Rationale for Revisions

Part AA
General Provisions

AA.1 Scope. All laser products manufactured on and after August 2, 1976, and any previously certified laser products, used in the State shall conform to Title 21, Part 1040 of the Code of Federal Regulations (21 CFR 1040). Existing Federal OSHA standard for the construction industry is also applicable as a minimum requirement in the States. Concern was expressed by physicians that regulations would limit the use of laser radiation as a diagnostic or therapeutic tool. These regulations will not prevent such usage. The regulations will apply to the user. These regulations have been developed recognizing compatibility with existing Federal standards.

Because the Suggested State Regulations for Lasers (SSRL) are oriented toward the user, situations will arise where certified laser products are modified. Such modified and non-certified laser products must conform to the requirements specified in the SSRL for that particular laser class.

AA.2 Definitions. Where applicable, the definitions are consistent with the American National Standard for the Safe Use of Lasers, ANSI Z136.1-1980; Performance Standard for Laser Products (21 CFR 1040); and Federal OSHA Standard for Construction (29 CFR 1926.54).

The terms, exposure and emission, are used throughout the SSRL. The exposure term is applicable to users and the emission term is applicable to lasers. This has become necessary because a user may modify or assemble his own laser not subject to 21 CFR 1040. These regulations provide for the classification of such lasers.

To avoid confusion with the Federal "Certified laser product," these suggested regulations reference lasers which may or may not be a certified product.

"Class I, II, III, and IV lasers." These classes are consistent with 21 CFR 1040.

"Laser." Although these broad frequency limits go beyond available instrumentation for evaluation under present technology, there are lasers that can operate in this range and the regulations shall apply.

To avoid confusion, these regulations reference lasers, laser systems, and laser products. A laser located in a room or a building is defined as a laser facility.

AA.3 Exemptions. Certified Class I, Class II, Class IIa, and Class IIIa laser products manufactured in accordance with the Federal Performance Standard for Laser Products are exempt from these regulations.

AA.4 Additional Requirements. This Section is consistent with the Ionizing Radiation Category of the Suggested State Regulations for Control of Radiation and is needed to cover new development uses and situations which may require additional precautions to protect the individual using the laser or the public exposed to radiation from the laser.

AA.5 Violations. No wording is suggested for enforcement of violations because this will vary from State to State.

AA.6 Impounding. Lasers can cause severe damage if they are used incorrectly. This provision is included in the SSRL to permit the Agency to take this severe step to ensure public health and safety. Some States may want to use other administrative or legal means to achieve the same end.

AA.8 Tests. These may be tests of safety interlocks, safety eyewear, measurements of the power or energy output of the laser, and other such tests necessary to evaluate the hazard of a laser.

AA.9 Administrative Review. No wording is suggested for administrative procedures as this may vary from State to State.

Registration

AA.13 Purpose. Alternate wording for those States who wish to register the laser and not the facility is "...and use of laser systems." There are cases where there is no permanent facility where the laser is used in which case the State may wish to register the mobile laser.

AA.15 Registration Requirements. Registration is mandatory for those facilities using lasers which could blind or burn a person using them incorrectly. Registration is also required for non-certified lasers of any class because of the need to assure adequate controls and safeguards in their use. This will assist the Agency in their laser inspection program.

AA.16 Exemptions from Registration Requirements. This Section provides exemptions from certain classes of certified lasers. Such certified lasers have a lower probability of causing laser radiation injuries and will permit the agency to concentrate its efforts on higher risk installations and mobile laser users.

AA.17 Laser Safety Officer (LSO). The most effective means of minimizing the hazards associated with lasers is by the instruction of personnel and the establishment of a laser safety program. The laser safety officer provides a mechanism for the accomplishment of this.

AA.18 Acceptance of Laser Safety Officer. Cases may arise where the designated laser safety officer is not qualified in the opinion of the Agency to assume such a position. In such cases, Section AA.18 grants authority to the Agency to require the registrant to designate a new LSO.
AA.19 Annual Report. The annual report will assure that the Agency has up-to-date

information on lasers in possession of registrant and the information will allow the Agency to set realistic inspection schedules.

AA.20 Termination of Registration. This Section provides for termination of registration if certain conditions are met.

AA.21 Validity of Registration. This Section provides for validation of registration and specifies that registration will remain valid until terminated or declared invalid. Some States may want to specify a certain time limit on registration.

AA.22 Registration Shall Not Imply Approval. This Section assures that no commercial advantage is taken of registration by registrant.

AA.23 Out-of-State Laser Radiation Sources. The requirements for temporary use by out-of-state laser firms are specified. This Section provides for free flow of commerce but it assures that the Agency will be notified and that laser safety requirements will be met.

Requirements for Protection Against Laser Radiation

AA.25 Maximum Permissible Exposure (MPE). The MPE limits for laser radiation are the same as specified in the American National Standard for the Safe Use of Lasers, ANSI Z136.1-1980. The limits are based on the recommendations of ANSI Subcommittee "Biological Effects of Lasers on the Eye," Dr. M.L. Wolbarsht, Chairman, and ANSI Subcommittee "Biological Effects of Lasers on the Skin," Dr. W.H. Parr, Chairman.

AA.26 Implementation of Protective Measures. This includes such things as establishing the standard operating procedures to be followed for the safe operation of the laser and instructing personnel in laser radiation safety.

