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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

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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 submissio (Supplements should be prepared using the same do submission.)	•	•
	of Submission is this? (Supplements should be submitted e 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

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	() 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 ther is an active question, select the appropriate product area or document type from the question's pick list.	e
What Type of P	roduct is this Radiation Safety Report about?	!*
Television Rece (CRT)	ivers, Television Projectors, Video and Computer Monitors containing Cathode Ray Tubes	
What Type of P	roduct is this Annual Report about?	
What Laser Ligh	nt Show Document are you filing?	
What Type of C	orrespondence is this?	
What Type of Pi	roduct is this Variance Request about?	

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Establishment Information: Establishment Name Division Name Home Page Physical Location: Address Telephone Number Fax Number Mailing Location: Address Telephone Number Fax Number Mary Seponsible Individual Note: The responsible individual is the highest level and most responsible individual affiliated with this establishment.		
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 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 Information: Contact Name Occupation Title Email Address **Establishment Information: Establishment Information: Establishment Information: Establishment Information: Establishment Information: Establishment Name Division Name Physical Location: Address Telephone Number	Manufacturer	Responsible for Product Compliance
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Email Address Establishment Information: Establishment Name Division Name Physical Location: Address Telephone Number	Contact Name	
Establishment Information: Establishment Name Division Name Physical Location: Address Telephone Number		
Establishment Name Division Name Physical Location: Address Telephone Number	Email Address	
Division Name Physical Location: Address Telephone Number	Establishment Ir	nformation:
Physical Location: Address Telephone Number	Establishment N	ame
Address Telephone Number	Division Name	
Telephone Number	Physical Location	n:
	Address	
Fax Number	·	ber
-	Fax Number	

Manufacturer Data

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Mailing Location	ı:		
Address			
Telephone Num	ber		
Fax Number			
Manufacturer	's Re	eporting Official	
Note:	addre repoi	is the person at the manufacturing facility that is knowledgeable and responsible for essing all aspects of the testing and quality control procedures for certification as rted to FDA in the product report. Documentation of changes intesting and quality rol procedures submitted to FDA must be signed by this individual.	
Select the Repo	rting (Official from Contact Address book: *	
Contact Informa	tion:		
Contact Name			
Occupation Title			
Email Address			
Establishment l	nforma	ation:	
Establishment N	lame		
Division Name			
Physical Location	on:		
Address			
Telephone Num	ber		
Fax Number			
Mailing Location	า:		
Address			
Telephone Num	ber		
Fax Number			
Report Subm	itter		
Note:	prepa by th	submitter may be a consulting individual or firm providing assistance in report aration and maintenance. Documents or submissions such as this one that are prepared be submitter must have an accompanying authorization letter from the manufacturer's rting 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	Division Name		

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Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	
Telephone Number	
Fax Number	
Comments:	
Internal Reference Nu	umber:
	<u>, </u>
Parent Establishm	ient
Is there a parent esta	blishment? *
	<u>'</u>
Select the Parent Est	ablishment and Contact from the Contact Address book:
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Establishment Inform	ation:
Establishment Name	
Division Name	
Physical Location:	
Address	
Telephone Number	
Fax Number	
Mailing Location:	
Address	
Telephone Number	
Fax Number	
Manufacturer Des	ignated United States Agent
Note: Manu	ufacturers exporting to the U.S. must designate a U.S. agent, see 21 CFR 1005.25.
Is there a United State	es agent that has been designated by the manufacturer? *
Importer	

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Additional Manufacturing Locations

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P	ro	d١	14	ct	ח	a	ta
	v	u	uι	J.	\boldsymbol{L}	а	La

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 co	ode?
To select the three let	ter product code,
- Select the appropria from which to choose - Select the best mate	
Category	
Product Code	
Performance Standard	
If Other, provide a cat	egory name for this specific product.

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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 a	any of its	attachmen	ts contain:
-------------------------	------------	-----------	-------------

A notification of noncompliance or defect?

You may provide an explanation and/or attach a document here:

Details

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Responses to Noncompliances or Defects

noncompliance or defect.

You may add an explanation and/or attach a document here:

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 "Followup 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

Exemption Requests

Details

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.

