

25 TEXAS ADMINISTRATIVE CODE

§289.302

**Registration and Radiation Safety Requirements for Use of
Laser Hair Removal Devices**

(effective September 1, 2010)

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§289.302. Registration and Radiation Safety Requirements for Use of Laser Hair Removal Devices.

(a) Purpose.

(1) This section establishes requirements for radiation safety in the use of lasers or pulsed light devices for hair removal procedures. This section includes requirements for laser hair removal (LHR) facility operations, training and qualifications for persons performing LHR procedures, customer notification, consulting physicians, enforcement, penalties, and responsibilities of the registrant, laser safety officer (LSO), certified individuals, and consulting physicians.

(2) This section establishes requirements for the registration of LHR facilities and the certification of individuals who perform or attempt to perform LHR procedures. No person may operate a LHR facility except as authorized in a certificate of LHR registration issued by the agency in accordance with the requirements of this section. No person may perform or attempt to perform LHR except as authorized in a certificate issued by the agency in accordance with this section.

(3) This section establishes fees and fee payment requirements for certificates of LHR registration for LHR facilities and individual LHR certificates for individuals who perform or attempt to perform LHR procedures. The fees and fee payment requirements apply to applications and renewals of certificates of LHR registration and individual LHR certificates.

(b) Scope.

(1) Except as otherwise specifically provided, this section applies to all persons who operate a location that provides LHR procedures using LHR devices and to all persons who perform or attempt to perform LHR procedures using LHR devices. This section does not apply to the manufacture of LHR devices.

(2) A LHR device used for nonablative hair removal procedures shall meet the applicable performance standards for light-emitting products specified in Title 21, Code of Federal Regulations (CFR), §1040.10 and §1040.11.

(3) Except for consulting physicians, this section does not apply to a physician or to a physician's employee or delegate acting under Occupations Code, Chapter 157.

(4) A certificate issued in accordance with subsection (k) of this section only authorizes a person to perform nonablative cosmetic LHR. The certificate issued in accordance with subsection (k) of this section does not authorize an individual to diagnose, treat, or offer to treat any client for any illness, disease, injury, defect or deformity of the human body.

(5) This section applies only to LHR devices used for nonablative hair removal. Lasers or pulsed light devices used for any other purpose shall comply with the requirements of §289.301 of this title (relating to Registration and Radiation Safety Requirements for Lasers and Intense-Pulsed Light Devices).

(6) A person who receives, possesses, uses, owns, or acquires LHR devices prior to receiving a certificate of LHR registration is subject to the requirements of this section.

(7) A health professional licensed under another law is not required to hold a certificate to perform laser hair removal procedures issued in accordance with this section if the performance of laser hair removal is within the scope of that professional's practice as determined by the professional's licensing board.

(8) The qualifications for eligibility for an applicant for a senior LHR technician certificate who is a licensed health professional shall be established by the entity that issues licenses for that health profession.

(9) Training programs complying with the requirements of subsection (j)(20) of this section are also subject to certain requirements of §289.226 of this title (relating to Registration of Radiation Machine Use and Services).

(10) A LHR device categorized by the United States Food and Drug Administration (FDA) as a prescription device shall meet the requirements for prescription use specified in Title 21, CFR, §801.109. For purposes of this section, the requirements for a consulting physician specified in subsection (i)(13) of this section shall satisfy the requirement for supervision by a physician specified in Title 21, CFR, §801.109. For purposes of this section, the requirement for a consulting physician to establish protocols for a LHR facility in accordance with subsection (i)(13) of this section shall satisfy the requirement for a prescription for use as specified in Title 21, CFR, §801.109. A LHR device shall be purchased by or on the order of a physician, in accordance with Title 21, CFR, §801.109 and subsection (q)(2) of this section.

(c) Prohibitions.

(1) The agency may prohibit the use of LHR devices that pose a significant threat or endanger occupational or public health and safety, in accordance with subsections (z) and (ee) of this section.

(2) A person shall not operate a LHR facility unless the person holds a certificate of LHR registration issued by the agency in accordance with subsection (k) of this section.

(3) An individual shall not use LHR devices to perform or attempt to perform LHR procedures unless the person holds the individual LHR certificate issued by the agency in accordance with subsection (k) of this section.

(4) An individual shall not operate a laser hair removal device with the intent to treat an illness, disease, injury, or physical defect or deformity unless the individual is:

(A) a physician;

(B) acting under a physician's order; or

(C) authorized under other law to treat the illness, disease, injury, or physical defect or deformity in that manner.

(5) A person who violates paragraph (4) of this subsection is practicing medicine in violation of Occupations Code, Title 3, Subtitle B, and is subject to the penalties under that subtitle and under Health and Safety Code, §401.522.

(6) A person shall not operate a LHR facility from a person's living quarters. A LHR facility shall be separated from living quarters by complete floor to ceiling partitioning and shall contain no access to living quarters.

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

(1) Act--Texas Radiation Control Act, Health and Safety Code, Chapter 401.

(2) Administrative penalty--Monetary penalty assessed by the agency in accordance with the Texas Radiation Control Act (Act), §401.384 and §401.522, to emphasize the need for lasting remedial action and to deter future violations.

(3) Adverse event--Any death or serious injury, as that term is defined in Title 21, CFR, §803.3, to a client or employee of a LHR facility that is a result of use, misuse, or failure of LHR devices or LHR safety equipment.

(4) Advertising--All representations disseminated in any manner or by any means for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of laser hair removal services.

(5) Agency--The Department of State Health Services or its successor.

(6) Applicant--A person seeking a certificate of LHR registration or individual LHR certificate, issued in accordance with the provisions of the Act and the requirements in this section.

(7) Certificate of LHR registration--A form of permission given by the agency to a LHR facility applicant who has met the requirements for LHR registration certification set out in the Act and this section. For purposes of this section, "certificate of LHR registration" is an equivalent term for "facility license" as specified in Health and Safety Code, §401.510.

(8) Certified individual--Any individual issued an individual LHR certificate by the agency in accordance with the Act and this section.

(9) Commissioner--The commissioner of the Department of State Health Services.

(10) Consulting physician--A physician who has a contract with a LHR facility in accordance with subsection (i)(13) of this section.

(11) Contract--A written legal document between a consulting physician and the operator of a LHR facility.

(12) Direct supervision--Direct observation by a senior LHR technician or a LHR professional of LHR procedures performed by a LHR apprentice-in-training. The senior LHR technician or LHR professional shall be available to give immediate assistance if required.

(13) Director--The director of the radiation control program in accordance with the agency's jurisdiction.

(14) Hearing--A proceeding to examine an application or other matter before the agency in order to adjudicate rights, duties, or privileges.

(15) Informal conference--A meeting held by the agency with a person to discuss the following:

(A) safety, safeguards, or environmental problems;

(B) compliance with regulatory or certificate of LHR registration condition requirements;

(C) proposed corrective measures including, but not limited to, schedules for implementation; and

(D) enforcement options available to the agency.

(16) Individual LHR certificate--A form of permission given by the agency to an individual applicant who has met the requirements for individual LHR certification set out in the Act and this section. The term includes certificates issued by the agency for a LHR professional, a senior LHR technician, a LHR technician, and a LHR apprentice-in-training.

(17) Inspection--An official examination and/or observation by the agency that includes, but is not limited to, records, tests, surveys, photographs, and monitoring to determine compliance with the Act and rules, orders, requirements, and conditions of the agency.

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(18) Laser hair removal--The use of a laser or pulsed light device for nonablative hair removal procedures. For purposes of this section, "laser hair reduction" is an equivalent term.

(19) Laser hair removal facility--A business location that provides laser hair removal.

(20) Laser hair removal procedure--The removal of hair from one of the four body areas specified below, conducted during the same or separate appointment. Each area is considered one procedure, regardless of how many individual body parts are treated within that area.

(A) head and neck;

(B) upper extremities, to include hands, arms (including armpits), and shoulders;

(C) torso, to include front and back (including pelvic region and buttocks);
or

(D) lower extremities, to include legs and feet.

