser radiation at the entryway. The level at the exterior of these devices cannot be more than the applicable MPE, as specified in ANSI.

(-c-) Within the laser controlled area, there is a visible or audible signal indicating 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 methods to accomplish this requirement.

(iv) For Class 4 indoor controlled areas, during tests requiring continuous operation, the person in charge of the controlled area is permitted to momentarily override the safety interlocks to allow access by other authorized personnel if it is evident 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 must be controlled to reduce the transmitted values of the laser radiation to levels at or below the appropriate ocular MPE, as specified in ANSI and the collateral limits listed in 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 is responsible for ensuring 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 specified in ANSI.

(vi) When the removal of panels or protective covers or overriding of interlocks becomes necessary, such as for servicing, testing, or maintenance, and accessible laser radiation exceeds the MPE, as specified in ANSI and the collateral limits listed in 21 CFR §1040.10, a temporary controlled area must be established and posted.

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

(r) Additional requirements for special lasers and applications.

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

(2) Laser optical fiber transmission system.

(A) Laser transmission systems employing optical cables are considered enclosed systems with the optical cable forming part of the protective housing.

(B) Disconnection of a connector resulting in exposure to radiation more than the applicable MPE limits, as specified in ANSI and the collateral limits listed in 21 CFR §1040.10, must take place in a controlled area. Except for medical lasers whose manufacture has been approved by the FDA, the use of a tool is required for the disconnection of a connector for service and maintenance purposes when the connector is not within a secured enclosure. All connectors must bear the appropriate label or tag as specified in subsection (u)(3) of this section.

(s) Additional requirements for safe operation.

(1) Eye protection. Protective eyewear must be worn by each individual exposed to laser radiation from IPL, Class 3B, or Class 4 levels of laser radiation. Protective eyewear devices must 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 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 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 must be discarded. Documentation of the examination is required to be maintained as specified in subsection (cc) of this section for inspection by the department.

(2) Skin protection. When there is a possibility of exposure to laser radiation more than the MPE limits for skin as specified in ANSI the registrant must require the use of appropriate PPE.

(t) NHZ. Where applicable, in the presence of unenclosed Class 3B and Class 4 laser beam paths, an NHZ must 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 more than the MPE, as specified in ANSI, that region is 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.

(u) Hazard signs, labels, and posting for lasers and IPL devices.

(1) General requirements. Except as otherwise authorized by the department, signs, symbols, and labels prescribed by this section must use the design and colors as specified in paragraph (3) of this subsection.

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

(3) Labeling lasers and posting laser facilities. All signs and labels associated with Class 2, 3a, 3B, and 4 lasers must contain the following wording or sign posting requirements found in ANSI.

(A) Danger sign.

(i) The signal word "DANGER" indicating death or serious injury will occur if required control measures are not implemented to mitigate the hazards within the laser controlled area. This signal word is restricted to those Class 4 lasers with high (e.g., multi-kilowatt) output power or pulse energies with exposed beams.

(ii) The danger sign must include:

(I) The signal word "DANGER" in white letters on a rectangular safety red background placed at the top of the sign.

(II) "Class 4 Laser Controlled Area."

(III) "Avoid eye or skin exposure to direct or scattered radiation."

(IV) "Laser eye protection required," and include:

(-a-) optical density;

(-b-) laser type;

(-c-) wavelength; and

(-d-) wattage.

(iii) The safety alert symbol must precede the signal word.

(I) The base of the symbol must be on the same horizontal line as the base of the letter of the signal word.

(II) The height of the safety alert symbol must be equal to or exceed the signal word letter height.

(III) The words "Avoid eye or skin exposure to direct or scattered radiation" must appear to the right of the safety alert symbol.

(iv) The following sign meets the requirements of this subparagraph.

Figure: 25 TAC §289.301(u)(3)(A)(iv)


(B) Warning sign.

(i) The signal word "WARNING" must be used with all signs and labels associated with lasers and laser systems whose output is more than the applicable MPE for irradiance, including all Class 3B and most Class 4 lasers and laser systems.

(ii) The warning sign must include:

(I) The signal word "WARNING" in black letters on a rectangular orange background placed at the top of the sign.

