

Radiation Regulatory Agency

1. Marked with a label that indicates the optical density protection afforded for the relevant laser wavelength;
 2. Maintained so that the protective properties of the eyewear are preserved;
 3. Inspected at intervals that do not exceed six months to ensure integrity of the protective properties; and
 4. Removed from service if the protective properties of the eyewear fall below the optical density on the label.
- C. A registrant shall maintain records of protective eyewear maintenance, inspection, and removal from service for five years.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Section heading amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1436. Reporting Laser Incidents

- A. A registrant shall notify the Agency by telephone within 24 hours of any incident that has caused or may have caused:
1. Permanent loss of sight in either eye; or
 2. Third-degree burns of the skin involving more than 5 percent of the body surface as estimated by the rule of nines.
- B. A registrant shall notify the Agency by telephone within five working days of any incident that has or may have caused:
1. Any second-degree burn of the skin larger than one inch (2.54 centimeter) in greatest diameter; or
 2. Any third-degree burn of the skin; or
 3. An eye injury with any potential loss of sight.
- C. Each registrant shall file a written report with the Agency of any known exposure of an individual to laser radiation or collateral radiation within 30 days of its discovery, describing:
1. Each exposure of the individual to laser or collateral radiation that exceeds the applicable MPE; and
 2. Any incident that triggered a notice requirement in subsections (A) or (B).
- D. Each report required by subsection (C) shall describe the extent of exposure to each individual including:
1. An estimate of the individual's exposure;
 2. The level of laser or collateral radiation involved;
 3. The cause of the exposure; and
 4. The corrective steps taken or planned to prevent a recurrence.
- E. A registrant shall not operate or permit the operation of any laser product or system that does not meet the applicable requirements in this Article.

Editor's Note: The tables referenced in subsection (A) were repealed effective January 2, 1996.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1); the tables previously referenced in subsection (A) were repealed effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1437. Special Lasers

A registrant operating a laser system with an unenclosed beam path shall:

1. Conduct an evaluation before operating the laser to determine the expected beam path and the potential hazards from reflective surfaces. Based on the evaluation the registrant shall exclude reflective surfaces from the beam path at all points where the laser radiation exceeds an applicable MPE;

2. Evaluate the stability of the laser platform to determine the constraints placed upon the beam traverse and the extent of the range of control; and
3. Refrain from operating or making a laser ready for operation until the area along all points of the beam path, where the laser radiation will exceed the applicable MPE, is clear of individuals, unless the individuals are wearing the correct protective devices.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

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

- A. Registration. A person who seeks to perform hair reduction 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, 2010, incorporated by reference, 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 health professional is qualified in accordance with A.R.S. § 32-516 or 32-3233, has 24 hours of didactic training on the subjects listed in Appendix C, and has passed an Agency-approved exam on subjects covered with a minimum grade of 80%;
 2. For any health professional in practice prior to October 1, 2010, proof of 24 hours of training on the subjects listed in Appendix C;
 3. Documentation endorsed by the prescribing health professional, acknowledging responsibility for the minimum level of supervision required for hair reduction procedures as defined in R12-1-1402 under "indirect supervision";
 4. Procedures to ensure that the registrant has a written order from a prescribing health professional before the application of radiation;
 5. If authorized, procedures to ensure that, in the absence of a prescribing health professional at the facility, the registrant has established a method for emergency medical care and assumed legal liability for the service rendered by an indirectly-supervised certified laser technician; and
 6. Documentation that the indirectly-supervised certified laser technician has participated in the supervised training required by A.R.S. § 32-516 or 32-3233.
- B. Hair Reduction 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 reduction procedures, the registrant shall:
 - a. Ensure that the device is only used by a health professional described in A.R.S. §§ 32-516(F)(3) and 32-3233(D)(1) or by a certified laser technician who is working under the indirect supervision of a health professional described in A.R.S. §§ 32-516(C)(1) and 32-3233(D) and (H)(1), and
 - b. Ensure that a prescribing health professional purchases or orders the Class II surgical device that will be used for hair reduction procedures.
 2. A registrant shall:

