

NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by first submitting to the Secretary of State's Office a Notice of Rulemaking Docket Opening followed by a Notice of Proposed Rulemaking that contains the preamble and the full text of the rules. The Secretary of State's Office publishes each Notice in the next available issue of the *Register* according to the schedule of deadlines for *Register* publication. Under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.), an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for making, amending, or repealing any rule. (A.R.S. §§ 41-1013 and 41-1022)

NOTICE OF PROPOSED RULEMAKING

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

Editor's Note: The following Notice of Proposed Rulemaking was reviewed per Laws 2009, 3rd Special Session, Ch. 7, § 28. (See the text of § 28 on page 708.) The Governor's Office authorized the notice to proceed through the rulemaking process on December 3, 2009.

[R10-42]

PREAMBLE

1. Sections Affected

R12-1-1438
R12-1-1438.01
R12-1-1439

Rulemaking Action

Amend
New Section
Amend

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing Statute: A.R.S. § 30-654(B)(5)

Implementing Statute: A.R.S. §§ 30-651, 30-654, 30-657, 30-671(B), 30-672, 30-673, 30-681, 30-687, 30-688, 30-689, 32-516, 32-3231, 32-3232, 32-3233, and 32-3234

3. A list of all previous notices appearing in the Register addressing the proposed rules:

Notice of Rulemaking Docket Opening: 14 A.A.R. 4112, October 31, 2008

Notice of Rulemaking Docket Opening: 15 A.A.R. 2148, December 25, 2009

4. The name and address of Agency personnel with whom persons may communicate regarding the rule:

Name: Jerry W. Perkins

Address: Radiation Regulatory Agency
4814 S. 40th St.
Phoenix, AZ 85040

Telephone: (602) 255-4845, ext. 272

Fax: (602) 437-0705

E-mail: jperkins@azrra.gov

5. An explanation of the rule, including the Agency's reasons for initiating the rule:

The Arizona State Legislature during the 48th Legislature, 2nd Regular Session enacted Laws 2008, Ch. 232, amending A.R.S. § 32-501; amending A.R.S. Title 32, Chapter 5, Article 2, by adding § 32-516; amending A.R.S. Title 32, Chapter 32 by adding Article 2; relating to cosmetic laser and injection procedures. As a result, the area of change included in this rulemaking contains requirements and terminology used in A.R.S. § 32-516. These changes are to clarify whom is qualified to supervise and perform the cosmetic procedures covered in the registration.

The sited legislation established a requirement for the Agency to certify that laser technicians are properly trained and to maintain a list of such individuals. The Agency, based on experience with other certification programs, anticipates the cost of maintaining such a list will cost \$30.00 per year per certified individual and \$100.00 per year per training facility.

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6. A reference to any study relevant to the rules that the agency reviewed and either proposes to rely on or not to rely on in its evaluation of or justification for the rules, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

None

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

This rulemaking does not change the registration fee facilities pay annually. It does implement a minimal certification fee to cover administrative costs for individuals wishing to be certified as laser technicians and for training programs wishing to be approved by the Agency.

9. The name and address of Agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Jerry W. Perkins
Address: Radiation Regulatory Agency
4814 S. 40th St.
Phoenix, AZ 85040
Telephone: (602) 255-4845 ext. 272
Fax: (602) 437-0705
E-mail: jperkins@azrra.gov

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

An oral proceeding at the Agency will be scheduled for June 3, 2010 at 9:00 a.m. at 4814 S. 40th St., Phoenix, AZ. A person also may submit written comments concerning the proposed rules by submitting them no later than 5:00 p.m., June 3, 2010, to the following person:

Name: Aubrey V. Godwin, Director
Address: Radiation Regulatory Agency
4814 S. 40th St.
Phoenix, AZ 85040
Telephone: (602) 255-4845
Fax: (602) 437-0705

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

The agency shall deposit monies collected pursuant to this subsection in the laser safety fund established by A.R.S. Title 32, Chapter 32, Article 2, § 32-3234.

