**Section 315.100 General Operator Requirements**

a) Administrative and Procedural Controls

1) The registrant shall provide personnel operating lasers written operating and safety procedures. These procedures shall include restrictions required for the safe operation of each laser and shall include the topics listed in the laser safety program of subsection (a)(2).

 AGENCY NOTE: Sample standard operating procedures for the use of laser systems are contained in Appendix A. The Agency recommends these procedures be modified and adopted for each registrant's specific use of lasers.

2) The registrant shall provide for initial and annual in-service training in laser safety for individuals using laser systems to ensure their awareness of the registrant's laser safety practices and policies. The in-service training shall include the following topics:

A) Operating and emergency procedures for the lasers;

B) Use of laser protective devices, including selection and use of protective eyewear;

C) Clear warnings and precautions to avoid possible exposure to laser radiation in excess of the MPE; and

D) Requirements for safe operation of lasers as described in this Part.

3) Personnel operating lasers shall be instructed in and able to demonstrate competence with the registrant's operating and safety procedures.

4) Alignment of laser optical systems (e.g., mirrors, lenses and beam deflectors) shall be performed in a manner that assures that no one is exposed to laser radiation above the MPE.

5) A controlled area shall be established when exposure to laser radiation in excess of the MPE limit is possible. The controlled area shall meet the following requirements:

A) Be posted as required by Section 315.150.

B) Access shall be only by permission of the laser safety officer or a trained designated representative.

6) Unenclosed Beam Paths

A) An evaluation of the expected beam path and the potential hazards from reflective surfaces that may be encountered shall be conducted before operating the laser. All reflective surfaces shall be excluded from the beam path at all points where the laser radiation exceeds the MPE.

B) If applicable, 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.

C) 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.

b) Requirements for Safe Operation

1) Operator Supervision

A) The laser system shall be operated at all times under the direct supervision or control of an experienced, trained operator who shall maintain visual surveillance of conditions for safe use and terminate laser emission in the event of malfunction or any other condition of unsafe use.

B) Unattended use of the laser system shall be permitted only when the laser safety officer has implemented appropriate control measures that provide adequate protection and laser safety training to those who may enter the laser controlled area during times of unattended use.

2) Maximum Permissible Exposure (MPE)

A) No individual shall be exposed to levels of laser radiation higher than the MPE, as described in Tables A and B.

B) In those cases in which MPE is known for particular wavelengths and pulse durations, exposure to laser radiation shall be prohibited.

C) Measurements and calculations performed to determine MPE limits shall be made in a manner consistent with the criteria contained in ANSI Z136.1-2000.

3) The minimum laser radiant energy or laser power level required for the application shall be used.

4) All service procedures shall be performed by qualified personnel who are trained in laser radiation protection.

5) Protective eyewear, when specified by the laser safety officer, when engineering or other procedural and administrative controls are inadequate to eliminate potential exposure in excess of the applicable MPE, shall be worn by all individuals with access to Class 3b and Class 4 levels of laser radiation. The protective eyewear devices shall meet the following requirements:

A) Provide a comfortable and appropriate fit all around the area of the eyes sufficient to protect the eyes from laser radiation.

B) 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 use of the device.

C) Be suitable for the specific wavelength of the laser and be of optical density adequate for the energy of the laser.

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

E) Be examined by the registrant's laser safety officer, or designee, at intervals not to exceed 6 months, to ensure the reliability of the protective filters and integrity of the protective filter frames.

F) Eyewear not meeting the requirements of this subsection (b)(5) shall not be utilized as protective eyewear.

6) When there is a possibility of exposure to laser radiation that exceeds the MPE limits for skin as specified in Table B, the registrant shall require the appropriate use of protective gloves, clothing and shields.

7) Laser products certified by a manufacturer to be compliant with the requirements of 21 CFR 1040 applicable at the date of manufacture shall be maintained in compliance with the requirements. Certified laser products that have been modified shall comply with this Part.

c) Engineering Controls

1) Each laser product shall have a protective housing that prevents, during operation, human access to laser radiation that exceeds the limits of a Class 1 laser (see 21 CFR 1040.10, Table I), wherever and whenever human access is not necessary in order for the laser system to perform its intended function.

2) Safety Interlocks

A) A safety interlock, which ensures that laser radiation is not accessible above MPE limits, shall be provided for any portion of the protective housing that, by design, can be removed or displaced without the use of tools during normal operation or maintenance.

B) Adjustment during operation, service, testing or maintenance of a laser containing interlocks shall not cause the interlocks to become inoperative or the laser radiation to exceed MPE limits outside the protective housing except where a controlled area, as specified in subsection (a)(5), is established.

C) For pulsed lasers, interlocks shall prevent firing of the laser.

D) For continuous wave lasers, the interlocks shall turn off the power supply or interrupt the beam.

E) An interlock shall not allow access to laser radiation in excess of MPE limits when the interlock is closed.

F) Multiple safety interlocks, or a means to preclude removal or displacement of the interlocked portion of the protective housing upon failure, shall be provided if failure of a single interlock would allow human access to levels of Class 3b or Class 4 laser radiation.

3) Viewing Optics and Windows

A) 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 radiation transmitted through the port to less than the MPE during maintenance or operation of the laser.

B) When optical systems such as lenses, telescopes and microscopes are used that were not supplied as part of a certified laser product, the laser safety officer shall determine the potential hazard and specify administrative procedures and the use of controls such as interlocks or filters.

4) Warning Systems

A) Each laser system shall provide visual or aural indication during the emission of accessible laser radiation.

B) Any visual indicator shall be clearly visible through protective eyewear designed specifically for the wavelengths of the emitted laser radiation.

C) Visual indicators shall be positioned so that viewing does not result in exposure to laser radiation in excess of the MPE.

D) An indication shall be provided prior to emission of the radiation to allow appropriate action to avoid exposure.

5) Additional Requirements for Indoor Class 4 Laser Controlled Areas

A) Latches, interlocks or other appropriate means shall be used to restrict access to controlled areas.

B) Measures shall be designed to allow both rapid exit by the laser personnel at all times and entrance to the controlled area in an emergency condition.

C) For emergency conditions, a control-disconnect switch or equivalent device (panic button) shall be available for deactivating the laser or closing the shutter.

D) During tests requiring continuous operation, the laser safety officer or a trained designated representative shall be permitted to momentarily override the safety interlocks to allow access to other authorized personnel if it is clearly evident that:

i) There is no optical radiation hazard at the point of entry; and

ii) The necessary protective devices are being worn by the entering personnel.

E) Optical paths (e.g., 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 the MPE. 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.

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