DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

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TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Safety Interlocks to Prevent Access to Class II Levels of Laser Radiation

BACKGROUND: The Federal performance standard for laser products requires that safety interlocks, unless defeated, prevent human access to laser and collateral radiation upon removal or displacement of the interlocked portion of the protective housing and preclude removal or displacement of the housing upon interlock failure (21 CFR 1040.10(f)(2)(i)). Laser products which incorporate safety interlocks which are designed to allow interlock defeat must also have a visual or audible indication of defeat when the interlocked portion of the protective housing is removed or displaced (21 CFR 1040.10(f)(2)(ii)). Replacement of a removed or displaced portion of the protective housing shall not be possible while required safety interlocks are defeated (21 CFR 1040.10(f)(2)(iii)).

The Bureau of Radiological Health has reassessed the need for certain of the safety interlock requirements of 21 CFR 1040.10(f)(2) as they pertain to operation and/or maintenance ports in the protective housing of laser products through which access to levels of visible laser radiation not exceeding Class II limits is possible. This reassessment has led to the regulatory policy stated below. This policy is considered warranted because eye damage, while possible from chronic exposure to Class II levels of laser radiation, is not likely to occur from acute exposure. Also, since the Class II limits can only be applied to visible radiation (400-700 nm) and any invisible radiation must be below the Class I limits, the user would have a visual indication of laser radiation in the event of interlock failure or defeat when the protective housing is removed or displaced. Therefore, in this case, the requirements of 21 CFR 1040.10(f)(2) are considered to be overly restrictive and properly designed standard electrical or mechanical interlocks with appropriate labels on the protective housing should be sufficient to meet the intent of the standard and protect the user from the hazards of Class II laser radiation.

POLICY: Under the following conditions the Food and Drug Administration will not object to certified laser products which deviate from the requirements of 21 CFR 1040.10(f)(2):

1. Interlocks Not Designed to Allow Defeat

   a. The requirements of 21 CFR 1040.10(f)(2)(i)(a) are satisfied,

   b. The interlock is operated according to its design specifications,

c. Failure of the interlock will not provide access to laser radiation levels in excess of the Class II limits in the wavelength range of 400 to 700 nm or in excess of Class I limits in all other wavelength ranges, and

d. The protective housing is labeled in accordance with 21 CFR 1040.10(g)(6)(i) with the following wording change - "CAUTION - Laser radiation when open and interlock failed. DO NOT STARE INTO BEAM."

2. Defeatable Interlocks

a. The requirements of 21 CFR 1040.10(f)(2)(i)(a) are satisfied,

b. The interlock is operated according to its design specifications,

c. Failure or defeat of the interlock will not provide access to laser radiation levels in excess of the Class II limits in the wavelength range of 400 to 700 nm or in excess of Class I limits in all other wavelength ranges,

d. The laser radiation is not emitted directly through the opening created by displacement or removal of the interlocked portion of the protective housing upon interlock defeat, and

e. The protective housing is labeled in accordance with 21 CFR 1040.10(g)(7)(i) with the following wording change - "CAUTION -Laser radiation when open and interlock failed or defeated. DO NOT STARE INTO BEAM."

INVITATION TO COMMENT: The Bureau of Radiological Health intends to propose an amendment to the Federal performance standard for laser products which will clearly permit performance under the conditions specified above. In the meantime, the Food and Drug Administration will not take action under Sections 359, 360B or 360C of the Radiation Control for Health and Safety Act of 1968 if certified laser products deviate from the requirements of 21 CFR 1040.10(f)(2) provided the above conditions are met since such deviation, while technically noncompliant with the present performance standard, does not create a significant risk of injury to any person. Comments on this policy are invited.

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