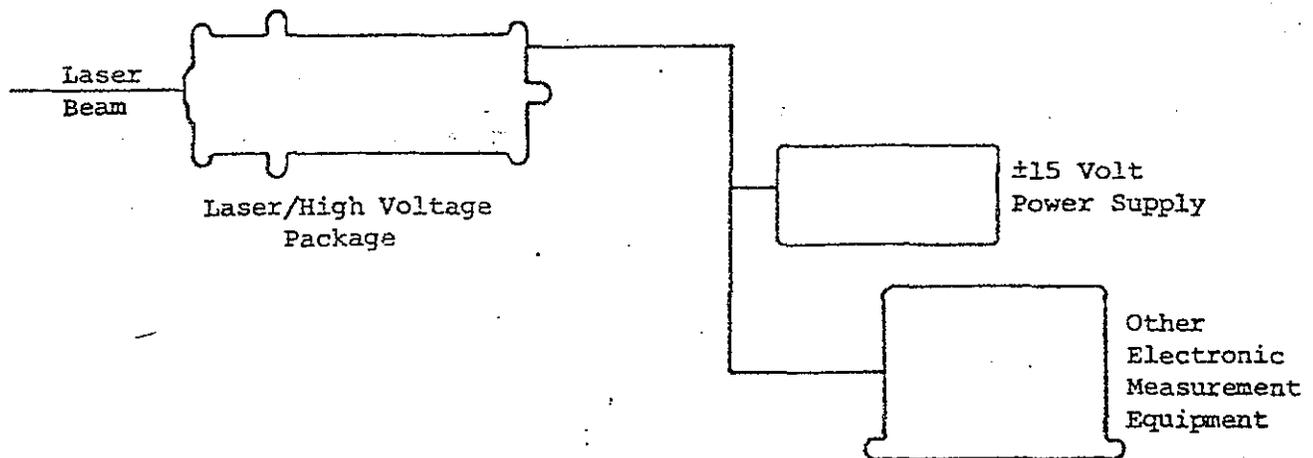


DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20812

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.

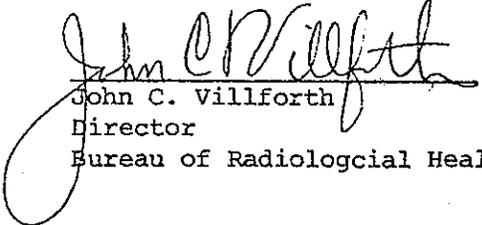


The laser is turned on with the other electronic measurement equipment when power is turned on to the ± 15 volt power supply. It would be possible to operate the laser from a separate ± 15 volt power supply but the laser, power supply and other electronic measurement equipment are sold as a complete 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.

ADVISORY OPINION: The +15 volt power supply is considered to be a laser energy source under the definition of Section 1040.10(b)(16), and is required by Section 1040.10(f)(5)(iii) to have an emission indicator. The fact that the +15 volt power supply is also used to power other specialized instruments is not enough to consider it as a general energy source. General energy sources can be used for many different purposes, and the manufacturer of a laser product has negligible control over either the manufacturing or sale of such energy sources.

In this case the +15 volt power supply derives power from the electrical supply mains, and turning on the power supply activates the laser, thereby necessitating an emission indicator. Furthermore, the power supply is manufactured and sold for use in conjunction with the laser. Therefore, it is considered a laser energy source and is required to comply with the applicable regulations.

Dated: NOV 21 1975


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