(21) Laser or pulsed light device--A device approved by the FDA for laser hair removal or reduction. For purposes of this section, "LHR device" is an equivalent term.

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

(23) LHR--An acronym for laser hair removal.

(24) Licensed health professional--An individual licensed in accordance with Occupations Code, Title 3.

(25) Living quarters--Any area used as a place of abode with provisions for sleeping, cooking, and sanitation.

(26) Mobile LHR facility--A business location self-contained within a vehicle that provides LHR procedures within the vehicle and meets all the requirements of this section.

(27) Nonablative hair removal procedure--A hair removal procedure using a LHR device that does not remove the epidermis.

(28) Notice of violation--A written statement prepared by the agency of one or more alleged infringements of a legally binding requirement.

(29) Operator--The owner of a LHR facility, an agent of an owner, or an independent contractor of a LHR facility.

(30) Order--A specific directive contained in a legal document issued by the agency.

(31) Person--Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, local government, any other state or political subdivision or agency thereof, or any other legal entity, and any legal successor, representative, agent, or agency of the foregoing.

(32) Physician--An individual who meets the definition in Occupations Code, Title 3, Subtitle B, Chapter 151.

(33) Preliminary report--A document prepared by the agency containing the following:

(A) a statement of facts on which the agency bases the conclusion that a violation has occurred;

(B) recommendations that an administrative penalty be imposed on the person charged;

(C) recommendations for the amount of that proposed penalty; and

(D) a statement that the person charged has a right to a hearing on the occurrence of the violation, the amount of the penalty, or both.

(34) Registrant--Any facility issued a certificate of LHR registration by the agency in accordance with the Act and this section. For purposes of this section, "certificate of LHR registration" is an equivalent term for "facility license" as specified in Health and Safety Code, §401.510.

(35) Rule--Any agency statement of general applicability that implements, interprets, or prescribes law or policy, or describes the procedure or practice requirements of an agency. The term includes the amendment or repeal of a prior section but does not include statements concerning only the internal management or organization of any agency and not affecting private rights or procedures.

(36) Severity level--A classification of violations based on relative seriousness of each violation and the significance of the effect of the violation on the occupational or public health or safety or the environment.

(37) Supervision--The physical presence of a senior LHR technician or LHR professional at the LHR facility.

(38) Termination--A release by the agency of the obligations and authorizations of the LHR registrant or certified LHR individual under the terms of the certificate of LHR registration or the individual LHR certificate. It does not relieve a person of duties and responsibilities imposed by law.

(39) Violation--An infringement of any rule, registration, or individual certificate condition, order of the agency, or any provision of the Act.

(e) Additional requirements. The agency may, by rule, order, or condition of certificate of laser registration, impose upon any registrant such requirements in addition to those established in this chapter as it deems appropriate or necessary to minimize danger to public health and safety or property or the environment.

(f) Communications.

(1) Except where otherwise specified, all communications and reports concerning this section and applications filed under it should be addressed to the Radiation Control Program, Department of State Health Services, Mail Code 1987, P. O. Box 149347, Austin, Texas, 78714-9347. Communications, reports, and applications may be delivered in person to the agency's office located at 8407 Wall Street, Austin, Texas.

(2) Documents transmitted to the agency will be deemed submitted on the date sent according to the postmark, telegram, telefacsimile, or electronic media transmission.

(g) Interpretations. Except as specifically authorized by the agency in writing, no interpretation of the meaning of this section by any officer or employee of the agency other than a written legal interpretation by the agency, will be considered binding upon the agency.

(h) Open records. All records are subject to the requirements of the Texas Public Information Act, Government Code, Chapter 552.

(i) Application requirements for a certificate of LHR registration.

(1) A separate LHR application shall be submitted for each LHR facility. A separate certificate of LHR registration is required for each LHR facility.

(2) A certificate of LHR registration for a LHR facility, issued in accordance with subsection (k) of this section, is not required for the following:

(A) a facility owned or operated by a physician for the practice of medicine;

(B) a licensed hospital; or

(C) a clinic owned or operated by a licensed hospital.

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(3) A certificate of LHR registration, issued in accordance with subsection (k) of this section, is required for a facility owned or operated by a physician that performs only LHR procedures. A certificate of LHR registration, issued in accordance with subsection (k) of this section, is not required for a facility owned or operated by a physician for both the practice of medicine and LHR procedures.

(4) A certificate of laser registration issued in accordance with §289.301 of this title may be required for the entities specified in paragraph (2)(A) - (C) of this subsection that own, possess, or use lasers for purposes other than LHR.

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

(6) A 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 requirements of subsection (n) of this section and carry out the responsibilities of subsection (o) of this section.

(7) A LHR professional(s) shall be designated on each application form. The LHR professional shall meet the applicable requirements of subsection (j)(6) of this section and carry out the responsibilities of subsection (q)(4) of this section.

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

(9) Each application for a certificate of LHR registration shall be accompanied by the appropriate fee prescribed in subsection (ff) of this section.

(10) 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 LHR registration should be granted or denied.

(11) 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 subsection (h) of this section.

(12) An application for a LHR facility shall be signed by an operator. The LHR application shall also be signed by the LSO if the LSO is someone other than the operator.

(13) Each application for a certificate of LHR registration shall be accompanied by copy of a written contract with a consulting physician. The contract shall be between the LHR facility applicant and the consulting physician and shall include the following:

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(A) proper protocols for the services provided by the consulting physician at the facility as specified in subsection (m)(5) and (6) of this section;

(B) a provision for the consulting physician to audit the LHR facility's protocols and operations in accordance with subsection (m)(2) of this section;

(C) a commitment that the consulting physician shall be available for emergency consultation with the LHR facility as appropriate to the circumstances, including, if the physician considers it necessary, an emergency appointment with the client; and

(D) a designated physician who shall be available for the consultation with the LHR facility relating to care for the client if the consulting physician is unavailable.

(j) Application requirements for an individual LHR certificate.

(1) Application for an individual LHR certificate shall be completed on forms prescribed by the agency and shall contain all the information required by the form and accompanying instructions.

(2) Each application for an individual LHR certificate shall be accompanied by the appropriate fee prescribed in subsection (ff) of this section.

(3) 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 individual LHR certificate should be granted or denied.

(4) 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 subsection (h) of this section.

(5) An application for an individual LHR certificate shall be signed by the individual seeking certification.

(6) An applicant for a LHR professional certificate shall meet the following requirements:

(A) be certified by a certification entity approved by the agency;

(B) meet the requirements for a senior LHR technician certificate in accordance with paragraph (10) of this subsection; and

(C) pass an examination approved by the agency.

(7) Written documentation of completion of the requirements in paragraph (6)(A) - (C) of this subsection shall be submitted with each LHR professional certificate application.

(8) An applicant for a LHR professional certificate who has met the requirements of paragraph (6)(A) and (C) of this subsection prior to September 1, 2010, is not required to meet the requirements of paragraph (6)(B) of this subsection.

(9) Written documentation of the requirements in paragraph (6)(A) and (C) of this subsection completed prior to September 1, 2010, shall be submitted to the agency with each LHR professional certificate application. Written documentation submitted in accordance with this paragraph will be accepted by the agency if postmarked, hand-delivered, or electronically submitted by December 31, 2010.

(10) An applicant for a senior LHR technician certificate shall meet the following requirements:

(A) meet the requirements for a LHR technician certificate in accordance with paragraph (14) of this subsection; and

(B) have directly supervised at least 100 LHR procedures within 12 months, as audited by a LHR professional. An individual shall not supervise LHR procedures without audit by a LHR professional until:

(i) 100 LHR procedures within 12 months have been directly supervised, as audited by a LHR professional; and

(ii) an individual senior LHR technician certificate has been issued by the agency in accordance with subsection (k) of this section.

(11) Written documentation of completion of the requirements in paragraph (10)(A) and (B) of this subsection shall be submitted with each senior LHR technician certificate application.

