

Notices of Final Rulemaking

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

3. The effective date of the rules:

February 5, 2005

4. A list of all previous notices appearing in the Register addressing the final rules:

Notice of Docket Opening: 10 A.A.R. 1627, April 23, 2004

Notice of Proposed Rulemaking: 10 A.A.R. 1582, April 23, 2004

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

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6. An explanation of the rules, including the agency's reason for initiating the rulemaking:

R12-1-209:

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:

The new registration requirements, formerly licensing requirements, in Article 14 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 R12-1-1412, R12-1-1413, R12-1-1414, and R12-1-1415 to keep Arizona abreast of the most current tanning standards. 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 governing lasers used for medical purposes are moving to R12-1-1440; the rules in R12-1-1440 are moving to R12-1-1441; and the rules in R12-1-1441 are moving to R12-1-1442 to accommodate other amendments to Article 14 that are occurring in rulemaking package, RMP-0052(IPL), noticed in 10 A.A.R. 954, March 12, 2004. The changes are made to accommodate the new training rules that regulate medical uses of lasers and IPLs, in RMP-0052(IPL). The outdated laser classification measurements listed in R12-1444 are replaced with an incorporated reference to the current federal standards. Most 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 is listed in a new Appendix B.

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

None

8. 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

9. The 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 extensive review and associated 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. The registration of these devices is needed because of the public hazard associated with their misuse.

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The deregulation of the 98 MRI registrants will result in a \$6000 loss of revenue for the state's General Fund (\$50 per unit, annual registration fee), which will indirectly affect the Agency's funding.

Tanning businesses that will now be required to install timers are responsible for the cost of a timer if a remote timer is not already installed. An estimate from a local company that installs timers indicates that the cost of installing a timer is approximately \$200.00, and requires from 2 to 3 hours of labor at approximately \$35.00 per hour. This cost is justified because of the potential for burns from excessive tanning by inexperienced or inadequately supervised tanning equipment users. The Agency has investigated four cases involving improper use of tanning equipment over the last two years.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

The definition of "indirect supervision" is deleted from R12-1-1402 because it no longer agrees with the definition for this term in a package that is listed in the *Register* under a different rulemaking (RMP-0052(IPL)). The deleted definition incorrectly references "cosmetic procedure". This term is not essential for this package; it is not used in rules contained in Article 14 rules in this rule package. A second term "radio frequency exposure limits" is also deleted because the term is no longer used in Article 14.

Two other definitions in R12-1-1402 are altered as well. These changes are needed to clarify the rules in this package. The first definition is "operator" which is moved from a specific definition section to the general definition section and changed so that the term can be used to define anyone that operates any of the nonionizing devices regulated under Article 14. The second term is "user" which was formerly "consumer" in the proposed rule package. This definition is unchanged. It is believed the term "user" better defines the person being tanned. These changes are not substantive in nature and simply clarify the rules as proposed.

Two new terms are added to the radio frequency and microwave radiation definition section in R12-1-1402. "Maximum permissible exposure" and "Root-mean-square" are included in the list to help the reader understand the RF requirements in Article 14. These new definitions meet national standards.

No changes were made as result of the comments received during the public hearing. Spelling and grammatical changes, as well as clarity, conciseness, and understandability changes were offered by the Board and the Governor's Regulatory Review Council (GRRC) staff. No written public comments were received. Other minor changes were made as a result of staff review, however, none of the changes are substantive in nature.

11. A summary of the comments made regarding the rules and the agency response to them:

No comments, specifically directed at the rules in this package, were received. Any discussion received concerning the level of supervision was directed at the rules proposed in another rulemaking, RMP-0052(IPL), which regulates the supervision of medical lasers and intense pulsed light (IPL) devices.

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

None

13. Any material incorporated by reference and its location in the text:

<u>Rule</u>	<u>Incorporation</u>
R12-1-1402	21 CFR 1040.10, in the definitions of "certified laser product," "collateral radiation," "federal performance standard for light-emitting products," and "uncertified laser product"
R12-1-1402	ANSI Z136.1-2000, <i>American National Standard for Safe Use of Lasers</i> , in the definition of "maximum permissible exposure"
R12-1-1402	21 CFR 1040.30(d), in the definition of "self-extinguishing lamp"
R12-1-1404(A)	IEEE Std C95.1-1999, Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields
R12-1-1405(A)	IEEE Std C95.1-1999, Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields
R12-1-1407	21 CFR 1030.10
R12-1-1413(A)	21 CFR 1040.20
R12-1-1413(D)	21 CFR 1040.20(c)
R12-1-1418	21 CFR 1040.30
R12-1-1422(C)(1)	21CFR 1040.20
R12-1-1425(A)	21 CFR 1040.10
R12-1-1425(B)	21 CFR 1040.10

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R12-1-1426(A)	ANSI Z136.1-2000, American National Standard for the Safe Use of Lasers
R12-1-1426(A)	21CFR 1040.10
R12-1-1426(B)	21CFR 1040.10
R12-1-1427(A)	ANSI Z136.1-2000, American National Standard for the Safe Use of Lasers
R12-1-1427(F)	21 CFR 1040.10
R12-1-1429	ANSI Z136.1-2000, American National Standard for the Safe Use of Lasers
R12-1-1441(A)	21 CFR 1040.10
R12-1-1441(S)	21 CFR 1040.10
R12-1-1442	ANSI Z136.1-2000, American National Standard for Safe Use of Lasers
R12-1-1444(B)	21 CFR 1040.10

14. Were these rules previously made as emergency rules?

No

15. The full text of the rules follows:

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

ARTICLE 2. 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. THE CONTROL OF NONIONIZING RADIATION REGISTRATION OF NONIONIZING RADIATION SOURCES AND STANDARDS FOR PROTECTION AGAINST NONIONIZING RADIATION

Section

- R12-1-1401. 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 Radiation: Maximum Permissible Exposure Limits
- R12-2-1406. Radio Frequency Hazard Caution Signs, Symbols, Labeling, and Posting
- R12-1-1407. ~~Special Requirements for Microwave Ovens~~
- R12-1-1408. Reporting of Radio Frequency Radiation Incidents
- R12-1-1409. Medical Surveillance for Workers Who May Be Exposed to Radio Frequency Occupational Workers Radiation
- R12-1-1410. Radio Frequency Compliance Measurements Criteria
- R12-1-1411. ~~Licensing of Tanning Facilities~~ Repealed
- R12-1-1412. ~~General Safety Requirements for the Operation of Tanning Facilities~~ Operations
- 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 of 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~~ Protective Devices
- R12-1-1423. Laser Prohibitions
- R12-1-1425. Laser Product Classification
- R12-1-1426. ~~Maximum Permissible Laser and Collateral Radiation Exposure Limits to Laser and Collateral Radiations~~
- R12-1-1427. Requirements for Laser Caution Signs, Symbols, and Labels
- R12-1-1429. Posting of Laser Facilities

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- R12-1-1433. ~~Laser-controlled Areas~~ Laser Use Areas that are Controlled
- R12-1-1434. ~~Laser safety officer duties~~ Safety Officer (LSO)
- 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~~
- 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~~ Radio Frequency Devices (Include, but are not limited to, the following)
- Appendix B. ~~Repealed Application Information~~

ARTICLE 2. 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 a 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. In the notice, the person shall provide the name and address of the person who receives 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. ~~THE CONTROL OF NONIONIZING RADIATION~~ REGISTRATION OF NONIONIZING RADIATION SOURCES AND STANDARDS FOR PROTECTION AGAINST NONIONIZING RADIATION

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

- A. A person shall not use a nonexempt nonionizing radiation source, unless the source is registered by the Agency.
- B. A person who possesses a nonexempt nonionizing source shall submit to the Agency an application for registration at least 30 days before its first use.
 - 1. A person who possesses a nonexempt source listed in R12-1-1302(F) shall register the source with the Agency.
 - 2. A person applying for the registration of a nonexempt source shall use an application form provided by the Agency.
 - 3. An 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, an applicant shall remit the applicable registration fee, specified in R12-1-1306.
- E. A person who is operating more than one facility, where one or more nonexempt nonionizing sources are used, shall apply for a separate registration for each facility.
- F. A person in the business of installing or servicing nonexempt nonionizing sources shall apply to the Agency for registration 30 days before furnishing the service. The person shall apply for registration on a form furnished by the Agency and shall provide the information required by 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 2D²/l from the antenna, where l 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 con-~~

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siderably in strength from point to point. For most antennas the outer boundary of the region shall be taken to exist at a distance $l/2p$ from the antenna surface, where l 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.
 - 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,

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- 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.
 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

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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.

C. 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:

"Controlled area" means any area to which human access is restricted for the purpose of protection from nonionizing radiation.

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

"Direct supervision" means that a licensed practitioner supervises the use of a source for medical purposes while the practitioner is present inside the facility where the source is being used.

"Licensed practitioner" (See R12-1-102)

"Medical director" means a licensed practitioner, as defined in R12-1-102, who delegates a laser, IPL, or other light-emitting medical device procedure to a non-physician and is qualified to perform the procedure within the scope of practice of the license.

"Nonexempt nonionizing source" means any system or device that contains a nonionizing source listed in R12-1-1302(F).

"Operator" means a person who is trained and knowledgeable about the control and function of a nonionizing device regulated under this Article

Laser definitions

"Accessible emission limit (AEL)" means the maximum accessible emission level of laser or collateral radiation permitted within a particular class.

"Accessible radiation" means laser or collateral radiation to which human access is possible.

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

"Aperture" means an opening in the protective housing or other enclosure of a laser product, through which laser or collateral radiation is emitted, 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 in accordance with the requirements of 21 CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

"CDRH" means the Center for Devices and Radiological Health.

"Classes of lasers" means the following categories of lasers, defined in 21 CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency: Class 1, Class 2, Class 2a, Class 3, Class 3a, Class 3b, and Class 4. This incorporation by reference contains no future editions or amendments.

"Collateral radiation" means any electronic product radiation, except laser radiation, emitted by a laser product as a result of operation of the laser or any component of the laser product that is physically necessary for operation of the laser. The accessible emission limits for collateral radiation are specified in 21 CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

"Continuous wave" (cw) means the output of a laser that is operated in a continuous rather than a pulsed mode. For pur-

poses of this Article, a laser operating with a continuous output for a period \leq 0.25 seconds, is regarded as a cw laser.

“Cosmetic procedure protocol” means a delegated written authorization to select specific laser settings, initiate a laser procedure, and conduct necessary follow-up procedures.

“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 of the laser system in which it is incorporated, where the system’s lower classification is due to engineering features that limit accessible emission.

“Enclosed laser” means a laser that is contained within its own protective housing or the protective housing of a laser or laser system in which it is incorporated. Opening or removing the protective housing provides more access to laser radiation above the applicable MPE than is possible with the protective housing in place. (An embedded laser is a type of enclosed laser.)

“Federal performance standards for light-emitting products” means the regulations in 21CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives, and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

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

“Incident” means an event or occurrence that results in actual or suspected accidental exposure to laser radiation that has 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 per steradian.

“Irradiance” means the time-averaged 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 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, are not considered laser energy sources by the Agency.

“Laser facility” means a facility where one or more lasers are used. For purposes of this definition a Class 1 facility is a facility that has one or more Class 1 lasers; a Class 2 facility is a facility that has one or more Class 2 or 2a lasers; a Class 3 facility is a facility that has one or more Class 3, 3a, or 3b lasers, and a Class 4 facility is a facility that has one or more Class 4 lasers. Facilities that contain more than one laser class are classified according to the highest laser class in use at the facility.

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

“Laser protective device” means any device used to reduce or prevent exposure of personnel to laser radiation. This includes: 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 or that is detectable with radiation so produced through the appropriate aperture stop and within the appropriate solid angle of acceptance.

“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 class of facility.

“Laser system” means a laser in combination with an appropriate laser energy source with or without additional incorporated components.

“Limited exposure duration (T_{max})” means an exposure duration that is specifically limited by design or intended use.

“Maintenance” means performance of those adjustments or procedures specified in operator information provided by the manufacturer with the laser product, which are to be performed by the operator to ensure the intended performance of the product. The term 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 values for eye and skin exposure are listed in ANSI Z136.1-2000, American National Standard for Safe Use of Lasers, 2000 edition, which is incorporated by reference, published by the Laser Institute of America, 13501 Ingenuity Drive, Suite 128, Orlando, FL 32826, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

“Medical laser product” means any laser product that is a medical device defined in 21 U.S.C. 321(h) and is manufactured, designed, intended, or promoted for in vivo laser irradiation of any part of the human body for the purpose of: diagnosis, surgery, therapy, or relative positioning of the human body.

“Operation” means the performance of the laser product over the full range of its function. It does not include maintenance or service as defined in this Section.

“Protective housing” means those portions of a laser product that are designed to prevent human access to laser or collateral radiation in excess of the prescribed accessible emission limits under conditions specified in this Article.

“Pulse duration” means the time increment measured between the half-peak-power points at the leading and trailing edges of a pulse.

“Pulse interval” means the period of time 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.

“Rule of nines” means a method for estimating the extent of burns, expressed as a percentage of total body surface. In this method the body is divided into sections of 9 percent or multiples of 9 percent, each: head and neck, 9 percent; anterior trunk, 18 percent; posterior trunk, 18 percent; upper limbs, 18 percent; lower limbs, 36 percent; and genitalia and perineum, 1 percent.

“Safety interlock” means a device associated with the protective housing of a laser product to prevent human access to excessive radiation.

“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 area to which casual access is impeded by various means, such as a door secured by a lock, latch, or screws.

“Service” means the performance of those procedures or adjustments described in the manufacturer’s service instructions that may affect any aspect of the product’s performance. The term does not include maintenance or operation as defined in this Section.

“T_{max}” See limited exposure duration.

“Uncertified laser product” means any laser that has not been certified in accordance with the requirements of 21CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

Radio frequency and microwave radiation definitions

“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 applicable, and to which human access is normally possible.

“Far field region” means the area in which locally uniform distribution of electric and magnetic field strengths exists in planes transverse to the direction of propagation. The far field region is presumed 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.

“Maximum permissible exposure MPE” means the rms and peak electric and magnetic field strengths, their squares, or the plane-wave equivalent power densities associated with these fields and the induced and contact currents to which a person may be exposed without harmful effect and with an acceptable safety factor.

“Near field region” means the area 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 is presumed to exist at a distance $\lambda/2\pi$ from the antenna surface, where λ is the wavelength.

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

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

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

“Root-mean-square (rms)” means the effective value, or the value associated with joule heating, of a periodic electromagnetic wave. The rms is obtained by taking the square root of the mean of the squared value of a function.

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

Ultraviolet, high intensity light, and intense pulsed light definitions

“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 lamp, including a mercury vapor or metal halide lamp that incorporates a high-pressure arc discharge tube with a fill that consists primarily of mercury and is contained within an outer envelope, except the tungsten filament self-ballasted mercury vapor lamp.

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“Intense pulsed light (IPL)” means, for purposes of R12-1-1438, any lamp-based device that produces an incoherent, filtered, and 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 treat the surfaces of equipment and devices using an EPA or FDA registered product that provides a specified concentration of chemicals, for a specified period of time, to reduce the bacterial count, including pathogens, to a safe level.

