REPORTING AND COMPLIANCE GUIDE FOR TELEVISION PRODUCTS

Including

Product Report (21 CFR 1002.10)

Supplemental Report (21 CFR 1002.11)

Radiation Safety Abbreviated Report (21 CFR 1002.12)

Annual Report (21 CFR 1002.13)

Information and Guidance

October 1995

(Address corrections Aug. 2008)

This Guide replaces the August 1982 edition
and June 1983 Annual Reporting Guide
(Address corrections Oct. 2005)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health
5600 Fisher Lane
Rockville, Maryland 20857

Foreword

This guide was developed by the Office of Compliance, Center for Devices and Radiological Health (CDRH), to assist electronic product manufacturers in providing adequate reporting of radiation safety testing and compliance with performance standards. Reporting requirements are specified in Title 21 of the Code of Federal Regulations (CFR), Part 1002.

Reports submitted on radiation safety of electronic products must follow the appropriate guide (21 CFR 1002.7), or contain a justification why it was not followed. CDRH may reject an incomplete report and return it for completion. When the report is adequate for filing, it will be logged into the CDRH computer system and assigned an accession number. The submitter of the report will receive an acknowledgment letter with the accession number we assign 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.

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

We are making our reporting guides available on the CDRH Electronic Docket, for downloading and reproduction. They are not copyrighted and may be reproduced as needed. The telephone number for access to the CDRH Electronic Docket via your personal computer's modem is 1-800-252-1366.

Please mail your reports to the address below (electronic submissions cannot be processed yet). Provide one original IN ENGLISH (no facsimile, please) unless specified otherwise in the guide. Make a copy of the completed report for your records. If you would like to comment on the reporting guides or the electronic docket or future electronic submissions, you may direct the comments to the same address. If you need additional

regulations for electronic products or medical devices, contact the Division of Small Manufacturers, International, and Consumer Assistance by telephone at 1-800-638-2041 or 301-443-6597, or by facsimile at 301-443-8818.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance

MAILING ADDRESS:

Center for Devices and Radiological Health
ATTN: Electronic Product Reports
Electronic Product Document Control (HFZ-309)
Office of Communication, Education, and Radiation Programs
9200 Corporate Blvd.
Rockville, MD 20850

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REPORTING AND CERTIFICATION REQUIREMENTS

Manufacturers of television products incorporating cathode ray tubes must submit reports pertaining to the radiation safety of the design and performance of these products as required by the Federal Food, Drug, and Cosmetic Act, Chapter V, Subchapter C - Electronic Product Radiation Control (referred to as the Act), and the regulations published pursuant to it. The manufacturer must also certify that the products meet the applicable performance standard, 21 Code of Federal Regulations (CFR) 1020.10. For legal purposes, an importer is considered under the law to be the manufacturer, though design and test information should be provided by the actual manufacturer.

The reporting and recordkeeping requirements are specified in Part 1002 of the Regulations. Section 1002.10 of the Regulations requires submission of a Product Report prior to introduction of any new regulated product into United States (U.S.) commerce. For certain products specified in Table 1 of Part 1002.1, a Radiation Safety Abbreviated Report is required in lieu of a full Product Report. An Annual Report is required under the provisions of Section 1002.13. Appropriate labels (certification, identification, and date of manufacture) are to be attached to the electronic products in accordance with Sections 1010.2 and 1010.3. Subsequent to filing the Product Reports, new selling models of a model family that do not involve changes that could affect x-radiation emission or compliance with other requirements are reported as supplements to the Annual Report in accordance with Section 1002.13, prior to their introduction into commerce. Subsequent to filing the Abbreviated Reports, new selling models will only have to be reported annually as part of the Annual Report.

This Television Products Reporting Guide contains fill-in-the-blank formats and attachments for the manufacturers to use in submitting required reports to CDRH. The appropriate formats should be photocopied or otherwise reproduced, filled in and submitted to the CDRH. The following chart briefly summarizes those Parts which are required for various types of submittals.

TYPE OF SUBMITTAL	PARTS OF REPORT
Product Report	Parts 1, 2, 3 and 5A through 6E plus corresponding attachments
Abbreviated Report	Parts 1, 2, 3 and 4
New Selling Models AFTER submitting Product Report (No changes in circuit design or compliance)	Parts 1, 2 and 8.8 (Annual Report)
New Selling Models AFTER submitting Abbreviated Report	New Models Are Reported Annually Under Part 8.5 of the Annual Report
Annual Report	Parts 1, 2 and all of 8 (except 8.8)
Supplemental Report (to update Product Report)	Parts 1, 2 and 3 plus any Parts affected
New Factory Locations	Parts 1, 2 and 3

TYPE OF SUBMITTAL	WHEN TO FILE?
Product Report	Prior to introduction into U.S. commerce
Abbreviated Report	Prior to introduction into U.S. commerce
New Selling Models (for Product Reports)	Quarterly (See Part 8.8)
New Selling Models (for Abbreviated Reports)	Annually by September 1 (See Part 8.5)
Annual Report	Annually by September 1
Supplemental Report	Prior to introduction into U.S. commerce
New Factory Locations	Prior to introduction into U.S. commerce

INSTRUCTIONS - Part 1 Identification

Items 1.1, 1.2 and 1.3 Manufacturer, U.S. Agent, or Importer

These items must be completed for each submission. Enter the address of the factory at which the final assembly takes place. If necessary, use Attachment C to list all factories, in case there is more than one. Also, include any coding information which enables CDRH to identify the factory at which a particular unit was manufactured. The coding may appear in the serial number, model number or elsewhere on the identification label but you should explain it clearly.

CONTACT OFFICIAL

The CDRH asks that a Contact Official be designated by manufacturers and importers doing business with CDRH. The Contact Official is considered the designated contact point within the company for CDRH television product matters.

U.S. AGENT (REQUIRED FOR FOREIGN MANUFACTURER)

If the television products are manufactured outside United States (U.S.), Federal regulation, 21 CFR 1005.25, requires that every foreign manufacturer designate a permanent resident of the U.S. as the manufacturer's agent. THE U.S. AGENT CAN BE AN INDIVIDUAL, A FIRM, A DOMESTIC CORPORATION OR AN IMPORTER.

IMPORTER

Provide the name and address of the importer unless it is the same as the U.S. Agent.

If there is insufficient space in Items 1.2, and 1.3, use ATTACHMENT D when reporting multiple brand names, multiple private label purchasers, or multiple importers. Provide the complete name and address of importers and private label purchasers. Include the name and telephone number of a contact person if available.

INSTRUCTIONS - PART 2 PURPOSE OF SUBMISSION AND PERFORMANCE CHARACTERISTICS

Item 2.1 - Check the appropriate box indicating the reason for the submission and provide the completed Parts and attachments as necessary.

