

4160-01

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

[DOCKET NO. 81P-0361 ET AL.]

APPROVED VARIANCES FOR LASER LIGHT SHOWS; AVAILABILITY

AGENCY: Food and Drug Administration.

53FR 7983  
3/28/88

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that variances from the performance standard for laser products have been approved by FDA's Center for Devices and Radiological Health (CDRH) for 17 organizations that manufacture and produce laser light shows, light show projectors, or both. The projectors provide a laser light display to produce a variety of special lighting effects. The principal use of these products is to provide entertainment to general audiences.

DATES: The effective dates and termination dates of the variances are listed in the table below under "Supplementary Information."

ADDRESS: The applications and all correspondence on the applications have been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Sally Friedman,  
Center for Devices and Radiological Health (HFZ-84),  
Food and Drug Administration,  
5600 Fishers Lane,  
Rockville, MD 20857,  
301-443-4874.

SUPPLEMENTARY INFORMATION: Under 21 CFR 1010.4 of the regulations governing establishment of performance standards under section 358 of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f), FDA has granted each of the 17 organizations listed in the table below a variance from the requirements of 21 CFR 1040.11(c) of the performance standard for laser products.

Each variance permits the listed manufacturer to introduce into commerce a demonstration laser product assembled and produced by the manufacturer, which is its particular variety of laser light show, laser light show projector, or both. Each laser product involves levels of accessible laser radiation in excess of Class II levels but not exceeding those required to perform the intended function of the product.

CDRH has determined that suitable means of radiation safety and protection are provided by constraints on the physical and optical designs and by warnings in the user manuals and on the products. Therefore, on the effective dates specified in the table below, FDA approved the requested variances by a letter to each manufacturer from the Deputy Director of CDRH.

So that each product may show evidence of the variance approved for the manufacturer of the product, each product shall bear on the certification label required by 21 CFR 1010.2(a) a variance number, which is the FDA docket number, and the effective date of the variance as specified in the table below.

| <u>Docket No.</u>       | <u>Organization Granted the Variance</u>  | <u>Demonstration Laser Product</u>  | <u>Effective Date</u><br><u>Termination Date</u> |
|-------------------------|---|---|--|
| ✓ 81P-0361<br>(renewal) | Siegfried and Roy<br>Entertainment, Incorporated<br>dba Beyond Belief<br>Frontier Hotel<br>3120 Las Vegas Boulevard, South<br>Las Vegas, Nevada 89109 | Siegfried and Roy Entertainment,<br>Incorporated "Beyond Belief" laser<br>light show incorporating the Laser<br>Media LMS projector.  | January 22, 1988 -<br>February 1, 1990           |
| ✓ 83P-0085<br>(renewal) | Hill Development Services Company<br>18160 Old Monte Rio Road<br>Guernwood Park, California 95446   | Laser light shows assembled and<br>produced by Hill Development Services,<br>Company incorporating the Class IV<br>Laserscape II krypton, the ABP-1<br>argon, and the CP-1 argon/krypton<br>laser projectors. | January 22, 1988 -<br>March 17, 1990             |
| 7 83V-0412<br>(renewal) | Western Michigan University<br>Dalton Center<br>Kalamazoo, Michigan 49008-5188  | INNOVA 90K Laser Light Shows and the<br>Class IV ion laser projection systems<br>and display devices assembled and<br>produced by Western Michigan<br>University.   | January 12, 1988 -<br>January 26, 1990           |
| ✓ 84V-0335<br>(renewal) | La Mama Experimental Theatre Club,<br>Incorporated<br>74A East 4th Street<br>New York, New York 10003   | Importation of the Campagnia Teatrale<br>Krypton laser projector and laser<br>light show for a two-week presentation<br>in the La Mama Theatre. The projector<br>is a Class IV argon projector.               | December 31, 1987 -<br>September 28, 1989        |
| 85V-0239<br>(amendment) | Laser Dreams<br>7345 Healdsburg Avenue<br>Suite 11<br>Sebastopol, California 95472  | Laser Dreams laser light shows<br>incorporating the Laser Dream Machine<br>Model 1 laser projector with argon,<br>helium-neon, and/or helium-cadmium<br>lasers.   | January 20, 1988 -<br>May 30, 1988               |

