Guidance for Industry and FDA Staff

Procedures for Renewal and Amendment of Certain Laser Light Show Variances (Laser Notice 55)

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For questions regarding this document contact the Office of Radiological Health at RadHealth@fda.hhs.gov.

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

Electronic Products Branch
Division of Mammography Quality and Radiation Programs
Office of Communication, Education, and Radiation Programs

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Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, 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.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/ocer/guidance/1639.html. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (**1639**) to identify the guidance you are requesting.

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This guidance represents the Food and Drug Administration's (FDA'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 FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

Under current radiological health regulations, the Center for Devices and Radiological Health (CDRH) may grant manufacturers of electronic products variances from requirements of the laser product performance standard subject to any conditions necessary to protect the public health and safety (21 CFR 1010.4). FDA also may amend or withdraw a variance for justified reasons (21 CFR 1010.4(c)(2)). This guidance provides CDRH's explanation of our decision to amend specified laser light show variances by changing their termination dates and the renewal process for certain laser light show variances currently in effect. CDRH has determined that the variance amendments described below are justified by 21 CFR 1010.4(a)(2). Affected variances will continue to provide suitable means for assuring radiation safety or protection. Notification of the amendment will be provided to affected variance holders by individually addressed letters.

FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device and 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 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 http://www.fda.gov/cdrh/ombudsman/.

1. Issue

All manufacturers of demonstration laser products, which includes all laser light shows and laser projection systems used in light shows, must comply with the requirements specified in Title 21 of the Code of Federal Regulations (21 CFR), Sections 1040.10 and 1040.11. The laser standard limits demonstration laser products to laser emission levels not in excess of the limits of Class IIIa in 21 CFR 1040.11(c). However, many laser light shows are intended to be produced in large spaces, requiring the use of laser emission levels of Class IIIb or Class IV to produce the desired visual effects. Class IIIb or Class IV shows may be produced only when there is a variance approved by CDRH in accordance with 21 CFR 1010.4 permitting the use of lasers exceeding the Class IIIa demonstration laser product limit. CDRH believes that the variance process is a necessary and appropriate means to ensure public health and safety when high power laser beams are used in entertainment and display. Variance renewals have become routine and unnecessarily burdensome when there are no significant changes from an existing approved variance. Therefore, CDRH is now modifying the variance renewal and amendment processes to improve the efficiency of the process as follows:

- Modifying the renewal and amendment processes to permit automatic renewal of certain laser light show variances if required annual reporting requirements are met,
- Amending certain laser light show variances currently in effect to revise their termination dates and set conditions for automatic renewal, and
- Amending all variances described in this guidance to permit the addition of any certified laser projectors (which are not designed or intended for audience scanning effects or projection of invisible laser radiation to produce visible effects) to the firm's laser shows without requiring variance amendments.

These modifications in accordance with 21 CFR 1010.4(c)(2) will reduce the regulatory burden on manufacturers of laser light shows without compromising the public health.

2. Guidance

What laser light show variances are affected by this guidance?

- Variances for laser light shows or projectors which do not employ audience scanning or exposure effects; and

- Variances for laser light shows or projectors which produce their visual effects by means of emissions only in the visible wavelength range from 400-700 nm and which do not use invisible laser emissions to produce visual effects, and

- Variances for which the types of locations or the types of laser light effects employed are not changing; and

- Variances which do not permit less than the normal clearance distances; and

- Variances which do not deviate from the other conditions described in the original variance approval letter issued by CDRH.

What changes are being made to the amendment process and to current variances?

Manufacturers of Class IIIb and IV laser light shows and/or projection systems, who currently have approved variances and meet all of the conditions given above, will have their variance amended as follows.

- The effective date (Paragraph B) of each current variance will be amended by replacing Paragraph B with a paragraph that will extend the current variance for one year effective December 31 of the current year on the condition that the required annual report for the current year has been submitted as required.

- The termination date (Paragraph C) of each current variance will be amended to become December 31st of the current year if the annual report for the current year has not been submitted as required.