TELEVISION PRODUCTS REPORTING FORM - PART 1 IDENTIFICATION

1.1 MANUFACTURER IDENTIFICATION

Company Name:

Address:

Place of manufacture if other than above:

Contact Official: (Name and Title) (Signature) (Telephone)

1.2 U.S. AGENT IDENTIFICATION (Required for Foreign Manufacturer)

Company Name:

Address:

Contact Official: (Name and Title) (Signature) (Telephone)

1.3 Importer

Company Name:

Address:

1.4 Date of this report:

TELEVISION PRODUCTS REPORTING FORM - PART 2 PURPOSE OF SUBMISSION AND OPERATIONAL CHARACTERISTICS

2.1 Purpose of Submission

[ ]I am reporting A NEW CHASSIS FAMILY by completing a Radiation Safety PRODUCT REPORT. An engineering analysis of a specially built worst-tolerance chassis has been performed under Phase III test conditions. The product's maximum voltage IS EQUAL TO OR GREATER THAN 25 kilovolts AND/OR the chassis power curve will reach or exceed the 0.1 mR/hr isoexposure rate limit curve (IRLC) for the cathode ray tube (CRT). Parts 1, 2, 3, the Checklist of Attachments, and 5A through 6E are attached.

[ ]I am reporting A NEW CHASSIS FAMILY by completing a Radiation Safety ABBREVIATED REPORT. An engineering analysis of a specially built worst-tolerance chassis has been performed under Phase III test conditions. The product's maximum voltage is LESS THAN 25 kilovolts AND the chassis power curve DOES NOT EXCEED 0.1 mR/hr isoexposure rate limit curve (IRLC) for the cathode ray tube (CRT). Parts 1, 2, 3 and 4 are attached.

[ ]I am reporting NEW SELLING MODELS IN THE SAME CHASSIS FAMILY previously reported in the PRODUCT REPORT [SEE NOTE BELOW]. There is no change in circuitry affecting radiation safety. Parts 1, 2 and 8.8 are attached.

The ACCESSION NUMBER of my Annual Report is:

[ ]I am reporting a NEW FACTORY LOCATION(s). Parts 1, 2 and 3 are attached.

[ ]I am submitting an ANNUAL REPORT for my company which is due September 1 of every year. The entire Part 8 (except 8.8) is attached.

[ ]I am reporting CHANGES IN THE INFORMATION submitted in a PRODUCT REPORT. Parts 1, 2 and other parts affected by the changes are attached.

The ACCESSION NUMBER of the Product Report is:

Indicate which parts of the previous report are changed:

NOTE: NEW SELLING MODELS under ABBREVIATED REPORTS are filed annually; see Part 8.5 of this guide.

INSTRUCTIONS - PART 3 MODEL IDENTIFICATION

USE THIS FORMAT TO IDENTIFY THE TELEVISION PRODUCTS WHEN SUBMITTING THE ABBREVIATED REPORT OR THE PRODUCT REPORT.

The chart in Part 3, Model Identification, is self-explanatory and the codes for product type and product display are provided below.

[NOTE: If you are reporting ONLY new selling models added to a previously reported chassis family, and there are no changes in the circuitry affecting x-radiation production or high voltage under Phase III test conditions, DO NOT USE THIS PART. Complete Part 8.8 in the Annual Report.]

"TV PLANT LOCATIONS" - codes may be used to identify the manufacturing plant for the television products. On a separate sheet, labeled as "Attachment C, Place of Manufacture Coding Information," provide the complete address for each television product's manufacturing location and identify any CODES:

PRODUCT TYPES:
- R = Television Receiver
- M = Monitor
- V = Camera Viewfinder
- P = Projector
- O = Other (explain)

(See Part 9B for explanation of Product Types)

PRODUCT DISPLAY:
- M = Monochrome
- C = Color

MODEL IDENTIFICATION - PART 3

Chassis Family No.:

Product Type : Display: (see codes)

TV Plant Locations:

Codes may be used to identify the manufacturing plants. On a separate sheet, labeled "Attachment C, Place of Manufacture Coding Information," identify any codes and provide the complete address for each manufacturing location.

BRAND NAMES	MODEL NUMBERS	CATHODE RAY TUBE MANUFACTURER & NUMBER	PLANT LOCATION (1)

INSTRUCTIONS - PART 4 RADIATION SAFETY ABBREVIATED REPORT (21 CFR 1002.12)

THE NEW RADIATION SAFETY ABBREVIATED REPORT (pages 4 and 5) is for reporting products that have low operating voltage and are designed to be safe in that they do not emit x-radiation under severe operating test conditions. When tested under Phase III conditions, the maximum voltage must be LESS THAN 25 kilovolts (kV) and the chassis power curve must NOT REACH OR EXCEED the 0.1 mR/hr isoexposure rate limit curve (IRLC) for the cathode ray tube (CRT).

Are you adding NEW SELLING MODELS After Filing The Abbreviated Report?

The regulations for reporting have been amended to reduce recordkeeping and reporting requirements. After filing the Abbreviated Report, if there are new selling models belonging to the same chassis family, the manufacturer (or importer) is not required to report them immediately to CDRH prior to introduction into commerce. The manufacturer should retain the new selling model numbers and production data for a period of one year (12 months period - from July 1 to June 30) and report them in Part 8.5 of the Annual Report. See Part 8.5 of this guide for further clarification and a form to use to report new selling models at the time of filing the Annual Report.

RADIATION SAFETY ABBREVIATED REPORT - PART 4

4.1 Chassis Family Identification and Operating Characteristics

Chassis Family No. or name:

Screen size (diagonal): inches, or centimeters

Operating Input voltage: VAC DC

Is there a hold-down safety circuit in the chassis?
( ) Yes or ( ) No

If Yes, the hold-down safety circuit activates at: kV +/- kV

Is a wiring schematic available? ( ) Yes or ( ) No
(do not submit unless requested)

Is a service manual available? ( ) Yes or ( ) No
(do not submit unless requested)

Is the 0.5 mR/hr or 0.1 mR/hr isoexposure rate limit curve for the CRT available? ( ) Yes or ( ) No

4.3 Engineering Analysis and Phase III Testing

Who assembled the worst-tolerance chassis? (give name and address of the manufacturer location or consulting laboratory):

Was the worst tolerance chassis assembled using critical components with the worst tolerance values for producing x-radiation?
( ) Yes or ( ) No

Who performed the engineering analysis and Phase III testing? (give name and address of manufacturer or consulting laboratory):

During Phase III testing, were ALL critical components in the chassis tested for worst failure? ( ) Yes or ( ) No

RADIATION SAFETY ABBREVIATED REPORT - PART 4

4.3 Engineering Analysis and Phase III Testing (continued)

Which critical component was found to be the worst?:

Were ALL user controls and service controls adjusted to worst settings for producing x-radiation? ( ) Yes or ( ) No:

Maximum x-radiation measured was: mR/hr or uSv/hr.
(If no x-radiation was detected, enter < 0.1 mR/hr or < 1.0 uSv/hr)

List the Name and model of the QUALITATIVE x-radiation survey meter(s) used for the Phase III test:

List the Name and model of the QUANTITATIVE x-radiation survey meter(s) used for the Phase III test:

Provide the SERIAL NUMBER(s) of the quantitative meter(s), and last calibration date:

ATTACH A COPY OF THE WORST-TOLERANCE CHASSIS POWER CURVE with the worst component failure, plotted on a graph with the IRLC (either 0.5 mR/hr or 0.1 mR/hr, but please label it).
(See Part 9C - Engineering Analysis for further details)

Power curve attached? ( ) Yes or ( ) No

4.4 Quality Control and Testing Program on Production Models

Does the manufacturer have in place an on-going quality control and testing program in which PRODUCTION MODELS will be routinely sampled and tested under Phase III test conditions? ( ) Yes or ( ) No

Who will do that testing (name and address)?:

What is the maximum x-radiation reject limit allowed for these products under Phase III test conditions? (give number):

mR/hr or uSv/hr.