| <u>Docket No.</u>         | <u>Organization Granted the Variance</u>  | <u>Demonstration Laser Product</u>  | <u>Effective Date</u><br><u>Termination Date</u> |
|---------------------------|---|---|--|
| ✓ 85V-0298<br>(renewal)   | Laser Light Systems, Incorporated<br>1414 Tilia<br>San Mateo, California 94402                    | Laser Light Systems' laser light shows and the incorporated laser projection system consisting of Laser Systems Development Corporation Model R3, C3, or C6 optics modules and Class IV argon or krypton lasers such as Spectra-Physics' Models 164 or 171 or Laser Light System's Model LLI. | January 5, 1988 -<br>January 9, 1990             |
| ✓ 85V-0305<br>(renewal)   | Sea World<br>1720 South Shores Road<br>San Diego, California 92109                                | Class IV Sea World Model SW-1 ion laser projector and the Sea World laser light shows, such as "Summer Nights" or "Starlight Spectacular" incorporating Laser Media LMS Series and Sea World Model SW-1 laser projectors.   | January 5, 1988 -<br>January 5, 1989             |
| ✓ 86V-0194<br>(amendment) | Lasertainment<br>428 B West County Road D<br>New Brighton, Minnesota 55112                        | Lasertainment laser light show using the Laser Fantasy Class IIIb or IV Rainbow Model Series Ar/HeNe laser projection systems.  | January 5, 1988 -<br>October 16, 1988            |
| ✓ 87V-0308                | Laser Entertainment and Display<br>Incorporated<br>2939 Arden Way<br>Sacramento, California 95825 | Class IV argon/krypton Model LED 1 laser projection system and laser light shows produced and assembled by Laser Entertainment and Display, Incorporated incorporating this projection system.  | December 6, 1987 -<br>December 6, 1989           |
| ✓ 87V-0342                | Allen County Memorial Coliseum<br>4000 Parnell Avenue<br>Fort Wayne, Indiana 96805                | Allen County Memorial Coliseum laser fiber optic scoreboard.  | December 1, 1987 -<br>December 1, 1989           |

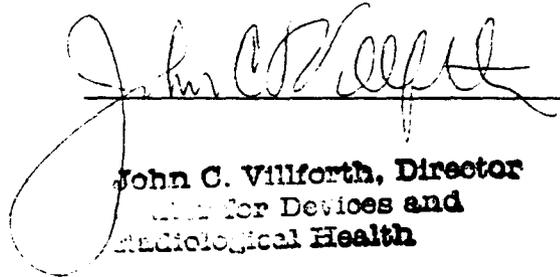
| <u>Docket No.</u> | <u>Organization Granted the Variance</u>  | <u>Demonstration Laser Product</u>  | <u>Effective Date</u><br><u>Termination Date</u> |
|-------------------|---|---|--|
| ✓ 87V-0359        | Diego's Incorporated<br>860 Garnet Avenue<br>San Diego, California 92109              | Club Diego's laser light show using the Entertainment Technology Industries Class IV Beam Master Model Three argon laser projection system.   | November 25, 1987 -<br>November 25, 1989         |
| ✓ 87V-0377        | NASA Ames Research Center<br>MS 247-2<br>Moffett Field, California 94035              | NASA Ames Research Center Wind Tunnel laser display using the Class IV argon Model LRVL laser product modified by NASA/ARC for this display.  | December 4, 1987 -<br>December 4, 1988           |
| ✓ 87V-0385        | The Bailey Controls Company<br>29801 Euclid Avenue<br>Wickliffe, Ohio 44092           | Bailey Controls Company laser light displays using the Centrak Laser Corporation Model CK-2 laser projector.  | December 24, 1987 -<br>December 24, 1989         |
| ✓ 87V-0388        | Benedum Natural Science Theater<br>Ogle Bay Park<br>Wheeling, West Virginia 26003     | Benedum Natural Science Theater Laser Light Show incorporating the Laser Fantasy Rainbow 2000 laser projector.  | January 21, 1988 -<br>January 21, 1990           |
| ✓ 87V-0394        | Spectra Laser Systems<br>10292 Lurline Drive<br>Huntington Beach, California<br>92646 | Laser light shows assembled and produced by Spectra Laser Systems and for the firm's Model Series 6000 Computer Controlled Laser Projectors which are incorporated into these shows.      | December 16, 1987 -<br>December 16, 1989         |
| ✓ 87V-0400        | Hyperion<br>2810 Hyperion Avenue<br>Los Angeles, California 90027                     | Hyperion laser light shows, incorporating an Entertainment Technology Industries Beam Master laser projector.   | December 29, 1987 -<br>December 29, 1989         |
| ✓ 87V-0401        | Chameleon Productions<br>500 E. Concord Street<br>Orlando, Florida 32803              | Chameleon Productions laser light shows, such as "Out of the Darkness," incorporating the Model TL24D laser projection system manufactured by Precision Projection Systems, Incorporated. | January 21, 1988 -<br>January 21, 1990           |