- a. Not permit an individual to use a medical laser or IPL device for hair reduction procedures unless the individual:
 - i. Completes an approved 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 health professional acting within the health professional's scope of practice, or a certified laser technician with a minimum of 100 hours of hands-on experience per procedure being taught;
 - ii. Is present in the room for at least 24 hours of hands-on training, conducted by a health professional or a certified laser technician as described in subsection (B)(2)(a)(i);
 - iii. Performs or assists in at least 10 hair reduction procedures; and
 - iv. Has the qualified health professional or qualified supervising certified laser technician certify that the laser technician has completed the training and supervision as described in subsection (B)(2)(a).
 - b. Ensure that the laser technician follows written procedure protocols established by a prescribing health professional; and
 - c. Ensure that the laser technician follows any written order, issued by a prescribing health professional, which describes the specific site of hair reduction.
3. A registrant shall maintain a record of each hair reduction procedure protocol that is approved and signed by a prescribing health professional, and ensure that each protocol is reviewed by a prescribing 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 by the laser technician commensurate with the individual's education, experience, and training. The protocol need not describe the exact steps that a qualified laser technician should take with respect to a hair reduction procedure.
 5. A registrant shall require that a prescribing health professional observe the performance of each laser technician during 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 health professional is qualified to perform hair reduction procedures by obtaining evidence that the health professional has received relevant training specified in subsection (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 health professional's licensing board.
 7. A registrant shall provide radiation safety training to all personnel involved with hair reduction procedures, designing each training program so that it matches an individual's involvement in hair reduction 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 health professional described in A.R.S. §§ 32-516(F)(3) and 32-3233(D)(1) or by a certified laser technician who is directly supervised by a health professional as described in A.R.S. §§ 32-516(C)(2) and 32-3233(D) and (H)(2); and
 - b. Ensure that a prescribing 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 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 health professional acting within the health professional's scope of practice, or a certified laser technician with a minimum of 100 hours of hands-on experience per procedure being taught;
 - b. Is present in the room for at least 24 hours of hands-on training, conducted by a health professional or a certified laser technician as described in subsection (C)(2)(a); and
 - c. Performs or assists in at least 10 cosmetic procedures governed by subsection (C), for each type of procedure (for example: spider vein reduction, skin rejuvenation, non-ablative skin resurfacing); and
 - d. Has the qualified health professional or qualified supervising certified laser technician certify that the laser technician has completed the training and supervision as described in subsection (C)(2).
 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 prescribing health professional, and ensure that each protocol is reviewed by a prescribing 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 judgment by the laser technician commensurate with the individual's education, experience, and training. The protocol need not describe the exact steps that a qualified laser technician should take with respect to a cosmetic procedure governed by subsection (C).
 4. A registrant shall verify that a health professional is qualified to perform laser, IPL, and related procedures, by obtaining evidence that the health professional has received relevant training specified in subsection (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 health professional's licensing board.

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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.** A laser shall be secured so that the laser cannot be removed from the facility and the on/off switch is 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.
9. Acquired Adult Hemangioma Reduction,
 10. Facial Erythema Reduction,
 11. Solar Lentigo Reduction (Age Spots),
 12. Ephelis Reduction (Freckles),
 13. Acne Scar Reduction,
 14. Photo Facial, or
 15. 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 described 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 is viewable by the public.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Repealed effective January 2, 1996 (Supp. 96-1). New Section made by final rulemaking at 11 A.A.R. 978, effective April 3, 2005 (05-1). Amended by final rulemaking at 16 A.A.R. 1703, effective August 10, 2010; Manifest typographical errors corrected at the request of the Agency, filed August 31, 2010, file no. M10-342 (Supp. 10-3).

