

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

APPLICATION FOR A VARIANCE
FROM 21 CFR 1040.11(c) FOR A
LASER LIGHT SHOW, DISPLAY,
OR DEVICE

Form Approved: OMB No. 0910-0025
Expiration Date: October 31, 2000
See Page 4 for OMB Statement.

DOCKET NUMBER

NOTE: No laser light show, projection system, or device may vary from compliance with 21 CFR 1040.11(c) in design or use without the approval of this application in accordance with 21 CFR 1010.4.

INSTRUCTIONS

- 1. Check all applicable boxes and type or print the requested information.
- 2. Submit an original and four (4) copies.
- 3. Mail your application to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 1-20, 12420 Parklawn Drive, Rockville, MD 20852.
- 4. Enter docket number if assigned. Room 1061, 5630 Fishers Lane.

1. NAME OF COMPANY

Linden Laser Systems

2. ADDRESS OF COMPANY (Include ZIP Code)(If P.O. Box is used, include actual street address also.)

2615 STATE Highway 13 hampe, mo 65681

3. NAME AND TITLE OF RESPONSIBLE PERSON

Paul Linden

4. TELEPHONE NO. (Include area code)

417-779-8050

5. DATE OF SUBMISSION

06-29-04

6. THE APPLICANT REQUESTS THE VARIANCE TO BE IN EFFECT FOR A PERIOD OF _____ YEARS FROM THE DATE OF ISSUE. (In general, the Agency will approve a variance for only two years. If a longer period is requested, a justification must be attached as part of the application.)

7. PRODUCT DESCRIPTION AND USE

a. LIST NAME AND/OR MODEL NUMBER(S) FOR THE LASER LIGHT SHOW(S) AND PROJECTOR(S)

b. PRODUCT FOR WHICH A VARIANCE IS REQUESTED

- A laser display device
- A projector for a laser light show
- A laser light show
- Other (Specify) _____

c. PROJECTORS ARE INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER LIGHT SHOW PRODUCERS

d. PRODUCT IS INTENDED FOR USE IN A

- Planetarium or other dome projection structure
- Theater
- Hotel/motel ballroom or meeting room
- Store displays
- Trade show or convention
- Discotheque or night club
- Pavilion
- Indoor arena
- Outdoor arena
- Museum
- Outdoor unenclosed area
- Other (Specify) _____

e. PRODUCT IS INTENDED TO BE USED

- At only one (Fixed) location
- At a variety of (Tour) locations
- Other (Specify) _____

f. PRODUCT IS INTENDED TO BE USED AT ANY ONE LOCATION

- More than 15 days
- More than 5 but not more than 15 days
- Less than 5 days

g. TOUR IS INTENDED TO RUN FOR

- More than 6 months
- 1-6 months
- Less than one month
- Not applicable (Not a tour)
- Other (Specify) _____

h. PRODUCT UTILIZES THE FOLLOWING LASER EFFECTS

- Front screen projections
- Rear screen projections
- Holographic displays
- Multiple reflection/diffraction effects
- Audience scanning (Also includes scanning any accessible uncontrolled areas)
- Reflections from stationary mirrors or mirrored surfaces (Beam Matrices)
- Stationary irradiation of rotating mirror balls, etc.
- Scanning irradiation of rotating mirror balls, etc.
- Fiber optic projections
- Fog, smoke, or other scattering enhancement effects
- Other (Specify) Fans, Beams, Down Caves, Lumi A

8. LASER RADIATION LEVELS

LASER MEDIUM (Ar, He-Ne, etc.)	WAVE LENGTHS (nm)	PEAK POWER (watts)
AR KR	450-520 500-676	25 12 18
AR/KR Dye	450-676 530-676	8
NID Yag	532	40

9. IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE

n/a / Yag 500 NS \leq 25 KHz
Vector SK Saan video 31.5 K Scan

10. REASON FOR REQUESTING VARIANCE

Compliance with the limits of 21 CFR 1040.11(c) would restrict the intended use of the product because compliance would limit the output power to the extent that the desired effects would not be sufficiently visible

