DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 21 1985

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Walk-In Workstations

BACKGROUND: The advent of very large materials processing machines that use lasers causes serious concern to manufacturers and the Agency with respect to product classification and protective housing requirements for these products. The protective housing is that portion of the product that prevents human access to laser or collateral radiation and is required wherever and whenever access is not necessary in order for the product to perform its intended function. Those levels of laser radiation to which access is necessary during operation in turn determine the class of the product.

The concept of a protective housing is relatively simple for small, table-top products where the protective housing is clearly recognized. However, the concept of protective housing becomes much more complex in cases where the product is very large. Many products incorporate work stations that enclose large multi-axis positioning tables and parts handling machinery. The enclosures may be large enough for persons to enter and in many instances may be considered as rooms. How can such an enclosure be an adequate protective housing when it is large enough for a person to be inside while the laser might be activated? There is considerable interest on the part of purchasers of such machines and from labor organizations for the products to be classified as Class I laser products. In addition, the standard requires that a laser product be in the lowest class in which the intended function can be accomplished. Although the product may have a safety interlock as required by the standard, the Agency is concerned about the possibility of an operator opening an access door, entering the work station enclosure, and closing the door, thereby gaining access to high laser radiation levels. The questions are: Under what circumstances will the Agency consider such a product to be Class I and the protective housing to be adequate?

POLICY: The Center for Devices and Radiological Health will not object to laser products that include work station enclosures large enough to permit entry to persons being classified as Class I laser products, and will accept the enclosure as meeting the requirement for a protective housing, providing the following conditions are met:

- The enclosure is adequate to satisfy the requirement for a protective housing during operation, i.e., when closed, human access is prevented,

- The enclosure is safety interlocked and labeled as required by the standard,

- A means is provided as part of the overall safety interlock scheme to detect the presence of persons within the enclosure, and/or to prevent operation of the laser when a person is inside the enclosure, and

- The user information clearly instructs operators to avoid procedures that could give access to hazardous levels of laser radiation.

The Center invites comments from the public on this interpretation of the requirements of the standard. Please address any comments to the Director, Office of Compliance, HFZ-300, Center for Devices and Radiological Health, 8757 Georgia Avenue, Silver Spring, Maryland 20910.

James S. Benson

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