

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ROCKVILLE, MARYLAND 20852

JUN 22 1976

REF:DOC

MA-3983

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Response to Question Concerning Brightness of Emission Indicators that Emit Visible Radiation, 21 CFR 1040.10(f)(5)

BACKGROUND AND QUESTION: A company manufactures leveling and alignment laser products that are typically used outdoors to project a beam several hundred feet under daylight illumination. The company desires to know over what distance a visual emission indicator is required to be visible and if an incandescent automotive type lamp would be adequate or if a xenon flash-lamp similar to an aircraft beacon must be used in order to be visible over the entire operational range.

RESPONSE: The emission indicator is to give indication concerning the emission of accessible laser radiation primarily to the operator of the laser product, and not necessarily to all persons within the distance the laser radiation could possibly project.

Although emission indicators are required by 21 CFR 1040.10(f)(5) for all laser systems of Class II or higher, the standard does not specify a minimum distance for visibility or audibility of the indicator; furthermore, the record of development of the standard indicates that the emission indicator should be suitable to the particular product (40 FR 32255). Active indicators such as xenon flashlamps may, in order to be visible at the working distances of the product, have to be of such intensity as to constitute at close range a more hazardous source of optical radiation than the laser itself. Furthermore, if a dangerously bright light would be needed to be visible even to the operator, the manufacturer should provide for a different visual signal or for an audible signal.

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