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FORM FDA 3640 (12/16)

Reporting Guide for Laser Light Shows and Displays

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This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

More industry guidance and assistance can be found at the FDA homepage, see: http://www.fda.gov/Radiation-EmittingProducts/.

Send your completed report to:

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER – WO66-G609
ATTN: ELECTRONIC PRODUCT REPORTS
10903 NEW HAMPSHIRE AVENUE
SILVER SPRING, MD 20993-0002

Questions about reporting and suggestions for changes to this guide may be sent to the above address or may be discussed by calling 1-800-638-2041.

Reporting Guide for Laser Light Shows and Displays (21 CFR 1002)

Office of Compliance
September 1995

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
Silver Spring, MD 20993

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Foreword

The Office of Compliance, Center for Devices and Radiological Health (CDRH) developed this guide. This guide will assist manufacturers[1] of electronic products which emit radiation in providing adequate reporting of radiation safety testing and compliance with federal performance standards. Title 21 of the Code of Federal Regulations (CFR), Parts 1002 and 1003 specify Reporting and Notification requirements[2,3].

Reports submitted on radiation safety of electronic products must follow the appropriate guide (21 CFR 1002.7). If the report does not follow an applicable guide it must contain a sufficient justification for any deviations. 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. If a report is incomplete or inadequate CDRH may reject it and return it for completion. CDRH will not enter a rejected report into our database. Also, a rejected report will not receive an accession number.

WE DO NOT APPROVE THESE REPORTS OR THE PRODUCTS BEING REPORTED. It is the manufacturer's responsibility to certify that their products comply with all applicable standards (21 CFR 1010 - 1050), based on a testing program in accordance with good manufacturing practices. Prior to the shipment of products in interstate commerce 21 CFR 1002 requires the manufacturer to submit the report and to comply with all applicable importation requirements (21 CFR 1005). If there are deficiencies, we may disapprove the firm's quality control and testing program, determine that the product contains a radiation defect, or determine that the product fails to comply with a standard. We will notify the manufacturer if we make such a determination. CDRH may require the manufacturer 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.

Please mail your reports to the address below (FDA can not process electronic submissions at this time). Provide the original report with appropriate signature(s) (no facsimiles, please). Provide extra copies only if this guide specifically requires them. Submit the report written in the English language. Translate any text that appears in a language other than English into English in a complete and accurate manner. Keep a copy of the completed reports in your records.

We are making our reporting guides and other regulatory information available on the Internet under http://www.fda.gov/Radiation-EmittingProducts/. No copyright exists for these guides. Reproduce these guides as needed. If you would like to comment on the reporting guides, web site, or future electronic submissions, you may direct the comments to the address below. If you need additional regulations for electronic products or medical devices, you should contact the Division of Small Manufacturers, International and Consumer Assistance by telephone at 1-800-638-2041 or by facsimile at 301-847-8149.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance

E-MAIL ADDRESS: dsmica@fda.hhs.gov

MAILING ADDRESS (see 21 CFR 1002.7 for further information):

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER – WO66-G609
ATTN: ELECTRONIC PRODUCT REPORTS
10903 NEW HAMPSHIRE AVENUE
SILVER SPRING, MD 20993-0002

[1] **Manufacturer** (see 21) CFR § 1000.3(n)) means any person engaged in the business of manufacturing, assembling, or importing electronic products.

[2] **Accidental Radiation Occurrences:** 21 CFR 1002.20 requires manufacturers to immediately report accidental radiation occurrences (see 21 CFR 1000.3(a) for the definition).

[3] **Notification:** Title 21 CFR Part 1003 requires manufacturers to provide Notification of Defects or Failure to Comply. Send these notifications to the above address.

CONTENTS

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," HHS publication FDA 86-8259. 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 and 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 and 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 report(s) to: Center for Devices and Radiological Health, Document Mail Center - WO66-G609, Attention, Electronic Product Reports, 10903 New Hampshire Avenue, Silver Spring, Maryland 20993-0002. 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 Manufacturer's Assistance (DSMA) in Rockville, Maryland at 1-800-638-2041. DSMA should be contacted for requests of any current documents and reporting guides.

More industry guidance and assistance can be found at the FDA homepage, see: http//www.fda.gov/Radiation-EmittingProducts/.

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 number _____ Email _____

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.

( ) Correspondence may also be addressed to submitter or person preparing report

I, the manufacturer of the laser light show, certify that all of the below information and statements are true, complete, and correct to the best of my knowledge and acknowledge that my variance application may be denied or my variance may be revoked if the information contained in this form is found to be false, misleading, or incorrect in any material way.

Signature _____

1.2 Importing agent (if applicable)

Name & title _____

Address _____

_____

Telephone number _____ Email _____

1.3 Submitter or person preparing report:

Name & title _____

Telephone number and Email address if different from manufacturer's phone number given above:

Telephone number _____ Email _____

I, the submitter or person preparing report, certify that all the below information and statements are true, complete, and correct to the best of my knowledge

Signature _____

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" (Form FDA 3632).

PART 2
IDENTIFICATION OF REPORT

2.1 Is this report pursuant to 21 CFR 1002?

( ) Yes ( ) No

2.2 This report is:

( ) a new laser light show report

( ) a supplemental report

2.3 If 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

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

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

PART 4
VARIANCE

4.1 Attach 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 enter current variance number: _____)

PART 5
PROJECTION EQUIPMENT

5.1 List 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

6.1 The 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 arena

(☐) 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

(☐) a variety of (tour) locations

(☐) Other (specify) _____

PART 7
SHOW LOCATIONS, DATES, AND TIMES

7.1 Give specific locations(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.

1 See 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, was 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 (☐) No

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)

2 See 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.

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 Is one readily accessible control or more 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.

For CDRH the written show notification requirement has been replaced with a condition requiring maintenance of certain records containing the same information. The firm or person to whom the variance is issued shall maintain complete records of all show events or itineraries with dates, locations, operator name, and the contact information clearly and completely identified. The records shall contain the specific equipment used, a basic description of proposed effects, and a statement of the maximum power output used. These records shall be available to the Food and Drug Administration upon request.

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 areas. 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 ensure 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 ensure 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), 13501 Ingenuity Drive, Suite 128, Orlando, FL 32826, (800) 345-2737 (request ANSI standard Z136.1).

APPENDIX
SAMPLE CHECKLIST AND DOCUMENTATION 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.

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: (____) _____
   d. Email: _____
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.

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.