In accordance with § 1010.4, the applications and all correspondence on the applications have been placed on public display under the designated docket number in the Dockets Management Branch (address above) and may be seen in that office between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.86).

Dated: 3/17/88.

**MAR 17 1988**

  
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John C. Villforth, Director  
Center for Devices and  
Radiological Health

1988  
CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



TAB A 87V-0401

JUN 21 1988

Ref: FDA Docket No. 87V-0401  
Accession No. 67a0206

Mr. John Markham  
Chameleon Productions  
500 East Concord Street  
Orlando, Florida 32803

Dear Mr. Markham:

In accordance with 21 CFR 1010.4(c)(1) notice is given that the petition of Chameleon Productions dated December 3, 1987, for a variance from 21 CFR 1040.11(c) of the performance standard for laser products is approved. This variance will allow the introduction into commerce of the laser light show products described in paragraph D below.

A. Variance Number

87V-0401

B. Effective Date

In accordance with 21 CFR 1010.4(c)(1), this variance shall become effective on the date of this letter.

C. Termination Date

This variance shall be terminated two (2) years from the date of this letter.

D. Product for which Variance is Granted

This variance is granted for the Chameleon Productions laser light shows, such as "Out of the Darkness," incorporating the Model TL240 laser projection system manufactured by Precision Projection Systems, Incorporated. The laser light shows may be presented in any type of location for any contract duration. The laser effects to be used are front or rear screen projections, holographic displays, multiple reflection/diffraction effects, reflections from stationary mirrors, stationary or scanning irradiation of rotating mirror balls, fiber optic projections, and enhanced scattering effects.

E. Provision from which Variance is Granted

This variance is granted from 21 CFR 1040.11(c) of the performance standard for laser products requiring that each demonstration laser product shall comply with all of the applicable requirements of 21 CFR 1040.10 for a Class I, IIa, II, or Class IIIa laser product and shall not permit human access to laser radiation in excess of the accessible emission limits of Class I and, if applicable, Class IIa, Class II, or Class IIIa.

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F. Conditions under which Variance is Granted

In lieu of the requirements referred to in Item D above, the conditions as specified below in Variance Attachment A and, if included, Variance Attachment B shall apply to the products and devices manufactured under this variance and to the shows assembled and produced under this variance.

G. Basis For Approval of Variance

In accordance with 21 CFR 1010.4(a)(2), it has been determined that the product is required to perform a necessary function or is intended for a special purpose which cannot be performed or accomplished with equipment meeting the requirements referred to in Item E. Suitable means of radiation safety and protection will be provided by constraints on the physical and optical design, and by warnings in the user/purchaser information.

H. Certification Label

The certification label required by 21 CFR 1010.2 shall be modified in accordance with 21 CFR 1010.4(d) to state: This product is in conformity with performance standards for laser products under 21 CFR Part 1040 except with respect to those characteristics authorized by Variance number 87V-0401 effective

This variance action is available for public disclosure in the FDA Dockets Management Branch and a notice of availability will be published in the Federal Register. The variance will remain in effect until the termination date unless a determination is made that the variance should be amended or withdrawn to protect the public health and safety.

