faxed to 202–260–8957. If you need special accommodations due to disability, please inform the contact person when you register. If, in addition, you desire to make an oral presentation during the meeting, when you register to attend you must inform the contact person of that desire and submit: (1) A brief written statement of the general nature of the evidence or arguments that you wish to present, (2) the names and addresses of the persons who will give the presentation, and (3) an indication of the approximate time that you request to make your presentation. Depending upon the number of people who register to make presentations, we may have to limit the time allotted for each such presentation. We anticipate that, if time permits, those attending the meeting will have the opportunity to ask questions during the meeting.

IV. Comments

You may, by May 11, 1999, submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may also send comments to the Dockets Management Branch at the following e-mail address: ''FDADockets@bangate.fda.gov'' or via the FDA Website ''http://www.fda.gov''. You should annotate and organize your comments to identify the specific issues to which they refer. You must submit two copies of any comments, identified with the docket number found in brackets in the heading of this document, except that you may submit only one copy if you are an individual. You may see received comments in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Transcripts

You may request transcripts of the meeting in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. You may also examine the transcript of the meeting after May 21, 1999, at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA Website ''http://www.fda.gov''.

VI. References

We have placed the following references on display in the Dockets Management Branch (address above). You may see them at that office between 9 a.m. and 4 p.m., Monday through Friday.

1. ''Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body,'' June 11, 1998.

2. Food Labeling: Use on Dietary Supplements of Health Claims Based on Authoritative Statements (64 FR 3250, January 21, 1999).

3. Memorandum from Donna E. Shalala, DHHS, to scientific bodies within the Public Health Service, March 17, 1998.

4. Memorandum from Donna E. Shalala, DHHS, to The Honorable Dan Glickman, USDA, March 17, 1998.

5. Notification to Donna E. Shalala, DHHS, from Jonathan W. Emord et al., Emord & Associates, P.C., Counsel for Weider Nutrition International, Inc., February 23, 1998.

6. Food Labeling: Health Claims; Interim Final Rule; Antioxidant Vitamins C and E and the Risk in Adults of Atherosclerosis, Coronary Heart Disease, Certain Cancers, and Cataracts (63 FR 34084, June 22, 1998).

7. Food Labeling: Health Claims; Interim Final Rule; Antioxidant Vitamin A and Beta-Carotene and the Risk in Adults of Atherosclerosis, Coronary Heart Disease, and Certain Cancers (63 FR 34092, June 22, 1998).

8. Food Labeling: Health Claims; Interim Final Rule; B-Complex Vitamins, Lowered Homocysteine Levels, and the Risk in Adults of Cardiovascular Disease (63 FR 34097, June 22, 1998).

9. Food Labeling: Health Claims; Interim Final Rule; Calcium Consumption by Adolescents and Adults, Bone Density and The Risk of Fractures (63 FR 34101, June 22, 1998).

10. Food Labeling: Health Claims; Interim Final Rule; Chromium and the Risk in Adults of Hyperglycemia and the Effects of Glucose Intolerance (63 FR 34104, June 22, 1998).

11. Food Labeling: Health Claims; Interim Final Rule; Omega-3 Fatty Acids and the Risk in Adults of Cardiovascular Disease (63 FR 34107, June 22, 1998).

12. Food Labeling: Health Claims; Interim Final Rule; Garlic, Reduction of Serum Cholesterol, and the Risk of Cardiovascular Disease in Adults (63 FR 34110, June 22, 1998).

13. Food Labeling: Health Claims; Interim Final Rule; Zinc and the Body's Ability to Fight Infection and Heal Wounds in Adults (63 FR 34112, June 22, 1998).

14. Food Labeling: Health Claims; Interim Final Rule; Vitamin K and Promotion of Proper Blood Clotting and Improvement in Bone Health in Adults (63 FR 34115, June 22, 1998).

15. Letter of August 13, 1998, to Michael A. Friedman, FDA, from The Honorable Dan Burton, House of Representatives, regarding the nine interim final rules that FDA published in the **Federal Register** of June 22, 1998.

16. Letter of October 26, 1998, to Jane Henney, FDA, from The Honorable Dan Burton, House of Representatives, regarding the nine interim final rules that FDA published in the **Federal Register** of June 22, 1998.

17. Letter of September 16, 1998, to The Honorable Dan Burton, House of Representatives, from Diane E. Thompson, FDA, regarding the nine interim final rules that FDA published in the **Federal Register** of June 22, 1998.

18. Letter of December 8, 1998, to The Honorable Dan Burton, House of Representatives, from Diane E. Thompson, FDA, regarding the nine interim final rules that FDA published in the **Federal Register** of June 22, 1998.

Dated: March 18, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–7115 Filed 3–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1010 and 1040

[Docket No. 93N–0044]

Laser Products; Proposed Amendment to Performance Standard

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the performance standard for laser products to achieve harmonization between the current standard and the International Electrotechnical Commission (IEC) standard for laser products and medical laser products. FDA is proposing additional changes that reflect FDA's understanding of how photobiological and behavioral factors, such as involuntary eye and body motion, affect the risk of injury from exposure. In addition, FDA is clarifying the requirement that manufacturers provide certain information to servicers. Generally, the proposed amendments will reduce the regulatory burden on affected manufacturers and improve the effectiveness of FDA's regulation of laser products. This action is being taken under the Federal Food, Drug, and Cosmetic Act as amended by Radiation Control for Health and Safety Act of 1968.

DATES: Written comments on the proposed rule should be submitted by June 22, 1999. See section IV of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments on the proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jerome E. Dennis, Center for Devices and Radiological Health (HFZ–342), Food and Drug Administration, 2094 Oak Grove Rd., Rockville, MD 20850, 301–594–4654, ext. 135.

SUPPLEMENTARY INFORMATION:

I. Background

On September 23, 1992, FDA's Center for Devices and Radiological Health (CDRH) mailed to all listed manufacturers and importers of laser products and interested persons a notice that FDA was considering amendments to the Federal performance standard for laser products (§§ 1040.10 and 1040.11) (21 CFR 1040.10 and 1040.11). Accordingly, in the **Federal Register** of May 10, 1993 (58 FR 27495), FDA published a notice of intent (NOI) that informed interested persons that FDA was considering amending the performance standard for laser products to: (1) Achieve greater consistency between the performance standard and the IEC standards for laser products and medical laser products (IEC 825–1 and IEC 601–2–22); (2) improve compliance; and (3) develop a more efficient enforcement program. The NOI explained that the impetus for many of the changes under consideration stemmed largely from extensive FDA involvement in international standardization efforts for laser products with IEC, an international standards development organization with participants from many countries. The NOI also informed interested persons that additional changes to the current standard that are unrelated to harmonization were being considered as a result of FDA's continuing effort to evaluate new information and experience enforcing the present laser standard and processing variance applications.

At this time, the agency is proposing specific amendments discussed in the NOI and is also proposing additional items responding to amendments to the IEC 825–1 standard. A significant amendment to the IEC standard, which was approved in 1993, expanded the scope of the IEC 825–1 standard to include light emitting diodes (LED's) and products incorporating LED's. This amendment was approved because LED's are: (1) Very similar to semiconductor laser diodes, (2) often electrically and mechanically interchangeable with laser diodes, and (3) considered to represent similar hazards to the eyes. After the publication of IEC 825–1, considerable controversy developed because manufacturers of LED's became aware that the conditions for measuring radiant power and energy to enable product hazard classification resulted in an exaggeration of the hazard of many LED's. Unlike lasers, LED's are often extended sources (i.e., have relatively large physical dimensions) and therefore are not capable of being focussed to as small and intense a retinal image as comparable lasers. At this time, it appears that the IEC will be publishing an amendment that will partially address this concern. However, FDA is not aware of any injuries that have occurred from LED radiation. In consideration of the economic impact of including LED's in the applicability of its standard, the FDA has reconsidered its former notifications and is eliminating LED products from this proposed rulemaking. The agency believes that other remedies exist that can be used if needed and can, in the future, propose additional amendments if warranted.

FDA recognizes its responsibility not only to participate in the development of radiation safety standards for electronic products, but also to use its role in the development of the standard to demonstrate leadership and to exert influence. Although harmonization with the IEC standard is in itself a worthwhile goal, FDA disagrees with certain parts of the IEC standard. Specifically, under the IEC standard, the conditions for the measurement of radiant energy and power for the purpose of product classification contain a requirement that assumes that the output of diverging laser sources will be collected by large aperture optical instruments at a short distance from the source, and that optical components to collimate the diverging sources are currently commercially offered as accessories. FDA believes that the present IEC approach fails to allow for realistic factors of risk likely in the use of the products. FDA also believes that when collimators are offered as accessories, the classification measurements are to be made using the collimators; this situation is equivalent to offering the collimated laser product in a kit form. The entire laser product industry, however, should not be burdened with excessive classification and requirements for controls, indicators, and warnings. Therefore, FDA is proposing that measurements of radiant energy and power be made in accordance with the scheme developed by Working Group 1 of the IEC Technical Committee 76 (IEC TC76/WG1) at its meeting in Washington, DC, in February, 1995, which does not require the use of large aperture optical instruments in all cases. The IEC TC76/WG1:1995 scheme is described in section II of this document.

Another departure from the requirements of IEC 825–1 relates to the criterion for human access that applies to levels of laser radiation that are less than the accessible emission limit (AEL) of Class 2 (Class II under FDA's current standard). Such levels of radiation are considered to be ocular hazards only for exposures longer than 0.25 seconds. However, the criterion for human access is based on skin exposure, i.e., interception by any part of the human body. FDA has recently identified laser products that are classified as Class 2 but have configurations that prevent direct eye exposure. The present classification is based upon the ability to insert a part of a hand or finger into a laser field that is not recognized to be a skin hazard. FDA recognizes that the classification of an eye hazard based on the possibility of skin exposure is unnecessarily burdensome on such products and is therefore proposing to amend this criterion. Although it is acknowledged that the possibility exists for a person to insert a mirror and extract the beam, this is not considered to be a realistic risk upon which all such products need be evaluated.

II. Contents of the Proposed Regulation

Proposed §§ 1010.2(d) and 1010.3(b) (21 CFR 1010.2(d) and 1010.3(b)) authorize the Director, Office of Compliance, CDRH, to approve alternate means of providing certification and identification information. The 1985 amendments to the standard authorized the Director, Office of Compliance, to give similar approvals for labeling required by part 1040 (21 CFR part 1040). FDA is now proposing to give the Director, Office of Compliance, similar authority under §§ 1010.2 and 1010.3.

In proposed § 1040.10(d)(4), FDA is introducing the concept of reduced emission duration for classification of products for which viewing of the radiation is not intended within the range of their applications. This is to harmonize with IEC 825–1 and to reduce the burden on manufacturers of products that have been in higher classes because of the use of emission durations for classification that are unrealistically long given the use of the products. Therefore, the current Class IIa would no longer be needed, and its definition, table of AEL, and warning label requirements would be eliminated.