(12) An applicant for a senior LHR technician certificate who has met the following requirements prior to September 1, 2010, is not required to meet the requirements of paragraph (10) of this subsection:

(A) performed 100 LHR procedures within 12 months;

(B) supervised 100 LHR procedures within 12 months; and

(C) has met the requirements of paragraph (18)(A), (B), and (D) of this subsection.

(13) Written documentation of the requirements in paragraph (12) of this subsection completed prior to September 1, 2010, shall be submitted to the agency with each senior LHR technician certificate application. Written documentation submitted in accordance with this paragraph will be accepted by the agency if postmarked, hand-delivered, or electronically submitted by December 31, 2010.

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(14) An applicant for a LHR technician certificate shall meet the following requirements:

(A) meet the requirements for a LHR apprentice-in-training certificate in accordance with paragraph (18) of this subsection; and

(B) have performed at least 100 LHR procedures within 12 months under the direct supervision of a senior LHR technician or a LHR professional. An individual shall not perform LHR procedures unsupervised until:

(i) 100 LHR procedures within 12 months have been performed under the direct supervision of a senior LHR technician or LHR professional; and

(ii) an individual LHR technician certificate has been issued by the agency in accordance with subsection (k) of this section.

(15) Written documentation of completion of the requirements in paragraph (14)(A) and (B) of this subsection shall be submitted with each LHR technician certificate application.

(16) An applicant for a LHR technician certificate who has met the following requirements prior to September 1, 2010, is not required to meet the requirements of paragraph (14) of this subsection:

(A) performed 100 LHR procedures within 12 months; and

(B) has met the requirements of paragraph (18)(A), (B), and (D) of this subsection.

(17) Written documentation of the requirements in paragraph (16) of this subsection completed prior to September 1, 2010, shall be submitted to the agency with each LHR technician certificate application. Written documentation submitted in accordance with this paragraph will be accepted by the agency if postmarked, hand-delivered, or electronically submitted by December 31, 2010.

(18) An applicant for a LHR apprentice-in-training certificate shall meet the following requirements:

(A) have at least 24 hours of training in:

(i) LHR device safety;

(ii) laser physics;

(iii) skin typing;

- (iv) skin reactions;
- (v) treatment protocols;
- (vi) burns;
- (vii) eye protection;
- (viii) emergencies; and
- (ix) post-treatment protocols;

(B) have an additional 16 hours of training in:

(i) cardio-pulmonary resuscitation (a valid cardio-pulmonary resuscitation certificate may be used to satisfy up to 8 hours of the training required by this subparagraph);

(ii) review of client's pre-existing conditions to determine if consultation with a consulting physician is needed for possible diagnosis or treatment;

(iii) review of client's previous hair removal procedures by another modality;

(iv) review of client's current medications to determine if any medications need to be brought to the attention of the consulting physician based on established protocols;

(v) proper signage and posting;

(vi) use of a LHR device; and

(vii) anesthesia used in conjunction with LHR procedures.

(C) shall work under the direct supervision of a senior LHR technician or a LHR professional; and

(D) shall be at least 18 years of age.

(19) Written documentation of completion of the requirements in paragraph (18)(A) - (D) of this subsection shall be submitted with each LHR apprentice-in-training certificate application.

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(20) Training required by paragraph (18)(A) and (B) of this subsection shall be obtained from an agency-accepted training program registered with the agency in accordance with the following.

(A) An agency-accepted training program is defined as a radiation service in accordance with §289.226(b)(10)(D) of this title. A radiation service shall be registered in accordance with §289.226(j) of this title. A training program specified in this paragraph shall meet the requirements of §289.226(a), (j)(1), (j)(2), (j)(3)(C), (k), (l), (m)(1)(A), (m)(4) - (7), (o) - (r), and (t)(1)(A) of this title. For purposes of this section, the responsibilities of a radiation safety officer specified in §289.226(j) of this title may be fulfilled by a LSO.

(B) An application submitted to the agency for an agency-accepted training program shall include the following:

(i) course syllabus, including topics covered and time allotted for each topic;

(ii) qualifications of instructors;

(iii) verification that exam(s) are administered to assess the student's knowledge of material presented;

(iv) the criteria for successful completion of the course;

(v) a copy of the certificate that will be issued upon successful completion of the training program; and

(vi) verification that the training program is in compliance with applicable state laws, including Texas Education Code, Chapter 132.

(21) A physician or other licensed health professional shall not perform the auditing activities of a LHR professional in accordance with paragraph (10)(B) of this subsection unless that individual meets the requirements for a LHR professional specified in paragraph (6) of this subsection. A physician or other licensed health professional shall not perform the direct supervision activities of a LHR professional or senior LHR technician in accordance with paragraph (14)(B) of this subsection unless that individual meets the requirements of paragraph (6) or (10) of this subsection.

(k) Issuance of a certificate of LHR registration and an individual LHR certificate.

(1) A certificate of LHR registration application or individual LHR certificate application will be approved if the agency determines that the application meets the requirements of the Act and this section. A certificate of LHR registration and an individual LHR certificate authorizes the activity in such form and contains such conditions and limitations as the agency deems appropriate or necessary.

(2) The agency may incorporate in the certificate of LHR registration or individual LHR certificate at the time of issuance, or thereafter by amendment, such additional requirements and conditions with respect to the registrant's or individual's possession, use, and transfer of LHR devices 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 LHR devices subject to this section.

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

(l) Specific terms and conditions of certificates of LHR registration and individual LHR certificates.

(1) Each certificate of LHR registration and individual LHR certificate 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 and orders of the agency.

(2) No certificate of LHR registration or individual LHR certificate 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.

(3) Each person registered by the agency for use of LHR devices in accordance with this section shall confine use and possession of the LHR devices to the location and purpose authorized in the certificate of LHR registration. If a LHR facility operator owns multiple LHR facilities, the operator may transfer a LHR device from facility to facility that the operator owns if each facility is registered in accordance with subsection (k) of this section.

(4) In making a determination whether to grant, deny, amend, renew, revoke, suspend, or restrict a certificate of LHR registration or individual LHR certificate, the agency may consider the technical competence and compliance history of an applicant or holder of a certificate of LHR registration or individual LHR certificate. After an opportunity for a hearing, the agency shall deny an application for, an amendment to, or a renewal of a certificate of LHR registration or individual LHR certificate if the applicant's compliance history reveals that at least three agency final enforcement 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 or individual laser hair removal certificate. An exception to this requirement may be made by the agency if it finds that the recurring pattern of conduct does not demonstrate a consistent disregard for the regulatory process because the applicant's overall conduct shows steady and significant improvement.

(m) Responsibilities of a consulting physician.

(1) The consulting physician shall be available for emergency consultation with the facility as appropriate to the circumstances, including, if the physician considers it necessary, an emergency appointment with the client. If the consulting physician is unavailable for an emergency consultation, another designated physician shall be available for the consultation with the facility relating to care for the client. The consulting physician and designated physician shall have a primary practice site located within 75 miles of the LHR facility that the physician has contracted with.

(2) The consulting physician shall conduct audits of the registrant's LHR facility to ensure that operations are being conducted in accordance with the protocols established by the contract specified in subsection (i)(13) of this section. The audits shall be unannounced, shall be conducted at the physical site of the LHR facility, and shall be conducted at least quarterly. The audits may be scheduled in advance if the consulting physician determines that advance notice does not compromise the ability to determine that operations are being conducted in accordance with established protocols. The audits may be conducted by the consulting physician, another designated physician or an advanced practice nurse or physician's assistant acting under the consulting physician's delegated authority. If the audit is conducted by an advanced practice nurse or physician's assistant, the consulting physician shall sign the audit as required by paragraph (3)(D) of this subsection.

(3) The consulting physician shall make records of audits conducted under the terms of the contract. The consulting physician audit records shall be maintained in accordance with subsection (nn) of this section for inspection by the agency. The record of the audit shall include at least the following:

(A) date audit was performed;

(B) name of the LHR facility audited;

(C) assessment of the LHR facility's performance of the protocols established by the written contract; and

(D) signature of the consulting physician and the LHR facility operator.

