DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
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To: All Manufacturers and Potential Manufacturers of Laser Products

SUBJECT: Manufacture and Certification of Laser Kits, 21 CFR 1040.10 and 1010.2

BACKGROUND AND QUESTION: A laser product is sold in kit form, complete with labels and instructions, such that the product will comply with the standard when properly assembled. How must such a product be identified and certified as complying with the standard?

RESPONSE: All laser products sold in kit form must meet all of the applicable requirements of the performance standard for laser products when properly assembled according to manufacturers' instructions.

For purposes of identification and certification the date of manufacture of a kit is considered to be that date on which the manufacturer assembles the components as a complete package for shipment. Because portions of the performance standard may be added to or changed and become effective at a later date, this particular date establishes the last date on which the manufacturer has control of a specific product and therefore determines the applicable requirements.

As with all laser products manufactured on or after the effective date of the standard, these products, when assembled properly, must have affixed an identification label as specified in 21 CFR 1010.3 and a certification label as specified in 21 CFR 1010.2. The certification label may indicate that the product complies with all applicable HEW standards under the Radiation Control for Health and Safety Act of 1968 (or HEW radiation performance standards, 21 CFR Subchapter J) in effect on the date of manufacture shown when assembled in accordance with the manufacturer's instructions.

The manufacturer has the responsibility to assure compliance throughout the useful life of the product under reasonably foreseeable conditions of assembly and use. Therefore, the following criteria are offered for evaluating a product of kit design:

1. The design should be such that it would be unlikely that an untrained assembler could make mistakes or omissions in assembly that would lead to noncompliance with the standard. In addition, the manufacturer should pretest the product design with maximized laser radiation levels and supply the purchaser with the appropriate labels.

2. The instructions for assembly should be such that an untrained assembler could follow them and produce a finished laser product which would be and remain in compliance with the standard. All assembly operations that are of importance to radiation safety should be clearly identified. Where careful adherence to directions is necessary to assure compliance, clear instructions to take the necessary care in assembly should be provided. Where alterations or omissions could lead to noncompliance, the instructions should provide clear warning against such alterations or omissions.

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