Under proposed § 1040.10(b), FDA would change to the use of Arabic numerals for class designations because Arabic numerals are less ambiguous. Also, changing to Arabic numerals will

harmonize with IEC 825–1 and the American National Standard Institute (ANSI) Z136.1 standards. However, FDA would not object to continued use of Roman numerals providing that the classification is correct as of the date of manufacture of the product as shown on the identification label required by § 1010.3.

Proposed § 1040.10(b)(7) redefines Class 3A (IIIa). The proposed new definition would expand the range of wavelengths included in the class and have an AEL for radiant power and energy that is five times that of Class 1 in addition to an AEL for radiant exposure and irradiance to account for increased hazard as a result of the use of collecting optics. Although the new Class 3A would exclude visible radiation if the irradiance exceeds 2.5 milliwatts per square centimeter (mW/cm^2), the performance and labeling requirement currently applicable to Class IIIa would apply to the new class.

Under proposed § 1040.10(d) and Table 1, FDA is deleting the Class 1 AEL for integrated radiance and replacing these limits with correction factors to the AEL for radiant energy and power based on the angular subtense of the radiation source. This concept is in accord with the current bioeffects science and will harmonize with IEC 825–1. Current bioeffects science indicates that repetitive pulse exposures have an increased hazard compared either to a simple summation of the individual pulses or to a continuous exposure to the same average power for the same duration. For this reason, the AEL for Class 1 should be reduced by a factor of the number of pulses raised to the negative one fourth power ($N^{-1/4}$).

The measurement parameters for radiant energy and power are those proposed by IEC TC76/WG1:1995 and endorsed by the U.S. Technical Advisory Group for that standards committee. This proposal would require two measurements for visible or near-infrared wavelengths, a 50 millimeters (mm) aperture at 2 meters (m) from the apparent source, and a 7 mm aperture at 100 mm. The measurement yielding the greater result is to be used for classification. For sources that have a high degree of divergence, the 7 mm aperture at a close distance is believed to accurately represent a worst practical viewing condition without the use of optical aides. This proposal by WG1 received a majority of the votes within IEC TC–76, but not a high enough number for acceptance. The TC–76 has, since approved, a more conservative proposal for the purpose of providing relief for LED's that can be considered to be extended sources. This more conservative approach, however, uses a 50 mm aperture at 100 mm from the apparent source and reflects the assumption that the classification will be based upon the hazard associated with viewing highly divergent sources through collecting optics, which increase the hazard. In addition, the use of the 7 mm aperture with sources that subtend greater than α_{min} permits the aperture to be placed at a distance greater than 100 mm from the apparent source. In order to be in further agreement with IEC 825–1, the aperture diameter over which the power or energy is averaged to determine the radiant exposure or irradiance is determined from a table (Table 6) and is determined by the wavelength and emission duration.

Under proposed § 1040.10(f)(5) and (f)(6), FDA would eliminate the requirements for an emission indicator and beam attenuator for systems in Class 2, 3A, and for systems in Class 3B having a visible output power of 5 mW or less. Because such systems present minimal hazard or, by virtue of the visibility of their output, give adequate warning of its presence, this relaxation is considered to be appropriate.

FDA is proposing to eliminate the requirement in § 1040.10(f)(9)(ii) that requires a scanning safeguard to determine if a change in scan parameters results from a failure or is intentional, and to react only to those changes resulting from failure. This requirement has not been invoked by the agency and has been found very difficult for the industry to understand.

Proposed § 1040.10(g) allows the use of warning logotype labels and protective housing labels that comply with IEC 825–1. The logotype labels in current § 1040.10(g) are of a design specified by ANSI. It is noted that the ANSI standard for laser safety allows use of the IEC style labels. The IEC labels for protective housings use the word ''CAUTION'' in all cases. In permitting use of the IEC labels, for consistency purposes, FDA will also permit this wording change.

The agency is not proposing significant changes to § 1040.10(h)(2)(ii); however, FDA is using this preamble to clarify the agency's interpretation of that provision in response to the evident confusion among manufacturers and servicers.

Finally, FDA is proposing to eliminate the quoted caution statement in § 1040.10(h)(1)(iv), while retaining the requirement in general terms. This proposed change will avoid otherwise unnecessary approvals or notifications and allow manufacturers to fulfill the requirement by using their own wordings for this warning.

III. Summary and Analysis of Comments and FDA's Response

The NOI set out the proposed changes to §§ 1040.10 and 1040.11 and invited comments and recommendations on such changes. Interested persons were given until August 9, 1993, to comment on the NOI. FDA received a total of 13 comments from laser product manufacturers, government organizations, a consultant, an industry association, and a professional medical association. These comments generally supported the proposed changes and the concept of harmonization with international requirements, except for the comments that follow.

1. Several comments suggested clarifying the proposed amendments to § 1040.10(d), which proposed reducing the emission durations to be used for the classification of Class 1 laser products that emit visible or infrared (IR) laser radiation not intended to be viewed, as determined from the design of the product or its intended function. These comments included the following:

A. Long-Term Viewing or Exposure

Four comments requested that FDA clarify the amendment as being applicable to products for which ''long-term'' viewing or exposure is intended or inherent in the design of the product, to differentiate between products in which viewing or exposure would only occur for short periods.

B. Products Emitting in the Near-IR Range

Four comments assumed that products which emit in the near-IR range that are classified on the basis of 100 seconds of emission would continue to be so classified, even if they are general purpose products. The comments noted that it would help to clarify the proposal by adding ''general construction'' to the applications listed for use with the 100 seconds classification time.

C. Surveying Lasers

Six comments stated that surveying lasers should not be included in the category with laboratory laser systems for a 10,000 seconds classification because they are not intended to be viewed for long durations. One comment noted that the purpose of the design of surveying lasers is to permit the beam to be viewed by electronic or mechanical devices. Two comments cited the existence of the Occupational Safety and Health Administration

regulations promoting safe use of surveying lasers. One manufacturer submitted an analysis stipulating that the current standard provides an adequate safety margin for its laser surveying products and noted that the proposed amendment would mandate a large reduction of output power for such products, which would render the technology useless.

FDA agrees with comments 1.A and 1.B of section III of this document. The proposed amendments have been drafted to incorporate the concepts and language of IEC 825–1, 1993. Although FDA agrees with the point in comment 1.C of section III of this document that invisible radiation intended for detection only by electronic means is not considered to be intended to be viewed, FDA notes that visible radiation emitted by surveying lasers that is used for leveling must be assumed to be intended to be viewed by the eyes. Further, viewing for more than 100 seconds cannot be considered to be unlikely. Therefore, the proposed 30,000 second maximum sampling interval is retained.

2. Four comments noted that the amendments to reduce the AEL for repetitively pulsed lasers should only be made if the change to reduce the time period for classification discussed in comment 1 of section III of this document is also made. If the proposed reduction in the AEL were made without reducing the time period for classification, the result would be a lowering of the allowable power for some products and an inconsistency with the IEC 825 standard. The comments also suggested that ''repetitively pulsed lasers'' be changed to ''products with scanning or repetitively pulsed outputs,'' to clarify that the requirement would also apply to scanning products.

FDA agrees with these comments and believes that the wording of the proposed amendments addresses the concern relating to the time period for classification. The clarification that the requirement applies both to repetitive pulses and scanned radiation has been made.

3. One comment suggested use of the revised ANSI AEL in the 1,150 to 2,800 nanometers (nm) spectral band rather than merely revising the AEL in the 1,535 to 1,540 nm spectral band. The comment noted that the revisions, which relate to both fiber optic exposure and so-called ''eye-safe'' laser exposure, are important to consider because of the greatly expanding technology in that spectral region.

FDA agrees that a revision of the AEL is appropriate to incorporate up-to-date understanding of the biological effects of exposure to certain spectral bands. The method used in the ANSI standard to determine the AEL is to calculate using the maximum permissible exposure. Although this is appropriate in the ANSI standard, which is primarily concerned with the safe use of lasers, FDA believes that it is appropriate to employ tables of AEL in a product standard. In addition, in the interests of global harmonization, the AEL in the proposed amendments to the standard are identical to those of IEC 825–1, which is accepted in most other countries.

4. One comment disagreed with FDA's approach in its proposal to amend the tables in § 1040.10(d) for the purpose of making the resulting classifications agree more nearly with the IEC and ANSI classifications. The comment disagreed with FDA's contention that the present structure of these tables should be retained because the existing structure is simpler than the corresponding ANSI and IEC tables. The comment stated that although the ANSI calculations are more complex, if more simplified tables (such as those in the FDA standard) result in some systems being considered more hazardous than they would be under the ANSI or IEC methods, then the more complex method should be used.

FDA partially agrees with this comment. Upon further consideration, it became clear that reformatting the IEC tables of AEL to conform to those in the present standard was practically unworkable. Therefore, the proposal contains tables of AEL that are identical to those of IEC 825–1. Further, FDA agrees that the standard should not result in an exaggeration of the hazard; therefore, the specified conditions for measurement of radiant energy and power for classification are more relaxed than those of IEC 825–1. FDA recognizes that this is a potential obstacle to harmonization and hopes that the IEC TC–76 will follow the agency's lead in this area.

5. Four comments stated that it would be helpful to clarify the amendment regarding relaxation of the laser radiation levels for which the requirements of § 1040.10(f)(2) for safety interlocks are applicable. These comments requested that FDA clarify that the relaxation discussed with regard to ''radiation emitted directly through the opening created by removal or displacement of the interlocked portion of the protective housing'' refers only to Class 3A radiation that is ''emitted out, not just any radiation level.''

FDA agrees with this comment and has inserted an explanatory note in the performance requirement for protective housing.

6. Five comments noted that the proposed interlock requirement (§ 1040.10(f)(2)) exceeds the requirements in Amendment 2 to IEC 825. One comment noted that safety interlocks are not now required by IEC 825 on Class 4 lasers and suggested a requirement that the lids of laser boxes be interlocked so that the laser turns off when the lid is lifted, or a requirement that the laser beam be fully enclosed within the box, inside a cover which is either interlocked itself or that requires a tool for removal.

FDA disagrees with this comment and notes that this performance requirement was made identical to that in the current CDRH standard in the amendments of the IEC standard that were approved in 1993. FDA has always maintained that interlock protection during operation or maintenance that entails human access to hazardous levels of laser radiation is equally appropriate for all classes of laser products.

7. Four comments noted that the proposed amendment of § 1040.10(f)(5) to require ''visible indications of actual emission from remote laser apertures of Class 3B and 4 laser systems'' exceeds the requirements of the IEC amendments, which only require such indications when the aperture could be emitting energy. The comments expressed concern that the proposed amendment, as worded, would be difficult to implement and may not provide additional safety for the user. FDA has considered these comments and decided that the proposed amendment would provide additional safety for the user and that any difficulty in implementation would be outweighed by the increase in safety. The proposed change addresses concern about some industrial workstations where the laser aperture is located at a considerable distance from either the laser or the control station. The concern is even greater for those situations in which the output of a single high power laser is shared by a number of workstations. The proposed requirements are in agreement with those under consideration by the IEC TC–76.

