Section: 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).

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.

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 ActSec 536 [21 U.S.C. 360mm](d)

Designation of agent for purposes of service

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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 effect

Role

What is your role?	[L]
Note:	If you are acting as an agent of the actual manufacturer, please select your role as, for example, perhaps an Importer or Consultant. Later in the report, under Manufacturer Data, you will be prompted to enter both manufacturer and submitter information.

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

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.) [QUESTION TYPE NOT YET IMPLEMENTED: HEADER STEP]	
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)

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. [QUESTION TYPE NOT YET IMPLEMENTED: HEADER STEP]
What Type of Product is this Radiation Safety Report about?
[L]
What Type of Product is this Annual Report about?
[L]
What Laser Light Show Document are you filing?
[L]
What Type of Correspondence is this?
[L]
What Type of Product is this Variance Request about?
[L]

FDA or State Inspector

Abbreviated Report Applicability

OEM Laser Applicability

Section: Manufacturer Data

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.

Regulatory information is available on the Internet under **www.fda.gov/Radiation-EmittingProducts/default.htm**. 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 **cdrhesub@cdrh.fda.gov**.

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).

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:

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

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"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 and Report Information

Confirmation:	This Manufacturer section of this report requests names, addresses, phone numbers, etc. for your firm, various officials of your firm, consultants who may assist in preparing the report, parent firm (if any), importer and designated agent (for foreign firms). Some of this information is mandatory and its absence will prevent you from completing the report submission. Because some of these entries may be redundant, utilize the 'Contact Address Book' feature so you can save your data and reselect the entries later and in the future. (See the upload/download buttons in upper right corner of the screens). You can check for missing data at any time using the "Missing Data Report" from the "Output" menu across the top of this application. The Missing Data Report lists all missing responses that are required (that have the blue dot).

Information:	Attention: Variance Applicants If you are acting as an agent or consultant for, or on behalf of, or filing for, a company that will be manufacturing or producing a Class IIIb or IV projector or laser light show or both which require an approved variance, the following explanations may provide further clarification. Manufacturer: This is the firm or company who is requesting the variance, will certify the product or show, and will be the holder and owner of the variance. This is not the agent or consultant who may be filing this report or Variance request for the manufacturer; that agent may be the submitter, identified in a later screen. Responsible Individual: This person works for the Manufacturer and is responsible for compliance of the projector and/or show. In the case of laser light shows, he or she may be the company president, CEO, or the laser light show head operator or a manager who oversees the shows. Reporting Official: This person works for the Manufacturer and is responsible for reports, recordkeeping, and submitting FDA required documents and correspondence.

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: [QUESTION TYPE NOT YET IMPLEMENTED: ESTABLISHMENT COMPLEX]

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: [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]

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: [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]	

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: [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]	
Internal Reference Number:	

Parent Establishment

Is there a parent establishment?	[L]

Select the Parent Establishment and Contact from the Contact Address book: [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]

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?	[L]

Written Agreement

Item: 1 (could contain up to 10 items with none required)

Note:	The manufacturer who is certifying the product being reported is the manufacturer of record. If this firm is not in the United States, please identify your current Importer(s).

Note:	If any of the required responses below do not apply to your designated agent, enter 'NOT APPLICABLE' or 'NA.'
Select the Designated Agent from the Contact Address book:	
Contact Name	
Occupation Title	

Email Address	
Establishment Name	
Division Name	
Address	
Telephone Number	
Fax Number	
Attach a copy of written agreement with the designated U.S. agent:	
[Multi-Line Plain Text]	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Importer

Item: 1 (could contain up to 10 items with none required)

Select the Importer from the Contact Address book: [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]

Additional Manufacturing Locations

Item: 1 (could contain up to 100 items with none required)

Note:	If any of the products certified in this report are manufactured at locations other than listed in the Manufacturer Responsiblefor Product Compliance section, then the names, addresses, and FDA registration numbers should be provided. In addition any codes used on labels to identify a manufacturing location must be provided. Each factory location must assure all production procedures are followed identically step by step as provided in this report.If the procedures are not the same then separate reports should be filed.
Select the Manufacturer Address from the Establishment Address book: [QUESTION TYPE NOT YET IMPLEMENTED: ESTABLISHMENT COMPLEX]	
Code used on identification labels:	

Section: 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

Note:	Each product that CDRH regulates is assigned a product code by CDRH.

