DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

JUN 24 1987

To: All Manufacturers and Potential Manufacturers of Laser Products

Subject: User Instructions for Industrial Multi-axis Laser Workstations

BACKGROUND:

The multi-axis, robotic medium/high power laser workstations which are not Class I laser products are of concern to the manufacturer, users, laser safety officers, and the Agency with respect to installation of such products and the hazard to personnel during use of these machines.

The capability of such machines to project the working beam in almost any direction is often a design requirement to permit working on parts having complex shapes. This requirement is often accompanied by a requirement for workstations to accommodate all sizes of workpieces which make designing a Class I protective housing for all possible workpieces infeasible. In addition, the mobility of the focusing optic introduces the possibility of the beam being projected or reflected beyond what would be considered a normal working area.

The combination of extreme flexibility of working beam direction and the justifiable absence of a Class I protective housing for the workstation present a significant danger that personnel will be exposed to hazardous levels of direct, reflected, or scattered laser radiation or collateral radiation.

Manufacturers of laser products are required by 21 CFR 1040.10(h)(1) to provide user instructions that include instructions for assembly or installation of the equipment. These instructions must include adequate safety precautions and warnings to avoid exposure of the operator or other persons to levels of radiation greater than Class I. What information, in addition to that which the manufacturer would normally provide, must be included in user instructions for this type laser of product to comply with the laser performance standard?

POLICY:

For the type of laser products of concern here, user instructions [21 CFR 1040.10(h)(1)] must include an identification of the locations at which laser radiation levels that exceed Class I may be present. Specifically, user instructions must include a complete description of the space surrounding the equipment within which the level of direct, reflected, or scattered laser radiation can exceed the Class I limits or the Maximum Permissible Exposure (MPE) of the American National Standard for the Safe Use of Lasers, Z136.1-1986, while the machine is in its normal operational mode.

In situations where the configuration of the machine or the output pattern or level of the laser radiation may be varied, the instructions must include procedures for calculation or measurement of the radiation output. Boundaries must be designated in the user information (manual) or the user information must provide instructions on how to determine such boundaries to assure that the operator and other personnel are not exposed to hazardous levels of laser radiation.

Further, if operational or maintenance personnel are required to be within these boundaries to perform their duties, appropriate control measures must also be specified in the user instructions.

Please note that this guidance is not to be interpreted as a relaxation of the performance requirements of 21 CFR 1040.10(f)(7) Location of Controls. This section requires manufacturers to position their product's operations controls so that exposure in excess of Class I levels is not necessary during operation of these controls. User information or warnings are provided in addition to, not in place of, proper positioning or shielding of controls.

The Center invites comments from the public on this notice. Please address any comments to the Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, 8757 Georgia Avenue, Silver Spring, Maryland 20190.

Sincerely yours,

Edwin A. Miller

Edwin A. Miller, Director
Division of Radiological Products
Office of Compliance
Center for Devices
and Radiological Health

American National Standard for the Safe Use of Lasers, Z136.1-1986
American National Standards Institute
1430 Broadway
New York, New York 10018