8. Several comments addressed the proposed amendments to warning labels, signal words, and labels for noninterlocked and defeatably interlocked protective housings. These comments are as follows:

A. Acceptance of IEC Labels

Five comments believed that the acceptance of IEC labels will ease the burden on manufacturers. Several of these comments expressed concern, however, that the differences in measurement criteria for classification between the IEC and FDA standards may cause problems and confusion. The comments noted that these problems might be addressed in the third set of amendments to the IEC standard.

B. Signal Words

One comment disagreed with eliminating the signal words ''CAUTION'' and ''DANGER'' because U.S. consumers are accustomed to the type of markings that include a signal word. The use of signal words resulted from consensus agreements between consumer and legal interests in the United States a number of years ago, and the standard 3-part marking specified in most U.S. product safety standards, which are ANSI approved, requires the use of a signal word.

C. Permission of the Word ''CAUTION'' in Place of the Word ''DANGER''

Three comments that agreed with the proposed amendment to § 1040.10(g)(6) permitting the word ''CAUTION'' in place of the word ''DANGER'' believed that this amendment should also apply to § 1040.10(g)(7).

D. Proposed Simplification

Four comments agreed with the proposed simplification of the requirements in § 1040.10(g)(6) and (g)(7) applicable to labels for noninterlocked and defeatably interlocked protective housings.

FDA is in general agreement with comment 8.A of section III of this document. Although it is true that differences in measurement criteria will cause problems and confusion for a small number of products, FDA believes that the disadvantages of adopting the present measurement criteria of IEC 825–1 outweigh the disadvantages of having different FDA and IEC criteria.

In response to comment 8.B of section III of this document, FDA believes that the benefit resulting from the use of ''CAUTION'' or ''DANGER'' is outweighed, in this case, by that of averting noncompliance through harmonized requirements.

FDA agrees with comment 8.C of section III of this document as it applies to Class 2 and certain Class 3A accessible laser radiation and collateral radiation. Proposed § 1040.10(g)(6) and (g)(7) permit use of the word ''CAUTION'' on labels for the protective housing on products emitting these levels of radiation.

Proposed § 1040.10(g)(6) and (g)(7) are simplified in accordance with the NOI and with comment 8.D of section III of this document.

9. One comment requested clarification of the proposed amendment to § 1040.11(a) requiring optical or electrical monitoring of the operation of lasers in Class 3B and 4 medical laser products. The proposed amendment states that ''an electrical or optical quantity that is directly related to the laser or LED level generated shall be continually monitored during operation.'' The comment noted that for very low repetition rate pulsed laser systems, the energy is usually measured before a procedure begins or between patient exposures. According to this comment, if an additional means of monitoring is required beyond the level of normal compliance, the ''additional means'' would be a ''significant engineering feat.'' This is because ''real-time'' monitoring of the pulsed energy during an actual treatment pulse requires an instantaneous shuttering or shutoff of the laser pulse while the specified energy level is reached. FDA believes that monitoring the voltage of a charged capacitor could satisfy this requirement for a pulsed laser system. The comment concluded that the cost of new pulsed laser systems would be increased substantially if this engineering change were required for new or existing laser systems.

FDA agrees with this comment and has clarified its intent in proposed § 1040.11(a). The item was intended to harmonize with the requirements of IEC 601–2–22 for medical laser and LED products. The present standard requires that Class 3B and 4 medical laser products incorporate a means of optical measurement of the level of laser radiation intended to be incident upon the target tissue. FDA has determined that this requirement can be met by a measurement at a location within the product or prior to emission from the distal aperture. IEC 601–2–22 addresses the same intent by imposing an accuracy specification relative to the preset or selected level. IEC 601–2–22 further requires that the operation of the laser be monitored electrically or optically, that there be an alarm if the actual monitored value differs by more than ±20 percent from the preset value, and that the user instructions specify how and when to actually measure the delivered output. Proposed § 1040.11(a) adopts these requirements.

10. One comment requested that a section be included in the amendment that certain low-power laser products be exempt from reporting. This section would condense and clarify provisions set forth in exemptions granted by Laser Notices 36, 41, and 42 and other notices as applicable. The author of the comment believes that inclusion of such a section would make this information available to the broad audience, and reduce misunderstandings associated with the administration of the regulation.

FDA agrees with this comment and believes the question has already been addressed in the amendments to part 1002 (21 CFR part 1002) published in the **Federal Register** of September 19, 1995 (60 FR 48374).

11. One comment believed that the lasers in compact disk (CD) players should be exempt from FDA regulation and should only be subject to general safety certification (UL, CSA, etc.)

FDA believes that the amendments to part 1002 have addressed this concern, but notes that the lasers themselves that are in CD players are generally Class 3B. However, when the laser is incorporated into a cell with a focusing lens, this assembly becomes the smallest component that is replaceable in service and is Class 1. Because of the low cost of such components, it is unlikely that any individual or firm would be motivated to disassemble the components and then to attempt to cause them to emit. FDA has determined that the level of laser radiation that could be accessible during service may be considered to be the maximum level accessible from the smallest replaceable component.

12. In addition, FDA has recently received inquiries, suggestions, and one trade complaint concerning the interpretation of § 1040.10(h)(2)(ii), which requires manufacturers of laser products to provide adequate instructional information to servicers and others upon request. Although the correspondence does not directly relate to the advanced notice of proposed rulemaking, the agency believes this proposal is an appropriate forum for presenting its construction of the current regulation and inviting comment from interested persons.

The correspondence FDA has received has reflected disagreement between manufacturers and independent servicers of laser products about whether the regulation authorizes manufacturers to interpret ''adequate'' to include training provided by the manufacturer. The agency believes that it is appropriate for the manufacturer to decide, in the first instance, what constitutes ''adequate'' servicing instructions. If the agency learns, however, through the inspection of laser

manufacturing facilities or otherwise, that manufacturers are using the requirement of ''adequate'' as a pretext for making the provision of servicing instructions contingent upon costly or burdensome training, FDA will deem the manufacturer's product to be noncompliant with the laser performance standard and will take appropriate regulatory action.

IV. Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 1 year after the date of publication of the final rule in the **Federal Register**.

V. Environmental Impact

The agency has determined under 21 CFR 25.34(c) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

FDA has examined the impact of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Regulatory Fairness Act of 1966 (Pub. L. 104–121)), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule in many instances decreases the regulatory burden from that imposed by the current regulations and increases the level of consistency between Federal law and international law to which small entities may be subject, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. In addition, this proposed rule will not impose costs of $100 million or more in either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act is not required.

VII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The burden hours required for § 1040.10(a)(4)(i), (h)(1)(i) through (h)(1)(vi), (h)(2)(i) and (h)(2)(ii), (i), and § 1040.11(a)(2)(iv) are reported and approved under OMB control number 0910–0213.

VIII. Comments

Interested persons may, on or before June 22, 1999, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 1010

Administrative practice and procedures, Electronic products, Exports, Radiation protection.

21 CFR Part 1040

Electronic products, Labeling, Lasers, Medical devices, Radiation protection, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 1010 and 1040 be amended as follows:

PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

1. The authority citation for 21 CFR part 1010 is revised to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360e–360j, 360hh–360ss, 371, 381.

2. Section 1010.2 is amended by revising paragraph (d) to read as follows:

§ 1010.2 Certification.

* * * * *

(d) In the case of products for which it is not feasible to certify in accordance with paragraph (b) of this section, upon application by the manufacturer or upon his or her initiative, the Director, Office of Compliance, Center for Devices and Radiological Health, may approve an alternate means by which such certification may be provided.

3. Section 1010.3 is amended by revising paragraph (b) to read as follows:

§ 1010.3 Identification.

* * * * *

(b) In the case of products for which it is not feasible to affix identification labeling in accordance with paragraph (a) of this section, upon application by the manufacturer or upon his or her initiative, the Director, Office of Compliance, Center for Devices and Radiological Health, may approve an alternate means by which such identification may be provided.

* * * * *

PART 1040—PERFORMANCE STANDARDS FOR LIGHT–EMITTING PRODUCTS

4. The authority citation for 21 CFR part 1040 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360e–360j, 371, 381; 42 U.S.C. 263b–263n.

5. Section 1040.10 is revised to read as follows:

§ 1040.10 Laser products.

(a) *Applicability*. The provisions of this section and § 1040.11, as amended, are applicable as specified to all laser products manufactured or assembled after (date 1 year after date of publication in the **Federal Register** of any final rule that issues based on this proposed rule), except when:

(1) Such a laser cannot under any conditions of operation, maintenance, service, or single failure emit radiation in excess of the accessible emission limits of a Class 1 laser product, or

(2) Such a laser is sold to a manufacturer of an electronic product for use as a component (or replacement) in such electronic product, or

(3) Such a laser is sold by or for a manufacturer of an electronic product for use as a component (or replacement) in such electronic product, provided that such laser:

(i) Is accompanied by a general warning notice that adequate instructions for the safe installation of the product are provided in servicing information available from the complete product manufacturer under paragraph (h)(2)(ii) of this section, and should be followed,

(ii) Is labeled with a statement that it is designated for use solely as a component of such electronic product and therefore is not required to comply with the appropriate requirements of this section and § 1040.11 for complete laser products, and

(iii) Is not a removable laser system as described in paragraph (c)(2) of this section; and

(4) The manufacturer of such a laser product, if manufactured after August 20, 1986,

(i) Registers and provides a listing by type of such laser products manufactured that includes the product name, model number, and laser medium or emitted wavelength(s). The registration and listing shall include the name and address of the manufacturer and shall be submitted to the Director, Office of Compliance (HFZ–342), Center for Devices and Radiological Health, 2098 Gaither Rd., Rockville, MD 20850; and

(ii) Maintains and allows access to any sales, shipping, or distribution records that identify the purchaser of such a laser product by name and address, the product by type, the number of units sold, and the date of sale (shipment). These records shall be maintained and made available as specified in § 1002.31 of this chapter.

(b) *Definitions.* As used in this section and § 1040.11, the following definitions apply:

(1) *Accessible emission level* means the magnitude of accessible laser or collateral radiation of a specific wavelength and emission duration at a particular point as measured according to paragraph (e) of this section. Accessible laser or collateral radiation is radiation to which human access is possible.

(2) *Accessible emission limit* means the maximum accessible emission level permitted within a particular class as set forth in paragraphs (c) and (d) of this section when measured according to paragraph (e) of this section.

(3) *Aperture* means any opening in the protective housing or other enclosure of a laser product through which laser or collateral radiation is emitted, thereby allowing human access to such radiation.

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

(5) *Class 1 laser* means any laser that does not permit access during the operation to levels of laser radiation in excess of the accessible emission limits contained in Table 1 of paragraph (d) of this section.[1]

(6) *Class 2 laser* means any laser that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits contained in Table 1 in paragraph (d) of this section, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in Table 2 of paragraph (d) of this section.[2]

(7) *Class 3A laser* means any laser that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits contained in Table 2 of paragraph (d) of this section, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in Table 3 of paragraph (d) of this section.[3]

(8) *Class 3B laser product* means any laser product that permits human access during operation to levels of laser radiation in excess of the accessible emission limits of Table 3 of paragraph (d) of this section, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in Table 4 of paragraph (d) of this section.[4]

(9) *Class 3 laser product* means any Class 3A or Class 3B laser product.

