Submission Report

eRadHealth Menu

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 FDA Electronic Submission (eSub) software is the next version of the application developed 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.

All electronic reports and correspondence can either be transferred to CD and mailed to the address below, or can be sent via the FDA Electronic Submissions Gateway to CDRH. If you follow instructions to set up an account with the FDA Gateway, it currently may take several weeks,, but when you submit through it you will receive your acknowledgement email message with Accession Number within minutes! Or, in the interest of faster turn-around for a one-time urgent report of if you submit few reports, you may simply fill out this template creating the submission and then at 'Packaging' follow the instructions to transfer the files to a CD to mail in. This method of submitting your report will be acknowledged by an email with the Accession Number within several days.

Information about the FDA Electronic Submissions Gateway can be found at **www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm**. Please contact the Gateway Helpdesk with your questions about that system.

Electronic submissions on CD should be mailed directly to the Document Control Center at:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Attn: eSubmitter Team
Document Mail Center - WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submissions received in the mail on CD will be processed within a few days of receipt.

Note about eSubmitter software:

Instructions provided in this software briefly summarize the requirements of the regulations under the Federal Food, Drug and Cosmetic Act (FFDCA), Chapter V, Subchapter C - Electronic Product

Radiation Control, that applies to manufacturers of electronic products that emit radiation. The software provides questions relevant to requirements in the performance standards and may include explanations or clarification about the performance, labeling, and informational requirements of the standard. It does not replace the regulations, however, and if there is any conflict between the software and the regulations, the regulations must prevail. Throughout this application, pertinent sections of Title 21, Code of Federal Regulations, Chapter I, Subchapter J, are cited in parentheses. Please consult them before making design or procedural decisions.

Regulatory requirements for radiological products can be found at **http://www.fda.gov/Radiation-EmittingProducts/default.htm** and for medical devices are located at **www.fda.gov/M/devaDvices/default.htm**. If you have specific questions about the regulations, please contact us at: **DSMICA@fda.hhs.gov**.

If you have specific questions regarding this software, please contact the eSub team by email at: **eSubmitter@fda.hhs.gov**.

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

Thank you for your continued support of the FDA Electronic Submission Program (eSub).

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. The OMB control number for this information collection is 0910-0025 (expires January 31, 2017).

Role

What is your role?	!*	Manufacturer

Information:	*The following screen provides several options for you to accurately define what type of eSubmission you intend to create for FDA. Below are explanations of your options. Please feel free to review this screen, advance to the next screen and view the picklists, but if you're confused, come back to read this screen again to be certain you are selecting the correct report or correspondence type you want to create.*

Submission Information

Step 1	**Use the radio buttons to identify the type of submission you are preparing. (Supplements should be prepared using the same document type as the original submission.)**

What Type of Submission is this? (Supplements should be submitted selecting the same document type as the original report.)	!*	(•) Radiation Safety Report (Product) Report (21 CFR 1002.10) ( ) Annual Report (21 CFR 1002.13) ( ) Laser Light Show Documents (all relevant documents) (21 CFR 1040.11(c)) ( ) Correspondence

	( ) Variance Request (General, not Laser Light Show) (21 CFR 1010.4) ( ) Laser Original Equipment/Component Manufacturer Registration (21 CFR 1040.10(a)(3)(ii)) ( ) Abbreviated Report (21 CFR 1002.12)

Step 2	**After answering the Submission Type question above, one of the questions below may become active and required (see the blue dot to the right of the question). If there is an active question, select the appropriate product area or document type from the question's pick list.**
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 Annual Report about?	
What Laser Light Show Document are you filing?	
What Type of Correspondence is this?	
What Type of Product is this Variance Request about?	