PART 5 PRODUCT REPORT
CHECKLIST OF ATTACHMENTS

Check all Attachments that are submitted with Parts 1 and 2 of this guide. FAILURE TO SUBMIT ANY OF THE REQUIRED ATTACHMENTS MAY LEAD TO REJECTION OF YOUR PRODUCT REPORT.

[ ] A.Model Identification, Part 3. THIS ATTACHMENT IS REQUIRED.

[ ] B.Selling Model - Chassis Family Coding Information (see Part 3).

[ ] C.Place of Manufacture Coding Information (see 5.1).

[ ] D.Private Label Purchaser and Importer Identification (see 1.3).

[ ] E.Service Instructions, Circuit Diagram and Parts List (see 5.2). THIS ATTACHMENT IS REQUIRED.

[ ] F.CRT Isoexposure Curve(s) and Corresponding Chassis Power Curve(s) (see 5.3). THIS ATTACHMENT IS REQUIRED.

[ ] G.(Not used)

[ ] H.Shielding Information (see 5.4).

[ ] I.Hold-down or Safety Circuit Information (see 5.5).

[ ] J.Engineering Analysis, Component Failure Data Sheets J-1 through J-6 (see 5.6). THESE ATTACHMENTS ARE REQUIRED.

[ ] K.Product labeling and Special Information (see 5.1). THIS ATTACHMENT IS REQUIRED.

[ ] L.Test Instruments Identification and Specifications (see 6.15).

[ ] M.Test Instrument Calibration Procedures and Certificates (see 6.15). THIS ATTACHMENT IS REQUIRED.

[ ] N.Incoming Component Sampling and Test Program (see 6.1).

[ ] O.Production Quality Control and Testing of Shielding/Circuits That May Affect Radiation (see 6.4).

[ ] P.Detailed (Step-by-Step) Procedures for Production X-Radiation Testing (see 6.14). THIS ATTACHMENT IS REQUIRED.

[ ] Q.Alternate Failure Selection and Justification (see 6.14).

[ ] R.General Production Sampling and Production X-Radiation Testing Program (6.8 - 6.13). THIS ATTACHMENT IS REQUIRED.

INSTRUCTIONS - PART 5 PRODUCT REPORT

PART 5A - PRODUCT LABELING AND SPECIAL INFORMATION

Item 5.1 - Labels, Radiation Warnings and Instructions (Attachment K)

WARNING - ATTACHMENT K IS REQUIRED FOR ALL PRODUCT REPORT SUBMITTALS. FAILURE TO PROVIDE ADEQUATE AND COMPLETE INFORMATION ACCORDING TO INSTRUCTIONS MAY LEAD TO REJECTION OF YOUR REPORT.

Attachment K should include actual copies of all required labels if possible. 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. For further details regarding labels, refer to Part 9D of this guide.

The place of manufacture may be expressed in code provided the manufacturer has supplied the CDRH with the key to such code (use Attachment C).

PART 5B - ENGINEERING AND TECHNICAL INFORMATION

Item 5.2 Service Instructions, Schematics and Parts List

WARNING - ATTACHMENT E IS REQUIRED FOR ALL PRODUCT REPORT SUBMITTALS. FAILURE TO PROVIDE ADEQUATE AND COMPLETE INFORMATION ACCORDING TO THE INSTRUCTIONS MAY LEAD TO REJECTION OF YOUR REPORT.

Submit preliminary service instructions and schematic or final service manual. MAKE SURE THAT ALL CRITICAL COMPONENTS (components that can affect high voltage or X-ray generation) ARE IDENTIFIED on all schematics and final parts lists.

Service instructions should contain complete instructions for replacement and adjustment of all critical parts, including precautions about using exact replacement parts. Preliminary service instructions should not include blueprints or parts lists for the product. A complete legible schematic, together with warnings, adjustment procedures and measurements, which are pertinent to x-radiation safety, is adequate for the preliminary service instruction. When the final service manual is available, submit the printed manual. (Photocopied manuals are sometimes difficult to read because notations, such as shading or coloring of parts and instructions, frequently are not reproduced by photocopying.)

Item 5.3 Chassis Power Curves and CRT Isoexposure Rate Limit Curve (IRLC)

WARNING - ATTACHMENT F IS REQUIRED FOR ALL PRODUCT REPORT SUBMITTALS. FAILURE TO PROVIDE ADEQUATE AND COMPLETE INFORMATION ACCORDING TO THE INSTRUCTIONS MAY LEAD TO REJECTION OF YOUR REPORT.

Submit in Attachment F, a copy of the CRT manufacturer's 0.5 mR/hr isoexposure rate limit curves (IRLC) for all CRT's used with the chassis family or selling models being reported. Attachment F ALSO MUST INCLUDE a

PART 5 PRODUCT REPORT

PART 5A - PRODUCT LABELING AND SPECIAL INFORMATION

5.1 Labels, Radiation Warnings and Instructions

Show in Attachment K the location and an ACTUAL sample or copy of the following labels:

[ ] Certification Label (21 CFR 1010.2)

[ ] Identification Label (21 CFR 1010.3(a)(1)) *

[ ] Date of Manufacture (21 CFR 1010.3(a)(2))

[ ] Critical Component Warning Label (21 CFR 1020.10(c)(4))

* The place of manufacture may be expressed in code provided the manufacturer has previously supplied to CDRH the key to such code:

[ ] Attachment C - Place of Manufacture - Keys to the Codes

PART 5B - ENGINEERING AND TECHNICAL INFORMATION

5.2 Service Instructions, Schematic and Parts Lists (submit for a model representative of the chassis family being reported)

[ ]Attachment E contains the schematic only. Final versions of the service manual will be submitted by (date):

[ ]Attachment E is the final service manual.

PART 5B - ENGINEERING AND TECHNICAL INFORMATION (cont.)

5.3 (cont.) graph of: (a) the worst-tolerance chassis power curve, obtained with the worst-tolerance components and the worst component failure (data from Attachment J-1), and (b) the design-center chassis power curve, obtained with design-center components and the worst component failure (data from Attachment J-4) (see Part 9C Engineering Analysis for further details). These two curves (a and b) must be plotted (with an appropriate scale) on the same graph as the CRT isoexposure curve(s). Additional Attachment F 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. INCLUDE THE EIA OR OTHER CURVE NUMBER if the CRT's are registered.

Item 5.4 Special Radiation Shielding

Attachment H is only necessary if the product includes 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.

Item 5.5 Hold-down and Safety Circuits

For each safety circuit included in the product, describe the circuit's operation accurately and concisely in Attachment I. 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.

Test procedures for each safety circuit should check as much of the electronics as possible that affect the circuit. Procedures for safety circuit testing should be included in final versions of service manuals.

