IMAGINEERING WITH LASERS

10801 Cosmonaut Blvd.
Orlando, FL 32824
Phone: 407.859.8166
Fax: 407.859.8254
www.av-imagineering.com

May 2, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1081
Rockville, MD 20857

Re: Variance No. 79P-0055
Accession No. 79A0118-18

To Whom It May Concern,

Enclosed is a copy of our variance application dated 2/12/01 and a copy of our approved variance. In reviewing the new variance, I noticed that the solid state lasers in our application were not included. I spoke with Collin Figueroa, who suggested I resubmit the application. Could you amend the variance to include these lasers? If you have any questions or concerns, please contact our company's president, Ward Davis, at 407-859-8166. Thank you for your attention to this matter.

Sincerely,

Teri Staten
Executive Assistant

79P-0055

AMD 4

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: 0910-0025
Expiration Date: August 31, 1988

DOCKET NUMBER
79P-0055

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 4-62, 5600 Fishers Lane, Rockville, MD 20857.
4. Enter Document Number if assigned.

1. NAME OF COMPANY
AUDIO VISUAL IMAGINEERING, INC.

2. ADDRESS OF COMPANY (*Include ZIP CODE*) (*If P.O. Box is used, include actual street address also.*)
10801 Cosmonaut Blvd., Orlando, Florida 32824

3. NAME AND TITLE OF RESPONSIBLE PERSON	4. TELEPHONE NO. (*Include area code*)	5. DATE OF SUBMISSION
Ward Davis, President	407-859-8166	02/12/2001

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)
AVI Laser Projection System - S/B Series (CDRH Accession No. 790118-12,-13,14,16)
Omniscan Laser Projection System Model Series 2000

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*) Laser Video Projection

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 1 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*) _____

8. **LASER RADIATION LEVELS**

LASER MEDIUM (*Ar, He-Ne, etc.*)	WAVE LENGTHS (nm)	PEAK POWER (*Watts*)
HELIUM NEON	632.8 nm	.05 watts
KRYPTON	488 - 647.1 nm	9 watts
ARGON	457.9 - 514.5 nm	25 watts
ARGON-KRYPTON	457.9 - 676.4 nm	28 watts
DIODE-PUMPED SOLID STATE	532 nm	11 watts
DIODE-PUMPED Nd:YV04	446 - 628 nm	19 watts

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

PLEASE REFER TO SECTION 14 AND ATTACHMENTS

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*)

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 PROVISION OF 21 CFR 1040.11(c) AS FOLLOWS:

PLEASE REFER TO ATTACHMENTS

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)

PLEASE REFER TO ATTACHMENTS

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 necesssary. 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 1002.12 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) IMMEDIATELY TERMINATE THE EMMISSION OF LIGHT SHOW RADIATION IN THE EVENT OF ANY UNSAFE CONDITION;

(2) BE LOCATED WHERE ALL BEAM PATHS CAN BE DIRECTLY OBSERVED AT ALL TIMES; AND

(3) BE AN EMPLOYEE OF THE VARIANCE HOLDER WHO WILL BE RESPONSIBLE FOR THE TRAINING AND CONDUCT OF THE OPERATOR.

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 LIMITERS 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.

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 USER'S INSTRUCTIONS FOR SAFE INSTALLATION AND OPERATION AND 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, 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 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 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-312), 8757 GEORGIA AVE., SILVER SPRING, MD 20910, 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 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 CAN NOT 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. (LISTS OF FEDERAL AND STATE OFFICES ARE AVAILABLE FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH UPON REQUEST.)

14. REMARKS

Our laser projector is designed to scan (i.e. reflect from mirrors attached to galvanomic scanners) laser beams direclty onto a screen surface to form patterns in such a way that laser and collateral radiation, measured where the audience is located, does not exceed the limits of Class I during operation. Each of the laser projector scanners has frequency range of: 60 cycles per second (minimum) to 4000 cycles per second (maximum). The amplitude (i.e. angle of laser beam deflection from each scanner) is: 0 degrees (minimum) to 180 degrees (maximum).

Diode-pumped solid state laser using an optical parametric oscillation to produce 446 - 628 nm wavelengths.
Peak pulse power: 34 kwatts
Avg. pulse power: 19 watts
Rep. rate: 80 MHZ, width: 7ps

Please also refer to attachments G-K.

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 1002.12 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	16. NAME (Type or Print)	17. TITLE
Ward Davis	Ward Davis	President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 30 2001

Ref: FDA Docket No. 79P-0055
Accession No. 79A0118-18

Mr. Ward Davis
President
Audio Visual Imagineering, Inc.
10801 Cosmonaut Boulevard
Orlando, Florida 32824

Dear Mr. Davis:

In accordance with 21 CFR 1010.4(c)(1) notice is given that the petition of Audio Visual Imagineering, Inc., dated February 15, 2001, for a renewal of their variance, Number 79P-0055, 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

79P-0055

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 on May 19, 2004.