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Message	: CI	ick the plus sign to list the requirements from which you are requesting a variance.
This subr	nission ind	cludes an application for a variance from certain requirements.
Item I	No Informa	ation Provided.
Provide a	n explana	tion and attach supporting files, if necessary. Click on the plus sign below to attach files.
Details		
Stop:	Thins Us U. Ce At. Do Sii Ac su Fo	or all Variance requests, two submissions must be made to the FDA. In electronic version should be submitted following the Packaging Files for Submission structions located under Output in the Menu bar, and explained in subsection 4.3 of the ser Manual. If sending a CD & submittal letter, please mail to: S. Food and Drug Administration enter for Devices and Radiological Health the esubmitter Team ocument Mail Center - WO66-0609 1903 New Hampshire Avenue (ver Spring, MD 20993-0002) Iditionally, a paper version (hard-copy) of the signed Variance request document should be bmitted to: In and Drug Administration (vision of Dockets Management (HFA-305) 130 Fishers Lane, Room 1061 100ckville, 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?	k
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)?	k .
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!

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	evant information or additional comments that would help expedite the review of this e 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 premarke	et 510(k), IDE, HDE, PDP, or PMA filing numbers related to this medical product, if one	

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.

of these numbers has been assigned by FDA yet.

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Television Data				
Model Designation				
Model Designation:				
Specify which Product Type this TV Product Report is for.	*			
Explain:				
Specify the Product Display of the Product Type selected above.	*			
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)(I)) [] 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 which an actual label is not available. Include an example of the date of manufactu 1995." Identify the location of each label.				
Details				
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.				
Details				
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				

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Attach copies of the above documents here. *			
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.			
Details			
Are the above mentioned CRT's registered? *			
Provide the EIA or other curve number for the CRT's. Item No Information Provided.			
Special Radiation Shielding			
Special Radiation Shielding:			
Does this product include special shielding in addition to the inherent CRT shielding and anode cap shielding?			
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.			
Details			
Hold-down Saftety Circuits			
Hold-down and Safety Circuits:			
Does the product have a hold-down or other safety circuit? *			
How many safety circuits does the product contain?			

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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.

Details

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 preproduction 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)

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Quality Control			
Quality C	entrol 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 C	mponent Incoming Inspection		
Production	n Inspection and Testing		
High Vol	ge Circuit		
High Volta	e Circuit:		
Specify wh	th type of circuit this product contains *		
Define the	/pe:		
Has this ci	uit been tested on a 100% basis? *		
Provide an	explanation for the deviation of 100% testing		
Details			
Percentage of production tested or checked: *			
How has th	circuit been tested or checked?		
Details			
Sealed C	introls		
Sampling Plan and Rejection Procedures			
Sampling	lan and Rejection Procedures:		
This manufacturer/program is related to:			
Is this program applicable to all production plants?			

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Explain and identify programs to applicable production plants in an attachment.				
Details				
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				
Provide the unit rejection limit (mR/hr). *				
What is the action taken if the unit rejection limit is exceeded?				
Details				
Provide the lot rejection limit (mR/hr). *				
What action is taken if the lot rejection limit is exceeded?				
Details				
X-Radiation Testing of Production Sets				
X-radiation resting of Froduction Sets				
X-Radiation Testing of Production Sets:				
Provide detailed step-by-step procedures for production x-radiation testing.				
Details				
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?				
Provide information regarding alternate failure selection and justification.				
Details				
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				

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(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 mR/hr. 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.

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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	Surve	/ Meter(s
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Quantitative X-Radiation Survey Meter(s)

Other Survey Meter(s)

AC/DC Input Voltmeter						
-	Model nar	ne:	•			
-	Model number:		*			
-	Name of Instrument Manufacturer:		k			
-	How ofter	is the meter calibrated?	k			
Beam Current Ammeater						
_	Model name:		•			
_	Model number:		*			
-	Name of Instrument Manufacturer: *		k			
-	. How often is the meter calibrated?		*			
High	Voltage N	leter				
-	_ Model name: *		*			
-	Model number:		k			
-	Name of Instrument Manufacturer: *		k			
-	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.				