“Self-extinguishing lamp” means any HID lamp that ceases operation in conformance with the requirements of the performance standard in 21 CFR 1040.30(d), April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

“Sunlamp product” means any electronic product designed to incorporate one or more ultraviolet lamps and intended for irradiation of any part of the living human body, by ultraviolet radiation with wavelengths in air between 200 and 400 nanometers, to induce skin tanning.

“Timer” means any device incorporated into a product that terminates radiation emission after a preset time interval.

“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 in the wavelength interval from 200 to 400 nanometers in air.

“User” 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.

R12-1-1403. General Safety Provisions and Exemptions

- ~~**A.** The Agency may waive compliance with specific requirements of this Article if:~~
- ~~1. Compliance requires replacement, or substantial modification, to an installation, and~~
 - ~~2. The licensee 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 shall:~~
- ~~1. Ensure that nonionizing radiation machines are operated only by individuals who have been trained and have demonstrated competence in the safe use of the equipment.~~
 - ~~2. Provide safety rules to individuals operating nonionizing radiation machines and shall make these individuals aware of any restrictions in operating techniques required for the safe use of the machines.~~
 - ~~3. Make, or cause to be made, physical radiation surveys as may be necessary to ensure compliance with the provisions of this Article.~~
 - ~~4. 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;~~
 - ~~c. Inventories to account for sources of radiation for two years;~~
 - ~~d. 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~~
 - ~~e. 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.** The licensee shall not operate, nor permit the operation of, a nonionizing radiation machine unless the machine complies with all applicable requirements of this Article.~~
- A.** Based on consideration of the following factors, the Agency may waive compliance with specific requirements of this Article:
1. Whether compliance requires product replacement or substantial modification of a product’s current installation, and
 2. Whether the registrant provided information requested by the Agency to determine if there are alternative methods of achieving the same or a greater level of radiation protection.
- B.** The registrant shall:
1. Ensure that any nonionizing source is operated by an individual who is trained and has demonstrated competence in the safe use of the source.
 2. Provide safety rules to each individual who operates a nonionizing radiation source and determine whether the individual is aware of operating restrictions and procedures associated with the safe use of the source.
 3. Make, or cause to be made, any physical radiation surveys required by this Article.
 4. Maintain the following records for 3 years for Agency review:
 - a. Results of any physical survey or calibration required by this Article;
 - b. Radiation source inventories;

- c. Maintenance, service, and modification records; and
- d. Incident reports of known or suspected exposure to nonionizing radiation that exceeds any MPE specified in this Article.

C. A registrant shall not operate a nonionizing radiation source unless the source complies with all of the applicable requirements of this Article.

R12-1-1404. Radio Frequency Equipment Requirements

- ~~A. Radiation machines emitting accessible emission levels exceeding the maximum permissible radio frequency exposure levels for uncontrolled areas specified 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 by reference and on file with the Department and the Office of the Secretary of State, 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 with warning signs meeting the specifications indicated in R12-1-1406, Figure 1.~~
- ~~B. Radio frequency machines which are required to 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 separated from the means of activation of the sources by a distance greater than 2 meters, shall be provided with visual or audible emission indicators at both the source and the point of activation.~~
- ~~D. Visual emission indicators shall be so located that 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. Machines emitting mechanically scanned radio frequency radiation shall not, as the result of scan failure or any other malfunction causing a change in angular velocity or amplitude, allow human exposure in excess of the radio frequency exposure limits.~~
- ~~G. Radio frequency machines shall be physically secured against unauthorized use or being tampered with when not in use.~~
- A. A registrant shall operate a radiation source that emits radio frequency radiation in a radio frequency controlled area, in a manner that will prevent human exposure that exceeds the MPE specified in IEEE Std C95.1-1999, 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, which is incorporated by reference, published by the Institute of Electrical and Electronic Engineers, Inc., 345 East 47th Street, New York, NY 10017, and on file with the Agency. This incorporation by reference contains no future editions or amendments. The registrant shall post each point of access into a radio frequency controlled area according to R12-1-1406.
- B. If a registrant is required to operate a radio frequency source in a controlled area, the registrant shall employ visual or audible emission indicators that function only during production of radiation.
- C. If a source of radio frequency emissions is physically separate from the source's means of activation by a distance greater than 2 meters, the registrant shall place a visual or an audible emission indicator at the source and the point of activation.
- D. A registrant shall place each visual emission indicator so that the location of the indicator does not require human exposure to radio frequency radiation that exceeds the applicable MPE.
- E. A registrant shall inspect each safety device designed to prevent human exposure to excessive radio frequency radiation for proper operation at intervals that do not exceed one month.
- F. If a machine emits mechanically scanned radio frequency radiation, a registrant shall ensure that the machine cannot, as the result of scan failure or any other malfunction, cause a change in angular velocity or amplitude, allowing human exposure that exceeds the applicable MPE.
- G. A registrant shall physically secure each radio frequency sources to prevent unauthorized use and tampering.

R12-1-1405. Radio Frequency Radiation: Maximum Permissible Exposure Limits

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 C95.1-1991, 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 by reference and on file with the Department and the Office of the Secretary of State, containing no future editions or amendments, with the following exclusions:

- 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 by reference and on file with the Department and the Office of the Secretary of State, containing no future editions or amendments, limits may be exceeded if the exposure conditions can be shown by laboratory procedures to produce specific

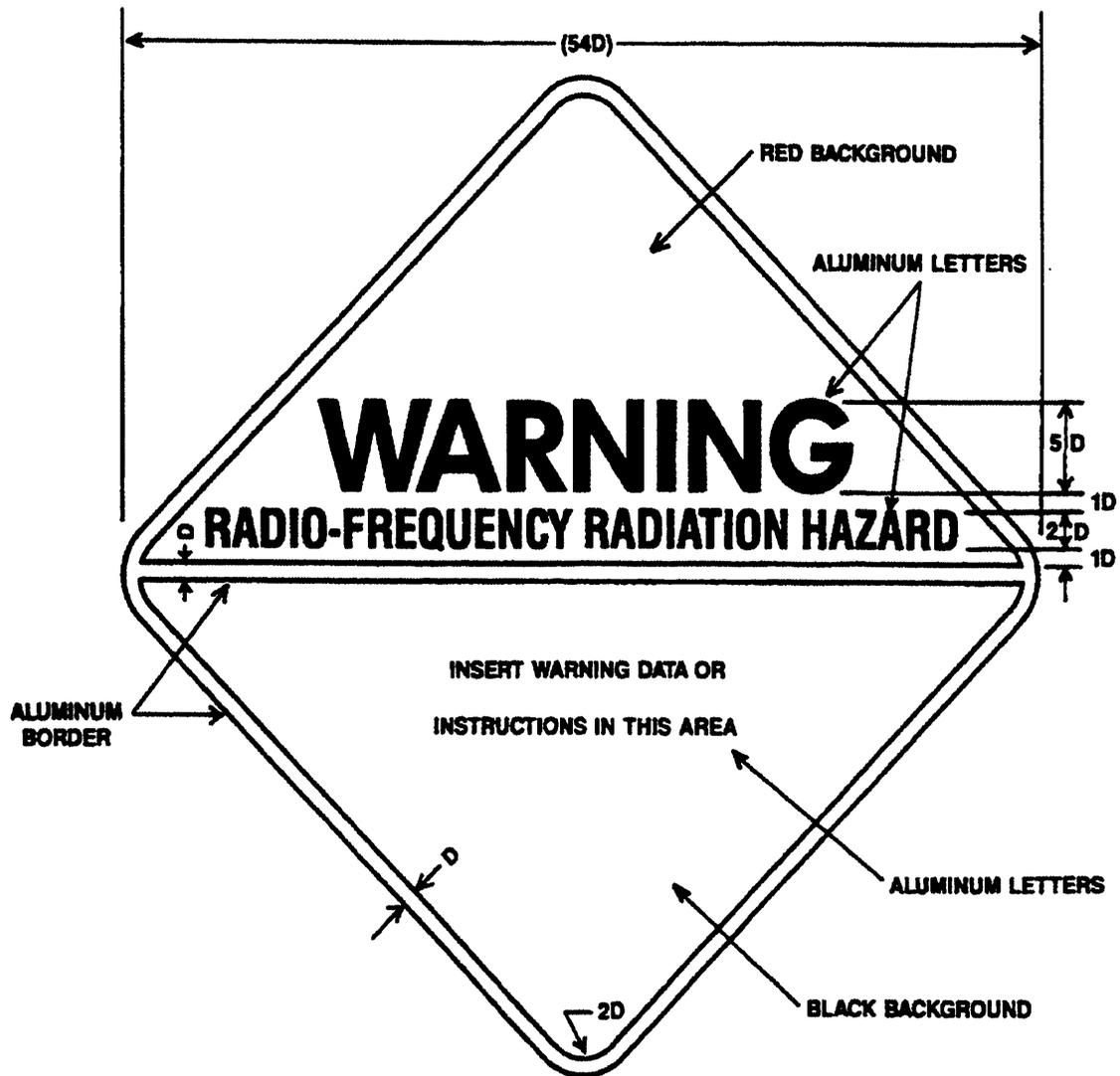
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absorption rates (SARs) below 0.4 watts per kilogram averaged over the whole body, and spatial peak SAR values below 8 watts per kilogram averaged over any 1 gram of tissue.

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 by reference and on file with the Department and the Office of the Secretary of State, containing no future editions or amendments, limits may be exceeded if the radio frequency input power to the radiating device is 7 watts or less.
- A. A registrant shall not expose a person to radio frequency radiation that exceeds the applicable MPE specified in IEEE Std C95.1-1999, 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, which is incorporated by reference, published by the Institute of Electrical and Electronic Engineers, Inc., 345 East 47th Street, New York, NY 10017, and on file with the Agency. This incorporation by reference contains no future editions or amendments.
 - B. At frequencies between 300 kHz and 100 GHz, a registrant may exceed the applicable MPE if exposure conditions can be shown by laboratory procedures to produce specific absorption rates (SARs) above 0.4 watts per kilogram, averaged over the whole body, and spatial peak SAR values above 8 watts per kilogram, averaged over 1 gram of tissue.
 - C. At frequencies between 300 kHz and 1 GHz, a registrant may exceed the applicable MPE, if the radio frequency input power to the radiating device is seven watts or less.

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

- ~~A. Radio frequency controlled areas shall be clearly posted with caution signs of the type designated in Figure 1 at each point of access to such areas.~~
- ~~B. 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. Warning signs and labels shall be located such that observation does not require unnecessary or excessive exposure to radio frequency radiation.~~
- A. A registrant shall post each point of access to a controlled area with caution signs of the type designated in Figure 1.



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.** A registrant shall post operating procedure restrictions or limitations, used to prevent unnecessary or excessive exposure to radio frequency radiation, in a location visible to the operator.
- C.** A registrant shall place each warning sign or label so that an observer is not exposed to radio frequency radiation that exceeds the applicable MPE.

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.

A person shall register with the Agency any microwave oven that does not meet the requirements in 21 CFR 1030.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. 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.
- 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.
- C.** Immediate notification shall be made to the Agency when radio frequency radiation exposure exceeds 500% of the limits.
- A.** A registrant shall report in writing to the Agency within 15 days of a known or suspected personnel exposure to radiation that exceeds the applicable MPE incorporated by reference in R12-1-1405.
- B.** A registrant shall report to the Agency within 24 hours of a known or suspected personnel exposure to radiation that exceeds 150% of an applicable MPE incorporated by reference in R12-1-1405.
- C.** A registrant shall immediately report to the Agency a known or suspected personnel exposure to radiation that exceeds 500% of an applicable MPE incorporated by reference in R12-1-1405.

R12-1-1409. Medical Surveillance for Workers Who May Be Exposed to Radio Frequency Occupational Workers Radiation

- 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.
- 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.** Upon request by the Agency, a registrant shall provide a medical examination to an individual exposed to radiation reported to the Agency according to R12-1-1408.
- B.** A registrant shall provide a copy of the results to the Agency if an individual undergoes a medical examination, requested under subsection (A).

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

- A.** Measurements made to determine compliance with R12-1-1405 shall be made with instrumentation appropriate for the field strength and frequency of the radiations to be evaluated.
- B.** Instrumentation used for compliance measurements shall 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 (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 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 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 amend-

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ments:

- ~~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 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 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.
- ~~E.~~ The measurement requirements of this Section shall be met if:
 - 1. Measurements of both electric and magnetic field strengths are obtained where the emission frequency is 300 megahertz or less, and
 - 2. Measurement of 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 by reference and on file with the Department and the Office of the Secretary of State, containing no future editions or amendments, the fraction of the appropriate exposure limit incurred within each frequency interval shall be determined, and the sum of all such fractions shall not exceed unity.
- ~~G.~~ Compliance measurements shall be made at distances 5 centimeters or greater from any object.
- ~~H.~~ 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.
- A. For obtaining measurements to determine compliance with R12-1-1405, the Agency shall use an instrument capable of measuring the field strength and frequency of radiation.
- B. The Agency shall ensure that each instrument used for compliance measurements is calibrated every 12 months. The calibration shall be performed in a manner that meets the standards in IEEE Std C95.1-1999, incorporated by reference in R12-1-1404(A).
- C. For compliance measurements of exposure conditions in the near field, the Agency shall obtain measurements of both the electric and magnetic field components. The applicable protection standards for near field measurements are the mean squared electric and magnetic field strengths (using the applicable MPE) referenced in R12-1-1405.
- D. If the Agency is obtaining measurements to determine compliance in far field exposure conditions, the Agency may use 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 are the power density values (using the applicable MPE) referenced in R12-1-1405.
- E. In obtaining measurements in accordance with this Section, the Agency shall measure the electric and magnetic field strength:
 - 1. Obtained at an emission frequency of 300 megahertz or less; and
 - 2. Expressed in terms of power density.
- F. For mixed or broadband fields at frequencies for which there are different protection standards, the Agency shall determine the fraction of the applicable MPE incurred within each frequency interval. To achieve compliance the sum of all the fractions shall not exceed unity (1).
- G. The Agency shall obtain compliance measurements at a distance of five centimeters or greater from any object.
- H. A registrant shall obtain measurements that are averaged over a six-minute period for pulsed and non-pulsed modes of radio frequency emission and make a correction 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. ~~General Safety Requirements for the Operation of Tanning Facilities Operations~~

~~The licensee~~ A registrant shall establish and maintain a program of written policies and procedures ~~for that are part of a radiation safety sufficient program~~ 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, 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, and this incorporation by reference contains no future editions or amendments, "Sunlamp products and ultraviolet lamps intended 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 device identification label.

