Submission Report

Section: Main Menu

Welcome

Welcome to the CDRH Electronic Submissions Software (CeSub)

This software application is intended to automate the current paper submission process. This software contains a number of data capturing tools and helpful dialog boxes to reduce redundant responses for you, and to allow us to capture data in a more useful, structured format. These benefits will enable CDRH to improve our review process and reduce lengthy review times.

For your convenience, an email account has been established to support any questions that you may have regarding the use of this software. Please email any questions or comments to the CeSub team at: **cdrhesub@cdrh.fda.gov.** Please be sure to include your name, company name and contact information in the email.

Thank you again for using our electronic product reporting software. We look forward to hearing from you soon.

What type of product is this submission referring to? *
Radiation Emitting Product (OMB No. 0910-0025; Expiration Date: December 31, 2006)

Welcome (Cont.)

Department of Health and Human Services
Food and Drug Administration

Form Approved:
OMB Number 0910-0025
Expiration Date: December 31, 2006

Section: eRadHealth Menu

Role

What is your role? *	Manufacturer

Submission Information

What Type of Submission is this? (Supplements should be submitted selecting the same document type as the original report.) *
Variance Request
What Type of Product is this Annual Report about?
What Type of Correspondence is this?
What Type of Product is this Radiation Safety Report about?
What Type of Product is this Variance Request about? *
Laser Light Shows
What Laser Light Show Documents are you filing?

Section: Manufacturer Data

Introduction

Electronic Product Radiation Safety Reporting Form

This software application is intended to automate the hard copy product reporting forms in the effort of the Center for Devices and Radiological Health (CDRH) to become capable of accepting electronic submissions from industry and to improve our review process. This CDRH Electronic Submission (CeSub) software is the next version of the application the CDRH is developing to allow us to accept all Radiological Health reports and other submissions electronically and improve the ability of CDRH to accomplish its mandated product and industry evaluations in a timely and efficient manner.

We have already received many electronic submissions and are looking forward to receiving more in the future. With this new release of the software we have updated our procedures for packaging a submission to make this a smoother process for all. All electronic reports (your new CD-ROMs) and any other documents you are submitting in hard copy because they cannot be provided in an acceptable electronic format must be mailed to CDRH. A signed hard copy of the submittal letter generated by the submission software, should be printed out and included with your electronic submission. This printed documentation will provide the Document Control Room with enough information to log the submission. The electronic submissions should be sent directly to the Document Control room, which is the same process for the standard paper

submission.

The submission must be addressed to:

Electronic Product Document Control (HFZ-309), Attn: CeSub Team, Center for Devices and Radiological Health, 2094 Gaither Road, Rockville, MD 20850

After sending your submission to the Document Control Room, please send an email to the cdrhesub@cdrh.fda.gov email account so we will know that your submission is forthcoming. Please remember that all correspondence concerning your submission MUST be sent to the Electronic Product Document Control (HFZ-309), at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official notification submission. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. You should also be familiar with the regulatory requirements for radiological products at www.fda.gov/cdrh/comp/eprc.html and medical devices available at Device Advice www.fda.gov/cdrh/devadvice/.

If you have specific questions regarding the software, please contact the CeSub team by email at: **cdrhesub@cdrh.fda.gov**.

Thank you for using our electronic product reporting software. Please communicate your comments and criticisms to the CeSub team as often as you like.

Thank you for your continued support of the CDRH eSubmission Pilot Program.

General Information

General Information for Radiological Health Products

Manufacturers of products subject to performance standards under the Federal Food, Drug, and Cosmetic Act (FFDCA), Chapter V, Subchapter C - Electronic Product Radiation Control are required to furnish various reports to the Center for Devices and Radiological Health (CDRH).

The Radiological Health staff, CDRH developed this software application for the Product and Annual reports. This application will assist manufacturers of electronic products that emit radiation in providing adequate reporting of radiation safety testing and compliance with federal performance standards. Title 21 of the Code of Federal Regulations (CFR), Parts 1002 and 1003 specify Reporting and Notification requirements 1,2,3.

