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.) *
Radiation Safety Report (Product Report)
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? *
High Intensity Mercury Vapor Discharge and Metal Halide Lamps
What Type of Product is this Variance Request about?
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 24 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	

Parent Establishment

Is there a parent 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 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 product type is being reported? *Please note that this list of 66 product types are grouped according to their radiation type and applicable regulations (e.g., laser products, microwave products, ionizing products, etc.) *
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.	

Error:	*If you are requesting a new variance, renewal, extension, or amendment, you must file a Variance Request separate from this report. To do this, open a new report (File > New) and select either "Laser Light Show Variance Request" or "Variance Request, Other" as your Type of Submission in the Submission Information Screen. If you select "Variance Request, Other" you must select the product for which you are requesting a variance at the end of the screen.*

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

Message:	*Click the "Add" button to select the desired requirement from which you are seeking a variance.*
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: Mercury Vapor Lamp Products

Lamp Type

Specify the type of lamp being reported. *	
If "Other" has been selected, please specify further.	

Product Description

Provide a description of the exterior including information on the base or socket of the reported model. The descriptions may include the photographs or drawings with dimension reference scale. Click on the Add... button below to add and select the files to be attached. *	
File Attachment	
Details	
Provide a description of the interior structures of the reported model. The description may consist of photographs or drawings of the interior structures with parts and component identification and with scale dimensions. Click on the Add... button below to add and select the files to be attached. *	
File Attachment	
Details	

Description of Operation

Provide a brief general description of the theory and process of operation including the start, warmup, and the steady-state condition of the reported model. *	
File Attachment	
Details	
Provide information on lamp starting voltage, and operating current of the reported model (reference may be made to ANSI standard). *	
File Attachment	
Details	
Specify the type of ballast that meets the specifications of the reported model's ratings for starting and operation (reference may be made to ANSI standard). *	
File Attachment	
Details	
Provide information on the life and warm-up time of the lamp. *	
File Attachment	
Details	
If the reported model is a self-extinguishing lamp, provide descriptions in detail of the self- extinguishing mechanism including its functioning theory and the conditions under which it renders the lamp inoperable.	
File Attachment	
Details	

General Labeling Requirements

Does the reported lamp model have a label certifying that the lamp conforms to the provisions of 21 CFR 1040.30 as required by 21 CFR 1010.2? *	
Where is the certification label?	
Submit a sample of the required certification label for the reported model, or a facsimile of the label if the label is inscribed on the lamp.	
File Attachment	
Details	
If no, provide an explanation.	

Does the reported lamp model have an identification label that conforms to the provisions of 21 CFR 1010.3? *	
Where is the identification label?	
Submit a sample of the required certification label for the reported model, or a facsimile of the label if the label is inscribed on the lamp.	
File Attachment	
Details	
How is the identification label permanently affixed, inscribed or marked on the lamp and/or the lamp packaging?	
If no, provide an explanation.	
Is the reported lamp model permanently labeled or marked in such a manner that the name of the manufacturer and the month and year of manufacture of the lamp can be determined on the intact lamp and after the outer envelope is broken or removed? *	
Attach a facsimile of the above identification label or mark for the reported model.	
File Attachment	
Details	
How are the name of the manufacturer and the date of the manufacture permanently labeled or marked on the lamp?	
If the name of the manufacturer and month and year of manufacture are expressed in code or symbols, you must provide the translation or explanation.	
Item	
Provide the location of the coded information or symbols (please attach a picture, drawing, or diagram showing location).	
File Attachment	
Details	

Requirements for Non-Self-Extinguishing Lamps

Note:	*This part should be completed when reporting non-self-extinguishing types of high intensity mercury vapor discharge lamp as defined in 21 CFR 1040.30 (b) (1).*

Lamp Labeling

Is the reported lamp model clearly marked with the letter R on the outer envelope?	
Provide an explanation as a file attachment or text in the box below.	
File Attachment	
Details	
Does the reported lamp model have the letter R also marked on another part of the lamp?	
Provide an explanation as a file attachment or text in the box below.	
File Attachment	
Details	
Identify the location of the letter R. Attach a picture, drawing, or diagram showing the location.	

File Attachment	
Details	

How is the letter R marked on the lamp?

Is the letter R visible after the outer envelope of the lamp is broken or removed?	