(4) The consulting physician shall be responsible for reviewing all adverse events and for determining whether such events are reportable in accordance with Title 21, CFR, Part 803.

(5) The protocols required in accordance with subsection (i)(13) of this section shall be:

(A) written instructions agreed upon and signed and dated by the consulting physician and the LHR facility operator;

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(B) maintained at the LHR facility; and

(C) reviewed and signed by the consulting physician and LHR operator at least annually.

(6) The protocols required in accordance with subsection (i)(13) of this section shall include at least the following:

(A) which LHR procedures require a particular level of individual LHR certification;

(B) the circumstances or conditions under which each procedure is to be performed;

(C) specific instructions to be followed for individual LHR certificate holders who are working under direct supervision or who are giving direct supervision;

(D) conditions under which emergency consultation is required;

(E) designated settings, in accordance with the manufacturer's instructions, at which the LHR device can be expected to safely remove hair; and

(F) list of medications taken by the client that should be reported to the consulting physician before LHR services are provided or that, if taken by the client, preclude a LHR procedure from being performed.

(7) The requirements in paragraph (1) of this subsection do not relieve a consulting physician or another health care professional from complying with applicable regulations prescribed by a state or federal agency.

(n) Requirements for LSOs. LSO qualifications shall be submitted to the agency with the application and shall include at least the following:

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

(2) familiarity with and experience in the use of LHR devices; and

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

(o) Responsibilities of LSOs. Specific duties of the LSO include, but are not limited to, the following:

(1) ensuring that users of LHR devices are trained in laser safety;

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

(3) ensuring that maintenance and other practices required for safe operation of the LHR devices are performed;

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

(5) ensuring compliance with the requirements in this section and with protocols specified by the registrant;

(6) ensuring audits required in accordance with subsections (m)(2) and (q)(7) of this section are conducted;

(7) maintaining records as required by this section; and

(8) ensuring that personnel are adequately trained, certified, and complying with this chapter, the conditions of the certificate of LHR registration, and the protocols of the registrant.

(p) Responsibilities of LHR facility registrant.

(1) The registrant shall notify the agency in writing of any changes that would render the information contained in the application for LHR registration or the certificate of LHR registration inaccurate. Notification is required within 30 days of the following:

(A) change in business name of the LHR facility;

(B) change in physical location of the LHR facility;

(C) change in street address where LHR devices will be used;

(D) change in LSO;

(E) loss or change of the LHR facility's LHR professional; or

(F) loss or change of the LHR facility's consulting physician.

(2) The registrant shall comply with the adverse reporting requirements for device user facilities in Title 21, CFR, Part 803 - Medical Device Reporting. Copies of all reports of adverse events submitted in accordance with Title 21, CFR, Part 803 shall be submitted to the agency within 24 hours of their initial submission to the manufacturer, FDA or both as determined by the consulting physician in accordance with subsection (m)(4) of this section.

(3) If the registrant loses the services of the consulting physician, the registrant may use another physician(s) who has been designated in the contract in accordance with subsection (i)(13)(D) of this section. If the registrant loses the services of the consulting physician and the other physician(s) designated in accordance with subsection (i)(13)(D) of this section, the registrant shall immediately cease LHR procedures until the registrant establishes a contractual relationship with a consulting physician as required by subsection (i)(13) of this section.

(4) No person shall make, sell, lease, transfer, or lend laser hair removal devices unless such devices, when properly placed in operation and use, meet the applicable requirements of this section.

(5) Each registrant shall conduct a physical inventory of all LHR devices in its possession at an interval not to exceed 1 year. Records of the inventories shall be made and maintained in accordance with subsection (nn) of this section for inspection by the agency, and shall include:

- (A) LHR device manufacturer's name;
- (B) model and serial number of the LHR device;
- (C) specific location of the LHR device (for example, room number);
- (D) name, title, and signature of the person performing the inventory; and
- (E) date the inventory was performed.

(6) Each registrant shall maintain records of receipt, transfer, and disposal for each LHR device in accordance with subsection (nn) of this section, for inspection by the agency. The records shall include the following information:

- (A) LHR manufacturer's name;
- (B) model and serial number of the LHR device;
- (C) date of the receipt, transfer, or disposal;
- (D) name and address of person LHR devices were received from, transferred to, or disposed of with; and
- (E) name of the individual recording the information.

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

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(A) Each registrant shall notify the agency, in writing, immediately following the filing with the court of a voluntary or involuntary petition for bankruptcy by the registrant or its parent company.

(B) A copy of the petition for bankruptcy, as filed with the court, shall be submitted to the agency along with the written notification.

(8) A LHR facility operator is responsible for maintaining the LHR facility's compliance with the requirements of this Act and the rules of this section relating to LHR devices used for hair removal procedures.

(9) A LHR facility operator shall not claim, advertise, or distribute promotional materials that claim that laser hair removal is free from risk or provides any medical benefit.

(10) A LHR facility operator shall not produce false or misleading advertising regarding the services offered at the facility. An advertisement of services using lasers for hair removal shall be deemed to be false or misleading if it is inaccurate or misleading in any particular regarding representations made or suggested or failure to reveal material facts with respect to consequences which may result from the use of such services.

(q) Operating requirements.

(1) A LHR device used in a LHR facility shall comply with all applicable federal and state laws and regulations. A person who adulterates or misbrands a LHR device under Health and Safety Code, §431.111 or §431.112 violates Health and Safety Code, Chapter 431. The agency may investigate a person accused of adulterating or misbranding a LHR device.

(2) A LHR device used by a LHR facility may be purchased either by a physician (such as the consulting physician or other designated physician for emergencies) or by a LHR facility pursuant to a written prescription or other order of a licensed physician in Texas. A prescription or other order from a licensed physician for the purchase of a LHR device must include at a minimum:

(A) the date of the order's issue;

(B) the name and quantity of the LHR device(s) authorized to be purchased;

(C) the name, address, and telephone number of the registered LHR facility authorized to purchase and own the laser;

(D) the intended use of the device is limited to nonablative laser hair removal;

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(E) the name, address, and telephone number of the physician at the physician's usual place of business, legibly printed or stamped;

(F) a statement that the prescription is valid up to 12 months from the date of issue; and

(G) the signature of the authorizing physician.

(3) A LHR device shall not be used for LHR procedures unless:

(A) the LHR device is approved for laser hair removal or reduction by the FDA for that purpose; and

(B) the LHR device is operated only at the settings expected to safely remove hair, in accordance with the manufacturer's instructions and protocols established by the consulting physician in accordance with subsections (m)(5) and (6) of this section.

(4) Except as provided by paragraph (5) of this subsection, a LHR facility shall have a LHR professional or a licensed health professional present to provide supervision of the LHR procedures performed at the facility during the facility's operating hours.

(5) A LHR facility may continue to perform LHR procedures after the facility's LHR professional leaves the facility or is continuously absent for up to 44 days if a senior LHR technician is present to perform or directly supervise each procedure. Not later than the 45th day after the date the facility's LHR professional leaves or is continuously absent from the facility:

(A) the facility's senior LHR technician shall become certified as a LHR professional in accordance with subsection (j) of this section; or

(B) the facility shall hire a new LHR professional.

(6) A LHR apprentice-in-training shall not perform LHR procedures unless under the direct supervision of a senior LHR technician or a LHR professional. Direct supervision shall include the following:

(A) the physical presence of senior LHR technician or LHR professional at the LHR facility;

(B) the availability of the senior LHR technician or LHR professional to give immediate assistance if required; and

(C) the direct observation by the senior LHR technician or LHR professional of LHR procedures performed by a LHR apprentice-in-training.

(7) The registrant shall ensure that the direct supervision of 100 LHR procedures performed by a LHR technician while obtaining the requirements of subsection (j)(10)(B)(i) of this section is audited by a LHR professional. The audit shall ensure that the requirements of this section, the conditions of the certificate of LHR registration, and protocols are followed by individuals performing LHR procedures.

