Reporting Guide for

Laser Light Shows and Displays

(21 CFR 1002)

Office of Compliance

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20850

Foreword

This guide was developed by the Office of Compliance, Center for Devices and Radiological Health (CDRH), to assist electronic product manufacturers in providing adequate reporting of radiation safety testing and compliance with performance standards. Reporting requirements are specified in Title 21 of the Code of Federal Regulations (CFR), Part 1002.

Reports submitted on radiation safety of electronic products must follow the appropriate guide (21 CFR 1002.7), or contain a justification why it was not followed. CDRH may reject an incomplete report and return it for completion. When the report is adequate for filing, it will be logged into the CDRH computer system and assigned an accession number. The submitter of the report will receive an acknowledgment letter with the accession number we assign to the report. Please reference this accession number in the future when providing additional information about this model family in either a supplement or the annual report.

WE DO NOT APPROVE THESE REPORTS OR THE PRODUCTS BEING REPORTED. It is the manufacturer's responsibility to certify that their products comply with the applicable standard (21 CFR 1010 - 1050), based on a testing program in accordance with good manufacturing practices. The manufacturer is required to submit the report (21 CFR 1002) and to comply with all applicable importation requirements (21 CFR 1005) prior to the shipment of products in interstate commerce. If there are deficiencies, we may disapprove the firm's quality control and testing program or determine that the product contains a radiation defect or fails to comply with a standard. We will notify the manufacturer if we make such a determination. Then the manufacturer may be required to cease introduction into U.S. commerce until deficiencies are corrected, and to initiate a corrective action program (21 CFR 1003 - 1004) for products already introduced into commerce.

We are making our reporting guides available on the CDRH web site at http://www.fda.gov/cdrh/comp/eprc.html, for downloading and reproduction. They are not copyrighted and may be reproduced as needed.

Please mail your reports to the address below (electronic submissions cannot be processed yet). Provide one original IN ENGLISH (no facsimile, please) unless specified otherwise in the guide. Make a copy of the completed report for your records. If you would like to comment on the reporting guides or the electronic docket or future electronic submissions, you may direct the comments to the same address. If you need additional regulations for electronic products or medical devices, contact the Division of Small Manufacturers, International, and Consumer

Assistance by telephone at 1-800-638-2041 or 301-443-6597, or by facsimile at 301-443-8818.

Lillian J. Gill

Director
Office of Compliance

MAILING ADDRESS:

Center for Devices and Radiological Health
Attn: Electronic Product Reports
Electronic Product Document Control (HFZ-309)
Office of Communication, Education, and Radiation Programs
9200 Corporate Blvd.
Rockville, MD 20850

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INTRODUCTION

This guide is to be used for reporting laser light shows or displays incorporating Class IIIb or Class IV lasers only. Separate reports are not required for shows or displays that incorporate Class I, IIa, II, or IIIa laser projection systems. Such show descriptions must be included in the user instructions and the report for the laser projector.

Laser projectors used in any light shows or displays regardless of the class of the projector must be certified by the manufacturer and reported using the guide titled, "Guide for Preparing Laser Product Reports for Lasers and Products Containing Lasers." These guides assist manufacturers in providing the information that the Center for Devices and Radiological Health (CDRH) needs to determine how laser light show projectors and laser light shows comply with the Federal standard for laser products (21 CFR 1040.10 and 1040.11) and with the conditions of an approved variance.

An approved variance from section 1040.11(c) is required for demonstration laser products (including projection systems and shows) that would be Class IIIb or Class IV. Applicable reports and application forms must be submitted and the variance approved by CDRH prior to the sale, lease, or use of a Class IIIb or IV projector or laser light show.

A report is to be submitted for each unique laser projector, light show, or display. If you later plan to add effects to a previously reported show or introduce a material change in the show, auxiliary projection equipment, or projector, you must submit a supplementary report describing the additions or changes. If you plan to introduce a projector or show that is substantially different, you must submit an additional laser product or light show report.

If you are the manufacturer of the projector AND a Class IIIb or IV light show, then the general laser product reporting guide must be used to provide a complete report on the whole projection system and this laser light show guide to describe all the effects. In the Laser Product Report you would identify the projector, including auxiliary components in the projection system, and describe any aspects of the design of those components that satisfy a requirement of the variance or the standard.