Sincerely yours,

James S. Benson  
Deputy Director  
Center for Devices  
and Radiological Health

cc: FDA Dockets Management Branch, Docket No. 87V-0401  
Attachment A

Variance Attachment 2  
Variance No. 877-0481  
Class

1. This variance is not transferrable to any other firm or person and applies only to the specific products identified in the variance.
2. All laser products, systems, shows, and projectors shall be certified to comply with 21 CFR 1040.10 and the conditions of this variance and be reported as required by 21 CFR 1002.10 and 1002.12 using the reporting guides provided for such purpose. These actions shall be accomplished prior to any introduction into commerce.
3. Effects not specifically indicated in the variance application shall not be performed. Any additional effects require the submission of an amendment request (using Form 3147 or in accordance with 21 CFR 1010.4) and the filing of product reports or supplements as applicable.
4. Scanning, projection, or reflection of laser and collateral radiation (light show radiation) into audience or other accessible uncontrolled areas shall not be permitted except for diffuse reflections produced by the atmosphere, added atmospheric scattering media, and target screens.
5. Access to radiation levels in excess of the limits of Class I by any person other than operators, performers, or employees shall not be permitted at any point less than 3.0 meters above any surface upon which such persons 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 shall not be required or allowed to view radiation above the limits of Class I or be exposed to radiation above the limits of Class II.
6. Any product which relies on scanning to limit access, exposure, or product class limits shall incorporate a scanning safeguard system which directly senses scanner motion and which will react fast enough to preclude exceeding the applicable limit.
7. All laser light shows shall be under the direct and personal control of a trained, competent operator(s). The operator(s) shall:
  - (a) immediately terminate the emission of light show radiation in the event of any unsafe condition;

(b) be located where all beam paths can be directly observed at all times; and

(c) be an employee of the variance holder who shall be responsible for the training and conduct of the operator.

6. The maximum laser projector output power shall not exceed the level required to obtain the intended effects.
7. The projection system (i.e., the projector and all other components used to produce the lighting effects) shall be securely mounted or immobilized to prevent unintended movement or misalignment. Beam limiters to prevent overfilling of screens, laser stops, targets, etc. shall be incorporated as an inherent part of the system design. Such devices may be adjustable if the system's intended use environment requires such capability.
10. In addition to the requirements of 21 CFR 1040.10(n), the manufacturer of laser projectors/systems shall provide to parties who purchase, lease, or borrow the equipment, adequate user's instructions for safe installation and operation. These instructions shall also 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 OSHA prior to the introduction into commerce of any laser light shows.
11. The requirements of 21 CFR 1002.30(a)(1) and (2) shall be accomplished through the use of written procedures for setup, alignment, testing, and performance of each show. These procedures shall 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 10010) or any other equivalent user consensus standard and, where applicable, state or local requirements.

Laser radiation areas which can contain radiation levels above Class I or II as applicable, shall be clearly identified by the posting of warning signs and/or restricting access through physical means (such as pressure switches, photocells, 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 shall retain the records of these procedures and the results of all tests as required by 21 CFR 1004.31. A copy of the variance application, the approval letter, current procedures, and records relating to each particular show shall be with the operator or other responsible individual and shall be made available for inspection by FDA and other responsible authorities.

12. Advance written notification shall 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 proposed effects including a statement of the maximum power output intended. Such notifications shall be made, but not necessarily be limited, to:

(a) The Center for Devices and Radiological Health (CDRH), Office of Compliance (address below) 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 the accession number(s) clearly referenced, each notice shall 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. To be considered timely, this written notice must be submitted 30 days prior to the opening of the subject show or, when the show becomes known to the manufacturer less than 30 days prior to the show date, the required information must be provided verbally in an immediate phone call to CDRH and also confirmed in the formal written notice that includes the date of the phone notification and the name of the official to whom the information was given.

(b) 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 shall be resolved and any conditions requested by FAA will be adhered to. If these conditions can not be met, the objectionable effects shall be deleted from the show.

(c) State and local radiation control offices/agencies for all shows to be performed within their jurisdictions. All requirements of State and local law shall be satisfied and any objections raised by local authorities shall be resolved or the effects deleted.