PART 5C - ENGINEERING ANALYSIS

WARNING - ATTACHMENTS J1 THROUGH J6 ARE REQUIRED FOR ALL PRODUCT REPORT SUBMITTALS. FAILURE TO PROVIDE ADEQUATE AND COMPLETE ATTACHMENTS J1 THROUGH J6 ACCORDING TO THE INSTRUCTIONS MAY LEAD TO REJECTION OF YOUR PRODUCT REPORT

Item 5.6 Component Failure Data Sheets

Attachments J1 through J6 (together with Attachment F) include the results of the Engineering Analysis of the worst-tolerance and design-center chassis. This analysis determines the safety of design and the worst case conditions which will be used during production testing of the product. It is this analysis which permits the manufacturer to test production units using a sampling plan. Without a meaningful Engineering Analysis, the manufacturer would have to conduct 100 percent compliance testing on production models. For further details, refer to Part 9C of this guide.

PART 5 PRODUCT REPORT

PART 5B - ENGINEERING AND TECHNICAL INFORMATION

5.3 CRT Isoexposure Curve(s) and Corresponding Chassis Power Curves for the Worst-Tolerance Chassis and Design-Center Chassis.

[ ]Attachment F is provided.

5.4 Special Radiation Shielding (Check One):

[ ]No special radiation shielding is used.

[ ]See Attachment H for details of special radiation shielding.

5.5 High Voltage Hold-down or Other Radiation Safety Circuits (Check one):

[ ]See Attachment I for circuit diagram and operating description of all hold-down or safety circuits.

[ ]None used.

PART 5C - ENGINEERING ANALYSIS

5.6 Attachments J-1 through J-6 Are Enclosed (check and confirm that all of the attachments are enclosed):

[ ]Attachment J-1 Worst-Tolerance Chassis, Component Failure Data Sheet

[ ]Attachment J-2 Worst-Tolerance Chassis, Component Information

[ ]Attachment J-3 Worst-Tolerance Chassis, Control Adjustment Information

[ ]Attachment J-4 Design-Center Chassis, Component Failure Data Sheet

[ ]Attachment J-5 Design-Center Chassis, Component Information

[ ]Attachment J-6 Design-Center Chassis, Control Adjustment Information

ATTACHMENT J-2

WORST-TOLERANCE CHASSIS

Component Information

Critical component	Design value	Tolerance	Worst-tolerance value used	Remarks

Examples: capacitors, resistors, high voltage transformers, deflection yokes, flyback transformer, diodes, etc., any components which can affect x-radiation.

If worst-tolerance value components were not used, explain and provide justification below:

ATTACHMENT J-3

WORST-TOLERANCE CHASSIS

Control Adjustment Information

Failed component	User control adjustments	Service control adjustments	Remarks

ATTACHMENT J-5

DESIGN-CENTER CHASSIS

Component Information

Critical component	Actual Design value	Tolerance	Value used	Remarks

ATTACHMENT J-6

DESIGN-CENTER CHASSIS

Control Adjustment Information

Failed components	User control adjustments	Service control adjustments	Remarks

INSTRUCTIONS - PART 6 PRODUCT REPORT

Quality Control and Testing Program

PART 6A - CRITICAL COMPONENT INCOMING INSPECTION PROGRAM

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, you, not the component manufacturers, are responsible for the compliance of your product. For further details, refer to Part 9B - General Information and Guidance.

Item 6.1 Incoming Inspection Information

For each critical component, indicate whether or not incoming testing is performed, and if so, what parameter(s) are measured, and provide the sampling plan and the rejection criteria. Narrative details of the incoming inspection information can be given in Attachment N, if the format used on the form is not sufficient or appropriate to describe the critical component incoming inspection program.

Item 6.2 Corrective Action Plan

When an incoming lot of components is rejected, the customer has two basic options: (1) to screen the lot (inspect at 100% and remove the defectives) or (2) to return the lot to the vendor. The first option is usually exercised only when the components are urgently needed. Outright lot rejection brings more pressure to bear on the vendor to improve the quality of his product. Of course, a record should be made of the rejection and the vendor's history may be reviewed for previous problems.

Item 6.3 Additional Information - Attachment N.

Such information as details of sampling plans used and criteria for tightened or reduced inspections may be reported in Attachment N.

PART 6 PRODUCT REPORT

PART 6A - CRITICAL COMPONENT INCOMING INSPECTION PROGRAM

6.1 Incoming Inspection Information

Critical component	Incoming Test Yes or No*	Parameter(s) measured	Sampling plan	Rejection criteria
CRT's				
Capacitors				
H.V. Transformers				
Yoke				
Shielding				
Other (describe):				

* If incoming inspection is not performed, show in Attachment N test data or certification required from the component or material vendor or other methods used to assure conformance of critical components to engineering specifications.

6.2 Corrective action upon rejection:

[ ]Attachment N provides additional information on critical component incoming inspection program.

INSTRUCTIONS - PART 6 PRODUCT REPORT

PART 6B - PRODUCTION INSPECTION AND TESTING

Item 6.4 Shielding

If the product relies on shielding or protective circuitry to maintain x-radiation safety, then checks should be made on each production unit to verify that these safeguards are within the engineering specifications. If a product employs shielding other than the anode cap and inherent CRT shielding, then its placement and configuration should be checked. For instance, some products may be capable under Phase III conditions of emitting radiation through gaps or holes in the shielding. On such products there should be at least a visual check to confirm shielding integrity.

Item 6.5 High Voltage Circuit

High voltage measurements should be performed on production units in order to maintain control of product safety. This type of test is particularly relevant when the product employs no high voltage hold-down or safety circuit. It also checks the cumulative effect on high voltage caused by variations within allowed tolerances of components. The high voltage rejection limit for normal production units should, of course, be lower than the maximum Phase III high voltage.

Item 6.6 Hold-Down and Safety Circuits

A hold-down or safety circuit is generally designed to limit the maximum high voltage or beam current. It may operate by interrupting set operation or acting to reduce the high voltage or beam current, once a certain threshold value is reached. See Part 9B - General Information and Guidance for additional information.

The explanation of the hold-down or safety circuit test, requested in Attachment O, should include a brief description of how the test procedure or jig actually tests the circuit. This description should include the point(s) at which measurements are made, control(s) that are adjusted, external voltages applied and components that are failed or added for this test.

Item 6.7 Sealed Controls

Sealed controls must be identified by both schematic designation and function. Sealing method and test procedures must also be identified. See Part 9B - General Information and Guidance for additional information.

PART 6B - PRODUCTION INSPECTION AND TESTING

6.4 Shielding (if installed)

Percentage of production tested or checked:

How tested or checked:

6.5 High voltage circuit

Percentage of production tested or checked:

How tested or checked:

6.6 High voltage hold-down or radiation safety circuits
(These circuits must be tested on a 100% basis. Any deviation from 100% testing must be explained in Attachment O.)

How tested or checked:

6.7Sealed controls

Identify each control that is sealed (component designation and function; for example: VR208, B+):

Sealing method and material used:

Percentage tested or checked:

How checked:

Production line quality control and testing of shielding and circuits that may affect radiation characteristics:

[ ]See Attachment O for description of in-process inspection and

testing

INSTRUCTIONS - PART 6 PRODUCT REPORT

PART 6C - SAMPLING PLAN AND REJECTION PROCEDURES

Item 6.8 Program Applicability

If separate programs are followed for monochrome and for color or other production, information must be submitted for each program. If different programs are followed at different production locations, the information must be submitted for each location.