If the projector or projection system was purchased and is certified by its manufacturer, you may provide information concerning the projector by reference to the manufacturer's report on the projector, specifying the model number, model name, and the CDRH Accession Number of that report.

However, if you have modified the projector (changed the protective housing, interlocks, apertures, installed lasers of a different class, added remote controls, etc.) or added auxiliary equipment such as mirrors, mirror balls, fiber optics, remote scanners, projection screens or other surfaces as targets, etc., the modified projection system must be reported by you, using the general laser product reporting guide. As above, the projector manufacturer's report may be referenced for any items of information that were not affected by your modifications.

A Laser Product Report or Supplemental Report must be submitted prior to introduction of changes. In addition, you should check your variance approval letter, specifically paragraph D and the conditions in any attachments, before you produce new shows to be certain that your variance allows the proposed changes. If it does not, then you must apply for and receive an approved amendment to your variance prior to introducing your new show or projector into commerce.

Your variance will be approved for a specific period of time. If you wish to produce shows after the expiration date, several months prior to its expiration date you must request an extension in writing. Variance extensions and renewals are subject to the adequacy and timeliness of all required reports, show notifications, and recordkeeping. Noncompliances in your shows, projection equipment, or quality control records would be grounds for denial of your request, or further regulatory actions.

Please submit your reports to the Center for Devices and Radiological Health, ATTN: Electronic Product Reports, Electronic Product Document Control (HFZ-309), Office of Communication, Education, and Radiation Programs, 9200 Corporate Blvd., Rockville, MD 20850. Attachments required by the guides should be numbered to correspond with the appropriate questions (i.e., information requested by item 7.0 should be numbered 7.0).

The Product Reporting Guides and Annual Reporting Guides are available from the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) in Rockville, Maryland at 1-800-638-2041. DSMICA should be contacted for requests of any current documents and reporting guides.

If you have specific questions regarding regulations or filling out these reports, call the Electronic Products Branch, Office of Communication, Education, and Radiation Programs at 240-276-3332.

REPORT ON LASER LIGHT SHOW OR DISPLAY

PART 1

IDENTIFICATION OF MANUFACTURER

1.1 Manufacturer of the laser light show

Manufacturer:

Address:

Firm's prime contact or responsible person

Name & title:

Telephone:

NOTE: The firm applying for the laser light show variance and intending to take responsibility for the laser light show would be considered the MANUFACTURER of the show.

1.2 Importing agent (if applicable)

Name & title:

Address:

Telephone:

1.3 Name of person preparing report:

Signature:

Name & title:

Telephone, if different from manufacturer's phone number given above:

_____

NOTE: Information on laser projectors and auxiliary projection equipment is to be submitted using the "Guide for Preparing Product Reports on Lasers and Products Containing Lasers."

PART 2

IDENTIFICATION OF REPORT

2.1Is this Report pursuant to 21 CFR 1002?

( ) Yes ( ) No

2.2This report is:

( ) a new laser light show report

( ) a supplemental report

2.3If this is a supplemental report, give CDRH accession number and date of the laser light show report that it supplements.

Accession number:

Date:

2.4 Date of this report:

PART 3

SHOW NAME

3.1What is (are) the name(s) of the light show or display?

NOTE: See Part 7 to provide dates, times, and locations of shows.

PART 4

VARIANCE

4.1Attach a copy of your variance application (FDA Form 3147) or, if approved, your variance approval letter (or variance number).

Is variance application attached? ( )Yes ( )No

Is a copy of your variance approval letter attached? ( )Yes ( )No

(Or provide current variance number:)

PART 5

PROJECTION EQUIPMENT

5.1List each projector used in the light show by manufacturer, model number or other designation, and CDRH accession number for the projector, if known.

Manufacturer	Model or designation	CDRH accession number
_____	_____	_____

PART 6

SHOW VENUE

6.1The laser light show or display takes place in:

( ) Planetarium or other dome projection structure

( ) Theater

( ) Hotel/Motel ballroom or meeting room

( ) Store displays

( ) Trade show or convention

( ) Discotheque or nightclub

( ) Pavilion

( ) Indoor arena

( ) Outdoor arena

( ) Museum

( ) Outdoor unenclosed area

( ) Other (specify)

NOTE: Be sure to provide beam path diagrams/floor plans for each of the types of venues checked off, unless certain drawings are general enough to cover more than one type. Drawings shall be attached following Part 9.