Unless otherwise specified by regulation (e.g., variance applications), all correspondence to be provided to the CDRH shall be addressed to:

Center for Devices and Radiological Health  
Office of Compliance (CDR-312)  
6757 Georgia Ave.  
Silver Spring, MD 20910

Phone: (301) 427-6226

TAB B

876-0401

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
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. 57R0068  
Use of this form is prohibited  
after July 31, 1984

DOCKET NUMBER

NOTE: No laser light show or display 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 Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20857.
4. Enter Docket Number if assigned.

1. NAME OF COMPANY

Chameleon Productions

2. ADDRESS OF COMPANY (Include ZIP Code)

500 E. Concord Street, Orlando, Florida 32803

3. NAME OF RESPONSIBLE PERSON

John Markham / Daniel Markham

4. TELEPHONE NO. (Include area code)

(305) 422-3444

5. DATE OF SUBMISSION

12/3/87

6. The applicant requests the variance to be in effect for a period of 2 years from the date of issue and requests to manufacture 1 units under this variance. (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 MODEL NUMBER(S)

Chameleon Productions Laser Lighting Effects

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. PRODUCT IS INTENDED FOR USE IN A

- PLANETARIUM OR OTHER DOME PROJECTION STRUCTURE
- THEATER
- DISCOTHEQUE OR NIGHT CLUB
- PAVILION
- INDOOR ARENA
- OUTDOOR ARENA
- MUSEUM
- OUTDOOR ENCLOSED AREA
- OTHER (Specify)

d. PRODUCT IS INTENDED TO BE USED

- AT ONLY ONE (fixed) LOCATION
- AT A VARIETY OF (tour) LOCATIONS
- OTHER (Specify)

e. 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

f. TOUR IS INTENDED TO RUN FOR

- MORE THAN 6 MONTHS
- 1-6 MONTHS
- LESS THAN 1 MONTH
- NOT APPLICABLE (not a tour)
- OTHER (Specify)

g. PRODUCT UTILIZES THE FOLLOWING LASER EFFECTS

- FRONT SCREEN PROJECTIONS
- REAR SCREEN PROJECTIONS
- HOLOGRAPHIC DISPLAYS
- MULTIPLE REFLECTIONS (multiple channel or diffraction effects)
- AUDIENCE SCANNING
- REFLECTIONS FROM STATIONARY MIRROR(S) OR MIRRORED SURFACES
- STATIONARY IRRADIATION OF ROTATING MIRROR BALL(S) OR OTHER MIRRORED SHAPES
- SCANNING IRRADIATION OF ROTATING MIRROR BALL(S)
- FIBER OPTIC PROJECTIONS
- FOG, SMOKE OR OTHER SCATTERING EFFECTS
- OTHER (Specify)

8. LASER RADIATION LEVELS

| LASER MEDIUM (Ar, He-Ne, etc.) | WAVELENGTHS (nm) | PEAK POWER (Watts) |
|--------------------------------|------------------|--------------------|
| Argon Gas                      | 454.5-528.7      | 20 W               |
| Krypton Gas                    | 476.2-676.4      | 10 W               |
| HeNe                           | 632.8            | 5 MW               |

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

20 kHz scan frequency amplitude  $\leq 60$  20 k pulses/sec 50 usec pulsewidth

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
- OTHER OR ADDITIONAL EXPLANATION (Specify)

EXCEED THE ACCESSIBLE LIMITS OF CLASS I OR CLASS II

IT IS PROPOSED TO DEVIATE FROM THE PROVISION 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. Explain any boxes not checked using additional sheets as necessary. If appropriate, state any other means of radiation protection that will be used.)*

