64E-4.001 Registration and Laser Radiation Requirements.

(1) Except as otherwise specifically exempted under these rules, all persons who receive, possess, acquire, transfer, own, manufacture, or use lasers which emit or may emit laser radiation shall register within 30 days after acquisition of a laser product and comply with these rules. Nothing in these rules shall be interpreted as limiting the intentional exposure of patients to laser radiation for the purpose of treatment or use commensurate with the licensed practitioner's use of the healing arts.

(2) A separate registration is required for each location with a laser device, on DH Form 1605 (09/14), "Laser Device Registration Form," incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-04839, or www.FloridaHealth.gov/radiation. Laser manufacturers must register on DH Form 1604 (09/14), "Manufacturer's Laser Device Registration Form," incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-04838, or www.FloridaHealth.gov/radiation. Subsequent registrations for each facility or mobile laser facility are required whenever additional laser devices are installed or previously registered laser devices are disposed of, altered, destroyed or moved to new locations. Subsequent registrations for each manufacturer are required only when the description of the laser devices manufactured by the manufacturer changes.

(3)(a) Laser products certified by a manufacturer to be compliant with the Federal laser product performance standard of 21 C.F.R. Part 1040 in effect at the date of manufacture shall be maintained in compliance with such requirements. Certified laser products which have been modified shall comply with these rules.

(b) Uncertified lasers shall meet the requirements of these rules.

(4) If any conflict arises between the requirements of these rules and the federal laser product performance standard, the requirements of the federal standard shall apply.

(5) Except as provided in this rule section, the contents of this rule chapter are contained in the Department of Health publication "Laser Radiation Requirements," (December 15, 2016, edition), incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-07888.

(6) Title 21 C.F.R. sections 1040.10 and 1040.11, (April 1, 2013, edition), are incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-07889.

(7) The publication ANSI Z136.1-2014, "American National Standard for Safe Use of Lasers" (ANSI), is incorporated by reference and available at www.lia.org. This publication may be examined and inspected at the Florida Department of Health, Bureau of Radiation Control, 4042 Bald Cypress Way, Suite 210, Tallahassee, Florida 32399-1741, and the Florida Department of State, Room 701, The Capitol, Tallahassee, Florida 32399-0250. The agency has determined that posting the publication on the internet for purposes of public inspection and examination would constitute a violation of federal copyright law.

(8) Completed registration forms or other correspondence or reports required by Chapter 64E-4, F.A.C., to be sent in writing to the Department can be mailed to Florida Department of Health, Bureau of Radiation Control, 4052 Bald Cypress Way, Bin #C-21, Tallahassee, Florida 32399-1741; faxed to (850)487-0435; or scanned and emailed to RadiationControl@FlHealth.gov in PDF, JPG or TIF format.

Rulemaking Authority 501.122(2) FS. Law Implemented 501.122(2) FS. History–New 9-6-84, Amended 5-7-96, 12-12-96, Formerly 10D-89.101, Amended 4-20-15, 3-28-17.

Note: This page is not part of Rule 64E-4.001, FAC, or the "Laser Radiation Requirements" reference document (December 15, 2016 edition) incorporated therein. This page is provided to help the user quickly find information by subject and page number in the reference document.

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Florida Department of Health

Laser Radiation Requirements

December 15, 2016 Edition

LASER RADIATION REQUIREMENTS

4.002

As used in rule chapter 64E-4 Florida Administrative Code and this publication:

(1) "Accessible emission level" means the magnitude of emission from laser or collateral radiation of a wavelength and emission duration to which human access is possible as measured under the conditions specified in Section 4.010, of this publication.

(2) "Accessible emission limit" means the maximum accessible emission level permitted within a particular class as set forth in 21 C.F.R. Part 1040 (See subsection 4.002(59)) below.

(3) "Accuracy" means the degree of conformity of a measure to a standard or a true value and not the degree of repeatability or precision with which a measurement is performed.

(4) "Act" means Section 501.122, Florida Statutes (F.S.).

(5) "ANSI" means ANSI Z136.1-2014, "American National Standard for Safe Use of Lasers,"(See Rule 64E-4.011).

(6) "Aperture" means any opening in a protective housing through which radiation is emitted, thereby allowing human access to such radiation.

(7) "Aperture stop" means an opening serving to limit the size and to define the shape of the area over which radiation is measured.

(8) "Attenuation" means the decrease in the radiant flux of any optical beam as it passes through an absorbing or scattering medium.

(9) "Certified laser product" means that the product is certified by a manufacturer pursuant to the requirements of 21 C.F.R. Part 1040 in effect at the time of manufacture.

(10) "Class I dual limits" means, for classification purposes, laser and collateral radiation in the wavelength range of greater than 400 nanometers but less than or equal to 1400 nanometers, which exceeds the accessible emission limits of Class I if it exceeds both:

(a) The Class I accessible emission limits for radiant energy within any range of emission duration specified in 21 C.F.R. Part 1040, and

(b) The Class I accessible emission limits for integrated radiance within any range of emission duration specified in 21 C.F.R. Part 1040.

