

NOTICES OF SUPPLEMENTAL PROPOSED RULEMAKING

After an agency has filed a Notice of Proposed Rulemaking with the Secretary of State's Office for *Register* publication and the agency decides to make substantial changes to the rule after it is proposed, the agency must prepare a Notice of Supplemental Proposed Rulemaking for submission to the Office, and the Secretary of State shall publish the Notice under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.). Publication of the Notice of Supplemental Proposed Rulemaking shall appear in the *Register* before holding any oral proceedings (A.R.S. § 41-1022).

NOTICE OF SUPPLEMENTAL PROPOSED RULEMAKING

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

PREAMBLE

1. Register citation and date for the original Notice of Proposed Rulemaking:

Notice of Proposed Rulemaking: 7 A.A.R. 5585, December 21, 2001

2. Sections Affected

Rulemaking Action

R12-1-209	Repeal
R12-1-209	New Section
R12-1-1401	New Section
R12-1-1402	Amend
R12-1-1403	Amend
R12-1-1404	Amend
R12-1-1405	Amend
R12-2-1406	Amend
R12-1-1407	Amend
R12-1-1408	Amend
R12-1-1409	Amend
R12-1-1410	Amend
R12-1-1411	Repeal
R12-1-1412	Amend
R12-1-1413	Amend
R12-1-1414	Amend
R12-1-1415	Amend
R12-1-1416	Amend
R12-1-1417	Repeal
R12-1-1418	New Section
R12-1-1421	Amend
R12-1-1422	Amend
R12-1-1423	Amend
R12-1-1425	Amend
R12-1-1426	Amend
R12-1-1427	Amend
R12-1-1429	Amend
R12-1-1433	Amend
R12-1-1434	Amend
R12-1-1435	Amend
R12-1-1436	Amend
R12-1-1437	Amend
R12-1-1438	New Section
R12-1-1439	Repeal
R12-1-1439	New Section
R12-1-1440	Repeal
R12-1-1440	New Section
R12-1-1441	Repeal
R12-1-1441	New Section
R12-1-1442	New Section
R12-1-1443	Amend
R12-1-1444	Amend

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Appendix A	Amend
Appendix B	New Section
Appendix C	New Section

3. The specific 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)

Implementing statutes: A.R.S. §§ 30-657, 30-671(B), 30-672, and 30-673

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

Name: Daniel H. Kuhl
Address: Arizona Radiation Regulatory Agency
4814 S. 40th Street
Phoenix, AZ 85040
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E-mail: dkuhl@arra.state.az.us

5. An explanation of the rules, including the agency's reasons for initiating the rules:

Introductory Statement: The purpose of this supplemental rule proposal is to establish training standards for operators of lasers and Intense-pulsed light (IPL) devices used for medical cosmetic procedures. Other changes are described in this proposal and in 7 A.A.R. 5585, December 21, 2001.

R12-1-209: This description of R12-1-209 is a repeat of a previous listing as noted above.

Licensing requirements for devices or equipment that produce nonionizing radiation are being moved to Article 14, where the devices are regulated. Article 2 returns to its original format which was the registration of devices or equipment that produce ionizing radiation. Additionally, the notification requirements in this Article are being combined into a single rule, R12-1-209, for clarification purposes.

Article 14: This description of the proposed rule changes in Article 14 is a repeat of the listing as noted above, with the exception of the change noted in the introductory paragraph. The new registration requirements, formerly licensing requirements, in R12-1-1401 are moved from Article 2, in an attempt to consolidate all of the nonionizing requirements in a single Article and to separate nonionizing regulations from ionizing regulations. With the separation it is believed that the use of "registration" rather than "license" better describes the regulatory process that is used to record the possession of nonionizing devices.

The definitions in R12-1-1402 are updated to correspond with current Federal standards. Definitions are added that will be helpful in understanding the training requirements for laser and IPL users.

A number of new requirements are added R12-1-1413, R12-1-1414, and R12-1-1415 to keep Arizona abreast of the most current tanning standards. Because of the potential hazard associated with laser and IPL devices, Class II and III medical devices that can be used medical cosmetic procedures, the Agency is proposing new rules regulating their use in R12-1-1438 and R12-1-1439, rather than R12-1-1417 as was listed in 7 A.A.R. 5585, December 21, 2001. The rules regulating the use of high intensity mercury lamps are moved to R12-1-1418. R12-1-1433 is rewritten to include the latest laser standards. Also, the rule is reorganized to more easily access this rule's requirements. The rules formerly in R12-1-1439 are moving to R12-1-1440; the rules formerly in R12-1-1440 are moving to R12-1-1441; the rules formerly in R12-1-1441 are moving to R12-1-1442. These changes are made to accommodate the new training rules regulating medical uses of lasers and IPLs, previously described. The new Class IIIa laser lighting and entertainment products used for commercial purposes will move to R12-1-1441 with this change. Because of the public hazard associated with their misuse, it is believed this rule is needed. The outdated laser classification measurements that are currently listed in R12-1-1444 will be replaced with an incorporated reference to the current federal standards. Many of the rules contained in Article 14 are being amended so that they will contain current language and format. Application information needed to register a nonionizing radiation producing machine will be listed in a new Appendix B. A new Appendix C will list the essential material for an acceptable training program for laser/IPL users.

6. An explanation of the substantial change which resulted in this supplemental notice:

As a result of comments received during the public hearing held for the original proposed rules, the Agency changed "direct supervision" of operators by a licensed practitioner, using a laser or IPL medical cosmetic procedures, to "indirect supervision." The change was made because of the hardship placed on many of the current operators, who at

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this time are not required to be supervised by a licensed practitioner and the relatively minor hazard associated with the operation of these Class II surgical devices. Additional comments were made concerning the qualifications of operators not being directly supervised. Therefore, the Agency, with the aid of the regulated community and other interested state agencies, developed training criteria for operators. (It should be noted that federal law requires that these devices only be sold to licensed practitioners.)

The new rules were originally located in R12-1-1417 and R12-1-1439. Definitions were added to R12-1-1402 to aid in the understanding of the new rules. This supplemental package removes R12-1-1417 and any reference to photo-thermolysis, and training requirements for laser users in R12-1-1439. New standards for operation of lasers and IPL's used for medical cosmetic procedures are proposed as a new rule, R12-1-1438 and requirements that must be met by anyone wishing to train operators are added. Standards for Agency approved training programs relisted in a new rule, R12-1-1439. Included in the change, an Appendix C is added. It lists the standards for an operator training program. With the changes noted above, rules originally located in R12-1-1439 through R12-1-1441 increase by one rule number so that R12-1-1441 will be R12-1-1442.

7. A showing of good cause why the rules are necessary to promote a statewide interest if the rules 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:

The changes proposed for Article 2 should not pose a financial burden on radiation-producing machine users. The changes are made in an attempt to reorganize and at the same time clarify the requirements associated with registration of ionizing radiation producing machines.

Article 14 has undergone the most extensive review and associated proposed changes. Many laser and tanning facility requirements are being incorporated from the most current Federal standards. These changes may present some increase in operating cost, if a user has not made an effort to stay abreast of industry safety. The actual cost associated with staying abreast of the new standards is unknown, however, it is believed to be minimal when compared to the cost of the machines that produce the nonionizing radiation. As stated above, new requirements for supervision and training for laser systems and IPL's used for medical cosmetic procedures are newly proposed at this time. The annual cost to register a system will be \$40. It is estimated that there are less than 25 users of IPL systems in the state at this time, affected by the new rules. The number of affected laser users is unknown. It is estimated that a training program for lasers and IPL's, used for medical cosmetic procedures will range from \$750 to \$2000. Lastly, with the addition of Class IIIa laser lighting and commercial entertainment products to R12-1-1441, a \$350 registration fee will be assessed because of the public hazard associated with their misuse.

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:

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Address: Arizona Radiation Regulatory Agency
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Phoenix, AZ 85040
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E-mail: dkuhl@arra.state.az.us

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

An oral proceeding at the Agency is scheduled for Thursday, September 25, 2003, at 9:00 a.m. A person may submit written comments concerning the proposed rules by submitting them no later than 5:00 p.m., September 25, 2003, to the following person:

Name: Aubrey V. Godwin, Director
Address: Arizona Radiation Regulatory Agency
4814 S. 40th Street
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:

Not applicable

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12. Incorporations by reference and their location in the rules:

<u>Rule</u>	<u>Incorporation</u>
R12-1-1402(B)	21 CFR 1040(10), there are 5 listings in this rule
R12-1-1402(B)	ANSI Z136-1, <i>American Standard for the Safe Use of Lasers</i>
R12-1-1402(C)	21 CFR 1040(30)(d)
R12-1-1404(A)	IEEE C95.1-1999, Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields
R12-1-1405(A)	IEEE C95.1-1999, Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields
R12-1-1407(F)	21 CFR 1040(30)
R12-1-1413(A)	21 CFR 1040(20)
R12-1-1413(D)	21 CFR 1040(10)
R12-1-1422(C)	21CFR 1040(10)
R12-1-1425(A)	21 CFR 1040(10)
R12-1-1425(B)	21 CFR 1040(10)
R12-1-1426(A)	ANSI Z136.1, <i>American Standard for the Safe Use of Lasers</i>
R12-1-1426(A)	21CFR 1040(10)
R12-1-1426(B)	ANSI Z136.1, <i>American Standard for the Safe Use of Lasers</i>
R12-1-1426(C)	ANSI Z136.1, <i>American Standard for the Safe Use of Lasers</i>
R12-1-1426(D)	ANSI Z136.1, <i>American Standard for the Safe Use of Lasers</i>
R12-1-1426(E)	21 CFR 1040(10)
R12-1-1427(A)	ANSI Z136.1, <i>American Standard for the Safe Use of Lasers</i>
R12-1-1429	ANSI Z136.1, <i>American Standard for the Safe Use of Lasers</i>
R12-1-1441(A)	21 CFR 1040(10)
R12-1-1441(R)	21 CFR 1040(10)
R12-1-1442	ANSI Z136.1, <i>American Standard for the Safe Use of Lasers</i>
R12-1-1444(B)	21 CFR 1040(10)

13. The full text of the rules follows:

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

**~~ARTICLE 2. RADIATION MACHINE FACILITY REGISTRATION OR LICENSING, INSTALLATION AND SERVICE REGISTRATION, AND MAMMOGRAPHIC FACILITY CERTIFICATION~~
REGISTRATION, INSTALLATION, AND SERVICE OF IONIZING RADIATION PRODUCING MACHINES;
AND CERTIFICATION OF MAMMOGRAPHY FACILITIES**

Section

R12-1-209. ~~Licensing Requirements for Nonionizing Radiation Machine Facilities~~ Notifications

~~ARTICLE 14. RULES FOR THE CONTROL OF NONIONIZING RADIATION~~

**REGISTRATION OF NONIONIZING RADIATION SOURCES AND STANDARDS FOR PROTECTION AGAINST
NONIONIZING RADIATION**

Section

R12-1-1401. ~~Repeated~~ Registration of Nonionizing Radiation Sources and Service Providers

R12-1-1402. Definitions

R12-1-1403. General Safety Provisions and Exemptions

R12-1-1404. Radio Frequency Equipment ~~Requirements~~

R12-1-1405. Radio Frequency Exposure Limits

R12-2-1406. Radio Frequency Hazard Caution Signs, Symbols, Labeling, and Posting

R12-1-1407. ~~Special Requirements for~~ Microwave Ovens

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- R12-1-1408. Reporting of Radio Frequency Radiation Incidents
- R12-1-1409. Medical Surveillance for Radio Frequency Occupational Workers
- R12-1-1410. Radio Frequency Compliance Measurements ~~Criteria~~
- R12-1-1411. ~~Licensing of Tanning Facilities~~ Repealed
- R12-1-1412. ~~Tanning Operations~~ General Safety Requirements for the Operation of Tanning Facilities
- R12-1-1413. Tanning Equipment Standards
- R12-1-1414. ~~Operation and Use of Tanning Equipment~~ Operators
- R12-1-1415. ~~Tanning Facility~~ Warning Signs and Statements for Tanning Facilities
- R12-1-1416. Reporting of ~~Tanning Injuries~~ Injuries In Tanning Facilities
- R12-1-1417. ~~High Intensity Mercury Vapor Discharge (HID) Lamps~~ Repealed
- R12-1-1418. ~~Reserved High Intensity Mercury Vapor Discharge (HID) Lamps~~
- R12-1-1421. Laser Safety ~~Requirements, Surveys, and Records~~
- R12-1-1422. ~~General Requirements for All Laser Facilities~~
- R12-1-1423. Laser Prohibitions
- R12-1-1425. Laser Product Classification
- R12-1-1426. ~~Maximum Permissible Exposure Limits to Laser and Collateral Radiations~~ Laser and Collateral Radiation Exposure Limits
- R12-1-1427. Requirements for Laser Caution Signs, Symbols, and Labels
- R12-1-1429. Posting of Laser Facilities
- R12-1-1433. Laser-controlled Areas
- R12-1-1434. Laser Safety Officer (LSO) ~~Duties~~
- R12-1-1435. Laser Protective Eye Wear for Use in Laser Facilities
- R12-1-1436. Reporting of Laser Incidents
- R12-1-1437. ~~Additional Requirements for Special Lasers and Applications~~ Special Lasers
- R12-1-1438. ~~Repealed Requirements for Laser and Light Based Cosmetic Procedures:~~
- R12-1-1439. ~~Additional Requirements for Medical Laser Applications~~ Laser/IPL User Safety Training Approval
- R12-1-1440. ~~Laser Light Shows~~ Medical Lasers
- R12-1-1441. ~~Measurements and Calculations to Determine MPE Limits for Lasers~~ Laser Light Shows and Demonstrations
- R12-1-1442. ~~Repealed Measurements and Calculations to Determine MPE Limits for Lasers~~
- R12-1-1443. Laser Compliance Measurement Instruments
- R12-1-1444. Laser Classification Measurements
- Appendix A. ~~Radiofrequency Devices~~ Radio frequency Devices
- Appendix B. ~~Repealed Application Information~~
- Appendix C. Cosmetic Laser/IPL Operator Training Program

**ARTICLE 2. ~~RADIATION MACHINE FACILITY REGISTRATION OR LICENSING, INSTALLATION AND SERVICE REGISTRATION, AND MAMMOGRAPHIC FACILITY CERTIFICATION~~
REGISTRATION, INSTALLATION, AND SERVICE OF IONIZING RADIATION PRODUCING MACHINES;
AND CERTIFICATION OF MAMMOGRAPHY FACILITIES**

- R12-1-209. Licensing Requirements for Nonionizing Radiation Machine Facilities Notifications**
- ~~A.~~ No person shall receive, possess, use, or transfer a nonexempt nonionizing radiation machine except as authorized pursuant to this Article.
 - ~~B.~~ The owner or persons having possession of any nonexempt nonionizing radiation machine shall apply for licensure with the Agency within 90 days following the effective date of this Article. Subsequent applications for license shall be submitted within 30 days after acquisition of a nonexempt nonionizing radiation producing machine. The application shall be on the form as prescribed in Appendix A in Article 2.
 - ~~C.~~ The licensee shall notify the Agency within 30 days of any change to the information contained in the license application.
 - ~~D.~~ In addition to the application form, the applicant shall remit the appropriate license fee, pursuant to R12-1-1303, and such other information as may be required to comply with Article 14.
 - A. A registrant shall notify the Agency within 30 days of any change to the information contained in the notice of registration or certificate issued according to R12-1-208.
 - B. A person who possesses a radiation machine registered by the Agency shall notify the Agency within 15 days if the machine is discarded or transferred to another person. The notification shall contain the name and address of the person receiving the machine, if it is sold, leased, or transferred to another person; the manufacturer, model, and serial number of the machine; and the date the machine was taken out of service.