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- ~~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 device as specified on the product label on the sunlamp products or with lamps or filters that are equivalent under the FDA regulations and policies applicable at the time of manufacture.~~
- ~~D. Each sunlamp product shall have a timer and control system which complies with the requirements of 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.~~
- ~~E. There shall be physical barriers as needed to protect users from injury induced by touching or breaking lamps.~~
- ~~F. Each tanning facility using stand-up booths shall comply with the following special requirements:
 - ~~1. There shall be physical barriers, handrails, floor markings, or other means to indicate the proper exposure distance between the ultraviolet lamps and the user's skin.~~
 - ~~2. The construction of the booth shall be such that it will withstand the stress of use and the impact of a falling person.~~
 - ~~3. Access to booths shall be through doors of rigid construction, opening outwardly. Handrails and non-slip floors shall be provided.~~~~
- A. A registrant operating a tanning facility shall use sunlamp products that are certified by the manufacturer to comply with 21 CFR 1040.20, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments. For sunlamp products in use before the effective date of this Article, the Agency shall determine compliance based on the standard in effect at the time of manufacture, as shown on the equipment identification label.
- B. A registrant shall replace burned-out or defective lamps or filters, before any use of a tanning device.
- C. A registrant shall replace a burned-out or defective lamp or filter with a lamp or filter intended for use in that equipment, as specified on the sunlamp product label, or that is equivalent to a lamp or filter specified on the sunlamp product label under the FDA regulations and policies applicable to the sunlamp product at the time of manufacture. If an equivalent lamp or filter is used instead of the Original Equipment Manufacturer (OEM) lamp or filter specified on the product label, the registrant shall maintain a copy of the equivalency certification, provided by the lamp supplier, on file for review by Agency inspectors.
- D. A registrant shall ensure that each sunlamp product has a timer and control system that complies with 21 CFR 1040.20(c), April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments. In addition the registrant shall ensure that:
 - 1. The timer interval does not exceed the manufacturer's maximum, recommended exposure time;
 - 2. The timer is functional and accurate to within +/- 10% of the maximum timer interval of the product;
 - 3. The timer does not automatically reset and cause radiation emission to resume for a period greater than the unused portion of the timer cycle;
 - 4. The timer is tested annually for accuracy;
 - 5. For a new facility (including existing facilities with change of ownership) a remote timer control system is installed before operation of sunlamp products. For an existing facility that has sunlamp products not equipped with a remote timer control system a remote timer control system (outside of the sunlamp product room) is installed no later than 6 months after the effective date of this Section; and
 - 6. Each sunlamp product is equipped with an emergency shutoff mechanism that allows manual termination of the UV exposure by the user.
- E. A registrant shall provide physical barriers between each sunlamp product to protect users from injury caused by touching or breaking a lamp.
- E. A registrant that employs a stand-up sunlamp product shall:
 - 1. Use physical barriers, handrails, floor markings, or other methods to indicate the proper exposure distance between the ultraviolet lamps and the user's skin;
 - 2. Construct each tanning booth so that it can withstand the stress of use and the impact of a falling person;
 - 3. Provide access to a tanning booth with doors of rigid construction that open outward, handrails, and non-slip floors; and
 - 4. Control the interior temperature of a sunlamp product so that it never exceeds 100 degrees Fahrenheit (38 degrees Centigrade).

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

- A. There shall be present during operating hours at least one operator knowledgeable in the correct operation of the tanning devices used at the facility and able to inform and assist each user in the proper use of the tanning devices.
- B. Prior to use of a tanning device by any individual, the operator shall:
 - 1. Provide sanitized, protective, sunlamp eye wear and directions for its proper use;
 - 2. Demonstrate the use of physical aids, as appropriate, to maintain proper exposure distance as recommended by the

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- manufacturer of the tanning device;
- 3. Set the timer.
- ~~C. 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. Prior to the first use of a tanning facility in each calendar year, 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;
 - 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.~~
- ~~A. A registrant shall ensure that at least one operator is present during operating hours. The operator shall:
 - 1. Limit the occupancy of the tanning room to one person when the tanning equipment is in use;
 - 2. Prevent use of the tanning equipment by anyone under 18 years of age unless the person has written permission from a parent or guardian;
 - 3. Limit exposure time to the manufacturer's recommendation on the equipment label or in the operator's manual;
 - 4. Limit exposure time during a 24 hour period to the maximum recommended for a 24 hour period by the manufacturer; and
 - 5. Maintain a record of each user's total number of tanning visits and exposure times for Agency inspection. The registrant shall maintain the records for three years from the date on the record.~~
- ~~B. Before use of tanning equipment an operator shall:
 - 1. Provide the user sanitized protective sunlamp eye wear and directions for its use;
 - 2. Demonstrate the use of any physical aids, necessary to maintain correct exposure distance for the user, as recommended by the manufacturer of the tanning equipment;
 - 3. Set the exposure timer so that the user is not exposed to excess radiation;
 - 4. Instruct the user on the maximum exposure time and correct distance from the radiation source as recommended by the manufacturer of the tanning equipment; and
 - 5. Instruct the user about the location and correct operation of the emergency shutoff switch~~
- ~~C. An operator shall control a sunlamp's timer. A registrant shall:
 - 1. Provide training to operators that covers:
 - a. The requirements of this Section;
 - b. Facility operating procedures, including:
 - i. Determination of skin type and associated duration of exposure;
 - ii. Procedures for use of minor and adult user consent forms;
 - iii. Potential harm associated with 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. The 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. Maintain records of training for Agency review, which include dates and material covered, for three years from the date the training is provided.
 - 3. Post a list of operators at the facility.~~
- ~~D. Before the first use of a tanning facility in each calendar year by a user:
 - 1. An operator shall request that the user read a copy of the warnings in R12-1-1415(A);
 - 2. The operator shall obtain the user's signature on a statement as an acknowledgment that the user has heard or read and understands the warnings in R12-1-1415(A); and
 - 3. For illiterate or visually handicapped persons, the operator shall read the warnings in R12-1-1415(A) in the presence of a witness. Both the witness and the operator shall sign the statement described in subsection (D)(2).~~

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

- ~~A. 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. The sign shall be clearly visible and unobstructed by any barrier or other item.~~

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- ~~C.~~ The sign shall read as follows:-
- ~~D.~~ 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.
- A. A registrant shall post the warning sign shown in this subsection within 1 meter (39.37 inches) of each tanning device, ensuring that the sign is clearly visible and easily viewed by the user before the tanning device is operated.

 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.

- B. A registrant shall post a warning sign, which contains the statement shown below, at or near the reception area.
 PERSONS UNDER AGE 18 ARE REQUIRED TO HAVE PARENT OR LEGAL GUARDIAN SIGN AN AUTHORIZATION TO TAN IN THE PRESENCE OF A TANNING FACILITY OPERATOR
- 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.

R12-1-1416. Reporting of ~~Tanning Injuries~~ injuries in tanning facilities

- ~~A.~~ The licensee shall report 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 possibly transmitted by use of the tanning device.
- ~~B.~~ The report shall be forwarded to the Agency within 10 working days of its occurrence or the date the registrant gained knowledge thereof.
- ~~C.~~ The report shall include:
 - 1. The name of the user,
 - 2. Name and location of the tanning facility,
 - 3. A description of nature of the injury,
 - 4. The name and address of the health care provider treating the user, if any, and
 - 5. Any other information the licensee may consider relevant to the incident.
- A. A registrant shall report any incident involving an eye injury; skin burn; fall injury, if the fall occurs within the tanning device or while entering or exiting the device; laceration; infection believed to have been transmitted by use of the tanning device; or any other injury reasonably related to the use of the tanning device.
- B. A registrant shall provide a written report of an incident to the Agency within 10 working days of its occurrence or within 10 working days of the date the registrant became aware of the incident.
- C. The report shall include:
 - 1. The name of the user;
 - 2. The name and location of the tanning facility;
 - 3. A description of and the circumstances associated with the injury;
 - 4. The name and address of the health care provider treating the user, if any; and
 - 5. Any other information the registrant considers 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 requirement:
 - 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,

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- b. ~~Non-self-extinguishing lamps, provided that the lamp is installed within a totally enclosed protective shield which protects the lamp from damage, or~~
 - e. ~~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 subparagraphs (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 ten 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

A person shall register with the Agency any HID lamp that does not meet the requirements in 21 CFR 1040.30, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. 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 Section. 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 that are used in accordance with the manufacturer's classification and instructions. If certain engineering controls may be inappropriate, are impractical during manufacture or research and development activities, the LSO shall specify alternate requirements to obtain equivalent laser safety protection.~~
- B.** ~~A registrant shall establish and maintain a laser radiation safety program. The licensee shall appoint a laser safety officer and shall establish and maintain an effective program of laser radiation safety.~~
- C.** ~~Each licensee If R12-1-1433 is applicable, a registrant shall make or cause to be made such laser radiation protection conduct surveys as may be necessary to comply a laser radiation protection survey to ensure compliance with R12-1-1433 before initial use, following initially prior to routine operation, upon system modifications, and routinely at intervals that do not to exceed six months. Surveys shall include but not be limited to During a survey the registrant shall:~~
- 1. ~~A determination that all Determine whether each laser protective devices are device is labeled correctly, and functioning within the design specifications, and are proper meets required standards for the type and class of lasers laser in use;~~
 - 2. ~~A determination that all Determine whether each warning devices are device is functioning within their design specifications;~~
 - 3. ~~A determination that each laser-controlled Determine whether each controlled area is properly identified, access is controlled, and the area is posted with accurate warning signs in accordance with R12-1-1427 this Article;~~
 - 4. ~~A reevaluation of Reevaluate potential hazards from surfaces which may be that are associated with Class III 3 and Class IV 4 beam paths; and~~
 - 5. ~~Additional surveys required to evaluate Evaluate the laser and collateral radiation hazard incident to the use of lasers.~~
- D.** ~~The licensee registrant shall retain maintain records of:~~
- 1. ~~No change~~
 - 2. ~~Records indicating any Any restriction in operating procedures necessary to prevent unnecessary or excessive exposure to laser or collateral radiation;~~
 - 3. ~~Records relating to any Any incident for which reporting to the Agency is required pursuant to R12-1-1436;~~
 - 4. ~~No change~~
 - 5. ~~No change~~

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

- A.** ~~Each laser product shall have a protective housing which prevents human access during operation to laser and collateral radiation that exceeds the limits 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. Wherever and whenever humans are able to access laser radiation levels that exceed the limits of Class I or the accessible emission limits from 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, these levels shall not exceed the limits of the lowest laser class necessary to per-~~

form the intended function.

- B.** 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, 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. For pulsed lasers, interlocks shall be designed so as to prevent firing of the laser.
 - 3. For Class IIIb and IV continuous wave (cw) lasers, the interlocks shall turn off the power supply or interrupt the beam.
 - 4. An interlock shall not allow automatic accessibility of radiation emission above MPE limits when the interlock is closed.
 - 5. If failure of a single interlock would allow:
 - a. Human access to levels of laser radiation in excess of the radiant power accessible emission limit of Class IIIa laser radiation; or
 - b. Laser radiation in excess of the accessible emission limit of Class 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.** All viewing ports, viewing optics, or display screens included as an integral part of an enclosed laser or laser system shall 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 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, and this incorporation by reference contains no future editions or amendments, under any conditions of operation of the laser. The laser safety officer shall determine the potential for increased hazard that the use of optical system, 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 III or IV laser product shall provide visual or audible indication during the emission of accessible laser radiation in excess of the limits of Class I.

 - 1. For Class IIIb, except those which allow access only to less than 5 milliwatts peak visible laser radiation, and Class IV lasers, the indication shall be sufficiently prior to emission of such radiation to allow appropriate action to avoid exposure.
 - 2. Any visual indicator shall be clearly visible through protective eye wear designed specifically for the wavelength of the emitted laser radiation.
 - 3. If the laser and laser energy source are housed separately and can be operated at a separation distance of greater than 2 meters, both laser and laser energy source shall incorporate visual or audible indicators.
 - 4. The visual indicators shall be positioned so that viewing does not require human access to laser radiation in excess of the MPE.
- 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 shall provide near the signs, symbols, and labels any additional information which is necessary to minimize exposure to laser 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.
- A.** A registrant shall ensure that each laser product has a protective housing that prevents access to laser and collateral radiation if it exceeds the exposure limits for Class 1 lasers in R12-1-1426. If a laser's accessible emission levels must exceed the limits for Class 1 lasers, the registrant shall use a laser from the lowest class that will enable the registrant to perform the intended function.
- B.** To prevent access to radiation above the applicable MPE, a registrant shall ensure that each laser has a safety interlock, which prevents operation of the laser if a person has removed any portion of the protective housing that can be removed or displaced without the use of tools during normal operation or maintenance. The registrant shall ensure that:

 - 1. Service, testing, or maintenance of a laser does not render the interlocks inoperative or increase radiation outside the protective housing to levels that exceed the applicable MPE, unless a controlled area is established as specified in R12-1-1433;
 - 2. For pulsed lasers, interlocks are designed to prevent the laser from firing;
 - 3. For Class 3b and 4 continuous wave (cw) lasers, interlocks turn off the power supply or interrupt the beam.
 - 4. An interlock does not allow automatic accessibility to radiation emission above the applicable MPE when the interlock is closed; and
 - 5. Multiple safety interlocks or a means to preclude removal or displacement of the interlocked portion of the protective housing is provided if failure of a single interlock could result in:

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- a. Human access to levels of laser radiation that exceed the radiant power accessible emission limit for Class 3a laser radiation, or
- b. Laser radiation that exceeds the accessible emission limit for Class 2, emitted directly through the opening created by removal or displacement of a portion of the protective housing.
- C. A registrant shall ensure that a laser with viewing ports, viewing optics, or display screens, included as an integral part of the enclosed laser or laser system has:
 - 1. A suitable means to attenuate laser and collateral radiation transmitted through the optical system to less than the accessible emission limit for collateral radiation required by 21 CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments;
and
 - 2. Specific written administrative procedures developed by the LSO, and use controls, such as interlocks or filters, if there is increased hazard to the eye or skin associated with the use of optical systems such as lenses, telescopes, or microscopes.
- D. A registrant shall ensure that each Class 3 or 4 laser product provides a visual or audible indication before the emission of accessible laser radiation that exceeds the limits for Class 1, as follows:
 - 1. For Class 3, except for laser products that allow access to less than 5 milliwatts peak visible laser radiation, and Class 4 lasers, the indication occurs before the emission of the radiation and allows enough time for action to avoid exposure;
 - 2. Any visual indicator is clearly visible through protective eye wear designed specifically for the wavelength of the emitted laser radiation;
 - 3. If the laser and laser energy source are housed separately and can be operated at a separation distance of greater than 2 meters, both the laser and laser energy source incorporate visual or audible indicators, and
 - 4. Any visual indicators are positioned so that viewing does not require human access to laser radiation that exceeds the applicable MPE.
- E. In addition to the information signs, symbols, and labels prescribed in R12-1-1427, R12-1-1428, and R12-1-1429, each registrant shall provide, near the signs, symbols, and labels within the laser facility, operating procedure restrictions and any other safety information required to ensure compliance with this Article and minimize exposure to laser and collateral radiation.

R12-1-1423. Laser Prohibitions

- ~~A. No individual shall 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 such beams or reflections exceeds the MPE limits in this Article.~~
- ~~B. The licensee shall not permit any individual to enter a laser-controlled area when skin exposure in excess of the MPE limits is likely unless the licensee provides and requires the use of protective clothing, gloves and shields.~~
- ~~C. Laser products emitting spatially scanned laser radiation shall not, as a result of scan failure or any other failure causing a change in angular velocity or amplitude, permit human access to laser radiation in excess of the accessible emission limits applicable to the class of the product.~~
- A. A registrant shall not require or permit an individual to look directly into a laser beam or directly at specular reflections of a laser beam, or align a laser by eye while looking along the axis of the laser beam if the intensity of the beam or the beam's reflections exceeds the applicable MPE.
- B. A registrant shall not permit an individual to enter a controlled area if the skin exposure exceeds the applicable MPE, unless the registrant provides and requires the use of protective clothing, gloves, and shields.
- C. A registrant shall ensure that any laser product, emitting spatially scanned laser radiation, does not, as a result of scan failure or any other failure that causes a change in angular velocity or amplitude, permit human access to laser radiation that exceeds the accessible emission limits applicable to that class of product.