(11) "Class I laser" means any laser which permits human access to laser radiation less than the accessible emission limits of 21 C.F.R. Part 1040 for any combination of emission duration and wavelength range.

(12) "Class II laser" means any laser which permits human access to laser radiation above the accessible emission limits of Class I lasers up to the accessible emission limits of Class II lasers 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. Class II lasers are separately designated as Class II or Class IIa. Class IIa lasers are those lasers which do not exceed the accessible emission limits of Class I for any emission duration less than or equal to 1×10^{3} seconds. Class II laser designation is given to all other Class II lasers as defined above.

(13) "Class III laser" means any laser which permits human access to laser radiation above the accessible emission limits of Class I lasers and Class II lasers, but below the accessible emission limits of Class IIIa and IIIb lasers. Class III lasers are separately designated as Class IIIa or Class IIIb. Class IIIa lasers are those lasers with an emission duration greater than 3.8×10^{-4} seconds 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 5×10^{-3} watts. Class IIIb laser designation is given to all other Class III lasers as defined above.

(14) "Class IV laser" means any laser which permits human access to laser radiation above the accessible emission limits of 21 C.F.R. Part 1040 standards.

(15) “Class I, II, III, or IV facility” means a facility which has one or more Class I, II, III, or IV lasers, respectively. In case of facilities possessing more than one laser class, the assigned facility classification shall be determined by the most hazardous class of laser contained therein.

(16) “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 section 4.016, below and ANSI.

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

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

(19) “Diffuse reflection” means the change of the spatial distribution of a beam of radiation when it is reflected in many directions by a surface or by a medium.

(20) “Electronic product” means:

(a) Any manufactured or assembled product which, when in operation,

1. Contains or acts as part of an electronic circuit and

2. Emits, or in the absence of effective shielding or other controls would emit, electronic product radiation, or

(b) Any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in paragraph 4.002(20)(a), above and which when in operation emits, or in the absence of effective shielding or other controls would emit, such radiation.

(21) “Electronic product radiation” means radiation which is emitted from an electronic product as the result of the operation of an electronic circuit in such product, and includes:

(a) Any ionizing or nonionizing electromagnetic or particulate radiation, or

(b) Any sonic, infrasonic, or ultrasonic wave.

(22) “Energy” means the capacity for doing work. Energy content is commonly used to characterize the output from pulsed lasers and is generally expressed in joules (J).

(23) “Energy density” see “Radiant exposure”.

(24) “Facility” means any location where one or more lasers are used, operated or manufactured. The confines of any facility shall be designated by the owner of such facility. A part of a building, an entire building, or other structure or plant or a specified out-of-doors location may be designated as a facility.

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

(26) “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.

(27) “Individual” means any human being.

(28) “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 ($J\ cm^{-2}\ sr^{-1}$).

(29) “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 ($W\ cm^{-2}$).

(30) “Joule” (J) means a unit of energy: 1 Joule = 1 watt second.

(31) “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.

(32) “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. See subsection 4.007(1), below for applicability requirements.

(33) “Laser protective device” means any device used to reduce or prevent exposure of personnel to laser radiation. Such devices may include protective eyewear, garments, engineering controls, and operational controls.

(34) “Laser radiation” means all electromagnetic radiation emitted by a laser product of frequencies between 3×10^{11} and 1.67×10^{15} hertz or wavelengths in air between 10^{-3} and 1.8×10^{-7} meter that is produced as a result of controlled stimulated emission or that is detectable with radiation so produced through the aperture stop having a diameter, a solid angle of acceptance, and collimating optics as specified in section 4.002, herein.

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

(36) “Laser system” means a laser in combination with a laser energy source, with or without additional incorporated components.

(37) “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 as defined in these rules.

(38) “Maximum permissible exposure” (MPE) means that level of laser or collateral radiation to which persons may be exposed without hazardous effect or adverse biological changes in the eye or skin. The criteria for the MPE for the cornea and skin are detailed in section 4.016, below and ANSI.

(39) “Mobile laser” means a laser which is used at temporary job sites.

(40) “Operable laser” means a laser system which can produce laser radiation.

(41) “Operation” means the performance of tasks required for the equipment to perform its intended functions. It does not include maintenance or service tasks as defined in these rules.

(42) “Optical density” (OD) means a logarithmic expression of the optical attenuation afforded by a material.

$$OD = \log^{10} \frac{\text{(incident power)}}{\text{(transmitted power)}}$$

(43) “Person” means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing.

(44) “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.

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

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

(47) “Radiance” means radiant power per unit area of a radiating surface per unit solid angle of emission, expressed in watts per square centimeter per steradian ($W\ cm^{-2}\ sr^{-1}$).

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

(49) “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 ($J\ cm^{-2}$).

(50) “Radiant power” means power emitted, transferred or received in the form of radiation, expressed in watts (W).

(51) “Registrant” means any person who registers a mobile laser, facility, or service organization with the Department pursuant to these rules.

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

(53) “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.

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

(55) “Service” means the performance of adjustments, repairs, or procedures required to return equipment to its intended state. These adjustments and procedures usually require specialized training or tools. Service does not include operation or maintenance as defined in these rules.