6.2 The laser light show or display takes place:

( ) at only one (fixed) location

( ) at a variety of (tour) locations

( ) other (specify)

PART 7
SHOW LOCATIONS, DATES, TIMES

7.1 Give specific location(s), date(s), and time(s) for the show, if known[1].

PART 8

LIGHT SHOW EFFECTS PRODUCED

8.1 The laser light show uses the following laser effects:

( )front screen projections

( )rear screen projections

( )holographic displays

( )multiple reflection/diffraction effects

( )audience scanning, including scanning any accessible, uncontrolled areas

( )reflections from stationary mirrors or mirrored surfaces

( )stationary irradiation of rotating mirror balls, etc.

( )scanning irradiation of rotating mirror balls, etc.

( )fiber optic projections

( )fog, smoke, or other scattering effects

( )other (specify)

NOTE: Be sure that the beam path diagrams included in your response to Part 9 are sufficient to illustrate all of the effects indicated above. Several effects may be included in a single diagram.

1see footnote 1 at the end of this Guide

PART 9

DIAGRAMS AND DRAWINGS OF SHOW VENUE

9.1 Provide both plan and elevation drawings with dimensions of the show or display. If the setup varies from show to show, then provide this information for a typical show. Be sure to include in the drawings:

1. the location of the projector(s) and control panel(s), audience, performer(s), operator(s), mirrors, mirror balls, display screens (or other targets), and beam termination points;

2. the direct and reflected laser radiation beam path;

3. the laser radiation levels in each beam including the wavelength, maximum power, and scan parameters (if scanned) for the worst case from a human access point of view;

4. the minimum separations of the laser radiation fields (or beams) from reference locations in audience and performer areas in both vertical and horizontal directions; and

5. any direct or reflected beams into audience or performer locations.

Drawings attached? ( )Yes ( )No (If "No," explain)

PART 10

LASER RADIATION LEVELS

10.1 Describe how each of the laser radiation levels, indicated on the drawings above, were determined. If any levels were derived from calculations rather than directly measured, provide the actual calculations that were made.

Description and calculations enclosed? ( ) Yes ( ) No

PART 11

SCANNING SAFEGUARDS

11.1 Will there be audience scanning[2] from any of the planned effects?

( ) Yes ( ) No

11.2 Do any of the planned effects require laser radiation (direct or scanned beams) to be viewed by operators, performers, or employees?

( ) Yes ( ) No

If the answer to either of the above questions is yes, describe how the radiation levels that reach into audience areas are maintained at Class I levels by scanning. Your description must include details of the required scan failure safeguard, including a discussion of the means of detection of the scanning, the theory of the operation of the scanning safeguard, and its speed of response in order to show that it will prevent the scanned radiation from exceeding the Class I limits.

Description attached? ( )Yes ( )No

11.3 Will any laser radiation greater than Class I STRIKE BUT NOT BE VIEWED by operators, performers, or other employees? ( ) Yes

If "Yes," describe, in detail, the operation of the scan failure safeguard or other means which will prevent exposure to beams exceeding Class II. If a scan safeguard is used, include a discussion of the detection of scanning, the operation, and the speed of response of the safeguard to show that it will prevent the scanned radiation from exceeding the limits of Class II. If other means are used, such as pressure pads or infrared beams, describe in detail as well.

Description attached? ( )Yes ( )No (If "No," explain)

2see footnote 2 at the end of this Guide

PART 12

OPERATOR CONTROLS

12.1 Is the show under the continuous control of an operator?
( ) Yes ( ) No

12.2 Does the laser operator perform tasks in addition to operation of the laser projector?
( ) Yes ( ) No

If "Yes," describe those tasks:

12.3 Can the operator see all of the propagating beam paths, their terminations, and the audience at all times during the performance?
( ) Yes ( ) No

If "No," explain how adequate surveillance is provided:

12.4 Do any other personnel assist in providing surveillance of the laser display?
( ) Yes ( ) No

If "Yes," state number of persons, their identification, their duties, and how they assist in providing surveillance. Describe how they are in constant communication with the operator.