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. [QUESTION TYPE NOT YET IMPLEMENTED: RH SINGLE PRODUCT CODE]

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

Examples of TV Products

Product Type:	Product Examples:
TV Receivers & Products Containing Same:	General Purpose and Medical Imaging Television Receiver, General Purpose and Medical Imaging Video Monitor, Projector, Surgical and Microsurgical Television Camera

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?	[L]
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?	[L]
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?	[L]
If you are requesting a renewal, extension, or amendment, please provide the variance number that was issued by CDRH.	

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

Note:	Check all items in this section that may apply to this submission.

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?		[L]
You may provide an explanation and/or attach a document here:		
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]	
Details	[HTML Text]	

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?	[L]
A request for an exemption from notification to purchasers (see 21 CFR 1003.21 and 1003.30)?	[L]
Corrective action plans you intend to implement to correct noncompliances or defects discovered in past or current production?	[L]
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?	[L]
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:	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

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)?	[L]
Exemption for products for government use from reporting and recordkeeping (21 CFR 1002.51)?	[L]
Special exemption of products from reporting and/or recordkeeping (21 CFR 1002.50)?	[L]
Request for approval of alternate labeling?	[L]
Application for alternate test procedures (21 CFR 1010.13)?	[L]
You may provide an explanation and/or attach any relevant documents here:	
[Multi-Line Plain Text]	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

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 1	
Item 2	
Item 3	
Provide an explanation and attach supporting files, if necessary. Click on the plus sign below to attach files.	
Details	[HTML Text]
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

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?	[L]
What was the date of the inspection?	[Date]
A response to a Warning letter or a Notification of Noncompliance or Defect from the FDA?	[L]
What was the date of the Warning Letter or other notification letter?	[Date]
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)?	[L]
What was the date of the inquiry?	[Date]
A response to any other communication from FDA?	[L]
What was the date of the communication?	[Date]
Provide an explanation:	
[Multi-Line Plain Text]	

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.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

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Private Labeling

Is the product sold by other companies under different brand names?	[L]

Private Labeling-Table

Item: 1 (could contain up to 20 items with 1 required)

Give the name and address of the manufacturer:	
Establishment Name	
Division Name	
Email Address	
Address	
Telephone Number	
Fax Number	
Give the firm establishment registration number of the manufacturer listed above (if known):	

Enter brand names and/or model designations in the following table by clicking on the Add button. If you prefer to attach a file, please click on the Add button and enter the text "See File Attachment" as the first table entry.	
Item 1	
Item 2	
Item 3	
List of Brand Names and/or Model Designations	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

The Original Equipment Manufacturer (OEM) accession number (if known):	

Explain how the brand names and model designations correspond with your own brand names and model designations:
[Multi-Line Plain Text]

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.
[Multi-Line Plain Text]

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.
[Multi-Line Plain Text]

Note:	See also http://www.fda.gov/MedicalDevices/default.htm for more information on medical device premarket clearance procedures.

Section: Television Data

Model Designation

Model Designation:

Specify which Product Type this TV Product Report is for.	[L]
Explain:	
Specify the Product Display of the Product Type selected above.	[L]

Product Labeling and Special Information

Labels, Radiation Warnings and Instructions:

What label(s) are you providing information for?	[ ] Certification Label (21 CFR 1010.2) [ ] Identification Label (21 CFR 1010.3(a)(l)) [ ] Date of Manufacture (21 CFR 1010.3(a)(2)) [ ] Critical Component Warning Label (21 CFR 1020.10(~)(4))

Provide a copy of the exact text of labels that are silk-screened onto or molded into the cabinet or those for which an actual label is not available. Include an example of the date of manufacture such as "February 1995." Identify the location of each label.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

The place of manufacture may be expressed in code provided the manufacturer has supplied the CDRH with the address(es) corresponding to each code. Please provide CDRH with the address(es) corresponding to each code for the attached Identification label.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Engineering and Technical Information

Service Instructions, Schematics and Parts List

Service Instructions, Schematics and Parts List:

Which of the following will you be providing?	[ ] Service Instructions and Schematics [ ] Complete Service Manual

Attach copies of the above documents here.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Final versions of the service manual will be submitted by (MM/YYYY):	

Chassis Family Power Curves and CRT Isoexposure Rate Mimit Curve (IRLC)

Chasis Family Power Curves and CRT Isoexposure Rate Limit Curve (IRLC):

Submit a copy of the CRT manufactureer's 0.5 mR/hr isoexposure rate limit curves (IRLC) for all CRT's used with the chassis family or selling models being reported.