(II) "Class 4 Laser Controlled Area."

(III) "Avoid eye or skin exposure to direct or scattered radiation."

(IV) "Do not enter when light is illuminated."

(IV) "Laser eye protection required," and include:

(-a-) optical density;

(-b-) laser type;

(-c-) wavelength; and

(-d-) wattage.

(iii) The safety alert symbol must precede the signal word.

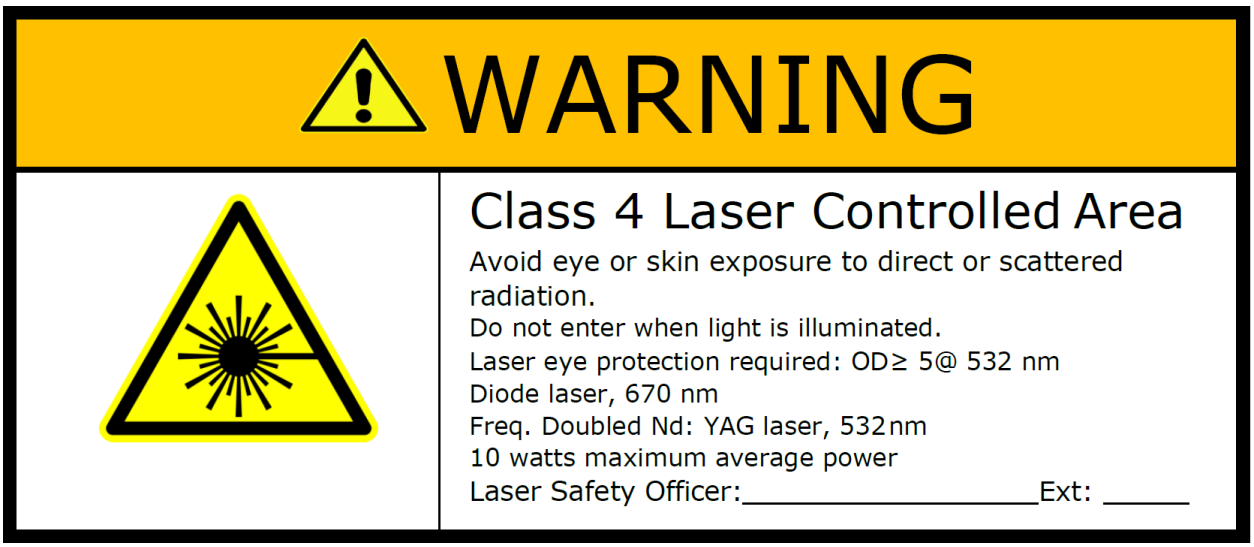
(I) The base of the symbol must be the same horizontal line as the base of the letter of the signal word.

(II) The height of the safety alert symbol must be equal to or exceed the signal word letter height.

(III) The words "Avoid eye or skin exposure to direct or scattered radiation" must appear to the right of the safety alert symbol.

(iv) The following sign meets the requirements of this subparagraph.

Figure: 25 TAC §289.301(u)(3)(B)(iv)




(C) Caution sign.

(i) The signal word "CAUTION" must be used with all signs and labels associated with Class 2 and Class 2M lasers and laser systems not more than the applicable MPE for irradiance.

(ii) The caution sign must include:

(I) The signal word "CAUTION" in black letters on a rectangular yellow background placed at the top of the sign.

(II) "Class 2M Laser In Use."

(III) "Do not stare into beam or view directly with optical instruments," and include:

(-a-) optical density;

(-b-) laser type;

(-c-) wavelength; and

(-d-) wattage.

(iii) The safety alert symbol must precede the signal word.