Items 6.9 through 6.13 Sampling Plan and Rejection Plan

For each item, describe the lot size, number of samples taken from each lot (or percentage), the minimum number of samples taken from each production line each day, and explain how the samples are selected, and what are the unit rejection limit and lot rejection limit. For further information regarding the sampling plan and rejection procedures, see Part 9B - General Information and Guidance.

PART 6 PRODUCT REPORT

PART 6C - SAMPLING PLAN AND REJECTION PROCEDURES

6.8 This program is applicable to:

[ ] Color [ ] Monochrome [ ] Both Color and Monochrome

(If not applicable to all production plants, please specify to which plant(s) this program applies.)

6.9 X-radiation sampling done as a part of regular production:

Lot size or lot definition (for rejection purposes):

Number of Sample(s) taken from each lot or % of lot tested:

6.10 Minimum number of units sampled from each production line each day (or shift):

6.11 Samples for x-radiation testing are taken of: (Check all that apply)

[ ] Each lot

[ ] Each selling model being manufactured

[ ] A selling model representative of each chassis/CRT-size combination within a chassis family

[ ] None of the above (explain in Attachment N)

6.12 Unit rejection limit (mR/hr):

Action taken if unit rejection limit is exceeded:

6.13 Lot rejection limit (mR/hr):

Action if lot rejection limit is exceeded:

INSTRUCTIONS - PART 6 PRODUCT REPORT

PART 6D - X-RADIATION TESTING OF PRODUCTION SETS

Item 6.14 X-Radiation Testing of Production Sets

WARNING - ATTACHMENT P IS REQUIRED FOR ALL PRODUCT REPORT SUBMITTALS. FAILURE TO PROVIDE ADEQUATE AND COMPLETE INFORMATION MAY LEAD TO REJECTION OF YOUR REPORT.

Submit in Attachment P the specific written test procedures issued to and used by the test technician for conducting the x-radiation test of the completed units of this chassis family. This attachment must be an actual copy, or literal English language translation, of the instructions to the test technician. As a check for the adequacy of Attachment P, consider whether a technical person, not previously schooled in compliance test procedures, could fill in for the regular test personnel on short notice using these procedures.

Further information regarding x-radiation testing of production sets can be found in Part 9B - General Information and Guidance (Item 6.14).

Note: Submit Attachment Q if the production test procedures employ a critical component failure or simulation that is different from the worst component failure determined for the engineering analysis.

PART 6E - X-RADIATION TESTING INSTRUMENTS

Item 6.15

Include in Part 6E identification and calibration information for all of the instruments used in radiation testing of the completed product. For further details, please refer to Part 9E of this guide.

PART 6 PRODUCT REPORT

PART 6D - X-RADIATION TESTING OF PRODUCTION SETS

6.14 Check below and confirm that the test procedures are enclosed with the Product Report.

[ ]Attachment P is enclosed regarding x-radiation testing of selected production sets

[ ]Attachment Q - Alternate Selection of Critical Failure Component

PART 6E - X-RADIATION TESTING INSTRUMENTS

6.15Production X-Radiation Test Instruments Identification and Calibration

QUALITATIVE X-Radiation Survey Meter(s)
Model Name and Number:

Name of Instrument Manufacturer:

Date of Purchase:

Is an operational check performed on the qualitative x-radiation survey meter prior to its use? [ ] Yes [ ] No

QUANTITATIVE X-Radiation Survey Meter(s)
Model Name and Number:

Name of Instrument Manufacturer:

Serial Number(s) (if more than one list them all):

Calibrated By (name of lab):

How often are the meters calibrated?

Give date(s) of last calibration(s):

PART 6E - X-RADIATION TESTING INSTRUMENTS (CONTINUED)

[ ]Attachment L - Additional information attached regarding instrument specification and identification, such as user operating manual.

[ ]Attachment M - Calibration Certificate for the Quantitative Meter Showing Current Calibration. (If more than one meter is used, submit copies of all of the certificates).
THIS ATTACHMENT IS REQUIRED.

AC/DC Input Voltmeter

Model Name and Number:

Name of Instrument Manufacturer:

How often is the meter calibrated?

Beam Current Ammeter

Model Name and Number:

Name of Instrument Manufacturer:

How often is the meter calibrated?

High Voltage Meter

Model Name and Number:

Name of Instrument Manufacturer:

How often is the meter calibrated?

PART 8 ANNUAL REPORTS

General Information on Filing of Annual Report on Radiation Safety Testing

Section 1002.13 requires manufacturers of electronic radiation products to submit an Annual Report summarizing the performance data on radiation safety, current production status, information from manufacturer's complaint files, and other necessary information to assure that products comply with performance standards.

General Instructions

1. Annual reports must be submitted by September 1 of each year. These reports include data on all products that were produced during the reporting year of July 1 through June 30.

2. Parts 1, 2 and 8.1 through 8.7 of this guide must be completed.

3. Manufacturers must answer all of the questions in Part 8.1 through 8.7 of the guide.

4. Part 8.5, page 23, current production tabulation, is required for all products, including those filed under the Abbreviated Report and Product Report. Identify the status of each model. All models listed as current in the previous year's Annual report must be accounted for.

5. Part 8.6, page 24, must be completed for all models EXCEPT those reported in an Abbreviated Report. X-radiation readings below 0.1 mR/hr may be reported as such. Actual x-radiation readings of 0.1 mR/hr or higher must be reported as indicated in the appropriate column on page 24.

6. Submit only the summaries requested in this guide. Do not submit copies of test data sheets or other material not called for.

7. Models in the same chassis family may be grouped together for reporting of test results.

8. Include, with EACH Annual Report, a CURRENT list of all factory locations. Also include importers' and private label purchasers' names, addresses, and brand names that they import or buy. The names and telephone numbers of contact persons, if available, should also be included.

INSTRUCTIONS - PART 8 ANNUAL REPORTS

PART 8.1 PRODUCTION STATUS

Check the statement that applies to your firm and take the indicated action. Manufacturers of products filed only under Abbreviated Report should complete only Parts 8.1, 8.2, 8.3 and 8.5 of the Annual Report.

PART 8.2 PROCEDURES FOR COMPLIANCE TESTING

You are required by 21 CFR 1002.30(a)(1) and (2) to maintain written procedures for compliance testing. The procedures in use and those submitted in the Product Report should be reviewed and updated. Calibration of test instruments should be reviewed and a copy of the latest calibration certificate for the quantitative x-ray survey meter should be attached.

Compare your current procedures with those submitted in your Product Report. Check the appropriate answers. If you answered no to either question, attach the current procedures if they apply to all chassis families. If they apply only to a specific chassis family, provide the current procedures in a supplement to the appropriate chassis family.

PART 8.3 CORRESPONDENCE CONCERNING RADIATION SAFETY

You are required by 21 CFR 1002.30(a)(4) to maintain copies of communications to or from dealers, distributors, and purchasers concerning radiation safety. Correspondence should be reviewed if it involves any of the following: complaints or concerns about radiation exposure; difficulties with safety components in use or servicing of the product; investigations made or instructions issued concerning use, adjustment or and repair.