D. Product for Which Variance is Granted

This variance is granted for the Class IIIb or IV Audio Visual Imagineering (AVI) Model S/B Series and the Omniscan Model 2000 laser projection systems incorporating certified argon, krypton, mixed-gas, and/or helium-neon lasers. This variance is also granted for the laser shows or displays assembled, produced, and operated by Audio Visual Imagineering, Inc. with these projection systems. The laser projection systems may also be sold, leased, or loaned to other parties who have obtained a variance as required to produce laser light shows with one of these projection systems.

The shows may be presented in any type of facility or outdoor, unenclosed area for any contracted duration. The shows may employ front or rear screen projections, multiple reflection/diffraction effects, reflections from stationary mirrors, 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 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.

F. Conditions under Which Variance is Granted

In lieu of the requirements referred to in Item E above, the conditions as specified below in Variance Attachment A, Variance Attachment B, and Variance Attachment C 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 complies with performance standards for laser products under 21 CFR Part 1040 except with respect to those characteristics authorized by Variance Number 79P-0055 effective May 19, 1980.

This variance action is available for public disclosure in the Food and Drug Administration (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,

Christy Foreman for

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

cc: FDA Dockets Management Branch, Docket No. 79P-0055

Attachments A, B, and C

Variance Attachment A
Variance No. 79P-0055
AVIS (Audio Visual Imagineering, Inc.)

1. This variance is not transferable 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 applicable requirements of 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 this variance approval 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. Laser projection systems and light shows manufactured, assembled, or produced under this variance shall not be transferred to any other party until the recipient has demonstrated that they have a variance, as required, in effect that permits them to produce certified laser light shows incorporating these laser projection systems. A notation of the recipient's variance number and its effective date, as applicable, shall be entered and retained in the records of compliance test results required by 21 CFR 1002.30.

5. 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.

6. 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. An exception to the above clearance requirements is specified in Variance Attachment C for the AVI Omniscan Laser Projection System Model 2000, 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.

7. Any product which relies on scanning to meet 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.

8. All laser light shows shall be under the direct and personal control of a trained, competent operator(s). The operator(s) shall:

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

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

   (c) immediately terminate the emission of light show radiation in the event of any unsafe condition and, for open air shows, at the request of any air traffic control officials.

9. The maximum laser projector output power shall not exceed the level required to obtain the intended effects.

10. 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.

    Electronic controls and circuits shall be adequately shielded to prevent electromagnetic sources (e.g., walkie talkies, head-set radios, wireless microphones, cellular telephones, etc.) in the vicinity of the projector, its active projection heads, and control system(s) from causing the laser emissions to be misdirected from their intended target area.

    Beam masking to prevent projections into prohibited areas or directions or overfilling of screens, beam 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.

11. In addition to the requirements of 21 CFR 1040.10(h), 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 manufac- turer to submit the required reports and apply for and obtain a variance from the Center for Devices and Radiological Health (CDRH) prior to the introduction into commerce of any laser light shows.

12. 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 any emergency shutdown requirements, and the control of access to radiation areas using the procedures described in the ANSI Z136.1-1993 Standard For The Safe Use of Lasers (available from The Laser Institute of America, 1242 Research Parkway, Suite 130, Orlando, Florida 32826) 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 setup 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 1002.31. 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.

13. 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) and the Electro Optic Specialist responsible for the location of the show (addresses 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) and the Department of Defense (DOD) for any projections into open airspace at any time (i.e., including setup, alignment, rehearsals, performances, etc.). If the FAA or DOD objects to any laser effects, the objections shall be resolved and any conditions requested by FAA and DOD 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 (HFZ-342)
2098 Gaither Road
Rockville, MD 20850
Phone: Voice: (301) 594-4654
FAX: (301) 594-4672

REGIONAL ELECTRO-OPTICS SPECIALISTS **10/3/2000**

For States: ME, NH, VT, MA, NY, CT, RI

Captain Max Lager, EOS
FDA (HFR-NE25)
1 Montvale Avenue
Stoneham, MA 02180-3542

781-279-1675 x1754
781-279-1687 (fax)
mlager@ora.fda.gov

For States: NJ, DE, MD, DC, VA, TN, NC, SC, GA, FL, PR, AL, MS, LA

Tom Goertz, EOS
FDA (HFR-SE450)
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

504-253-4508
504-253-4566 (fax)
jgoertz@ora.fda.gov

For States: NJ, DE, MD, DC, VA, PA, WV, KY, OH, IN, IL, MI, WI, MN, ND, SD

James E. Frye, EOS
FDA (HFR-CE450)
6751 Steger Drive
Cincinnati, OH 45237

513-679-2700 x149
513-679-2772 (fax)
jfrye@ora.fda.gov

For States: IA, MO, AR, NE, KS, OK, TX, WY, CO, NM, UT

Dennis Butcher, EOS
FDA (HFR-SW49)
12 Sunnen Drive, Suite 122
St. Louis, MO 63143