(10) *Class 4 laser product* means any laser product that permits human access during operation to levels of laser radiation in excess of the accessible emission limits contained in Table 4 of paragraph (d) of this section.[5]

(11) *Collateral radiation* means any electronic product radiation, except laser radiation, emitted by a laser product as a result of the operation of the laser(s) or any component of the laser product that is physically necessary for the operation of the laser(s).

(12) *Demonstration laser product* means any laser product manufactured, designed, intended, or promoted for purposes of demonstration, entertainment, advertising display, or artistic composition. The term ''demonstration laser product'' does not apply to laser products which are not manufactured, designed, intended, or promoted for such purposes, even though they may be used for those purposes or are intended to demonstrate other applications.

(13) *Emission duration* means the temporal duration of a pulse, a series of pulses, or continuous operation, expressed in seconds, during which human access to laser or collateral radiation could be possible as a result of operation, maintenance, or service of a laser product.

(14) *Human access* means the capacity to intercept laser or collateral radiation by any part of the human body. For laser products that contain Class 3B or 4 levels of laser radiation, ''human access'' also means access to laser radiation that can be reflected directly onto any part of the human body by any single introduced flat surface from the interior of the product through any opening in the protective housing of the product.

(15) *Invisible radiation* means laser or collateral radiation having wavelengths of equal to or greater than 180 nm but less than or equal to 400 nm or greater than 700 nm but less than or equal to 1,000,000 nm (1 millimeter).

(16) *Irradiance* means the time-averaged radiant power incident on an element of a surface divided by the area of that element, expressed in watts per square centimeter.

(17) *Laser* means any device that can be made to produce or amplify electromagnetic radiation at wavelengths greater than 180 nm but less than or equal to 1,000,000 nm (1 millimeter) primarily by the process of controlled stimulated emission.

(18) *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.

(19) *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 that is intended for use as a component of an electronic product shall itself be considered a laser product.

(20) *Laser radiation* means all electromagnetic radiation emitted by a laser product within the spectral range specified in paragraph (b)(17) of this section that is produced as a result of controlled stimulated emission or that is detectable with radiation so produced through the appropriate aperture stop as

[1] Class 1 levels of laser or radiation are not considered to be hazardous.

[2] Class 2 levels of laser radiation are considered to be a chronic viewing hazard.

[3] Class 3A levels of laser radiation are considered to be either an acute viewing hazard at visible or near-infrared (700 to 1,400 nanometers (nm)) wavelengths if viewed directly with optical instruments, or a nominal hazard at wavelengths outside these ranges.

[4] Class 3B levels of laser radiation are considered to be an acute hazard to the skin and eyes from direct radiation.

[5] Class 4 levels of laser radiation are considered to be an acute hazard to the skin and eyes from direct and scattered radiation.

specified in paragraph (e) of this section.

(21) *Laser system* means a laser in combination with an appropriate laser energy source with or without additional incorporated components. See paragraph (c)(2) of this section for an explanation of the term ''removable laser system.''

(22) *Maintenance* means performance of those adjustments or procedures specified in user information provided by the manufacturer with the laser product which are to be performed by the user for the purpose of assuring the intended performance of the product. It does not include operation or service as defined in paragraphs (b)(27) and (b)(37) of this section.

(23) *Maximum output* means the maximum radiant power and, where applicable, the maximum radiant energy per pulse of accessible laser radiation emitted by a laser product during operation, as determined under paragraph (e) of this section.

(24) *Maximum angular subtense* means the value of angular subtense of the apparent source above which the AEL's are independent of the source size (α_{max} = 0.1 rad (100 mrad)).

(25) *Medical laser* means any laser product which is a medical device as defined in 21 U.S.C. 321(h) and is manufactured, designed, intended, or promoted for in vivo laser irradiation of any part of the human body for the purpose of:

(i) Diagnosis, surgery, or therapy; or

(ii) Relative positioning of the human body.

(26) *Minimum angular subtense* means the value of angular subtense of the apparent source above which the source is considered to be an extended source. Maximum permissible exposures (MPE's) and AEL's are independent of source size for angles less than the minimum angular subtense (α_{min}).

α_{min} = 0.0015 rad $t \leq 0.7s$

$0.002t^{3/4}$ rad $0.7s \leq t \leq 10s$

0.01rad $t \leq 10s$

(27) *Operation* means the performance of the laser product over the full range of its functions. It does not include maintenance or service as defined in paragraphs (b)(22) and (b)(37) of this section.

(28) *Protective housing* means those portions of a laser product which are designed to prevent human access to laser or collateral radiation in excess of the prescribed accessible emission limits under conditions specified in this section and in § 1040.11.

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

(30) *Radiant energy* means energy emitted, transferred or received in the form of radiation, expressed in joules (J).

(31) *Radiant exposure* means the radiant energy incident on an element of a surface divided by the area of the element, expressed in joules per square centimeter (Jcm^{-2}).

(32) *Radiant power* means time-averaged power emitted, transferred or received in the form of radiation, expressed in watts (W).

(33) *Remote interlock connector* means an electrical connector which permits the connection of external remote interlocks.

(34) *Safety interlock* means a device associated with the protective housing of a laser product to prevent human access to excessive radiation in accordance with paragraph (f)(2) of this section.

(35) *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).

(36) *Scanned laser radiation* means laser radiation having a time-varying direction, origin or pattern of propagation with respect to a stationary frame of reference.

(37) *Service* means the performance of those procedures or adjustments described in the manufacturer's service instructions which may affect any aspect of the product's performance for which this section and § 1040.11 have applicable requirements. It does not include maintenance or operation as defined in paragraphs (b)(22) and (b)(27) of this section.

(38) *Surveying, leveling, or alignment laser product* means a laser product manufactured, designed, intended, or promoted for one or more of the following uses:

(i) Determining and delineating the form, extent, or position of a point, body, or area by taking angular measurement;

(ii) Positioning or adjusting parts in proper relation to one another; and

(iii) Defining a plane, level, elevation, or straight line.

(39) *Visible radiation* means laser or collateral radiation having wavelengths of greater than 400 nm but less than or equal to 700 nm.

(40) *Warning logotype* means a logotype as illustrated in either Figure 1 or Figure 2 of paragraph (g) of this section.

(41) *Wavelength* means the propagation wavelength in air of electromagnetic radiation.

(c) *Classification of laser*—(1) *All laser products.* Each laser shall be classified in Class 1, 2, 3A, 3B, or 4 in accordance with definitions set forth in paragraphs (b)(5) through (b)(10) of this section. The product classification shall be based on the highest accessible emission level(s) of laser radiation to which human access is possible during operation in accordance with paragraphs (d), (e), and (f)(1) of this section.

(2) *Removable laser systems.* Any laser system that is incorporated into a laser product subject to the requirements of this section and that is capable, without modification, of producing laser radiation when removed from such laser product, shall itself be considered a laser product and shall be separately subject to the applicable requirements in this subchapter for laser products of its class. It shall be classified on the basis of the accessible emission level of laser radiation the system is capable of producing when so removed.

(d) *Accessible emission limits.* Accessible emission limits for laser radiation in each class are specified in Tables 1, 2, 3, and 4 of this paragraph. Accessible emission limits for collateral radiation are specified in Table 7 of this paragraph.

NOTE APPLICABLE TO TABLES 1, 2, 3, 4, AND 6

The variable t in the expressions of emission limits is the magnitude of the sampling interval in units of seconds.

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Table 1 - Accessible emission limits for Class 1 laser products

Emission Duration t (s) / Wavelength λ	$< 10^{-9}$	10^{-9} to 10^{-7}	10^{-7} to 1.8×10^{-5}	1.8×10^{-5} to 5×10^{-5}	5×10^{-7} to 1×10^{-3}	1×10^{-3} to 3	3 to 10	10 to 10^{3}	10^{3} to 10^{4}	10^{4} to 3×10^{4}
180 to 302.5	2.4×10^{4} W	2.4×10^{-5} J								
302.5 to 315		$7.9\times10^{-7}C_1$ J ($t<T_1$)						$7.9\times10^{-7}C_2$ J ($t>T_1$)	$7.9\times10^{-7}C_2$ J	
315 to 400		$7.9\times10^{-7}C_1$ J							7.9×10^{-3} J	7.9×10^{-6} W
400 to 550	$200C_6$ W	$2\times10^{-7}C_6$ J		$7\times10^{-4}t^{0.75}C_6$ J					$3.9\times10^{-3}C_6$ J	$3.9\times10^{-7}C_6$ W
550 to 700								($t<T_2$) $7\times10^{-4}t^{0.75}$ J	($t>T_2$) $3.9\times10^{-3}C_3C_6$ J	$3.9\times10^{-7}C_3C_6$ W
700 to 1,050	200 C_4C_6 W	$2\times10^{-7}C_4C_6$ J		$7\times10^{-4}t^{0.75}C_4C_6$ J					$1.2\times10^{-4}C_4C_6$ W	
1,050 to 1,400	$3\times10^{3}C_6C_7$ W	$2\times10^{-6}C_6C_7$ J			$3.5\times10^{-3}t^{0.75}C_6C_7$ J				$6\times10^{-4}C_6C_7$ W	
1,400 to 1,500	8×10^{5} W	8×10^{-4} J					$4.4\times10^{-3}t^{0.25}$ J	$5.4\times10^{-2}t^{0.25}$ J	10^{-2} W	
1,500 to 1,800	8×10^{6} W	8×10^{-3} J						0.1 J		
1,800 to 2,600	8×10^{5} W	8×10^{-4} J					$4.4\times10^{-3}t^{0.25}$ J	$5.4\times10^{-2}t^{0.25}$ J		
2,600 to 4,000	8×10^{4} W	8×10^{-5} J	$4.4\times10^{-3}t^{0.25}$ J							
4,000 to 10^{6}	10^{7} W•cm^{-2}	10^{-2} J•cm^{-2}	$0.56\times10^{1}t^{0.25}$ J•cm^{-2}						0.1 W•cm^{-2}	

For correction factors and units, see table 5.