- a.  ALL LASER PRODUCTS, SYSTEMS AND PROJECTORS WILL COMPLY WITH 21 CFR 1040.10 FOR LASER PRODUCTS OF THEIR CLASS *(Specify class(es))*  
**& Class IV**
- 
- b.  LASER AND COLLATERAL RADIATION MEASURED WHERE THE AUDIENCE IS LOCATED, SHALL NOT EXCEED THE LIMITS OF CLASS I DURING OPERATION *(includes reflections from targets and scattering materials).*
- c.  OPERATORS, PERFORMERS AND EMPLOYEES WILL BE ABLE TO PERFORM THEIR FUNCTIONS WITHOUT THE NEED TO VIEW LASER AND COLLATERAL RADIATION IN EXCESS OF THE LIMITS OF CLASS I AND WITHOUT BEING EXPOSED TO LASER RADIATION IN EXCESS OF THE LIMITS OF CLASS II. HUMAN EXPOSURE TO CLASS III OR CLASS IV LEVELS OF RADIATION SHALL NOT BE PERMITTED.
- d.  SCANNING DEVICES, INCLUDING MIRROR BALLS, WILL INCORPORATE A SCANNING SAFEGUARD TO PREVENT LASER EMISSION IF SCAN FAILURE OR OTHER FAILURE CAUSING A CHANGE IN EITHER SCAN VELOCITY OR AMPLITUDE WOULD RESULT IN VIOLATION OF ITEMS 13b OR 13c.
- e.  WHEN LASER LIGHT SHOWS OR DISPLAYS ARE NOT OPERATED AT ALL TIMES UNDER THE DIRECT CONTROL OF AN OPERATOR, LASER RADIATION LEVELS WILL NOT EXCEED THE LIMITS OF CLASS II AT ANY POINT LESS THAN 6 METERS ABOVE ANY SURFACE UPON WHICH A PERSON IN THE AUDIENCE IS PERMITTED TO STAND, OR AT ANY POINT LESS THAN 2.5 METERS IN LATERAL SEPARATION FROM OR BELOW ANY POSITION WHERE A PERSON IN THE AUDIENCE IS PERMITTED DURING THE PERFORMANCE OR DISPLAY. A DESIGNATED PERSON(S) WILL BE RESPONSIBLE, AT ALL TIMES DURING THE SHOW OR DISPLAY, FOR THE IMMEDIATE TERMINATION OF LASER RADIATION IN THE EVENT OF EQUIPMENT MALFUNCTION, AUDIENCE UNRULINESS, OR OTHER UNSAFE CONDITIONS. ONE OR MORE READILY ACCESSIBLE CONTROLS TO EFFECT IMMEDIATE TERMINATION OF LASER RADIATION WILL BE PROVIDED FOR THIS PURPOSE.
- f.  WHEN LASER LIGHT SHOWS OR DISPLAYS ARE OPERATED AT ALL TIMES UNDER THE DIRECT CONTROL OF A TRAINED OPERATOR LASER RADIATION LEVELS WILL NOT EXCEED THE LIMITS OF CLASS II AT ANY POINT LESS THAN 3 METERS ABOVE ANY SURFACE UPON WHICH A PERSON IN THE AUDIENCE IS PERMITTED TO STAND OR 2.5 METERS IN LATERAL SEPARATION FROM OR BELOW ANY POSITION WHERE A PERSON IN THE AUDIENCE IS PERMITTED TO BE UNLESS PHYSICAL BARRIERS RESTRICT ACCESS BY THE AUDIENCE TO SUCH LEVELS. THE OPERATOR WILL MAINTAIN CONSTANT SURVEILLANCE OF THE LASER DISPLAY AND IMMEDIATELY TERMINATE EMISSION OF LASER RADIATION IN THE EVENT OF EQUIPMENT MALFUNCTION, AUDIENCE UNRULINESS OR OTHER UNSAFE CONDITIONS.
- g.  THE MAXIMUM LEVELS OF LASER RADIATION *(output power)* WILL NOT EXCEED THOSE REQUIRED TO PERFORM THE INTENDED FUNCTION OF THE PRODUCT.
- h.  WRITTEN SET-UP, ALIGNMENT AND TEST PROCEDURES WILL BE PROVIDED TO AND FOLLOWED BY THE OPERATOR OR OTHER RESPONSIBLE PERSON PRIOR TO USE OF THE LASER LIGHT SHOW AT EACH LOCATION. THESE STEP-BY-STEP PROCEDURES WILL BE DESIGNED SO THAT WHEN FOLLOWED, THE LASER LIGHT SHOW WILL COMPLY WITH THE CONDITIONS OF THE APPROVED VARIANCE. THE RESULTS OF THE REQUIRED TEST AND CHECKS WILL BE RECORDED AND A COPY RETAINED WITH THE LIGHT SHOW BY THE OPERATOR OR OTHER RESPONSIBLE PERSON. THE RECORD WILL INCLUDE (1) SKETCHES SHOWING THE LOCATION OF THE LASER PROJECTOR(S), OPERATOR(S), PERFORMER(S), AUDIENCE, BEAM PATHS, VIEWING SCREENS, WALLS, MIRROR BALLS, AND OTHER SURFACES THAT MAY BE STRUCK BY THE LASER BEAM; (2) INFORMATION ON SCANNING PATTERNS, VELOCITY AND FREQUENCY; AND (3) LASER RADIATION LEVELS.
- i.  SET-UP, ALIGNMENT, CHECKOUT AND TESTING SHALL BE PERFORMED USING THE MINIMUM LASER RADIATION LEVELS NECESSARY.
- j.  PROCEDURES WILL BE ESTABLISHED AND FOLLOWED FOR THE WRITTEN NOTIFICATION OF APPROPRIATE FEDERAL, STATE, AND LOCAL AGENCIES OF THE ITINERARIES, OR ANY OTHER REQUIRED INFORMATION. SPECIFICALLY, THE FEDERAL AVIATION ADMINISTRATION (FAA) WILL BE NOTIFIED IN ADVANCE OF SHOWS USING PROJECTIONS INTO THE SKY. STATE AND LOCAL RADIATION CONTROL OFFICES WILL BE NOTIFIED IN ADVANCE OF ALL SHOWS WITHIN THEIR RESPECTIVE JURISDICTIONS. *(Lists of Federal and State offices are available from the Bureau of Radiological Health upon request.)*