Fill in the number of documents received and sent. Attach a summary or sample of each. Samples of notices or brochures DO NOT include service or user manuals.

NOTE: This summary does not replace the notification requirements for potential defects or noncompliances under 21 CFR 1003.10 or for suspected accidental radiation occurrences under 21 CFR 1002.20.

PART 8.4 DISTRIBUTION RECORDS (for products > 0.1 mR/hr IRLC only)

Under the new regulations, distribution records are only required for products that will have power curves greater than the CRT's 0.1 mR/hr isoexposure rate limit curve (IRLC).

Fill in the information on the location of records storage and check the means of tracing products.

PART 8 ANNUAL REPORT

PART 8.1 PRODUCTION STATUS

[ ] Products were manufactured during this period and the firm is still in business. If you check this, COMPLETE AND MAIL Parts 8.1 through 8.7. (For models in Abbreviated Reports, complete 8.2, 8.3, 8.5 only.)

[ ] No products were manufactured during this period but the firm is still in business and expects to manufacture in the future. If you check this, COMPLETE THIS PAGE ONLY WITH Parts 1 and 2 of this guide.

[ ] No products were manufactured during this period and the firm is now out of business. If you check this, COMPLETE THIS PAGE ONLY WITH Parts 1 and 2 of this guide.

[ ] Products were manufactured during this period but the firm is now out of business. If you check this, COMPLETE Parts 8.1 through 8.7. (For models in Abbreviated Reports, complete Parts 8.2, 8.3 and 8.5 only.)

PART 8.2 COMPLIANCE TESTING PROCEDURES

Provide the DATE of the last management review to verify that the written procedures for assessing and controlling radiation and for maintaining equipment used in testing are up-to-date, complete, and accurate:

The calibration of all test instruments should be reviewed. A copy of the latest calibration certificate(s) for the quantitative x-ray survey meter(s) is (are) attached? [ ] YES [ ] NO

The required reports provided to CDRH for each chassis family currently in production have been reviewed and the procedures contained in them are up-to-date, complete, and accurate. [ ] YES [ ] NO

PART 8.3 CORRESPONDENCE CONCERNING RADIATION SAFETY

The number of letters received from users, dealers, or others about possible radiation exposure during use of the product was:

The number of notices or brochures sent to users, dealers, or service personnel on precautions or actions to be taken to maintain radiation safety of the product was:

PART 8.4 DISTRIBUTION RECORDS (for products > 0.1 mR/hr IRLC only)

Production facility shipping records are maintained at:

Products can be traced from these records by:
[ ] Model [ ] Serial Number

[ ] Date of Manufacture [ ] Other, specify:

INSTRUCTIONS - PART 8 ANNUAL REPORT

PART 8.5 CURRENT PRODUCTION TABULATION

Provide annual production data for all television products including those filed under the Product Reports, Supplement to the Annual Report (Part 8.8), AND THOSE NEW SELLING MODELS THAT ARE IN THE SAME CHASSIS FAMILY as those reported in the Abbreviated Reports. Production status or tabulation is the only information required for models reported under Abbreviated Reports.

The regulations for reporting have been amended to reduce recordkeeping and reporting requirements for television products that qualify for filing of the Abbreviated Reports. After filing the Abbreviated Report for a new chassis family (< 25 kV AND < 0.1 mR/hr IRLC under Phase III test conditions), if there are new selling models belonging to the same chassis family, the manufacturer (or importer) IS NOT REQUIRED to report them immediately to CDRH prior to introduction into commerce. The manufacturer should retain the new selling model numbers and production data for a period of one year (12 months period - from July 1 to June 30) and it is due September 1 of each year.

If additional space is needed, use another copy of the form or attach a separate sheet and label it Part 8.5 (continuation).

Models reported in the Abbreviated Report must be listed with their production status, but no additional information is required on them.

"Accession No.": For previously reported models list the Accession Number of the Product Report or Abbreviated Report for the Chassis Family. CDRH will have assigned this number and reported it to you.

"Brand(1)": You may use a code for each brand in the chart. On a separate sheet, provide the complete address for each importer or distributor of each brand and identify any codes. Label the sheet as "Part 8.5, Brands - Codes, Name and Addresses of Importers/Distributors."

"Product Type/Display": Use the codes listed in Part 3 (for example "R/C" means a television receiver with a color display, or "R/M" means a television receiver with a monochrome display, or "M/M" means a monitor with a monochrome display, or "V/M" means a camera viewfinder with a monochrome display, or "P/C" means a projector with a color display).

"Factory Location(1)": Codes may be used to identify the factory locations. On a separate sheet, provide the complete address of the factory and identify any codes. Label the sheet as "Part 8.5, Factory Locations - Codes and Addresses."

PART 8 ANNUAL REPORT

PART 8.5 - CURRENT PRODUCTION TABULATION

Accession Number	Chassis Family	Selling Model No./Brand(1)	Product Type/Display	Factory Location(1)

(1) Codes may be used, see instructions.

INSTRUCTIONS - PART 8 ANNUAL REPORTS

PART 8.6 - RESULTS OF PRODUCTION TESTS UNDER PHASE III CONDITIONS

You are required by 21 CFR 1002.30(a)(2) to maintain results of compliance tests. For each product introduced into commerce, you should evaluate test results to be certain that the total program is adequate to assure radiation safety and compliance with the standard (21 CFR 1020.10).

Complete the table, or provide comparable data on a separate sheet and label it Part 8.6.

"Number of sets produced" : For each model number give the total number of sets produced.

"Number of sets tested": For each model number, give the number of sets tested under Phase III conditions.

"Maximum radiation (mR/hr)": Give the maximum radiation reading obtained with the quantitative x-radiation survey meter (measured minus background) in mR/hr obtained from among all the units of a given chassis or model that were tested during the reporting period. If ALL x-radiation readings were less than 0.1 mR/hr, list <0.1 in the "Maximum" column. No further calculations are required.

"Number of sets/lots rejected": Put down the number of units or lots that were rejected because of excess x-radiation emission.

"Company Audit": Provide the name of the company manager and the date of last audit of the production test procedure to verify proper training of the technician, procedures are up-to-date, instruments are working properly and calibrated, and technician is performing the Phase III tests correctly.

PART 8 ANNUAL REPORT

PART 8.6 - SUMMARY OF TEST RESULTS

Results of production tests under Phase III conditions

Chassis Family	Model Number	Number of sets produced	tested	Maximum radiation (mR/hr)	No. of sets/lots rejected

Company Audit

Name of Company Manager:

Date of audit:

INSTRUCTIONS - PART 8 ANNUAL REPORTS

PART 8.7 - RESULTS OF LIFE TESTING UNDER PHASE III CONDITIONS

You are required by 21 CFR 1002.30(a)(3) to maintain results of life tests.

Complete the table, or provide comparable data on a separate sheet and label the sheet Part 8.7.