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 operational capability which results, any time during the useful life of such product or installation, in accordance with the requirements of the federal performance standards for light emitting products contained in 21 CFR 1040.10.~~
- ~~B. The modification of any laser product or installation, which affects any aspect of performance or intended functions of such product or installations, shall require reclassification and relabeling in accordance with 21 CFR 1040.10.~~
- ~~C. Any laser system that is incorporated into a laser product subject to the requirements of this Article and that is capable, without modification, of producing laser radiation when removed from 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. It shall be classified on the basis of accessible emission of laser radiation when so removed.~~
- A. Each laser product is classified on the basis of emission level, emission duration, and wavelength of accessible laser radi-

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ation emitted over the full range of resulting operational capability, any time during the useful life of the product, according to the federal performance standards for light-emitting products contained in 21 CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

- B.** Any person that modifies a certified laser product in a manner that affects any aspect of performance or intended functions of the product, shall recertify and reidentify the product in accordance with 21 CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference 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 capable, without modification, of producing laser radiation when removed from the laser product, is considered a laser product, subject to the applicable requirements of this Article. Upon removal of the laser system described in this subsection, the laser product is classified on the basis of accessible laser radiation emission.

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

- A.** ~~No licensee shall use, or permit the use of, any laser products or installation which allows human exposure in excess of the MPE limits 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, and accessible emission limits 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.~~
- 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 Department and the Office of the 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 Z136.1-1993, 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.~~
- 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 Department and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.~~
- E.** ~~Exposure to collateral radiation shall not exceed the limits 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.~~
- A.** A registrant shall not use, or permit the use of a laser product that will result in a human exposure that exceeds the applicable MPE or accessible emission limit (AEL) listed in ANSI Z136.1-2000, American National Standard for Safe Use of Lasers, 2000 edition, which is incorporated by reference, published by the Laser Institute of America, 13501 Ingenuity Drive, Suite 128, Orlando, FL 32826, and on file with the Agency. Accessible emission limits are listed in 21 CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. These incorporations by reference contain no future editions or amendments.
- B.** A registrant shall not allow exposure to collateral radiation that exceeds any accessible emission limit in 21 CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. 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 Z136.1-1993, 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.~~
- B.** ~~The word "invisible" shall immediately precede the word "radiation" on labels and signs required by this Section for wavelengths of laser and collateral radiation that are outside of the range of 400 to 710 nanometers.~~
- C.** ~~The words "visible and invisible" shall immediately precede the word "radiation" on labels and signs required by this Section.~~

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- tion for wavelengths of laser and collateral radiation that are both within and outside the range of 400 to 710 nanometers.
- ~~D.~~ All labels placed on lasers or signs posted 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.
 - ~~E.~~ Labels and signs required by this Section shall be clearly visible, legible, and permanently attached to the laser or facility.
 - ~~F.~~ Each laser shall have a label permanently and legibly affixed which identifies, in accordance with the requirements in 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, containing no future editions or amendments, the classification of the laser.
 - ~~G.~~ 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 III and 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:
 - ~~1.~~ "AVOID EXPOSURE - Laser radiation is emitted from this aperture," if the radiation emitted through such aperture is laser radiation.
 - ~~2.~~ "AVOID EXPOSURE - Hazardous electromagnetic radiation is emitted from this aperture," if the radiation emitted through such aperture is collateral radiation.
 - ~~3.~~ "AVOID EXPOSURE - Hazardous x rays are emitted from this aperture," if the radiation emitted through such aperture is collateral x ray radiation.
 - ~~I.~~ Each non-interlocked or defeatably interlocked portion of the protective housing or enclosure 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 be labeled as follows:
 - ~~1.~~ For laser radiation in excess of the accessible emission limits of Class I or Class II, as applicable, but not in excess of the accessible emission limits of Class 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 III, the wording: "DANGER - laser radiation when open, AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION".
 - ~~3.~~ For collateral radiation in excess of the accessible emission limits:
 - ~~a.~~ If the limits for collateral laser radiation are exceeded, the wording: "CAUTION - Hazardous Electromagnetic Radiation when open"; and
 - ~~b.~~ If the limits for collateral x ray radiation are exceeded, the wording: "CAUTION - Hazardous X ray Radiation".
 - ~~4.~~ For protective housing or enclosures which provide a defeatable interlock, the words "and interlock defeated" shall be included in the labels specified above.
 - A. Except as otherwise authorized by the Agency, a registrant shall use signs, symbols, and labels prescribed by this Section and the design and colors specified in ANSI Z136.1- 2000, American National Standard for Safe Use of Lasers, 2000 edition, which is incorporated by reference, published by the Laser Institute of America, 13501 Ingenuity Drive, Suite 128, Orlando, FL 32826, and on file with the Agency. This incorporation by reference contains no future editions or amendments.
 - B. A registrant shall ensure that the word "invisible" immediately precedes the word "radiation" on labels and signs required by this Section for lasers that only produce wavelengths of laser and collateral radiation that are outside of the range of 400 to 710 nanometers.
 - C. A registrant shall ensure that the words "visible and invisible" immediately precede the word "radiation" on labels and signs required by this Section for lasers that produce wavelengths of laser and collateral radiation that are both within and outside the range of 400 to 710 nanometers.
 - D. A registrant shall position any label placed on lasers or signs posted in laser facilities so that the reader of the label or sign is not exposed to laser or collateral radiation that exceeds the applicable MPE or accessible emission limit while reading the label or sign.
 - E. A registrant shall use labels and signs that are clearly visible, legible, and permanently attached to the laser or facility.
 - F. A registrant shall ensure that a permanent and legible label is affixed to each laser, identifying the classification of the laser in accordance with 21 CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.
 - G. For a Class 3 or Class 4 laser a registrant shall ensure that a permanent and legible label is affixed to each laser, specifying the maximum output of laser radiation, the pulse duration if applicable, and the laser medium or emitted wavelength.
 - H. For a Class 3 or Class 4 laser, used in the practice of medicine, a registrant shall ensure that a permanent and legible label is affixed to each laser providing one or more of the following warnings near each aperture that emits laser radiation or collateral radiation that exceeds the applicable MPE, as follows:
 - 1. "AVOID EXPOSURE - Laser radiation is emitted from this aperture" if the radiation emitted through the aperture is laser radiation;

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2. “AVOID EXPOSURE - Hazardous electromagnetic radiation is emitted from this aperture” if the radiation emitted through the aperture is collateral radiation; or
3. “AVOID EXPOSURE - Hazardous x-rays are emitted from this aperture” if the radiation emitted through the aperture is collateral x-ray radiation.
- I. A registrant shall ensure that there is a label on each non-interlocked or defeatable interlocked portion of the protective housing or enclosure that permits human access to laser or collateral radiation. The label shall include one or more of the following warnings, as applicable:
 1. For laser radiation that exceeds the applicable accessible emission limit for a Class 1 or Class 2 laser, but does not exceed the applicable accessible emission limit for a Class 3 laser, the warning: “DANGER - Laser radiation when open, AVOID DIRECT EXPOSURE TO THE BEAM.”
 2. For laser radiation that exceeds the applicable accessible emission limit for a Class 3 laser, the warning: “DANGER - Laser radiation when open, AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION.”
 3. For collateral radiation that exceeds an applicable accessible emission limit:
 - a. If the applicable limit for collateral laser radiation is exceeded, the warning: “CAUTION - Hazardous electromagnetic radiation when open”; and
 - b. If the applicable limit for collateral x-ray radiation is exceeded, the warning: “CAUTION - Hazardous x-ray radiation”.
 4. For a protective housing or an enclosure that has a defeatable interlock, the warning “and interlock defeated” in addition to the warnings in subsections (1) through (3).

R12-1-1429. Posting of Laser Facilities

Facilities shall be posted in a manner consistent with 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 in writing by the Agency.

Unless other methods are approved by the Agency, a registrant shall post each laser facility in accordance with ANSI Z136.1-2000, American National Standard for Safe Use of Lasers, 2000 edition, which is incorporated by reference, published by the Laser Institute of America, 13501 Ingenuity Drive, Suite 128, Orlando, FL 32826, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

R12-1-1433. ~~Laser-controlled Areas~~ Controlled Area for a Laser

- ~~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 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 registrant shall establish a controlled area for a laser if it is possible for a person to be exposed to laser radiation from a Class 3b laser, except a Class 3b laser of less than 5 milliwatts visible peak power, or a Class 4 laser that exceeds the

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applicable MPE or AEL in R12-1-1426.

B. A registrant shall ensure that a controlled area associated with a Class 3b laser is:

1. The responsibility of a LSO;
2. Posted in accordance with this Article; and
3. Access controlled by the LSO or a trained, designated representative.

C. A registrant shall ensure that a controlled area associated with a Class 4 laser is:

1. The responsibility of a LSO;
2. Posted in accordance with this Article;
3. Access controlled by the LSO or a trained, designated representative; and
4. If an indoor controlled area:
 - a. Equipped with latches, interlocks, or another means of preventing unexpected entry into the controlled area;
 - b. Equipped with a control-disconnect switch, panic button, or an equivalent device for deactivating the laser during an emergency;
 - c. Operated so that the person in charge of the controlled area can momentarily override the safety interlocks during tests that require continuous operation to provide access to other personnel if there is no optical radiation hazard at the point of entry and the entering personnel are wearing required protective devices; and
 - d. Controlled in a way that reduces the transmitted values of laser radiation through optical paths such as windows, to levels at or below the applicable ocular MPE and AEL in R12-1-1426. If a laser beam with an irradiance or radiant-exposure above the applicable MPE or AEL will exit the indoor controlled area (as in the case of exterior atmospheric beam paths), the registrant and the operator are responsible for ensuring that the beam path is limited to controlled air space or controlled ground space.

D. If a panel or protective cover is removed or an interlock bypassed for service, testing, or maintenance, a registrant shall establish an accessible controlled area. The registrant, through a LSO or a designated representative, shall comply with laser safety requirements for all potentially-exposed individuals.

R12-1-1434. ~~Laser safety officer duties~~ Safety Officer (LSO)

~~The Laser Safety officer shall administer the laser radiation protection program and shall:~~

- ~~1. Assure that maintenance and service for Class IIb and Class IV lasers shall be performed only by technicians trained to provide such service by either the manufacturer's service organization or the institution's staff;~~
- ~~2. Approve written service and maintenance operating procedures;~~
- ~~3. Investigate, document and report all incidents and accidents as required by R12-1-1436;~~
- ~~4. Select protective eye wear as required pursuant to R12-1-1435, along with any other appropriate protective equipment;~~
- ~~5. For health care facilities, establish authorization and operating procedures, including preoperative and postoperative checklists, for use by operating room personnel;~~
- ~~6. Assure the training of authorized personnel in the assessment and control of laser hazards;~~
- ~~7. Select proper signs and warning posters as required by R12-1-1427;~~
- ~~8. Perform laser radiation protection surveys as required by R12-1-1424 and R12-1-1441;~~
- ~~9. Classify or verify classification of laser and laser systems used under the LSO's jurisdiction;~~
- ~~10. Be responsible for hazard evaluation of laser use areas, treatment areas, and laser control areas, as described in R12-1-1428(E).~~

A. Each registrant shall designate a Laser Safety Officer (LSO).

B. The LSO shall administer the laser radiation protection program and shall:

1. Ensure that maintenance or service for Class 3b and Class 4 lasers is performed only by technicians trained to provide the maintenance or service by either the manufacturer's service organization or the registrant;
2. Approve or reject written service, maintenance, and operating procedures;
3. Investigate, document, and report all incidents as required by R12-1-1436;
4. Select protective eye wear as required by R12-1-1435, along with any other protective equipment;
5. For health care facilities, establish authorization and operating procedures, including preoperative and postoperative checklists, for use by operating room personnel;
6. Ensure that authorized personnel are trained in the assessment and control of laser hazards;
7. Select signs, symbols, and labels as required by R12-1-1427;
8. Perform laser radiation protection surveys as required by R12-1-1421 and R12-1-1441;
9. Classify or verify the classification of lasers and laser systems used under the LSO's jurisdiction;
10. Evaluate the hazard of laser use areas, treatment areas, and controlled areas, as required by R12-1-1421(C).

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

~~**A.** Protective eye wear, as specified by the laser safety officer, shall be worn:~~

- ~~1. By all individuals with access to Class IV levels of laser radiation.~~
- ~~2. When required by the laser safety officer, by all individuals with access to Class IIb levels of laser radiation.~~

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- ~~B.~~ Protective eye wear shall:
 - ~~1. Be legibly and permanently labeled indicating the optical density at the wavelengths for which each such device affords adequate protection;~~
 - ~~2. Be maintained in proper condition to assure the protective properties are retained;~~
 - ~~3. Be inspected at intervals not to exceed six months to ensure integrity of the protective properties;~~
 - ~~4. Be removed from service should the device be determined to be in a condition resulting in decreased protection.~~
- ~~C.~~ Records of maintenance, inspections and removal from service shall be retained for five years.
- ~~A.~~ A registrant shall require that protective eye wear, as specified by the LSO, be worn by an individual who has access to:
 - ~~1. Class 4 laser radiation; or~~
 - ~~2. Class 3b laser radiation.~~
- ~~B.~~ A registrant shall, through the LSO, shall provide protective eye wear that is:
 - ~~1. Marked with a label that indicates the optical density protection afforded for the relevant laser wavelength;~~
 - ~~2. Maintained so that the protective properties of the eye wear are preserved;~~
 - ~~3. Inspected at intervals that do not exceed six months to ensure integrity of the protective properties; and~~
 - ~~4. Removed from service if the protective properties of the eye wear fall below the optical density on the label.~~
- ~~C.~~ A registrant shall maintain records of protective eye wear maintenance, inspection, and removal from service for 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.~~ The Agency shall be notified within 24 hours by telephone of any incident which has caused or may have caused:
 - ~~1. The permanent loss of sight in either eye; or~~
 - ~~2. Third-degree burns of the skin involving more than 5 percent of the body surface as estimated by the rule of nines.~~
- ~~C.~~ Each licensee shall notify the Agency by telephone within 5 working days of any incident which has or may have caused:
 - ~~1. Second-degree burns of the skin larger than 1 inch (2.54 centimeter) in greatest diameter; or~~
 - ~~2. Any third-degree burns of the skin; or~~
 - ~~3. An eye injury with potential loss of sight.~~
- ~~D.~~ Each licensee shall make a report in writing within 30 days to the Agency of:
 - ~~1. Each exposure of an individual to laser and collateral radiation in excess of the MPE limits.~~
 - ~~2. Any incident of which notification is required by subsection (B) or (C).~~
- ~~E.~~ Each report required by subsection (D) shall describe the extent of exposure of individuals to laser or collateral radiation, including:
 - ~~1. Estimates of each individual's exposure;~~
 - ~~2. Levels of laser or collateral radiation involved;~~
 - ~~3. The cause of the exposure; and~~
 - ~~4. Corrective steps taken or planned to be taken to assure against a recurrence.~~
- ~~A.~~ A registrant shall notify the Agency by telephone within 24 hours of any incident that has caused or may have caused:
 - ~~1. Permanent loss of sight in either eye; or~~
 - ~~2. Third-degree burns of the skin involving more than 5 percent of the body surface as estimated by the rule of nines.~~
- ~~B.~~ A registrant shall notify the Agency by telephone within five working days of any incident that has or may have caused:
 - ~~1. Any second-degree burn of the skin larger than one inch (2.54 centimeter) in greatest diameter; or~~
 - ~~2. Any third-degree burn of the skin; or~~
 - ~~3. An eye injury with any potential loss of sight.~~
- ~~C.~~ Each registrant shall file a written report with the Agency of any known exposure of an individual to laser radiation or collateral radiation within 30 days of its discovery, describing:
 - ~~1. Each exposure of the individual to laser or collateral radiation that exceeds the applicable MPE; and~~
 - ~~2. Any incident that triggered a notice requirement in subsections (A) or (B).~~
- ~~D.~~ Each report required by subsection (C) shall describe the extent of exposure to each individual including:
 - ~~1. An estimate of the individual's exposure;~~
 - ~~2. The level of laser or collateral radiation involved;~~
 - ~~3. The cause of the exposure; and~~
 - ~~4. The corrective steps taken or planned to prevent a recurrence.~~
- ~~E.~~ A registrant shall not operate or permit the operation of any laser product or system that does not meet the applicable requirements in this Article.

