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Department of Health and Human Services

Food and Drug Administration

Laser Products; Intent to Amend Performance Standard

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1040

[Docket No. 80N-0364]

Laser Products; Intent To Amend Performance Standard

AGENCY: Food and Drug Administration.

ACTION: Advance Notice of Proposed Rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is considering amending the laser product performance standard to require certain reporting, recordkeeping, and labeling for original equipment manufacturer component sales, to simplify the definition for "human access," and to clarify the concepts of "protective housing" and "product classification." Additionally, there may be a need to extend the wavelength range of control, to relax the general requirements for safety interlocks and viewing optics, and to eliminate the requirements for a remote control connector and an emission indicator delay on Class III products below 5 milliwatts peak power output. A change may also be proposed to clarify the need for scanning safeguards on certain lasers as a function of product classification, to require an emission indicator on operator controls separated from the laser system in excess of 2 meters, and to require a new "manual reset mechanism" performance feature for Class III and Class IV laser products. The standard may also be amended to incorporate appropriate requirements for laser light shows. FDA's experience in administering the laser standard has indicated a need to make changes.

DATE: Comments and data by January 6, 1981.

ADDRESS: Written comments and supporting data to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Richard S. Sternchak, Bureau of Radiological Health (HFX-460), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: FDA issued the performance standard for laser products in Part 1040 (21 CFR Part 1040) as a final rule in the Federal Register of July 31, 1975 (40 FR 32252). Based on its experience in administering the laser standard since it became effective on August 2, 1976, FDA has recognized that some provisions of the standard needed to be revised. The agnecy issued amendments to the performance standard as a final rule in the Federal Register of November 28, 1978 (43 FR 55387). These amendments removed unneeded criteria for determining human access to laser or collateral radiation; specified more appropriate parameters for measuring the accessible emission levels of laser and collateral radiation, including scanned laser radiation; relaxed the accessible emission limits for collateral radiation in the wavelength range of greater than 400 nanometers (nm); relaxed the labeling and performance requirements for some Class II laser products; and allowed more administrative flexibility in determining the wording of warning labels. These amendments solved major problems in the standard. They also reduced the burden on manufacturers by increasing the design latitude within each of the graded risk classes for laser products without compromising the public health and safety.

As a result of the agency's continuing effort to evaluate the significance of new information and its experience enforcing the present laser standard and processing variance applications, FDA has concluded that other amendments may be necessary. The modifications under consideration, FDA believes, would further clarify the standard without affecting the hazard classification scheme; would appreciably reduce the burden on affected manufacturers without compromising the public health; and would generally improve the effectiveness of regulation of the laser industry without imposing undue constraints.

This notice is being issued under FDA's policy of seeking early public participation in performance standard amendment activities. Comments and supporting data concerning the rationale for the proposed amendments discussed below would be particularly useful:

1. The agency believes that there may be a need to require manufacturers of laser products not subject to the performance standard to maintain relevant records, to provide certain reports, and to affix additional labeling. Any laser product sold to, by, or for a manufacturer of an electronic product subject to the performance standard for use as a component (or replacement thereof) in such electronic product, commonly referred to as an original equipment manufacturer (OEM) component, currently is not subject to the performance standard for laser products set forth in § 1040.10(a) (1) and (2) (21 CFR 1040.10(a) (1) and (2)) and is excluded from the reporting and recordkeeping requirements for electronic products set forth in § 1002.1(b) (21 CFR 1002.1(b)). Under these circumstances, FDA's Bureau of Radiological Health (the Bureau) cannot ensure that these laser products actually meet the conditions required for exclusion from the standard.

FDA has information that some manufacturers have been selling uncertified and noncompliant laser components to end users rather than to actual laser product manufacturers. To prevent these unauthorized sales, the agency is considering actions to ensure the proper identity, use, and traceability of OEM laser products. These could include the requirement that a label listing the manufacturer's name and address, the date of manufacture, and model and unit identification be placed on all components. A requirement that OEM manufacturers verify, prior to shipment, that all sales of laser products not subject to the performance standard are sold to, by, or for other manufacturers for use as components in electronic products could be imposed. The records that manufacturers may be required to maintain would be similar to those required by § 1002.30(a) (4) and (b) (21 CFR 1002.30(a) (4) and (b)) and would include records of OEM sales verification. Records to be obtained by dealers and distributors would be the same as those listed in § 1002.40 (21 CFR 1002.40). The conditions for the preservation, inspection, and disposition of records would be in accordance with §§ 1002.31 and 1002.41 (21 CFR 1002.31 and 1002.41). One proposal is to limit reporting to annual reporting under the provisions of § 1002.11 (21 CFR 1002.11), except that the submission might need only to summarize the contents of the records to be maintained under § 1002.30(a) (4) and (b).

2. The current definition of "laser" in § 1040.10(b)(15) specifies the applicability of the laser product performance standard to a wavelength range between 250 and 13,000 nm. The agency is considering extending the wavelength range for the classification limits of laser products, because it has found that laser products are being manufactured outside the present control range. At the low end of the wavelength spectrum, excimer (rare gas-holgen combination) lasers are commercially available that emit short, intense pulses in the shortwave ultraviolet (UV). These include argon fluoride (ArFl) and krypton chloride

(KrCl) lasers that radiate at 193 nm and 220 nm wavelengths, respectively. Fluorine (Fl) lasers operating at 157 nm are also available but may not be placed under performance standard control because they operate in the vacuum-UV range.