Information attached? ( ) Yes ( ) No

12.5 What qualifications are required of laser operators for your show?[3]

3 see footnote 3 at the end of this Guide

OPERATOR CONTROLS (Continued)

12.6 If your show is not under the continuous control of an operator, is a person designated to be responsible for the immediate termination of the laser radiation in the event of equipment malfunction, audience unruliness, or other unsafe conditions?

( ) Yes ( ) No ( ) Not applicable

If "No," explain alternate control:

12.7 How is this person designated? What are his or her duties?

12.8 What qualifications are required of this person?

PART 13

PROJECTION EQUIPMENT CONTROLS

13.1 Are one or more readily accessible controls provided to immediately terminate laser radiation?

( ) Yes ( ) No

Number of controls:

13.2 Describe the location of these controls and their operation relative to your show.

PART 14

TEST PROCEDURES

14.1 Attach a copy of the written setup, alignment, and test procedures to be followed prior to the operation of the laser light show at each location (see sample checklist for laser light shows in the Appendix).

Procedures attached? ( )Yes ( )No (If "No," explain)

14.2 When are these setup, alignment, and test procedures performed?

14.3 What laser radiation levels are used during setup, alignment, and checkout?

milliwatts

14.4 Is a written record of the results of the setup, alignment, and test procedures maintained?

( ) Yes ( ) No

If "No," explain how adequate quality assurance is maintained:

NOTE: Adequate recordkeeping would include, but not be limited to: (1) sketches showing the location of the laser projector(s), operator(s), performer(s), audience, beam paths, viewing screens, wall mirrors, mirror balls, and other surfaces that may be struck by the laser beams; (2) information on scanning patterns, velocity, and frequency; and/or (3) laser radiation levels used in each effect.

PART 15

NOTIFICATION PROCEDURES

15.1 What procedures are followed for notification of appropriate Federal (CDRH, FAA), State, and local agencies?

Procedures and/or form letters attached?

( ) Yes ( ) No (If "No," explain why)

15.2 What Federal, State, or local agencies are notified or would be notified?

List of agencies attached: ( ) Yes ( ) No

If "No," explain:

FOOTNOTES

1. Show notification:

Provide the location(s), date(s), and time(s) for this show if this information is known at the time this report is submitted. If not, advanced written notification must be made as early as possible to appropriate Federal, State, and local authorities. To be considered timely, this written notice must be submitted 30 days prior to the opening of the show. When the show dates become known to the manufacturer less than 30 days prior to the show date, the required information must be provided verbally by phone or by FAX to CDRH. A confirming formal written notice, including the date of the phone notification and the name of the CDRH individual to whom the information was given must be submitted to CDRH within 14 days. Written confirmation would not be needed following a FAXed notification.

CDRH must be notified of every show that your firm intends to produce. If notifications are not routinely received in a timely manner your variance may be revoked.

2. Audience scanning:

Audience scanning is considered to be any scanning, projection, or reflection of laser or collateral radiation into audience or other accessible, uncontrolled area. Scattered radiation coming from diffuse reflectors such as fog, smoke, mist or similar diffusing media is not considered audience scanning. However, all radiation must be below Class I levels if it reaches into audience or other uncontrolled areas. A scanning safeguard is required whenever a laser light show includes audience scanning to assure that the laser radiation levels in audience areas will not exceed Class I limits if there is a scan failure. See the companion publication, "Compliance Guide for Laser Products," for further discussion.

3. Qualifications:

Holders of variances are required by the variance to employ trained operators or to assure that the operators receive adequate training to qualify them for the safe use of the laser projection system and presentation of the light show effects. Useful information including training films, reference books, and programs on the safe use of lasers may be obtained from the Laser Institute of America (LIA), 12424 Research Parkway, Suite 130, Orlando, Florida 32826, (407) 380-1553; and from the American National Standards Institute, 1430 Broadway, New York, New York 10018 (request ANSI standard Z136.1).

