

## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

## PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ROCKVILLE, MARYLAND 20852

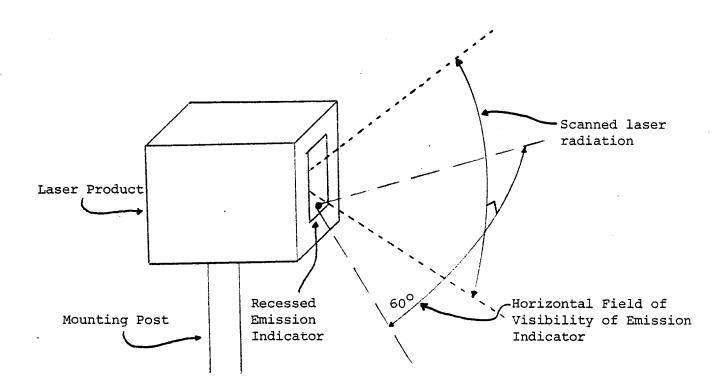
REF:DOC MA-3991

AUG 3 1 1976

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Response to Question Concerning Visibility of Visual Emission Indicators, 21 CFR 1040.10(f)(5)

BACKGROUND AND QUESTION: A company manufactures a laser product that generates a vertical plane of accessible scanned laser radiation when the product is operated in an upright position, but is mounted on a post for operation in several optional positions (diagram below). To fulfill the requirement for an emission indicator, the manufacturer incorporates a lamp into the lower portion of the rectangular exit window. The company desires to know over what angle a visual emission indicator must be visible, and if an emission indicator incorporated into the exit window, that radiates over about 60° total in each orthogonal plane, is adequate.



RESPONSE: The purpose of an emission indicator is to give indication of the emission of accessible laser radiation primarily to the operator and others in the vicinity of the laser product.

Although each Class II, III and IV laser product will be required by 21 CFR 1040.10(f)(5) to incorporate an emission indicator, the standard does not specify the angle of visibility for a visual indicator. Furthermore, to specify visibility or audibility of emission indicators which would be appropriate under all conditions and for all products is not practical; the indicator, whether visual or aural, must fulfill its function and must be suitable to the particular product.

Visual emission indicators are to be located so that viewing does not require human exposure to laser or collateral radiation in excess of the accessible emission limits of Class I and Table III of Section 1040.10(d) (21 CFR 1040.10(f)(5)(v)), and to be readily visible to the operator in most operating configurations. Although a visible emission indicator that is recessed into the scanning window and is visible over 60° might not require exposure to laser radiation such a design may lead to the operator being exposed unwittingly while viewing the indicator, and therefore does not meet the intent of the standard, especially for Class III and Class IV products. Designs for emission indicators will be evaluated on an individual basis as to whether the feature performs its intended function and is suitable to the particular product.

Robert G. Britain

Director

Division of Compliance

Bureau of Radiological Health