(56) “Specular reflections” means mirror-like reflections.

(57) “Watt” (W) means the unit of power or radiant flux; 1 watt = 1 joule per second ($J\ sec^{-1}$).

(58) “Uncontrolled area” means any area to which access is not controlled by the registrant for purposes of protection from radiation hazards.

(59) “21 C.F.R. Part 1040” means Title 21 of the Code of Federal Regulations, sections 1040.10 and 1040.11 that were in effect at the time of manufacture for those laser products certified by a manufacturer to be compliant with these sections on the date of manufacture. For all other laser products, it means Title 21 of the Code of Federal Regulations, sections 1040.10 and 1040.11, April 1, 2013 edition.

4.003

The following are exemptions for laser products which are not deemed to have the degree of hazard which would warrant registration and regulation.

(1) All Class I, Class II, Class IIA, and Class IIIA laser products, except for those that allow access to other classes of laser radiation during servicing, are exempted from registration, provided that the laser product is maintained as a Class I, Class II, Class IIA, or Class IIIA laser product throughout its useful life.

(2) These rules do not apply to lasers in storage, during shipment or sale, provided such lasers are inoperable or not operated.

4.004

The registrant shall designate a LSO who is responsible for laser radiation protection and who shall be responsible for the following duties:

(1) Establish and supervise a program of laser radiation safety for effective compliance with the requirements of these rules.

(2) Provide instructions concerning hazards and safety practices to individuals who may be exposed to laser radiation and to individuals who operate the lasers.

4.005

(1) Whenever any laser device or source of laser radiation is to be brought into the State, for any temporary use, the person proposing to bring such source of laser radiation into the State shall give written notice to the Department at least 20 days before such source of laser radiation is to be used in the State. The notice shall include:

(a) The type of laser radiation source;

(b) The nature, duration, and scope of use; and

(c) The exact locations where the laser radiation source is to be used.

(2) The person referred to in this section above, shall comply with all rules of the Department.

4.006

(1) No individual shall be exposed to levels of laser or collateral radiation higher than are specified in ANSI or 21 C.F.R. 1040 and section 4.016, below. Exposure levels should be maintained as far below the MPE values as practicable.

(2) In those cases where no MPE is shown for particular wavelengths and pulse durations, all exposure shall be prohibited.

4.007

(1) Applicability. These requirements are for laser products in their intended mode of operation and include special requirements for service, testing, maintenance, and modification. During research and development activities, it may not be possible to use all types of engineering controls. In this case, the LSO shall specify alternate requirements to obtain equivalent laser safety protection.

(2) Engineering Controls.

(a) Protective Housing. 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 21 C.F.R. Part 1040 wherever and whenever such human access is not necessary in order for the product to perform its intended function. Wherever and whenever human access to laser radiation levels that exceed the limits of Class I and 21 C.F.R. Part 1040 is necessary, these levels shall not exceed the limits of the lowest laser class necessary to perform the intended functions.

(b) Safety Interlocks.

1. 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 operation or maintenance, and thereby allows access to radiation above MPE limits.

2. Adjustments during operation, service, testing, or maintenance of a laser containing interlocks shall not cause the interlock to become inoperative or the radiation to exceed MPE limits outside protective housing except where a laser controlled area as specified in paragraph 4.007(2)(e) below is established.

3. For pulsed lasers, interlocks shall be designed so as to prevent firing of the laser, for example, by dumping the stored energy into a dummy load.

4. For Class IIIb and Class IV continuous wave (cw) lasers, the interlocks shall turn off the power supply or interrupt the beam, for example, by means of shutters.

5. An interlock shall not allow automatic accessibility of radiation emission above MPE limits when the interlock is closed.

6. 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 limits 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) Viewing Optics and Windows.

1. All viewing ports, viewing optics or display screens included as an integral part of an enclosed laser or laser system shall incorporate suitable means to attenuate the laser and collateral radiation transmitted through the port to less than the MPE and 21 C.F.R. Part 1040 limits under any conditions of operation of the laser.

2. Since optical systems such as lenses, telescopes, and microscopes may increase the hazard to the eye or the skin, the LSO shall determine the potential hazard and specify administrative procedures and the use of controls such as interlocks or filters.

(d) Warning Systems. Each laser product shall provide visual or aural indication during the emission of accessible laser radiation in excess of the limits for Class I except that, in the case of Class IIIb, except those which allow access only to less than 5 mW peak visible laser radiation, and Class IV lasers, this indication shall be sufficiently prior to emission of such radiation to allow action to avoid exposure. Any visual indicator shall be clearly visible through protective eyewear designed specifically for the wavelengths of the emitted laser radiation. If the laser and laser energy source are housed separately and can be operated at a separation distance of greater than two meters, both laser and laser energy source shall incorporate visual or aural indicators. The visual indicators shall be positioned so that viewing does not require human access to laser radiation in excess of the MPE.