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

Installations operating laser systems with unenclosed beam path shall:

- ~~1. Conduct an evaluation of the expected beam path and the potential hazards from incidental reflective surfaces which~~

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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. 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. 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.

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

1. Conduct an evaluation before operating the laser to determine the expected beam path and the potential hazards from reflective surfaces. Based on the evaluation the registrant shall exclude reflective surfaces from the beam path at all points where the laser radiation exceeds an applicable MPE;
2. Evaluate the stability of the laser platform to determine the constraints placed upon the beam traverse and the extent of the range of control; and
3. Refrain from operating or making a laser ready for operation until the area along all points of the beam path, where the laser radiation will exceed the applicable MPE, is clear of individuals, unless the individuals are wearing the correct protective devices.

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.~~
- 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.~~

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

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 conducting laser light show or laser demonstration, a registrant shall provide documentation to the Agency that a variance from 21 CFR 1040.10 has been obtained form the FDA.~~
- B. A registrant shall notify the Agency in writing, at least three working days in before a proposed laser light show or demonstration, and include all of the following information:
 1. The location, time, and date of the light show or demonstration;
 2. Sketches showing the locations of each laser, operator, performer, laser beam path, viewing screen, wall, mirror ball, or any other reflective or diffuse surface that could be hit by or reflect the laser beam;
 3. Scanning beam patterns, scan velocity, and frequency in occupied areas; and
 4. Physical surveys and calculations made to comply with this Article.
- C. A registrant shall supply any additional information required by the Agency for the safety evaluation of the proposed activity.
- D. Before an outdoor laser light show, a registrant shall notify the Federal Aviation Administration of the proposed show.
- E. If a light show or demonstration involves laser radiation emissions outside the spectral range of 400 to 700 nanometers, a registrant shall prevent the emissions from exceeding the applicable Class 1 accessible emission limit.
- F. If it is likely that an audience member or any operator, performer, or employee will view laser or collateral radiation, a registrant shall prevent the radiation from exceeding the applicable Class 1 accessible emission limit.
- G. Even if it is unlikely that an individual, including any operator, performer, or employee in the vicinity of a laser light show or demonstration will view or be exposed to laser or collateral radiation, a registrant shall prevent the radiation from exceeding the applicable Class 2 accessible emission limit.

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- H. A registrant shall identify any area where levels of laser radiation exceed the applicable Class 2 accessible emission limit by posting warning signs and using barriers or guards to prevent entry.
- I. If a registrant uses a scanning device, the registrant shall not use a device which, as a result of scan failure or any other failure, can change its angular velocity or amplitude, permitting audience exposure to laser radiation that exceeds the applicable Class 1 accessible emission limit.
- J. If a mirror ball is used with a scanning laser, a registrant shall meet the requirements of subsections (F) and (G) when the mirror ball is stationary or during any failure mode that results in a change in the rotational speed of the mirror ball.
- K. A registrant shall ensure that an operator is at all times directly and personally supervising a laser light show or demonstration, except in cases where the maximum laser power output level is less than 5 milliwatts (all spectral lines) and the laser beam path is located at all times at least 6 meters above any surface upon which an individual in the audience is permitted to stand, and at any point, more than 2.5 meters in lateral separation from any position where an individual in the audience is permitted during the performance.
- L. A registrant shall prevent laser radiation levels from exceeding the applicable Class 2 accessible emission limit at any point less than three meters above any surface upon which an individual in the audience is permitted to stand and 2.5 meters in lateral separation from any position where an individual in the audience is permitted, unless physical barriers are present that prevent human access to the radiation.
- M. A registrant shall limit the maximum power output of any laser to a level sufficient to produce the desired effect.
- N. If a registrant is required to limit output power to a level less than the available power to meet the requirements of this Article, the registrant shall adjust, measure, and record the laser output power before the laser light show or demonstration.
- O. A registrant shall functionally test and evaluate all safety devices and procedures necessary to comply with this Article after setup, and before a laser light show or demonstration.
- P. A registrant shall secure a laser system, when not in use, against unauthorized operation or tampering
- Q. A registrant shall perform laser alignment procedures with the laser output power reduced to the lowest practicable level, and ensure that any operator, performer, or other employee wears protective eye wear as necessary to prevent exposure to radiation levels that exceed the applicable MPE. The registrant shall only allow individuals who are performing the alignment be present during alignment procedures.
- R. A registrant shall not conduct a laser light show or demonstration unless the Agency has specifically exempted the show or demonstration from the requirements of 21 CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

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

A registrant shall take measurements to determine MPE values in a manner consistent with the procedures contained in ANSI Z136.1-2000, American National Standard for Safe Use of Lasers, 2000 edition, which is incorporated by reference, published by the Laser Institute of America, 13501 Ingenuity Drive, Suite 128, Orlando, FL 32826, and on file with the Agency. This incorporation by reference contains no future editions or amendments

R12-1-1443. Laser Compliance Measurement Instruments

Each determination requiring a measurement for compliance with this Article shall use instrumentation which is calibrated and designed for use with the laser that is 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.

A registrant shall ensure that the radiation output measurement is performed with an instrument that is calibrated and designed for use with the laser that is being evaluated for compliance. The registrant shall specify the date of calibration, accuracy of calibration, wavelength range, and power or energy of calibration on a legible, clearly visible label attached to the instrument.

R12-1-1444. Laser Classification Measurements

Measurement of accessible emission for classification shall be made:

1. Under those operational conditions and procedures which maximize the accessible emission levels including start-up stabilized operation, and shutdown of the laser or facility;
2. With all controls and adjustments listed in the operating and service instructions adjusted for the appropriate maximum accessible emission level of laser radiation which is not expected to be detrimental to the functional integrity of the laser or enclosure;
3. At points in space to which human access is possible for a given laser configuration. If operations may include removal of portions of the protective housing or enclosure and defeat of safety interlocks, measurements shall be made at points accessible in that configuration;
4. With the measuring instrument detector so positioned and so oriented with respect to the laser as to result in the maximum detection of radiation by the instrument; and
5. For a laser other than a laser system, with the laser coupled to that type of laser energy source specified as compatible by the laser fabricator and which produces the maximum emission of accessible laser radiation from that laser.
6. Accessible emission levels for classification of laser and collateral radiation shall be based upon the following mea-

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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 1 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 1 milliradian with collimating optic of 5 diopters or less, divided by the area of the aperture stop in square centimeters.
- c. 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 7 millimeter diameter and within the circular solid angle of acceptance with collimating optics applicable under subsections (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 5 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.

A. A registrant shall measure accessible emission for classification:

- 1. Under the operational conditions and procedures that maximize accessible emission levels, including start-up, stabilized operation, and shutdown of the laser or laser facility;
- 2. With all controls and adjustments listed in the operating and service instructions adjusted for the maximum accessible emission level of laser radiation that is not expected to be detrimental to the functional integrity of the laser or enclosure;
- 3. At points in space to which human access is possible for a given laser configuration. If operations include the defeat of safety interlocks or removal of portions of the protective housing or enclosure, the registrant shall measure accessible emission at points accessible in that configuration;
- 4. With the measuring instrument detector positioned so that the maximum possible radiation is measured by the instrument; and
- 5. With the laser coupled to the type of laser energy source specified as compatible by the laser manufacturer and producing the maximum emission of accessible laser radiation.

B. A registrant shall perform measurements of accessible emission levels, used to classify laser and collateral radiation in accordance with 21 CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

Appendix A. Radiofrequency Radio Frequency Devices

Radiofrequency Devices Include But are Not limited To:

- Dielectric Heaters and Sealers
- Industrial Microwave Ovens And Dryers
- Medical Diathermy Units
- Asher Echer 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

- Dielectric heaters and sealers
- Medical diathermy units
- Radar
- R.F. activated alarm systems
- Sputter devices
- R.F. activated lasers
- Edge gluers

- Industrial microwave ovens and dryers
- Asher-etcher equipment
- R.F. welding equipment
- Medical surgical coagulators

Notices of Final Rulemaking

Appendix B ~~Repealed~~

Application Information

The Agency shall issue a registration if an applicant provides the following information and fee as required in R12-1-1401(D). The Agency shall provide an application form to the applicant with a guide and upon request, assist the applicant to ensure that correct information is provided on the application form.

- | | |
|---|--|
| <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>Contact person</u> |
| <u>Type of request: amendment, new, or renewal</u> | <u>Appropriate fee listed in Article 13 schedule</u> |
| <u>Protection survey results, if applicable</u> | |
| <u>Radiation Safety Officer name, if applicable</u> | |
| <u>Laser class and type, if applicable</u> | |
| <u>Information required by Article 14 for the specific source</u> | |

NOTICE OF FINAL RULEMAKING

TITLE 12. NATURAL RESOURCES

CHAPTER 5. STATE LAND DEPARTMENT

PREAMBLE

1. Sections Affected

Rulemaking Action

- | | |
|-----------|-------------|
| R12-5-101 | Repeal |
| R12-5-101 | New Section |
| R12-5-102 | New Section |
| R12-5-103 | New Section |
| R12-5-104 | New Section |
| R12-5-105 | New Section |
| R12-5-106 | New Section |
| R12-5-107 | New Section |
| R12-5-108 | New Section |
| R12-5-109 | New Section |
| Article 2 | Amend |
| R12-5-201 | Repeal |
| R12-5-201 | New Section |
| R12-5-202 | Repeal |
| R12-5-202 | New Section |
| R12-5-203 | Repeal |
| R12-5-203 | New Section |
| R12-5-204 | Repeal |
| R12-5-204 | New Section |
| R12-5-205 | Repeal |
| R12-5-205 | New Section |
| R12-5-206 | Repeal |
| R12-5-206 | New Section |
| R12-5-207 | Repeal |
| R12-5-207 | New Section |
| R12-5-208 | Repeal |
| R12-5-208 | New Section |
| R12-5-209 | Repeal |
| R12-5-209 | New Section |
| R12-5-210 | Repeal |
| R12-5-210 | New Section |
| R12-5-211 | Repeal |

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R12-5-211	New Section
R12-5-212	Repeal
R12-5-212	New Section
R12-5-213	Repeal
R12-5-213	New Section
R12-5-213	Amend
R12-5-214	Repeal
R12-5-214	New Section
R12-5-215	Repeal
R12-5-215	New Section
R12-5-216	Repeal
R12-5-216	New Section
R12-5-217	Repeal
R12-5-217	New Section
R12-5-218	Repeal
R12-5-218	New Section
R12-5-219	Repeal
R12-5-220	Repeal
R12-5-221	Repeal
R12-5-222	Repeal

2. 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. § 37-132(A)(1)

Implementing statutes: A.R.S. §§ 37-132(B)(1), 37-301, 37-312, 37-332(D), 37-1038(A), and 27-557(C)

3. The effective date of the rules:

February 5, 2005

4. A list of all previous notices appearing in the Register addressing the final rule:

Notice of Rulemaking Docket Opening: 9 A.A.R. 5066, November 21, 2003

Notice of Proposed Rulemaking: 10 A.A.R. 542, February 20, 2004

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

Name: Richard B. Oxford, Director
Land Information, Title & Transfer Division

Address: State Land Department
1616 W. Adams
Phoenix, AZ 85007

Telephone: (602) 542-4602

Fax: (602) 542-5223

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

Article 1, provides definitions and general rules applicable to all transactions with the Department. The rules under Article 1 are adopted to provide definitions of terms and phrases as well as general rules applicable to all transactions with the Department. The rules clarify language and provide the general public with an understanding of what is expected when conducting business with the Department.

Article 2 provides guidelines applicable to the conduct of a hearing relating to State land where an auction for the sale of State land or natural products or a long-term commercial lease may be protested pursuant to A.R.S. § 37-301. An "auction protest" hearing is exempt from the hearing procedures under the Office of Administrative Hearings (OAH) pursuant to A.R.S. § 41-1092.02(G). Under A.R.S. § 37-301, the Commissioner must enter a decision regarding an "auction protest" within a compressed time-frame. In view of the time restrictions, the hearing rules under OAH would not be compatible with the time-frames outlined in A.R.S. § 37-301.

The rules under Article 2 clarify the Article's purpose as only addressing hearing procedures relating to protested auctions pursuant to A.R.S. § 37-301 and not to appealable agency actions or contested cases pursuant to A.R.S. § 41-1092.02. The rules address the appointment of a hearing officer, communication among all parties, representation, noticing, hearing records, filing of documents, guidelines for evidence, hearing procedures, decision, and rehearing restrictions.

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

The Land Department did not review any study relevant to the rules.

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8. 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

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

The Arizona State Land Department manages 9.3 million acres of state owned "Trust" lands. These lands were granted to the state of Arizona under the provisions of the federal Enabling Act that provided for Arizona's statehood in 1912. The lands are held in trust for various beneficiaries including the common schools (K-12) and 13 other public institutions. The Trust's beneficiaries receive revenue from leasing, selling, or using State Trust land and its resources.

The Department has adopted rules that provide guidelines for entities proposing to conduct business with the Arizona State Land Department as well as rules addressing the conduct of hearings administered by the State Land Commissioner. The adopted rules are separated into Article 1 (General Provisions) and Article 2 (Practice and Procedure in Administrative Hearings Before the Arizona State Land Commissioner).

The rules in Article 1 apply to virtually every entity that proposes to lease, purchase, or use Trust land and its resources. Article 1 provides definitions of terms and phrases as well as general rules applicable to all transactions with the Department. The rules clarify language and provide the general public and other entities an understanding of what is expected when conducting business with the Department.

Economically, the rules under Article 1 will save an applicant time, will eliminate unnecessary expenses, and avoid confusion when applying for a lease, permit, or land sale or other use of Trust land or its resources or conducting general business transactions with the Department.

Article 2 provides guidelines applicable to the conduct of a hearing held as a result of a protest of a sale of State land or natural products or the auction of a long-term lease of State land. The rules under Article 2 will save time for hearing participants by explaining the hearing process and outlining what is expected of the Department and participants in order to address the issue in a fair and impartial manner.