2004/V-0277

VARI

11. MANNER IN WHICH IT IS PROPOSED TO DEVIATE FROM THE REQUIREMENTS OF THE APPLICABLE STANDARD

- It is proposed to deviate from the provisions of 21 CFR 1040.11(c) in that the accessible emission level would exceed the accessible emission limits specified in 21 CFR 1040.11(c).
- It is proposed to deviate from the provisions of 21 CFR 1040.11(c) as follows:

12. ADVANTAGES TO BE DERIVED FROM SUCH DEVIATION

- Laser light shows and displays are accepted popular media in entertainment and the arts. Use of power levels in excess of the limits imposed by 21 CFR 1040.11(c) is necessary to achieve the required effects in these media.
- Other or additional advantages *(describe and explain)*.

13. EXPLAIN THE ALTERNATE MEANS OF RADIATION PROTECTION TO BE PROVIDED. *(Check as many boxes as apply. In item 14 "Remarks," justify any boxes not checked, using additional sheets as necessary. State any other means of radiation protection that will be used.)*

- a. All laser products, systems, shows, and projectors will be certified to comply with 21 CFR 1040.10 and the conditions of this variance and will be reported as required by 21 CFR 1002.10 AND 1002.11 using the reporting guides provided for such purpose. These actions will be accomplished prior to any introduction into commerce.
- b. Effects not specifically indicated in this variance application will not be performed. No other effects will be added until an amendment to the variance has been obtained and the required reports or supplements, as applicable, have been submitted.
- c. Scanning, projection, or reflection of laser and collateral radiation *(Light show radiation)* into audience or other accessible uncontrolled areas will not be permitted except for diffuse reflections produced by the atmosphere, added atmospheric scattering media, and target screens.
- d. Laser radiation levels in excess of the limits of Class I will not be permitted at any point less than 3.0 meters above any surface upon which persons other than operators, performers, or employees are permitted to stand or 2.5 meters below or in lateral separation from any place where such persons are permitted to be. Operators, performers, and employees will not be required or allowed to view radiation above the limits of Class I or be exposed to radiation above the limits specified in 21 CFR 1040.11(c).
- e. Any product which relies on scanning to meet access, exposure, or product class limits will incorporate a scanning safeguard system which directly senses scanner motion and which will react fast enough to preclude exceeding the applicable limit.
- f. All laser light shows shall be under the direct and personal control of trained, competent operator(s). The operator(s) will:
- (1) Be an employee of the variance holder who will be responsible for the training and the conduct of the operator;
 - (2) Be located where all beam paths can be directly observed at all times; and
 - (3) Immediately terminate the emission of light show radiation in the event of any unsafe condition; or, for outdoor shows, upon request by any air traffic control officials.
- g. The maximum laser projector output power will not exceed the level required to obtain the intended effects:
- h. The projection system *(i.e., the projector and all other components used to produce the lighting effects)* will be securely mounted or immobilized to prevent unintended movement or misalignment. Beam masking will be provided as an inherent part of the system design to prevent overfilling of screens, beam stops, targets, etc.
- i. Laser projectors will not be delivered to any other party under an agreement of sale, lease, or loan unless and until the recipient demonstrates that they have a variance in effect at the time of delivery that permits them to produce laser light shows incorporating such projector(s).
- j. In addition to the requirements of 21 CFR 1040.10(h), the manufacturer of laser projectors/systems will provide to parties who purchase, lease, or borrow the equipment, adequate users' instructions for safe installation and operation which explain the responsibility of the recipient as an independent light show manufacturer to submit the required reports and apply for and obtain a variance from CDRH prior to introduction into commerce of any laser light shows.
- k. The requirements of 21 CFR 1002.30(a)(1) and (2) will be accomplished through the use of written procedures for setup, alignment, testing, and performance of each show. These procedures will be in sufficient detail to ensure compliance with 21 CFR 1040.10, the conditions of this variance, and the control of access to radiation areas using the procedures described in the ANSI Z136.1 standard for the safe use of lasers *(American National Standards Institute, 1430 Broadway, New York, NY 10018)* or any other equivalent user consensus standard and, where applicable, state or local requirements. Laser radiation areas which can contain radiation levels above the limits specified in 21 CFR 1040.11(c) will be clearly identified by the posting of warning signs and/or restricting access through physical means *(such as pressure switches, photo cells, barriers, guards, etc.)*. These requirements apply to temporary areas *(such as during set up and alignment procedures)* and to final or permanent areas. The variance holder will retain the records of these procedures and the results of all tests as required by 21 CFR 1002.31. A copy of the variance application, the approval letter, current procedures, and records relating to each particular show will be with the operator or other responsible individual and will be made available for inspection by FDA and other responsible authorities.