(e) Laser Controlled Area. With a Class IIIb, or Class IV laser, a laser controlled area shall be established when exposure to the laser radiation in excess of the MPE or ANSI limits is possible. The controlled area shall meet the requirements of subparagraphs 4.007(2)(e)1. through 3., for Class IIIb lasers and the requirements of subparagraphs 4.007(2)(e)1. through 7. below, for Class IV lasers:

1. The area shall be the responsibility of the LSO.

2. The area shall be posted as required by section 4.008 below.

3. Access to the laser controlled area shall be only by permission of the LSO or a trained designated representative.

4. For Class IV indoor controlled areas, latches, interlocks, or other means shall be used to prevent unexpected entry into laser controlled areas. 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. For such emergency conditions, a control-disconnect switch or equivalent device, such as a panic button shall be available for deactivating the laser.

5. For Class IV indoor controlled areas, during tests requiring continuous operations, 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.

6. For Class IV indoor controlled areas, optical paths, for example, 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 ocular MPE and ANSI limits. 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 MPE and ANSI limits.

7. When the removal of panels or protective covers or overriding of interlocks becomes necessary, such as for service, testing, or maintenance, and accessible laser radiation exceeds MPE and ANSI limits, a temporary laser controlled area shall be established. The LSO or a designated representative shall ensure that the necessary laser safety requirements for all potentially exposed individuals shall be established.

(3) Administrative and Procedural Controls.

(a) General. Unless otherwise specified, administrative and procedural controls shall apply only to Class IIIb and Class IV lasers.

(b) Output Emission Limitations. The minimum laser radiant energy or laser power level required for the application shall be used.

(c) Education and Training. The degree and level of education and training on laser safety concepts and procedures should be in accordance with industry standards.

(d) Operation and Maintenance. Class IIIb and Class IV lasers shall be operated and maintained only by qualified personnel.

(e) Alignment Procedures. Alignment of laser optical systems, for example, mirrors, lenses, and beam deflectors, shall be performed in such manner that assures that no one is exposed to laser radiation above MPE and ANSI limits.

(f) Eye Protection. Protective eyewear, as specified by the LSO, shall be worn by all individuals with access to Class IV levels of laser radiation. Protective eyewear, when specified by the laser safety officer, shall be worn by all individuals with access to Class IIIb levels of laser radiation. At intervals not to exceed 6 months, each registrant shall examine protective eyewear devices to ensure the reliability of the protective filters and integrity of the protective filter frames. Eyewear in suspicious condition shall be discarded or tested for acceptability. Protective eyewear devices shall meet the following requirements:

1. Provide a comfortable fit all around the area of the eye.

2. Be in proper condition to ensure the optical filters and holder provide the required optical density or greater at the desired wavelengths, and retain all protective properties during its use.

3. The required optical density shall be determined based on the type of potential exposure requiring protection.

4. Have the optical density or densities and associated wavelengths permanently labeled on the filters or otherwise permanently identified.

(g) Service Procedures and Modifications. All service procedures shall be performed by qualified personnel who are trained in laser radiation protection. The service personnel shall comply with information supplied by the manufacturers and instructions provided by the LSO. Following any service or maintenance of lasers which could affect the output power or operating characteristics, the LSO shall specify whether any changes in control measures are required. Whenever modifications are made that could change the laser class and affect the output power or operating characteristics, the LSO shall specify whether any changes in control measures are required.

(h) Skin Protection. When there is a possibility of exposure to laser radiation which exceeds the MPE limits for skin as specified in ANSI, the registrant shall require the use of protective gloves, clothing, and shields.

(i) Other Personal Protective Equipment. Respirators and other personal protective equipment shall be required, as a temporary control measure, whenever engineering controls cannot provide protection from toxic air contaminants and other hazards.

(4) Special Lasers and Applications.

(a) Infrared Laser – Greater than 710 Nanometers. The beam from a Class IIIb or Class IV laser shall be terminated in fire-resistant material where necessary. Periodic inspection of absorbent material shall be made since many materials degrade with use.

(b) Laser Optical Fiber Transmission System.

1. Laser transmission systems which employ optical cables shall be considered enclosed systems with the optical cable forming part of the protective housing.

2. Disconnection of a connector resulting in access to radiation in excess of the MPE or ANSI limits shall take place in a controlled area. A tool shall be required to disconnect a connector for service and maintenance when the connector is not within a secured enclosure. All connectors shall bear the appropriate label or tag specified in subparagraph 4.008(3)(a)8.,below.

4.008

(1) General.

(a) Except as otherwise authorized by the Department, signs, symbols, and labels prescribed by this section shall use the design and colors specified in Figures 1 and 2, 21 C.F.R. Part 1040.

(b) In addition to the signs, symbols, and labels prescribed in this section, a registrant may provide near such signs, symbols, and labels additional information to aid individuals to minimize exposure to laser or collateral radiation within a facility.

(2) Posting and Instructions.

(a) The controlled area shall be conspicuously posted with a sign or signs as specified in subsection 4.008(3), herein, and Figures 1 and 2, 21 C.F.R. Part 1040.

(b) Operating personnel of each laser shall be provided with adequate written instructions for safe use, including clear warnings and precautions to avoid possible exposure to laser and collateral radiation in excess of the MPE and 21 C.F.R. Part 1040 limits.

