



AUG 11 1995

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

To: All Manufacturers and Potential Manufacturers of Medical
Laser Products

Subject: User Instructions for Medical Laser Products.

BACKGROUND:

Medical laser systems are very varied in their construction and configuration. Some emit radiation of wavelengths in the ultraviolet, visible and infrared spectral bands and may include delivery optics that may be fixed, articulated or flexible. Emissions may be collimated or have differing degrees of convergence or divergence. Some systems deliver their energy through unsheathed fiber optics that are subject to breakage during use which can result in emission at unintended locations and in unintended directions. Other concerns involve applications with endoscopes, side-firing fibers, and interactions of the laser with substances likely to be encountered in the use environment. These factors make it difficult to determine the precautions that are necessary to avoid possible exposure to hazardous levels of radiation.

The Federal Performance Standard for Laser Products, 21 CFR 1040.10 and 1040.11, requires that user instructions for laser products include "Adequate instructions for assembly, operation and maintenance, including clear warnings concerning precautions to avoid possible exposure to laser and collateral radiation..." [See 21 CFR 1040.10(h)(1)(i)]. The Center for Devices and Radiological Health (CDRH) has received numerous inquiries from manufacturers and users about the practical implementation of this requirement.

The CDRH recognizes that the American National Standards Institute (ANSI) Z136 series are the most widely accepted standards of safety in the use of lasers in the United States. These standards include Z136.1 (1993) - American National Standard for the Safe Use of Lasers, and Z136.3 (1988)¹ - American National Standard for the Safe Use of Lasers in Health Care Facilities. These standards define maximum permissible exposures, give procedures for establishment of hazard zones in the vicinity of laser equipment, provide guidance on protective equipment such as eyewear and establish the responsibilities of laser safety officers.

¹ A revision to this standard may be published in 1995.

INTERPRETATION:

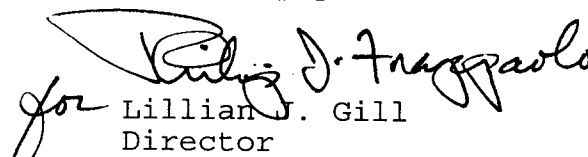
The CDRH interprets the regulation in 21 CFR 1040.10(h)(1)(i) to require that the user information to be supplied with medical laser products is to be in sufficient detail to enable users to readily comply with accepted user safety standards such as the ANSI Z136.1 and Z136.3. This information would include:

- Definition of the emitted radiation propagation pattern(s) and the nominal hazard zone in which the radiation level exceeds the Maximum Permissible Exposure (MPE) level during operation, maintenance and reasonably expected conditions of failure;
- Protective equipment, such as eyewear, by make and model or performance specifications and the location and conditions of recommended use;
- Placement of the laser and delivery system relative to the location of doorways or other access to minimize the risk of accidental exposure; and
- Description of failures that may be reasonably expected to occur, such as optical fiber breakage, that would result in unintended emission and the safety measures to be taken to avoid exposure to hazardous emission in such occurrences.

The CDRH believes that the manufacturers of health care laser systems are the most knowledgeable in the operation and emission characteristics of their products and are best able to provide this information. The CDRH is also concerned that many health care facilities, especially individual practices or free-standing facilities, may lack the capability to establish a laser safety program as comprehensive as might be expected in major hospitals. For this reason, the CDRH is issuing this notice of interpretation to underscore the requirement already contained in the regulation for manufacturers of laser products to furnish adequate instructions for assembly, operation and maintenance including procedures to avoid unnecessary exposure to laser or collateral radiation.

The CDRH welcomes comments on this notice. Please address any comments to Director, Office of Compliance (HFZ-342), Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, MD 20850.

Sincerely yours,


for Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health