Table 2 - Accessible emission limits for Class 2 laser products

Wavelength λ nm	Emission duration t s	Class 2 AEL
400 to 700	t = < 0.25	Same as Class 1 AEL
	t = > 0.25	$C_6 \times 10^{-3}$ W*

* For correction factors and units see Table 6

Table 3 - Accessible emission limits for Class 3A laser products

Wavelength λ \ Emission Duration t (s)	$<10^{-9}$	10^{-9} to 10^{-7}	10^{-7} to 1.8×10^{-5}	1.8×10^{-5} to 5×10^{-5}	5×10^{-5} to 1×10^{-3}	1×10^{-3} to 0.25	0.25 to 3	3 to 10	10 to 10^{3}	10^{3} to 3×10^{4}
180 to 302.5	1.2×10^{5} W and 3×10^{6} W•cm^{-2}	1.2×10^{-4} J and 3×10^{-3} J•cm^{-2}								
302.5 to 315		$4\times10^{-6}C_1$ J and $10^{-4}C_1$ J•cm^{-2} ($t<T_1$)							$4\times10^{-6}C_2$ J and $10^{-4}C_2$ J•cm^{-2}	$4\times10^{-6}C_2$ J•cm^{-2} ($t>T_1$)
315 to 400		$4\times10^{-6}C_1$ J and $10^{-4}C_1$ J•cm^{-2}							4×10^{-2} J and 1 J•m^{-2}	4×10^{-5} W and 10^{-3} W•cm^{-2}
400 to 700	1,000 C_6 W and 500 C_6 W•cm^{-2}	$10^{-6}C_6$ J and $0.5\times10^{-7}C_6$ J•cm^{-2}	$3.5\times10^{-3}t^{0.75}C_6$ J and $1.8\times10^{-3}C_6$ J•cm^{-2}				$5\times10^{-3}C_6$ W and 2.5×10^{-3} W•cm^{-2}			
700 to 1,050	1,000C_4C_6 W and 500C_4C_6 W•cm^{-2}	$10^{-6}C_4C_6$ J and $5\times10^{-7}C_4C_6$ J•cm^{-2}	$3.5\times10^{-3}t^{0.75}C_4C_6$ J and $1.8\times10^{-3}C_4C_6$ J•cm^{-2}							$6\times10^{-4}C_4C_6$ W and $3.2\times10^{-4}C_4C_6$ W•cm^{-2}
1,050 to 1,400	$10^{4}C_6C_7$ W and $5\times10^{3}C_6C_7$ W•cm^{-2}	$10^{-5}C_6C_7$ J and $5\times10^{-6}C_6C_7$ J•cm^{-2}	$1.8\times10^{-2}t^{0.75}C_6C_7$ J and $9\times10^{-3}t^{0.75}C_6C_7$ J•cm^{-2}							$3\times10^{-3}C_6C_7$ W and $1.6\times10^{-2}C_6C_7$ W•cm^{-2}
1,400 to 1,500	4×10^{6} W and 10^{8} W•cm^{-2}	4×10^{-3} J and 0.1 J•cm^{-2}				$2.2\times10^{-2}t^{0.25}$ J and $0.56t^{0.25}$ J•cm^{-2}		$0.27t^{0.25}$ J and $0.56t^{0.25}$ J•cm^{-2}	5×10^{-2} W and 0.1 W•cm^{-2}	
1,500 to 1,800	4×10^{7} W and 10^{9} W•cm^{-2}	4×10^{-2} J and 1 J•cm^{-2}						0.5 J and 1 J•cm^{-2}		
1,800 to 2,600	4×10^{6} W and 10^{8} W•cm^{-2}	4×10^{-3} J and 0.1 J•cm^{-2}				$2.2\times10^{-2}t^{0.25}$ J and $0.56t^{0.25}$ J•cm^{-2}		$0.27t^{0.25}$ J and $0.56t^{0.25}$ J•cm^{-2}		
2,600 to 4,000	4×10^{5} W and 10^{7} W•cm^{-2}	4×10^{-4} J and 0.01 J•cm^{-2}	$2.2\times10^{-2}t^{0.25}$ J and $0.56t^{0.25}$ J•cm^{-2}							
4,000 to 10^{6}	10^{7} W•cm^{-2}	0.01 J•cm^{-2}	$0.56t^{0.25}$ J•cm^{-2}						0.1 W•cm^{-2}	

For correction factors and units, see table 5.

Table 4 - Accessible emission limits for Class 3B laser products

Emission duration t s / Wavelength λ nm	$< 10^{-9}$	10^{-9} to 0.25	0.25 to $3x10^{4}$
180 to 302.5	$3.8x10^{5}$ W	$3.8x10^{-4}$ J	$1.5x10^{-3}$ W
302.5 to 315	$1.25x10^{4}C_2$ W	$1.25x10^{-5}C_2$ J	$5x10^{-5}C_2$ W
315 to 400	$1.25x10^{8}$ W	0.125 J	0.5 W
400 to 700	$3x10^{7}$ W	0.03 J for t< 0.06 s 0.5 W for t ≥ 0.06 s	0.5 W
700 tp 1,050	$3x10^{7}C_4$W	$0.03C_4$ J for t < $0.06C_4$ s 0.5 W for t ≥ $0.06C_4$ s	0.5 W
1,050 to 1,400	$1.5x10^{8}$ W	0.15 J	0.5 W
1,400 to 10^{6}	$1.25x10^{8}$ W	0.125 J	0.5 W
For correction factors and units, see Table 5			

Table 5 - Notes to Tables 1 to 4

Parameter	Spectral Range nm
$C_1 = 5.6 \times 10^3 t^{0.25}$	302.5 to 400
$T_1 = 10^{0.8(\lambda-295)} \times 10^{-15} s$	302.5 to 315
$C_2 = 10^{0.2(\lambda-295)}$	302.5 to 315
$T_2 = 10 \times 10^{0.02(\lambda-550)} s$	550 to 700
$C_3 = 10^{0.015(\lambda-550)}$	550 to 700
$C_4 = 10^{0.002(\lambda-700)}$	700 to 1,050
$C_5 = N^{-1/4}$ (for pulse durations < 0.25 s)	400 to 10^6
$C_6 = 1$ (for $\alpha \leq \alpha_{min}$)	400 to 1,400
$C_6 = \alpha/\alpha_{min}$ for $\alpha_{min} < \alpha \leq \alpha_{max}$	400 to 1,400
$C_6 = \alpha_{max}/\alpha_{min}$ for $\alpha > \alpha_{max}$	400 to 1,400
$C_7 = 1$	1,050 to 1,150
$C_7 = 10^{0.018(\lambda-1150)}$	1,150 to 1,200
$C_7 = 8$	1,200 to 1,400

Table 6 - Apertures for the Determination of Irradiance or Radiant Exposure

Spectral region nm	Duration s	Aperture diameter for	
		Eye mm	Skin mm
180 to 400	$t \leq 3X10^4$	1	1
400 to 1,400	$t \leq 3X10^4$	7	3.5
1,400 to 10^5	$t \leq 3$	1	1
1,400 to 10^5	$t > 3$	3.5	3.5
10^5 to 10^6	$t \leq 3X10^4$	11	11

TABLE 7

ACCESSIBLE EMISSION LIMITS FOR COLLATERAL

RADIATION FROM LASER OR LED PRODUCTS

1. Accessible emission limits for collateral radiation having wavelengths greater than 180 nanometers but less than or equal to 1.0×10^6 nanometers are identical to the accessible emission limits for Class 1 laser or LED radiation.
i. In the wavelength range of less than or equal to 400 nanometers, for all emission durations;
ii. In the wavelength range of greater than 400 nanometers, for all emission durations less than or equal to 1×10^3 seconds, and when applicable under paragraph (f)(8) of this section, for all emission durations.
2. Accessible emission limit for collateral radiation within the x-ray range of wavelengths is 0.5 milliroentgen in an hour, averaged over a cross-section parallel to the external surface of the product, having an area of 10 square centimeters with no dimension greater than 5 centimeters.

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(1) *Beam of a single wavelength.* Laser or collateral radiation single wavelength exceeds the accessible emission limits of a class if its accessible emission level is greater than the accessible emission limit of that class within any of the ranges of emission duration specified in Tables 1, 2, 3, and 4 of this paragraph.

(2) *Beam of multiple wavelengths in same range.* Laser or collateral radiation having two or more wavelengths within any one of the wavelength ranges specified in Tables 1, 2, 3, and 4 of this paragraph exceeds the accessible emission limits of a class if the sum of the ratios of the accessible emission level to the corresponding accessible emission limit at each such wavelength is greater than unity for that combination of emission duration and wavelength distribution which results in the maximum sum.

(3) *Beam with multiple wavelengths in different ranges.* Laser or collateral radiation having wavelengths within two or more of the wavelength ranges specified in Tables 1, 2, 3, and 4 of this paragraph exceeds the accessible emission limits of a class if it exceeds the applicable limits within any one of those wavelength ranges. This determination is made for each wavelength range in accordance with paragraph (d)(1) or (d)(2) of this section.

(4) *Maximum sampling interval.* Three maximum sampling intervals are used for the classification of laser. Which interval applies depends upon the accessible emission level of the product and whether viewing the radiation is an inherent feature of the product. The accessible emission limits of a class are exceeded, if exceeded within any emission duration less than or equal to the following maximum sampling intervals:

(i) 30,000 seconds for wavelengths less than or equal to 400 nm and for wavelengths greater than 400 nm if intentional viewing of the radiation is inherent in the design or function of the product, or

(ii) 100 seconds for wavelengths greater than 400 nm unless intentional viewing of the radiation is inherent in the design or function of the product.

(iii) 0.25 seconds for Class 2 and for Class 3A laser radiation within the wavelength range from 400 to 700 nm.

(5) *Repetitively pulsed or scanned laser radiation.* For repetitively pulsed or scanned laser radiation in the wavelength range from 400 nm to 1,000,000 nm (1 millimeter) the AEL is determined by using the most restrictive of requirements in paragraphs (d)(4)(i), (d)(4)(ii), and (d)(4)(iii) of this section as appropriate. For wavelengths less than 400 nm, the AEL is determined by using the most restrictive of requirements in paragraphs (d)(4)(i) and (d)(4)(ii) of this section.

(i) The emission level of any single pulse within a pulse train shall not exceed the AEL for a single pulse.

(ii) The average power of a pulse train of duration t shall not exceed the power corresponding to the AEL given in Tables 1, 2, 3, and 4 of this paragraph, respectively, for a single pulse of duration t.

(iii) The emission level of any single pulse within a pulse train shall not exceed the AEL for a single pulse multiplied by the correction factor C_5:

$AEL_{train} = AEL_{single} \times C_5$

NOTE: C_5 is only applicable to pulse durations shorter than 0.25 sec. where:

AEL_{train} = AEL for any single pulse in the pulse train

AEL_{single} = AEL for a single pulse

$C_5 = N^{-1/4}$

N = number of pulses in the pulse train during the sampling interval.

NOTE: In some cases, AEL_{train} this value may fall below the AEL that would apply for continuous operation at the same peak power using the same time base. Under these circumstances, the AEL for continuous operation may be used.

(e) *Tests for determination of compliance*—(1) *Tests for certification.* Tests on which certification under

§ 1010.2 of this chapter is based shall account for all errors and statistical uncertainties in the measurement process. Because compliance with the standard is required for the useful life of a product, such tests shall also account for increases in emission and degradation in radiation safety with age.