314-645-1167 x160
314-645-2969 (fax)

dbutche1@ora.fda.gov

For States: AZ, Southern California

Suzie Kent, EOS
FDA (HFR-PA2545)
19900 MacArthur Blvd., Suite 300
Irvine, CA 92615-2445

949-798-7657
949-798-7750 (fax)

skent@ora.fda.gov

For States: Northern California

Francis (Frank) Eng, EOS
FDA (HFR-PA1530)
96 N. Third St., Room 325
San Jose, CA 95112

408-291-7548 x15
408-291-7228 (fax)

feng@ora.fda.gov

For States: Northern CA, NV, MT, ID, OR, WA, AK, HI

Gary Zaharek, EOS
FDA (HFR-PA1530)
96 N. Third Street
San Jose, CA 95112

408-291-7548 x12
408-291-7228 (fax)

gzaharek@ora.fda.gov

Reserve EOS - NE Region

Emir Galevi
FDA/WEAC (HFR-NE480)
109 Holton Street
Winchester, MA 01890

781-729-5700 x 724
781-729-3593 (fax)

egalevi@ora.fda.gov

Variance Attachment B
Variance No. 79P-0055
AVIS

This attachment provides the list of information to be provided to the Federal Aviation Administration (FAA) and the Department of Defense (DOD) in notifications of outdoor laser light shows (demonstrations) which cause projections into the sky. This information is required to permit FAA and DOD jointly to do the aeronautical study necessary to determine whether or not the proposed effects are objectionable.

CONTENT OF NOTIFICATIONS

a. Proponent notifications to the FAA regional office will include the following information on all proposed outdoor demonstrations:

1. Laser group/company (point of contact).
2. Business addresses.
3. Telephone number.
4. CDRH Variance number and expiration date.
5. Date(s) and time(s) of setup and alignment.
6. Date(s) and time(s) of shows(s).
   (a) Show length
   (b) Running time.
7. Location of the show.
   (a) Show place name and address.
   (b) Latitude and longitude of show place in Degrees, Minutes and Seconds.
   (c) Maps (USGS 7.5 Quadrangle or acceptable alternate).
8. Class/Type of Laser (CW or Pulsed*)
9. Maximum emitted power (watts)/repetition frequency (Khz) at the projector as certified to CDRH.
10. Azimuth direction of beams.
11. Elevation of beams in degrees above the horizon.
    (a) maximum
    (b) minimum
12. Beam divergence (milliradians).
13. Maximum distance from source for irradiance of 2.6 mW/cm^2, 100 $\mu W/cm^2$, and 5 $\mu W/cm^2$ based on maximum emitted power.
14. Maximum altitude above source for irradiance of 2.6 mW/cm^2, 100 $\mu W/cm^2$, and 5 $\mu W/cm^2$ based on maximum emitted power.
15. A diagram depicting all beam arrays terminated/unterminated.
16. Laser safety officer/operator:
    (a) Local address and phone number, to include an operational telephone number at the site.
    (b) Additional safety procedures:
        (1) Communications procedures during the show.
        (2) Visual aircraft spotters.
        (3) Other.

17. Quality Assurance Program, describing physical/procedural control of:
    (a) laser power
    (b) beam divergence
    (c) azimuth and elevation of beam paths
    (d) beam termination surfaces
    (e) emergency shutdown procedures

Note: Repetitive pulsed laser data (e.g., equipment type, pulse duration, etc.) shall be validated by the CDRH, and shall accompany submission to the FAA.

b. Supplementary information if applicable. Include the CDRH letter validating the measures which result in a smaller affected area than that shown in the Laser Projector Power/Range Table (Table 34-8, FAA Order 7400.2D, Chg.1).

SUBMISSION OF PROPOSAL

a. The last condition of Attachment A of the variance requires that you provide written notification to the Federal Aviation Administration (FAA) and the Department of Defense (DOD) and satisfy any requirements they may specify before conducting an outdoor laser light show.

b. In detail, this requirement means that:

    1. All notifications are to be directed to the Air Traffic Division at the FAA regional office having jurisdiction over the area where the laser show will take place.

    2. FAA needs at least 30 days advance notice to process a request and conduct an aeronautical study. The FAA recognizes that industry conditions may not always permit the advance notice desired. While FAA endeavors to accommodate all requests, proper conduct of the aeronautical study to determine airspace effects is essential to air safety. This is particularly true when the nature of the demonstration is in close proximity to an airport or would necessitate protection of large amounts of airspace. In these cases, it may be impossible for the FAA to respond to short-notice requests.

