DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

FDA COMPLIANCE POLICY GUIDE

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SUBJECT: Interim Enforcement Policy for Certain Laser Light Shows and Displays (21 CFR 1040.10 and 1040.11)

BACKGROUND:

On November 23, 1977, the Bureau of Radiological Health issued an FDA compliance policy guide on the applicability of the Federal laser product performance standard to laser light shows and displays (policy statement number 22). That document established the policy that a person who is engaged in the business of assembling laser light shows or displays is a manufacturer of a demonstration laser product and is thus subject to the requirements of the Radiation Control for Health and Safety Act of 1968 including the Federal performance standard for laser products (21 CFR 1040.10 and 1040.11). The policy also stated that laser light shows and displays which cannot comply with the requirements of the standard for demonstration laser products (i.e., they are classified as Class III or IV laser products) cannot be introduced into commerce unless a variance (specific authorization to vary from the standard) has been obtained. The intent of the agency to consider an amendment to the standard to negate the need for a variance was also expressed.

Either processing a variance application or promulgating a significant amendment to the performance standard involves a lengthy process. In the meanwhile the Bureau of Radiological Health is concerned with the fact that laser light shows which fail to comply with the performance standard have already been assembled since August 1, 1976, and are currently in operation. Also, if the lead time to produce a laser light show were too short to permit processing a variance, the show might be unnecessarily prevented from introduction into commerce.

While a laser light show or display might not fully comply with the performance standard requirements for a demonstration laser product in that it is classified as a Class III or even a Class IV laser product and a variance has not been granted, such light show may not create a significant risk of injury if properly designed, assembled and operated (i.e., it meets the safety criteria presented below). There should be no reason to institute enforcement action against a person who has assembled a laser light show if the person has applied for a variance and the agency has inspected the product in its operational configuration(s) and has concluded that it meets the safety criteria presented below.

POLICY:

The Bureau of Radiological Health will not object to the assembly and continued operation of a laser light show or display, regardless of its class, if the following conditions are satisfied:

(1) the laser light show or display meets the Federal performance standard for its class;

(2) the manufacturer has submitted a report as required by 21 CFR 1002.10 or 1002.12;

and in addition for Class III or IV laser products:

(3) the manufacturer has applied for a variance from the requirements of 21 CFR 1040.11(c);

(4) the laser light show or display is designed, and operated, in accordance with the safety criteria presented below; and

(5) the manufacturer allows representatives of the Food and Drug Administration to examine the product and the control procedures to assure conformance to the above conditions.

The Food and Drug Administration will take appropriate enforcement action to prevent the assembly, introduction into commerce and continued operation of laser light shows or displays which fail to meet the above conditions.

LASER SAFETY CRITERIA FOR CLASS III AND CLASS IV LASER LIGHT SHOWS AND DISPLAYS

1. Laser radiation emission at wavelengths outside the range from 400 to 710 nanometers must not exceed the emission limits of Class I under any possible conditions of operation.

2. Laser and collateral radiation, measured where the audience is normally located, must not exceed the limits of Class I during operation. Radiation to be measured includes reflections from targets and scattering materials.

3. Operators, performers and employees must be able to perform their functions without the need for exposure to laser and collateral radiation in excess of the limits of Class I if such radiation is intended to be viewed by them in order to perform their functions, or in excess of the limits of Class II if such radiation is not intended to be viewed.

4. Scanning devices, including mirror balls, must incorporate a scanning safeguard to prevent laser emission if scan failure or other failure causing a change in either scan velocity or amplitude would result in violation of criteria 2 or 3 above.

5. If the laser light show does not operate at all times under the direct supervision or control of an operator, laser radiation levels to which "human access" (21 CFR 1040.10(b)(12)) can be gained must not exceed the limits of Class II at any point less than 6 meters above any surface upon which a person in the audience is permitted to stand or at any point less than 2.5 meters in lateral separation from any position where a person in the audience is permitted during the performance or display.

6. Laser light shows or displays which do not meet criteria (5) shall be operated at all times under the direct supervision or control of a trained operator who shall maintain constant surveillance of the laser display and terminate emission of laser radiation in the event of equipment malfunction, audience unruliness or other unsafe conditions. Laser radiation levels to which "human access" can be gained must not exceed the limits of Class II at any point less than (1) 3.0 meters above any surface upon which the audience is permitted to stand, or (2) 2.5 meters in lateral separation from any position where a person in the audience is permitted to be unless physical barriers obstruct access by the audience to such levels.

7. All laser light shows or displays must be provided with one or more readily accessible controls to effect immediate termination of laser radiation. If the light show or display is not required to be under the continuous supervision or control of an operator during its operation, there must be a person at all times at the show or display who is designated to be responsible for the immediate termination of the laser radiation in the event of equipment malfunction, audience unruliness or other unsafe conditions.

8. The maximum output power above Class II shall be limited to that required to perform the intended function of the product.

9. The laser light show or display must meet any other radiation safety criteria which the Bureau of Radiological Health believes is necessary to adequately protect public health and safety.

10. All tests and measurements for the determination of compliance shall be performed in accordance with the conditions of 21 CFR 1040.10(e) with the understanding that all measurements of radiant power, radiant energy, irradiance, or radiant exposure shall be made with a detector having a solid angle of acceptance of 2π steradians, or its equivalent.

In addition, the laser operator and/or the laser safety officer responsible for producing a laser light show should contact the local or state radiation control officials or health department prior to a show to determine that any applicable local or state requirements are satisfied and clearances obtained before the show or display goes on.

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