(2) *Test conditions.* Except as provided in § 1010.13 of this chapter, tests for compliance with each of the applicable requirements of this section and § 1040.11 shall be made as appropriate during operation, maintenance, service, or single failure as follows:

(i) Under those conditions and procedures that maximize the accessible emission levels, including start-up, stabilized emission, and shut-down of the laser product; and

(ii) With all controls and adjustments listed in the operation, maintenance, and service instructions adjusted in combination to result in the maximum accessible emission level of radiation; and

(iii) At locations where human access to laser radiation is possible, e.g., if operation may require removal of portions of the protective housing and defeat of safety interlocks, measurements shall be made at points accessible in that product configuration; and

(iv) With the measuring instrument detector so positioned and so oriented with respect to the laser product as to result in the maximum detection of radiation by the instrument; and

(v) For a laser product other than a laser system, with the laser connected to that type of laser energy source that is specified as compatible by the laser product manufacturer and that produces the maximum emission level of accessible radiation from that product.

(3) *Measurement parameters.* Accessible emission levels of laser and collateral radiation shall be based upon the measurements in paragraph (e)(3)(i) of this section as appropriate, or their equivalent. For the purposes of the measurements in paragraphs (e)(3)(i)(A) through (e)(3)(i)(D), and paragraph (e)(3)(ii) of this section, the 50-millimeter aperture will be the limiting case with collimated beams, and the measurement distances referring to the apparent source are measured from the apparent source irrespective of any optical element placed between the source and the measurement aperture.

(i) Radiant power (W) or radiant energy (J) measurable under the following conditions:

(A) Within a circular aperture stop of 50-millimeter diameter placed at a distance of 2 meters from the closest point of human access. In general, the 50-millimeter aperture will be the limiting case with collimated beams, or

(B) In the wavelength range from 400 nm to 1,400 nm within a circular aperture stop of 7-millimeter diameter placed at a distance of 100 millimeters from the apparent source.

(C) For apparent sources subtending an angle (α) (measured at a minimum distance of 100 millimeters) less than α_{max} and within the wavelength range from 400 nm to 1,400 nm, within a circular aperture stop of 7-millimeter diameter positioned at a distance (r) from the source depending upon the angular subtense α (between a minimum of 1.5 mrad and a maximum of α_{max}) of the source. The distance (r) of the 7-millimeter measurement aperture from the source is determined by:

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$$r = (100\ mm)\sqrt{\frac{\alpha + 0.46\ mrad}{\alpha_{max}}}$$

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NOTE: In cases where the apparent source is recessed within the product at a distance greater than that specified in paragraph (e)(3)(i)(B) or (e)(3)(i)(C) of this section, the minimum measurement distance should be at the closest point of human access, such as the exit window or lens. This measurement is needed to determine the user information required for Class 1 laser products (see paragraph (h)(1)(vi) of this section).

(D) For wavelengths less than 400 nm and greater than 1,400 nm, within a circular aperture stop of 7-millimeter diameter (or as otherwise specified) placed at a distance of 14 millimeters from the closest point of human access.

(E) For the calculation of the AEL expressed in terms of radiant power, radiant energy, irradiance, or radiant exposure, the value of the angular subtense of a rectangular or linear source is determined by the arithmetic mean of the two angular dimensions of the source. Any angular dimension that is greater than α_{max} or less than α_{min} shall be limited to α_{max} or α_{min}, respectively, prior to calculating the mean.

(F) For scanned laser radiation, 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/second.

(ii) The irradiance (Wcm^{-2}) or radiant exposure (Jcm^{-2}) equivalent to the radiant power (W) or radiant energy (J) measurable through a circular aperture stop having a diameter as specified in Table 6 of paragraph (d) of this section shall be divided by the area of the aperture stop.

(f) *Performance requirements*—(1) *Protective housing.* Each laser product shall have a protective housing that prevents human access during operation to laser and collateral radiation that exceed the limits of Tables 1 or 7 of paragraph (d) of this section wherever and whenever such human access is not necessary for the product to perform its intended function. Wherever and whenever human access to laser radiation levels that exceed the limits of Class 1 is necessary, these levels shall not exceed the limits of the lowest class necessary to perform the intended function(s) of the product.

NOTE: If there is an opening or openings, such as for cooling, in a protective housing that encloses Class 3B or 4 levels of laser radiation, the adequacy of the protective housing shall be determined by whether the level of radiation that can be reflected out through the opening(s) by a single flat reflector exceeds the accessible emission limits of Class 1.

(2) *Safety interlocks*—(i) Each laser, regardless of its class, shall be provided with at least one safety interlock for each portion of the protective housing which is designed to be removed or

displaced during operation or maintenance, if removal or displacement of the protective housing could permit, in the absence of such interlock(s), human access to:

(A) Laser radiation in excess of the accessible emission limits of Class 3A; or

(B) Laser radiation in excess of the accessible emission limits of Class 2 to be emitted directly through the opening created by removal or displacement of the interlocked portion of the protective housing.

(ii) Each required safety interlock, unless defeated, shall prevent human access to laser radiation as described in paragraphs (f)(2)(i)(A) through (f)(2)(i)(B) of this section upon removal or displacement of such portion of the protective housing.

(iii) Either multiple safety interlocks or a means to preclude removal or displacement of the interlocked portion of the protective housing shall be provided, if failure of a single interlock would allow:

(A) Human access to a level of laser radiation in excess of the accessible emission limits of Class 3A; or

(B) Laser radiation in excess of the accessible emission limits of Class 2 to be emitted directly through the opening created by removal or displacement of the interlocked portion of the protective housing.

(iv) Laser products that incorporate safety interlocks designed to allow safety interlock defeat shall incorporate a means of visual or aural indication of interlock defeat. During interlock defeat, such indication shall be visible or audible whenever the laser product is energized, with and without the associated portion of the protective housing removed or displaced.

(v) Replacement of a removed or displaced portion of the protective housing shall not be possible while required safety interlocks are defeated.

(3) *Remote interlock connector.* Each laser system classified as a Class 3B or 4 laser product, except for Class 3B with not more than five times the AEL of Class 2 in the wavelength range of 400 to 700 nm, shall incorporate a readily available remote interlock connector having an electrical potential difference of no greater than 130 root-mean-square volts between terminals. When the terminals of the connector are not electrically joined, human access to all laser and collateral radiation from the laser product in excess of the accessible emission limits of Class 1 and Table 7 of paragraph (d) of this section shall be prevented.

(4) *Key control.* Each laser system classified as a Class 3B or 4 laser product, except for Class 3B with not more than five times the AEL of Class 2 in the wavelength range of 400 to 700 nm, shall incorporate a key-actuated master control. The key shall be removable and the laser shall not be operable when the key is removed.

(5) *Laser radiation emission indicator*—(i) Each laser system classified as a Class 3B or 4 laser product, except for Class 3B with not more than five times the AEL of Class 2 in the wavelength range of 400 to 700 nm, 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 1, and sufficiently prior to emission of such radiation to allow appropriate action to avoid exposure to the laser radiation.

(ii) For laser systems manufactured on or before August 20, 1986, 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 paragraph (f)(5)(i) of this section.

(iii) Any visible signal required by paragraph (f)(5)(i) or (f)(5)(ii) of this section shall be clearly visible through protective eyewear designed specifically for the wavelength(s) of the emitted laser radiation.

(iv) Emission indicators required by paragraph (f)(5)(i) or (f)(5)(ii) of this section shall be located so that viewing does not require human exposure to laser or collateral radiation in excess of the accessible emission limits of Class 1 and Table 7 of paragraph (d) of this section.

(6) *Beam attenuator*—(i) Each laser system classified as a Class 3B or 4 laser product, except for Class 3B with not more than five times the AEL of Class 2 in the wavelength range of 400 to 700 nm, shall be provided with one or more permanently attached means, other than laser energy source switch(es), electrical supply main connectors, or the key-actuated master control, capable of preventing access by any part of the human body to all laser and collateral radiation in excess of the accessible emission limits of Class 1 and Table 7 of paragraph (d) of this section.

(ii) Upon written application by the manufacturer or on the initiative of the Director, Office of Compliance, Center for Devices and Radiological Health, the Director may, upon determination that the configuration, design, or function of the laser product would make unnecessary compliance with the requirement in paragraph (f)(6)(i) of this section, approve alternate means to accomplish the radiation protection provided by the beam attenuator.

(7) *Location of controls.* Each Class 2, 3, or 4 laser product shall have operational and adjustment controls located so that human exposure to laser or collateral radiation in excess of the accessible emission limits of Class 1 and Table 7 of paragraph (d) of this section is unnecessary for operation or adjustment of such controls.

(8) *Viewing optics.* All viewing optics, viewports, and display screens incorporated into a laser product, regardless of its class, shall limit the levels of laser and collateral radiation accessible to the human eye by means of such viewing optics, viewports, or display screens during operation or maintenance to less than the accessible emission limits of Class 1 and Table 7 of paragraph (d) of this section. For any shutter or variable attenuator incorporated into such viewing optics, viewports, or display screens, a means shall be provided:

(i) To prevent access by the human eye to laser and collateral radiation in excess of the accessible emission limits of Class 1 and Table 7 of paragraph (d) of this section whenever the shutter is opened or the attenuator varied.

(ii) *To preclude, upon failure of such* means as required in paragraph (f)(8)(i) of this section, opening the shutter or varying the attenuator when access by the human eye is possible to laser or collateral radiation in excess of the accessible emission limits of Class 1 and Table 7 of paragraph (d) of this section.

(9) *Scanning safeguard.* Laser products that emit accessible scanned laser radiation shall not, as a result of any failure causing a change in either scan velocity or amplitude, permit human access to laser radiation in excess of the accessible emission limits of the class of the product.

(10) *Manual reset mechanism.* Each laser system manufactured after August 20, 1986, classified as a Class 4 laser shall be provided with a manual reset to enable resumption of laser radiation emission after interruption of emission caused by the use of a remote interlock or after an interruption of emission in excess of 5 seconds duration due to the unexpected loss of main electrical power.

(g) *Labeling requirements.* In addition to the requirements of §§ 1010.2 and 1010.3 of this chapter, each laser product shall be subject to the applicable labeling requirements of this paragraph. Labeling in accordance with the International Electrotechnical Commission (IEC) Document 825–1 will

satisfy the requirements of paragraphs (g)(1) through (g)(10) of this section.

(1) *Class 2 designation and warnings.* Each Class 2 laser product shall have affixed a label bearing the warning logotype A (Figure 1 in this paragraph) that includes the following wording:

[Position 1 on the logotype]

''LASER RADIATION—DO NOT STARE INTO BEAM''; and

[Position 3 on the logotype]

''CLASS 2 LASER PRODUCT''.