The rules under Article 2 are designed to allow the Commissioner or the designated hearing officer to conduct a hearing in an organized, fair, and expeditious manner. By understanding the hearing process, participants will be able to prepare and present information or testimony in an efficient and organized manner. The Department and participants will save time and expense. Costs to the participants may include legal or consultant services to prepare documents, provide testimony or represent parties that may be affected by the hearing decision.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

To ensure clarification of the rules, technical and grammatical changes were made. No changes, however, altered the substance or intent of the applicable rule.

11. A summary of the principal comments and the agency response to them:

No comments were received by the agency

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

Not applicable

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

None

14. Was this rule previously adopted as an emergency rule?

No

15. The full text of the rules follows:

TITLE 12. NATURAL RESOURCES

CHAPTER 5. STATE LAND DEPARTMENT

ARTICLE 1. GENERAL PROVISIONS

Section

R12-5-101. ~~Relating to Proceedings Before the State Land Department~~ Definitions

R12-5-102. ~~Repeated~~ Computation or Extension of Time

R12-5-103. ~~Repeated~~ Records; Correction of Errors; Public Docket; Removal of Records

R12-5-104. Application Forms; Legal Status; Submission of Applications; Applications Confer No Rights

R12-5-105. Manner of Signing Documents before the Department

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- R12-5-106. Assignments; Subleases
- R12-5-107. Fees; Remittances
- R12-5-108. Predecision Administrative Hearing
- R12-5-109. Rejection of Hearing Request

ARTICLE 2. PRACTICE AND PROCEDURE IN ~~CONTESTED CASES~~ ADMINISTRATIVE HEARINGS FOR PROTESTING AUCTIONS BEFORE THE ARIZONA STATE LAND COMMISSIONER

Section

- R12-5-201. ~~Appointment of Hearing Officer; Disqualification~~ Applicability
- R12-5-202. ~~Initiation of a Contested Case-~~ Appointment of Hearing Officer
- R12-5-203. ~~Request for Hearing-~~ Ex Parte Communications
- R12-5-204. ~~Denial of Request for Hearing-~~ Failure to Appear
- R12-5-205. ~~Failure to Appear; Default-~~ Representation
- R12-5-206. ~~Amendment of Notice of Hearing; Request More Definite Statement-~~ Notice of Hearing
- R12-5-207. ~~Communications Regarding Matters Related to Contested Case~~ Hearing Record
- R12-5-208. ~~Representation~~ Consolidation
- R12-5-209. ~~Notice of Hearing or Prehearing Conference~~ Filing
- R12-5-210. ~~Contested Case Record~~ Service; Proof of Service
- R12-5-211. ~~Intervention-~~ Subpoenas
- R12-5-212. ~~Consolidation Severance-~~ Procedure at Hearing
- R12-5-213. ~~Prehearing Conference, Procedure and Prehearing Order~~ Evidence
- R12-5-214. ~~Filing; Computation of Time; Extension of Time-~~ Judicial Notice; Technical Facts
- R12-5-215. ~~Service; Proof of Service-~~ Stipulations
- R12-5-216. ~~Subpoenas~~ Recommended Decision
- R12-5-217. ~~Procedure at Hearing~~ Decision
- R12-5-218. ~~Evidence~~ Rehearing of Decision
- R12-5-219. ~~Stipulations~~ Repealed
- R12-5-220. ~~Recommended Decision~~ Repealed
- R12-5-221. ~~Decision~~ Repealed
- R12-5-222. ~~Review and Rehearing of Decision~~ Repealed

ARTICLE 1. GENERAL PROVISIONS

R12-5-101. ~~Relating to Proceedings Before the State Land Department-Definitions~~

Except as otherwise provided in Article 2:-

1. ~~Computation of time. In computing any period of time prescribed or allowed by these rules, by order of court or by any applicable statute, the day of the act, event, or default after which the designated period of time begins to run is not to be included; the last day of the period so computed is to be included, unless it is a Saturday, Sunday, or legal holiday, in which event the period runs until the end of the next day which is neither a Saturday, Sunday, nor a holiday. When the period of time prescribed or allowed is less than seven days, intermediate Saturdays, Sundays, and holidays shall be excluded in the computation.~~
2. ~~Enlargement of time. When, by these rules or by a notice given thereunder or by order of the Commissioner, an act is required or allowed to be done at or within a specified time, the Commissioner may, for cause shown at any time in the Commissioner's discretion with notice, order the period enlarged if request therefor is made before the expiration of the period originally prescribed or as extended by a previous order or upon request made after the expiration of the specified period permit the act to be done where the failure to act was the result of excusable neglect.~~
3. ~~Record. Every document and other object filed in the Department shall constitute a part of the record thereof and shall be available for public inspection except as prohibited by law.~~
4. ~~Inspection of records. The records of the Department, except as prohibited by law, may be inspected by any person at any time during the office hours of the Department.~~
5. ~~Withdrawal of papers. No instruments, documents, or other papers or objects on file with the Department may be taken from the Department office, except for the use of the Commissioner or the Commissioner's duly appointed deputies or employees or by order of a court of competent jurisdiction.~~
6. ~~Clerical mistakes. Clerical mistakes in decisions, orders, instruments, or other records of the Department or parts thereof and errors therein arising from oversight or omission may be corrected by the Commissioner at any time on the Commissioner's own initiative or on motion of any party and after such notice, if any, as the Commissioner orders. During the pendency of an appeal, such mistakes may be so corrected before the appeal is docketed in the appellate court and thereafter, while the appeal is pending, may be corrected with leave of the appellate court.~~
7. ~~Forms supplied. All applications or reports required by law or under these rules to be filed with the Department shall be submitted upon forms prescribed and furnished by the Department, unless accepted or authorized in writing by the~~

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Commissioner.

8. ~~No application will be accepted without the payment of the required application fee and unless all answers to questions and all information and other data required by the Commissioner have been furnished.~~
9. ~~Manner of signing instruments before the Department; acknowledgment. All instruments are required to be signed in the same manner as the applicant's, lessee's, or permittee's name appears of record in the Department or in the manner in which a new instrument is requested to be issued. All assignments of instruments shall be signed and acknowledged in the same manner as required for the signing and acknowledgment of a deed or conveyance of real property.~~

A. Unless the context otherwise requires, a word, term, or phrase that is defined in A.R.S. Title 27 or 37 has the same meaning when used in Articles 1 through 9, 11, 17 through 22, 24, and 25 of this Chapter.

B. Except as otherwise provided in subsection (A), the following words, terms, and phrases apply to Articles 1 through 9, 11, 17 through 22, 24, and 25 of this Chapter.

1. "Best interest of the state" means best interest of the Trust.
2. "Common mineral materials and products" means cinders, sand, gravel and associated rock, fill-dirt, common clay, disintegrated granite, boulders and loose float rock, waste rock, and materials of similar occurrence commonly used as aggregate road material, rip-rap, ballast, borrow, or fill for general construction and similar purposes.
3. "Contiguous" means two parcels of land that have at least part of one side in common or have a corner touching.
4. "Grantee" means the holder of a right-of-way and includes the holder of an approved assignment of a right-of-way other than an assignment for the purpose of granting a security interest.
5. "Hearing officer" means the Commissioner or a hearing officer appointed by the Commissioner and includes the Deputy Commissioner or any officer of the Department.
6. "Lease" means any validly executed document that entitles the lessee to surface or subsurface use or occupancy of State land. "Lease" includes any validly assigned lease other than an assignment for the purposes of granting a security interest.
7. "Lessee" means the holder of a lease and includes the holder of an approved assignment of a lease other than an assignment for the purpose of granting a security interest, and a permittee or grantee of a right-of-way.
8. "Lessor" means the Department.
9. "Natural product" means any material or substance occurring in its native state that when extracted, is subject to depletion and includes water, vegetation, common mineral products and materials that are severable from the land, except geothermal resources and those substances subject to the mineral exploration permit and mineral leasing laws of this State.
10. "Non-conflicted application" means an application for the use of State land that is not conflicted by one or more applications for the same use of the land filed within the time frame for a conflicting application to be filed under A.R.S. § 37-284.
11. "Party" means a person or agency named or admitted as a party in a proceeding or someone seeking to intervene and may include the Department.
12. "Permit" means any Department-issued document that entitles the permittee to surface or subsurface use or occupancy of State land. "Permit" includes a validly assigned permit other than an assignment for the purposes of granting a security interest.
13. "Permittee" means the holder of a permit and includes the holder of an approved assignment of a permit, where assignments are provided by law, other than an assignment for the purpose of granting a security interest.
14. "Person" means a corporation, company, partnership, firm, association or society, as well as a natural person. When the word "person" is used to designate the party whose property may be the subject of a criminal or public offense, the term includes the United States, this state, or any territory, state or country, or any political sub-division of this state that may lawfully own any property, or a public or private corporation, or partnership or association. When the word "person" is used to designate the violator or offender of any law, it includes corporation, partnership or association of persons.
15. "Public Records" means the area designated by the Commissioner within the offices of the Department for the submission of all documents to be filed with the Department.
16. "Right-of-way" means a right of use and passage over, through, or beneath the surface of State land, for an express purpose and to travel to a specific location.
17. "Special Land Use Permit" means a Department-issued document that entitles a permittee to occupy or use State lands for an express purpose, not otherwise expressly provided for by law, and for a specific duration.
18. "Sublease" means an agreement, approved by the Commissioner, between a lessee and a third person to lease the property where the lessee retains an interest in the lease.

R12-5-102. Repealed Computation or Extension of Time

A. Computation of time. In computing any time period prescribed or allowed under this Chapter, except a time period prescribed under Article 2 of this Chapter, the Department shall exclude the day from which the designated time period begins to run. The computation of time includes intermediate Saturdays, Sundays, and legal holidays. The last day of the period is included unless it is a Saturday, Sunday, or legal holiday, in which event the period runs until the end of the next

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day that is not a Saturday, Sunday, or a legal holiday. When the time period is 10 days or less, the Department shall exclude Saturdays, Sundays, and legal holidays.

- B.** Extension of time. At the Commissioner's initiative, or upon request, the Commissioner may extend any time period to perform or complete any ordered or required action. The Commissioner shall extend a time period only if the person making a request shows good cause for the extension.

R12-5-103. Repealed Records; Correction of Errors; Public Docket; Removal of Records

- A.** Record. The Department shall stamp every document and other object filed in the Department to record date and time of receipt. A filed document or other object constitutes a part of the record and is available for public inspection, except as prohibited by statute, at any time during the office hours of the Department.
- B.** Correction of errors. On the Commissioner's own initiative or upon request by a party, the Commissioner may correct a manifest typographical or clerical error in a decision, order, instrument, or other record of the Department resulting from oversight or omission. The Commissioner shall provide notice of any correction in the form the Commissioner deems appropriate.
- C.** Public docket. A person may obtain a copy of a public docket, maintained by the Department pursuant A.R.S. § 37-102(F), listing the matters pending before the Department by requesting a copy at the Phoenix Office in person or by mail or e-mail. The Department shall charge to cover the costs of copying a public docket in accordance with A.R.S. §39-121.01.
- D.** Removal of papers. A person shall not remove an instrument, document, or other paper or object on file with the Department from the Department, except as authorized by the Commissioner, the Commissioner's duly appointed deputy or employee or by order of a court of competent jurisdiction.

R12-5-104. Application Forms; Legal Status; Submission of Applications; Applications Confer No Rights

- A.** Forms supplied. A person shall submit an application, report, or other document required by statute or this Chapter to be filed with the Department upon a form prescribed and furnished by the Department. The Department shall accept for filing other instruments, such as corporation papers, liens or mortgages, powers of attorney, affidavits of heirship, death certificates, and other legal documents.
- B.** Required information as to legal status. A corporation, limited partnership, or association authorized to conduct business in this state that is applying to purchase, lease, or sublease State lands or any interest in State lands shall state in its application that it is authorized to conduct business in this state.
- C.** Submission of application, report, document, or other instrument. A person shall submit an application, report, document, or other instrument to the Department's Phoenix Office to the attention of Public Records along with payment of the required fee.
- D.** Application confers no rights. A pending application to lease, purchase, or use State land confers no rights to the applicant.
1. The Department may allow a lessee who files a conflicted or non-conflicted application for renewal of an existing lease to remain in possession or continue to occupy or use the land in accordance with the provisions of the lease sought to be renewed until the application to renew is granted or denied. The Department shall grant permission for interim use if:
 - a. The rental is current;
 - b. The lessee is in possession, or otherwise occupies or uses the land; and
 - c. The lessee is in good standing under the lease sought to be renewed.
 2. A lessee who remains in possession with the Department's permission under this Section shall pay any rental or other monies owed, such as penalty and interest on delinquent rent or irrigation district assessments.

R12-5-105. Manner of Signing Documents before the Department

- A.** A person shall sign a document requiring signature in the same manner as the person's name appears of record with the Department or in the manner in which the person is requesting the Department issue a new document.
- B.** If a document is executed for the benefit of:
1. One individual, the document shall be signed by that individual or by an authorized representative of the individual;
 2. More than one individual, the document shall be signed by each individual or by the individual's authorized representative; or
 3. A business entity or an association of any kind, the document shall be signed by an authorized representative of the entity or association.
- C.** The Department shall not accept the signature of an authorized representative unless the individual, business entity, or association files with the Department written authority for the authorized representative to sign.

R12-5-106. Assignments; Subleases

- A.** A person shall not assign or sublease any right, entitlement, or interest, in whole or in part, in State land, or possession, occupancy, or right to remove anything, in whole or in part, from State land unless:
1. The person has made application for the assignment or sublease; and

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2. The Commissioner has approved the assignment or sublease in writing.
- B.** In addition to the conditions and provisions of the lease sought to be subleased, any approved sublease is subject to further conditions and provisions as the Commissioner may determine are necessary to further the best interest of the Trust, including but not limited to provisions relating to ownership of improvements on the lease and disposition of proceeds relating to the improvements.
 - C.** The Department may cancel a lease if a sublessee violates a provision of a lease.
 - D.** The Department shall hold the lessee and sublessee jointly and severally liable for damages arising out of a violation of a provision of a lease.
 - E.** The Department shall not approve a sublease of a sublease for State land.

R12-5-107. Fees; Remittances

- A.** A person shall pay fees and other remittances to the Department by cash, money order, bank draft, or check payable to the "Arizona State Land Department."
- B.** A person shall pay all billing statements issued by the Department, whether relating to rent, royalty, or other monies owed to the Department, within 30 days of the date of issuance, unless otherwise specified on the billing statement. If payment does not arrive in the Department's Phoenix Office on or before the close of business on the due date, the Department shall assess penalty and interest as required by law.
- C.** The Department is not responsible for any payment not personally hand delivered and received for by the Cashier in the Department's Phoenix Office. The Department shall not credit any payment not received.

R12-5-108. Predecision Administrative Hearing

The Commissioner may initiate a predecision administrative hearing to investigate an issue, gather information, or review facts to assist the Commissioner in the decision-making process before issuing a decision on any matter pending before the Department.

R12-5-109. Rejection of Hearing Request

The Commissioner shall reject any request for a hearing under A.R.S. Title 41, Chapter 6 that the Commissioner determines not to be subject to A.R.S. Title 41, Chapter 6.

