



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

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TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Response to Question Concerning Requirement for Remote Control Connectors, 21 CFR 1040.10(f)(3)

BACKGROUND AND QUESTION: A company manufactures a laser product which is operated from a battery or from an AC converter. The manufacturer desires to know if the connection to the battery or converter box meets the requirement for a remote control connector since both battery and converter box are portable and provide a means for quick disconnection.

RESPONSE: A primary electrical power cable connector for connection to the power line mains, battery, or converter box (if present) does not satisfy the requirement in the performance standard for a remote control connector (21 CFR 1040.10(b)(30) and (f)(3)). The requirement states that when the terminals of the connector are not electrically joined, human access to all laser and collateral radiation from the product ...shall be prevented. This language implies that human access would be possible when the terminals are electrically joined (simple connection between them). Connecting the terminals to the battery or supply mains cannot be considered as electrically joining in the sense used in the standard (21 CFR 1040.10(f)(3)). The connector is to be for the connection of an optional remote interlock switch or other appropriate control external to the product. *The remote control connector should be a separate, independent performance feature which is readily identifiable for that purpose.*

The connector may be supplied with a shorting plug to complete the circuit. The plug is left in place when the user does not wish to use the remote control feature; the connector, however, provides a convenient means of connection if the use of the remote control feature is desired. However, for a remote control connector to be considered satisfactory, the necessary mating plug for connecting the optional remote interlock switch or other appropriate control should be available commercially.

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