... OF EACH LASER... TO BE GIVEN UNDER THE APPROVED VARIANCE AS SOON AS THE PLACE AND DATE CAN BE DETERMINED. THE APPLICANT, IN ADDITION, A DESCRIPTION OF EACH SHOW AND A LISTING OF ALL EFFECTS TO BE UTILIZED IN EACH LOCATION, IN SUFFICIENT DETAIL TO CONFIRM COMPLIANCE WITH THE CONDITIONS OF THE VARIANCE, WILL BE PROVIDED TO THE BUREAU OF RADIOLOGICAL HEALTH. THIS NOTIFICATION WILL BE SENT TO THE DIRECTOR, DIVISION OF COMPLIANCE, HF X-400, BUREAU OF RADIOLOGICAL HEALTH, 5600 FISHERS LANE, ROCKVILLE, MARYLAND 20857.

15. REMARKS

The laser lighting effects for this show are produced by one model TL-24 D laser projection system manufactured by Precision Projection Systems Incorporated located at 10755 Artesia Blvd. #M, Artesia, CA 90701. Serial # 242

This system has been certified by Precision Projection Systems to be in compliance with the performance standards for laser productions except for certain characteristics as authorized by variance # 83V-0151 effective June 6, 1986.

Further information on this system and the operator is available in the form of a Laser Product Report and any various supplementary reports filed with the CDRH under accession number to be issued by the CDRH.

A report on a laser light show which describes in detail the laser effects used in this production has been submitted to the CDRH. The accession number for this submission will be available upon issuance by the CDRH.

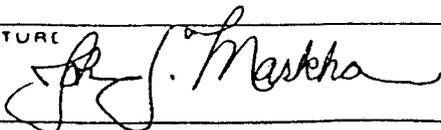
Performances will be conducted with the employees of Chameleon Productions acting as system operators.

Chameleon Productions projectors will utilize LM scanning software and hardware; therefore, the radiation levels will be the same. Please refer to LM's file on calculations for scanned laser radiation by Seigi Inatsugu, PhD. These calculations will be the same as to the reference to LM and LMS projectors.

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/will submit all reports required by 21 CFR 1002.10 and 1002.12 on the laser equipment and show(s). I further understand that I may be required by regulation or by the Director, Bureau of Radiological Health to supply such other information that may be necessary to evaluate and act on this application.

16. SIGNATURE



17. TITLE

General Partner