R12-1-1438.01. Certification and Revocation of Laser Technician Certificate

- 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.** The applicant shall pay a nonrefundable fee of \$30.00. A duplicate certificate may be requested at the time of initial application or renewal at a fee of \$10.00 per certificate. To obtain a duplicate certificate at other times a laser technician shall pay \$20.00 per certificate.
- C.** Initial certificates are issued for 12 months and 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.** Under A.R.S. § 32-3233(I) and (J), the Agency may take appropriate disciplinary action, including revocation of the certificate of a certified laser technician. The Agency may discipline a certified laser technician who has had a relevant professional license suspended or revoked, or been otherwise disciplined by a health professional board or the Board of Cosmetology. The Agency may also discipline the certified laser technician for falsifying documentation related to training, prescriptions, or other required documentation. As provided in Article 12 of this Chapter, the Agency may assess civil penalties, suspend, revoke, deny, or put on probation a certified laser technician.
- E.** A laser technician who has been using laser and IPL devices prior to November 24, 2009 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 for one or more of the following procedures:
1. Hair Reduction,
 2. Skin Rejuvenation,
 3. Non-Ablative Skin Resurfacing,
 4. Spider Vein Reduction,
 5. Skin Tightening,
 6. Wrinkle Reduction,
 7. Laser Peel,
 8. Telangiectasia Reduction,

Historical Note

New Section made by final rulemaking at 16 A.A.R. 1703, effective August 10, 2010 (Supp. 10-3).

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

- A.** A person seeking to initiate a medical laser or IPL laser technician training program shall submit an application to the Agency for certification 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 R12-1-1438 through this Section, and Appendix C.
- B.** The Agency shall review the application and other documents required by subsections (A) and (E) in a timely manner, using an administrative completeness review time-frame of 40 days and a substantive review time-frame of 20 days with an overall time-frame of 60 days.
- C.** The Agency shall maintain a list of certified laser or IPL training programs.
- D.** Applicants for approval as a certified laser or IPL training program shall pay a nonrefundable \$100.00 fee.
- E.** Initial certification 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 certification 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 shall also contain the training required by A.R.S. § 32-3233(E) or clearly state the portions of the training that 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 certified by the Agency.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1). Section repealed; new Section made by final rulemaking at 11 A.A.R. 978, effective April 3, 2005 (Supp. 05-1). Amended by final rulemaking at 16 A.A.R. 1703, effective August 10, 2010 (Supp. 10-3).

R12-1-1440. Medical Lasers

- A.** A registrant shall ensure that a Class 3 and Class 4 laser product used in the practice of medicine has a means for measuring the level of laser radiation with an error in measurement of no greater than +20%, when calibrated in accordance with the laser product manufacturer's calibration procedure.
- B.** A registrant shall calibrate a laser used in the practice of medicine according to the manufacturer's specified calibration procedure, at intervals that do not exceed those specified by the manufacturer.
- C.** In a medical facility where several medical disciplines or a number of different practitioners use Class 3b and Class 4 lasers, a registrant shall form a Laser Safety Committee to govern laser activity, establish use criteria, and approve operating procedures, as follows:
1. With regard to membership of the committee the registrant shall include at least one representative of the Nursing staff, the LSO, one management representative, and one representative of each medical discipline that uses the lasers;
 2. The committee shall review actions by the LSO related to hazard evaluation and the monitoring and control of laser hazards; and
 3. The committee shall approve or deny requests by potential operators and ancillary personnel to operate or assist in the operation of a laser under the direction of a licensed practitioner.
- D.** A registrant shall use Class 3b and Class 4 Lasers that have a guard mechanism on the switch to control patient exposure and prevent inadvertent exposure.
- E.** A registrant shall establish a written laser safety training program that provides a thorough understanding of established procedures for each type of laser in use and the medical procedures associated with use of the laser. The registrant shall make program documentation available for Agency review and, at minimum, address all of the following in the documentation:
1. Regulatory requirements and the laser classification system;
 2. Fundamentals of laser operation and the significance of specular and diffuse reflections;
 3. Biological effects of laser radiation on the eye and skin;
 4. Non-beam hazards (for example: electrical, chemical, and reaction by-product hazards) and ionizing radiation hazards (for example: x-rays from power sources and target interactions, if applicable) of lasers; and
 5. Responsibilities of management and employees regarding control measures.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1). Section repealed; new Section made by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1441. Laser Light Shows and Demonstrations

