



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
ROCKVILLE, MARYLAND 20857

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TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: EMISSION DELAY FOLLOWING USE OF REMOTE CONTROL UTILIZING REMOTE CONTROL CONNECTOR, 21 CFR 1040.10(f)(3) and (5)(ii)

BACKGROUND: The Federal performance standard for laser products requires that each Class III and IV laser system have a remote control connector (21 CFR 1040.10(f)(3)) and an emission indicator (21 CFR 1040.10(f)(5)(ii)). The indicator must provide a visible or audible signal during emission of accessible laser radiation in excess of the accessible emission limits of Class I and sufficiently prior to emission of such radiation to allow appropriate action to avoid exposure to laser radiation. The standard does not explicitly state that the emission indicator must deactivate when emission is terminated by a remote control operated through the remote control connector and that there must be a delay before emission of accessible laser radiation is resumed. Therefore, a question has arisen as to the intent of the standard as it applies to the functioning of the emission indicator and delay element upon termination of emission through use of the remote control connector.

POLICY: The remote control connector is intended to allow use of external protective barrier interlocks such as a door interlock or other remote control safety switch (38 FR 34085). Such switches are used to interrupt and prevent emission of laser radiation upon entry to a hazardous or controlled area and not as an operator control for the laser product. Laser emission in excess of the accessible emission limits should not resume immediately after closure of the contacts of an interlock or remote control safety switch functioning through the remote control connector since resumption of emission without adequate forewarning would defeat the purpose of the switch. Therefore, it is the intent of 21 CFR 1040.10(f)(5)(ii) to require that following termination of laser radiation emission by operation of a remote control through utilization of the remote control connector, a visible or audible signal precede resumption of such emission for a period of time sufficient to allow appropriate action to avoid exposure to laser radiation. This requirement is necessary to assure that remote control operation through utilization of the remote control connector can be accomplished with the same degree of safety as nonremote control operation.

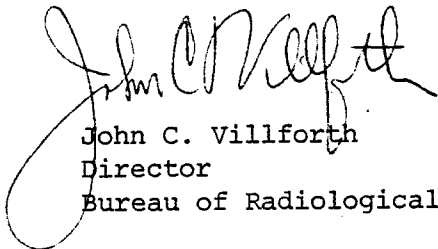
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This policy will not apply to laser products manufactured before March 1, 1978 in order to allow time for design modifications where necessary to bring laser products into conformance with this policy.

INVITATION TO COMMENT: The Food and Drug Administration may propose an amendment to Federal performance standard for laser products (21 CFR 1040.10 and 1010.11) which will explicitly incorporate the above policy into the standard. Therefore, comments on this policy are invited.

Consideration is also being given to the alternate possibility of an amendment requiring manual restart of laser products following termination of laser radiation emission by operation of a remote control through utilization of the remote control connector or by loss of supply voltage. Comments on the need for such amendment are also invited.



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