(8) Individuals 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 be taken when using the LHR device. Each individual receiving the instructions shall document that they have read and understand the instructions. The instructions and the documentation that each individual has read and understands the instructions shall be maintained in accordance with subsection (nn) of this section for inspection by the agency.

(9) A controlled area shall be established within a room in which LHR devices are used. The controlled area shall be posted as required by paragraphs (17) and (18) of this subsection.

(10) Each LHR device shall incorporate a key-actuated or computer-actuated master control. The key shall be removable and the LHR device shall not be operable when the key is removed. When the LHR device is not being prepared for operation or is unattended, the controlled area shall be secured to prevent unauthorized access.

(11) Protective eyewear shall be worn by all individuals using a LHR device or all individual present, including clients, in the room where a LHR device is being used. 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 frame 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 (nn) of this section for inspection by the agency.

(12) The registrant shall secure LHR devices from unauthorized removal.

(13) The registrant shall give each client a written statement outlining the relevant risks associated with LHR procedures, including a warning that failure to use the eye protection provided to the client by the LHR facility may result in damage to the eyes.

(14) Compliance with the written statement requirement specified in paragraph (13) of this subsection does not affect the liability of the LHR facility operator or a manufacturer of a LHR device.

(15) The registrant shall display the certificate of LHR registration issued in accordance with subsection (k) of this section in an open public area of the LHR facility.

(16) Each certified individual shall display the individual LHR certificate issued in accordance with subsection (k) of this section in an open public area of the LHR facility. Copies of an individual's certification document issued by the agency may be made for display in multiple facilities.

(17) The registrant shall post a warning sign in a conspicuous location that is readily visible to a person entering the LHR facility. The warning sign shall meet the following requirements:

(A) be of a size with dimensions at least 8 and 1/2 inches by 11 inches;

(B) contain wording with a font size no smaller than size 26;

(C) contain at least the following wording:

(i) Laser hair removal devices emit electromagnetic radiation that is considered to be an acute hazard to the skin and eyes from direct and scattered radiation. Laser hair removal procedures provide no medical benefit and may result in adverse effects.

(ii) To make a complaint, contact the Department of State Health Services at this toll-free number: 1-888-899-6688.

(18) The LHR controlled area shall be conspicuously posted with signs or labels as 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.

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(19) Signs required by paragraphs (17) and (18) of this subsection shall be clearly visible, legible, and securely attached to the facility.

(20) Records shall be made of each audit conducted as specified in paragraph (7) of this subsection. The records shall be maintained in accordance with subsection (nn) of this section for inspection by the agency. The records shall include, but not be limited to, the following:

- (A) name of the LHR professional;
- (B) name(s) of the individual(s) being audited;
- (C) date of the procedure; and
- (D) evaluation of the items specified in paragraph (7) of this subsection.

(21) Records shall be made of each LHR procedure and maintained in accordance with subsection (nn) of this section for inspection by the agency. Each record shall include, but not be limited to, the following:

- (A) client identification;
- (B) date of the LHR procedure;
- (C) indication that the client was given the notification specified in paragraph (4) of this subsection;
- (D) name of the individual performing the LHR procedure;
- (E) type of individual LHR certificate possessed by the individual performing the LHR procedure;
- (F) name of the senior LHR technician or LHR professional providing direct supervision, if applicable; and
- (G) manufacturer, model number, and serial number of the LHR device and the settings used to perform the procedure.

(22) If a person submits a written request to the registrant for documentation of LHR procedures that an individual performed at the facility to satisfy training requirements specified in subsection (j)(10)(B)(i) or (j)(14)(B)(i) of this section, the registrant shall provide the pertinent procedure record required by paragraph (21) of this subsection to that person.

(r) Continuing education requirements.

(1) Each individual who holds an individual LHR certificate issued by the agency shall obtain continuing education.

(2) The certified individual shall obtain 8 hours of continuing education units to include, but not be limited to, the following:

(A) refresher training in the topics specified in subsection (j)(18)(A) and (B) of this section;

(B) LHR technology updates;

(C) applicable regulatory changes; and

(D) other health and safety related topics.

(3) The continuing education units shall be obtained within the two-year period beginning with the issuance date of the individual LHR certificate and ending with the expiration date specified in the individual LHR certificate. The requirements for continuing education units specified in paragraph (2) of this subsection shall be met for each two-year period for which the individual LHR certificate is renewed. For certificates issued for 1 year in accordance with subsection (t)(1)(A) of this section, 4 hours of continuing education units shall be obtained within the one-year period beginning with the issuance of the individual LHR certificate and ending with the expiration date specified in the individual LHR certificate.

(4) The continuing education units required by this subsection may be obtained by web-based online training or a home-study training program.

(s) General provisions for records.

(1) All records required by this chapter shall be current, accurate, and factual. These records shall be maintained by the registrant in accordance with subsection (nn) of this section for inspection by the agency.

(2) Records are only valid if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated.

(3) Each record required by this chapter shall be legible throughout the specified retention period.

(4) The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period.

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(5) The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period.

(6) The registrant shall maintain adequate safeguards against tampering with and loss of records.

(7) Except as provided by paragraph (8) of this subsection, the registrant or any other person may not disclose a client record required to be kept by the agency.

(8) The registrant or any other person may disclose a client record if:

(A) the client or a person authorized to act on behalf of the client requests the record;

(B) the agency, the Texas Medical Board, a health authority, or an authorized agency requests the record;

(C) the client consents in writing to disclosure of the record to another person;

(D) the client is a victim, witness, or defendant in a criminal proceeding and the record is relevant to that proceeding;

(E) the record is requested in a criminal or civil proceeding by court order or subpoena; or

(F) disclosure is otherwise prohibited by law.

(t) Expiration of certificates of LHR registration and individual LHR certificates.

(1) A certificate of LHR registration or individual LHR certificate issued between the effective date of these rules and August 31, 2011, is valid for:

(A) 1 year and expires on the expiration date specified on the certificate of LHR registration or individual LHR certificate, if the birth year of the applicant (or the birth year of the LHR facility operator if the applicant is not an individual) is an odd number; or

(B) 2 years and expires on the expiration date specified on the certificate of LHR registration or individual LHR certificate, if the birth year of the applicant (or the birth year of the LHR facility operator if the applicant is not an individual) is an even number.

(2) Each certificate of LHR registration or individual LHR certificate issued on or after September 1, 2011, is valid for 2 years and expires on the expiration date specified on the certificate of LHR registration or individual LHR certificate.

(3) Each application for renewal of a certificate of LHR registration or individual LHR certificate shall be accompanied by the renewal fee specified in subsection (ff) of this section. A certificate of LHR registration or individual LHR certificate issued in accordance with paragraph (1)(A) of this subsection shall submit one-half of the appropriate fee as specified in subsection (ff) of this section. A certificate of LHR registration or individual LHR certificate issued in accordance with paragraphs (1)(B) or (2) of this subsection shall submit the full amount of the appropriate fee as specified in subsection (ff) of this section.

(4) If a registrant does not submit an application for renewal of the certificate of LHR registration in accordance with subsection (v) of this section, the registrant shall on or before the expiration date specified in the certificate of LHR registration:

(A) terminate use of all LHR devices; and

(B) submit to the agency a record of the disposition of the LHR devices, and if transferred, to whom the devices were transferred.

(5) Expiration of the certificate of LHR registration does not relieve the registrant of the requirements of this section. Expiration of the individual LHR certificate does not relieve the individual of the requirements of this section.

(u) Termination of certificates of LHR registration. When a registrant decides to terminate all activities involving LHR devices authorized under the certificate of LHR registration, the registrant shall immediately do the following:

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

(2) submit to the agency a record of the disposition of the LHR devices, and if transferred, to whom the devices were transferred.

(v) Renewal of certificate of LHR registration and individual LHR certificates.

(1) An application for renewal of a certificate of LHR registration shall be filed in accordance with subsection (i) of this section. An application for renewal of an individual LHR certificate shall be filed in accordance with subsection (j) of this section.