Reports submitted on radiation safety of electronic products must follow the appropriate

form (21 CFR 1002.7). This software application serves the same report responsibility, so long as the submitter or manufacturer prints out the cover letter and sends it in along with the CD containing the report files. The submitter of the report will receive an acknowledgment letter (or email message) with the accession number that CDRH assigns to the report. Please reference this accession number in the future when providing additional information about this model family in either a supplement or the annual report. If a report is incomplete or inadequate CDRH may reject it and return it for completion. CDRH will not enter a rejected report into our database.

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

CDRH can now accept and process 'CeSub' electronic submissions at this time, if all attachments are PDF files only, and the cover letter is printed out and included with a real signature. Translate any text that appears in a language other than English into English in a complete and accurate manner. Keep a copy (save a copy to your hard drive) of the completed report in your records.

We are providing our new software applications for the old reporting forms upon request during this beta testing period of development in Spring, 2005. Other regulatory information is still available on the Internet under http://www.fda.gov/cdrh/comp/eprc.html. No copyright exists for these forms.

Reproduce these forms as needed. If you would like to comment on the reporting forms, website, or future electronic submissions, you may direct the comments to the address below.

A complete Product Report is required for each product model or model family. Product Reports are now more generally referred to as Radiation Safety Reports to distinguish the Radiological Health submissions from medical device submissions. CDRH suggests that a complete report on one model of a family be submitted, with a separate Supplemental Report for each of the other models in the family. The Supplemental Report should respond in detail to the parts of the form where there are differences to report, referencing the number of the affected item. Items that are unchanged will still appear in the supplement from the original report.

When new models of a product are introduced, if the models satisfy the criteria for an established reporting exemption or if the new models do not involve changes in radiation emission or performance requirements, then the manufacturer need not report the models prior to introduction into commerce. Rather, the manufacturer is only required to identify them in the annual report, or in quarterly updates to the annual report. Quarterly updates to annual reports may be submitted using the Annual Report software included in this application. [See 21 CFR 1002.13(c).]

All symbols, units, and unusual terms in the report must be adequately defined and consistently used. Please use the terms as defined in Section 1040.10(b) and in the IEEE Standard Dictionary of Electrical and Electronic Terms (IEEE Std. 1001972 and ANSI C42.1001972).

Definitions

Definitions for Rad Health Products

Manufacturers

Manufacturer is any person or organization engaged in the business of manufacturing, assembling, or importing of electronic products (21 CFR1000.3(n)). Manufacturers of electronic products subject to 21CFR1000-1050 must:

- Design and manufacture their products to be in compliance with applicable performance standards;
- Test their products to assure compliance;
- Certify compliance of their products;
- Maintain test and distribution records and a file of correspondence concerning radiation safety, safety complaints, and inquiries;
- Use the published reporting forms or electronic software application to submit reports to CDRH, including Product reports describing the manner of compliance of the product design and testing program and Annual Reports summarizing their compliance testing;
- Report accidental radiation occurrences (i.e., possible, suspected,or known exposures);
- Report any radiation defects or noncompliances; and
- Recall (i.e., repair, replace, or refund the purchase price of) defective or noncompliant products.

Accidental Radiation Occurrences

An accidental radiation occurrence means a single event or series of events that has/have resulted in injurious or potentially injurious exposure of any person to electronic product

radiation as a result of the manufacturing, testing, or use of an electronic product.

Importers

Importer is any person of organization engaged in the business of importing electronic products. An importer is considered to be a manufacturer. The requirements for Manufacturers given above also apply to importers if the requirements have not been done by the foreign manufacturer.

United States Agent for Foreign Manufacturers

Every manufacturer of electronic products, prior to offering such product for importation into the United States, shall designate a permanent resident of the United States as the manufacturer`s agent upon whom service of all processes, notices, orders, decisions, and requirements may be made for and on behalf of the manufacturer as provided in section 536(d) of the Radiation Control for Health and Safety Act of 1968 (21U.S.C. 360mm(d)) and this section. The agent maybe an individual, a firm, or a domestic corporation. For purposes of this section, any number of manufacturers may designate the same agent.