ARTICLE 14. RULES FOR THE CONTROL OF NONIONIZING RADIATION

**REGISTRATION OF NONIONIZING RADIATION SOURCES AND STANDARDS FOR PROTECTION AGAINST
NONIONIZING RADIATION**

R12-1-1401. ~~Repeated~~ Registration of Nonionizing Radiation Sources and Service Providers

- A.** A person shall not use a nonexempt nonionizing radiation source, defined in R12-1-1402, unless the source is registered by the Agency.
- B.** A person possessing a nonexempt nonionizing radiation source shall submit to the Agency an application for registration at least 30 days prior to its first use.
 - 1. Nonexempt nonionizing sources requiring a registration are listed in R12-1-1302.
 - 2. The person applying for the registration of a nonexempt nonionizing source shall use an application form provided by the Agency.
 - 3. The applicant shall provide the information identified in Appendix B of this Article.
- C.** A registrant shall notify the Agency within 30 days of any change to the information contained in the registration, or sale of a source that results in termination of the activities conducted under the registration.
- D.** In addition to the application form, the applicant shall remit the appropriate registration fee specified in R12-1-1306.
- E.** Persons operating more than one facility, where nonionizing radiation producing sources are used, shall apply for a separate registration for each facility.
- F.** A person in the business of installing or servicing nonionizing radiation sources shall apply for registration of the business activities with the Agency 30 days prior to furnishing the service. Application for registration shall be on a form provided by the Agency and shall contain the information required in A.R.S. § 30-672.01.

R12-1-1402. Definitions

- A.** The following terms have the meaning given when used in rules pertaining to radio frequency and microwave radiation:
 - 1. "Accessible emission level" means the level of radio frequency radiation emitted from any source, expressed in terms of power density in milliwatts per square centimeter or electric and magnetic field strength as appropriate, and to which human access is normally possible.
 - 2. "Far field region" means the region in which locally uniform distribution of electric and magnetic field strengths exists in planes transverse to the direction of propagation. The far field region shall be taken to exist at distances greater than $2D^2/\lambda$ from the antenna, where λ is the wavelength and D is the largest antenna aperture dimension.
 - 3. "Near field region" means the region near an antenna in which the electric and magnetic field components vary considerably in strength from point to point. For most antennas the outer boundary of the region shall be taken to exist at a distance $\lambda/2\pi$ from the antenna surface, where λ is the wavelength.
 - 4. "Radio frequency controlled area" means any area to which access is controlled for the purpose of protection from radio frequency radiation.
 - 5. "Radio frequency exposure limits" means the maximum permissible whole body exposure to humans, from any source of radio frequency radiation.
 - 6. "Radio frequency machine" means a radiation machine or system which produces electromagnetic radiation in the frequency spectrum.
 - 7. "Radio frequency radiation" means that electromagnetic radiation (including microwave radiation) with frequencies in the range of 0.3 megahertz to 100 gigahertz.
 - 8. "Safety device" means any device incorporated into a radio frequency machine which is designed to prevent human access to excessive levels of radio frequency radiation.
- B.** The following terms have the meaning given when used in rules applicable to lasers:
 - 1. "Accessible emission level" means the magnitude of emission of laser or collateral radiation to which human access is possible.
 - 2. "Accessible emission limit" means the maximum accessible emission level of laser radiation permitted within a particular class.
 - 3. "Angular subtense" means the apparent visual angle, α , as calculated from the source size and distance from the eye.
 - 4. "Aperture" means any opening in a protective housing through which radiation is emitted, thereby allowing human access to the radiation.
 - 5. "Aperture stop" means an opening serving to limit the size and to define the shape of the area over which radiation is measured.
 - 6. "Certified laser product" means that the product is certified by a manufacturer pursuant to the requirements of 21 CFR 1040, 1993 edition, published April 1, 1993, by the Office of the Federal Register, National Archives and Records Administration, incorporated by reference and on file with the Department and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.
 - 7. "Class I laser" means any laser which permits human access during operation to laser radiation less than the accessible emission limits for any combination of emission duration and wavelength range.

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- a. "Class I dual limits" means, for classification purposes, laser or collateral radiation in the wavelength range of greater than 400 nanometers but less than or equal to 1,400 nanometers exceeds the accessible emission limits of Class I if it exceeds both:
 - i. The Class I accessible emission limits for radiant energy within any range of emission duration, and
 - ii. The Class I accessible emission limits for integrated radiance within any range of emission duration.
8. "Class II Laser" means any laser which permits human access during operation to laser radiation above the Class I accessible emission limits, up to the accessible emission limits of Class II accessible emission limits and does not permit human access to laser radiation in excess of the accessible emission limits of Class I for any other emission duration or wavelength range.
9. "Class IIa laser products" means any laser product that permits human access during operation to levels of visible laser radiation in excess of the Class II accessible emission limits but does not permit human access during operation to levels of laser radiation in excess of the accessible Class IIa emission limits.
10. "Class III Laser" means any laser which permits human access during operation to laser radiation above the Class I accessible emission limits and, if applicable, Class II, but below the Class IIIa accessible emission limits. Class III lasers are separately designated as Class IIIa or Class IIIb:
 - a. Class IIIa lasers are those lasers with an emission duration greater than 380 microseconds and in the wavelength range greater than 400 nanometers but less than or equal to 710 nanometers, with a radiant power of less than or equal to 5 milliwatts.
 - b. Class IIIb lasers are all other Class III lasers as defined above.
11. "Class IV laser" means any laser which permits human access during operation to laser radiation above the Class III accessible emission limits.
12. "Class I, II, III, IV facility" means a facility which has one or more Class I, II (including IIa), III (including IIIa and IIIb), or IV lasers respectively. Facilities containing more than one class of laser shall be classified according to the highest laser class contained therein.
13. "Collateral radiation" means any electronic product radiation, except laser radiation, emitted by a laser as a result of the operation of the laser or any component of the laser product that is physically necessary for the operation of the laser. The accessible emission and maximum permissible exposure limits for collateral radiation are specified in 21 CFR 1040.10, 1993 edition, published April 1, 1993, by the Office of the Federal Register, National Archives and Records Administration, incorporated by reference and on file with the Department and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.
14. "Demonstration laser" means any laser manufactured, designed, intended, or used for purposes of demonstration, entertainment, advertising display, or artistic composition.
15. "Federal performance standard for light-emitting products" means the regulations in 21 CFR 1040.10, 1993 edition, published April 1, 1993, by the Office of the Federal Register, National Archives and Records Administration, incorporated by reference and on file with the Department and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.
16. "Human access" means access to laser or collateral radiation by any part of the human body.
17. "Incident" means an event or occurrence which results in a real or suspected accidental exposure to laser radiation which caused or is likely to cause biological damage.
18. "Integrated radiance" means radiant energy per unit area of a radiating surface per unit solid angle of emission, expressed in joules per square centimeter-steradian.
19. "Irradiance" means the radiant power incident on an element of a surface divided by the area of that element, expressed in watts per square centimeter.
20. "Laser controlled area" means any area into which human access is restricted for the purpose of radiation protection.
21. "Laser energy source" means any device intended for use in conjunction with a laser to supply energy for the operation of the laser. General energy sources, such as electrical supply mains or batteries, shall not be considered to constitute laser energy sources.
22. "Laser product" means any manufactured product, or assemblage of components which constitutes, incorporates, or is intended to incorporate a laser or laser system. A laser or laser system which is intended for use as a component of an electronic product shall itself be considered a laser product.
23. "Laser protective device" means any device used to reduce or prevent exposure of personnel to laser radiation. Such devices shall include protective eye wear, garments, engineering controls, and operational controls.
24. "Laser radiation" means all electromagnetic radiation emitted by a laser product, within the spectral range specified in the definition in Article 1, which is produced as a result of controlled stimulated emission.
25. "Laser Safety Officer" (LSO) means any individual, qualified by training and experience in the evaluation and control of laser hazards, who is designated by the licensee and has the authority and responsibility to establish and administer the laser radiation protection program for a particular facility.
26. "Laser system" means a laser in combination with an appropriate laser energy source, with or without additional incorporated components.

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27. "MPE" means the maximum permissible exposure limits for human exposure to laser or collateral radiation established by this Article. MPE limits for eye and skin exposure listed in ANSI Z136.1-1993, American National Standard for Safe Use of Lasers, 1993 edition, published by the Laser Institute of America, incorporated by reference and on file with the Department and the Office of the Secretary of State (this incorporation by reference contains no future editions or amendments) and for collateral radiation, in 21 CFR 1040.10, 1993 edition, published April 1, 1993, by the Office of the Federal Register, National Archives and Records Administration, incorporated by reference and on file with the Department and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.
 28. "Maintenance" means the performance of those adjustments or procedures by the user to keep equipment in its intended operating condition. Maintenance does not include operation or service.
 29. "Protective housing" means any panel, partition, dividing wall, or similar device which prevents human access to laser or collateral radiation in excess of the prescribed accessible emission limit.
 30. "Pulse duration" means the time increment measured between the halfpeak power points at the leading and trailing edges of a pulse.
 31. "Pulse interval" means the time duration between identical points on two successive pulses.
 32. "Radiance" means the time-averaged radiant power per unit area of a radiating surface per unit solid angle of emission, expressed in watts per square centimeter per steradian.
 33. "Radiant energy" means energy emitted, transferred or received in the form of radiation, expressed in joules.
 34. "Radiant exposure" means the radiant energy incident on an element of a surface divided by the area of that element, expressed in joules per square centimeter.
 35. "Radiant power" means the time-averaged power emitted, transferred, or received in the form of radiation, expressed in watts.
 36. "Safety interlock" means a device associated with the protective housing of a laser product, system, or facility which prevents human access to laser and collateral radiation in excess of the prescribed accessible emission limit.
 37. "Sampling interval" means the time interval during which the level of accessible laser or collateral radiation is sampled by a measurement process. The magnitude of the sampling interval in units of seconds is represented by the symbol "t".
 38. "Secured enclosure" means an enclosure to which casual access is impeded by appropriate means, such as a door secured by lock, by latch, or by screws.
 39. "Uncertified laser product" means any laser which has not been certified in accordance with the requirements of 21 CFR 1040, 1993 edition, published April 1, 1993, by the Office of the Federal Register, National Archives and Records Administration, incorporated by reference and on file with the Department and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.
- Ⓒ. The following terms have the meaning given when used in rules on ultraviolet and high-intensity light sources:
1. "High-intensity mercury vapor discharge (HID) lamp" means any mercury vapor or metal halide lamp incorporating a high-pressure arc discharge tube that has a fill consisting primarily of mercury and that is contained within an outer envelope but does not include the tungsten filament self-ballasted mercury vapor or metal halide lamp.
 2. "Protective sunlamp eye wear" means any device designed to be worn by users of a sunlamp product to reduce radiation exposures to the eyes.
 3. "Self-extinguishing lamp" means any HID lamp which ceases operation in conformance with the requirements of the performance standard in 21 CFR 1040.30(d), 1993 edition, published April 1, 1993, by the Office of the Federal Register, National Archives and Records Administration, incorporated by reference and on file with the Department and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.
 4. "Sunlamp product" means any electronic device which incorporates one or more ultraviolet lamps and is intended for use to induce skin tanning.
 5. "Tanning device" means any room, booth, cabinet, tanning bed, or other enclosure which houses sunlamp products for the purpose of irradiating any part of the human body for cosmetic or nonmedical purposes.
 6. "Ultraviolet lamp" means any light source that produces ultraviolet radiation and that is intended for use in any sunlamp product.
 7. "Ultraviolet radiation" means electromagnetic radiation with a wavelength in air of between 200 and 400 nanometers.

General definitions:

"Cosmetic procedure" means: Use of medical lasers or intense pulse light (IPL) devices, approved by the Federal Food and Drug Administration (FDA), for the purpose of hair removal, spider vein removal, skin rejuvenation, non-ablative skin resurfacing, skin resurfacing, port wine stain removal, epidermal pigmented skin lesion, or tattoo removal.

"Indirect supervision" means: For lasers or IPL used for cosmetic procedures: there shall be, as a minimum, responsible supervision and control by a licensed practitioner who is easily accessible by telecommunication. The supervising practitioner shall have ordered the application of radiation prior to its application, shall have established a method for emergency medical care in the absence of the supervising practitioner, and shall assume legal liability for the service

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rendered by the indirectly supervised operator, who has participated in sufficient supervised training, as specified in R12-1-1438, to allow the supervised operator to function under indirect supervision.

“Licensed practitioner” (see A.A.C. R12-1-102).