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WARNING LOGOTYPE A

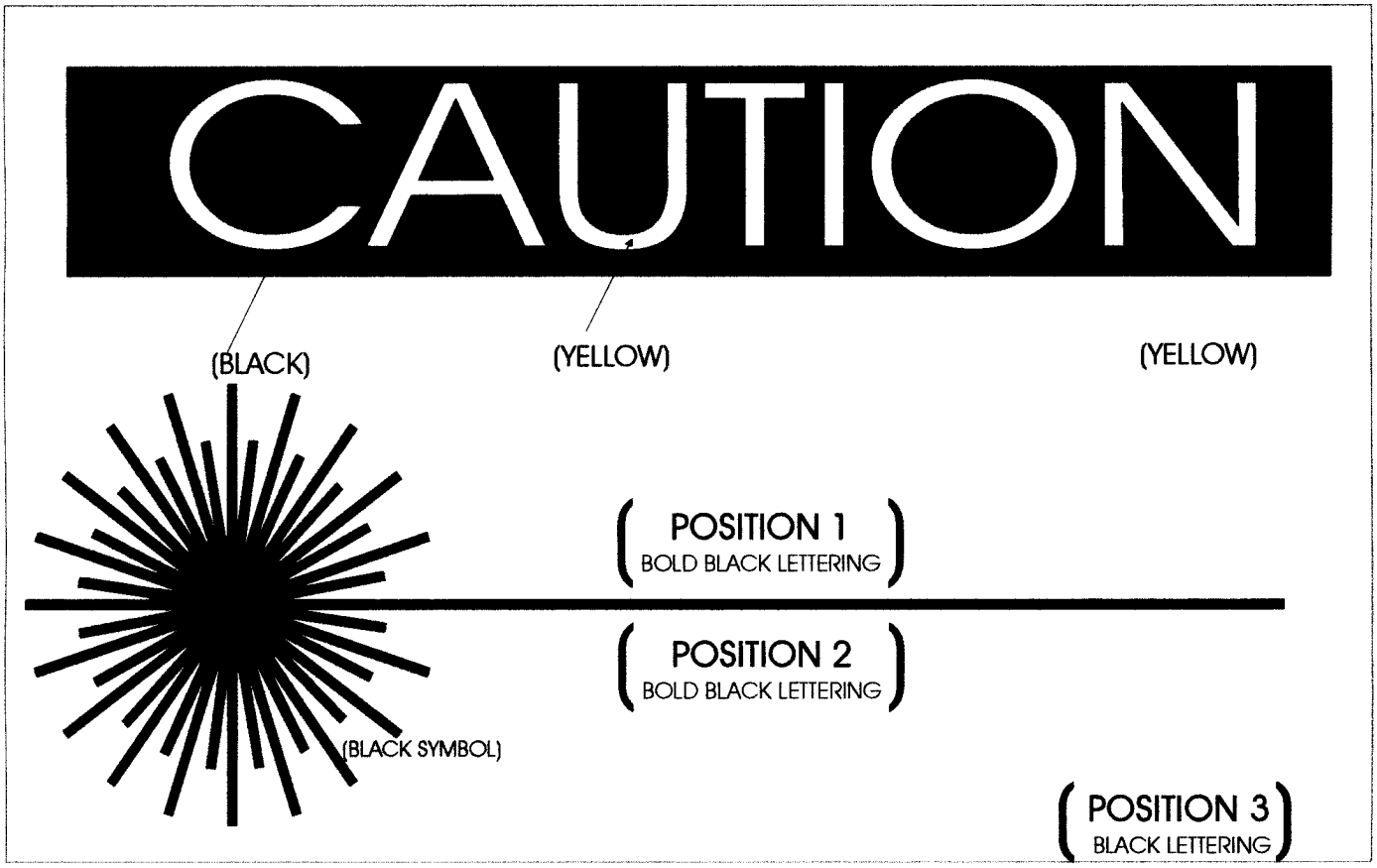

FIGURE 1

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(2) *Class 3A and 3B designations and warnings.* (i) Each Class 3 laser product that does not exceed the accessible emission limits of Table 3A shall have affixed a label bearing the warning logotype A (Figure 1 of paragraph (g)(1) of this section) that includes the following wording:

[Position 1 on the logotype]

''LASER RADIATION DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS''; and,

[Position 3 on the logotype]

''CLASS 3A LASER PRODUCT''.

(ii) Each Class 3 laser product that exceeds the accessible emission limits of Table 3A in the wavelength range of 400 to 700 nm and less than the AEL of Class 3A at other wavelengths shall have affixed a label bearing the warning logotype B (Figure 2 in this paragraph) and including the following wording:

[Position 1 on the logotype]

''LASER RADIATION AVOID DIRECT EYE EXPOSURE''; and,

[Position 3 on the logotype]

''CLASS 3B LASER PRODUCT''.

BILLING CODE 4610–01–F

WARNING LOGOTYPE B

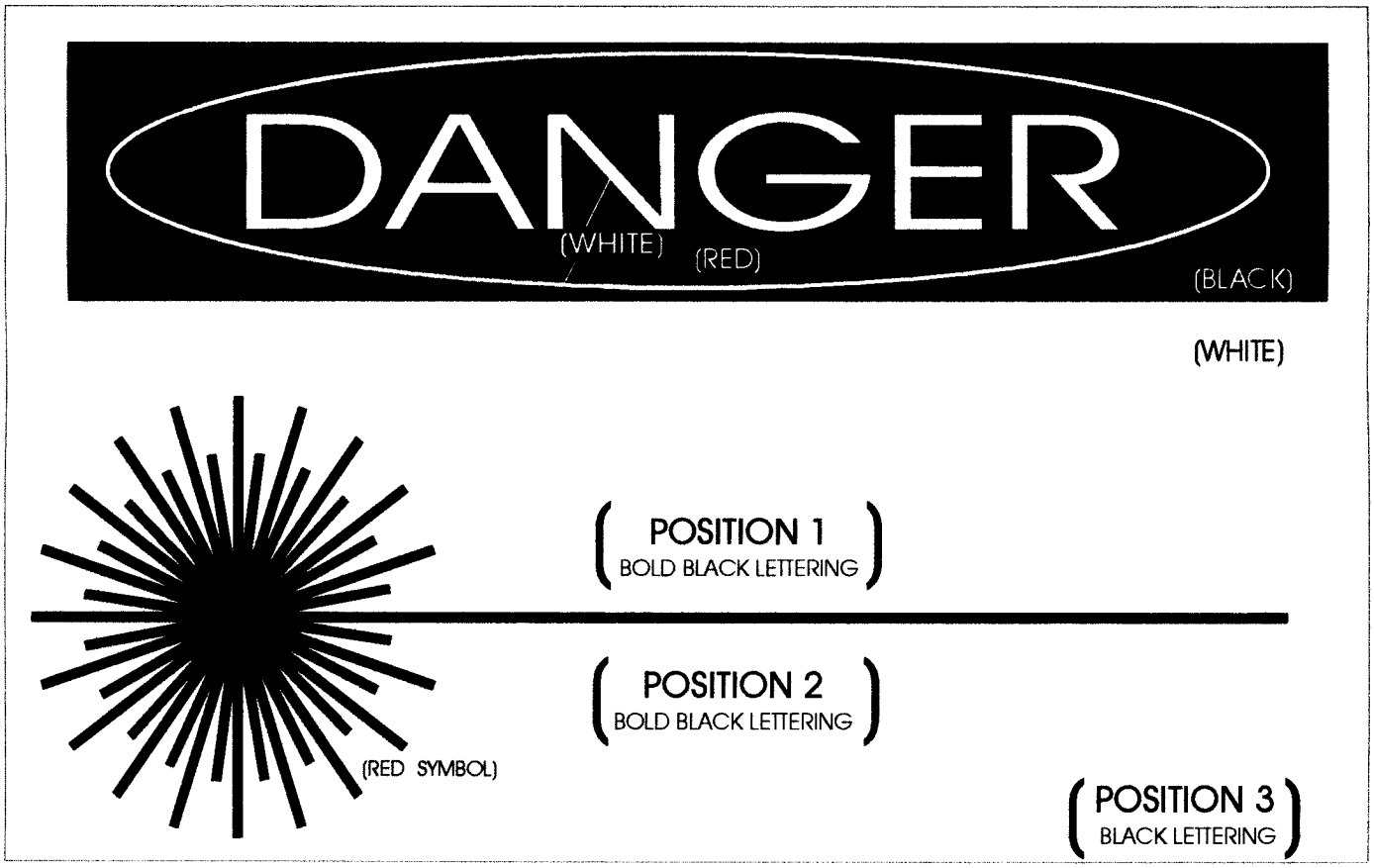

FIGURE 2

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(iii) Each Class 3B laser product except as specified in (g)(2)(ii) shall have affixed a label bearing the warning logotype B (Figure 2 of paragraph (g)(2)(ii) of this section) and including the following wording:

[Position 1 on the logotype]

''LASER RADIATION AVOID DIRECT EXPOSURE TO BEAM''; and,

[Position 3 on the logotype]

''CLASS 3B LASER PRODUCT''.

(3) *Class 4 designation and warning.* Each Class 4 laser product shall have affixed a label bearing the warning logotype B (Figure 2 of paragraph (g)(2)(ii) of this section), and including the following wording:

[Position 1 on the logotype]

''LASER RADIATION—AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION''; and,

[Position 3 on the logotype]

''CLASS 4 LASER PRODUCT''.

(4) *Radiation output information on warning logotype.* Each Class 2, 3, and 4 laser product shall state in appropriate units, at position 2 on the required warning logotype, the maximum output of laser radiation, the pulse duration when appropriate, and the laser medium or emitted wavelength(s).

(5) *Aperture label.* Each laser, except medical lasers, shall have affixed, in close proximity to each aperture through which is emitted accessible laser or collateral radiation in excess of the accessible emission limits of Class 1 and Table 7 of paragraph (d) of this section, a label or labels bearing the following wording as applicable:

(i) ''AVOID EXPOSURE—Laser radiation is emitted from this aperture,'' if the radiation emitted through such aperture is laser radiation.

(ii) ''AVOID EXPOSURE—Hazardous electromagnetic radiation is emitted from this aperture,'' if the radiation emitted through such aperture is collateral radiation described in Table 7, item 1 of paragraph (d) of this section.

(iii) ''AVOID EXPOSURE—Hazardous x-rays are emitted from this aperture,'' if the radiation emitted through such aperture is collateral radiation described in Table 7, item 2 of paragraph (d) of this section.

(6) *Labels for noninterlocked protective housings.* For each laser product, labels shall be provided for each portion of the protective housing which has no safety interlock and which is designed to be displaced or removed during operation, maintenance, or service, and thereby could permit human access to laser or collateral radiation in excess of the limits of Class 1 and Table 7 of paragraph (d) of this section. Such labels shall be visible on the protective housing prior to displacement or removal of such portion of the protective housing and visible on the product in close proximity to the opening created by removal or displacement of such portion of the protective housing, and shall include the wording:

(i) ''CAUTION—Laser radiation when open. DO NOT STARE INTO BEAM.'' for Class 2 accessible laser radiation.

(ii) ''CAUTION—Laser radiation when open. DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS.'' for Class 3A accessible laser radiation.

(iii) ''DANGER—Laser radiation when open. AVOID DIRECT EYE EXPOSURE.'' for Class 3B accessible

laser radiation with an irradiance greater than 0.0025 W/cm^{-2} and with not more than five times the AEL of Class 2 in the wavelength range of 400 to 700 nm.