12. Any material incorporated by reference and its location in the rules:

<u>Rule</u>	<u>Incorporated Material</u>
R12-1-1438	21 CFR 801.109

13. The full text of the rules follows:

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

ARTICLE 14. REGISTRATION OF NONIONIZING RADIATION SOURCES AND STANDARDS FOR PROTECTION AGAINST NONIONIZING RADIATION

Section

R12-1-1438. Hair Removal and Other Cosmetic Procedures Using Laser and Intense Pulsed Light

R12-1-1438.01. Certification and Decertification of Laser Technician and Training Laser Technician

R12-1-1439. ~~Laser and IPL Operator~~ Laser Technician and Laser Safety Training Programs

ARTICLE 14. REGISTRATION OF NONIONIZING RADIATION SOURCES AND STANDARDS FOR PROTECTION AGAINST NONIONIZING RADIATION

R12-1-1438. Hair Removal and Other Cosmetic Procedures Using Laser and Intense Pulsed Light

- A. Registration. A person who seeks to perform hair removal or other cosmetic procedures shall apply for registration of any medical laser or IPL device that is a Class II surgical device, certified as complying with the labeling standards in 21 CFR 801.109, revised April 1, 2003 2010, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency, and available under R12-1-101. This incorporated material contains no future editions or amendments. The applicant shall provide all of the following information to the Agency with the application for registration:
1. Documentation demonstrating that the ~~licensed practitioner~~ health professional is qualified in accordance with ~~this Section A.R.S. § 32-516 or 32-3233, and has 24 hours of didactic training on the subjects listed in Appendix C as well as proof of passage of an Agency approved exam on subjects covered with a minimum grade of 80%;~~
 2. Health professionals that are in practice prior to October 1, 2010 shall provide proof to the Agency of 24 hours of training on the subjects listed in Appendix C;
 - 3.2. Documentation endorsed by the ~~licensed practitioner~~ supervising health professional, acknowledging responsibility for the minimum level of supervision required for hair removal procedures as defined in R12-1-1402 under “indirect supervision”;
 - 4.3. Procedures to ensure that the registrant has a written order from a supervising, ~~licensed practitioner~~ health professional before the application of radiation;
 - 5.4. If authorized ~~under this Section~~, procedures to ensure that, in the absence of a supervising, ~~licensed practitioner~~ health professional, the registrant has established a method for emergency medical care and assumed legal liability for the service rendered by an indirectly-supervised ~~operator~~ certified laser technician; and
 - 6.5. Documentation that the indirectly-supervised ~~operator~~ certified laser technician has participated in the supervised training required by ~~this A.R.S. § 32-516 or 32-3233.~~
- B. Hair Removal Procedures
1. If a registrant is using a medical laser or an IPL device that is a Class II surgical device, certified in accordance with the labeling standards in subsection (A), for hair removal procedures, the registrant shall:
 - a. Ensure that the device is only used by a ~~licensed practitioner~~ health professional or by ~~an operator~~ a certified laser technician who is working under the indirect supervision of a ~~licensed practitioner~~ supervising health professional.
 - b. Ensure that a ~~licensed practitioner~~ health professional purchases or orders the Class II surgical device that will be used for hair removal procedures.
 2. A registrant shall:
 - a. Not permit an individual to use a medical laser or IPL device for hair removal procedures unless the individual:
 - i. Completes an approved ~~operator~~ laser technician didactic training program of at least 40 hours duration. To successfully complete the training program, the individual shall pass a test that consists of ~~a~~ at least 50 multiple choice questions on subjects covered with a minimum grade of 80%. The training program shall be provided by an individual who is a ~~certified laser safety officer or is eligible, through training and experience, to apply for laser safety officer certification~~ health professional, or a certified laser technician with 100 hours of hands-on experience per procedure being taught;
 - ii. Is ~~directly supervised within the room~~ for at least 24 hours ~~of on-the-job~~ on-the-job training, conducted by a licensed practitioner health professional or a certified laser technician as described above; and
 - iii. Performs or assists in at least 10 hair removal procedures. ~~The individual shall obtain this hands-on experience under the direct supervision of a licensed practitioner; and~~
 - iv. Has the supervising health professional or supervising certified laser technician, certify that the training laser technician has completed the training and supervision as described by this Section.
 - b. Ensure that the ~~operator~~ laser technician follows written procedure protocols established by a ~~licensed practitioner~~ supervising health professional; and
 - c. Ensure that the ~~operator~~ laser technician follows any written order, issued by a ~~licensed practitioner~~ health professional, which describes the specific site of hair removal.
 3. A registrant shall maintain a record of each hair removal procedure protocol that is approved and signed by a ~~licensed practitioner~~ supervising health professional, and ensure that each protocol is reviewed by a ~~licensed practitioner~~ supervising health professional, at least annually.
 4. A registrant shall:
 - a. Maintain each procedure protocol onsite, and ensure that the protocol contains instructions for the patient concerning follow-up monitoring; and
 - b. Design each protocol to promote the exercise of professional ~~judgment~~ judgment by the ~~operator~~ laser technician commensurate with the individual’s education, experience, and training. The protocol need not describe the

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exact steps that a qualified ~~operator~~ laser technician should take with respect to a hair removal procedure.