“Nonexempt nonionizing radiation source” means any system or device containing a nonionizing radiation source listed in R12-1-1302(F).

“Medical Director” means a licensed practitioner, as defined in A.A.C. R12-1-102, who delegates a laser, IPL or other light emitting medical device procedure to a non-physician. The medical director shall be qualified to do the procedures themselves within their license scope of practice.

Radio frequency and microwave radiation:

“Accessible emission level” means the level of radio frequency radiation emitted from any source, expressed in terms of power density in milliwatts per square centimeter or electric and magnetic field strength as appropriate, and to which human access is normally possible.

“Far field region” means the region in which locally uniform distribution of electric and magnetic field strengths exists in planes transverse to the direction of propagation. The far field region shall be taken to exist at distances greater than $2D^2/\lambda$ from the antenna, where λ is the wavelength and D is the largest antenna aperture dimension.

“Near field region” means the region near an antenna in which the electric and magnetic field components vary considerably in strength from point to point. For most antennas the outer boundary of the region shall be taken to exist at a distance $\lambda/2\pi$ from the antenna surface, where λ is the wavelength.

“Radio frequency controlled area” means any area to which access is controlled for the purpose of protection from radio frequency radiation.

“Radio frequency exposure limits” means the maximum permissible whole body exposure to humans, from any source of radio frequency radiation.

“Radio frequency source” means a radiation source or system which produces electromagnetic radiation in the frequency spectrum.

“Radio frequency radiation” means that electromagnetic radiation (including microwave radiation) with frequencies in the range of 0.3 megahertz to 100 gigahertz.

“Safety device” means any device incorporated into a radio frequency source which is designed to prevent human access to excessive levels of radio frequency radiation.

Laser:

“Accessible emission level (AEL)” means the maximum accessible emission level permitted within a particular class. For purposes of this Article this term is synonymous with “accessible emission limit.”

“Accessible radiation” means radiation to which it is possible for the human eye or skin to be exposed in normal usage.

“Angular subtense” means the apparent visual angle, α , as calculated from the source size and distance from the eye.

“Aperture” means an opening through which radiation can pass allowing human access to the radiation.

“Aperture stop” means an opening serving to limit the size and to define the shape of the area over which radiation is measured.

“Certified laser product” means that the product is certified by a manufacturer pursuant to the requirements of 21 CFR 1040, 2003 edition, Published April 1, 2003, by the Office of Federal Register National Archives and Records Administration, incorporated by reference and on file with the Agency. This incorporation by reference contains no future editions or amendments.

“CDRH” means the Center for Devices and Radiological Health.

“Class 1 laser” means a laser or laser system that may produce visible or invisible laser radiation. Under all normal conditions of operation, a Class 1 laser is considered to be incapable of causing injury from directly viewing the radiation beam.

“Class 2 laser” means a laser or laser system that produces low-power visible laser radiation not exceeding 1 mW. Eye protection is normally afforded by the natural blink reflex time (0.25 s). Direct viewing of the radiation beam from a Class 2 laser is prohibited.

“Class 2a laser products” means any laser product that permits human access to levels of visible laser radiation in excess of the Class 2 accessible emission limits, during its operation, but does not permit human access to levels of laser radiation in excess of the accessible Class 2a emission limits.

“Class 3a laser” means a laser or laser system that produces moderate levels of visible or invisible laser radiation of 1 to 5 mW and requires more stringent control than a Class 2 laser. For those Class 3a lasers whose output is visible, the normal aversion response is generally sufficient to prevent eye injury. However, the use of collecting optics, e.g. bin-

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oculars, can produce retinal injury. Because the radiation beam is not observed in Class 3a laser that produces ultraviolet or infrared emissions the accessible emission level does not rely upon the normal aversion response, but rather on the fact that the eye of the exposed individual will not fixate on the radiation beam long enough to cause injury.

“Class 3b Laser” means a laser or laser system that produces visible laser radiation of 5 to 500 mW of visible continuous wave output and 5 to 500 mW of invisible infrared laser radiation. A Class 3b laser is considered medium power laser and is capable of producing eye injury when viewed directly or with optics, even if viewed momentarily. The normal aversion response (0.25 s) to a Class 3b laser does not prevent injury. A Class 3b laser does not usually produce a hazardous diffuse reflection or fire hazard. At the upper end of the Class 3b power range skin burns may be possible.

“Class 4 laser” means a laser or laser system that produces visible or invisible laser radiation capable of causing injury to the eye and skin, and dangerous specular and diffuse reflections. Improper use may result in a fire hazard.

“Class 1, 2, 3, 4 facility” means a facility which has one or more Class 1, 2 (including 2a), 3 (including 3a and 3b), or 4 lasers respectively. Facilities containing more than one class of laser shall be classified according to the highest laser class.

“Collateral radiation” means any electronic product radiation, except laser radiation, emitted by a laser as a result of the operation of the laser or any component of the laser product that is physically necessary for the operation of the laser. The accessible emission and maximum permissible exposure limits for collateral radiation are specified in 21 CFR 1040(10), 2003 edition, published April 1, 2003, by the Office of Federal Register National Archives and Records Administration, incorporated by reference and on file with the Agency. This incorporation by reference contains no future editions or amendments.

“Continuous wave” (cw) means the output of a laser which is operated in a continuous rather than a pulsed mode. For purposes of these rules, a laser operating with a continuous output for a period ≥ 0.25 seconds, is regarded as a cw laser.

“Controlled area” means an area where the occupancy and activity of those within is subject to control and supervision for the purpose of protection from radiation hazards.

“Demonstration laser” means any laser manufactured, designed, intended or used for purposes of demonstration, entertainment, advertising display, or artistic composition.

“Embedded laser” means an enclosed laser with an assigned class number higher than the inherent capability for the laser system in which it is incorporated, where the systems lower classification is appropriate due to the engineering features limiting accessible emission.

“Enclosed laser” means a laser that is contained within a protective housing of itself or of the laser system in which it is incorporated. Opening or removal of the protective housing provides additional access to laser radiation above the applicable MPE than possible with the protective housing in place. (An embedded laser is an example of one type of enclosed laser.)

“Federal performance standard for light-emitting products” means the regulations in 21 CFR 1040(10), 2003 edition, published April 1, 2003 by the Office of Federal Register National Archives and Records Administration, incorporated by reference and on file with the Agency. This incorporation by reference contains no future editions or amendments.

“Human access” means access to laser or collateral radiation by any part of the human body.

“Incident” means an event or occurrence which results in a real or suspected accidental exposure to laser radiation which caused or is likely to cause biological damage.

“Integrated radiance” means radiant energy per unit area of a radiating surface per unit solid angle of emission, expressed in joules per square centimeter - steradian.

“Irradiance” means the radiant power incident on an element of a surface divided by the area of that element, expressed in watts per square centimeter.

“Laser” See the definition in Article 1.

“Laser controlled area” means any area into which human access is restricted for the purpose of radiation protection.

“Laser energy source” means any device intended for use in conjunction with a laser to supply energy for the operation of the laser. General energy sources such as electrical supply mains or batteries, shall not be considered to constitute laser energy sources.

“Cosmetic procedure protocols” means delegated written authorization to select specific laser/IPL settings, initiate laser/IPL procedure, and exercise appropriate follow-up.

“Laser product” means any manufactured product or assemblage of components which constitutes, incorporates, or is intended to incorporate a laser or laser system. A laser or laser system which is intended for use as a component of an electronic product shall itself be considered a laser product.

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“Laser protective device” means any device used to reduce or prevent exposure of personnel to laser radiation. Included are: protective eye wear, garments, engineering controls, and operational controls.

“Laser radiation” means all electromagnetic radiation emitted by a laser product, within the spectral range specified in the definition of “laser,” which is produced as a result of controlled stimulated emission.

“Laser Safety Officer” (LSO) - means any individual, qualified by training and experience in the evaluation and control of laser hazards, who is designated by the registrant and has the authority and responsibility to establish and administer the laser radiation protection program for a particular facility.

“Laser system” means an assembly of electrical mechanical, and optical components which include a laser.

“Limited Exposure Duration (T_{max})” means an exposure duration which is specifically limited by the design or intended use(s).

“Maintenance” means performance of those adjustments or procedures specified in user information provided by the manufacturer with the laser or laser system, which are to be performed by the user to ensure the intended performance of the product. It does not include operation or service as defined in this Section.

“Maximum permissible exposure (MPE)” means the level of laser radiation to which a person may be exposed without hazardous effect or adverse biological changes in the eye or skin. MPE limits for eye and skin exposure listed in ANSI Z136.1-2000, American National Standard for Safe Use of Lasers, 2001 Edition, Published by the Laser Institute of America, Incorporated by reference and on file with the Agency and the Office of Secretary of State, and for collateral radiation, in 21 CFR 1040(10), 2001 edition, published April 1, 2001, by the Office of Federal Register National Archives and Records Administration, incorporated by reference and on file with the Agency. Both incorporation by references contain no future editions or amendments.

“Maintenance” means the performance of those adjustments or procedures by the user to keep equipment in its intended operating condition. Maintenance does not include operation or service.

“Operation” means the performance of the laser or laser system over the full range of its intended functions (normal operation). It does not include maintenance or service as defined in this Section.

“Protective housing” means any panel, partition, dividing wall, or similar device which prevents human access to laser or collateral radiation in excess of the prescribed accessible emission limit.

“Pulse duration” means the duration of a laser pulse; usually measured as the time interval between the half power points on the leading and trailing edges of the pulse.

“Pulse interval” means the time duration between identical points on two successive pulses.

“Radiance” means the time-averaged radiant power per unit area of a radiating surface per unit solid angle of emission, expressed in watts per square centimeter per steradian.

“Radiant energy” means energy emitted, transferred or received in the form of radiation, expressed in joules.

“Radiant exposure” means the radiant energy incident on an element of a surface divided by the area of that element, expressed in joules per square centimeter.

“Radiant power” means the time-averaged power emitted, transferred, or received in the form of radiation, expressed in watts.

“Safety interlock” means a device associated with the protective housing of a laser product, system or facility which prevents human access to laser and collateral radiation in excess of the prescribed accessible emission limit.

“Sampling interval” means the time interval during which the level of accessible laser or collateral radiation is sampled by a measurement process. The magnitude of the sampling interval in units of seconds is represented by the symbol “t”.

“Secured enclosure” means an enclosure to which casual access is impeded by appropriate means, such as a door secured by lock, by latch, or by screws.

“Service” means the performance of those procedures or adjustments described in the manufacturer’s instructions which may effect any aspect of the performance of the laser or laser system. It does not include maintenance or operation as defined in this Article.

“ T_{max} ” See limiting exposure duration.

“Uncertified laser product” means any laser which has not been certified in accordance with the requirements of 21 CFR 1040(10), 2003 edition, Published April 1, 2003, by the Office of Federal Register National Archives and Records Administration, incorporated by reference and on file with the Agency. This incorporation by reference contains no future editions or amendments.

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Ultraviolet, high intensity light, and intense pulsed light source:

“Consumer” means any member of the public who is provided access to a tanning device in exchange for a fee or other compensation, or any individual who, in exchange for a fee or other compensation, is afforded use of a tanning device as a condition or benefit of membership or access.

“EPA” means the United States Environmental Protection Agency.

“FDA” means the United States Food and Drug Administration.

“High intensity mercury vapor discharge (HID) lamp” means any mercury vapor or metal halide lamp incorporating a high-pressure arc discharge tube that has a fill consisting primarily of mercury and that is contained within an outer envelope but does not include the tungsten filament self-ballasted mercury vapor or metal halide lamp.

“Intense pulsed light device” means, for purposes of R12-1-1438, any lamp-based device that produces an incoherent filtered intense light.

“Maximum exposure time” means the greatest continuous exposure time interval recommended by the manufacturer of a product.

“Protective sunlamp eye wear” means any device designed to be worn by a user of a product to reduce exposure of the eyes to radiation emitted by the product.

“Sanitize” means the effective bacterial treatment of surfaces of equipment and devices by an EPA or FDA registered product which provides a sufficient concentration of chemicals, and enough time to reduce the bacterial count, including pathogens, to a safe level. Chemical germicides that are registered with the EPA as hospital disinfectants when used at recommended dilutions and directions, may be approved for sanitizing of tanning devices.

“Self-extinguishing lamp” means any HID lamp which ceases operation in conformance with the requirements of the performance standard in 21 CFR 1040(30)(d), 2003 edition published April 1, 2003, by the Office of Federal Register National Archives and Records Administration, incorporated by reference and on file with the Agency. This incorporation by reference contains no future editions or amendments.

“Sunlamp product” means any electronic device which incorporates one or more ultraviolet lamps and is intended for use to induce skin tanning.

“Tanning device” means any equipment, that emits electronic radiation with wavelengths in the air between 200 and 400 nanometers including, but not limited to, a sunlamp, ultraviolet lamp, tanning booth, facial unit, UVA wand, or tanning bed. A tanning device also means any accompanying equipment, including, but not limited to, protective eye wear, timers, ballasts, starters, lamps, reflectors, cooling fans, acrylics, comfort pillows and hand rails, room, booth, cabinet, or other enclosure which houses sunlamp products for the purpose of irradiating any part of the human body for cosmetic or non-medical purposes.

“Timer” means a device provided to terminate radiation exposure at a preset time.

“Ultraviolet lamp” means any light source that produces ultraviolet radiation and that is intended for use in any sunlamp product.

“Ultraviolet radiation” means electromagnetic radiation with a wavelength in air of between 200 and 400 nanometers.