(c) Service personnel shall be provided with:

1. Adequate training and instructions for service adjustments and procedures for each laser or facility, including clear warnings or precautions to be taken to avoid possible exposure to laser or collateral radiation.

2. Service instructions which shall contain a listing of controls and procedures which can increase accessible emission levels of laser or collateral radiation, and a clear description of the location of displaceable portions of the protective housing or enclosure which could allow access by personnel to laser and collateral radiation in excess of the MPE and ANSI limits.

(3) Labeling and Posting. With respect to laser products only, the labeling requirements found in 21 C.F.R. Part 1040 may be used in lieu of this subsection 4.008(3).

(a) Labeling Laser Products and Posting Laser Facilities.

1. Uncertified Class I lasers shall have a label including the following wording: "CLASS I LASER"; Class I facilities need not be posted.

2. Class II lasers which do not exceed accessible emission limits of Class I for any emission duration less than or equal to 1×10^3 seconds shall have a label with the following wording: "Class IIa Laser (or Laser Product) Avoid Long Term Viewing of Direct Laser Radiation"; Class IIa laser facilities need not be posted.

3. Class II laser facilities need not be posted. Class II lasers other than those specified in subparagraph 4.008(3)(a)2. herein shall have a label with the warning logotype A specified in Figure 1 and include the following wording:

(Position 1 on the logotype)

"LASER RADIATION – DO NOT STARE INTO BEAM"

(Position 3 on the logotype)

"CLASS II LASER (OR LASER PRODUCT)"

4. Each laser or facility classified in Class III solely because of the emission of accessible laser radiation in the wavelength range of greater than 400 but less than or equal to 710 nanometers, with an irradiance of less than or equal to 2.5×10^{-3} watts per square centimeter, and with a radiant power less than or equal to 5.0×10^{-3} watts, shall have a label and be posted with signs with the warning specified in Figure 1 and include the following wording:

(Position 1 on the logotype)

"LASER RADIATION – DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS"

(Position 3 on the logotype)

"CLASS IIIA LASER (OR LASER PRODUCT)"

a. Class IIIA laser products must be posted with the warning logotype B specified in Figure 2 and include the following wording:

(Position 2 on the logotype)

“PRODUCT CONTAINS HIGH ENERGY LASER SOURCE”

b. Class III lasers or facilities other than those specified in sub-subparagraph 4.008(3)(a)4.a. herein, shall have a label and be posted with signs with the warning specified in Figure 2 and include the following wording:

(Position 1 on the logotype)

“LASER RADIATION – AVOID DIRECT EXPOSURE TO BEAM”

(Position 2 on the logotype)

“PRODUCT CONTAINS HIGH ENERGY LASER SOURCE”

5. Class IV lasers and facilities shall have affixed a label and be posted with signs with the warning specified in Figure 2 and include the following wording:

(Position 1 on the logotype)

“LASER RADIATION – AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION”

(Position 2 on the logotype)

“PRODUCT CONTAINS HIGH ENERGY LASER SOURCE”

(Position 3 on the logotype)

“CLASS IV LASER (OR LASER PRODUCT)”

6. Class II, III, or IV lasers, shall have labels in close proximity to each aperture through which is emitted accessible laser or collateral radiation in excess of the limits specified in ANSI with the following wording:

a. “AVOID EXPOSURE – Laser radiation is emitted from this aperture”, if the radiation emitted through such aperture is laser radiation.

b. “AVOID EXPOSURE – Hazardous electromagnetic radiation is emitted from this aperture”, if the radiation emitted through such aperture is collateral radiation.

c. “AVOID EXPOSURE – Hazardous x-rays are emitted from this aperture”, if the radiation emitted through such aperture is collateral x-ray radiation.

7. Each Class II, III, and IV laser shall state, at position 2 on the required warning logotype, the maximum output of laser radiation, the pulse duration if the laser is pulsed, and the laser medium or emitted wavelengths.

8. 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 hereby would permit human access to laser or collateral radiation, shall have labels as follows:

a. For laser radiation in excess of the accessible emission limits of Class I but not in excess of the accessible emission limits of Class II, the wording: “CAUTION – Laser radiation when open. DO NOT STARE INTO BEAM”.

b. For laser radiation in excess of the accessible emission limits of Class I or Class II, but not in excess of the accessible emission limits of Class III, the wording: “DANGER – Laser radiation when open, AVOID DIRECT EXPOSURE TO BEAM”.

c. 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”.

d. For collateral radiation in excess of the emission limits of 21 C.F.R. Part 1040,

(I) If the limits in 21 C.F.R. 1040 for electromagnetic radiation are exceeded, the wording: “CAUTION – Hazardous Electromagnetic Radiation when open”; and

(II) If the limits of 21 C.F.R. 1040 for x-radiation are exceeded, the wording: “CAUTION – Hazardous x-ray Radiation”.

e. For protective housing or enclosure which provide a defeatable interlock, the words “and interlock defeated” shall be included in the labels specified in sub-subparagraphs 4.008(3)(a)8.,a., b., c., and d.