    3. Notifications are required for all demonstrations in which laser light beams may be directed or reflected into airspace (including set-up, alignment, and rehearsals). Notifications should contain sufficient technical information to allow proper evaluation. The primary concern is the range and elevation from the source of the airspace which may be affected by the display.

    4. A proponent wishing to provide supplementary information about measures which will result in a smaller actual danger area than that shown in the Laser System Range Table (Table 34-8, FAA Order 7400.2D, Chg.1) should submit the data in advance to CDRH for review. CDRH will validate the information and issue a letter to the proponent to include with their notification to the FAA.

Variance Attachment C
Variance No. 79P-0055
AVIS

This attachment is applicable only to the laser light shows or displays produced by Audio Visual Imagineering that incorporate their OMNISCAN Laser Projection System Model 2000.

1. The OMNISCAN Laser Projection System Model 2000 units covered under this attachment will be permanently installed in a planetarium as a tool to be used in the regular astronomy education programs with the star-field projector and other projection systems.

2. When the design of the planetarium dome does not permit meeting the requirements for 3 meter clearance above the floor and 2.5 meter lateral separation for laser emission levels in excess of the Class I limits as specified in Attachment A, Condition 6 of this variance, the following conditions in lieu of Condition 6 shall be satisfied:

   a. The scanned laser emissions shall not exceed the limits of Class I at any height less than 2 meters above and 0.6 meters lateral separation from the floor of the public access area of the planetarium outside the projection system's restricted area and shall not exceed the limits of Class II at heights less than 3 meters and greater than or equal to 2 meters above the floor.

   b. The OMNISCAN Model 2000 projector shall have a means to monitor the direction of projection. There shall also be a means to dynamically reduce of the beam power when the beam is directed into regions of projection space that fall below the 3-meter level. The means for reducing the beam power shall prevent the emission level from exceeding the Class II limits during the scanning with the specified beam velocity.

   c. Further, the OMNISCAN Model 2000 projector shall also have redundant scan fail safeguard systems which monitor both the specified beam velocity and the achieved beam velocity. They shall terminate the beam with an acousto-optic modulator and a galvanometer shutter in the event that the scan velocity falls below a set limit.

IMAGINEERING WITH LASERS

10801 Cosmonaut Blvd.
Orlando, FL 32824
Phone: 407.859.8166
Fax: 407.859.8254
www.av-imagineering.com

February 15, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1081
Rockville, MD 20857

Dear Sir/Madam,

I request that our variance (No. 79P-0055, effective 5/11/98 from 21 CFR 1040.11[c] of the performance standard from laser products) to be extended for the maximum possible time period. We plan to manufacture, produce, and assemble laser light shows as specified in our Initial Report and Supplements (CDRH Accession No. 79A0118-12,-13,-14). Our current variance is due to expire on May 19, 2001.

I look forward to your response. Please contact me if you have any questions.

Sincerely,

Ward Davis
President

WD:ts

7000 1670 0010 8539 2799

7000 1670 0010 8539 2799

U.S. Postal Service
CERTIFIED MAIL RECEIPT
(Domestic Mail Only; No Insurance Coverage Provided)

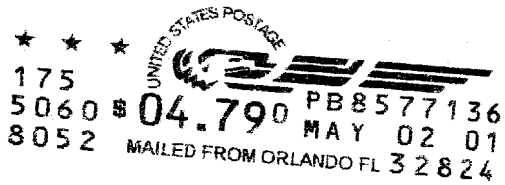
OFFICIAL USE

Postage	$1.39
Certified Fee	1.90
Return Receipt Fee (Endorsement Required)	1.50
Restricted Delivery Fee (Endorsement Required)	
Total Postage & Fees	$4.79

Sent To: Dockets Management Branch (HFA-305) F.D.A.
Street, Apt. No.; or PO Box No.: 5630 Fishers Lane, Rm 1061
City, State, ZIP+4: Rockville MD 20857

PS Form 3800, May 2000 — See Reverse for Instructions

SOUTH CREEK ORLANDO FLA
MAY 03 2001
Postmark Here
USPS - 32837



175
5060 $04.790 PB8577136
8052 MAY 02 01
MAILED FROM ORLANDO FL 32824

FROM:

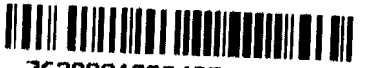
SERV: CER

TRK#: 700016700010853927

05/09/01 03:25

TO: HFA-305 ROOM1061

OF PCS: 1



7629021232487

RM: HFA-305 ROOM1061

IMAGINEERING WITH LASERS

10801 Cosmonaut Blvd.
Orlando, FL 32824 U.S.A.
Phone: 407.859.8166

Dockets Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane
Rockville, MD 20857