R12-1-1403. General Safety Provisions and Exemptions

- A. No change
1. No change
 2. The ~~licensee~~ registrant provides sufficient information to enable the Agency to determine that alternative methods of achieving the same or a greater level of radiation protection will be used.
- B. The ~~licensee~~ registrant shall:
1. Ensure that nonionizing radiation sources are operated ~~only~~ by individuals who have been trained and have demonstrated competence in the safe use of the sources equipment.
 2. Provide safety rules to individuals operating nonionizing radiation ~~machines~~ sources and ~~ensure the shall make these~~ individuals are aware of any operating restrictions and procedures needed ~~restrictions in operating techniques required~~ for the safe use of the machines sources.
 3. No change
 4. The following records shall be retained for three years for Agency review: ~~Retain records, including but not limited to:~~
 - a. Results of all physical surveys and calibrations required by this Article for five years,
 - b. ~~The calibration of radiation survey instruments for five years,~~
 - e-b. Radiation source inventories; ~~Inventories to account for sources of radiation for two years;~~
 - d-c. Maintenance, service, and modifications; and ~~Records of maintenance, servicing or modifications which could affect the radiation emission characteristics of a machine for the life of the machine plus two years, and~~

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~~e.d. Incidents involving known or suspected exposure to nonionizing radiation in excess of the limits permanent documentation of each incident involving known or suspected exposure to nonionizing radiation in excess of the maximum permissible exposure limits specified in this Article.~~

- C. ~~A registrant~~ The licensee shall not operate, ~~nor permit the operation of,~~ a nonionizing radiation ~~machine~~ source unless the ~~machine~~ source complies with all of the applicable requirements of this Article.

R12-1-1404. Radio Frequency Equipment Requirements

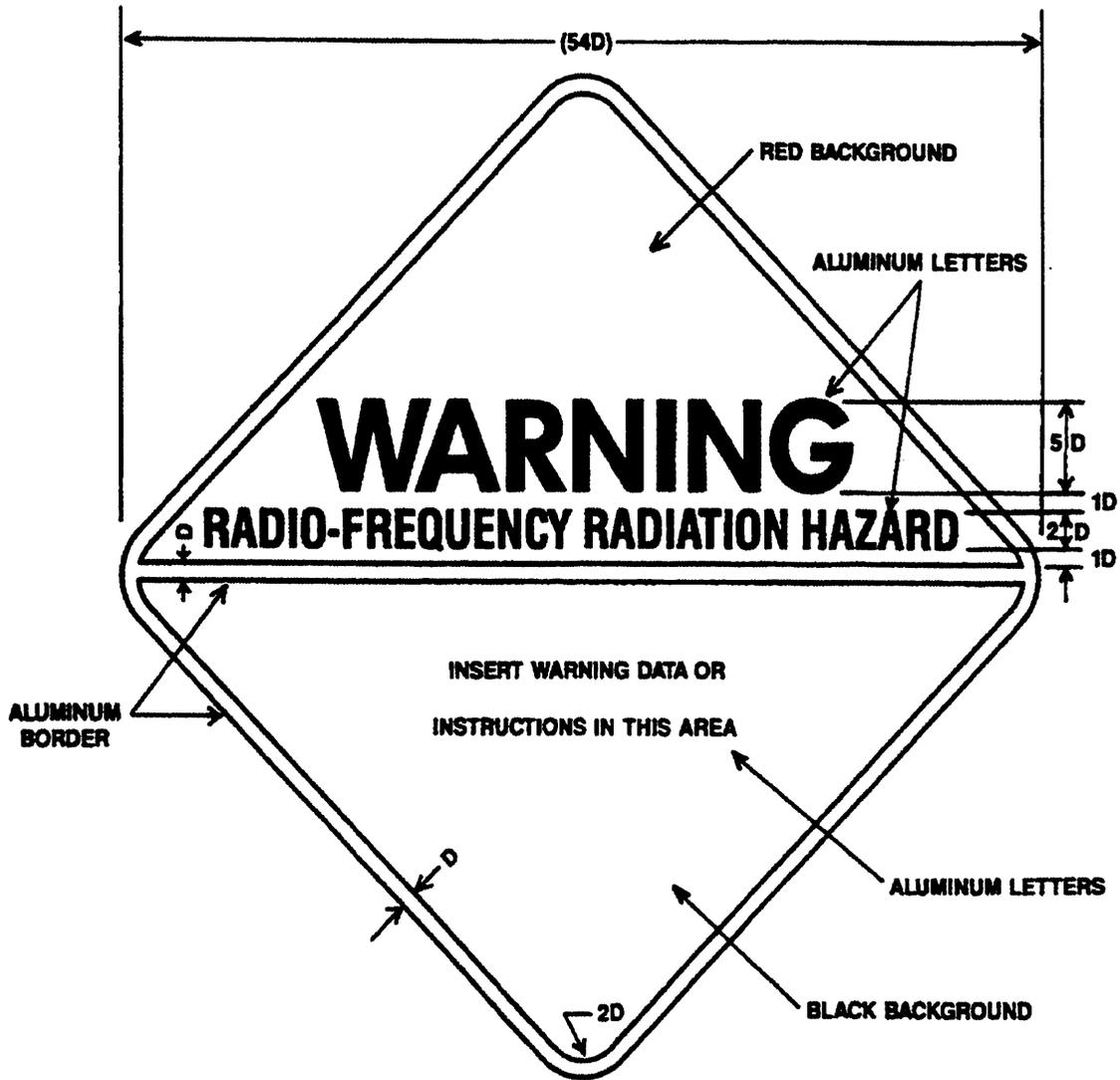
- A. ~~A radiation source~~ Radiation machines emitting accessible emission levels exceeding the maximum permissible radio frequency exposure levels for uncontrolled areas specified in IEEE C95.1 ~~1999~~ 1991, Institute of Electrical and Electronics Engineers Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3kHz to 300 GHz, 1999 edition ~~1991 Edition~~, Published by the Institute of Electrical and Electronic Engineers, Inc., incorporated ~~herein~~ by reference, ~~and on file with the Agency the Office of Secretary of State, and containing no future editions or amendments,~~ shall be operated only in a radio frequency controlled area, so arranged as to prevent human exposure in excess of the applicable values. Each point of access into a radio frequency controlled area shall be posted according to R12-1-1406, ~~with warning signs meeting the specifications indicated in R12-1-1406, Figure 1.~~
- B. Radio frequency ~~machines~~ sources which are required to operate in a ~~be operated in a~~ radio frequency controlled area shall incorporate visual or audible emission indicators which function only during production of radiation.
- C. Sources of radio frequency emissions, which are physically separate ~~separated~~ from the source's means of activation ~~of the sources~~ by a distance greater than 2 ~~two~~ meters, shall be provided with a visual or an audible emission indicator ~~at indicators at both~~ the source and the point of activation.
- D. Visual emission indicators shall be ~~so~~ located so that use of the indicators ~~observation~~ does not require human exposure to radio frequency radiation in excess of the applicable values in the radio frequency exposure limits.
- E. Safety devices designed to prevent human exposure to excessive radio frequency radiation shall be inspected for proper operation at intervals not to exceed one month.
- F. No change
- G. Radio frequency ~~machines~~ sources shall be physically secured against unauthorized use and tampering ~~or being tampered with when not in use.~~

R12-1-1405. Radio Frequency Exposure Limits

- A. ~~A registrant shall not expose a person to radio frequency radiation in excess of the limits specified in~~ The licensee shall not allow, as a result of operation of radio frequency machines under the licensee's control, human exposure to radio frequency radiation in excess of the maximum permissible radio frequency exposure levels in IEEE C95.1-~~1999~~ 1991, Institute of Electrical and Electronics Engineers Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3kHz to 300 GHz, 1999 edition ~~1991 Edition~~, published Published by the Institute of Electrical and Electronic Engineers, Inc., incorporated ~~herein~~ by reference and on file with the Agency the Office of Secretary of State, and containing no future editions or amendments. ~~with the following exclusions:~~
- B.1. ~~At frequencies between 300 kHz and 100 GHz, IEEE C95.1-1991, Institute of Electrical and Electronics Engineers Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3kHz to 300 GHz, 1991 Edition, Published by the Institute of Electrical and Electronic Engineers, Inc., incorporated herein by reference and on file with the Office of Secretary of State, the exposure limits may be exceeded if the exposure conditions can be shown by laboratory procedures to produce specific absorption rates (SARs) below 0.4 watts per kilogram averaged over the whole body, and spatial peak SAR values below 8 eight watts per kilogram averaged over 1 any one gram of tissue.~~
- C.2. ~~At frequencies between 300 kHz and 1 GHz, the IEEE C95.1-1991, Institute of Electrical and Electronics Engineers Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3kHz to 300 GHz, 1991 Edition, Published by the Institute of Electrical and Electronic Engineers, Inc., incorporated herein by reference and on file with the Office of Secretary of State, the exposure limits may be exceeded if the radio frequency input power to the radiating device is 7 seven watts or less.~~

R12-2-1406. Radio Frequency Hazard Caution Signs, Symbols, Labeling, and Posting

- A. Each point of access to controlled ~~Radio frequency controlled~~ areas shall be clearly ~~clearly~~ posted with caution signs of the type designated in Figure 1 ~~at each point of access to such areas.~~



1. Place handling and mounting instructions on reverse side.
2. D = Scaling unit
3. Lettering: Ratio of letter height to thickness of letter lines.
 - Upper triangle: 5 to 1 Large
6 to 1 Medium
 - Lower triangle: 4 to 1 Large
6 to 1 Medium
4. Symbol is square, triangles are right-angle isosceles.

Fig. 1

- B. ~~Operating procedure restrictions or limitations used to prevent unnecessary or excessive exposure to radio frequency radiation shall be posted in a location clearly visible to the operator.~~ Any limitations or restriction in operating procedures required to prevent unnecessary or excessive exposure to radio frequency radiation shall be posted in a location clearly visible to the operator.
- C. ~~The location of warning signs and labels shall not result in the observer being exposed to be located such that observation does not require unnecessary or excessive exposure to radio frequency radiation.~~ The location of warning signs and labels shall not result in the observer being exposed to be located such that observation does not require unnecessary or excessive exposure to radio frequency radiation.

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R12-1-1407. Special Requirements for Microwave Ovens

- ~~A. The power density of microwave radiation emitted by a microwave oven measured at any time subsequent to acquisition by a user shall not exceed 5 milliwatts per square centimeter at any point 5 centimeters from the external surface of the oven.~~
- ~~B. Compliance measurements shall be made with the oven operating at its maximum output, and containing a load of 275 ±15 milliliters of tap water at 20 ± 5° C, within the oven cavity at the center of the load-carrying surface provided by the manufacturer. The water container shall be a low-form 600 milliliter beaker having an inside diameter of approximately 8.5 centimeters and made of an electrically nonconductive material such as glass or plastic.~~
- ~~C. Microwave ovens shall be provided with at least two safety interlocks, one of which is not accessible to humans without disassembly of the oven or door. The interlocks shall prevent microwave radiation emission in excess of the requirements of subsection (A). The failure of one interlock shall not cause failure of the second.~~
- ~~D. Service performed on microwave ovens shall not result in failure of safety interlocks or the emission limits specified in subsection (A) to be exceeded.~~
- ~~E. Microwave ovens not meeting the standards prescribed in this Section shall be removed from service and not put back into service until the repairs necessary to achieve compliance have been completed.~~
- ~~F. Microwave ovens manufactured after October 6, 1971, shall be maintained in conformance with the requirements of 21 CFR 1040.30, 1993 edition, published April 1, 1993, by the Office of the Federal Register, National Archives and Records Administration, incorporated by reference and on file with the Department and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.~~

Microwave ovens not meeting the requirements in 21 CFR 1040(30), 2003 edition, published April 1, 2003, by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Agency, shall be registered with the Agency. This incorporation by reference contains no future editions or amendments.

R12-1-1408. Reporting of Radio Frequency Radiation Incidents

- ~~A. When it is known or suspected that any individual has been exposed to radio frequency radiation in excess of the limits in R12-1-1405 the licensee shall report the incident to the Agency in writing within 15 days. A registrant shall report in writing to the Agency within 15 days a known or suspected personnel exposure to radiation in excess of the limits in R12-1-1405.~~
- ~~B. When it is known or expected that any individual has been exposed to radio frequency radiation in excess of 150% of the limits in R12-1-1405 the licensee shall report the incident to the Agency within 24 hours. A registrant shall report to the Agency within 24 hours a known or suspected personnel exposure to radiation in excess of 150% of the limits in R12-1-1405.~~
- ~~C. Immediate notification shall be made to the Agency when radio frequency radiation exposure exceeds 500% of the limits. A registrant shall report to the Agency immediately a known or suspected personnel exposure in excess of 500% of the limits in R12-1-1405.~~

R12-1-1409. Medical Surveillance for Radio Frequency Occupational Workers

- ~~A. The Agency may require the licensee to provide medical examinations as necessary to protect the health of any individual exposed to radio frequency radiation produced by equipment under the licensee's control. A registrant shall provide a medical examination upon request by the Agency to an individual exposed to radiation reported to the Agency according to R12-1-1408.~~
- ~~B. The licensee shall request the individual to provide to the Agency a copy of the results of medical examinations ordered pursuant to subsection (A). Such reports shall be held confidential by the Agency, unless all information which could identify the patient has been removed. A registrant shall request an individual under going a medical examination in accordance with subsection (A), to provide a copy of the results to the Agency.~~

R12-1-1410. Radio Frequency Compliance Measurements ~~Criteria~~

- ~~A. Measurements made to determine compliance with R12-1-1405 shall be made with instrumentation capable of measuring appropriate for the field strength and frequency of the radiation in question radiations to be evaluated.~~
- ~~B. Instrumentation used for compliance measurements shall be calibrated every 12 months, have been calibrated within the preceding year. The calibration shall be traceable to a national standard maintained by the National Institute of Standards and Technology (NIST). (formerly known as the National Bureau of Standards.)~~
- ~~C. Compliance measurement of exposure conditions in the near field shall consist of measurements of the electric and magnetic field components. The applicable protection standards for near field measurements shall be the mean squared electric and magnetic field strengths referenced in R12-1-1405 in IEEE C95.1-1991, Institute of Electrical and Electronics Engineers Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3kHz to 300 GHz, 1991 Edition, Published by the Institute of Electrical and Electronic Engineers, Inc., incorporated herein by reference and on file with the Office of Secretary of State.~~
- ~~D. Measurements to determine compliance in far field exposure conditions may be actual measurements of power density in milliwatts per square centimeter, or the calculated equivalent plane wave power density based on measurement of either the electric or magnetic field strength. The applicable protection standards shall be the power density values referenced in R12-1-1405, in IEEE C95.1-1991, Institute of Electrical and Electronics Engineers Standard for Safety Levels with~~

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Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3kHz to 300 GHz, 1991 Edition, Published by the Institute of Electrical and Electronic Engineers, Inc., incorporated herein by reference and on file with the Office of Secretary of State.