From The Federal Food, Drug, and Cosmetic Act

Sec 536 [21 U.S.C. 360mm](d) Designation of agent for purposes of service

It shall be the duty of every manufacturer offering an electronic product for importation into the United States to designate in writing an agent upon whom service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made for and on behalf of said manufacturer, and to file such designation with the Secretary, which designation may from time to time be changed by like writing, similarly filed. Service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made upon said manufacturer by service upon such designated agent at his office or usual place of residence with like effect as if made personally upon said manufacturer, and in default of such designation of such agent, service of process, notice, order, requirement, or decision in any proceeding before the Secretary or in any judicial proceeding for enforcement of this part or any standards prescribed pursuant to this part may be made by posting such process, notice, order, requirement, or decision in the Office of the Secretary or in a place designated by him by regulation.

Sec. 531 [21 U.S.C. 360hh] (1) the term **''electronic product radiation''**means:

(A) any ionizing or non-ionizing electromagnetic or particulate radiation, or

(B) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product.

Sec. 531 [21 U.S.C. 360hh](2) the term **''electronic product''**means:

(A) any manufactured or assembled product which, when in operation,(i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or

(B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation.

Burden to Industry

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1.2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, completing, and 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:

Food and Drug Administration CDRH (HFZ-240)
1350 Piccard Drive Rockville, MD 20850

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."

Manufacturer Responsible for Product Compliance

Note:	*This is the firm that takes responsibility for certification that the product meets the performance standard. This firm develops and maintains the quality control and testing program that is the basis for the certification of this product. Additionally, this firm usually is the owner of the product design and manufacturing process design.*

Copy from the establishment address book *	
Establishment Information:	
Establishment Name	
Division Name	
Home Page	
Physical Location:	
Address	
Telephone Number	

Fax Number	
Mailing Location:	
Address	

Responsible Individual

Note:	*The responsible individual is the highest level and most responsible individual affiliated with this establishment.*

Copy from contact address book *	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	

Manufacturer's Reporting Official

Note:	*This is the person at the manufacturing facility that is knowledgeable and responsible for addressing all aspects of the testing and quality control procedures for certification as reported to FDA in the product report. Documentation of changes intesting and quality control procedures submitted to FDA must be signed by this individual.*

Copy from contact address book *	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	

Electronic Signature

Electronic signature (not available in this release of the software)	
File Attachment	

Report Submitter

Note:	*The submittermaybe a consulting individual or firm providing assistance in report preparation and maintenance. All documents prepared by the submitter must have the manufacturer's reporting official signature for authenticity of submitted documentation.*
Copy from contact address list *	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	

Manufacturer Designated United States Agent

Note:	*Manufacturers exporting to the U.S. must designate a U.S. agent, see 21 CFR 1005.25.*
Is there a United States agent that has been designated by the manufacturer? *	

Section: Product Data

Product Type Reported

What is the product code? *

If you know the three letter code, enter it in the space provided.

If you do not,

- Click the filter search icon (next to the trash can). You will see a product code filter dialog box.
-Enter a keyword to search the database. You will be provided a list of product codes from which to choose.
(If you are not finding the correct product, try other words and/or variations of the keywords.)
- Select the best match to your product.
- The remaining fields will be filled in for you when you select your product code.
- If you do not find the code that you are looking for, use RZZ (Other)

Product Code	
Device Class	
Classification Panel	
C.F.R. Section	

If Other, please identify the specific product type.

Report Information

Is this the first time you've submitted a report on the particular type of product selected in the Product Type Reported section? *	
Since this is not the first time you've reported on this type of product, then is this a report supplement to a previously reported model family?	
Provide the Accession Number of the report for which this is a supplement (Do not enter any Device Premarket Application or Notification document number here, such as PMAs, 510(k)s, IDEs, etc.):	
Are you requesting a new variance, a renewal, extension or amendment to a previous variance? *	
If you are requesting a renewal, extension, or amendment, please provide the variance number that was issued by CDRH.	
If you have a Docket Number that was issued by FDA's Division of Dockets Management, please provide it here.	