(2) Written documentation of successful completion of the continuing education requirements in subsection (r) of this subsection shall be submitted with each application for renewal of an individual LHR certificate.

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

(w) Inspections.

(1) The agency may enter public or private property at reasonable times to determine whether, in a matter under the agency's jurisdiction, there is compliance with the Act, the agency's rules, certificate of LHR registration conditions, and orders issued by the agency.

(2) Each registrant shall afford the agency, at all reasonable times, opportunity to inspect LHR devices and the premises and facilities wherein such LHR devices are used or stored.

(3) Each registrant shall make available to the agency for inspection, upon reasonable notice, records made and maintained in accordance with this section.

(4) Inspection of LHR facilities.

(A) Routine inspections by agency personnel will be made no more frequently than every 2 years.

(B) Notwithstanding the inspection intervals specified in subparagraph (A) of this paragraph, the agency may inspect registrants more frequently due to:

(i) the persistence or severity of violations found during an inspection;

(ii) investigation of an incident or complaint concerning the facility;

(iii) a request for an inspection by a worker(s) in accordance with subsection (ll) of this section; or

(iv) a mutual agreement between the agency and registrant.

(x) Training for agency inspectors of LHR devices and facilities. A person who inspects LHR devices and facilities will have training in the design and uses of the devices.

(y) Denial of an application for a LHR certificate or individual LHR.

(1) When the agency contemplates denial of an application for a LHR certificate of registration or individual LHR certificate, the applicant, LHR registrant, or individual LHR certificate holder shall be afforded the opportunity for a hearing. Notice of the denial shall be delivered by personal service or certified mail, addressed to the last known address, to the applicant, LHR registrant, or individual LHR certificate holder.

(2) Any applicant, LHR registrant, or individual LHR certificate holder against whom the agency contemplates an action described in paragraph (1) of this subsection may request a hearing by submitting a written request to the director within 30 days of service of the notice.

(A) The written request for a hearing shall contain the following:

(i) statement requesting a hearing; and

(ii) name and address of the applicant, LHR registrant, or individual LHR certificate holder.

(B) Failure to submit a written request for a hearing within 30 days will render the agency action final.

(z) Compliance procedures for LHR facility registrants, individual LHR certificate holders, and other persons.

(1) A LHR registrant, individual LHR certificate holder, or other person who commits a violation(s) will be issued a notice of violation. The person receiving the notice shall provide the agency with a written statement and supporting documentation. The agency may require responses to notices of violation to be under oath. The written statement and supporting documentation shall be submitted to the agency by the date stated in the notice, describing the following:

(A) steps taken by the person and the results achieved;

(B) corrective steps to be taken to prevent recurrence; and

(C) the date when full compliance was or is expected to be achieved.

(2) The terms and conditions of all certificates of LHR registration and individual LHR certificates shall be subject to amendment or modification. A certificate of LHR registration, or individual LHR certificate may be modified, suspended, or revoked by reason of amendments to the Act, or for violation of the Act, the requirements of this section, a condition of the certificate of LHR registration or individual LHR certificate, or an order of the agency.

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

(A) any material false statement in the application or any statement of fact required in accordance with 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 LHR registration, or individual LHR certificate on an original application;

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

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

(4) Each certificate of LHR registration or individual LHR certificate 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 LHR registration or individual LHR certificate, or on the revocation date stated in the determination, or as otherwise provided by the agency order.

(5) If another state or federal entity takes an action such as modification, revocation, or suspension of the certificate of LHR registration or individual LHR certificate, the agency may take a similar action against the LHR registrant, or certified LHR individual.

(6) When the agency determines that the action provided for in paragraph (9) of this subsection or subsection (bb) of this section is not to be taken immediately, the agency may offer the LHR registrant, or certified LHR individual an opportunity to attend an informal conference to discuss the following with the agency:

(A) methods and schedules for correcting the violation(s); or

(B) methods and schedules for showing compliance with applicable provisions of the Act, the rules, LHR registration or individual LHR certificate conditions, or any orders of the agency.

(7) Notice of any informal conference shall be delivered by personal service, or certified mail, addressed to the last known address. An informal conference is not a prerequisite for the action to be taken in accordance with paragraph (9) of this subsection or subsection (bb) of this section.

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

(9) When the agency contemplates modification, suspension, or revocation of the certificate of LHR registration or individual LHR certificate, the LHR registrant or certified LHR individual shall be afforded the opportunity for a hearing. Notice of the contemplated action, along with a notice of violation, shall be given to the LHR registrant or certified LHR individual by personal service or certified mail, addressed to the last known address.

(10) Any applicant, LHR registrant, or certified LHR individual against whom the agency contemplates an action described in paragraph (9) of this subsection or subsection (bb) of this section may request a hearing by submitting a written request to the director within 30 days of service of the notice.

(A) The written request for a hearing shall contain the following:

(i) statement requesting a hearing; and

(ii) name, address, and identification number of the LHR registrant or certified LHR individual against whom the action is being taken.

(B) Failure to submit a written request for a hearing within 30 days will render the agency action final.

(aa) Violations. A court injunction or agency order may be issued prohibiting any violation of any provision of the Act or any rule or order issued thereunder. Any person who violates any provision of the Act or any rule or order issued thereunder may be subject to civil and/or administrative penalties. A person who intentionally or knowingly violates any provision of the Act or any rule or order issued thereunder may also be guilty of a misdemeanor and upon conviction, may be punished by fine or imprisonment or both, as provided by law.

(bb) Assessment of administrative penalties.

(1) When the agency determines that monetary penalties are appropriate, proposals for assessment of and hearings on administrative penalties shall be made in accordance with the Act, §401.384 and §401.522, applicable provisions of the Administrative Procedure Act, Government Code, Chapter 2001, 1 Texas Administrative Code (TAC) Chapter 155, and applicable sections of the Formal Hearing Procedures, §§1.21, 1.23, 1.25, and 1.27 of this title (relating to the Texas Board of Health).

(2) Assessment of administrative penalties shall be based on the following criteria:

(A) the seriousness of the violation(s);

(B) previous compliance history;

(C) the amount necessary to deter future violations;

(D) efforts to correct the violation; and

(E) any other mitigating or enhancing factors.

(3) Application of administrative penalties. The agency may impose differing levels of penalties for different severity level violations.

(A) Administrative penalties may be imposed for severity level I and II violations. Administrative penalties may be imposed for severity level III, IV, and V violations when they are combined with those of higher severity level(s) or for repeated violations.

(B) The maximum amount for an administrative penalty per violation is \$5,000.

(C) The following table shows the percentages of the maximum amount that may be used by the agency in making adjustments in accordance with subparagraph (D) of this paragraph.

Percentage of Maximum Amount Based on
Severity Level of Violation

Severity Level	Percent of Maximum Amount
I	100
II	80
III	50
IV	15
V	5

(D) Adjustments to the percentages of base amount in the table of subparagraph (C) of this paragraph may be made for the presence or absence of the following factors:

- (i) prompt identification and reporting;
- (ii) corrective action to prevent recurrence;
- (iii) compliance history;
- (iv) prior notice of similar event;
- (v) multiple occurrences; and
- (vi) negligence that resulted in or increased adverse effects.

(4) The department may conduct settlement negotiations.

(cc) Severity levels of violations for LHR registrants, certified LHR individuals, or other persons.

(1) Violations for LHR registrants, certified LHR individuals, or other persons shall be categorized by one of the following severity levels.

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(A) Severity level I are violations that are most significant and may have a significant negative impact on occupational and/or public health and safety or on the environment.

(B) Severity level II are violations that are very significant and may have a negative impact on occupational and/or public health and safety or on the environment.

(C) Severity level III are violations that are significant and which, if not corrected, could threaten occupational and/or public health and safety or the environment.

(D) Severity level IV are violations that are of more than minor significance, but if left uncorrected, could lead to more serious circumstances.

(E) Severity level V are violations that are of minor safety or environmental significance.