- E. Measurements made in accordance with this rule shall include: ~~The measurement requirements of this Section shall be met if:~~
1. Measurements of both Both electric and magnetic field strength obtained with an strengths are obtained where the emission frequency is 300 megahertz or less; and
 2. Measurement of The electric or magnetic field strength ~~is~~ expressed in terms of power density.
- F. For mixed or broadband fields at a number of frequencies for which there are different values of protection standards in IEEE C95.1-1991, Institute of Electrical and Electronics Engineers Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3kHz to 300 GHz, 1991 Edition, Published by the Institute of Electrical and Electronic Engineers, Inc., incorporated herein by reference and on file with the Office of Secretary of State, the fraction of the appropriate exposure limit incurred within each frequency interval shall be determined, and the sum of all ~~the such~~ fractions shall not exceed unity (1).
- G. A compliance measurement ~~Compliance measurements~~ shall be made at distances of 5 ~~five~~ centimeters or greater from any object.
- H. A registrant shall make measurements that are ~~Measurements shall be~~ averaged over a six-minute period for pulsed and non-pulsed modes of radio frequency emission. Correction shall be made for duty cycle in determining the average field strength.

R12-1-1411. Licensing of Tanning Facilities Repealed

- A. ~~No person shall operate a tanning facility unless the person has properly applied for a license on forms provided by the Agency.~~
- B. ~~A facility operating prior to the effective date of this section may continue to operate, provided that the use of the license shall be registered within six months of the effective date.~~

R12-1-1412. Tanning Operations General Safety Requirements for the Operation of Tanning Facilities

A registrant ~~The licensee~~ shall establish and maintain a program of written policies and procedures for radiation safety sufficient to assure compliance with the requirements in R12-1-1412 through R12-1-1416.

R12-1-1413. Tanning Equipment Standards

- A. Only sunlamp products manufactured and certified to comply with 21 CFR 1040.20, 2003 edition, published April 1, 2003 ~~1993 edition, published April 1, 1993,~~ by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Agency ~~the Office of Secretary of State,~~ and containing no future editions or amendments. ~~“Sunlamp products and ultraviolet lamps intend for use in sunlamp products”~~, shall be used in tanning facilities. Compliance shall be based on the standard in effect at the time of manufacture as shown on the equipment ~~device~~ identification label.
- B. Defective or burned-out lamps, or filters, shall be replaced before further use of the tanning device.
- C. The defective or burned-out lamp, or filter, shall be replaced with a type intended for use in that equipment ~~device~~ as specified on the sunlamp product label ~~on the sunlamp products,~~ or, with lamps or filters that are equivalent under the FDA regulations and polices applicable at the time of manufacture. If equivalent lamps are used instead of the Original Equipment Manufacturer (OEM) required lamps, a copy of the equivalency certification, provided by the lamp supplier, shall be maintained on file for review by Agency inspectors.
- D. Each sunlamp product shall have a timer and control system which complies with 21 CFR 1040.10, 2003 edition, published April 1, 2003, ~~the requirements of Title 21, Code of Federal Regulations, Section 1040.10, 1993 Edition, Published April 1, 1993,~~ by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Agency ~~the Office of Secretary of State.~~ This incorporation contains no future editions or amendments. The timer and control system shall meet the following requirements:
1. The timer interval shall not exceed the manufacturer’s maximum recommended exposure time.
 2. Each timer shall be functional and accurate to within +/- 10% of the maximum timer interval of the product.
 3. The timer may not automatically reset and cause radiation emission to resume for a period greater than the unused portion of the timer cycle, when the emission from the sunlamp has been terminated.
 4. The registrant shall ensure that the timer is tested annually for accuracy.
 5. New facilities (including existing facilities with change of ownership) shall install remote timer controls prior to the operation of sunlamp products. Existing sunlamp products not equipped with a remote timer control system are required to have remote timer controls (outside of sunlamp product room) installed no later than six months after June 1, 2002.
 6. Each sunlamp product shall be equipped with an emergency shutoff mechanism to allow manual termination of the UV exposure by the consumer.
- E. Each sunlamp product shall have physical barriers to protect users from injury caused by touching or breaking lamps. ~~There shall be physical barriers as needed to protect users from injury induced by touching or breaking lamps.~~

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- F. Each tanning facility using stand-up ~~booths~~ sunlamp products shall comply with the following: ~~special requirements:~~
1. ~~Physical~~ There shall be physical barriers, handrails, floor markings or other means shall be present to indicate the proper exposure distance between the ultraviolet lamps and the user's skin.
 2. ~~The A tanning booth shall be constructed in such a way as to~~ construction of the booth shall be such that it will withstand the stress of use and the impact of a falling person.
 3. A tanning booth shall be accessed ~~Access to booths shall be~~ through doors of rigid construction, opening outwardly. Handrails and non-slip floors shall be provided.
 4. The interior temperature of a tanning device shall be controlled such that it does not exceed 100 degrees Fahrenheit (38 degrees Centigrade).

R12-1-1414. Operation and Use of Tanning Equipment Operators

- A. ~~At~~ There shall be present during operating hours at least one operator knowledgeable in the correct operation of the tanning equipment ~~devised~~ used at the facility shall be present during operating hours ~~and able to inform and assist each user in the proper use of the tanning devices.~~ The operator shall:
1. Ensure that only one person is in the tanning room when the tanning equipment is being operated;
 2. Ensure that no one under 18 years of age is allowed to use the tanning equipment without written permission from a parent or guardian.
 3. Limit exposure time to the exposure time to manufacturer's recommendation provided on the equipment label or operator's manual.
 4. Ensure the maximum exposure time in a 24-hour period recommended by the manufacturer is not exceeded.
 5. Maintain a record of each user's total number of tanning visits and tanning times for Agency inspection. The records shall be kept for three years from the date of the recording.
- B. ~~Prior to use of a tanning device~~ tanning equipment the operator shall: ~~by any individual the operator shall:~~
1. Provide to the user sanitized protective sunlamp eye wear and directions for its use; ~~its proper use.~~
 2. Demonstrate to the user any the use of physical aids, used as appropriate, to maintain proper exposure distance as recommended by the manufacturer of the tanning equipment; ~~device.~~
 3. Ensure the exposure timer is set so that the user is not exposed to excess radiation; ~~Set the timer.~~
 4. Instruct the user on the maximum exposure time and proper distance from the radiation source recommended by the manufacturer of the equipment; and
 5. Instruct the user as to the location and proper operation of the emergency shutoff switch
- C. A trained operator shall control a sunlamp's timer.
1. Training of operators shall include:
 - a. The requirements of this Section;
 - b. Facility operating procedures, to include:
 - i. Determination of skin type and associated duration of exposure;
 - ii. Procedures for use of minor and adult user consent forms;
 - iii. Potential for photosensitizing foods, cosmetics, and medications;
 - iv. Requirements for use of protective eye wear by users of the equipment; and
 - v. Proper sanitizing procedures for the facility, equipment, and eye wear,
 - c. Manufacturer's procedures for operation and maintenance of tanning equipment;
 - d. Recognition of injury or overexposure; and
 - e. Emergency procedures used in the case of an injury.
 2. Records of training shall include dates and material covered, and be maintained for three years from the date the training was provided, for Agency inspection.
 3. A list of trained operators shall be posted at the facility. The operator shall limit each individual to the manufacturer's maximum recommended exposure time for the tanning device.
- ~~D.~~ The interior temperature of a tanning device shall be controlled such that it does not exceed 38° C (100° F).
- ~~E.~~ D. ~~Prior to the first use of a tanning facility in each calendar year;~~
1. The user shall be required to read a copy of the warning in Section R12-1-1415;
 2. The user shall sign a statement that the information in subsection (D)(1) has been read and understood.
 3. For illiterate or visually handicapped persons, the warning statement shall be read by the operator in the presence of a witness. Both the witness and the operator shall sign the statement. ~~each user shall be required to read a copy of the warning specified in Section R12-1-1415. The user shall sign a statement that the information has been read and understood. For illiterate or visually handicapped persons, the warning statement shall be read by the operator in the presence of a witness. Both the witness and the operator shall sign the statement.~~
- ~~F.~~ A record shall be kept by the operator of each user's total number of tanning visits and tanning times.
- ~~G.~~ Each operator shall be trained and records of training retained in the facility. Training shall include:
1. The requirements of this Section;
 2. Procedures for correct operation of the facility;
 3. Manufacturer's procedures for operation and maintenance of tanning equipment;

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- 4. Recognition of injury or overexposure;
- 5. Emergency procedures in case of injury.

H. A list of operators trained in accordance with R12-1-1414(G) shall be posted at the facility.

R12-1-1415. Tanning Facility Warning Signs and Statements for Tanning Facilities

A. A registrant shall conspicuously post the warning sign described in subsection (B) within 1 meter (39.37 inches) of each tanning device. The sign shall be clearly visible, not obstructed by any barrier, equipment or other object, and easily viewed by the user before operating the tanning device. The sign shall read as follows:

DANGER - ULTRAVIOLET RADIATION
 1. Follow instructions.
 2. Avoid overexposure. As with natural sunlight, exposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin, dryness, wrinkling, and skin cancer.
 3. Wear protective eye wear.
FAILURE TO USE PROTECTIVE EYE WEAR MAY RESULT IN SEVERE BURNS OR LONG TERM INJURY TO THE EYES.
 4. Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult a physician before using a sunlamp if you are using medications or have a history of skin problems or believe you are especially sensitive to sunlight.
 5. If you do not tan in the sun, you are unlikely to tan from use of this device.

A warning sign shall be posted in the area where a tanning device is used or where each user must pass before entering a tanning device.

B. A sign shall be posted in conspicuous view at or near the reception area with the following text:

PERSONS UNDER AGE 18 ARE REQUIRED TO HAVE PARENT OR LEGAL GUARDIAN SIGN
 AUTHORIZATION TO TAN IN THE PRESENCE OF A TANNING FACILITY OPERATOR

B. The sign shall be clearly visible and unobstructed by any barrier or other item.

C. The lettering on each warning sign shall be at least 10 millimeters high for all words shown in capital letters and at least 5 millimeters high for all lower case letters.

C. The sign shall read as follows:-

DANGER - ULTRAVIOLET RADIATION
 1. Follow instructions.
 2. Avoid overexposure. As with natural sunlight, exposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin, dryness, wrinkling, and skin cancer.
 3. Wear protective eye wear.
FAILURE TO USE PROTECTIVE EYE WEAR MAY RESULT IN SEVERE BURNS OR LONG TERM INJURY TO THE EYES.
 4. Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult a physician before using a sunlamp if you are using medications or have a history of skin problems or believe you are especially sensitive to sunlight.
 5. If you do not tan in the sun, you are unlikely to tan from use of this device.

D. The lettering on each warning sign shall be at least ten millimeters high for all words shown in capital letters and at least five millimeters high for all lower case letters.

R12-1-1416. Reporting of Tanning Injuries Injuries In Tanning Facilities

A. A registrant ~~The licensee~~ shall report an incident involving any eye injury, skin burn, fall injury, if the fall occurs within the tanning device or while entering or exiting the device, laceration, or infection believed to be possibly transmitted by use of the tanning device.

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- B. ~~A registrant shall provide a written report of the incident to the Agency within 10 working days of its occurrence or the date the registrant became aware of the incident~~ The report shall be forwarded to the Agency within ten working days of its occurrence or the date the registrant gained knowledge thereof.
- C. No change
1. The name of the user; ;
 2. Name and location of the tanning facility; ;
 3. A description of ~~nature of the injury~~ and its causes; ;
 4. The name and address of the health care provider treating the user, if any; ; and
 5. Any other information the ~~licensee~~ registrant may consider relevant to the incident.

R12-1-1417. High Intensity Mercury Vapor Discharge (HID) Lamps Repealed

- A. ~~Unless otherwise approved by the Agency, each facility using HID lamps shall meet the following requirements:~~
1. ~~For indoor facilities, HID lamps shall be:~~
 - a. ~~Self-extinguishing lamps bearing the letter "T" on the label, or~~
 - b. ~~Non-self-extinguishing lamps, bearing the letter "R" on the label, provided that the lamp is installed within a totally enclosed protective shield which protects the lamp from damage.~~
 2. ~~For outdoor facilities, HID lamps shall be:~~
 - a. ~~Self-extinguishing lamps bearing the letter "T" on the label,~~
 - b. ~~Non-self-extinguishing lamps, provided that the lamp is installed within a totally enclosed protective shield which protects the lamp from damage, or~~
 - c. ~~Exempted by the Agency as a result of the licensee providing sufficient information to the Agency to enable the Agency to determine that precautions taken to minimize the exposure to ultraviolet radiation with wavelengths less than 320 nanometers are at least as effective as the requirements of subsections (a) and (b) above.~~
 - d. ~~Street lighting and security lighting fixtures permanently mounted 18 feet (5.5 meters) or higher above ground level are exempted from the requirements of this subsection.~~
- B. ~~A written report of any injury due to overexposure to ultraviolet light from a HID lamp shall be forward to the Agency by the owner of the facility within 10 working days of its occurrence or of the date that the licensee gained knowledge thereof. The report shall include:~~
1. ~~The names of all individuals known to have been injured,~~
 2. ~~The name and location of the facility,~~
 3. ~~The name and address of the health care providers treating the injuries, if any,~~
 4. ~~The type of lamp involved ("T" or "R"), lamp model designation and manufacturer,~~
 5. ~~Any other information the licensee may consider relevant to the incident.~~

R12-1-1418. Reserved High Intensity Mercury Vapor Discharge (HID) Lamps

HID lamps not meeting the requirements in 21 CFR 1040(20), 2003 edition, published April 1, 2003, by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Agency, shall be registered with the Agency. This incorporation by reference contains no future editions or amendments.