It must also include a graph of: (a) the worst-tolerance chassis power curve, obtained with the worst-tolerance components and the worst component failure, and (b) the design-center chassis power curve, obtained with design-center components and the worst component failure. These two curves (a and b) must be plotted (with an appropriate scale) on the same graph as the CRT isoexposure curve(s). Graphical plots should be necessary only when the product employs several different CRT's or is designed to operate at several different horizontal scan frequencies or input voltages. Clearly label each curve, including identification of the chassis and failed component.

File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Are the above mentioned CRT's registered?	[L]

Provide the EIA or other curve number for the CRT's.	
Item 1	
Item 2	
Item 3	

Special Radiation Shielding

Special Radiation Shielding:

Does this product include special shielding in addition to the inherent CRT shielding and anode cap shieldng?	[L]

Provide the description and specification for the special radiation shielding other than the anode cap. Indicate components shielded, shielding material and thickness, shielding attenuation characteristics, and specifications.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Hold-down Saftety Circuits

Hold-down and Safety Circuits:

Does the product have a hold-down or other safety circuit?	[L]
How many safety circuits does the product contain?	

For each safety circuit, describe the circuit's operation accurately and concisely. Identify the high voltage, B plus, or beam current at which the circuit operates, and whether it is intended to limit or shut down the unit if these limits are exceeded.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Engineering Analysis

Note:	This engineering analysis is used to determine whether a given product design has a sufficient margin of safety with respect to the CRT x-radiation isoexposure rate limit curve, and thus with respect to the 0.5 mRlhr x-radiation emission limit. The data submitted in Attachments J-1 through J-6 are important in establishing that the manufacturer has identified the proper test conditions for each television chassis and is conveying to CDRH the margin of x-radiation safety of the chassis design. In Attachment J-1 through 5-6, CDRH requires an engineering analysis of the following: 1. Worst-Tolerance Chassis. A chassis fitted with the worst-tolerance components. 2. Design-Center Chassis. A chassis with design or nominal value components. A pre-production television product can be used as a design-center chassis. 3. Worst-Comvonent Failure. That single component failure which is determined, by the engineering analysis, to be most likely to cause the greatest increase in x-radiation emission. Such analysis must, of course, be confirmed by subsequent measurements. 4. Phase 111 Test Conditions. Those conditions at which the potential to emit x-radiation is maximized. This includes the Worst-Component Failure and adjustment of all controls and input voltage to the point or region of the power curve at which x-radiation is maximized, i.e. the point at which the power curve most closely approaches or most exceeds the IRLC.

Component Failure Data Sheets (Tables J1-J6)

Item: 1 (could contain up to 20 items with 1 required)

Worst-Tolerance and Design-Center Chassis:

Was a worst-tolerance chassis used?	[L]

Provide justification.	
Details	[HTML Text]
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

CRT Type Number:

3659 TV Product Rpt (OMB 0910-0025)

TEPAC Number:		
Choose the circuit functional area for which there is a failure consideration.		[L]
Identify the "other" area not covered above.		
Define the component for which there is a failure consideration.		
Explain the failure.		
Input Voltage:		
Message:	Minimum Beam Current:	
–	kV	
–	uA	
Message:	Intermediate Beam Current 1	
–	kV	
–	uA	
Message:	Intermediate Beam Current 2	
–	kV	
–	uA	
Message:	Intermediate Beam Current 3:	
–	kV	
–	uA	
Message:	Maximum Beam Current:	
–	kV	
–	uA	
Maximum Radiation Measured (mR/hr):		
Design value (provide the unit of measurement. Ex: 5pf):		
Tolerance (Ex: +/- 5%):		
Worst tolerance used (include unit of mearurement):		
Actual value used (include unit of mearurement):		
User control adjustments (provide the unit of measurement. Ex: 5pf):		
Service control adjustments (provide the unit of measurement):		

Provide any additional necessary information.	
Details	[HTML Text]
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Quality Control

Quality Control and Testing

Note:	In order to ensure that critical components affecting the radiation safety remain within specified tolerance limits, components should be sampled to check appropriate parameters. These components can be checked by the television manufacturer or by the component vendor. Incoming test procedures or test data provided by the component suppliers must be sufficient to satisfy the television manufacturer that the components meet design specifications. Remember, vou, not the component manufacturers, are responsible for the compliance of your product.