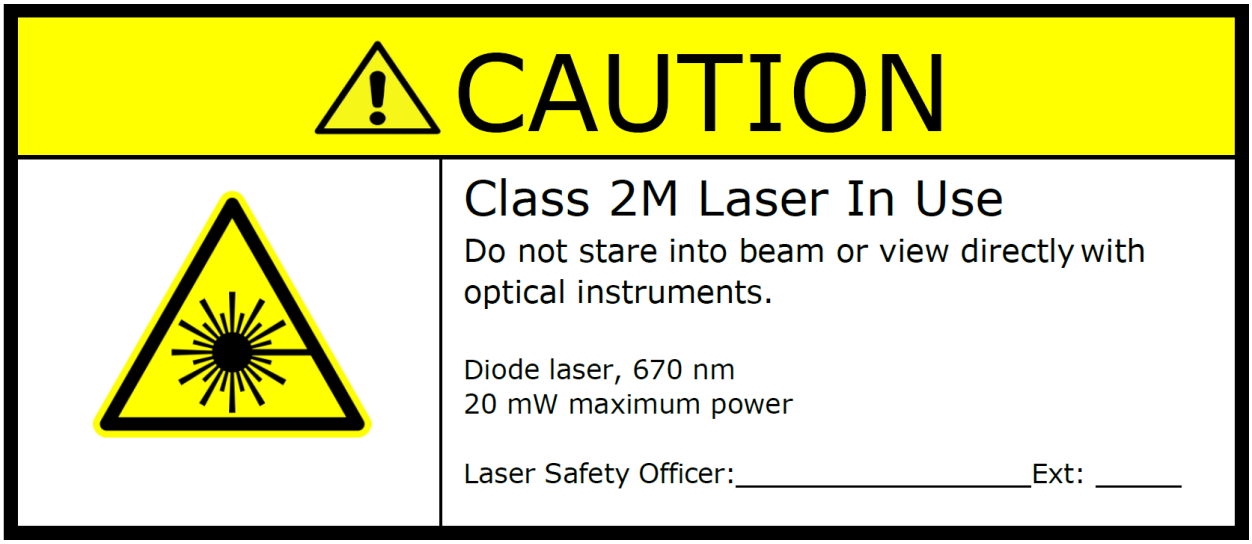
(I) The base of the symbol must be on the same horizontal line as the base of the letters of the signal word.

(II) The height of the safety alert symbol must be equal to or exceed the signal word letter height.

(III) The words "Do not stare into beam or view directly with optical instruments" must appear to the right of the safety alert symbol.

(iv) The following sign meets the requirements of this subparagraph.

Figure: 25 TAC §289.301(u)(3)(C)(iv)



(D) Lasers, except a laser used in the practice of medicine or veterinary medicine, must have a label in close proximity to each aperture emitting accessible laser or collateral radiation in excess of the limits specified in ANSI and the collateral limits listed in 21 CFR §1040.10, labeled with the following, as applicable:

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

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

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

(E) Each defeatable or non-interlocked portion of the protective housing or enclosure designed to be displaced or removed during normal operation or servicing that permits human exposure to laser or collateral radiation must have the following label:

(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 more than the emission limits as specified in 21 CFR §1040.10, "CAUTION - HAZARDOUS ELECTROMAGNETIC RADIATION WHEN OPEN" and "CAUTION - HAZARDOUS X-RAY RADIATION" as applicable.

(F) For protective housing or enclosures providing a defeatable interlock, the words "and interlock defeated" must be included in the labels as specified in subparagraph (E)(i) and (ii) of this paragraph.

(G) Other required information.

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

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

(H) Labels and signs required by this subparagraph must be clearly visible, legible, and permanently attached to the laser or facility.

(4) In lieu of the requirements in paragraphs (1) - (3) of this subsection, the department will accept labeling and signage as specified by:

(A) 21 CFR §1040.10;

(B) ANSI; and

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

(v) Surveys. Each registrant must conduct surveys necessary to comply with this section and maintain records of the surveys as specified in subsection (cc) of this section for inspection by the department. Surveys must be performed at intervals not to exceed 12 months, and include:

(1) a determination if 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 if all warning devices are functioning within their design specifications;

(3) a determination if the controlled area is properly controlled and posted with accurate warning signs as specified in subsection (u) of this section;

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

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

(w) Records or documents. Each registrant must maintain current records or documents required by this subsection as specified in subsection (cc) of this section for inspection by the department.

(x) Measurements and instrumentation. Each determination requiring a measurement for compliance with this section must use instrumentation calibrated and designed for use with the laser or IPL device to be tested. Records of measurements and instrumentation must be maintained as specified in subsection (cc) of this section.