R12-1-1421. Laser Safety Requirements, Surveys, and Records

- A. ~~The requirements contained in this rule~~ These requirements, including special requirements for testing, maintenance, and modification, shall apply to laser products in their intended mode of operation only. During manufacture and research and development activities, when some engineering controls may be inappropriate, the LSO shall specify alternate requirements to obtain equivalent laser safety protection.
- B. ~~A registrant shall establish and maintain a program of laser radiation safety. The licensee shall appoint a laser safety officer and shall establish and maintain an effective program of laser radiation safety.~~
- C. ~~Each licensee registrant shall conduct~~ make or cause to be made such laser radiation protection surveys as may be necessary to comply with R12-1-1433 prior to initial use, initially prior to routine operation, upon following system modifications, and regularly at intervals not to exceed six months. Surveys shall include ~~but not be limited to:~~
1. A determination that all laser protective devices are labeled correctly and functioning within the design specifications, and are proper for the type and class of lasers in use; ;
 2. A determination that all warning devices are functioning within their design specifications; ;
 3. A determination that each laser controlled area is properly identified, access is controlled, and the area is posted with accurate warning signs in accordance with R12-1-1427; ;
 4. A re-evaluation of potential hazards from surfaces which may be associated with Class 3 ~~III~~ and Class 4 ~~IV~~ beam paths; and -
 5. No change
- D. ~~A registrant~~ The licensee shall retain records of:
1. Surveys ~~Results of all physical surveys~~ made to determine compliance with this Article;
 2. Operating ~~Records indicating any restriction in operating~~ procedures necessary to prevent unnecessary or excessive exposure to laser or collateral radiation;
 3. Incidents ~~Records relating to any incident~~ for which reporting to the Agency is required in pursuant to R12-1-1436;

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4. ~~Medical Results of medical~~ surveillance to determine extent of injury resulting from exposure to laser or collateral radiation;
5. No change

R12-1-1422. General Requirements for All Laser Facilities

- A. Each laser product shall have a protective housing which prevents ~~human access during operation~~ to laser and collateral radiation that exceeds the limits ~~for Class 1 lasers of Class I and paragraphs A and B of Table X in R12-1-1426, , wherever and whenever such human access is not necessary in order for the product to perform its intended function. Accessible~~ ~~Wherever and whenever humans are able to access to laser radiation levels that exceed the limits of Class 1 I or the acces-~~ ~~sible emission limits from Title 21, Code of Federal Regulations, Section 1040.10, 1993 Edition, Published April 1, 1993, by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Office of Secretary of State, containing no future editions or amendments, these levels shall not exceed the limits of the lowest laser class necessary to perform the intended function.~~
- B. ~~To prevent access to radiation above MPE limits each laser devise shall have a safety interlock, which prevents operation of the laser when removing A safety interlock, which shall ensure that radiation is not accessible above MPE limits, shall be provided for any portion of the protective housing which, by design, can be removed or displaced without the use of tools during normal operation or maintenance, and thereby allow access to radiation above MPE limits.~~
1. ~~Adjustment during operation, service~~ Service, testing, or maintenance of a laser containing interlocks shall not cause the interlocks to become inoperative or the radiation to exceed MPE limits outside protective housing except where a laser controlled area as specified in R12-1-1433 is established.
 2. No change
 3. For Class ~~3b IIIb~~ and ~~4 IV~~ continuous wave (cw) lasers, the interlocks shall turn off the power supply or interrupt the beam.
 4. No change
 5. Multiple safety interlocks or a means to preclude removal or displacement of the interlocked portion of the protective housing shall be provided if ~~if~~ failure of a single interlock ~~could result in: would allow;~~
 - a. Human access to levels of laser radiation in excess of the radiant power accessible emission limit of Class ~~3a IIIa~~ laser radiation, or
 - b. Laser radiation in excess of the accessible emission limit of Class ~~2 II~~ ~~to be~~ emitted directly through the opening created by removal or displacement of that portion of the protective housing; ~~then, either multiple safety interlocks or a means to preclude removal or displacement of the interlocked portion of the protective housing upon such failure shall be provided.~~
- C. ~~A laser with All~~ viewing ports, viewing optics, or display screens included as an integral part of an enclosed laser or laser system shall:
1. Incorporate a suitable means to attenuate the laser and collateral radiation transmitted through the port to less than the MPE and the accessible emission limits for collateral radiation ~~from in 21 CFR 1040(10), 2003 edition, published April 1, 2003, Title 21, Code of Federal Regulations, Section 1040.10, 1993 Edition, Published April 1, 1993, by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Agency Office of Secretary of State. This incorporation by reference contains no future editions or amendments; and, under any conditions of operation of the laser.~~
 2. Have specific administrative procedures and use controls such as interlocks or filters determined by the LSO if there is increased hazard to the eye or skin associated with the use of ~~The laser safety officer shall determine the potential for increased hazard that the use of optical systems such as lenses, telescopes, and microscopes may cause to the eye or the skin, and specify administrative procedures and the use of controls such as interlocks or filters.~~
- D. Each Class ~~3 III~~ or ~~4 IV~~ laser product shall provide visual or audible indication during the emission of accessible laser radiation in excess of the limits of Class ~~1 I~~.
1. For class ~~3 IIIb~~, except those which allow access only to less than 5 milliwatts peak visible laser radiation, and Class ~~4 IV~~ lasers, the indication shall be sufficiently prior to emission of such radiation to allow appropriate action to avoid exposure.
 2. No change
 3. No change
 4. No change
 5. Class 3b and Class 4 lasers for human use shall only be used by a licensed practitioner, or under the indirect supervision of a licensed practitioner.
- E. In addition to the contents of signs, symbols and labels prescribed in R12-1-1427, R12-1-1428, and R12-1-1429, each ~~licensee~~ registrant shall provide near the signs, symbols and labels within the laser facility operating procedure restrictions and any additional information ~~which is necessary to ensure compliance with this Article and~~ minimize exposure to laser ~~and~~ or collateral radiation ~~within a facility.~~
- F. ~~Any restrictions in operating procedures required to ensure compliance with this Article shall be legibly posted at a position clearly visible to the laser operator.~~

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R12-1-1423. Laser Prohibitions

- A. ~~An~~ No individual shall not be permitted to look directly into a laser beam, directly at specular reflections of a laser beam, or align a laser by eye while looking along the axis of a beam when the intensity of ~~the such~~ beams or reflections exceed the MPE limits. ~~exceeds the MPE limits in this Article.~~
- B. A registrant ~~The licensee~~ shall not permit an ~~any~~ individual to enter a laser- controlled area if the ~~when~~ skin exposure is ~~in~~ excess of the MPE limits, is likely ~~unless the licensee~~ registrant provides and requires the use of protective clothing, gloves, and shields.
- C. No change

R12-1-1425. Laser Product Classification

- A. Each laser product or installation shall be classified on the basis of ~~that combination of~~ emission level, emission duration, and wavelength of accessible laser radiation emitted over the full range of resulting operational capability which results, any time during the useful life of the such product or installation, according to in accordance with the requirements of the federal performance standards for light-emitting products contained in 21 CFR 1040.10, 21 CFR 1040(10), 2003 edition, published April 1, 2003, by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Agency. This incorporation contains no future editions or amendments.
- B. The modification of any laser product or installation, which affects any aspect of performance or intended functions of the such product or installations, shall require reclassification and relabeling according to in accordance with 21 CFR 1040.10 21 CFR 1040(10) 2003 edition, published April 1, 2003, by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Agency and the Office of Secretary of State. This incorporation contains no future editions or amendments.
- C. Any laser system that is incorporated into a laser product that is subject to the requirements of this Article and that is capable, without modification, of producing laser radiation when removed from the such laser product, shall itself be considered a laser product, and shall be separately subject to the applicable requirements of this Article for laser products in its class. Upon removal it ~~it~~ shall be classified on the basis of accessible laser radiation emission ~~of laser radiation when so removed.~~

R12-1-1426. ~~Maximum Permissible Exposure Limits to Laser and Collateral Radiations~~ Laser and Collateral Radiation Exposure Limits

- A. A registrant ~~No licensee~~ shall not use, or permit the use of a any laser product ~~products~~ or installation which allows human exposure in excess of the MPE limits. Included are the intrabeam MPE limits for the eye, MPE to the eye for extended source viewing, and the MPE limits for skin exposure. The MPE limits are in ANSI Z136.1-2000 1993, American National Standard for Safe Use of Lasers, 2000 edition 1993 Edition, Published by the Laser Institute of America, Incorporated herein by reference and on file with the Office of Secretary of State Agency, and accessible emission limits in 21 CFR 1040(10), Title 21, 2003 edition, published April 1, 2003, Code of Federal Regulations, Section 1040.10, 1993 Edition, Published April 1, 1993, by the Office of Federal Register National Archives and Records Administration, incorporated by reference and on file with the Agency the Office of Secretary of State. This incorporation by reference contains no future editions or amendments.
- ~~B. Maximum permissible exposure limits to the eye for intrabeam viewing shall not exceed those shown in ANSI Z136.1-1993, American National Standard for Safe Use of Lasers, 1993 Edition, Published by the Laser Institute of America, Incorporated by reference and on file with the Office of Secretary of State. This incorporation by reference contains no future editions or amendments.~~
- ~~C. Maximum permissible exposure to the eye for extended source viewing shall not exceed the limits shown in ANSI Z136.1-2000, American National Standard for Safe Use of Lasers, 2000 Edition, Published by the Laser Institute of America, Incorporated by reference and on file with the Office of Secretary of State. This incorporation by reference contains no future editions or amendments.~~
- ~~D. Skin exposure to laser radiation shall not exceed the MPE limits shown in ANSI Z136.1-1993, American National Standard for Safe Use of Lasers, 1993 Edition, Published by the Laser Institute of America, Incorporated by reference and on file with the Office of Secretary of State. This incorporation by reference contains no future editions or amendments.~~
- ~~E.B.~~ Exposure to collateral radiation shall not exceed the accessible emission limits in 21 CFR 1040(10), 2003 edition, published April 1, 2003, Title 21, Code of Federal Regulations, Section 1040.10, 1993 Edition, Published April 1, 1993, by the Office of Federal Register National Archives and Records Administration, incorporated by reference and on file with the Agency the Office of Secretary of State. This incorporation by reference contains no future editions or amendments.

R12-1-1427. Requirements for Laser Caution Signs, Symbols, and Labels

- A. Except as otherwise authorized by the Agency, signs, symbols and labels prescribed by this Section shall use the design and colors specified in ANSI Z136.1- 2000 1993, American National Standard for Safe Use of Lasers, 2000 edition 1993 Edition, published by the Laser Institute of America, Incorporated herein by reference and on file with the ~~Office of Secretary of State~~ Agency. This incorporation by reference contains no future editions or amendments.
- B. No change
- C. No change

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- D. All labels placed on lasers or signs posted in ~~to~~ laser facilities shall be positioned so as to make unnecessary, during reading, human exposure to laser or collateral radiation in excess of the MPE and AEL. that the reader of the label or sign is not exposed to laser or collateral radiation in excess of the MPE and AEL limits while reading the label or sign.
- E. No change
- F. Each laser shall have a label permanently and legibly affixed which identifies, ~~in accordance with the requirements in Title 21, Code of Federal Regulations, Part 1040, 1993 Edition, the classification of the laser according to 21 CFR 1040(10), 2003 edition, published April 1, 2003~~ Published April 1, 1993, by the Office of Federal Register National Archives and Records Administration, incorporated by reference and on file with the Agency ~~the Office of Secretary of State. This incorporation contains~~ no future editions or amendments. ~~the classification of the laser.~~
- G. At position 2 on the warning logotype affixed to a Class 3 and Class 4 Each Class III and IV laser shall state, at position 2 on the required warning logotype, the maximum output of laser radiation, the pulse duration when appropriate, and the laser medium or emitted wavelength.
- H. Class 3 III and 4 IV lasers, except lasers used in the practice of medicine, shall have a label ~~in close proximity to each aperture through which is emitted accessible laser or collateral radiation in excess of the MPE limits specified in R12-1-1426, with the following wording as applicable:~~ containing the following wording near each aperture that emits laser radiation or collateral radiation in excess of the MPE limits:
1. No change
 2. No change
 3. No change
- I. Each non-interlocked or defeatable ~~defeatably~~ interlocked portion of the protective housing or enclosure which permits human access to laser or collateral radiation which is designed to be displaced or removed during normal operation, maintenance, or servicing, and which thereby would permit human access to laser or collateral radiation, shall have a label containing the following wording ~~be labeled as follows:~~
1. For laser radiation in excess of the accessible emission limits of Class 1 I or Class 2 II as applicable, but not in excess of the accessible emission limits of Class 3 III, the wording: "DANGER - Laser radiation when open, AVOID DIRECT EXPOSURE TO THE BEAM."
 2. For laser radiation in excess of the accessible emission limits of Class 3 III, the wording: "DANGER - laser radiation when open, AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION."
 3. No change
 - a. No change
 - b. No change
 4. For protective housing or enclosures which have ~~provide~~ a defeat able interlock, the words "and interlock defeated" shall be included in the labels specified above.

R12-1-1429. Posting of Laser Facilities

Each laser facility ~~Facilities~~ shall be posted in accordance ~~a manner consistent~~ with ANSI Z136.1-2000 ~~1993~~, American National Standard for Safe Use of Lasers, 2000 edition ~~1993 Edition~~ Edition, Published by the Laser Institute of America, Incorporated ~~herein~~ by reference and on file with the Agency ~~Office of Secretary of State. This incorporation by reference contains~~ no future editions or amendments, or as otherwise approved in writing by the Agency.