Manufacturer Data

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.* *Be sure to enter address information for each tab below:*

Select the Manufacturer's address from the Establishment Address book: *	
Establishment Information:	
Establishment Name	
Division Name	
Home Page	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	
Telephone Number	
Fax Number	

Responsible Individual

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

Select the Responsible Individual from the 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	
Telephone Number	
Fax Number	

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.*

Select the Reporting Official 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	
Telephone Number	
Fax Number	

Report Submitter

Note:	*The submitter may be a consulting individual or firm providing assistance in report preparation and maintenance. Documents or submissions such as this one that are prepared by the submitter must have an accompanying authorization letter from the manufacturer's reporting official for authenticity.*

Select the Submitter from the 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	
Telephone Number	
Fax Number	
Comments:	

Internal Reference Number:	

Parent Establishment

Is there a parent establishment? *	

Select the Parent Establishment and Contact from the 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	
Telephone Number	
Fax Number	

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? *	

Importer

Additional Manufacturing Locations

Product Data

Product and Model Identification

Attention - Information about this section

In this section you'll be asked to identify several required or optional things which will help FDA/CDRH staff to prioritize their reviews. You'll be asked to consider the following aspects:

(1) Identify your product's radiation type and the CDRH Product Code.

(2) Enter an Accession number if this will be a report supplment. If you are preparing a supplement, you'll see that after entering a valid 7-digit Accession number many questions will no longer be required (they will either be disabled or will be optional, meaning they will no longer have the blue dot).

(3) You will also have several questions that are of high significance for FDA/CDRH - why you might be submitting this report or correspondence. Please read these questions carefully, referring to the 21 CFR regulations on the website www.FDA.gov if you are unsure if the question is relevant to your firm's situation.

(4) If you find that you have more information that you want the FDA/CDRH to read but it doesn't seem to fit under other questions, we have a final "***Additional Information***" question in this section which invites you to add comments and/or attach a file that provides further information from your firm about this submission. This is the place to add that extra information.

Product Type Reported

What is the product code? *

To select the three letter product code,

- Click the plus sign. You will see a product code filter dialog box.
- Select the appropriate category name from the pick list. You will be provided a list of product codes from which to choose.
- Select the best match to your product.
- The remaining fields will be filled in for you when you select your product code.

Category	
Product Code	
Performance Standard	

If Other, provide a category name for this specific product.

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 original report for which this is a supplement: (Note: Do not enter any Device Premarket Application or Notification document number here, such as PMAs, 510(k)s, IDEs, etc. See Accession number description below.)	

Are you requesting a new variance, a renewal, extension or amendment to a previous variance? *	
Stop:	*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 (General, not Laser Light Show)" as your Type of Submission in the Submission Information Screen. If you select "Variance Request (General, not Laser Light Show)r" you must select the product for which you are requesting a variance with the pick list in the bottom section of the screen.*

Special Considerations

Information:	*If this product will require a formally approved Variance from a certain performance requirement, you will need to complete two Reports for FDA, both (1) this Radiation Safety Report (RSR) on this product, and (2) a Variance Request report. This eSubmitter software application package includes a general Variance Request form as well as the specific Laser Light Show Variance Request form. Both the Product RSR file and the appropriate Variance Request Correspondence file must be submitted to CDRH following the regular files packaging procedures in this application. Both may be transferred to the same CD or submitted via the FDA ESG to submit to the FDA/CDRH.* *In addition, any Variance Request form must be printed out and the signed hard-copy sent to FDA's Division of Dockets Management at:* *Division of Dockets Management (HFA-305)* *Food and Drug Administration* *5630 Fishers Lane* *Rockville, MD 20852* *NOTE: There is no need to send a copy of the CD to Division of Dockets Management.*

Noncompliances or Defects

Does this document or any of its attachments contain:	
A notification of noncompliance or defect? *	
You may provide an explanation and/or attach a document here:	
Details	

Responses to Noncompliances or Defects

Does this document or any of its attachments contain any of these responses concerning noncompliances or defects?	
A refutation of noncompliances or defects identified to your firm? *	
A request for an exemption from notification to purchasers (see 21 CFR 1003.21 and 1003.30)? *	
Corrective action plans you intend to implement to correct noncompliances or defects discovered in past or current production? *	
Note:	*If you are submitting a Corrective Action Plan (CAP) following 21 CFR 1004 and information on design changes for future production, the design change information must be submitted in a Radiation Safety (Product) Report or supplemental report. Both the proposed CAP and the design changes may be submitted in one document if you prepare a product report and choose to include the CAP in it as a file attachment. Alternatively, you may create a separate eSubmission for the CAP using the "Correspondence" type template and selecting "Follow-up correspondence to FDA."*
A description of any design changes that correct noncompliances for future production? *	
Note:	*If you are submitting information on product design changes for future production due to a discovery of noncompliances or defects in current production, you must use the Radiation Safety (Product) Report template to create the report . Correspondence templates may be used to submit other information such as a proposed corrective action plan pertaining to a noncompliance or defect.*
You may add an explanation and/or attach a document here:	
Details	