Critical Component Incoming Inspection

Item: 1 (could contain up to 10 items with 1 required)

Indicate the critical component:	[L]
Describe.	

Is incoming testing performed?	[L]

Provide test data or certification required from the component or material vendor or other methods used to assure conformance of critical components to engineering specifications.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

What parameters are measured?	
Details	[HTML Text]
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Provide the sampling plan.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Provide the rejection criteria.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Provide the corrective action upon rejection.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Production Inspection and Testing

Shielding

Shielding:

Is shielding installed?	[L]
Percentage of production tested or checked:	

How is the shielding tested or checked?	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

High Voltage Circuit

High Voltage Circuit:

Specify which type of circuit this product contains	[L]
Define the type:	
Has this circuit been tested on a 100% basis?	[L]

Provide an explanation for the deviation of 100% testing	
Details	[HTML Text]
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Percentage of production tested or checked:	

How has the circuit been tested or checked?	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Sealed Controls

Item: 1 (could contain up to 10 items with 1 required)

Do you have any sealed controls?	[L]
How many sealed controls do you have?	
Identify the control which is sealed:	[L]

Provide the unique identifier for the control (ex: VR208, B+).	

What is the sealing method and materials used?	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Percentage of production tested or checked:	

How has the seal been tested or checked?	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Provide information for production line quality control and testing of shielding and circuits that may affect radiation characteristics.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Sampling Plan and Rejection Procedures

Sampling Plan and Rejection Procedures:

This manufacturer/program is related to:	[L]
Is this program applicable to all production plants?	[L]

Explain and identify programs to applicable production plants in an attachment.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

What are the minimum number of units sampled from each production line each day (or shift)?	

Samples for x-radiation testing are taken from (check all that apply):

[ ] Each lot
[ ] Each selling model being manufactured
[ ] A selling model representative of each chassisICRT-size combination within a chassis family
[ ] None of the above

Explain (may include attachment):	
Details	[HTML Text]
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Provide the unit rejection limit (mR/hr).	

What is the action taken if the unit rejection limit is exceeded?	
Details	[HTML Text]
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Provide the lot rejection limit (mR/hr).	

What action is taken if the lot rejection limit is exceeded?	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

X-Radiation Testing of Production Sets

X-Radiation Testing of Production Sets:

Provide detailed step-by-step procedures for production x-radiation testing.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Do the production test procedures employ a critical component failure or simulation that is different from the worst component failure determined for the engineering analysis?	[L]

Provide information regarding alternate failure selection and justification.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

X-Radiation Testing Instruments

Note:	The standard method for detecting x-radiation from TV products is to use a large-area, fast-response, qualitative survey instrument (such as the Johnson TVX-1 or 1B) for locating areas of radiation emission and approximating emission levels. A precisely calibrated instrument (such as the Victoreen 440 RFIC or D) with the proper performance specifications (21 CFR 1020.10(~)(2)) should then be used for quantitative results. The CDFW does not endorse these specific instruments, but rather, uses them as typical examples. Instruments other than those described here must be identified in Item 6.15 of the guide and fully described in Attachment L. The maufacturer must assure CDFW that they have a proper compliance radiation instrument because it must be specifically designed to measure low energy x-rays and meet the measurement requirements of the Federal Performance Standard for Television Receivers. 21 CFR 1020.1 O(c)(2). The quantitative x-radiation survey meter must be appropriate for measuring low energy x-rays down to 20 keV, which is the approximate energy level that may be emitted by television products. If not, large correction factors will have to be applied to compensate for the instrument's inability to respond

