



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

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TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Optional Interlocks and Related Labeling, 21 CFR 1040.10(f)(2) and (g).

BACKGROUND: A laser product has a cover that is intended to be opened or removed for service only. The standard does not require the service cover to be provided with a safety interlock even though laser radiation in excess of Class I levels would be accessible when the cover is removed. However, the manufacturer has provided a defeatable interlock on the cover for protection from internal high voltage. As a result of removal of the high voltage, generation of laser radiation is terminated. However, the interlock does not comply with the requirements of 21 CFR 1040.10(f)(2) for safety interlocks in that removal of the cover is not prevented in the event of interlock failure, there is no indication of interlock defeat, and the cover could be replaced when the interlock is defeated. The manufacturer asks whether the product must be labeled in accordance with the requirements of either subparagraph (g)(6) or (g)(7) of 21 CFR 1040.10 and, if so, which subparagraph would apply.

POLICY: A portion of the protective housing can be intended by design or instruction to be displaced or removed only during service. The manufacturer has, within the requirements of the standard, the option of using:

1. A safety interlock that is not designed to be defeated, or
2. A safety interlock designed to be defeated, or
3. No safety interlock at all,

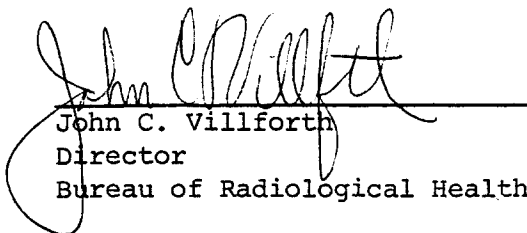
on that portion of the protective housing.

If a safety interlock is not used, then the product must be labeled in accordance with the requirements of Section 1040.10(g)(6) - Labels for noninterlocked protective housings. If a defeatable safety interlock is used, the product must be labeled in accordance with the requirements of Section 1040.10(g)(7) - Labels for defeatably interlocked protective housings. A label is not required when a safety interlock that is not designed to be defeated is used. An interlock, to be considered a *safety interlock* within the meaning of the definition of this term in the standard, must conform to all of the performance criteria set forth in 21 CFR 1040.10(b)(31) and (f)(2). Unless the interlock used conforms to all of the performance criteria for a *safety interlock* the protective housing must be considered to be without a safety interlock, and a label meeting the requirement of Section 1040.10(g)(6) must be used.

However, since the cover is interlocked (although not with a safety interlock), a modification in the wording specified by Section 1040.10(g)(6) would be appropriate. Therefore, the Bureau will not object if the wording "and interlock failed or defeated" is added to the required label statement as in the following example for Class II levels of laser radiation accessible under conditions of service (21 CFR 1040.10(g)(6)(i)):

"CAUTION - Laser radiation when open and interlock failed or defeated.
DO NOT STARE INTO BEAM."

INVITATION TO COMMENT: The Bureau is considering an amendment to the performance standard for laser products which may provide an opportunity in the future for manufacturers to seek greater flexibility in the wording of warning logotype and other required labels. In the interim, the above policy shall apply to the circumstances as described. Comments on this policy are invited.



John C. Villforth
Director
Bureau of Radiological Health