5. A registrant shall require that a ~~licensed practitioner~~ supervising health professional observe the performance of each ~~operator~~ laser technician during actual procedures at intervals that do not exceed six months. The registrant shall maintain a record of the observation for three years from the date of the observation.
6. A registrant shall verify that a ~~licensed practitioner~~ health professional is qualified to perform hair removal procedures by obtaining evidence that the ~~licensed practitioner~~ health professional has received relevant training specified in R12-1-1438(A)(1) and in physics, safety, surgical techniques, pre-operative and post-operative care and can perform these procedures within the relevant scope of practice, as defined by the ~~practitioner's~~ health professional's licensing board.
7. A registrant shall provide radiation safety training to all personnel involved with hair removal procedures, designing each training program so that it matches an individual's involvement in hair removal procedures. The registrant shall maintain records of the training program and make them available to the Agency for three years from the date of the program, during and after the individual's period of employment.

C. Other Cosmetic Procedures

1. If a registrant is using a medical laser or an IPL device that is a Class II surgical device, certified in accordance with the labeling; standards in subsection (A), for other cosmetic procedures, the registrant shall:
 - a. Ensure that the device is only used by a ~~licensed practitioner~~ health professional or by an operator a certified laser technician who is working under the direct supervision of a ~~licensed practitioner~~ supervising health professional; and
 - b. Ensure that a ~~licensed practitioner~~ health professional purchases or orders the Class II surgical device that will be used for other cosmetic procedures.
2. A registrant shall not permit an individual to use a medical laser or IPL device for other cosmetic procedures unless the individual:
 - a. Completes an approved ~~operator~~ laser technician didactic training program of at least 40 hours duration. To successfully complete the training program the individual shall pass a test that consists of at least 50 multiple choice questions on subjects covered with a minimum grade of 80%. The training program shall be provided by an individual who is a ~~certified laser safety officer or is eligible, through training and experience, to apply for laser safety officer certification~~ health professional, or a certified laser technician with 100 hours of hands-on experience per procedure being taught;
 - b. Is ~~directly supervised within the room~~ for at least 24 hours of on-the-job on-the-job training, conducted by a licensed practitioner health professional or a certified laser technician as described above; and
 - c. Performs or assists in at least 10 cosmetic procedures governed by subsection (C), for each type of procedure (for example: spider vein removal, skin rejuvenation, non-ablative skin resurfacing); ~~The individual shall obtain this hands-on experience under the direct supervision of a licensed practitioner.~~
 - d. Has the supervising health professional or supervising certified laser technician, certify that the laser technician has completed the training and supervision as described in this Section.
3. A registrant shall maintain a record of each protocol for a cosmetic procedure governed by subsection (C) that is approved and signed by a ~~licensed practitioner~~ supervising health professional, and ensure that each protocol is reviewed by a ~~licensed practitioner~~ supervising health professional, at least annually. The registrant shall:
 - a. Maintain each protocol onsite, and ensure that the protocol contains instructions for the patient concerning follow-up monitoring; and
 - b. Design each protocol to promote the exercise of professional ~~judgement~~ judgment by the ~~operator~~ laser technician commensurate with the individual's education, experience, and training. The protocol need not describe the exact steps that a qualified ~~operator~~ laser technician should take with respect to a cosmetic procedure governed by subsection (C).
4. A registrant shall verify that a ~~licensed practitioner~~ health professional is qualified to perform laser, IPL, and related procedures, by obtaining evidence that the ~~licensed practitioner~~ health professional has received relevant training specified in R12-1-1438(A)(1) and in physics, safety, surgical techniques, pre-operative and post-operative care and can perform these procedures within the relevant scope of practice, as defined by the ~~practitioner~~ health professional's licensing board.
5. A registrant shall provide radiation safety training to all personnel involved with cosmetic procedures governed by subsection (C), designing each training program so that it matches an individual's involvement in each procedure. The registrant shall maintain records of the training program and make them available to the Agency for three years from the date of the program, during and after the individual's period of employment.