Provide an explanation as a file attachment or text in the box below.

File Attachment	
Details	

Lamp Packaging

Does the lamp packaging for the reported lamp model clearly and prominently display the letter R?	

Provide an explanation as a file attachment or text in the box below.

File Attachment	
Details	

Does the lamp packaging for the reported lamp model clearly and prominently display the following warning? WARNING: This lamp can cause serious skin burn and eye inflamation from shortwave ultraviolet radiation if outer envelope of the lamp is broken or punctured. Do not use where people will remain for more than a few minutes unless adequate shielding or other safety precautions are used. Certain types of lamps that will automatically extinguish when the outer envelope is broken or punctured are commercially available.	

Provide an explanation as a file attachment or text in the box below.

File Attachment	
Details	

The required warning statement for a non-self-extinguishing lamp appears on the following location(s) for the reported model(s):	[ ] Lamp Carton [ ] Outer Wrapping [ ] Other Means of Containment

If Other Means of Containment was selected, please specify further.

Attach a sample or facsimile of the label on lamp packaging as required by 1040.30 (e) (2) for the reported model.

File Attachment	
Details	

Describe other radiation safety related information, if any, provided on or with the lamp packaging for the reported model and the reason for providing that information.

Lamp Advertisement

Does the advertising for the reported model prominently display the following warning statement? WARNING: This lamp can cause serious skin burn and eye inflamation from shortwave ultraviolet radiation if outer envelope of the lamp is broken or punctured. Do not use where people will remain for more than a few minutes unless adequate shielding or other safety precautions are used. Certain types of lamps that will automatically extinguish when the outer envelope is broken or punctured are commercially available.	

Provide an explanation as a file attachment or text in the box below.

File Attachment	

Details	

The required warning statement in advertisement for a non-self-extinguishing lamp is included in:	[ ] The Catalog [ ] Specification Sheet [ ] Price List [ ] Other Description or Commercial Brochure and Literature

If Other Description or Commercial Brochure and Literature was selected, please specify further.
Attach copies of all advertisements containing the warning label as required by 1040.30 (e) (3) for the reported model (material may be submitted in draft form as long as it is marked as a draft and final copies are to be submitted as report supplements when available.) Click on the Add button below to add and select files to be attached.

File Attachment	
Details	

Describe other radiation safety-related information, if any, provided in advertisement for the reported model and the reason for providing that information.

Quality Control Tests for Non-Self-Extinguishing Lamps

Note:	*This part should be completed by manufacturers of non-self-extinguishing types of high intensity mercury vapor discharge lamps as defined in 21 CFR 1040.30 (b) (1).*

Quality Control Tests
What tests or checks are conducted to assure the presence of the required labels and markings prior to and after completion of the manufacturing process? Click on the Add button below to add and select files to be attached.

File Attachment	
Details	

Action Upon Rejection
Describe actions to be taken for rejected units and rejected lots. Click on the Add button below to add and select files to be attached.

File Attachment	
Details	

Requirements for Self-Extinguishing Lamps

Note:	*This part should be completed when reporting self-extinguishing types of high intensity mercury vapor discharge lamps as defined in 21 CFR 1040.30 (b) (1) and (7).*

Maximum Cumulative Operating Time	
The reporting lamp model is designed to cease operation within a cumulative operating time not to exceed _____ minutes, following complete breakage or removal of the outer envelope (with no fragment of the outer envelope extending more than 50 millimeters from the base shell.) Provide the number of minutes.	
The reported lamp model is designed to cease operation within a cumulative operating time not to exceed _____ minutes, following breakage or removal of at least three square centimeters of continguous surface of the outer envelope. the outer envelope (with no fragment of the outer envelope extending more than 50 millimeters from the base shell.) Provide the number of minutes or indicate NA if not applicable.	

Lamp Labeling

Is the reported lamp model clearly marked with the letter T on the outer envelope?	

