DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 30 1985

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF MEDICAL LASER PRODUCTS

SUBJECT: Delivery System Interlocks for Medical Laser Products

BACKGROUND: Medical laser products deliver laser radiation to patients through a wide variety of means. These include various sizes and lengths of fiber optic cables, bare fibers, and multi-mirrored articulating arms. These may in turn be attached to accessories such as hand pieces, operating microscopes, slitlamps, etc. The bare fibers may also be used by insertion into endoscopes for treatment internal to the body. Many circumstances during a surgical procedure may require that the physician exchange or request exchange of accessories or of the delivery system as a whole. Clearly, any such exchange involves removal of a part of the protective housing, since any accessory is protective housing when in place. A question has been raised concerning the need for a safety interlock to prevent access to radiation when such protective housing (beam delivery accessory) is removed during operation or maintenance.

DISCUSSION: It has been the policy of CDRH to require safety interlocks at the laser console-delivery system connection point, if the delivery system as a whole may be removed during operation or maintenance. An example of such a situation is the fiber delivery system on a surgical Nd:YAG laser for which the fiber may often be exchanged during a procedure. In this case, safety is enhanced by the interlock since the point of laser radiation delivery and the point of disconnection may be physically separate, presenting the possibility of accidental exposure due to communication errors between the surgeon and attendants. However, the presence of safety interlocks for passive accessories attached to the distal end of the delivery system and immediate to the surgeon and the point of delivery would not significantly enhance safety, providing that the surgeon has control of emission by means of a foot switch or other control. There should then be little risk of accidental exposure. In addition, these accessories may be supplied by other than the laser manufacturers so that there is a question of the practicality of universal interlock devices.

POLICY: CDRH will not object to the absence of a safety interlock in a user removable beam delivery accessory attached to the distal end of its delivery system provided the laser product incorporates a means to allow the user to positively control and terminate laser radiation emission from a point in close proximity to such accessory.

INVITATION TO COMMENT: We encourage submission of comments on this policy from manufacturers and users of medical laser products. In the meantime, we also encourage the use of additional safety mechanisms for all laser accessories, including the use of "smart" accessories which can disable the laser if detached or if a new calibration of the delivered output is necessary in order to comply with the requirements of 21 CFR 1040.11(a)(1) and (2).

Sincerely yours,

James S. Benson
Deputy Director
Center for Devices
and Radiological Health