Noncompliances or Defects

Does this document or any of its attachments contain:	
A self-declaration or notification of noncompliance or defect? *	
Provide an explanation:	

Responses to Noncompliances or Defects

Does this documentor any of its attachments contain:	
A refutation of noncompliances? *	
A request for an exemption from notification and corrective action? *	
Information on corrective actions you may be conducting? *	
A description of any design changes for future production? *	
Provide an explanation:	

Exemption Requests

Does this document or any of its attachments contain:	
Exemption of a product for government use from a standard (1010.5)? *	

Exemption for products for government use from reporting and recordkeeping (1002.51)? *	
Special exemption of products from reporting and/or recordkeeping (1002.50)? *	
Request for approval of alternate labeling? *	
Application for alternate test procedures (1010.13)? *	
Provide an explanation:	
Attach any necessary files.	
File Attachment	

Variance Requests

This submission includes an application for a variance from certain requirements.	
Item	
Provide an explanation and attach supporting files, if necessary. Click on the Add... button below to attach files.	
Details	
File Attachment	
Error:	*In addition to the electronic copy of this submission, please be sure to submit one hard-copy of the signed variance request document to the following address:* *Division of Dockets Management (HFA-305)* *Food and Drug Administration* *Rm 1061, 5630 Fishers Lane* *Rockville, MD 20852*

Responses to Communications from FDA

Does this document or any of its attachments contain:	
A response to an inspection? *	
What was the date of the inspection?	
A response to a warning letter from the Food and Drug Administration (FDA)? *	
What was the date of the Warning Letter?	
A response to a report review inquiry from the Center for Devices and Radiological Health (CDRH) (the inquiry may have been in the form of a letter, email, or phone call)? *	
What was the date of the inquiry?	
A response to any other communication from FDA? *	
What was the date of the communication?	
Provide an explanation:	

Use Environment

Who are the intended users?
[ ] Children and/or Youth [ ] Consumers [ ] Elderly [ ] Employees/Workers [ ] Engineers or Scientists [ ] General Public [ ] Medical Staff [ ] Patients [ ] Other
What is the use environment?
[ ] Consumer Home [ ] Hospital or Clinic [ ] Industrial Facility or Factory [ ] Office/Warehouse/Store [ ] Outdoors [ ] Public Arena [ ] Schools, Gymnasium/Auditorium [ ] Lab or Research Facility [ ] Transportation Facility [ ] Other
Please select the best match for the affected population:
[ ] Children and/or Youth [ ] Consumers [ ] Elderly [ ] Employees/Workers [ ] Engineers or Scientists [ ] General Public [ ] Medical Staff [ ] Patients [ ] Other

Additional Information

Is there any other relevant information or additional comments that would help expedite the review of this submission? Click the Add... button below to attach any supporting files.	
File Attachment	
Details	

Private Labeling

Is the product sold by other companies under different brand names? *	

Medical Devices

Provide the premarket 510(k), IDE, HDE, PDP, or PMA filing numbers related to this medical product, if one of these numbers has been assigned by FDA yet.
If it has not been assigned yet, provide an explanation and submit it as soon as you receive such a filing number.

Electromagnetic Compatibility and Interference

Electromagnetic Compatibility with other Products
Provide description of analysis and indicate any shielding you have for your product to protect other products from EMI:

Susceptibility to EMI from other Products
Provide description of analysis and indicate any protective shielding your product has to protect it from EMI:

Section: Variance Application Form

1.0 Introduction

Department of Health and Human Services
Food and Drug Administration

Laser Light Show Variance Application Form 3147

Information:	*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 with this application in accordance with 21 CFR 1010.4*
Note:	*Instructions: Submit one hard-copy of the application and one copy of the signed cover letter to the Division of Dockets Management (HFA-305), Food and Drug Administration, Rm 1061, 5630 Fishers Lane, Rockville, MD 20852.*

The applicant requests the variance to be in effect for a period of how many years from the date of issue? *	
Note:	*In general, the Agency will approve a variance for only two years. If other is selected as the time period, attach a justification as part of the application.*

Attach file and supply details.	
File Attachment	

2.0 Product Description and Use

List the name(s) for the laser light show(s): *	
Item	

List the names and/or model number(s) for the laser light show projector(s): *	
Item	