D. Persons governed by this Section shall also comply with other applicable licensing and safety laws.

E. Lasers shall be secured such that the laser cannot be removed from the facility and the on/off switch turned to the "off" position with the key removed when a certified laser technician or a health professional is not present in the room where the laser is located.

R12-1-1438.01. Certification and Decertification of Laser Technician and Training Laser Technician

- A.** An applicant for a laser technician certificate shall submit a completed application and certification that the applicant has received the training specified in A.R.S. § 32-516(A) or 32-3233(E).
- B.** Pay a nonrefundable fee of \$30.00. Duplicate certifications may be requested at the time of initial application or renewal at a fee of \$10.00 per certificate. Duplicate or replacement certificates applied for at other times shall pay \$20.00 per certificate.
- C.** Initial certificates shall be issued for 12 months and shall expire on the last day of the month. A renewal application shall be accompanied by a renewal fee of \$30.00 each year in addition to \$10.00 per duplicate certificate requested.
- D.** A certified laser technician may be suspended, revoked or otherwise disciplined as the individual's aesthetician or cosmetology license is suspended, revoked or otherwise disciplined or if an individual falsifies documentation related to training, prescriptions, or other required documentation. In addition, as provided for in Article 12 of these regulations the Agency may assess civil penalties, suspend, revoke, deny, or put on probation a certified laser technician.
- E.** A laser technician that has been using laser and IPL devices prior to the effective date of this Section may continue to do so if the technician applies for and receives a certificate from the Agency before October 1, 2010.
- F.** Certification may be issued in one or more of the following procedures:
 - 1. Hair Removal.
 - 2. Skin Rejuvenation.
 - 3. Non-Ablative Skin resurfacing.
 - 4. Spider Vein Removal.
 - 5. Skin Tightening.
 - 6. Wrinkle Reduction.
 - 7. Wart Removal.
 - 8. Laser Peel.
 - 9. Vascular Lesions.
 - 10. Pigmented Lesion Removal.
 - 11. Acne/Acne Scar Removal.
 - 12. Photo Facial, or
 - 13. Additional Procedures as approved by the Agency after consultation with other health professional boards as defined in A.R.S. § 32-516(F)(3) or 32-3233(D)(1).
- G.** For any application relating to the certification of laser technicians, as defined in A.R.S. § 41-1072, there is an administrative completeness review time-frame of 30 days and a substantive review time-frame of 30 days with an overall time-frame of 60 days.
- H.** Certified Laser Technicians shall display a valid original certificate as issued by the Agency in a location that would reasonably be viewable by the public.

R12-1-1439. Laser and IPL ~~Operator~~ Laser Technician and Laser Safety Training Programs

- A.** A person seeking to initiate a medical laser or IPL ~~operator~~ laser technician training program shall submit an application to the Agency for approval that contains a description of the training program. In addition, the person shall submit a syllabus and a test that consists of at least 50 multiple choice questions on subjects covered. In the program materials, the person shall address the subjects in ~~R12-1-1421~~ R12-1-1438 through R12-1-1444 R12-1-1439, Appendix C, and Appendix D, with emphasis on personnel and public safety.
- B.** The Agency shall review the application and other documents required by subsection (A) in a timely manner according to R12-1-1223.
- C.** The Agency shall maintain a list of approved laser or IPL training programs.
- D.** Applicants for registration as an approved laser or IPL training program shall pay a nonrefundable \$100.00 fee.
- E.** Initial registrations shall be issued for 12 months and shall expire on the last day of the month. A renewal application shall be accompanied by a renewal fee of \$100.00 each year.
- F.** A person seeking to initiate a medical laser or IPL laser technician safety training program shall submit an application to the Agency for approval that contains a description of the training program. In addition, the person shall submit a syllabus and a test that consists of at least 50 multiple choice questions on subjects covered. In the program materials, the person shall address the subjects in R12-1-1421 through R12-1-1444, Appendix C, and Appendix D, with emphasis on personal and public safety. The program also shall contain the requirements of A.R.S. § 32-3233(E) or clearly state which parts are not provided or met if didactic certification is to take place in another program. The applicant shall conduct training in accordance with the program submitted to the Agency and approved by the Agency.