Several types of lasers are available in which far-infrared output is obtained by illuminating a gas with a carbon dioxide (CO_2) or carbon monoxide (CO) laser. These lasers generally produce low-power, pulsed, or continuous-wave output for spectroscopic purposes. Molecules used in these lasers include methanol of 119 micrometer (μm) output, hydrogen cyanide for 311 μm or 337 μm, ammonia for 34 to 388 μm, and methyl fluoride for 496.1 μm. The agency is considering extending the wavelength range of control to between 180 nm and 10^6 nm (1 millimeter) to include these laser products.

Of concern is the lack of biological data upon which limits would be based in the expanded regions. Without such data, it may not be possible to effect this change. The agency invites submission of relevant biological effects data. This expanded wavelength range, however, does coincide very nearly with the 200 nm to 10^6 nm wavelength range contained in the American National Standards Institute (ANSI), Inc.'s recommended "Standard for the Safe Use of Lasers" (ANSI–Z 136.1–1980, revision pending).

3. Reference to a line-of-sight path of up to 100 centimeters (cm) was included in the present definition of "Human access" in § 1040.10(b)(12)(ii) to account for the possible insertion into a laser product of optical fiber probes, tools, or other foreign objects that could allow access to specularly reflected laser radiation. These types of objects inserted through a small hole, crack, or opening in a protective housing could possibly reach points accessible by a straight, unobstructed path of up to 100 cm from any part of the human body and reflect accessible laser radiation. The likelihood of this occurring may not be sufficiently great to warrant the added design difficulty posed by this requirement. The agency is considering whether the 100 cm line reference should be modified for clarification or simply be deleted. Modification may require the specification of the maximum allowable size of dimensions of permanent openings in protective housings other than exit apertures and temporary openings that result from intended portions of the protective housing being removed and displaced.

4. Based on the review of initial reports and the inspection of actual products, FDA has found that laser product manufacturers have particular difficulty interpreting the present laser performance standards requirements for protective housings. Consequently, manufacturers have had difficulty designing products with protective housings that comply with the standard. Therefore, the agency is considering rewording § 1040.10(f)(1) to make it easier to understand. This action may include stating the general requirement more simply, clarifying the phrase "wherever and whenever", and relating the concept of protective housing more closely to the amended definition of human access.

5. FDA, from experience, recognizes that product classification is a complex process. That process involves the simultaneous consideration of a set of interrelated criteria for permitting or preventing human access to laser or collateral radiation. These criteria vary with the individual function and form of each product. This complexity often leads to misclassification of laser products. The agency believes that the wording of § 1040.10(c)(1) can be improved to make product classification more understandable. It is considering restructuring the section by providing more procedural details, using simplified terms and sentence structure, and integrating the concept of protective housing more closely with the concept of product classification.

6. The agency is considering relaxing the requirements for safety interlocks. Under the conditions currently defined in § 1040.10(f)(2), each laser product, regardless of its class, requires a safety interlock for each portion of the protective housing that is designed to be removed or displaced during operation or maintenance, if removal of displacement of that portion of the protective housing could permit human access to laser or collateral radiation in excess of the limit of the lowest class necessary for the performance of the intended function of the product. To comply with the current standard, safety interlocks must prevent human access to unnecessary laser and collateral radiation upon removal or displacement of the interlocked portion of the protective housing and preclude the removal or displacement of that portion of the housing upon failure of the interlock to prevent human access to radiation in excess of the required limit. If defeatable, the safety interlock must also provide an indication of interlock defeat, and when defeated, it must preclude replacement of the removed or displaced portion of ther protective housing.

The requirements for safety interlocks and the concepts for meeting them are discussed in the Bureau's Interpretative Guideline No. 12, dated September 9, 1976. Since that time, the Bureau has relaxed its policies on safety interlock requirements. The Bureau states in Interpretative Guideline No. 20, dated July 1, 1977, that it will not object to the use of standard electrical and mechanical interlocks with appropriate labeling for operation and maintenance ports in the protective housing of laser products through which access to levels of visiable laser radiation not exceeding Class II limits is possible. This relaxation was considered warranted because eye damage, while possible from chronic exposure to Class II levels of laser radiation, is not likely to occur from acute exposure. The agency is now considering relaxation of the laser standard regarding safety interlocks because experience has shown that the current requirements may be overly restrictive. With regard to laser products that could permit human access to visible laser or collateral radiation through portions of the protective housing intended for removal or displacement, the agency is considering elimination of interlock requirements for accessible levels below the limits of Class II. It may also eliminate the requirements of § 1040.10(f)(2)(i)(*b*) for accessible visible laser radiation levels in excess of the limits of Class II but equal to or less than 5 milliwatts (mW) peak power, as long as an interlock and interlock failure indicator are provided. In addition, the agency is considering allowing the use of dual interlocks in lieu of the requirements of § 1040.10(f)(2)(i)(*b*) when access to visible laser radiation levels in excess of 5 mW peak power can be gained. Panels intended for removal or displacement during operation or maintenance may still require safety interlocks meeting all requirements of the present § 1040.10(f)(2) if access could be gained to laser radiation above 710 nm or less than 400 nm wavelengths. These changes would make the safety interlock requirements of the laser standard more consistent with the less restrictive guidelines recommended in ANSI–Z 136.1–1980, (revision pending) and by the International Electrotechnical Commission (IEC).