APPENDIX

SAMPLE CHECKLIST FOR LASER LIGHT SHOWS

(Your actual modified checklist should be submitted under 14.1)

NOTE: In order to keep your variance for a laser light show that uses Class IIIb or IV levels of laser radiation in effect, it is essential that you maintain your show in strict compliance with the conditions of the variance. You are therefore expected to perform checks as often as appropriate to make sure that you have not departed from any of the conditions of the variance, and to maintain records in order to be ready for inspection by regulatory authorities without warning.

This sample checklist shows the types of checks that should be performed during preparation for a laser light show. It is not intended that you adopt this sample without any modification. Individual aspects of your show may make it important to add some new items and delete others. Attach a copy of your checklist to this report and maintain in your records those checklists that you complete for each performance.

SAMPLE LASER LIGHT SHOW CHECKLIST AND DOCUMENTATION

All items must be brought to a satisfactory state before being checked off.

A. IDENTIFICATION

1. Name of show:

2. Location of show:

3. Date(s) and time(s) of show:

4. Operator responsible for safety of show:

5. Manufacturer of the laser light show projector/display device:

   a. Name:

   b. Address:

   c. Area code and telephone:

6. Name and title of responsible person:

B. EQUIPMENT CHECKS - (you may want to list these items in a table format for daily preshow check-off)

1. Are all protective housings in place with proper tight fit?

2. Is the projector secured rigidly in place?

3. Before activating the laser, check that all beam shutters are operable and are left in the closed positions.

4. Make sure that the laser cannot be energized without the key and that key removal terminates operation.

5. Check that all accessories such as mirrors and targets are secured firmly in place.

6. Energize the laser at the lowest possible power (without allowing the beam to emerge and with shutters closed).

7. Confirm that all emission indicators and the emission delay operate properly.

8. Verify that all required labels are in place and visible on the projector:

   ( )Certification - projector's label with variance number.

   ( )Certification - light show's label with variance number.

   ( )Identification of light show manufacturer

   ( )Aperture(s)

   ( )Noninterlocked (or defeatably interlocked) protective housing(s)

   ( )Warning logotype

C. ALIGNMENT CHECKS

1. Evacuate all but essential personnel from the facility. These checks must be performed with no audience present.

2. Make certain that you have visual control of the entire projection space from your operating location (especially the audience space) and that areas are adequately secured (see the current ANSI Z136.1 standard for guidance).

3. Operate the laser at the lowest possible power, open the shutters, and perform alignments.

4. Perform a physical survey to confirm that beams exceeding Class I will be separated from the audience by at least the minimum distances required. (In general, for shows under operator control, a 3 meter vertical separation and a 2.5 meter horizontal separation from audience locations are required, For shows not under continuous operator control, a 6 meter vertical and 2.5 meter horizontal separation would be required.)

5. Review your proposed projections with venue management to be certain that the audience will not be permitted access to locations resulting in a violation of item 4 above.

SAMPLE LASER LIGHT SHOW CHECKLIST AND DOCUMENTATION (Continued)

6. Operate the projector at the power required for the show, making sure that there are no spurious projections into unintended areas and that the conditions of item 4 are maintained. Determine and record the power levels in accordance with the levels reported in Part 9 of your laser light show report.

7. Confirm that all projectors and optics are rigidly secured and cannot be disturbed during subsequent setup operations or during the show itself.

8. Check for operation and proper setting of all devices related to safety, including:

   ( ) beam blocks

   ( ) scanning safeguards

   ( ) emergency stop controls

9. Maintain continuous surveillance of the projectors and all optics between the time of alignment and start of the show to be certain that the alignment of the projector and optics is not disturbed.

D. MEASUREMENT/PARAMETRIC CHECKS

1. List the effects to be performed.

   (a)

   (b)

   (c)

   (d)

   (e)

   (f)

   (g)

2. For each effect, give, if applicable, time duration, intended and measured power in the beams, scan frequency and amplitude, and identification of the measuring instrument used.

   (a)

   (b)

   (c)

   (d)

   (e)

   (f)

   (g)

E. ADMINISTRATIVE CHECKS

1. List the name and title of the person responsible for safety at the show facility.

2. List those agencies you have notified of your show.

   Attach a copy of your notifications.

3. Attach plan and evaluation drawings showing the locations of all projectors, external optics, projections, and audience.

NOTE: Safety considerations mandate that you account for all specular reflections and that the operator have visual control of all projections at all times.