PART 8 ANNUAL REPORT

PART 8.7 - RESULTS OF LIFE TESTING UNDER PHASE III CONDITIONS

Chassis Family	Model Number	No. of sets tested	Test Duration (hrs)	Max. Radiation Detected (mR/hr)

INSTRUCTIONS - PART 8 ANNUAL REPORT

PART 8.8 - NEW SELLING MODELS (PRODUCT REPORTS ONLY)

This form is to be used to report new selling models added to a chassis family previously reported in a Product Report. The reported new models should have the common characteristics of the chassis family already on file with CDRH including (1) the same circuitry in the high voltage, horizontal oscillator and power supply sections, (2) the same worst component failures used in the Phase III testing, and (3) the same shielding design and installation (if applicable).

New models may be reported because of the following reasons:

a. models with cosmetic changes

b. models with new brand names

c. models with changes in circuitry that do not have an effect on high voltage under Phase III test conditions.

"Anticipated Date of Marketing": Check the quarterly calendar period for which the new selling model report supplement is being filed.

"Annual Report Accession Number": Give the accession number for the most recent manufacturer's annual report.

"Accession No. of Product Report": Give the accession number of the Product Report for the basic chassis family that the new selling model(s) belong to.

"Brand Names": Indicate the brand of the model(s). On the bottom of the form, provide the brand name and complete address of each importer and or distributor.

"Factory Location": Codes may be used. On the bottom of the form, provide the name and complete address of each plant location.

[Note: if more space is needed, provide the additional information on a separate sheet, label the sheet as "Part 8.8 - New Selling Models."]

PART 8 ANNUAL REPORT

PART 8.8 - NEW SELLING MODELS REPORT SUPPLEMENT

Last Annual Report Accession Number:

Anticipated Date of Marketing	Report Due Date (no later than)
( ) Jan., Feb., March	January 1
( ) Apr., May, June	April 1
( ) July, August, Sept.	July 1
( ) Oct., Nov., Dec.	October 1

Product Report Accession No.	Chassis Family	Model Number	Selling Brand Names(1)	Factory Location(2)

(1) Brand Name _____ Name and Address of Importer/Distributor _____

(2) Factory Code _____ Factory Address _____

PART 9 - INFORMATION AND GUIDANCE

PART 9A - FREQUENTLY ASKED QUESTIONS AND ANSWERS

What FDA requirements do I have to meet to market a television product in the U.S.?

There are three basic requirements:

A television product must be designed and tested under the worst-tolerance, worst-adjustment and worst fault conditions to meet the x-ray limits of the Federal Performance Standard, 21 CFR 1020.10.

Based on a similar test of each product, or a valid sampling test program, each product must be certified by the manufacturer as complying with the standard.

A report describing the engineering test, the production test and labeling must be submitted to the FDA's Center for Devices and Radiological Health (CDRH).

I'm a new manufacturer and I never reported to CDRH before. What should I do?

First of all look at the quick reference chart below and find out which reporting category your product belongs to. After identifying the type of report, you can look in Part 2 of the reporting guide and find the appropriate instructions and attachments:

Operating voltage under Phase III test conditions and chassis power curve	Type of Report
Less than 25 kV and less than 0.1 mR/hr IRLC	Abbreviated
Equal to or greater than 25 kV and less than 0.1 mR/hr IRLC	Product
Equal to or greater than 0.1 mR/hr IRLC	Product

What is an Abbreviated Report?

As the name suggests, it is a short report appropriate for television products that have low operating voltage such as camera viewfinders, small size monochrome (black and white) displays and some color monitors or televisions that operate at less than 25 kV and the chassis power curve is less than 0.1 mR/hr IRLC under Phase III test

conditions.

What are "Phase III test conditions?"

They are specific test procedures required by the Federal Performance Standard, 21 CFR 1020.10(c)(iii). The Phase III test conditions are performed with the worst component failure in place, and all user and service controls that affect the beam current and high voltage settings adjusted to where the chassis power curve comes closest to or most exceeds 0.5 mR/hr isoexposure rate limit curve (IRLC) of the cathode ray tube (CRT). For a valid test there must be a useable picture (synchronized and transmitting some viewable intelligence) and the input voltage must be adjusted up to the maximum test voltage specified in 21 CFR 1020.10(b)(2).

I have submitted an Abbreviated Report to CDRH before, but I want to report a different chassis family with new circuitry and it operates at less than 25 kV and less than the 0.1 mR/hr IRLC under Phase III test conditions. What type of report should be submitted?

You need to file a separate Abbreviated Report because it is a completely "new" chassis family.

What is a Product Report?

The Product Report is a full report concerning the product design specifications, labeling, x-radiation safety features and or shielding, engineering analysis of the worst-tolerance chassis and the design-center chassis, and the manufacturer's quality control and testing program. The Product Report is appropriate for television products, monitors or projectors that are capable of producing operating voltage equal to or greater than 25 kV and/or a power curve above the 0.1 mR/hr IRLC under Phase III test conditions.

What about reporting new selling models for the chassis family that I already reported in the Product Report?

If you are reporting new selling models that do not involve changes in circuitry affecting radiation emission, those models may be reported in the form of a supplement to the Annual Report, Part 8.8.

What about reporting new selling models for the chassis family that I already reported in the Abbreviated Report?

Under the new reporting and recordkeeping requirements, the manufacturer (or importer) should retain the new selling model numbers and production data for a period of one year and report them in Part 8.5

of the Annual Report. See Part 8 for further clarification.

I used to submit model change reports to CDRH in the past. What report should I use this time?

Because of the new reporting regulations, check and confirm if the product's operating voltage is less than 25 kV under Phase III test conditions and the power curve is less than the 0.1 mR/hr IRLC. If the product meets this criteria, then use the Abbreviated Report. If not, use the Product Report.

My product design is capable of generating a power curve of greater than the 0.1 mR/hr IRLC under Phase III test conditions, what report should I use?

The Product Report.

I would like to report a new product to CDRH and this product does have a power curve above the 0.1 mR/hr IRLC under Phase III test conditions. What type of report should be submitted?

The Product Report.

What is an engineering analysis of the worst-tolerance chassis?

For every new chassis family, the manufacturer (or consulting laboratory) must construct and analyze a "worst-tolerance" chassis to demonstrate that the product is designed conservatively with respect to its potential for emitting x-radiation. The worst-tolerance chassis represents the worst television product that could possibly be produced on the production line given the acceptable tolerances for all critical components as set by the manufacturer. See Part 9C of this guide for full explanation of the engineering analysis.

For each NEW chassis family, am I required to conduct an engineering analysis of the worst-tolerance chassis under Phase III test conditions?

Yes, if you are creating a new chassis family, or making any major changes in the chassis critical to x-radiation safety, you must conduct an engineering analysis on a worst-tolerance chassis.

My company manufacturers small 5 inch diagonal screen sets for closed-circuit security system and it's maximum operating high voltage is 10 kilovolts. Do I still have to conduct an engineering analysis of the worst-tolerance chassis even though I know this product's operating high

voltage and zero beam current will produce conditions which are far below the 0.1 mR/hr IRLC for the cathode ray tube?

Yes, an engineering analysis is required for all new chassis designs.

I heard that I may use a consulting contract laboratory to conduct an engineering analysis of a "new" chassis. Is that true?

Yes, a manufacturer may contract with an independent laboratory to conduct an engineering analysis of the worst-tolerance chassis. Either the manufacturer or the contract laboratory must construct a worst-tolerance chassis. However, the contracting laboratory must be thoroughly familar with the engineering analysis and Phase III testing requirements and BE READY, if necessary, to provide additional information to CDRH to determine compliance with the performance standard.