R12-1-1433. Laser-controlled Areas

- ~~A. With a Class IIIb or Class IV laser, except those Class IIIb lasers which allow access only to less than 5 milliwatts visible peak power, a laser-controlled area shall be established when exposure to the laser radiation in excess of the MPE or AEL in R12-1-1426 is possible. The controlled area shall meet the requirements of subsections (B) through (D) for Class IIIb lasers and the requirements of subsections (B) through (H) for Class IV lasers.~~
- ~~B. The area shall be the responsibility of the laser safety officer.~~
- ~~C. The area shall be posted as required by R12-1-1427.~~
- ~~D. Access to the laser-controlled area shall be only by permission of the laser safety officer or a trained, designated representative.~~
- E. For Class IV indoor controlled areas, latches, interlocks, or other appropriate means shall be used to prevent unexpected entry into laser-controlled areas:
1. ~~Such measures shall be designed to allow both rapid egress by the laser personnel at all times and admittance to the laser-controlled area in an emergency condition.~~
 2. ~~For emergency conditions, a control disconnect switch, panic button, or equivalent device shall be available for deactivating the laser.~~
- ~~F. For Class IV indoor controlled areas, during tests requiring continuous operation, the individual in charge of the controlled area shall be permitted to momentarily override the safety interlocks to allow access to other authorized personnel if it is clearly evident that there is no optical radiation hazard at the point of entry and if the necessary protective devices are being worn by the entering personnel.~~
- ~~G. For Class IV indoor controlled areas, optical paths such as windows from an indoor facility shall be controlled in such a manner as to reduce the transmitted values of the laser radiation to levels at or below appropriate ocular MPE and AEL in~~

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R12-1-1426. When the laser beam must exit the indoor controlled area (as in the case of exterior atmospheric beam paths), the operator shall be responsible for ensuring that the beam path is limited to controlled air space or controlled ground space when the beam irradiance or radiant exposure is above the appropriate MPE and AEL.

- H.** ~~In cases where removal of panels or protective covers or overriding of interlocks becomes necessary, such as for service, testing, or maintenance, accessible laser-controlled areas shall be established. The laser safety officer or a designated representative shall ensure that the necessary laser safety requirements for all potentially exposed individuals shall be established.~~
- A.** A laser-controlled area shall be established when it is possible for a person to be exposed to laser radiation from a Class 3b, not to include 3b lasers of less than 5 milliwatts visible peak power, or the radiation from a Class 4 laser in excess of the MPE or AEL in R12-1-1426.
- B.** A controlled area associated with the Class 3b laser described in subsection (A) shall:
1. Be the responsibility of a LSO;
 2. Be posted in accordance with R12-1-1427; and
 3. Be access controlled by a LSO or a trained, designated representative.
- C.** A controlled area associated with a Class 4 laser shall:
1. Be the responsibility of a LSO;
 2. Be posted in accordance with R12-1-1427;
 3. Be access controlled by a LSO or a trained, designated representative; and
 4. Indoor controlled areas shall:
 - a. Have latches, interlocks, or other appropriate means to prevent unexpected entry into the laser-controlled areas;
 - b. Have a control-disconnect switch, panic button, or equivalent available for deactivating the laser during an emergency;
 - c. Be operated in such a manner that the person in charge of the controlled area can momentarily override the safety interlocks during tests requiring continuous operation to allow access to other personnel if there is no optical radiation hazard at the point of entry and if the entering personnel are wearing the necessary protective devices; and
 - d. Be controlled in such a manner as to reduce the transmitted values of the laser radiation through optical paths such as windows, to levels at or below appropriate ocular MPE and AEL in R12-1-1426. When the laser beam must exit the indoor controlled area (as in the case of exterior atmospheric beam paths), the operator shall be responsible for ensuring that the beam path is limited to controlled air space or controlled ground space when the beam irradiance or radiant exposure is above the appropriate MPE and AEL.
 5. When panels or protective covers are removed or interlocks bypassed for service, testing, or maintenance, accessible laser-controlled areas shall be established. The LSO or a designated representative shall ensure that the necessary laser safety requirements for all potentially exposed individuals are established.

R12-1-1434. Laser Safety Officer (LSO) Duties

- A.** Each registrant shall appoint a LSO.
- B.** The Laser Safety Officer shall administer the laser radiation protection program and shall:
1. Assure that maintenance and service for Class ~~3b~~ ~~IIIb~~ and Class ~~4~~ ~~IV~~ lasers ~~are~~ ~~shall be~~ performed only by technicians trained to provide the maintenance and such service by either the manufacturer's service organization or the institution's staff;
 2. Approve written service and maintenance, and operating procedures;
 3. Investigate, document, and report all incidents and accidents as required by R12-1-1436;
 4. No change
 5. No change
 6. No change
 7. No change
 8. No change
 9. Classify or verify the classification of ~~lasers~~ ~~laser~~ and laser systems used under the LSO's jurisdiction;
 10. No change

R12-1-1435. Laser Protective Eye Wear for Use in Laser Facilities

- A.** Protective eye wear, as specified by the ~~LSO laser safety officer~~, shall be worn:
1. By all individuals having with access to ~~Class 4~~ ~~Class IV~~ levels of laser radiation.
 2. ~~When required by the laser safety officer, by all individuals with access to Class IIIb levels of laser radiation. By all individuals having access to Class 3b laser radiation, and as designated by the LSO.~~
- B.** No change
1. ~~Have a label indicating the optical density for the wavelength~~ Be legibly and permanently labeled indicating the optical density at the wavelengths for which each such affords adequate protection;
 2. Be maintained ~~so that in proper condition to assure~~ the protective properties of the protective eye wear are retained;
 3. Be inspected at intervals not to exceed six months to ensure integrity of the protective properties;

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4. Be removed from service ~~when it has been determined that the same level of protective properties is no longer provided to the wearer, should the be determined to be in a condition resulting in decreased protection.~~
- C. Records of protective eye wear maintenance, inspections and removal from service shall be retained for three ~~five~~ years.

R12-1-1436. Reporting of Laser Incidents

- ~~A.~~ The licensee shall be responsible for the reporting to the Agency any incident involving known or suspected exposure to laser or collateral radiation, from a source possessed by the licensee, in excess of the MPE limits in R12-1-1426, Tables VII through X.
- ~~B.~~ A registrant shall notify the Agency by telephone ~~The Agency shall be notified within 24 hours by telephone~~ of any incident which has caused or may have caused:
1. No change
 2. No change
- ~~C.~~ A registrant ~~Each licensee~~ shall notify the Agency by telephone within five working days of any incident which has or may have caused:
1. Second-degree burns of the skin larger than 1 one ~~one~~ inch (2.54 centimeter) in greatest diameter; or
 2. No change
 3. No change
- ~~D.~~ A registrant ~~Each licensee~~ shall file a written report of a known exposure of an individual to laser radiation or collateral radiation with the Agency ~~make a report in writing within 30 days of its discovery, describing: to the Agency of:~~
1. No change
 2. Any incident of which notification is required by subsection (A) or (B) ~~(B)~~ ~~or (C)~~.
- ~~E.~~ Each report required by subsection (C) ~~(D)~~ shall describe the extent of exposure to each individual, ~~of individuals to laser or collateral radiation,~~ including:
1. An estimate of the ~~Estimates of each~~ individual's exposure;
 2. The level ~~Levels~~ of laser or collateral radiation involved;
 3. No change
 4. The corrective ~~Corrective~~ steps taken or planned to be taken to assure against a recurrence.
- ~~F.~~ A registrant ~~The licensee~~ shall not operate, nor permit the operation of, any laser product or system which does not meet all of the applicable requirements of this Article.

R12-1-1437. ~~Additional Requirements for Special Lasers and Applications~~ Special Lasers

- A registrant operating a laser system with an ~~Installations operating laser systems with~~ unenclosed beam path shall:
1. Conduct an evaluation before operating the laser to determine ~~of~~ the expected beam path and the potential hazards from incidental reflective surfaces which may be encountered before operating the laser. Incidental reflective surfaces shall be excluded from the beam path at all points where the laser radiation exceeds MPE limits.
 2. Evaluate the ~~The~~ stability of the laser platform shall be evaluated to determine the constraints that shall be placed upon the beam traverse and the extent of the range of control.
 3. Not operate or make ready for operation a laser ~~No laser shall be operated or made ready for operation~~ until the area along all points of the beam path where the laser radiation will exceed the MPE is clear of individuals, unless the individuals are wearing appropriate protective devices.

R12-1-1438. ~~Repeated~~ Requirements for Laser and Light Based Cosmetic Procedures

- A. When using a medical laser or an IPL device that is a Class II or III surgical device certified as complying with the design, labeling, and manufacturing standards of the FDA, for cosmetic procedures, a registrant shall:
1. Ensure the device is only used by a licensed practitioner, or by an operator under indirect supervision of a licensed practitioner.
 2. Ensure that a licensed practitioner purchases a Class II or III surgical device that will be used for cosmetic procedures.
- B. A registrant shall not permit an individual to use a medical laser or IPL system for cosmetic procedures until the individual has:
1. Completed an approved medical laser assistant didactic training course of at least 40 hours in duration. Successful completion of the training program will be based on a test consisting of a least 50 multiple choice questions on subjects covered, with a minimum grade of 80%. The training should be provided by an individuals who is eligible, through training and experience, to apply for laser safety officer certification or is a certified laser safety officer; and
 2. Completed a minimum of 16-40 hours of observation and hands on experience, per cosmetic procedure, shall be conducted under the direct supervision of a medical director. Cosmetic procedures performed shall follow written protocols and shall follow the prescribed orders established for the specific site by the medical director.
- C. A registrant shall ensure that cosmetic procedure protocols are approved by the medical director in writing, and reviewed at least annually. Protocols shall be:
1. Maintained onsite, and shall contain instructions to be given to the patient for follow-up monitoring; and

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2. Designed to promote the exercise of professional judgement by the nurse or assistant commensurate with their education, experience and training; and need not describe the exact steps that a qualified assistant take with respect to laser cosmetic procedures.

D. A registrant shall ensure the medical director observes the performance of each assistant operator during actual procedures at intervals not to exceed six months.

E. A registrant shall ensure the medical director is qualified to do laser, IPL and related procedures, by virtue of providing evidence to the registrant that the medical director has received appropriate training in physics, safety, surgical techniques, pre and post operative care.

F. Radiation safety training shall be provided to the following personnel and shall be commensurate with their involvement with a laser or IPL system: LSO's, USER's (e.g. physicians, dentists, podiatrists, veterinarians, non-practitioner etc.), Laser/IPL technical support staff (e.g. clinical engineers, laser technicians, etc.), Perioperative team members (e.g. anesthesiologists, nurses, dental hygienists, assistants, etc.), and Laser/IPL system service personnel, including either in-house or contractor provided service personnel. All radiation safety training activities shall be documented and be available for Agency review for three years following assistant operator's period of employment.

R12-1-1439. Additional Requirements for Medical Laser Applications Laser/IPL User Safety Training Approval

A. Each Class III and Class IV medical laser product shall incorporate the means for measurement of the level of laser radiation intended for human irradiation, with an error in measurement of no greater than $\pm 20\%$, when calibrated in accordance with the laser product manufacturer's calibration procedure.

B. Medical lasers used for human irradiation shall be calibrated in accordance with the manufacturer's specified calibration procedure, at intervals not to exceed those specified by the manufacturer.

C. The licensee shall ensure that medical lasers shall not be used for human irradiation unless all applicable requirements of this Article are met.

D. In institutions where a number of different practitioners may use Class IIIb and Class IV lasers, a laser safety committee shall be formed to govern laser activity, establish use criteria, and approve operating procedures:

1. Membership on the committee shall include at least a representative of the Nursing staff, the Laser Safety Officer, a representative of institution management, and a representative of each medical discipline that utilizes the lasers.

2. The committee shall review actions by the Laser Safety Officer in hazard evaluation and the monitoring and control of laser hazards.

3. Users, and those ancillary personnel who may operate or assist in the operation of the lasers under the direction of the users, shall be approved by the committee.

E. For Class IIIb and IV lasers, the switch which controls patient exposure shall have a guard mechanism to prevent inadvertent exposure.

A. An applicant seeking to open a medical laser/IPL user training program shall apply to the Agency for approval of the program. The application shall include a course syllabus, including a test consisting of at least 50 multiple choice questions on subjects covered. The course material shall address all of the safety issues in R12-1-1421 through R12-1444, and Appendix B.

B. The Agency shall review the application in subsection (A) in a timely manner as required in A.A.C. R-12-2-301.

C. The Agency shall maintain a list of approved laser/IPL training programs.

R12-1-1440. ~~Laser Light Shows~~ Medical Lasers

A. Prior to the performance of a laser light show, the licensee shall provide to the Agency documentation that a variance has been obtained in accordance with 21 CFR 1040.10, 1993 edition, published April 1, 1993, by the Office of the Federal Register, National Archives and Records Administration, incorporated by reference and on file with the Department and the Office of the Secretary of State, containing no future editions or amendments, to conduct the show.

B. The licensee shall notify the Agency in writing, at least two days in advance of the proposed laser light show, and shall include the following information:

1. The location, time, and date of the light show;

2. Sketches showing the location of the laser, operators, performers, laser beam path, viewing screens, walls, mirror balls, and other reflective or diffuse surfaces which may be struck by the laser beam;

3. Scanning beam patterns, scan velocity, and frequency in occupied areas;

4. Physical surveys and calculations made to ensure compliance with this Article.

C. The licensee shall also supply such additional information as may be required by the Agency for the evaluation of the safety of the proposed performance.

D. Prior to the performance of an outdoor laser light show, the licensee shall notify the Federal Aviation Administration of the proposed show.

E. Laser radiation emissions outside the spectral range 400 to 700 nanometers shall not exceed Class I accessible emission limits.

F. Levels of laser and collateral radiation, where the audience is located, and where operators, performers, and employees are located if the radiation is intended to be viewed by them, shall not exceed Class I accessible emission limits.