(2) Criteria to elevate or reduce severity levels.

(A) Severity levels may be elevated to a higher severity level for the following reasons:

(i) more than one violation resulted from the same underlying cause;

(ii) a violation contributed to or was the consequence of the underlying cause, such as a management breakdown or breakdown in the control of LHR activities;

(iii) a violation occurred multiple times between inspections;

(iv) a violation was willful or grossly negligent;

(v) compliance history; or

(vi) other mitigating factors.

(B) Severity levels may be reduced to a lower level for the following reasons:

(i) the LHR registrant or certified LHR individual identified and corrected the violation prior to the agency inspection;

(ii) the LHR registrant's or certified LHR individual's actions corrected the violation and prevented recurrence; or

(iii) other mitigating factors.

(3) Examples of severity levels. Examples of severity levels are available upon request to the agency.

(dd) Impoundment of a LHR device.

(1) In the event of an emergency, the agency shall have the authority to impound or order the impounding of LHR devices possessed by any person not equipped to observe or failing to observe the provisions of the Act, or any rules, LHR registration or individual certification conditions, or orders issued by the agency. The agency shall submit notice of the action to be published in the *Texas Register* no later than 30 days following the end of the month in which the action was taken.

(2) At the agency's discretion, the impounded LHR devices may be disposed of by:

(A) returning the LHR devices to a properly registered facility operator, who did not cause the emergency, upon proof of LHR facility ownership;

(B) releasing the LHR devices as evidence to police or courts;

(C) returning the LHR devices to a LHR registrant after the emergency is over and any compliance action is settled; or

(D) sale, destruction or other disposition within the agency's authority.

(3) If agency action is necessary to protect the public health and safety, no prior notice need be given the owner or possessor. If agency action is not necessary to protect the public health and safety, the agency will give written notice to the owner and/or the possessor of the impounded LHR device of the intention to dispose of the LHR device. Notice shall be the same as provided in subsection (z)(9) of this section. The owner or possessor shall have 30 days from the date of personal service or mailing to request a hearing in accordance with Government Code, Chapter 2001, 1 TAC Chapter 155, and the Formal Hearing Procedures, §§1.21, 1.23, 1.25, and 1.27 of this title, and in accordance with subsection (z)(10) of this section, concerning the intention of the agency. If no hearing is requested within that period of time, the agency may take the contemplated action, and such action is final.

(4) Upon agency disposition of a LHR device, the agency may notify the owner and/or possessor of any expense the agency may have incurred during the impoundment and/or disposition and request reimbursement. If the amount is not paid within 60 days from the date of notice, the agency may request the Attorney General to file suit against the owner/possessor for the amount requested.

(5) If the agency determines from the facts available to the agency that an impounded LHR device is abandoned, with no reasonable evidence showing its owner or possessor, the agency may make such disposition of the LHR device as it sees fit.

(ee) Emergency orders.

(1) When an emergency exists requiring immediate action to protect the public health or safety or the environment, the agency may, without notice or hearing, issue an order citing the existence of such emergency and require that certain actions be taken as it shall direct to meet the emergency. The agency shall, no later than 30 days following the end of the month in which the action was taken, submit notice of the action for publication in the *Texas Register*. The action taken will remain in full force and effect unless and until modified by subsequent action of the agency.

(2) An emergency order takes effect immediately upon service.

(3) Any person receiving an emergency order shall comply immediately.

(4) The person receiving the order shall be afforded the opportunity for a hearing on an emergency order. Notice of the action, along with a complaint, shall be given to the person by personal service or certified mail, addressed to the last known address. A hearing shall be held on an emergency order if the person receiving the order submits a written request to the director within 30 days of the date of the order.

(A) The hearing shall be held not less than 10 days nor more than 20 days after receipt of the written application for hearing.

(B) At the conclusion of the hearing and after the proposal for decision is made as provided in the Texas Administrative Procedure Act, Texas Government Code, Chapter 2001, the commissioner shall take one of the following actions:

(i) determine that no further action is warranted;

(ii) amend the certificate of LHR registration or individual LHR certification;

(iii) revoke or suspend the certificate of LHR registration, or individual LHR certification;

(iv) rescind the emergency order; or

(v) issue such other order as is appropriate.

(C) The application and hearing shall not delay compliance with the emergency order.

(ff) Fees.

(1) Each application for a certificate of LHR certification shall be accompanied by a nonrefundable fee specified in paragraph (6) of this subsection. Each application for an individual LHR certificate shall be accompanied by a nonrefundable fee specified in paragraph (7) of this subsection.

(2) No application will be accepted for filing or processed prior to payment of the full fee amount specified.

(3) A nonrefundable renewal fee for a certificate of LHR registration, as specified in paragraph (6) of this subsection, shall be paid every 2 years, based on the month listed as the expiration month on the certificate of LHR registration, and shall be paid in full on or before the last day of the expiration month. A nonrefundable renewal fee for an individual LHR certificate, as specified in paragraph (7) of this subsection, shall be paid every 2 years based on the month listed as the expiration month on the certificate, and shall be paid in full on or before the last day of the expiration month.

(4) Fee payments may be made by cash, by check, or by money order made payable to the Department of State Health Services. The payments may be made by personal delivery to the Exchange Building, Radiation Control, Department of State Health Services, 8407 Wall Street, Austin, Texas or to the central office, 1100 West 49th Street, Austin, Texas, or mailed to Radiation Control, Department of State Health Services, Mail Code 2003, P. O. Box 149347, Austin, Texas, 78714-9347.

(5) Renewal payments may be processed through texas.gov or another electronic payment system specified by the agency. For all types of electronic fee payments, the agency will collect additional fees, in amounts determined by texas.gov or the agency, to recover costs associated with electronic payment processing.

(6) The two-year application fee and two-year renewal fee for a certificate of LHR registration is \$1,260.

(7) The two-year application fees and two-year renewal fees for an individual LHR certificate are as follows:

- (A) LHR professional--\$150;
- (B) senior LHR technician--\$100;
- (C) LHR technician--\$70; and
- (D) LHR apprentice-in-training--\$50.

(gg) Reports of stolen, lost, or missing LHR devices.

§289.302(gg)(1)

(1) Each registrant shall report to the agency by telephone a stolen, lost, or missing LHR device within 72 hours after its occurrence becomes known to the registrant.

(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 LHR 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 LHR device involved;

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

(E) procedures or measures that have been taken to prevent the loss or theft of LHR devices in the future.

(3) Subsequent to filing the written report, the registrant shall also report additional substantive information on the loss or theft within 30 days after the registrant learns of such information.

(hh) Posting of notices to workers.

(1) Each laser registrant shall post current copies of the following documents:

(A) the requirements in this section;

(B) the certificate of LHR registration, the individual's LHR certificate of registration, conditions or documents incorporated into the certificate of LHR registration by reference, and amendments thereto;

(C) any notice of violation involving radiological working conditions associated with use of a LHR device issued in accordance with subsection (z)(1) of this section or order issued in accordance with subsection (ee) of this section.

(2) If posting of a document specified in paragraph (1) of this subsection is not practicable, the registrant shall post a notice that describes the document and states where it may be examined.

(3) The following form, Radiation Control (RC) Form 302-1, "Notice to Employees," or an equivalent document containing at least the same wording as RC Form 302-1, shall be posted by each registrant as required by this section.

Department of State Health Services
1100 West 49th Street
P.O. Box 149347
Austin, Texas 78714-9347
Complaint Reports 1-888-899-6688

NOTICE TO EMPLOYEES

The Department of State Health Services has established standards for your protection against radiation hazards, in accordance with the Texas Radiation Control Act, Health and Safety Code, Chapter 401 and 25 Texas Administrative Code (TAC) §289.302.

YOUR EMPLOYER'S RESPONSIBILITY

Your employer is required to-

1. Apply these rules to work involving laser hair removal devices.
2. Post or otherwise make available to you a copy of the Department of State Health Services rules, certificate of laser registration, notices of violations, and protocols that apply to your work, and explain their provisions to you.