9.a. The word “Invisible” shall immediately precede the word “radiation” on labels and signs required by subsection 4.008(3), herein, for wavelengths of laser and collateral radiation that are outside of the range of 400 to 710 nanometers.

b. The words “Visible and Invisible” shall immediately precede the word “radiation” on labels and signs required by subsection 64E-4.008(3), F.A.C. for wavelengths of laser and collateral radiation that are both within and outside the range of 400 and 710 nanometers.

10. All labels placed on lasers or signs posted in laser facilities shall be positioned so as to make unnecessary human exposure to laser or collateral radiation, during reading, in excess of the MPE and 21 C.F.R. Part 1040 limits.

11. Labels and signs required by subsection 4.008(3), herein shall be clearly visible, legible, and permanently attached to the laser or facility.

4.009

Each registrant shall make or cause to be made such radiation protection surveys as may be necessary to comply with this section. At intervals not to exceed six months, surveys shall be performed which include but are not limited to:

(1) A determination that all laser protective devices are labeled correctly and functioning within the design specifications and are properly chosen for lasers in use.

(2) A determination that all warning devices are functioning within their design specifications.

(3) A determination that the laser controlled area is properly controlled and posted with accurate warning signs in accordance with section 4.008, above.

(4) A re-evaluation of potential hazards from surfaces which may be associated with Class IIIb and Class IV beam paths.

(5) Additional surveys required to evaluate the laser and collateral radiation hazard incident to the use of lasers.

4.010

Each determination requiring a measurement for compliance with these rules 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.

(1) Measurement of accessible emissions for classification shall be made:

(a) Under those operational conditions and procedures which maximize the accessible emission levels including startup, stabilized operation, and shutdown of the laser or facility,

(b) With all controls and adjustments listed in the operating and service instructions adjusted for the maximum accessible emission level of laser radiation which is not expected to be detrimental to the functional integrity of the laser or enclosure,

(c) At points in space to which human access is possible for a given laser configuration, for example, if operation 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 laser configuration,

(d) 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,

(e) 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.

(2) Compliance with the requirements of the rules shall be determined by measurements or their equivalent which account for all errors and statistical uncertainties in the measurement process.

(3) Accessible emission levels for classification of laser and collateral radiation shall be based upon the following measurements:

(a) The radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 80 millimeters, except for scanned laser radiation, and within a circular solid angle of acceptance of 1×10^{-3} steradian with collimating optics of 5 diopters or less.

(b) The irradiance (W cm^{-2}) or radiant exposure (J cm^{-2}) equivalent to the radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 7 millimeters and, for irradiance, within a circular solid angle of acceptance of 1×10^{-5} steradian with collimating optics of 5 diopters or less, divided by that solid angle (sr) and by the area of the aperture stop ($cm^{-2)}$.

(c) The radiance (W cm^{-2} sr^{-1}) or integrated radiance (J cm^{-2} sr^{-1}) equivalent to the radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 7 millimeters and within a circular solid angle of acceptance of 1×10^{-5} steradian with collimating optics of 5 diopters or less, divided by that solid angle (sr) and by the area of the aperture stop (cm^{-2}).

(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 specified under paragraphs 4.010(3)(a), (b), and (c), above. 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.

(4) Measurements for maximum permissible exposure shall be measured as specified in section 4.016, below, and ANSI.

4.011

(1) Immediate Notification. Each registrant shall notify the Department immediately by telephone at (407)297-2095 of any incident involving any source of laser or collateral radiation possessed by the registrant and which has or may have caused:

(a) An exposure to an individual of greater than 100 times the MPE limits of laser or collateral radiation; or

(b) An exposure to an individual which involves the partial or total loss of sight in either eye; or

(c) An exposure to an individual which involves perforation of the skin or other serious injury exclusive of eye injury.

(2) Twenty-four Hour Notification. Each registrant shall notify the Department by telephone at (407)297-2095 within 24 hours of any incident involving any source of laser or collateral radiation possessed by the registrant and which has or may have caused:

(a) An exposure to an individual of greater than five times the MPE limits of laser or collateral radiation; or

(b) An exposure to an individual with second- or third-degree burns to the skin or potential injury and partial loss of sight.

(3) Each registrant shall make a report in writing within 30 days to the Department of:

(a) Each exposure of an individual to laser and collateral radiation in excess of the MPE limits,

(b) Any incident for which notification is required by subsection 4.011(1) or (2), herein.

(4) Each report required by subsection 4.011(3), herein, shall describe the extent of exposure of individuals to laser or collateral radiation, including estimates of each individual's exposure; levels of laser or collateral radiation involved; the cause of the exposure; and corrective steps taken or planned to be taken to assure against a recurrence.

(5) Any report filed with the Department pursuant to subsection 4.011(3), herein, shall include the full name of each individual exposed, an estimate of each individual's exposure and a description of any injuries. The report shall be prepared so that this information is stated in a separate part of the report.

(6) When a registrant is required to report to the Department any exposure of any individual to laser or collateral radiation, the registrant shall also provide to the individual a report on the exposure data included therein. Such reports shall be transmitted at a time not later than the date of transmittal to the Department.

4.012

(1) Each registrant shall maintain current records, which shall be kept available to inspection by the Department, showing:

(a) The results of all surveys required under section 4.009, herein.