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- G.** Operators, performers, and employees shall be able to perform their functions without being exposed to laser or collateral radiation exceeding Class II accessible emission limits when the radiation is not intended to be viewed by them.
- H.** Areas where levels of laser radiation exceed the Class II accessible emission limit shall be identified by posting of warning signs and through use of barriers or guards to prevent individuals from entering these areas.
- I.** Scanning devices shall not, as a result of scan failure or any other failure causing a change in either angular velocity or amplitude, permit audience exposure to laser radiation in excess of the accessible emission limits for a Class I laser product.
- J.** Where a mirror ball is used with a scanning laser, the conditions of subsections (E) and (F) shall be met with the mirror ball stationary or during any failure mode resulting in a change in rotational speed of the mirror ball.
- K.** Laser light shows shall be at all times under the direct and personal supervision of the laser operator 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 less than 2.5 meters in lateral separation from any position where an individual in the audience is permitted during the performance.
- L.** Laser radiation levels shall not exceed the accessible emission limits for Class II laser products at any point less than 3 meters above any surface upon which any 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 which prevent human access to such levels.
- M.** The maximum laser power output shall be limited to a level sufficient to produce the desired effect.
- N.** When laser output power must be limited to less than available power in order to satisfy the requirements of this Article, the laser output power shall be adjusted, measured, and recorded prior to the performance of the laser light show.
- O.** All safety devices and procedures necessary to comply with this Article shall be functionally tested and evaluated after setup and prior to the performance of laser light show to ensure compliance.
- P.** The laser system, when not in use, shall be secured against unauthorized operation or tampering.
- Q.** Laser alignment procedures shall be performed with the laser output power reduced to the lowest practicable level, and protective eye wear shall be worn where necessary to prevent exposure to radiation levels exceeding MPE. Only persons required to perform the alignment shall be present during such procedures.
- R.** The licensee shall ensure that no laser light show is conducted except as specifically authorized in a variance issued in accordance with 21 CFR 1040.10, 1993 edition, published April 1, 1993, by the Office of the Federal Register, National Archives and Records Administration, incorporated by reference and on file with the Department and the Office of the Secretary of State, containing no future editions or amendments, and applicable requirements of this Article.
- A.** A Class 3 and Class 4 medical laser product shall incorporate a means for measurement of the level of laser radiation intended for human irradiation, with an error in measurement of no greater than + 20%, when calibrated in accordance with the laser product manufacturer's calibration procedure.
- B.** A Medical laser shall be calibrated according to the manufacturer's specified calibration procedure, at intervals not to exceed those specified by the manufacturer.
- C.** In a medical facility using multiple medical disciplines where a number of different practitioners may use Class 3b and Class 4 lasers, a Laser Safety Committee shall be formed to govern laser activity, establish use criteria, and approve operating procedures.
 1. Membership on the committee shall include at least a representative of the Nursing staff, the LSO, a representative of institution management, and a representative of each medical discipline that utilizes the lasers.
 2. The committee shall review actions by the LSO in hazard evaluation, and the monitoring and control of laser hazards.
 3. Users, and those ancillary personnel who may operate or assist in the operation of the lasers under the direction of the users, shall be approved by the committee.
- D.** A Class 3b and Class 4 Laser shall have a switch with a guard mechanism to prevent inadvertent exposure which controls patient exposure.
- E.** Each registrant shall establish a laser safety training program that provides a thorough understanding of established procedures for the type of laser in use and the medical procedures being performed. The program shall be recorded for Agency review, and as a minimum, address the following:
 1. Regulatory requirements and the laser classification system;
 2. Fundamentals of laser operation and the significance of specular and diffuse reflections;
 3. Bio-effects of laser radiation on the eye and skin;
 4. Non-beam hazards of lasers (electrical, chemical, reaction by-products, etc.) and ionizing radiation hazards (x-rays from power sources and target interactions when applicable; and
 5. The responsibilities of management and employee as they relate to control measures.

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R12-1-1441. ~~Measurements and Calculations to Determine MPE Limits for Lasers~~ Laser Light Shows and Demonstrations

Measurements to determine MPE limits shall be made in a manner consistent with the procedures contained in ANSI Z136.1-1993, American National Standard for Safe Use of Lasers, 1993 edition, published by the Laser Institute of America, incorporated by reference and on file with the Department and the Office of the Secretary of State, containing no future editions or amendments, or as otherwise approved by the Agency.

- A.** Before a laser light show or laser demonstration, a registrant shall provide to the Agency, documentation that a variance has been obtained in accordance with 21 CFR 1040(10), 2003 edition, published April 1, 2003, by the Office of Federal Register National Archives and Records Administration, incorporated by reference and on file with the Agency, to conduct the show. This incorporation by reference contains no future editions or amendments.
- B.** Class IIIa laser lighting and entertainment products used for commercial purposes shall licensed as laser lights and meet the requirements of subsections (C) through (S).
- C.** A registrant shall notify the Agency in writing, at least three working days in advance of the proposed laser light show or laser demonstration, and shall include the following information:
 - 1. The location, time, and date of the light show;
 - 2. Scanning beam patterns, scan velocity, and frequency in occupied areas; and
 - 3. Physical surveys and calculations made to ensure compliance with this Article.
- D.** A registrant shall also supply such additional information as may be required by the Agency for the evaluation of the safety of the proposed activity.
- E.** Before an outdoor laser light show, a registrant shall notify the Federal Aviation Administration of the proposed show.
- F.** Laser radiation emissions outside the spectral range 400 to 700 nanometers shall not exceed Class 1 accessible emission limits.
- G.** Levels of laser and collateral radiation, where the audience is located, and where operators, performers, and employees are located if the radiation is intended to be viewed by them, shall not exceed Class 1 accessible emission limits.
- H.** All persons, including operators, performers, and employees, in the vicinity of the laser light show or laser demonstration shall not be exposed to laser or collateral radiation exceeding Class 2 accessible emission limits when the radiation is not intended to be viewed by them.
- I.** Areas where levels of laser radiation exceed the Class 2 accessible emission limit shall be identified by posting of warning signs and through use of barriers or guards to prevent individuals from entering these areas.
- J.** Scanning devices shall not, as a result of scan failure or any other failure causing a change in either angular velocity or amplitude, permit audience exposure to laser radiation in excess of the accessible emission limits for a Class 1 laser product.
- K.** Where a mirror ball is used with a scanning laser, the conditions of subsections (F) and (G) shall be met with the mirror ball stationary or during any failure mode resulting in a change in rotational speed of the mirror ball.
- L.** At all times a laser light show or laser demonstration shall be under the direct and personal supervision of the operator 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 less than 2.5 meters in lateral separation from any position where an individual in the audience is permitted during the performance.
- M.** Laser radiation levels shall not exceed the accessible emission limits for Class II laser products at any point less than three meters above any surface upon which any 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 which prevent human access to the radiation.
- N.** The maximum laser power output shall be limited to a level sufficient to produce the desired effect.
- O.** When laser output power must be limited to less than available power in order to satisfy the requirements of this Article, the laser output power shall be adjusted, measured, and recorded prior to the laser light show laser demonstration.
- P.** All safety devices and procedures necessary to comply with this Article shall be functionally tested and evaluated after setup, and prior to a laser light show or laser demonstration.
- Q.** The laser system, when not in use, shall be secured against unauthorized operation or tampering.
- R.** Laser alignment procedures shall be performed with the laser output power reduced to the lowest practicable level, and protective eye wear shall be worn where necessary to prevent exposure to radiation levels exceeding MPE. Only persons required to perform the alignment shall be present during the alignment procedures.
- S.** A registrant shall ensure that no laser light show or laser demonstration is conducted except as specifically authorized in the variance authorized in 21 CFR 1040(10), 2003 edition, published April 1, 2003, by the Office of Federal Register National Archives and Records Administration, incorporated by reference and on file with the Agency. This incorporation by reference contains no future editions or amendments.

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R12-1-1442. ~~Repeated Measurements and Calculations to Determine MPE Limits for Lasers~~

~~A registrant shall make measurements to determine MPE limits in a manner consistent with the procedures contained in ANSI Z136.1-2000, American National Standard for Safe Use of Lasers, 2000 edition, published by the Laser Institute of America, Incorporated by reference and on file with the Agency, or as otherwise approved by the Agency. This incorporation by reference contains co future editions or amendments.~~

R12-1-1443. Laser Compliance Measurement Instruments

~~A registrant shall ensure the Each radiation output measurement determination requiring a measurement for compliance with this Article shall is performed with an instrument that use instrumentation which is calibrated and designed for use with the laser that is being evaluated for compliance to be tested. The date of calibration, accuracy of calibration, wavelength range, and power or energy of calibration shall be specified on a legible, clearly visible label attached to the instrument.~~

R12-1-1444. Laser Classification Measurements

A. Measurement of accessible emission for classification shall be made:

1. Under ~~the those~~ operational conditions and procedures which maximize the accessible emission levels including start-up stabilized operation, and shutdown of the laser or facility;
2. No change
3. No change
4. With the measuring instrument detector ~~so~~ positioned ~~in a manner that the maximum possible radiation is measured by and so oriented with respect to the laser as to result in the maximum detection of radiation by the instrument; and~~
5. ~~With For a laser other than a laser system, with~~ the laser coupled to ~~the that~~ type of laser energy source specified as compatible by the laser fabricator and which produces the maximum emission of accessible laser radiation from ~~it that laser.~~

B.6. Accessible emission levels ~~used to classify for classification of laser and collateral radiation shall be based upon measurements performed according to 21 CFR 1040(10), 2003 edition, published April 1, 2003, by the Office of Federal Register National Archives and Records Administration, incorporated by reference and on file with the Agency. This incorporation by reference contains co future editions or amendments.~~ the following measurements:

- a. ~~For laser products intended to be used in a locale where the emitted laser radiation is unlikely to be viewed with optical instruments, the radiant power in watts or radiant energy in joules detectable through a circular aperture stop having a diameter of 7 millimeters, except for scanned laser radiation, and within a circular solid angle of acceptance of one milliradian with collimating optics of 5 diopters or less.~~
- b. ~~The irradiance in watts per square centimeter or radiant exposure in joules per square centimeter equivalent to the radiant power or radiant energy detectable through a circular aperture stop having a diameter of 7 millimeters and, for irradiance, within a circular solid angle of acceptance of one milliradian with collimating optic of 5 diopters or less, divided by the area of the aperture stop in square centimeters.~~
- e. ~~The radiance in watts per square centimeter per steradian or integrated radiance in joules per square centimeter per steradian equivalent to the radiant power or radiant energy detectable through a circular aperture stop having a diameter of 7 millimeters with a circular solid angle of acceptance of 10 microsteradian with collimating optics of 5 diopters or less, divided by that solid angle and by the area of the aperture stop in square centimeters.~~
- d. ~~Accessible emission levels of scanned laser radiation shall be based upon the measurement of radiation detectable through a stationary circular aperture stop having a seven millimeter diameter and within the circular solid angle of acceptance with collimating optics applicable under subparagraphs (a), (b) and (c). The direction of the solid angle of acceptance shall change as needed to maximize detectable radiation, with an angular speed of up to five radians per second. A 50 millimeter diameter aperture stop with the same collimating optics and acceptance angle will be used for all other laser products.~~

Appendix A. Radiofrequency Devices

Radiofrequency Devices Include But Are Not Limited To:

- ~~Dielectric Heaters And Sealers~~
- ~~Industrial Microwave Ovens And Dryers~~
- ~~Medical Diathermy Units~~
- ~~Asher - Etcher Machines~~
- ~~Radar~~
- ~~Radio And Television Transmitters~~
- ~~R.f. Activated Alarm Systems~~
- ~~Microwave Relay Links~~
- ~~Sputter Machines~~
- ~~R.f. Welding Equipment~~
- ~~R.f. Activated Lasers~~
- ~~Medical Surgical Coagulators~~
- ~~Edge Gluers~~

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Appendix A. Radio Frequency Devices

Include but are not limited to the following:

<u>Dielectric heaters and sealers</u>	<u>Industrial microwave ovens and dryers</u>
<u>Medical diathermy units</u>	<u>Asher-etcher equipment</u>
<u>Radar</u>	<u>R.F. welding equipment</u>
<u>R.F. activated alarm systems</u>	<u>Medical surgical coagulators</u>
<u>Sputter devices</u>	
<u>R.F. activated lasers</u>	
<u>Edge gluers</u>	

Appendix B. Repealed Application Information

A registration will be issued if an application contains the following information as required in R12-1-1401(B)(3). The Agency shall provide an application form to an applicant with a guide, if available, or shall assist the applicant to ensure only correct information is provided in the application.

<u>Name and mailing address of applicant</u>	<u>Use location</u>
<u>Person responsible for radiation safety program</u>	<u>Telephone number</u>
<u>Type of facility</u>	<u>Facility subtype</u>
<u>Legal structure and ownership</u>	<u>Signature of certifying agent</u>
<u>Radiation source information</u>	<u>Equipment identifiers</u>
<u>Shielding information</u>	<u>Scale drawing</u>
<u>Equipment operator instructions and restrictions</u>	<u>Physicist name and training, if applicable</u>
<u>Classification of professional in charge</u>	<u>applicable</u>
<u>Type of request: amendment, new, or renewal</u>	<u>Contact person</u>
<u>Protection survey results, if applicable</u>	<u>Appropriate fee listed in Article 13</u>
<u>Radiation Safety Officer name, if applicable</u>	<u>schedule</u>
<u>Laser class and type, if applicable</u>	
<u>Other licensing requirements in Article 14</u>	

Appendix C. Cosmetic Laser/IPL Operator Training Program

General Considerations

1. Training programs shall be specific to the medical laser/IPL system in use, and to the clinical procedure to be performed.
2. Program criteria and content shall be in accordance with the facility policy and procedure, applicable standards, federal and state regulations.
3. The degree and type of training shall be appropriate for the hazards associated with the laser or IPL's in use.

Technical Considerations

1. Description of lasers and IPL's
2. Definitions
3. Laser/IPL radiation fundamentals
4. Laser mediums and types of lasers – solid, liquid, diodes, and gas and IPL's
5. Biological effects of laser/IPL light
6. Damage mechanisms
 - a. Eye hazard
 - b. Skin hazard (skin type and skin anatomy)
 - c. Absorption – wavelength effects
 - d. Thermal effects
7. Photo chemistry
8. Criteria for setting Maximum Permissible Exposure (MPE) levels for eye and skin Associated hazards
9. Explosive, electrical, and chemical hazards
10. Photosensitive medications
11. Fire, ionizing radiation, cryogenic hazards, and others as applicable

General Laser/IPL safety

1. Laser/IPL classifications
2. Control measures including protective equipment
3. Management and user responsibilities
4. Medical surveillance practices
5. Federal and state regulatory requirements
6. Related safety issues
 - a. Controlled access
 - b. Plume management
 - c. Equipment testing, aligning, and troubleshooting
7. Administrative controls
 - a. Role of LSO and IPL safety officer
 - b. Development of policies and procedures
 - c. Documentation methods
 - d. Regulations, standards, and recommended professional practices
 - e. Certification criteria and skills validation
 - f. Medical surveillance