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

(1) Each registrant of Class 3B or Class 4 lasers or user of an IPL device must immediately seek appropriate medical attention for the injured individual and notify the department 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 involving the partial or total loss of sight in either eye; or

(B) an injury to an individual involving intentional perforation of the skin or other serious injury excluding eye injury.

(2) Each registrant of Class 3B or Class 4 lasers or user of an IPL device must, within 24 hours of the discovery of an injury, notify the department of any injury involving a laser possessed by the registrant or IPL device possessed by a user, as applicable, other than intentional exposure of patients for medical purposes, that has or may have caused, or threatens to cause, exposure to an individual with second or third-degree burns to the skin or potential injury and partial loss of sight. Record of a notification of injury must be documented and maintained as specified in subsection (cc) of this section.

(z) Reports of injuries.

(1) Each registrant of Class 3B or Class 4 lasers or user of an IPL device must make a report, in writing, or by electronic transmittal, within 30 days to the department of any injury required to be reported as specified in subsection (y) of this section.

(2) Each report must describe:

(A) the extent of injury to each individual from radiation caused by 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 prevent a recurrence.

(3) A report filed with the department as specified in this subsection must include the full name of each individual injured and a description of the injury. The report must include personally identifying information in a separate part of the report.

(4) When a registrant or user of an IPL device is required, as specified in paragraphs (1) - (3) of this subsection, to report to the department any injury of an individual caused by radiation from a laser or IPL device, the registrant or user of an IPL device must notify the individual. The notice must be sent to the individual at the same time the report is sent to the department. Record of a report of injury must be documented and maintained as specified in subsection (cc) of this section.

(aa) Medical event.

(1) The registrant of a Class 3B or Class 4 laser or user of an IPL device must notify the department, by telephone or electronic transmittal, within 24 hours of the discovery of a medical event involving a Class 3B or Class 4 laser resulting in or death of a patient. Within 30 days after a 24-hour notification is made, the registrant of a Class 3B or Class 4 laser or the user of an IPL device must submit a written report to the department of the event. Record of a medical event must be documented and maintained as specified in subsection (cc) of this section.

(2) The written report must include:

(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 legal guardian.

(3) When a medical event occurs, the registrant or user must promptly investigate its cause, make a record for department review, and retain the records as specified in subsection (cc) of this section.

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

(1) Each registrant of Class 3B or Class 4 lasers or user of an IPL device must report to the department by telephone at (512) 458-7460, or email at RAMAssist@dshs.texas.gov, 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 as specified in paragraph (1) of this subsection must, within 30 days after making the telephone or email report, make a written report to the department including:

(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 taken, or to be taken, to recover the laser or IPL device; and

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

(3) Report of a stolen, lost, or missing Class 3B or Class 4 laser and IPL device must be maintained as specified in subsection (cc) of this section.

(cc) Record or document retention requirements for registration of a radiation machine. Each registrant must maintain the following records or documents at each site, including authorized records sites for mobile services at the time intervals specified for inspection by the department.

Figure: 25 TAC §289.301(cc)

| Name of Record | Rule Cross-Reference | Time Interval for Record Keeping |
|---|---|---|
| Current certificate of laser registration | (h)(1) | Until termination of laser registration |
| Inventory | (j)(5) | Until termination of laser registration |
| Receipt, transfer, and disposal | (j)(10) | Until termination of laser registration |
| Alignment, calibration, and repair | (j)(13) | 10 years |
| Providers of equipment | (j)(14) | 10 years |
| Demonstrations and sales | (j)(15) | 10 years |
| Instructions to personnel | (q)(2) | Until termination of laser registration |
| Eye protection | (s)(1) | 5 years |
| Surveys | (v) | 5 years |
| Measurements and instrumentation | (x) | 5 years |
| Notification of injury | (y) | 5 years |
| Reports of injuries | (z) | 5 years |
| Medical event | (aa) | 5 years |
| Reports of stolen, lost, or missing lasers | (bb) | Until termination of laser registration |
| Reports of stolen, lost, or missing IPL devices | (bb) | 5 years |