(b) The results of all instrument calibrations under section 4.010, herein.

(c) The reports of incidents as described under Chapter 64E-4, F.A.C.

(2) The registrant shall maintain such records required by this section 4.012, for 5 years.

4.013

(1) Laser radiation outside the spectral range 400 to 710 nanometers shall be as low as practicable but shall not, in any case, exceed the Class I limits under any possible conditions of operation.

(2) Levels of laser and collateral radiation, measured where the audience is normally located, and laser and collateral radiation measured where the operators, performers, and employees are located if the radiation is intended to be viewed by them, shall not exceed the limits of Class I during operation. Radiation which shall be measured includes reflections from targets and scattering materials.

(3) Operators, performers, and employees shall be able to perform their functions without the need for exposure to laser and collateral radiation in excess of the limits of Class II when the radiation is not intended to be viewed by them. Areas where levels of laser radiation in excess of the limits of Class I exist shall be clearly identified by posting or through use of barriers or guards to prevent entry of operators or performers into these areas.

(4)(a) Except as noted below, laser light shows shall be under the direct and personal supervision of a competent laser operator and the laser beam to which human access can be gained shall not exceed the limits of Class I at any point less than:

1. 3.0 meters above any surface upon which the audience or general public is permitted to stand; and

2. 2.5 meters in lateral separation from any position where a person in the audience or general public is permitted during the performance or display, unless physical barriers are present which obstruct access by the audience or general public to such levels.

(b) A laser operator need not be continuously present if other provisions of these rules and all of the provisions below are met:

1. The maximum laser output power level is less than 5 milliwatts including all wavelengths.

2. The laser beam path is located at least 6 meters above any surface upon which a person in the audience or general public is permitted to stand.

3. The laser beam path is located at least 2.5 meters in lateral separation from any position where a person in the audience or general public is permitted during the performance or display.

(c) All laser light shows shall have a key operated "on-off" switch. If the supervision of a laser operator is not required as specified in (a) above, there shall be a designated individual present who can turn off and secure the laser in case of unsafe operating conditions.

(d) The maximum laser output power shall be limited to a level required to obtain the intended effect.

(e) The laser system, including projector, shall be rigidly mounted to prevent unintended movement or accidental misalignment.

(f) The laser operators shall be able to view performers, audience, beam paths, and laser display at all times during laser operation.

(g) If laser output power must be limited to less than the maximum power available to comply with sections 4.013 and 4.014, herein, the laser output power shall be measured, adjusted, and recorded before it is operated at each light show. All safety devices necessary to meet sections 4.013 and 4.014, herein, shall be tested and the results recorded before each light show.

(h) The laser system shall be secured against unauthorized operation.

(i) The following precautions shall be taken during alignment procedures:

1. Alignment shall be performed by a competent and qualified individual and with the laser radiation emission reduced to the lowest practicable level.

2. Only persons required to perform alignment shall be in or near the beam paths.

3. Protective eyewear shall be worn where necessary to prevent hazardous exposure.

4.014

Scanning devices shall incorporate a means to turn off the beam or to prevent laser emission in case the beam stops scanning or slows down significantly. In cases where a mirror ball is used with a scanning beam, the limits of subsection 4.013(2), above, shall be met with the mirror ball stationary; or the mirror ball shall incorporate a means to turn off the beam or to prevent laser emission if the mirror ball stops rotating or slows down significantly such that the limits of subsection 4.013(2) or (3), herein, are exceeded. Any such scan failure safeguard system must have a reaction time fast enough to preclude audience access to levels in excess of Class I.

4.015

In addition to the requirements of section 4.005, above, before the laser light show is permitted to operate either at a permanent or temporary job site, the laser light show operator or an authorized representative shall provide the Department with sufficient information, data, and measurements to establish that the requirements of sections 4.013 and 4.014, herein, will be met during use. This shall include sketches showing the location of laser, operators, performers, viewers, beam paths, viewing screens, walls, mirror balls, and other reflective or diffuse surfaces which may be struck by laser beam, scanning beam patterns, scanning velocity and frequency in occupied areas and where beam strikes wall or other structure, radiometric measurement data including output power and location of all measurements. In the case of open air shows where a laser beam is projected into the sky, the information submitted shall also include beam spot size, beam divergence, and beam power measured at the projector, and a copy of the notification provided to the Federal Aviation Administration.

4.016

When a laser emits radiation at several widely different wavelengths, or where pulses are superimposed on a continuous wave (cw) background, computation of the MPE is complex. Exposures from several wavelengths in the same time domain are additive on a proportional basis of spectral effectiveness with due allowance for all correction factors. The simultaneous exposure to pulses and cw radiation is not strictly additive and may be synergistic and caution should be used in these situations until more data are available.

(1) Limiting Aperture. The limiting aperture specified in ANSI shall be the maximum circular area over which irradiance and radiant exposure can be averaged for measurements and calculations of all MPE values.

(2) Intrabeam or Extended-Source Ocular Exposures.