Provide an explanation as a file attachment or text in the box below.	
File Attachment	
Details	
Does the reported lamp model have the letter T on another part of the lamp?	
Provide an explanation as a file attachment or text in the box below.	
File Attachment	
Details	
Identify the location of the letter T. Attach a picture, drawing, or diagram showing the location.	
File Attachment	
Details	
How is the letter T marked on the lamp?	
Is the letter T visible after the outer envelope of the lamp is broken or removed?	
Provide an explanation as a file attachment or text in the box below.	
File Attachment	
Details	

Lamp Packaging

Does the lamp packaging for the reported lamp model clearly and prominently display the letter T?	
Provide an explanation as a file attachment or text in the box below.	
File Attachment	
Details	
Does the lamp packaging for the reported lamp model clearly and prominently display the words: This lamp should self-extinguish within 15 minutes after the outer envelope is broken or punctured. If such damage occurs, TURN OFF AND REMOVE LAMP to avoid possible injury from hazardous shortwave ultraviolet radiation?"	
Provide an explanation as a file attachment or text in the box below.	
File Attachment	
Details	
The required warning statement for a self-extinguishing lamp appears on the following location(s) for the reported model(s):	[ ] Lamp Carton [ ] Outer Wrapping [ ] Other Means of Containment
If Other Means of Containment was selected, please specify further.	
Attach a sample or facsimile of the label on lamp packaging as required by 1040.30 (d) (3) for the reported model.	
File Attachment	
Details	
Describe other radiation safety related information, if any, provided on or with the lamp packaging for the reported model and the reason for providing that information.	

Quality Control, Life, and Reliability Tests (Self-Extinguishing Lamps)

Note:	*This part should be completed by manufacturers of self-extinguishing type of high intensity mercury vapor discharge lamp as defined in 21 CFR 1040.30(b) (7). Wherever appropriate, information attached should include quality control procedures for the tests performed, parameters measured, physical conditions under which tests are conducted, measurement instrumentation and techniques, uncertainty evaluations of the measurements, sampling plans, the rejection criteria or confidence limits used, and the justification for the particular choice of such limits, methods of data analysis, etc.*

Quality Control Tests

Quality control tests conducted before the lamp is manufactured:	
What tests were conducted on preproduction or prototype models prior to initiation of manufacturing to assure that the lamp was adequately designed for compliance within the performance standard? Click on the Add... button below to add and select the necessary files to be attached.	
File Attachment	
Details	
What tests are conducted on the components of the self-extinguishing mechanism of the lamp prior to their incorporation into the lamp? Click on the Add... button below to add and select the necessary files to be attached.	
File Attachment	
Details	
Quality control tests done during and after manufacture of the lamp:	
What tests or checks are conducted on the components of the self-extinguishing mechanism of the lamp prior to their incorporation into the lamp? Click on the Add... button below to add and select the necessary files to be attached.	
File Attachment	
Details	
What tests or checks are conducted to assure proper functioning of the self-extinguishing mechanism after completion of the manufacturing process? Click on the Add... button below to add and select the necessary files to be attached.	
File Attachment	
Details	
What tests or checks are conducted to assure the presence of the required labels and markings prior to and after completion of the manufacturing process? Click on the Add... button below to add and select the necessary files to be attached.	
File Attachment	
Details	

Action Upon Rejection

Describe actions to be taken for rejected units and rejected lots if they have been rejected for problems concerning compliance with 21 CFR- 1040.30. If retesting is required, state the criteria and procedures for retesting. Click on the Add... button below to add and select the necessary files to be attached.	
File Attachment	
Details	

Life and Reliability Tests

Provide descriptions of the life and reliability tests of the self-extinguishing mechanism of reported model, including testing procedures, accept or reject criteria, lot and sample size and action following rejection. Click on the Add... button below to add and select the necessary files to be attached.

File Attachment	
Details	

Results of Tests

Identify the type of tests related to compliance with 21CFR 1040.30 for which results are presented including reference to applicable portions of this part of the report as appropriate. Click on the Add... button below to add and select the necessary files to be attached.	
File Attachment	
Details	
Identify the time period represented by results presented for each test. Click on the Add... button below to add and select the necessary files to be attached.	
File Attachment	
Details	
Provide information on the total number of units manufactured or received in the case of components, the number of units tested, and the number of units that initially failed to meet the quality control acceptance criteria for each test related to compliance with 21 CFR 1040.30. Click on the Add... button below to add and select the necessary files to be attached.	
File Attachment	
Details	
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.*
Message:	*FDA 3646 (03/06) Mercury Vapor Lamp Products Radiation Safety Report*