7. Section § 1040.10(b)(30) currently defines a remote control connector as an electrical connector which permits the connection of external controls placed apart from other components of the laser product to prevent human access to all laser and collateral radiation in excess of the limits specified in §§ 1040.10 and

1040.11 (21 CFR 1040.10 and 1040.11). The agency questions the need for a remote control connector on products intended for outdoor use and certain other products that radiate at or below 5 mW peak power in the visible wavelength range. This is because external barrier interlocks and optional remote switches are almost never used on products in this category, which includes surveying, leveling, and alignment laser products. Furthermore, these laser systems are generally not used under conditions that would pose a high risk of injury due to retinal burns. Both the IEC and ANSI only recommend the implementation of this performance feature on Class III_b and Class IV laser products.

8. The agency is considering requiring a new performance feature for Class III lasers above 5 mW peak power output and Class IV systems to protect the operator from dangers associated with the unexpected resumption of radiation emission following interruption of product operation due to any temporary power failure, interlock failure or defeat, or use of the remote control connector. A "manual reset mechanism" safety feature may be added to laser products that exceed 5 mW peak power to preclude the high risk of injury to an attendant from the sudden automatic reenergizing of the product.

9. Section 1040.10(f)(5)(ii) states that each laser system classified as a Class III or IV laser product shall incorporate an emission indicator which provides a visible or audible signal during emission of accessible laser radiation in excess of the accessible emission limits of Class I, and sufficiently prior to emission of such radiation to allow appropriate action to avoid exposure to the laser radiation. Technically, visible radiation of 5 mW peak radiant power is a level at which biological damage to human tissue is possible from acute direct exposure, and direct viewing should be prevented. There is no clear distinction, however, between the bioeffects of lasers at the low end of Class III and that of lasers at the upper levels of Class II, where radiation may be viewed under carefully controlled exposure. Therefore, the agency is considering not requiring an emission delay for laser products radiating in the visible up to 5 mW peak power output because of the marginal safety benefit that would be provided by this requirement. The degree of risk involved by not providing an emission delay in these circumstances may not justify the cost of implementation.

10. On the other hand, the agency may require an emission indicator on operator controls that are separated from the laser head and the laser energy source by a distance of greater than 2 meters. Experience has shown that the requirement of a second emission indicator is often more appropriate on the controller than on a power supply under the same condition of separation. This requirement would be consistent with the safety criteria set forth in § 1040.10(f)(5)(iii), which states that, "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 an emission indicator as required in accordance with § 1040.10(f)(5)(i) or (ii)."

11. FDA is also considering an amendment to relax the requirements for viewing optics during the performance of service functions. Unlike operation and maintenance, service must often be performed under compromised circumstances of human access to higher levels of laser and collateral radiation. However, these activities are generally performed under controlled conditions, for shorter periods, and by individuals having more technical awareness. For these reasons, the agency is considering allowing Class II accessible emission levels through viewing optics during service.

12. The agency believes that it may be necessary to clarify the requirement for a scanning safeguard on laser products which emit accessible scanned laser radiation for laser products classified at a higher level than would be exceeded upon scan failure. There is a question concerning the need, under all circumstances, for a scan failure safeguard to preclude change of class of scanned radiation as now required in § 1040.10(f)(9).

13. FDA is considering modifications to the specific purpose section of the laser product performance standard, § 1040.11(c) (21 CFR 1040.11(c)), to include requirements for laser light show products. At the time of the development of the laser standard, the widespread use of higher powered lasers in light shows was not anticipated. Consequently, in most cases, it is impossible for a laser light show to meet the requirements of the standard for "demonstration laser products." Therefore, those light show products are now regulated by the use of procedures for variance from the laser performance standard. FDA is considering amending the standard to incorporate the appropriate requirements for these special laser products to negate the need for variances.

Interested persons are invited to participate in these efforts to improve the laser product performance standard by submitting written data, views, or arguments concerning the matters discussed in this notice and any associated environmental and economic concerns. Written comments or data should be sent (preferably four copies) to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. The comments should be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Comments submitted before December 3, 1980, may be discussed at the next meeting of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), tentatively scheduled for December 3–4, 1980, as part of its review of possible proposed amendments resulting from this notice. This committee, a statutory advisory committee to the Secretary of Health and Human Services, must be consulted prior to the establishment of standards under the Radiation Control for Health and Safety Act of 1968. All comments received will be considered to the fullest possible extent in formulating the proposed amendment(s). Information submitted in response to this notice will be available for public inspection in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the authority of the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177–1179 (42 U.S.C. 263f) and the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1).

Dated: November 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

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