(a) For the purpose of these rules:

1. Sources such as laser arrays, diodes, and diffuse reflecting surfaces shall be considered extended sources if their angular subtense, that is, apparent visual angle, is equal to or greater than α_{min} in as specified in ANSI. The angular subtense is not the beam divergence of the source. It is the apparent visual angle as calculated from the source size and distance from the eye. The limiting angular subtense is that apparent visual angle which divides intrabeam viewing from extended-source viewing. An extended source subtends an angle at the observer's eye equal to or greater than the angular subtense, α_{min} as specified in ANSI, across the greatest angular dimension of the source as viewed by the observer.

2. All other lasers, such as those with collimated beams which produce a small, that is, nearly diffraction-limited, retinal image and also point sources, shall be considered intrabeam viewing cases and shall have an angular subtense, that is, apparent viewing angle, less than α_{min} as specified in ANSI. Sources such as laser arrays, multiple diodes, or multiple diffuse reflecting surfaces shall be considered intrabeam viewing cases for any of the separate images whose angular subtense is less than α_{min}. Any sources whose centers are separated by an angle less than α_{min} are treated as extended sources.

3. If measurements or calculations are required, distinction shall first be made between intrabeam viewing and extended-source viewing in the 0.4 to 1.4 micrometer wavelength region.

(b) MPE values for direct ocular exposure to single pulses or exposures in intrabeam viewing are specified in ANSI. Special qualifications and use requirements are provided in subsections 4.016(4) and (5), herein, and ANSI.

(c) MPE values for ocular exposure to extended sources for single pulses or exposures are specified in ANSI for the cornea. Special qualifications and use requirements are provided in ANSI.

(d) MPE values for broad band collateral radiation shall be weighted with regard to spectral content in 50 nanometer increments.

(3) MPE for Skin Exposure to a Laser Beam. MPE values for skin exposure to a laser beam are specified in ANSI. These levels are for worst-case conditions and are based on the best available information. For repetitive-pulsed lasers, the MPE's for skin exposure are applied as follows: Exposure of the skin shall not exceed the MPE based upon a single-pulse exposure, and the average irradiance of the pulse train shall not exceed the MPE for the total exposure train length.

(4) Special Qualifications – Visible and Near-Infrared Multiple Pulses.

(a) Multiple-Pulse Trains, Pulsed and Scanning Lasers with Multiple Exposures. The MPE for energy or power in multiple-pulse for multiple-exposure trains where the instantaneous pulse repetition frequency of any pulses within a train exceeds 1 per second has the limits specified as follows:

1. The irradiance of radiant exposure, that is, radiance or integrated radiance, in any individual pulse in a train is limited to the MPE for a comparable pulse, as specified in paragraphs 4.016(2)(b), (c), and (3), herein.

2. The average irradiance or radiant exposure, that is, radiance or integrated radiance, for the pulse train is limited to the MPE as specified in paragraphs 4.016(2)(b), (c), and (3), herein, for one pulse of this irradiance or radiant exposure whose duration is the same as that of the pulse train.

3. Any and all groups of pulses within the train are limited to the MPE of one pulse with the same duration as the group in the manner specified in subparagraph 4.016(4)(a)2., herein.

4. For individual pulses with duration less than 10 microseconds, the MPE of subparagraph 4.016(4)(a)1., herein, is reduced as specified in ANSI. In no case shall this reduction be less than the reciprocal of the number of pulses within 0.25 second when the pulse train duration is less than 0.25 second.

5. When the individual pulse duration is 10 microseconds or greater, the MPE for an individual pulse in a train shall be calculated from the MPE for the total "on time" pulse (TOTP), which has a duration equal to the sum of all

the individual pulse durations in the train, as follows: The MPE irradiance of an individual pulse within the train shall be reduced to the MPE for the TOTP. The MPE radiant exposure or integrated radiance of an individual pulse within the train shall be reduced to the MPE for the TOTP divided by the number of pulses within the train. The following formula shall be used to evaluate the MPE for each pulse:

$$MPE_{single} = \frac{MPE_{nt}}{n}$$

Where n = number of pulses in the train; t = individual pulse width; and MPE_{nt} = MPE for a pulse of width nt, in seconds. An additional limitation is that the average irradiance in the pulse train shall not exceed the MPE as specified in subparagraph 4.016(4)(a)2., herein, and the MPE's for the individual pulses or pulsed repetition frequency shall be reduced to keep within this limitation.

(b) Repetitive pulses at repetition rates of less than 1 hertz (Hz) shall be considered additive over a 24-hour period.

(c) Pulse trains whose duration is 18 microseconds or less shall have their pulses summed into a single pulse with the MPE.

(d) Pulse trains whose duration is less than 0.25 second and whose instantaneous pulse repetition frequency is 10 Hz or less shall not have their MPE's reduced by the limitations of subparagraph 4.016(4)(a)4., herein.

(5) Special Qualifications – Infrared. Available data are not sufficient to define wavelength corrections relative to 1.06 micrometers (um), over the entire infrared range (1.4 um^{-1} mm). At 1.54 um, the MPE given in ANSI is increased by a factor of 10^2 for time periods shorter than 1 microsecond. However, no extrapolation to other wavelengths is justified on the basis of present information.