In the case of mobile lasers a State may want to place additional requirements on the user, such as, obtaining certification through demonstration of ability to safely use the laser by written or practical exam.

AA.27 General Requirements for the Safe Operation of all Facilities

AA.27.c.vi. Laser safety eyewear should be used as a last resort for laser safety. The primary emphasis should be placed on the design, installation, and utilization of the laser equipment to eliminate the exposure of personnel. For additional information on use of laser safety eyewear, see DHEW Publication (FDA) 79-8086 "Evaluation of Commercially Available Laser Protective Eyewear."

AA.28 Additional Requirements for Special Lasers and Applications. It is believed that special precautions are required for such facilities because of the high energy/power outputs of the lasers. Energy or power outputs at this level may also be capable of producing scattered

radiation which exceeds the MPE and therefore represents a far greater ocular exposure hazard than if only the direct beam is hazardous.

AA.29 Additional Requirements for Safe Operation

AA.29.a. This will eliminate the possibility of a laser beam entering the safety goggles from behind and being reflected from the inside surface of the filter into the eye.

Some laser safety eyewear now being manufactured only has the optical density(s) and wavelength(s) specified on the case or on a tag which can easily be lost. If the optical density and wavelength are not labeled on the eyewear, this may lead to the misuse of eyewear intended for protection against one type of laser radiation being used for protection against another.

AA.30 Caution Signs, Labels, and Posting. These signs, labels, and symbols are compatible with the ANSI and CDRH standards.

AA.31 Surveys. Surveys are required to provide evidence to the laser safety officer and the Agency that control measures are operational and are utilized. Surveys also provide a basis for the establishment or deletion of additional control measures in the judgement of the laser safety officer and the Agency.

AA.32 Measurement and Instrumentation. When all control measures are used with a particular laser class, and there is not any additional human access to laser or collateral radiation, then measurements are not required. However, for classification purposes (no Federal Classification label) and for human access conditions, measurements (or their equivalent) are required to indicate that levels normally encountered are below the MPE's. Measurements should only be attempted by persons trained or experienced in laser technology and radiometry.

AA.32.c.i, ii, iii, and iv. These measurement criteria affect product performance features and labeling requirements and are identical to the Federal laser products performance standard, as amended.

AA.32.d. MPEs are a user control concept and this paragraph is identical to the user standard, ANSI Z136.1-1980.

AA.34 Notification of Incidents. A requirement for reporting incidents is common in State and local agency health and safety codes. The working group urges State and local officials to report all laser injuries to the National Center for Devices and Radiological Health (CDRH) for tabulation and inclusion in the Radiation Incidents Registry.

AA.37 Records. The preservation period for records has not been designated. This should be determined by individual states.

Tables

Section 360F, EFFECT ON STATE STANDARDS, of the Public Health Service Act as added by Public Law 90-602, Radiation Control for Health and Safety Act of 1968, states "Whenever any standard prescribed pursuant to section 358 with respect to an aspect of performance of an electronic product is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, any standard which is applicable to the same aspect of performance of such product and which is not identical to the Federal standard..." (42 USC 263h). It is primarily because of this statute that the product classification levels found in the tables are compatible with those levels found in the Federal Laser Product Performance Standard and not those found in the ANSI Z136.1-1980 laser standard.

Based on comments received during the review of previous drafts of the Suggested State Regulations for Lasers (SSRL), it was agreed that the use of the Federal laser products performance standard's Class I Accessible Emission Limit (AEL) as a Maximum Permissible Exposure (MPE) limit was not appropriate. Therefore, the American National Standard Z136.1-1980 MPE's are used.

Collateral radiation from laser products includes non-coherent optical and x-radiation. An example of a laser product where both collateral radiations could be present is an actively mode-locked solid state laser. Optical radiation could radiate from the pump lamp, and x-radiation could radiate from the high-voltage power supply. The concept of collateral radiation is found in the Federal Performance Standard for Laser Products and this approach ensures consistency.

Table V. Since this is a performance requirement, it must be identical to the Federal laser products performance standard, as amended.

Appendix A - Medical Surveillance. This is included as a guide to States for information on medical examinations, frequency of examination, eye effects and surveillance, skin effects, and other medical evaluations for laser users.

Appendix B - Guidelines for Laser Light Shows. Because of the increasing number and current popularity of laser light shows, the pertinent requirements for such shows based on CDRH safety criteria are summarized herein.

Appendix C - Application for Registration of Laser Facility, Mobile Laser, or Service Organization. To aid in the promulgation and implementation by individual States of the registration requirement of the Suggested State Regulations for Lasers, a suggested format for the registration form is included.

Appendix D - Training. The material on training is included, due to the importance placed on training in the SSRL to achieve laser health and safety. In addition, the material is consistent

with similar material in the ANSI Z136.1-1980 standard on the Safe Use of Lasers.

Appendix E - Measurements for Maximum Permissible Exposure. Since there is a wide range of spectral, time duration, and geometric distribution of laser sources to which an individual might be exposed, the MPE measurement criteria as specified in ANSI Z136.1 guide are included to ensure a consistent interpretation of the limits.

Matters for Future Consideration

The Suggested State Regulations for Lasers is complete and up-to-date as of this writing (October 1982). It is anticipated, due to the pace of developments in several laser areas, that revisions will be necessary. In addition, it is expected that users of the SSRL will feed back their experiences and ideas for improvement in its content.

One area that may need future elaboration is "associated hazards" since, in some instances, these hazards are specific to lasers.