YOUR RESPONSIBILITY AS A WORKER

You should familiarize yourself with those provisions of the rules and the protocols that apply to your work. You should observe the rules for your own protection and protection of your co-workers.

WHAT IS COVERED BY THESE RULES

1. Operating requirements for use of laser hair removal devices;
2. Warning signs, client notifications;
3. Options for worker participation regarding agency inspections; and
4. Related matters.

INSPECTIONS

All registered activities are subject to inspection by representatives of the Department of State Health Services. In addition, any worker or representative of the workers who believe that there is or may be a violation of the Texas Radiation Control Act, the rules issued thereunder, or the terms of the employer's registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by sending a notice of the alleged violation to the Department of State Health Services. The request must state the specific grounds for the notice, and must be signed by the worker or the representative of the workers. During inspections, agency inspectors may confer privately with workers, and any worker may bring to the attention of the inspectors any past or present condition that the individual believes contributed to or caused any violation as described above.

POSTING REQUIREMENT

Copies of this notice shall be posted in a sufficient number of places in every establishment where employees are employed in activities registered, in accordance with 25 TAC §289.302 (relating to Registration and Radiation Safety Requirements for Use of Laser Hair Removal Devices), to permit employees to observe a copy on the way to or from their place of employment.

25 TAC §289.302 may be reviewed online, at www.dshs.state.tx.us/radiation/rules.shtm. Our certificate of laser hair removal registration and any associated documents, our protocols, and any "Notice of Violation" or order issued by the agency may be reviewed at the following location:

(4) Documents, notices, or forms posted in accordance with this subsection shall:

(A) contain current information;

(B) appear in a sufficient number of places to permit individuals engaged in work under the certificate of LHR registration to observe them on the way to or from any particular work location to which the document applies;

(C) be conspicuous; and

(D) be replaced if defaced or altered.

(ii) Presence of representatives of LHR registrants and workers during inspection.

(1) Each registrant shall afford to the agency at all reasonable times an opportunity to inspect LHR devices, activities, facilities, premises, and records in accordance with this section.

(2) During an inspection, agency inspectors may consult privately with workers as specified in subsection (jj) of this section. The registrant may accompany agency inspectors during other phases of an inspection.

(3) If, at the time of inspection, an individual has been authorized by the workers to represent them during agency inspections, the registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(4) Each workers' representative shall be routinely engaged in work under control of the registrant.

(5) Different representatives of registrants and workers may accompany inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one registrant's and one workers' representative at a time may accompany the inspectors.

(6) With the approval of the registrant's and the workers' representative, an individual who is not routinely engaged in work under control of the registrant, for example, a consultant to the registrant or to the workers' representative, shall be afforded the opportunity to accompany agency inspectors during the inspection of physical working conditions.

(7) Notwithstanding the other provisions of this section, agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the registrant to enter that area.

(jj) Consultation with workers during inspections.

(1) Agency inspectors may consult privately with workers concerning matters of occupational laser safety and protection and other matters related to applicable provisions of agency regulations and certificates of LHR registration to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(2) During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which that individual has reason to believe may have contributed to or caused any violation of the Act, the requirements in this section, or certificate of LHR registration conditions. Any such notice in writing shall comply with the requirements of subsection (kk)(1) of this section.

(kk) Requests by workers for inspections.

(1) Any worker or representative of workers who believes that a violation of the Act, the requirements of this section, or certificate of LHR registration conditions exists or has occurred in work under a certificate of LHR registration with regard to working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the agency. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the registrant by the agency no later than at the time of inspection. Upon the request of the worker giving such notice, the agency will evaluate whether the worker's name and the name(s) of individual(s) referred to in such copy or on any record published, released, or made available by the agency, may be withheld.

(2) If, upon receipt of such notice, the agency determines that the request meets the requirements set forth in paragraph (1) of this subsection, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections performed in accordance with this section need not be limited to matters referred to in the request.

(3) No registrant, contractor or subcontractor of a registrant shall discharge or in any manner discriminate against any worker because such worker:

(A) has filed any request or instituted or caused to be instituted any proceeding under this section;

(B) has testified or is about to testify in any such proceeding; or

(C) on behalf of that individual or others, has exercised any option afforded by this section.

(II) Inspections not warranted.

(1) If the agency determines, with respect to a request made in accordance with subsection (kk)(1) of this section, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the agency shall notify the requestor in writing of such determination.

(2) If the agency determines that an inspection is not warranted because the procedural requirements of subsection (kk)(1) of this section have not been met, the agency shall notify the requestor in writing of such determination. Such determination shall be without prejudice to the filing of a new request meeting the requirements of subsection (kk)(1) of this section.

(mm) Criteria for certifying entities, certification programs, and examinations.

(1) To be approved by the agency, a certifying entity shall meet the following requirements:

(A) be a non-governmental organization such as a society, association, business, or school that has an interest in or whose members participate in, or have an interest in, the field of laser hair removal;

(B) if a society or association, make its membership available to the general public nationwide that is not restricted because of race, color, religion, age, national origin or disability;

(C) if a society or association, have a certification program open to nonmembers, as well as members;

(D) be an incorporated, nationally recognized entity in good standing, that is involved in setting national standards of practice within its fields of expertise;

(E) have an adequate staff, a viable system for financing its operations, and a policy- and decision-making review board;

(F) have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;

(G) have a committee, whose members can carry out their responsibilities impartially, to review and approve their certification guidelines and procedures, and to advise the organization's staff in implementing the certification program;

(H) have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions;

(I) have written procedures describing all aspects of its certification program, maintain records of the current status of an individual's certification and the administration of its certification program;

(J) have procedures to ensure that certified individuals are provided due process with respect to the administration of a certification program, including the process of becoming certified and any sanctions imposed against certified individuals;

(K) have procedures for proctoring examinations, including qualifications for proctors. These procedures shall ensure that the individuals proctoring each examination are not employed by the same company or corporation (or a wholly-owned subsidiary of such company or corporation) as any of the examinees;

(L) exchange information about certified individuals with the agency and other certifying entities and allow periodic review of its certification program and related records by the agency; and

(M) provide a description to the agency of its procedures for choosing examination sites and for providing an appropriate examination environment.

(2) To be approved by the agency, a certification program shall meet the following requirements:

(A) require applicants for certification to:

(i) receive training in the topics specified in subsection (j)(18) of this section; and

(ii) satisfactorily complete a written examination covering these topics.

(B) require applicants for certification to provide documentation that demonstrates that the applicant has:

(i) received training in the topics specified in subsection (j)(18) of this section; and

(ii) satisfactorily completed a minimum period of on-the-job training.

(C) include procedures to ensure that all examination questions are protected from disclosure;

(D) include procedures for denying an application and revoking, suspending, and reinstating a certificate;

(E) provide a certification period of not less than 3 years nor more than 5 years;

(F) include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and continuing education units as specified in subsection (r) of this section;

(G) provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.

(3) To be approved by the agency, an examination administered or used by a certifying entity shall be designed to test an individual's knowledge and understanding of at least the topics specified in subsection (j)(18) of this section.

(4) Documentation shall be submitted to the agency showing how the certifying entity meets the requirements of paragraphs (1) - (3) of this subsection.

(nn) Time requirements for record keeping. The following are time requirements for record keeping.

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Specific Subsection	Name of Record	Time Interval Required for Record Keeping
(m)(3)	Consulting Physician Audits	3 years
(p)(5)	Inventory	3 years
(p)(6)	Receipt, Transfer, and Disposal	Until termination or expiration of Certificate of LHR Registration
(q)(8)	Instruction to Individuals	3 years
(q)(11)	Protective Eyewear Examination	3 years
(q)(20)	Audits by LHR Professional	3 years
(q)(21)	LHR Procedures Performed	3 years
(hh)	Current Certificate of LHR Registration Current Individual LHR Certificate Current 25 TAC §289.302 Notice of Violation from Last Inspection, if applicable	Until termination or expiration of Certificate of LHR Registration or Individual LHR Certificate