ARTICLE 2. PRACTICE AND PROCEDURE IN ~~CONTESTED CASES~~ ADMINISTRATIVE HEARINGS FOR PROTESTING AUCTIONS BEFORE THE ARIZONA STATE LAND COMMISSIONER

R12-5-201. ~~Appointment of Hearing Officer; Disqualification~~ Applicability

- A.** The Commissioner may appoint a hearing officer to conduct any contested case on the Commissioner's behalf.
- B.** If a hearing officer is disqualified pursuant to this rule or for any reason cannot continue to preside at the hearing of a contested case a new hearing officer.
- C.** Any party may file a request to disqualify the hearing officer for cause.
 - 1. The request shall be filed with the Department within ten days of service of the initial notice of hearing or prehearing conference or within five days after the discovery of facts indicating cause exists to disqualify the hearing officer.
 - 2. The request shall be accompanied by an affidavit setting forth the facts that show cause for disqualification.
 - 3. The request shall allege one or more of the following causes for disqualification:
 - a. That the hearing officer, if a lawyer, has represented a party to the contested case before the Department within the past two years;
 - b. That the hearing officer has a financial interest in the outcome of the contested case;
 - c. That the hearing officer is related to a party;
 - d. That the hearing officer has been employed by a party, other than the Department, within the past two years;
 - e. That the hearing officer is a witness;
 - f. That the party filing the affidavit has cause to believe and does believe that the party cannot obtain a fair and impartial hearing because of the bias, prejudice, or interest of the hearing officer.
 - 4. While a request to disqualify is pending before the Commissioner, the hearing officer shall take no further action in the contested case except to make such temporary orders as are necessary to prevent immediate and irreparable injury, loss, or damage from occurring.

This Article applies to an administrative hearing resulting from a protest of an auction pursuant to A.R.S. §37-301, hereinafter referred to in this Article as "a hearing".

R12-5-202. ~~Initiation of a Contested Case~~ Appointment of Hearing Officer

- A.** A ~~contested case~~ may be initiated by the Department on its own volition. The Commissioner may serve as the hearing officer or may appoint a hearing officer to conduct a hearing under A.R.S. § 37-301.
- B.** The following persons may request a hearing:
 - 1. Any person whose legal rights, duties, or privileges have been directly and adversely affected by a written order or decision of the Commissioner concluding a matter under consideration by the Department, if that order or decision is not preceded by an opportunity for a hearing;

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2. ~~Any person whose legal rights, duties, or privileges are required to be determined after an opportunity for a hearing by statute, rule, or as otherwise provided by law;~~
3. ~~After a notice of default or failure to comply has been mailed, any lessee or certificate of purchase holder, or any person who has registered with the Department as a mortgagee or other lienholder of the interest of the lessee or certificate holder.~~

If a hearing officer, for any reason, cannot continue to preside at the hearing, the Commissioner shall appoint a new hearing officer.

- ~~C. A request for hearing shall be filed within the time allowed by statute to cure or comply. The purpose of the hearing shall be to determine whether a formal cancellation order shall be entered, and any other issues relevant to the cancellation that are within the jurisdiction of the commissioner to decide. Notwithstanding subsections (a) and (c) of this rule, no opportunity for a hearing shall be granted when automatic termination of a lease or automatic cancellation of a certificate of purchase is mandated by statute.~~
- ~~D. No other person has standing to initiate a contested case.~~
- ~~E. Unless a different period is provided by statute, rule, or within the order or decision, a request for hearing shall be filed within 20 days of mailing, by certified mail, of the commissioner's order or decision.~~
- ~~F. The hearing shall take place before the commissioner or before the board of appeals, whichever has jurisdiction to hear the matter.~~
- ~~G. The department shall initiate a contested case by serving a copy of the notice of hearing on the named parties.~~
- ~~H. If no request for a hearing is timely filed, the order or decision of the commissioner shall be final and not subject to further review.~~

R12-5-203. Request for Hearing Ex Parte Communications

When a request for a hearing is filed with the Department, the request shall be in writing and shall state the specific actions of the Department which are the basis of the hearing request and the statute, rule, or other legal basis entitling the person to a hearing.

A party shall not communicate on matters substantive to the hearing, either directly or indirectly, with the hearing officer, the Commissioner, the Deputy Commissioner, or any member of the Commissioner's staff involved in the decision-making process unless:

1. All parties are present; or
2. It is during a scheduled proceeding where an absent party fails to appear after proper notice pursuant to R12-5-210.

R12-5-204. Denial of Request for Hearing Failure to Appear

If the Commissioner denies the request for a hearing, the denial shall be in writing and shall state the reasons therefor. A denial of a request for hearing is final and not subject to further administrative review.

If a party fails to appear at a hearing, the hearing officer may vacate the hearing or allow the appearing party to present evidence.

R12-5-205. Failure to Appear; Default Representation

- ~~A. If, after being served by the Department with notice, a party fails to appear at the time and place of hearing, or prehearing conference, or other proceeding of a contested case, the hearing officer may serve upon all parties a proposed default order that includes a statement of the reasons to default the nonparticipating party.~~
- ~~B. Within seven days after service of a proposed default order, the party against whom it was issued may file a written request to vacate the proposed default order, including a statement of the reasons it should be vacated.~~
- ~~C. Before the default order is vacated or entered, the hearing officer may either adjourn the proceedings or conduct them without the party against whom a proposed default order was issued, maintaining due regard for the interest of justice and the orderly and prompt conduct of the proceedings.~~
- ~~D. The hearing officer shall either enter or vacate the default order promptly after expiration of the time specified in subsection (B) of this rule or upon filing of the request to vacate.~~
- ~~E. After entering a default order, the hearing officer may conduct any further proceedings necessary to complete the contested case without the defaulted party and shall determine all issues in the hearing, including those affecting that party.~~

A party may participate in a hearing in person or through an attorney, except that a corporation shall be represented by an attorney. A partnership may appear through any partner, an association through a key administrator or other executive officer, and an agency or a political subdivision or unit of a political subdivision may appear through an employee.

R12-5-206. Amendment of Notice of Hearing; Request for More Definite Statement Notice of Hearing

- A. No later than ten days after a notice of hearing is issued, a party may request a more definite statement of the issues or assertions or both. If the request is granted, the hearing officer shall set a date for filing a more definite statement.

Upon determination by the Commissioner that a hearing will be held, the Department shall issue a notice of hearing that contains:

1. A caption referencing the Department's case number, a brief description of the matter to be heard, the name or names of the parties and their status, or both;

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2. The date, time, and place of the hearing;
3. A reference to the particular sections of the statutes and rules under which the hearing is to be held;
4. A short, plain statement of the matter to be heard;
5. The name, mailing address, and telephone number of the hearing officer;
6. The names and mailing addresses of persons to whom notice is being given; and
7. Any other information required by statute or rule.

B. ~~At any time before the hearing commences, the Department may amend the notice of hearing to add additional issues or make additional assertions. The hearing officer may reschedule the hearing, maintaining due regard for the interests of justice and the orderly and prompt conduct of the proceedings.~~

An applicant for sale or long-term lease of State Trust land is a party to an administrative hearing conducted under A.R.S. § 37-301.

R12-5-207. ~~Communications Regarding Matters Related to Contested Case Hearing Record~~

~~Once a notice of hearing has been issued, all communications relating to the contested case between any person listed in paragraph (1) and any person listed in paragraph (2) below shall take place in a formal hearing or conference, in the presence of all parties or their attorneys, if represented, or be filed in accordance with R12-5-215.~~

- ~~1. Any party, any person whose interest may be affected by the outcome of the case, or any person acting on behalf of any of them.~~
- ~~2. The Commissioner, the Deputy Commissioner, or any officer of the Department, if acting as the decision maker in the Commissioner's stead, any member of the Commissioner's staff involved in the decisional process, or the hearing officer.~~

A. After the notice of hearing is issued, the hearing file shall be available for inspection at the Department's Public Records Office, Phoenix, during regular business hours.

B. Hearings shall be electronically recorded or stenographically reported by the Department. The hearing officer shall designate the official record of the proceedings. If a hearing is recorded electronically, the tapes shall be available for review in the Department's Public Records Office, Phoenix, during regular business hours. The cost for copies of tapes shall be paid by the person requesting them. The Department shall maintain the original transcript of the official record of the proceeding, if available, as part of the hearing file.

R12-5-208. Representation Consolidation

Parties may participate in the hearing in person or through an attorney, except that a corporation shall be represented by an attorney. A partnership may appear through any partner, an association through a key administrator or other executive officer, and an agency or a governmental subdivision or unit of a governmental subdivision may appear through an employee.

When multiple protests of the same auction are pending before the Department, the Department may consolidate the protests into a single hearing.

R12-5-209. Notice of Hearing or Prehearing Conference Filing

A. The notice of hearing shall contain:

1. A caption referencing the official Department case number and a brief matter name or the names of the parties and their status, or both;
2. The time, place, and nature of the hearing;
3. A statement of the legal authority and Jurisdiction under which the hearing is to be held;
4. A short, plain statement of the subject matter and issues presented, with citation to any statute or rule relied upon;
5. The name, mailing address, and telephone number of the hearing officer;
6. The names and mailing addresses of persons to whom notice is being given, including any attorney or employee who has been designated to appear for a Department Division; and
7. Any other matters required by statute or rule.

B. This notice may set the time, place, and subject matter of a prehearing conference and include any other matters the presiding officer considers desirable to expedite the proceedings.

All papers filed with the Department in a hearing shall be typewritten or legibly written on paper no larger than 8 ½ by 11 inches, include the name and address of the party or individual filing the paper, be properly captioned and designate the title and case number, state the name and address of each party served with a copy, and be signed by the party or, if represented, by the party's attorney. The signature certifies that the signer has read the paper, that to the best of the signer's knowledge, information, and belief there is good ground to support its contents, and that it is not filed for delay.

R12-5-210. Contested Case Record Service; Proof of Service

A. After the notice of hearing is issued, the contested case file shall be available for inspection upon request during regular business hours.

After a notice of hearing is issued, a copy of every paper filed by a party, or person seeking to intervene, shall be served on all parties to the hearing, or the party's counsel if the party is represented, at the same time the paper is filed. Service is complete at the time of personal service or on the date mailed if served by certified or regular mail addressed to the last

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address of record in the hearing file.

- B. ~~All hearings shall be electronically or stenographically reported. The hearing officer shall designate the official record of the proceedings. This rule shall not be construed as prohibiting or limiting any person from having the proceedings stenographically reported or from making their own recording, so long as the proceedings are not disrupted by the recording equipment or operators. The cost of a court reporter and the transcript shall be paid by the person making the request, unless assessment of the cost is waived by the Department. When hearings are recorded electronically, tapes shall be available for review during regular business hours. The cost of copies of tapes shall be paid by the person requesting them. The original transcript of the official record of any proceeding, if available, shall be filed as a part of the case file. The following is evidence that service is complete:~~
1. ~~If personally served, an affidavit of personal service, sworn to by the person serving the paper and stating that the server personally served the paper on the person to whom it was directed, where service was made, and the date of service;~~
 2. ~~If served by certified mail, the return receipt signed by the party served or someone authorized to act on behalf of the party served; or~~
 3. ~~If served by regular mail, either a statement subscribed on the paper filed with the Department, or an affidavit indicating the date mailed and listing those to whom it was mailed.~~
- C. ~~The Department shall serve the notice of hearing decision and final order, either by personal service or by certified mail. The Department or a party shall serve all other papers by regular or certified mail or by personal service.~~
- D. ~~When a party is represented by an attorney, service shall be made on the attorney. If a notice of hearing shows service on the Attorney General, all papers served thereafter shall be served on the Assistant Attorney General named on the notice of hearing or who later appears on behalf of the Department, or, if no Assistant Attorney General is named, on the Attorney General, Civil Division, Chief Counsel, Natural Resources Section.~~

R12-5-211. ~~Intervention Subpoenas~~

- A. ~~A person seeking to intervene in any contested case shall file a written request to intervene. Intervention shall be granted only if the hearing officer determines that:~~
1. ~~The legal interests of the person requesting to intervene may be substantially affected by the outcome of the contested case;~~
 2. ~~Intervention will not unduly delay or bias the hearing;~~
 3. ~~The interest of the person requesting to intervene is not adequately represented by another party to the contested case; and~~
 4. ~~The proposed intervention is in the interests of justice.~~
- ~~The hearing officer may issue subpoenas for witnesses to appear and testify at the hearing or to produce books, records, documents, and other evidence, or both, on the hearing officer's own volition or at the request of a party.~~
- B. ~~The request shall state the claims or defenses for which intervention is sought, briefly describing the interests that may be affected by the outcome of the case and including such facts as demonstrate those interests, and may address the other issues to be determined by the hearing officer. A request for a hearing subpoena shall be in writing, filed with the hearing officer, and served on each party at least seven days before the date set for hearing and state:~~
1. ~~The caption of the hearing, the case number, and the date, time, and place where the witness is expected to appear and testify;~~
 2. ~~The name and address of the witness or custodian of records subpoenaed; and~~
 3. ~~The documents, if any, subpoenaed.~~
- C. ~~The request shall be filed and served upon all parties at least 15 days prior to hearing. The hearing officer shall grant the request if the hearing officer determines there is reasonable need, such as relevant facts expected to be established by the person or document subpoenaed, and the production of documents is not unduly repetitious or burdensome.~~
- D. ~~Any party may file a response to the request to intervene within five days of service of the request upon the party. A party or person subpoenaed may file an objection to the subpoena with the hearing officer. The party or person shall file the objection within five days after service of the subpoena, or on the first day of the hearing, whichever is earlier.~~
- E. ~~The hearing officer shall decide on the request to intervene at least three days prior to the hearing date and shall promptly notify the person requesting to intervene and all parties of the decision. The hearing officer may reschedule a hearing or prehearing conference to provide sufficient time for the parties to respond to a request to intervene or to prepare for the hearing or prehearing conference. The party requesting the subpoena shall prepare the subpoena and cause it to be served upon the person to whom the subpoena is directed. A person who is not a party and is at least eighteen years of age may serve a subpoena. The person shall serve the subpoena by delivering a copy to the person to be served. The person serving the subpoena shall provide proof of service by filing with the hearing officer a certified statement of the date and manner of service and the name of the person served.~~

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R12-5-212. Consolidation and Severance Procedure at Hearing

- A. When proceedings involving a common question of law or fact or common parties are pending before the Department, the hearing officer may, upon the hearing officer's own volition or upon request of any party, order a joint hearing on any or all the matters at issue.
The hearing officer shall preside over the hearing, giving all parties the opportunity to testify, respond, present evidence, argument, witnesses, conduct examination and cross-examination, and submit rebuttal evidence. The hearing may be conducted in an informal manner and without adherence to the rules of evidence required in judicial proceedings. The hearing officer shall make rulings necessary to prevent argumentative, repetitive, or irrelevant questioning and to expedite questioning to the extent consistent with the disclosure of all relevant testimony and information.
- B. In furtherance of convenience, to avoid prejudice, or when separate hearings will be conducive to expedition and economy, the hearing officer may, upon the hearing officer's own volition or upon request of any party, order any proceeding severed with respect to some or all issues or parties.
If all parties agree, the hearing officer may conduct all or part of the hearing by telephone or other electronic means, if each party has an opportunity to participate in the entire proceeding.
- C. A hearing is open to the public, except if the hearing is required to be closed pursuant to an express provision of law. The Department shall make a hearing conducted by telephone or other electronic means available to the public by the opportunity to view or listen to the tape of the hearing, and to inspect any transcript of the hearing that has been prepared and filed with the Department.
- D. The hearing officer may exclude from participation or observation a person whose conduct at the hearing is disruptive or shows contempt for the proceedings.

