

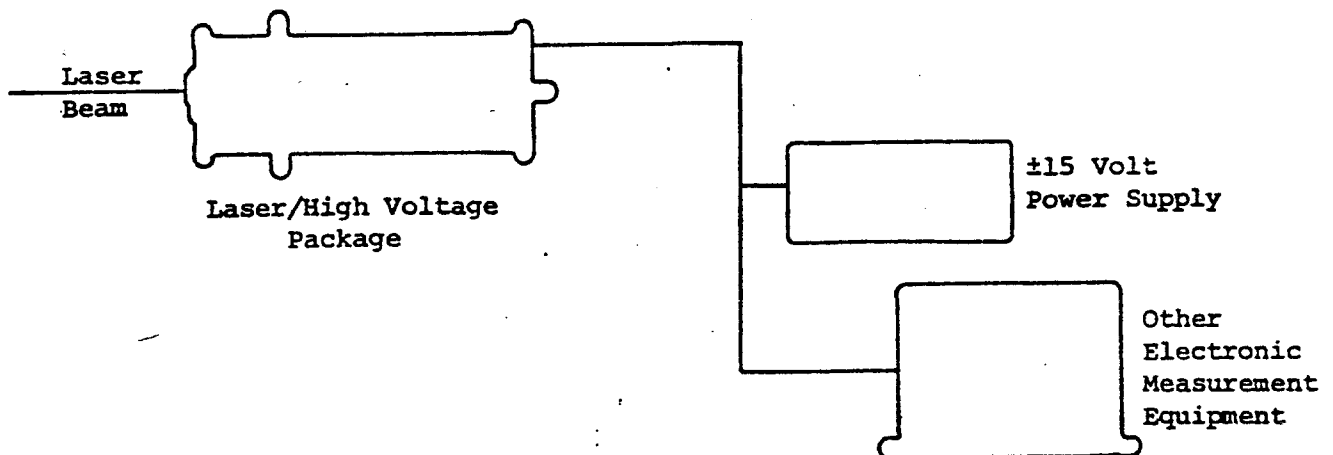


DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

A D V I S O R Y O P I N I O N

SUBJECT: REQUIREMENTS FOR LASER RADIATION EMISSION INDICATORS WHEN THE LASER AND LASER ENERGY SOURCE ARE HOUSED SEPARATELY:
21 CFR 1040.10(f) (5) (iii)

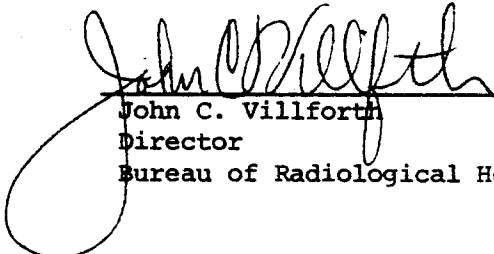
QUESTION: A company manufactures a laser product consisting of a Class II Helium Neon laser packaged with its high voltage supply, a +15 volt power supply and other electronic measurement equipment including a computer and/or calculator with optional display units (See Diagram). Power is supplied to the laser/high voltage package by the +15 volt power supply which derives its power from the electrical mains. The laser/high voltage package is housed in a single separate component located 6 ft to 100 ft from the +15 volt power supply.



The laser is turned on with the other electronic measurement equipment when power is turned on to the +15 volt power supply. It would be possible to operate the laser from a separate +15 volt power supply but the laser, power supply and other electronic measurement equipment are sold as a complete system. An emission indicator is required on the laser/high voltage package. The question is whether the +15 volt power supply is considered a laser energy source and as such is required to have an emission indicator, or is it considered a general energy source and therefore, is not required to have an emission indicator.

The Standard is a performance standard rather than a design standard. Thus, indicator lights of a specific color are not required, nor does the Standard prohibit an indicator consisting of a combination of two or more lights as long as there is one indicator and its meaning and significance are clear. An emission indicator fails to comply with the Standard if it is not visible through protective eyewear recommended by the manufacturer of the laser product or through other available protective eyewear generally considered as suitable for laser radiation emitted by the product. Laser product manufacturers should make every reasonable effort to assure visibility of emission indicators when used with all the protective eyewear which can be expected to be used with the laser product.

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