I. Advance written notification will be made as early as possible to appropriate federal, state, and local authorities providing show itinerary with dates and locations clearly and completely identified, and a basic description of the proposed effects including a statement of the maximum power output intended. Such notifications will be made, but not necessarily be limited, to:

- (1) The Center for Devices and Radiological Health, Office of Compliance (HFZ-342), 2098 Gaither Road, Rockville, MD 20850, providing the initial and closing dates for fixed installations and the itinerary for mobile shows. In addition, unless all aspects of each show have been reported and accession numbers clearly referenced, each notice will include detailed descriptions of each show and a listing of all effects to be performed in sufficient detail to confirm compliance with the regulations and this variance.
- (2) The Federal Aviation Administration (FAA) for any projections into open airspace at any time (i.e., including set up, alignment, rehearsals, performances, etc.). If the FAA objects to any laser effects, the objections will be resolved and any conditions requested by FAA will be adhered to. If these conditions cannot be met, the objectionable effects will be deleted from the show
- (3) State and local radiation control offices/agencies for all shows to be performed within their jurisdictions. All requirements of state and local law will be satisfied and any objections raised by local authorities will be resolved or the effects deleted. (A list of federal and state offices is available from the Center for Devices and Radiological Health upon request.)

14. REMARKS

CERTIFICATION

I CERTIFY that all of the above 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 this application is found to be false, misleading or incorrect in any material way. I have submitted and will submit all reports required by 21 CFR 1002.10 and 1002.11 on the laser equipment and show(s). I further understand that I may be required by regulation or by the Director, Center for Devices and Radiological Health, to supply such other information as may be necessary to evaluate and act on this application.

15. SIGNATURE

Paul Linden

16. NAME (Type or Print)

Paul Linden

17. TITLE

OWNER - Linden
Laser
Systems

Public reporting burden for this collection of information is estimated to average .5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS Reports Clearance Officer
Paperwork Reduction Project 0910-0025
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

<- Please DO NOT RETURN this application to this address.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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

Office of Compliance
September 1995

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

Forward

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 Electronic Docket, for downloading and reproduction. They are not copyrighted and may be reproduced as needed. The telephone number for access to the CDRH Electronic Docket via your personal computer's modem is 1-800-252-1366.

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

Sincerely yours,



Lillian G. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

MAILING ADDRESS:

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF COMPLIANCE (HFZ-307)
ATTN: ELECTRONIC PRODUCT REPORTS
2098 GAITHER ROAD
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," 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 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 report(s) to the Director, Office of Compliance (HFZ-300), Attn: Electronic Product Reports, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 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 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.

If you have specific questions regarding regulations or filling out these reports, call the Nonmedical Radiological Devices Branch, Office of Compliance at (301) 594-4654.

