Responsibilities of Laser Light Show Projector Manufacturers, Dealers, and Distributors; Final Guidance for Industry and FDA

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Electronic Products Devices Branch
Division of Enforcement III
Office of Compliance

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance contact LT Sean Boyd, USPHS, at (301) 594-4654, ext. 128, or by electronic mail at SBB@cdrh.fda.gov.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/comp/guidance/1349.pdf, or CDRH Facts-On-Demand. In order to receive this document via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1349 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Responsibilities of Laser Light Show Projector Manufacturers, Dealers, and Distributors

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

To Laser Light Show Projector Manufacturers, Dealers, and Distributors

Subject Clarification of Responsibilities of Laser Light Show Projector Manufacturers, Dealers, and Distributors.

Purpose
This guidance clarifies the regulatory requirements that apply to manufacturers who deliver laser light show projectors to dealers and distributors, and addresses the corresponding responsibilities of dealers and distributors of laser light show projectors.

Issue
We at the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) receive many inquiries about the specific legal requirements that apply to laser light show manufacturers and about the related laser light show variance approval process. The inquiries suggest that some of you in the laser light show industry, either as a manufacturer or as a dealer and distributor, may be confused about your regulatory responsibilities. We also know that some manufacturers of laser light show projectors sell equipment to customers without obtaining an approved variance from us, which is not acceptable.

Background
We may grant a variance from the requirements of the Federal Laser Performance Standard for Lasers and for demonstration laser products. The criteria and procedures for submitting a variance request are explained in detail in federal regulations at 21 CFR sec. 1010.4. We may grant a variance when you provide an acceptable alternative means of laser radiation safety and protection where a laser light show projector fails to meet the requirements of 21 Code of Federal Regulations (CFR) 1040.11(c). The variance, therefore, allows you as the manufacturer of laser light show and projector to deviate

from the existing performance standards required by federal regulation. (See 21 CFR 1040.10 and 1040.11(c).)

As you know, all manufacturers of Class IIIb and IV laser light shows and laser light show projectors must have approved variances from us to perform laser light shows and introduce laser light show projectors into U.S. commerce. Prior to performing laser light shows or introducing laser light show projectors into U.S. commerce, the manufacturer must submit the following to us at CDRH:

- A Product Report describing the laser projector
- A Laser Light Show Report describing the laser light show, and
- A variance application requesting permission to deviate from the Federal Laser Performance Standards.

Only the Laser Light Show Report and variance application must be submitted if an individual or firm purchases a certified laser projector for which a Product Report has already been submitted by the projector manufacturer.

These three documents describe how the laser light show and projector comply with the Federal Laser Performance Standards, how and why these products deviate from the standards, and what alternative means of laser radiation safety and protection are provided where these products do not comply with the standards. A laser light show production may not begin until we issue a variance approval letter that indicates the conditions under which the laser light show may be produced.

Several conditions are placed upon performance of laser light shows to protect the public from exposure to hazardous levels of laser radiation. One laser light show variance condition states that laser projectors may only be delivered to customers having an approved variance.

Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of electronic product regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that the information requested in the guidance is not relevant to the decision-making process or that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at variance allowing specific use of that projector. The intent of this condition is to ensure that only individuals or firms who are aware of laser light show radiation safety and protection practices and regulatory requirements acquire laser light show projectors. http://www.fda.gov/cdrh/resolvingdisputes/ombudsman.html.

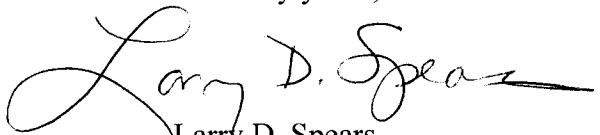
Guidance for Dealers and Distributors
Dealers and distributors of laser light show projectors must have approved laser light show variances to purchase equipment from projector manufacturers. This requirement ensures that awareness of laser light show radiation safety and protection practices and regulatory requirements are transferred from one variance holder to the next.

Additionally, we assume that dealers and distributors may need to demonstrate the capabilities of the laser light show projectors to customers during the course of sale. In doing so, dealers and distributors are manufacturing a laser light show, which requires a laser light show variance.

Therefore, any dealer or distributor of laser light show projectors must submit the required reports and apply for a variance to purchase and sell laser light show projectors. Laser light show projectors shall not be purchased until that variance application is approved and the purchasing party provides the projector manufacturer the purchaser's variance number and its effective date.

Getting More Information
Additional information on the requirements for lasers and laser light shows is available on our electronic product radiation control web page at http://www.fda.gov/cdrh/radhlth/. If you have any questions regarding this notice, contact LT Sean Boyd, CDRH, Office of Compliance (HFZ-342), 2094 Gaither Rd., Rockville, MD 20850, via phone 301-594-4654, x128, fax 301-594-4672, or e-mail sbb@cdrh.fda.gov.

Sincerely yours,



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