DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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TO: TO ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Class II and IIIa laser light show projectors and shows.

BACKGROUND: On August 20, 1985, the Food and Drug Administration (FDA) published amendments to the Federal performance standard for laser products. As a result, Class IIIa laser light show products no longer require a variance from the standard for introduction into commerce. There was no change in the requirements for the manufacturer to certify and report the projection system with its supporting literature and the general show configuration prior to its introduction into commerce.

This has resulted in the increased promotion of Class II and IIIa low/moderate power laser products for producing laser light show effects in establishments or at locations having severely restricted space limitations, which, in some cases, may constitute unsafe installation and use of these products.

The preamble to the final rule published in the Federal Register [50 FR 33687, Aug. 20, 1985, Comment 27] recognizes that this type of demonstration laser product, although of moderate power, still presents a hazard if not installed and used safely. The preamble also advised manufacturers: "... that instructions for assembly, operation, and maintenance need to include warnings to avoid possible exposure to laser and collateral radiation in excess of the limits of Class I. Such warnings should be based on the laser safety concepts contained in laser light show variances issued by FDA."

POLICY: In keeping with this recognition of a hazard and the advice given, the Center for Devices and Radiological Health (CDRH) will object to any intentional exposure of the public to hazardous levels (i.e., greater than Class I levels) of laser or collateral radiation (light) from this type of equipment. Further, the CDRH will object to any instructions or promotion of Class II or IIIa demonstration laser products (projectors, scanners, shows, etc.) that do not adequately warn the user to prevent such exposure.

MANUFACTURER GUIDANCE: The manufacturer, during production and marketing of Class II and IIIa demonstration laser products, must consider the following points. This is necessary to assure that the user is adequately informed of the hazards involved with the use of the product as well as the responsibility of the purchaser/operator to provide a safe environment for their patrons.

1. Class I audience exposure levels.

   Only Class I levels of laser radiation have no known hazard and these are the only exposure levels that are considered safe for direct exposure of people. Exposure of the audience to levels in excess of the Class I limits is not to be promoted or encouraged in any way.

2. Class II warning: CAUTION Laser Radiation (or Light)
Do Not Stare Into Beam

Class IIIa warning: DANGER Laser Radiation (or Light)
Avoid Direct Eye Exposure

These levels are hazardous to the eyes. No direct or reflected beams may be directed into audience areas or used to scan the audience in any way. A projector certified as Class II or IIIa cannot be used for audience scanning unless the projector is equipped with an adequate scanning safeguard which will prevent scanning above the Class I limits and adequate user instructions for achieving the Class I levels are provided (as discussed below.)

3. Installation restrictions/limitations.

Although the purchaser/operator is responsible for providing a safe environment for patrons and for configuring the laser light to avoid public exposure to unsafe levels of laser light, the projector manufacturer is required to provide the purchaser/operator with adequate directions for creating such an installation.

The CDRH is aware that the laser Class II and IIIa emissions are a lesser hazard than the higher levels emitted in shows that require a variance. Nevertheless, the CDRH recommends that the 3 meter (about 10 feet) vertical and 2.5 meter (about 8 feet) lateral clearance distances from audience area floors be used for Class II and IIIa laser light shows. This will provide the same degree of safety that is imposed by the variance requirements for higher power laser light shows. Smaller clearance distances should be used only if there is assurance that people in the audience and general public areas are not exposed to Class II and IIIa levels. It would be prudent to use a minimum beam height of 7 feet if it is not possible to achieve the standard laser light show clearance distances in a particular installation. This clearance gives some assurance that people in the audience will not receive direct eye exposures.

The American National Standard for the Safe Use of Lasers, ANSI Z136.1 - 1986, published by the American National Standards Institute, Inc. should be consulted before undertaking any laser light shows or effects. This is a voluntary safety standard established by representatives of the laser industry for users of all types of lasers. It should be noted that this standard also requires that Class IIIa and Class II projection devices be set up so as not to expose people to the direct beam (or its mirror reflection) unless the beam irradiance has been dropped to (or below) the applicable MPE (Maximum Permissible Exposure). The beam should NOT be directed at the eye, and, in an unsupervised location, steps must be taken to PREVENT access of the public to the direct beam (or its mirror reflections.)

4. Scanning safeguard.

As noted above, projection systems designed for scanning beams or images into a public area with possible exposure of the audience must have a scanning safeguard. The scanning safeguard must be designed to meet the laser performance standard (21 CFR 1040.10 and 1040.11) and therefore must maintain all beams and effects scanning the audience within Class I at all times or terminate the effect before the Class I limits are exceeded.

5. Measurement parameters.

When determining the levels of laser radiation to which the audience could be exposed, appropriate measurement parameters must be used. This must include the use of a 50 mm aperture since viewing optics such as cameras, binoculars, and similar devices may easily be used by the audience. Likewise, worst case considerations must be applied in this evaluation, including (but not limited to) such factors as: (1) the worst case scan pattern permitted by a scan safeguard system, (2) the closest point of approach to the projector within the audience area, etc.

6. User information, Owner's Manuals, or Instructions.

a. The written information provided to the purchaser/owner must be clear enough so that someone not technically oriented and/or not familiar with lasers can learn of the hazards associated with lasers, can install and operate the product (projector and show) correctly, and can produce the intended effects without creating a hazardous environment for the viewer.

b. The user manual must contain specific warnings that any levels exceeding the Class I limits are considered hazardous to the eye and exposure of the viewer by direct or reflected beams must not be permitted. If Class I levels can be achieved by following the manufacturer's instructions (discussed below) and the projector is equipped with a scanning safeguard that meets the Federal requirements, then, and only then, may intentional exposure of people be used as an effect.

c. User instructions for projectors equipped with scanners and scanning safeguards must thoroughly explain in simple, nontechnical language the procedures for setting up, adjusting, and operating the equipment in a manner to achieve and maintain the Class I levels in audience areas.

d. The user instructions must contain a description or graphic representation of typical show installations and effects. This provides the essential elements of the required show report for products intended for sale only. Thus, the laser light show reporting requirement may be considered satisfied in this case.

e. The manufacturer must submit a FINAL (not preliminary) user manual in the required product report. This will allow FDA to evaluate the user instructions to determine whether adequate warnings have been provided. Also, if audience exposure to Class I effects is intended, this manual will be reviewed to ensure that adequate, straightforward instructions have been provided to achieve and maintain the required Class I radiation levels.

7. Advertising and promotion.

A manufacturer is responsible for promotion of the product(s) in accordance with the safety instructions contained in the users' manual. Failure to do this would be considered inadequate user instruction and the manufacturer would be in noncompliance with the laser standard.

8. Misuse or disregarding user instructions.

a. The manufacturer is responsible for providing user information which will instruct the purchaser/operator how to use the product safely.

b. The purchaser/operator is responsible for learning and following the operational procedures for safe use provided in the instructions.

The CDRH 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, Silver Spring, Maryland 20910.

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Center for Devices
and Radiological Health