Exemption Requests

Does this document or any of its attachments contain:	
Exemption of a product for government use from a standard (21 CFR 1010.5)? *	
Exemption for products for government use from reporting and recordkeeping (21 CFR 1002.51)? *	
Special exemption of products from reporting and/or recordkeeping (21 CFR 1002.50)? *	
Request for approval of alternate labeling? *	
Application for alternate test procedures (21 CFR 1010.13)? *	
You may provide an explanation and/or attach any relevant documents here:	

Variance Requests

Information:	*Please note: in addition to responding to these questions below, a separate General Variance Request or Laser Light Show Variance Request form must be completed and submitted to CDRH, with a hard copy sent to FDA's Division of Dockets Management as instructed below for any variance request. The information requested on this screen does not constitute the full structured content of the variance request. The 2 types of Variance forms can be created in eSubmitter by selecting the appropriate Variance submission type under the eRad Health Menu section of this application.*

Message:	*Click the plus sign to list the requirements from which you are requesting a variance.*
This submission includes an application for a variance from certain requirements.	
Item	No Information Provided.
Provide an explanation and attach supporting files, if necessary. Click on the plus sign below to attach files.	
Details	
Stop:	*For all Variance requests, two submissions must be made to the FDA.* *The electronic version should be submitted following the Packaging Files for Submission instructions located under Output in the Menu bar, and explained in subsection 4.3 of the User Manual. If sending a CD & submittal letter, please mail to:* *U.S. Food and Drug Administration* *Center for Devices and Radiological Health* *Attn: eSubmitter Team* *Document Mail Center - WO66-0609* *10903 New Hampshire Avenue* *Silver Spring, MD 20993-0002* *Additionally, a paper version (hard-copy) of the signed Variance request document should be submitted to:* *Food and Drug Administration* *Division of Dockets Management (HFA-305)* *5630 Fishers Lane, Room 1061* *Rockville, MD 20857*

Responses to Communications from FDA

Does this document or any of its attachments contain:		
A response to an FDA inspection?	*	
What was the date of the inspection?		
A response to a Warning letter or a Notification of Noncompliance or Defect from the FDA?	*	
What was the date of the Warning Letter or other notification letter?		
A response to a report review inquiry from the 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:		

Additional Information

Here's your opportunity to add anything else to this submission that you want to tell the FDA!

Is there any other relevant information or additional comments that would help expedite the review of this submission? Click the plus sign below to attach any supporting files.	
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 submitted yet, or if your device is exempt from premarket clearance or approval, please provide an explanation. The device regulations can be found in 21 CFR 807 - device manufacturer registration and device listing.

Mercury Vapor Lamp Products

Lamp Type

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

Product Identification

Note:	*Report the model name and/or number, model family, brand name, or other designation of the product. If reporting a model family, provide the model designation of each model. If you do not have a model family or brand name, leave the field blank.*

Enter the Model Designation (Names and/or Numbers): *

Item	Model Name	Family Name	Brand Name

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. *	
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. *	
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. *	
Details	
Provide information on lamp starting voltage, and operating current of the reported model (reference may be made to ANSI standard). *	
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). *	
Details	
Provide information on the life and warm-up time of the lamp. *	
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.	
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.	
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.	
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.	
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	No Information Provided.
Provide the location of the coded information or symbols (please attach a picture, drawing, or diagram showing location).	
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.	
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.	
Details	
Identify the location of the letter R. Attach a picture, drawing, or diagram showing the location.	
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.	
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.	
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.	
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.	
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.	
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.	
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.	
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.	
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.	
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.	
Details	
Identify the location of the letter T. Attach a picture, drawing, or diagram showing the location.	
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.	
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.	
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.	
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.
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.	
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.	
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.	
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.	
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.	
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.	
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.	
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.	
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.	
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.	
Details	
Stop:	*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.*