- Paragraph D of each current variance will be amended to permit the firm to manufacture and certify Class IIIb or IV laser light show projectors and to incorporate any Class IIIb or IV laser light show projectors which have been certified by their manufacturers, with the exception of projection systems designed or intended to produce visible effects by means of invisible laser emissions and/or to produce audience scanning effects.

- Variance Attachment A, Condition 2 will be amended by expanding Condition 2 to require submission of the current annual report as a condition for extension of the variance on December 31st of the current year and to require that the annual report have attached a list identifying the manufacturer, model designation, and accession number for the product report of all the laser projectors used in the firm's laser light shows during the reported year.

- Variance Attachment A, Condition 12 (or, alternately, the equivalent condition dealing with setup, alignment, testing procedures and records to be available with a show) will be amended to add keeping a copy of Laser Notice 55, the variance amendment notice, the firm's most recent annual report, and the CDRH acknowledgment of receipt of the annual report to the records already included in this requirement.

What conditions apply to these changes?

- The laser light show manufacturers must currently have approved variances from 21 CFR 1040.11(c) in effect, and

- The laser light show manufacturers must submit their annual reports every year as required by 21 CFR 1002.13. The regulation specifies that the annual report is due by September 1, covering the previous 12 month period from July 1 through June 30.

How will affected variances be amended?

Each current variance holder will be notified by a letter in accordance with 21 CFR 1010.4(c)(1) that its variance has been amended in accordance with 21 CFR 1010.4(c)(2). The notification will include the amendment specifications and will have this Laser Notice (Laser Notice 55) attached.

What laser light show variances are NOT affected by this guidance?

Variances for projection systems and laser light shows intended to produce audience scanning or visible effects using invisible laser emissions, such as fluorescence or plasma breakdown, are not subject to this guidance. Such projectors and light show effects produced in excess of the Class I limits must be specifically approved by CDRH.

- Manufacturers wishing to incorporate or add such products and effects may apply for variances (or an amendment to an existing variance) in accord with the process described in 21 CFR 1010.4.

- Any variances for which audience scanning or invisible laser emissions are currently permitted shall retain the original effective date and termination date and shall be subject to renewal in accord with the process described in 21 CFR 1010.4.

Variances requesting additional types of effects to be employed, additional location types where shows will be presented, or deviations from the normal clearance or other conditions are not subject to this guidance.

- Manufacturers wishing make such changes may apply for amendment to their existing variances in accord with the process described in 21 CFR 1010.4.

What requirements must continue to be met for all laser light show and projector products?

Manufacturers must continue to meet requirements for laser light shows and projectors, including:

- 21 CFR 1002.10, (Product Reports) requires manufacturers to submit product reports for new shows and projectors not yet reported to CDRH.

- 21 CFR 1002.11, (Supplemental Reports) requires manufacturers to submit supplemental reports for changes to shows and projectors that effect radiation emission or manner of compliance with the Federal laser standards.

- 21 CFR 1002.20, (Reporting of Accidental Radiation Occurrences) requires manufacturers to report incidents involving public exposure to radiation.

- 21 CFR 1002.30(a) and 1002.31, (Manufacturer's Records) require manufacturers to retain records specified in the regulation.

- 21 CFR 1003, (Notification of Defects or Failure to Comply) requires manufacturers to notify CDRH of products that have electronic product defects or that fail to comply with an applicable standard.

- 21 CFR 1004 (Repurchase, Repair, or Replacement of Electronic Products) requires manufacturers to repurchase, repair or replace products containing a defect or failing to comply with an applicable standard.

- All conditions specified in the manufacturers' currently approved variances, in the variance attachments, and as amended by letter and explained in this guidance.

Can the Center revoke a variance?

Yes. CDRH may withdraw any variance if necessary to enforce the Electronic Product Radiation Control Provisions of the Federal Food, Drug, and Cosmetic Act and applicable regulations. Such action may be appropriate if CDRH has reason to believe a manufacturer is creating a public heath or safety hazard by not complying with applicable requirements and the specific conditions of their variance.

3. Getting More Information

You can get more information about our requirements for lasers from our electronic product radiation control web page at our electronic product radiation control web page.