- A.** Before a conducting laser light show or laser demonstration, a registrant shall provide documentation to the Agency that a variance from 21 CFR 1040.10 has been obtained from the FDA.
- B.** A registrant shall notify the Agency in writing, at least three working days in before a proposed laser light show or demonstration, and include all of the following information:
1. The location, time, and date of the light show or demonstration;
 2. Sketches showing the locations of each laser, operator, performer, laser beam path, viewing screen, wall, mirror

- ball, or any other reflective or diffuse surface that could be hit by or reflect the laser beam;
3. Scanning beam patterns, scan velocity, and frequency in occupied areas; and
 4. Physical surveys and calculations made to comply with this Article.
- C.** A registrant shall supply any additional information required by the Agency for the safety evaluation of the proposed activity.
- D.** Before an outdoor laser light show, a registrant shall notify the Federal Aviation Administration of the proposed show.
- E.** If a light show or demonstration involves laser radiation emissions outside the spectral range of 400 to 700 nanometers, a registrant shall prevent the emissions from exceeding the applicable Class 1 accessible emission limit.
- F.** If it is likely that an audience member or any operator, performer, or employee will view laser or collateral radiation, a registrant shall prevent the radiation from exceeding the applicable Class 1 accessible emission limit.
- G.** Even if it is unlikely that an individual, including any operator, performer, or employee in the vicinity of a laser light show or demonstration will view or be exposed to laser or collateral radiation, a registrant shall prevent the radiation from exceeding the applicable Class 2 accessible emission limit.
- H.** A registrant shall identify any area where levels of laser radiation exceed the applicable Class 2 accessible emission limit by posting warning signs and using barriers or guards to prevent entry.
- I.** If a registrant uses a scanning device, the registrant shall not use a device which, as a result of scan failure or any other failure, can change its angular velocity or amplitude, permitting audience exposure to laser radiation that exceeds the applicable Class 1 accessible emission limit.
- J.** If a mirror ball is used with a scanning laser, a registrant shall meet the requirements of subsections (F) and (G) when the mirror ball is stationary or during any failure mode that results in a change in the rotational speed of the mirror ball.
- K.** A registrant shall ensure that an operator is at all times directly and personally supervising a laser light show or demonstration, except in cases where the maximum laser power output level is less than 5 milliwatts (all spectral lines) and the laser beam path is located at all times at least 6 meters above any surface upon which an individual in the audience is permitted to stand, and at any point, more than 2.5 meters in lateral separation from any position where an individual in the audience is permitted during the performance.
- L.** A registrant shall prevent laser radiation levels from exceeding the applicable Class 2 accessible emission limit at any point less than three meters above any surface upon which an individual in the audience is permitted to stand and 2.5 meters in lateral separation from any position where an individual in the audience is permitted, unless physical barriers are present that prevent human access to the radiation.
- M.** A registrant shall limit the maximum power output of any laser to a level sufficient to produce the desired effect.
- N.** If a registrant is required to limit output power to a level less than the available power to meet the requirements of this Article, the registrant shall adjust, measure, and record the laser output power before the laser light show or demonstration.
- O.** A registrant shall functionally test and evaluate all safety devices and procedures necessary to comply with this Article after setup, and before a laser light show or demonstration.
- P.** A registrant shall secure a laser system, when not in use, against unauthorized operation or tampering
- Q.** A registrant shall perform laser alignment procedures with the laser output power reduced to the lowest practicable level, and