DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

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FDA COMPLIANCE POLICY GUIDE

SUBJECT: Applicability of Laser Product Performance Standard to Laser Light Shows (21 CFR §§ 1040.10(a) and 1040.11(c))

BACKGROUND:

The Bureau of Radiological Health has observed that there is a growing use of lasers in the music, entertainment, and advertising industries. In particular, musical groups and discotheque operators have been using lasers to create visual effects to complement the music being played. Lasers are also being used for visual effects in theaters and planetariums, and in the advertising industry. A system for creating the desired visual effects is frequently assembled using a general purpose laser (usually Class III or IV) with the addition of beam scanners, laser housing, fiber optic tubes, display screens, and/or other devices necessary for the creation of a laser light show.

In view of these applications of lasers, the FDA was asked if musical groups and other persons responsible for laser light shows are regarded as "manufacturers" of laser products subject to the laser product performance standard (21 CFR 1040.10 and 1040.11). The applicability of the FDA performance standard to the assembly of such products depends on whether (1) the assembly process described above constitutes "manufacturing" within the meaning of the Radiation Control for Health and Safety Act and, (2) the date of completion of the assembly process occurs before or after the effective date of the standard (August 2, 1976).

POLICY:

Laser products manufactured for use in light shows are considered to be demonstration laser products. A demonstration laser product is defined as a laser product designed, intended, or promoted for purposes of demonstration, entertainment, advertising display or artistic composition (21 CFR 1040.10(b)(10)). Demonstration laser products must comply with all of the applicable requirements for Class I or Class II laser products and not exceed the accessible emission limits of those classes (21 CFR 1040.11(c)).

Although a general purpose laser was "manufactured" when it was first assembled for commercial purposes by a person engaged in the business of such assembly, the act of assembly of a laser light show using a previously manufactured general purpose laser or laser product results in the creation or manufacture of a "new" product. The creation of this new product may involve addition of such components as scanners, display screens and optics but may also result from merely changing the intent and use of the original laser. Hence, the person who produces the "new" product is considered a "manufacturer" if such person is engaged in the business of manufacturing laser light shows.

A person is considered to be "engaged in the business" of manufacturing a laser product if he commercially sells his services as a manufacturer or assembler of light shows. Therefore, an individual, for example, under contract with a musical group, who is responsible for assembling a light show for the group would be a "manufacturer" within the meaning of the Act. Similarly one who creates his own laser light show and uses it in conjunction with the performance of services which he offers to the public for compensation would also be considered a "manufacturer". Consequently, a musical group that purchases a general purpose laser and creates its own light show could not evade the requirements of the Act if the light show was used as a part of the group's performances.

The second factor in determining the applicability of the laser performance standard is the date of manufacture of the product. There are three possibilities to consider:

(1) laser products originally manufactured after August 2, 1976;

(2) laser products originally manufactured prior to August 2, 1976 but "remanufactured" as a laser light show after August 2, 1976;

(3) laser products manufactured and converted to light show use prior to August 2, 1976.

Laser products in the first category are obviously covered by the performance standard and are therefore subject to certification when originally manufactured and to recertification if "remanufactured". Products in the second category would not be subject to the standard when first manufactured. "Remanufacture" after the effective date of the standard would, however, subject the laser to the performance standard. As for those laser products manufactured and "remanufactured" before August 2, 1976, they are not subject to the performance standard.

If a manufacturer desires to introduce into commerce a demonstration laser product that cannot comply with the requirements of 21 CER 1040.10 or 1040.11, he must apply for a variance from the standard as specified in 21 CFR 1010.4. The Bureau will review these requests as rapidly as possible and grant a variance only if there are adequate controls over both stationary (discotheque) and mobile light shows (musical groups). If the manufacturer's variance request does not assure suitable means for providing radiation safety or protection or if the manufacturer fails to conform to the conditions required by the variance, then the variance will be denied or canceled, as appropriate.

INVITATION TO COMMENT:

Once the Agency collects additional data on the variety of alternative means for providing radiation safety and protection in the operation of demonstration laser products of this type, consideration will be given to amending 21 CFR 1040.11(c) to establish new and specific requirements for demonstration laser products, thus avoiding the need for a variance. Until such a change in the standard becomes effective, the FDA will vigorously enforce the present regulations. Comments on this policy are invited.

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