R12-5-213. Prehearing Conference, Procedure and Prehearing Order Evidence

- A. The hearing officer may hold a prehearing conference to consider matters set forth in subsection (B) of this rule and shall promptly notify the parties and any person whose request to intervene is pending. Any party may request a prehearing conference.
All witnesses shall testify under oath or affirmation. All parties shall have the right to present oral or documentary evidence and to conduct cross-examination as required for a full and true disclosure of the facts. The hearing officer shall receive evidence, rule upon offers of proof, and exclude evidence the hearing officer determines to be irrelevant, immaterial, or unduly repetitious. The hearing officer shall admit the kind of evidence on which reasonably prudent people would rely, even if the evidence would be inadmissible in a civil court trial.
- B. A prehearing conference may be convened to consider consolidation; severance; intervention; settlement; stipulations; clarification of issues; the extent of prehearing discovery, if any; rulings regarding issuance of subpoenas, discovery orders, and protective orders; rulings on identity of and limitation of the number of witnesses; objections to proffers of evidence; use of written presentation for direct evidence, rebuttal evidence, or cross-examination; use of telephone, television, or other electronic means as a substitute for proceedings in person; order of presentation of evidence and cross-examination; and such other matters as will promote the orderly and prompt conduct of the hearing.
Unless otherwise ordered by the hearing officer, a party shall not present documentary evidence larger than 8½ by 11 inches. The submitting party shall identify documentary exhibits by number or letter and party and shall furnish a copy of each exhibit to each party present. If evidence offered by a party appears in a larger work that contains other information, the party shall plainly designate the portion offered. If the evidence offered is in a volume of a length that would unnecessarily encumber the record, the hearing officer shall not receive the book, paper, or document in evidence but the evidence may be marked for identification and, if properly authenticated, the designated portion may be read into or photocopied for the record. All documentary evidence offered is subject to appropriate and timely objection.
- C. The hearing officer may conduct all or part of the prehearing conference by telephone, television, or other electronic means so long as each participant in the conference has an opportunity to participate during the entire proceeding.
- D. The hearing officer shall issue a prehearing order incorporating the matters determined at the prehearing conference. If a prehearing conference is not held, the hearing officer may issue a prehearing order based on the contested case record.

R12-5-214. Filing; Computation of Time; Extension of Time Judicial Notice; Technical Facts

- A. All papers concerning a contested case shall be filed with the Department within the time limit, if any, for such filing.
- B. All papers filed with the Department in any contested case shall be typewritten or legibly written on paper no larger than 8½ by 11 inches in size, shall contain the name and address of the party or other correspondent, shall be properly captioned and designate the title and case number, shall state the name and address of each party served with a copy, and shall be signed by the party or, if represented, by the party's attorney. The signature certifies that the signer has read the paper, that to the best of the signer's knowledge, information, and belief there is good ground to support its contents, and that it is not interposed for delay.
- C. In computing any period of time prescribed or allowed by this Article, or any notice or order concerning a, the day of the act, event, or default after which the designated period of time begins to run shall not be included. The last day of the period shall be included unless it is a Saturday, a Sunday, or a holiday, in which event the period runs until the end of the next day which is not a Saturday, a Sunday, or a holiday. The computation shall include intermediate Saturdays, Sundays,

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and holidays.

D. Whenever a party has the right or is required to do some act within a prescribed period after the service of a paper upon the party by another party, and the paper is served by mail, five days shall be added to the prescribed period. This subsection has no application to notices, orders, or other papers issued by the hearing officer or the Commissioner.

E. For good cause shown, the hearing officer may grant continuances and extensions of time.

When conducting a hearing, the hearing officer may take notice of judicially cognizable facts as permitted under the Arizona Rules of Evidence. The Commissioner or the hearing officer may take judicial notice of generally recognized technical or scientific facts within the Commissioner's, the hearing officer's, or the Department's specialized knowledge. The Commissioner or the hearing officer may use experience, technical competence, and specialized knowledge in the evaluation of any information and evidence submitted in a hearing.

R12-5-215. Service; Proof of Service Stipulations

A. After a notice of hearing has initiated a contested case, a copy of every paper filed by a party, or person seeking to intervene, shall be served on all parties to the contested case, or their lawyers if represented, at the same time the paper is filed. Service shall be complete at the time of personal service or on the date placed in the mail if served by certified or regular mail addressed to the last address of record in the contested case file.

B. The following evidences completed service:

1. If personally served, an affidavit of personal service, sworn to by the person serving the paper and stating that the server personally served the paper on the person to whom it was directed, where service was made, and the date of such service; or
2. If served by certified mail, the return receipt signed by the party served or someone authorized to act on behalf of the party served; or
3. If served by regular or certified mail, either a statement subscribed on the paper filed with the Department, or an affidavit indicating the date mailed and listing those to whom it was mailed.

C. The Department shall serve notices of hearing or prehearing conference, findings, conclusions, and recommended decisions of the hearing officer, and decisions and final orders, either by personal service or by certified mail. All other papers required to be served may be served by regular or certified mail or may be personally served.

D. When a party is represented by an attorney, service shall be made on the attorney. If a notice of hearing shows service on the Attorney General, all papers served thereafter shall be served on the Assistant Attorney General named on the notice of hearing or who later appears on behalf of a Division of the Department, or, if no Assistant Attorney General is named, then on the Attorney General, Civil Division, Chief Counsel, Land and Natural Resources Section.

Parties to a hearing may agree, in writing, to any issue addressed in the hearing, including matters of procedure, subject to the approval of the hearing officer. If approved by the hearing officer, an agreement on matters of procedure or substantive matters is binding upon the parties to the stipulation. The hearing officer may require presentation of evidence for proof of stipulated facts. No agreement by the parties on substantive matters is binding upon the Department unless incorporated into the decision of the Commissioner.

R12-5-216. Subpoenas Recommended Decision

A. The hearing officer may issue subpoenas for witnesses to appear and testify at the hearing or produce books, records, documents, and other evidence, or both, on the hearing officer's own volition or at the request of a party.

B. A request for a hearing subpoena shall be in writing, filed with the Department, and served on each party at least seven days prior to the date set for hearing and shall state:

1. The name of the contested case, the case number, and the time and place where the witness is expected to appear and testify;
2. The name and address of the witness subpoenaed; and
3. The documents, if any, sought to be provided.

C. A request for a prehearing deposition or a subpoena for the production of documents prior to the hearing shall be in writing and may be granted at the hearing officer's discretion only upon a showing of a reasonable need, including facts expected to be established by the person or document subpoenaed and the reasons such facts are relevant and material and not unduly repetitious.

D. The person to whom a subpoena is directed shall comply with its provisions unless, prior to the date set for hearing, the hearing officer grants a written request to quash or modify the subpoena. The request shall state the reasons why it should be granted. The hearing officer shall grant or deny such request by order.

E. The party requesting the subpoena shall prepare it and cause it to be served upon the person to whom it is directed, in the same manner as provided for service of subpoenas in civil matters before the superior court. The return of service shall be filed with the Department.

If a hearing officer other than the Commissioner presides at a hearing, the hearing officer shall prepare a recommended decision for the Commissioner within 10 days of the close of the hearing, or no later than eight days before the auction date, whichever is earlier.

R12-5-217. Procedure at Hearing Decision

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- ~~A. At the hearing the hearing officer shall regulate the course of the proceedings, giving all parties the opportunity to testify, respond, present evidence, argument, present witnesses, conduct examination and cross-examination, and submit rebuttal evidence, except as restricted by a limited grant of intervention or by the prehearing order.~~
- ~~B. The hearing officer may give non-parties an opportunity to present, under oath, oral or written statements. The hearing officer shall give all parties an opportunity to cross-examine a nonparty witness and to challenge or rebut statements of non-parties.~~
- ~~C. The hearing officer may conduct all or part of the hearing by telephone, television, or other electronic means, as long as each party has an opportunity to participate in the entire proceeding as it takes place.~~
- ~~D. All hearings are open to public observation, except where closed pursuant to an express provision of law. A hearing conducted by telephone television, or other electronic means shall be made available to members of the public by the opportunity to view or listen to the tape of the hearing, and to inspect any transcript of the hearing that has been prepared and filed with the Department.~~
- ~~E. If for any reason a hearing officer cannot continue with a contested case, a new hearing officer shall use any existing record and may conduct such further proceedings as the interests of justice may require.~~
- ~~F. Conduct at any hearing that is disruptive or shows contempt for the proceedings shall be grounds for exclusion from further participation or observation.~~

The Commissioner's decision shall include separate findings of fact and conclusions of law. The Commissioner's decision shall also include policy reasons for the decision if it is an exercise of the Commissioner's discretion, including the reason for the remedy ordered.

R12-5-218. Evidence Rehearing of Decision

- ~~A. All witnesses shall testify under oath or affirmation. All parties shall have the right to present such oral or documentary evidence and to conduct such cross-examination as may be required for a full and true disclosure of the facts. The hearing officer shall receive evidence, rule upon offers of proof, and exclude evidence the hearing officer has determined to be irrelevant, immaterial, or unduly repetitious. The hearing officer shall admit the kind of evidence on which reasonably prudent people would rely, even if it would be inadmissible in a civil court trial.~~

As specified A.R.S. § 37-301 (C), a request for rehearing shall be filed with the State Land Commissioner, State Land Department, Phoenix, and shall specify the particular grounds for rehearing. A rehearing of the decision may be granted for any of the following reasons materially affecting the requesting party's rights:

1. Irregularity in the proceedings or any order or abuse of discretion that deprived the requesting party of a fair hearing;
2. Misconduct of the Commissioner, Departmental employees, the hearing officer, or the prevailing party;
3. Accident or surprise that could not have been prevented by ordinary prudence;
4. Newly discovered material evidence that could not with reasonable diligence have been discovered and produced at the original hearing;
5. Excessive or insufficient remedies;
6. Error in the admission or rejection of evidence or other errors of law; or
7. The decision is not justified by the evidence or is contrary to law.

- ~~B. Unless otherwise ordered by the hearing officer, documentary evidence shall be limited in size when folded to 8 ½ by 11 inches. The submitting party shall identify documentary exhibits by number or letter and party and furnish a copy of each exhibit to each party present. One additional copy shall be furnished to the Department, unless the hearing officer otherwise directs. When evidence offered by any party appears in a larger work, containing other information, the party shall plainly designate the portion offered. If the evidence offered is in such volume as would unnecessarily encumber the record, the book, paper, or document shall not be received in evidence but may be marked for identification and, if properly authenticated, the designated portion may be read into or photocopied for the record. All documentary evidence offered shall be subject to appropriate and timely objection.~~

On review of the request for rehearing, the Commissioner may affirm the decision or grant a rehearing. An order granting a rehearing shall specify with particularity the grounds on which the rehearing is granted, and the rehearing shall cover only those matters specified. All parties to the hearing may participate as parties at any rehearing.

R12-5-219. Stipulations Repealed

~~Parties to any contested case may stipulate, in writing, agreement upon any matter involved in the proceeding. If approved by the hearing officer, agreement on matters of procedure shall be binding upon the parties to the stipulation. The hearing officer may require presentation of evidence for proof of stipulated facts for the hearing officer's consideration. No substantive matter agreed to by the parties shall be binding upon the Department unless incorporated into the decision of the Commissioner.~~

R12-5-220. Recommended Decision Repealed

- ~~A. If a hearing officer presides at the hearing, a recommended decision shall be prepared for the Commissioner.~~
- ~~B. A recommended decision shall be delivered to the Commissioner within 30 days after the close of the hearing or the date ordered for submission of proposed findings or legal memoranda, whichever comes last, unless the Commissioner extends the period for good cause.~~

R12-5-221. Decision Repealed

- A.** A decision shall include separately stated findings of fact, conclusions of law, and policy reasons for the decision if it is an exercise of the Commissioner's discretion, including the reasoning for the remedy recommended. The experience, technical competence, or specialized knowledge of the Commissioner and that of the Commissioner's staff may be utilized in evaluating the evidence.
- B.** When the Commissioner is the hearing officer, the decision shall be rendered with 60 days following the final day of the hearing or the date ordered for submission of proposed findings or legal memoranda, whichever comes last.
- C.** Within 30 days after receipt of any recommended decision from the hearing officer, the Commissioner shall render a decision adopting the recommended decision, or modifying it and setting forth the reasons for departing from the recommendation, and the evidence supporting the modification.
- D.** If no request for rehearing or review has been timely filed by a party, a decision in a contested case is effective ten days from the date served on that party and is not subject to judicial review pursuant to A.R.S. § 37-134.

R12-5-222. Review and Rehearing of Decision Repealed

- A.** Except as provided in subsection (G) of this rule, any party to a contested case before the Commissioner who is aggrieved by a decision rendered in such case may file with the Department, not later than ten days from the date of service of the decision, a written request for rehearing or review of the decision. The request shall specify the particular grounds for rehearing or review.
- B.** A party may file a response to a request for rehearing or review within ten days after service of the request or amended request by any other party. The Commissioner may require the filing of written argument on any issue raised in the request and may provide for oral argument.
- C.** A rehearing of the decision may be granted for any of the following reasons materially affecting the requesting party's rights:
 - 1. Irregularity in the proceedings or any order or abuse of discretion, whereby the requesting party was deprived of a fair hearing;
 - 2. Misconduct of the Commissioner, Department employees, the hearing officer, or the prevailing party;
 - 3. Accident or surprise that could not have been prevented by ordinary prudence;
 - 4. Newly discovered material evidence that could not with reasonable diligence have been discovered and produced at the original hearing;
 - 5. Excessive or insufficient remedies;
 - 6. Error in the admission or rejection of evidence or other errors of law occurring in the proceedings;
 - 7. The decision is not justified by the evidence or is contrary to law.
- D.** On review the Commissioner may affirm or modify the decision or grant a rehearing as to all or any of the parties and on all or part of the issues for any of the reasons set forth in subsection (C) of this rule. An order granting a rehearing shall specify with particularity the grounds on which the rehearing is granted, and the rehearing shall cover only those matters specified. All parties to the contested case may participate as parties at any rehearing.
- E.** The Commissioner may, on the Commissioner's volition, order a rehearing or review of the Commissioner's decision within ten days after a decision is rendered, for any reason for which a rehearing on request of a party might have been granted. The order granting such a rehearing shall specify the grounds therefor.
- F.** When a request for rehearing is based on affidavits, they shall be served with the request. An opposing party may, within ten days after the service, serve opposing affidavits.
- G.** If in a particular decision the Commissioner makes specific findings that the immediate effectiveness of such decision is necessary for the immediate preservation of the public peace, health, and safety and that a rehearing or review of the decision is impracticable, unnecessary, or contrary to the public interest, the decision may be issued as a final decision without an opportunity for a rehearing or review. If a decision is issued as a final decision without an opportunity for rehearing, any application for judicial review of the decision shall be made within the time limits permitted for applications for judicial review of the Commissioner's final decision.
- H.** If, after a timely request for rehearing or review, the decision is affirmed or modified without rehearing, the decision is final on the date affirmed or modified. If a rehearing is granted, the decision made after rehearing is final on the date rendered. A final decision is subject to judicial review pursuant to A.R.S. § 37-134.