REPORT ON LASER LIGHT SHOW OR DISPLAY

PART 1

IDENTIFICATION OF MANUFACTURER

1.1 Manufacturer of the laser light show:

Manufacturer Linden Laser Systems

Address 2615 State Highway 13
Lampe, Mo 65681

Firm's prime contact or responsible person:

Name & title Paul Linden Owner

Telephone 417-779-8050

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 N/A

Address N/A

N/A

Telephone N/A

1.3 Name of person preparing report:

Signature Paul Linden

Name & title Paul Linden

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

2.1 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:

n/A

Date:

2.4 Date of this report:

6/29/04

PART 3
SHOW NAME

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

Generic Sample Corporate Show
hinden laser Systems

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

will comply with footnote # 1 attached

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? (X) Yes () No

Is a copy of your variance approval letter attached?

New Request for Variance () Yes (X) No

(Or provide current variance number: _____)

Applying for Variance for upcoming shows who's dates are yet to be determined but will comply with all Rules & Reqs. as per 21CFR1010.4

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.

<u>Manufacturer</u>	<u>Model or designation</u>	<u>CDRH accession number</u>
Laser Media	LMS	78A0261-15
" "	LM	" " "
" "	Mirco 10	" " "
" "	Stingray	" " "
" "	Fiber Ray	" " "
Laser Rentals	Taurus Laser Video Projector	89A1981-08
Bramin Lasers	BL-14	85A0454-10
" "	TL-16	" " " "
" "	TL-16 Ext	" " " "

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 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 known¹.

Typical Show 8:00 PM

Refer Footnote 1. Advanced written notice will be filed as early as possible

PART 8

LIGHT SHOW EFFECTS PRODUCED

8.1 The laser light show uses the following laser effects:

- X front screen projections
- X rear screen projections
- holographic displays
- X multiple reflection/diffraction effects
- N/A audience scanning, including scanning any accessible, uncontrolled areas
- X reflections from stationary mirrors or mirrored surfaces
- N/A stationary irradiation of rotating mirror balls, etc.
- N/A scanning irradiation of rotating mirror balls, etc.
- X fiber optic projections
- X fog, smoke, or other scattering effects
- X other (specify) Fans, Cones, Lumina

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? (X) 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? (X) Yes () No

Direct Measurement with factory power meters
Beam Divergence measured with calculator + measuring tape
Beam Termination Check by operators.

PART 11

SCANNING SAFEGUARDS

11.1 Will there be audience scanning² from any of the planned effects? () Yes (X) 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 (X) 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 (X) No

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

N/A

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

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

- 12.4 Do any other personnel assist in providing surveillance of the laser display?
(X) Yes (~~3~~) 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

1. two, Laser Safety, spotters, with radios to operator
2. Outside shows two spotters, fieldglasses and Radios

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

Passing Rockwell Laser Safety test
+ Field Experience
Have 25 years Experience

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?

(X) Yes () No () Not applicable

If "No," explain alternate control:

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

Laser Safety - To maintain surveillance at all times of Audience and projection Equipment to keep secure

- 12.8 What qualifications are required of this person?

See 12.5
All have been trained to qualify them for safe use.
All have 25 years experience

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: 3

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

1. at operator site
2. E-stop
3. interlocks and operator

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? (X) Yes () No (If "No," explain)

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

During setup and prior to each show.

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

LOWEST possible milliwatts 500 mw to 1 watt Idle mode

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

(X) 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?

Written notification
All procedures in accordance with 21CFR1010.4
as in item 1 on Footnote

Procedures and/or form letters attached?

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

This is for Pending shows at several locations and states all will be notified as per Compliance.

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

List of agencies attached: (X) Yes () No

If "No," explain:

- ① Office of Compliance and Surveillance HFZ 343
2098 Gaithers Rd
Rockville, Maryland 20805
- ② Radiological Health Section
State Dept of Health Services
of appropriate State.
- ③ FAA if necessary

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 IIb 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.

SAMPLE LASER LIGHT SHOW CHECKLIST AND DOCUMENTATION (Continued)

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)

SAMPLE LASER LIGHT SHOW CHECKLIST AND DOCUMENTATION (Continued)

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.