(iv) ''DANGER Laser radiation when open. AVOID DIRECT EXPOSURE TO BEAM.'' for Class 3B accessible laser radiation other than that described in paragraph (g)(6)(iii) of this section.

(v) ''DANGER Laser radiation when open. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION.'' for Class 4 accessible laser radiation.

(vi) ''CAUTION Hazardous electromagnetic radiation when open.'' for collateral radiation in excess of the accessible emission limits in Table 7, item 1 of paragraph (d) of this section.

(vii) ''CAUTION Hazardous x-rays when open.'' for collateral radiation in excess of the accessible emission limits in Table 7, item 2 of paragraph (d) of this section.

(7) *Labels for defeatably interlocked protective housings.* For each laser product, labels shall be provided for each defeatably interlocked (as described in paragraph (f)(2)(iv) of this section) portion of the protective housing which is designed to be displaced or removed during operation, maintenance, or service, and which upon interlock defeat could permit human access to laser or collateral radiation in excess of the limits of Class 1 or Table 7 of paragraph (d) of this section. Such labels shall be visible on the product prior to and during interlock defeat and shall be in close proximity to the opening created by the removal or displacement of such portion of the protective housing, and shall include the wording:

(i) ''CAUTION—Laser radiation when open and interlock defeated. DO NOT STARE INTO BEAM.'' for Class 2 accessible laser radiation.

(ii) ''CAUTION—Laser radiation when open and interlock defeated. DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS.'' for Class 3A accessible laser radiation with an irradiance less than or equal to 0.0025 W/cm^{-2}.

(iii) ''DANGER Laser radiation when open and interlock defeated. AVOID DIRECT EYE EXPOSURE.'' for Class 3B accessible laser radiation with an irradiance greater than 0.0025 W/cm^{-2} and with not more than five times the AEL of Class 2 in the wavelength range of 400 to 700 nm.

(iv) ''DANGER Laser radiation when open and interlock defeated. AVOID DIRECT EXPOSURE TO BEAM.'' for Class 3B accessible laser radiation other than that described in paragraph (g)(7)(iii) of this section.

(v) ''DANGER Laser radiation when open and interlock defeated. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION.'' for Class 4 accessible laser radiation.

(vi) ''CAUTION Hazardous electromagnetic radiation when open and interlock defeated.'' for collateral radiation in excess of the accessible emission limits in Table 7 item 1 of paragraph (d) of this section.

(vii) ''CAUTION Hazardous x-rays when open and interlock defeated.'' for collateral radiation in excess of the accessible emission limits in Table 7, item 2 of paragraph (d) of this section.

(8) *Warning for visible and/or invisible radiation.* On the labels specified in this paragraph, if the laser or collateral radiation referred to is:

(i) Invisible radiation, the word ''invisible'' shall appropriately precede the word ''radiation''; or

(ii) Visible and invisible radiation, the words ''visible and invisible'' or ''visible and/or invisible'' shall appropriately precede the word ''radiation.''

(iii) Visible laser radiation only, the phrase ''laser light'' may replace the phrase ''laser radiation.''

(9) *Positioning of labels.* All labels affixed to a laser product shall be positioned so as to make unnecessary, during reading, human exposure to laser radiation in excess of the accessible emission limits of Class 1 radiation or the limits of collateral radiation established to Table 7 of paragraph (d) of this section.

(10) *Label specifications.* Labels required by this section and § 1040.11 shall be permanently affixed to, or inscribed on, the laser product, legible, and clearly visible during operation, maintenance, and service, as appropriate. Upon written application by the manufacturer, or on the initiative of the Director, Office of Compliance, Center for Devices and Radiological Health, the Director may, upon determination that the size, configuration, design, or function of the laser product would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective, approve alternate means of providing such label(s) or alternate wording for such label(s) as applicable.

(h) *Informational requirements*—(1) *User information.* Manufacturers of laser products shall provide as an integral part of any user instruction or operation manual which is regularly supplied with the product, or, if not so supplied, shall cause to be provided with each laser:

(i) Adequate instructions for assembly, operation, and maintenance, including clear warnings concerning precautions to avoid possible exposure to laser and collateral radiation in excess of the accessible emission limits in Tables 1, 2, 3, 4, and 7 of paragraph (d) of this section determined under paragraph (e) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and, if applicable, § 1040.11.

(ii) A statement of the magnitude, in appropriate units, of the pulse duration(s), maximum radiant power and, where applicable, the maximum radiant energy per pulse of the accessible laser detectable in each direction in excess of the accessible emission limits in Table 1 of paragraph (d) of this section.

(iii) Legible reproductions (color optional) of all labels and hazard warnings required by paragraph (g) of this section and, if applicable, § 1040.11, to be affixed to the laser product or provided with the laser product, including the information and warnings required for positions 1, 2, and 3 of the applicable logotype (Figure 1 of paragraph (g)(1) or Figure 2 of paragraph (g)(2)(ii) of this section). The corresponding position of each label affixed to the product shall be indicated or, if provided with the product, a statement that such labels could not be affixed to the product but were supplied with the product and a statement of the form and manner in which they were supplied shall be provided.

(iv) A listing of all controls, adjustments, and procedures for operation and maintenance, including a cautionary warning that the use of controls or adjustments or performance of procedures other than specified may result in hazardous radiation exposure.

(v) In the case of laser products other than laser systems, a statement of the compatibility requirements for a laser energy source that will assure compliance of the laser product with this section and, if applicable, § 1040.11.

(vi) For Class 1 laser products, if the output power (or energy) measured according to paragraph (e)(3)(i)(D) of this section is greater than that measured in accordance with paragraph (e)(3)(i)(A) or (e)(3)(i)(B) of this section and that level exceeds the Class 1 limit, an additional warning is required. This warning shall state that viewing the laser output with optical instruments having a magnifying power greater than

2.5 (e.g., eye loupes) may pose an eye hazard.

(2) *Purchasing and servicing information.* Manufacturers of laser products shall provide or cause to be provided:

(i) In all catalogs, specification sheets, and descriptive brochures pertaining to each laser product, a legible reproduction (color optional) of the class designation and warning required by paragraph (g) of this section to be affixed to that product, including the information required for positions 1, 2, and 3 of the applicable logotype (Figure 1 of paragraph (g)(1) or Figure 2 of paragraph (g)(2)(ii) of this section).

(ii) To servicing dealers and distributors and to others upon request, at a cost not to exceed the cost of preparation and distribution, adequate instructions for service adjustments and service procedures for each laser product model, including clear warnings and precautions to be taken to avoid possible exposure to laser and collateral radiation in excess of the accessible emission limits in Tables 1, 2, 3, 4, and 7 of paragraph (d) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and, if applicable, § 1040.11. All such service instructions shall include a listing of those controls and procedures that could be used by persons other than the manufacturers or their agents to increase accessible emission levels of radiation and a clear description of the location of displaceable portions of the protective housing that could allow human access to laser or collateral radiation in excess of the accessible emission limits in Tables 1, 2, 3, 4, and 7 of paragraph (d) of this section. The instructions shall include protective procedures for service personnel to avoid exposure to levels of laser and collateral radiation known to be hazardous for each procedure or sequence of procedures to be accomplished, and legible reproductions (color optional) of required labels and hazard warnings.

(i) *Modification of a certified product.* The modification of a laser product, previously certified under § 1010.2 of this chapter, by any person engaged in the business of manufacturing, assembling, or modifying laser products constitutes manufacturing under the Federal Food, Drug, and Cosmetic Act if the modification affects any aspect of the product's performance or intended function(s) for which this section or § 1040.11 have an applicable requirement. The person who performs such modification shall recertify and reidentify the product in accordance with the provisions of §§ 1010.2 and 1010.3 of this chapter.

5. Section 1040.11 is revised to read as follows:

§ 1040.11 Specific purpose laser products.

(a) *Medical laser products.* Each medical laser product shall comply with all of the applicable requirements of § 1040.10 for laser products of its class. In addition:

(1) A label bearing the wording: ''Laser aperture.'' shall be affixed in close proximity to each aperture through which is emitted accessible laser radiation in excess of the accessible emission limits of Class 1, and

(2) For each Class 3B or 4 medical laser system, except those of Class 3B not exceeding 5 milliwatts at visible wavelengths and not intended for ocular exposure:

(i) The accessible emission level, shall not deviate from the preset or selected level by more than ±20 percent,

(ii) An electrical or optical quantity that is directly related to the laser level generated shall be continually monitored during operation,

(iii) A visible or audible indication shall be given whenever the monitored quantity denotes deviation from the preset or selected level by more than ±20 percent,

(iv) The user instructions shall specify an instrument, procedure, and schedule for calibration of the accessible emission level,

(v) If the system emits either continuously or a series of pulses for longer than 0.25 seconds, the system shall incorporate a visual or audible indication of actual emission in addition to the emission indicator required by § 1040.10(f)(5),

(vi) The system shall include a hand or foot operated control to stop the emission of laser radiation. The switch shall be colored red and be located so that it is clearly visible and quickly accessible to the operator from the operating position. If it is a push-button type, it shall be of the ''mushroom-head'' type.

(b) *Surveying, leveling, and alignment laser products.* Each surveying, leveling, or alignment laser product shall comply with all of the applicable requirements of § 1040.10 for a Class 1, 2 or 3A laser product and shall not permit human access to laser radiation in excess of the accessible emission limits of Class 3A.

(c) *Demonstration laser products.* Each demonstration laser product shall comply with all of the applicable requirements of § 1040.10 for a Class 1, 2, 3A or Class 3B laser, except for Class 3B with not more than five times the AEL of Class 2 in the wavelength range of 400 to 700 nanometers, and shall not permit human access to laser radiation in excess of the accessible emission limits of such classes.

Dated: March 17, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–7158 Filed 3–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Part 57

RIN 1219–AB11

Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Proposed rule; notice of hearings; and close of record.

SUMMARY: MSHA is announcing public hearings on the Agency's proposed rule about diesel particulate matter exposure of underground metal and nonmetal miners, which was published in the **Federal Register** on October 29, 1998. These hearings will be held under section 101 of the Federal Mine Safety and Health Act of 1977.

The rulemaking record will remain open until July 26, 1999.

DATES: If you want to make an oral presentation for the record, submit your request at least 5 days prior to the hearing date. However, you do not have to make a written request to speak. The public hearings will be held at the following locations on the dates indicated:

May 11, 1999, Salt Lake City, Utah
May 13, 1999, Albuquerque, New Mexico
May 25, 1999, St. Louis, Missouri
May 27, 1999, Knoxville, Tennessee

Each hearing will be held from 8:30 a.m. to 5 p.m., but will continue into the evening if necessary.

The rulemaking record will remain open until July 26, 1999.

ADDRESSES: Send requests to make oral presentations to: MSHA, Office of Standards, Regulations, and Variances, Room 631, 4015 Wilson Boulevard, Arlington, VA 22203–1984.

The hearings will be held at the following locations:

1. May 11, 1999, Doubletree Hotel, 255 South West Temple, Salt Lake City, Utah 84101, Tel. No. 801–328–2000.