Select the product for which a variance is requested. (Select all that apply) *	
Item	
If "other" please describe further:	

Check if projectors are intended for sale, lease, or loan to other laser light show producers.	[ ]

Select the place where the product is intended to be used. (Select all that apply.) *	
Item	
If "other" please describe further:	

Select the number of locations where the product is intended to be used. (Select all that apply.) *	
Item	
If "other" please describe further:	

Product is intended to be used at any one location for: *	

Select how long the Tour is intended run. (Select all that apply).	
Item	
If "other" please describe further:	

Select the laser effects that the product utilizes. (Select all that apply). *	
Item	
If "other" please describe further:	

3.0 Laser Radiation Levels

Item: 1

List the Laser Medium: (Ar, He-Ne, etc.)	
List the Wavelengths: (nm)	
Peak Power: (watts)	
If any laser radiation is pulsed or scanned, give the following measurements:	
Pulse Duration:	
Pulse Rate:	
Scanning Frequency:	
Scanning Amplitude:	

4.0 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):	
Manner in which it is Proposed to Deviate from the Requirements of the Applicable Standard:	
It is proposed to deviate from the provisions of 21CFR 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 10.40.11(c) as follows:	
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 10.40.11(c) is necessary to achieve the required effects in these media.	[ ]
Other or additional advantages (describe and explain):	

5.0 Explain the Alternate Means of Radiation Protection to be Provided

Note:	*Check as many boxes as apply. In the "Remarks" section 6.0, justify any boxes not checked. State any other means of radiation protection that will be used in section 6.0, "Remarks."*	
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 atany 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 21CFR 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 do the following:	[ ]
.	*Message:*	*Be an employee of the variance holder who will be responsible for the training and the conduct of the operator.*
.	*Message:*	*Be located where all beam paths can be directly observed at all times.*
.	*Message:*	*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, andthe control of access to radiation areas using the procedures described in the ANSIZ136.1 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 thevariance application, the approval letter, current procedures, and records relating to eachparticular show will be with the operator or other responsible individual and will be made available for inspection by FDA and other responsible authorities.	[ ]
l.	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 the following:	[ ]

▪	*Message:*	*The Center for Devices and Radiological Health, Office of Communication, Education, and Radiation Programs (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.*
▪	*Message:*	*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.*
▪	*Message:*	*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.)*

6.0 Remarks

Please include any necessary additional remarks:

7.0 Certification

The manufacturer certifies the following: * All of the above information and statements are true, complete, and correct to the best of my knowledge. The manufacturer acknowledges that the variance application may be denied or the variance may be revoked if this application is found to be false, misleading or incorrect in any material way. The manufacturer has submitted and will submit all reports required by 21 CFR 1002.10 and 1002.11 on laser equipment and show(s). The manufacturer further understands that they 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.	
Copy from the contact address book. *	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Information:	
Establishment Name	

Division Name	
FDA Establishment Identifier (FEI)	
Central File Number (CFN)	
Registration Number	
Owner/Operator Number	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	

8.0 Packaging Instructions

Error:	*You have reached the end of this report. Please verify that all PDFs that are to be included in this submission are correctly attached to a specific file attachment question. Otherwise, they will not be packaged with your report. Check to make sure you have no missing data (select Missing Data Report from the Output menu). Once you have confirmed that there is no missing data and all your files are attached, click on the Package Submission icon on the tool bar.*
Error:	*In addition to the electronic copy of this submission, please be sure to submit one hard-copy of the signed variance request document to the following address:* *Division of Dockets Management (HFA-305)* *Food and Drug Administration* *Rm 1061, 5630 Fishers Lane* *Rockville, MD 20852*
Note:	*In a few weeks you should receive a Docket number from Dockets Management and a Variance number from CDRH. Both of these numbers may be saved with this report in the following procedure:* *1. Reopen this report* *2. Click on the File Menu and select Properties* *3. In the Comments field, you may enter these identifying numbers and any other pertinent information for future reference.*
Message:	*FDA 3147 (03/06) Application for a Variance From 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device*