	accurately at the low energy level. It is also important that the quantitative survey meter comply with the cross-sectional area requirements specified in the Federal Performance Standard for Television Receivers, 21 CFR 1020.10(~)(2), as follows: "compliance with the erposilre rate limit defined in paragraph (c)(l) of this section shall be determined by measurements made with an instrument, the radiation sensitive volume of which shall have a cross section parallel to the external surface of the receiver with an area of ten (10) square centimeters and no dimensions larger than five (5) centimeters." Measurements with instruments having other areas must be corrected for spatial non-uniformity of the radiation field to obtain the exposure rate averaged over a ten square centimeter area. The quantitative survey instrument must also be able to operate properly in the vicinity of electronics equipment which may have large electrostatic, magnetic, andlor electromagnetic (RF) fields associated with it. The instrument must also have the ability to be checked daily using some check source and a record of this check should be made and kept. The quantitative survey instrument must be calibrated at least annually by exposure to an x-ray field having an exposure rate and energy representative of those to be measured. The Victoreen Models 440 RF/C and D Radiation Exposure Rate Survey Meters have been specifically designed to measure low-intensity gamma or x-radiation fields and to meet the measurement requirements of the Federal Performance Standard for Television Receivers, specifically 21 CFR 1020.10(~)(2). Response to gamma radiation over the energy range of 6 keV to 1.2 MeV is achievable with field intensities as low as 0.1 mR/hr. The upper limit of measurable exposure rate is 100 mRlhr. This instrument is valuable for x-ray leakage detection, especially in the vicinity of electronics equipment which may have large electrostatic, magnetic, and/or electromagnetic (RF) fields associated with it. The 440 RFIC and D are entirely nonresponsive to such fields and respond only to ionizing radiation. Proper operation of the quantitative measuring instrument, e.g., the Victoreen Model 440 RFIC, should be checked daily with its built-in check source prior to use and a record of this check should be made and kept. The instrument must be calibrated on an annual basis by a qualified laboratory. A certificate of calibration should be obtained from the laboratory and the instrument should be labeled to indicate the dates of last calibration and next scheduled calibration. William B. Johnson TVX-1 or TVX-IB Survey Meter (Qualitative) The TVX-I and TVX-1B survey meters detect radiation including x-radiation, that may emanate from television products. They are sensitive to x-rays in the energy and intensity ranges encountered in television testing. The meters are portable, easy to operate, and particularly adaptable for field use. They are based on an original design by Stoms and Kuerze of the United States Public Health Service. The TVX-1 and TVX-1B survey meters consist of six Geiger-Mueller tubes spaced equidistantly in an array to provide a search area of 18 x 4 inches. Only the tube that reads the highest amount of radiation will activate the meter. On the TVX-1, once radiation has been discovered, a pushbutton will energize a search tube so that the source may be pinpointed. Sensitivity of the TVX-I extends to below 0.1 mRlhr. On the TVX-IB a light will show which tube is reading the highest amount of radiation. The CST-1 or CST-2 is a check source for the TVX-1 and TVX-1B survey meters. They consist of a sealed radioisotope source (approximately 10 microcuries of cadmium-109) affixed inside a plastic tube. This permits positioning over a detector tube during the periodic check. The TVX-I and TVX-1B should be checked daily for proper operation prior to use, using the check source. Each tube must be checked individually. A record of these daily checks should be made. A more precise and carefully controlled periodic check of response should be conducted every 30 to 90 days and recorded. The instrument should be labeled to indicate the dates of last "calibration" and next scheduled calibration. All instruments used in the x-radiation testing program must be controlled to assure that these calibrations are conducted as scheduled.

Qualitative X-Radiation Survey Meter(s)

Item: 1 (could contain up to 10 items with 1 required)

Model name:	
Model number:	
Date of purchase (mm/yyyy):	
Is an operational check performed on the qualitiative x-radiation survey meter prior to its use?	[L]
This meter has been calibrated by (name of lab):	
How often are the meters calibrated?	
Provide the date of the last calibration.	
Provide the calibration certificate for the meter showing the current calibration.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Quantitative X-Radiation Survey Meter(s)

Item: 1 (could contain up to 10 items with 1 required)

Model name:	
Model number:	
Date of purchase (mm/yyyy):	
Is an operational check performed on the qualitiative x-radiation survey meter prior to its use?	[L]
This meter has been calibrated by (name of lab):	
How often are the meters calibrated?	
Provide the date of the last calibration.	
Provide the calibration certificate for the meter showing the current calibration.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Other Survey Meter(s)

AC/DC Input Voltmeter		
–	Model name:	
–	Model number:	
–	Name of Instrument Manufacturer:	

–	How often is the meter calibrated?	
Beam Current Ammeater		
–	Model name:	
–	Model number:	
–	Name of Instrument Manufacturer:	
–	How often is the meter calibrated?	
High Voltage Meter		
–	Model name:	
–	Model number:	
–	Name of Instrument Manufacturer:	
–	How often is the meter calibrated?	
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.	
Note:	FDA Form 3659 Television Products Product Report (10/31/2013)	