Six months ago, I filed a report for a chassis family Model XYZ. This time I want to report new selling models (no change in circuitry). What should I do?

For any "new" selling models in the same chassis family (no change in circuitry affecting radiation safety), you may file the new selling models as a supplement to the Annual Report on a quarterly basis.

I used to report "exempt" models to CDRH in the past. What report should I use this time for "exempt" models?

As you may be aware, there are no "exempt models" because the exemption criteria have been replaced by the new Abbreviated Reports regulations, 21 CFR 1002.12. The filing procedures are similar, however, if the product operating voltage is less than 25 kV and the power curve is always less than the 0.1 mR/hr IRLC under Phase III test conditions, then it should be reported in an Abbreviated Report. Subsequent new selling models can be reported in supplements to the Annual Report (see Part 8.8).

There is an Annual Report requirement mentioned in the guide. However, my company has not manufactured products this year for the U.S. market. Should I file one?

Yes, if you have not manufactured any television products for the U.S. market, but you still intend to do so, you still should file an Annual Report, on September 1, to declare your production status.

The Product Report asks for a lot of information about the manufacturer's quality control and testing program, whereas the Abbreviated Report does not ask for it. Why is there such a big difference?

CDRH is concerned about television products that may emit x-radiation. Our experience has been that products which meet the criteria for Abbreviated Reports do not emit measurable amounts of x-radiation, even under Phase III test conditions. If you are manufacturing products that meet the operating voltage and IRLC criteria for the Abbreviated Report, then quality control information is not required to be filed with CDRH unless it is requested in a separate letter. If you are manufacturing products which exceed 25 kV under Phase III test conditions or its chassis power curve will exceed the 0.1 mR/hr IRLC, then CDRH will ask for detailed information about your quality control and testing program to determine whether you have acted or are acting in compliance with the Federal performance standard.

I heard that I am supposed to test some of the sets on each production run. Is that true?

Yes, the certification of your products is based on an adequate quality control and testing program and good manufacturing practices which assure that all products are in compliance with the Federal performance standard for television products. The level of sampling and testing depends on several factors but primarily on how likely a set is to emit x-radiation. In general at least one set from each production run (model/production line/day) must be tested under Phase III conditions. Models that have been found likely to emit x-radiation will require more samples and more testing while those meeting the criteria for Abbreviated Reports may require less.

Can I get a laboratory to do the Phase III test on the production sets?

Yes, the laboratory may assist in the Phase III testing of the products taken from production. However, the manufacturer is ultimately responsible for the entire testing program and the certification of their products.

Where should reports be submitted?

Submit all reports, including responses to routine review letters to:

Center for Devices and Radiological Health
ATTN: Electronic Product Reports
Electronic Product Document Control (HFZ-309)
Office of Communication, Education, and Radiation Programs
9200 Corporate Blvd.
Rockville, MD 20850

PART 9 - INFORMATION AND GUIDANCE

PART 9B - GENERAL INFORMATION AND GUIDANCE

Part 9B reviews certain items of the reporting guide and provides guidance so that the manufacturer can have a thorough understanding of what information is necessary for the completion of the report so it can be reviewed expediently by CDRH. Manufacturers should take notice that Section 1002.7 requires that the submitted reports conform to the applicable guide.

More importantly, this Part 9B also serves as guidance to the manufacturer on the adequacy of the testing program. Section 1010.2(c) requires that the certification of the products shall be based on a test, in accordance with the standard, of each unit or on a testing program in accordance with good manufacturing practices. Failure to maintain an adequate testing program may result in disapproval of the program by CDRH. Any manufacturer of television products, whose testing program has been disapproved by CDRH, will be denied entry into U.S. commerce of future products until corrections have been made and the disapproval rescinded.

Model Identification (Part 3)

A television product is an electronic product capable of displaying a television picture. For the purposes of the Federal Performance Standard for Television Receivers (21 CFR 1020.10), we consider a television picture to be any form of transient visual image (other than alphanumeric characters) displayed on a cathode ray tube. The television product is the device which converts the input signal into the visual image. The method of generating the signal is irrelevant for the purposes of the standard, whether it be by transmitter, video recorder, camera or computer.

Products commonly described as video display devices, video display terminals, graphics monitors, and other similar products are subject to the performance standard UNLESS THEY ARE LIMITED BY DESIGN TO DISPLAY ONLY ALPHANUMERIC CHARACTERS. The manufacturer of the display unit, or the system manufacturer must report and certify the product. This is normally done by the display unit manufacturer because he is usually better equipped to perform the engineering analysis and x-radiation testing.

Within the general classification of "Television Product" as defined above, the following type classifications are used to describe the function of the product:

a) Receiver - A product which accepts a television signal either broadcast or from a VCR, or from a disc player. Receiver/monitors and receivers which include stereo sound, radios, disc or tape players or other additional features are properly classified as receivers.

b) Monitor - A product which accepts and displays a signal from a separate tuner, computer, game, camera, video tape or disc player, and other similar electronic device.

c) Camera Viewfinder - An electronic viewfinder employing a CRT, which is used exclusively with or built as a part of a video camera.

d) Projector - A television product which projects its image on a screen rather than direct view. This includes front and rear projections. Signal type may be any of those described in a, b or c above.

e) Terminal - An alphanumeric dedicated display which is not otherwise subject to the television standard (see product classification above) which the manufacturer has chosen to certify.

Critical Component Incoming Inspection Program (Part 6A)

The best practice to ensure component quality is to sample each purchased lot at incoming inspection. Check all critical components listed in Attachment J2 for which appropriate tests can be devised. Limits of acceptance for a tested component should correspond to the tolerance limits stated in Attachment J2.

If the component vendor performs the testing, he should provide data in support of each shipment to the television product manufacturer. Under such an arrangement the television product manufacturer would be well advised to maintain close relations with the vendor, and good communications between his own engineering and procurement departments. Periodic visits to observe vendor testing may be useful in this regard. New suppliers should receive particular attention.

In addition, cathode ray tubes (CRT's) and shielding should be tested at incoming inspection. The CRT is not a certified product though, in fact, it is the only component in most modern television products that can produce x-radiation. Since there is no performance standard for CRT's, TV manufacturers must make certain that the CRT meets the engineering x-radiation specifications. As with other electrical components, quality testing for CRT's can be performed by either the vendor or the purchaser. If the vendor performs the testing, he should be required to provide test data in support of each shipped lot. If the television manufacturer elects to test CRT's, some tubes from each lot should be checked at the CRT manufacturer's specified registration voltage and corresponding beam current (250 microamperes for monochrome, 300 microamperes for color). The parameter to be measured is x-radiation exposure and the rejection limit must be set no higher than 0.5 mR/hr. (Ref:ANSI/EIA Publications 501-A-90 and 503-A-90).

If the television manufacturer alters the shielding characteristics of the CRT after purchase (perhaps by the application of lead tape to the tube)

and thereby claims a new x-radiation specification, the test outlined above should be performed after the alteration is completed. If the CRT itself is not altered, but external shielding is employed in the product to reduce emissions, the shielding may be a critical component requiring incoming inspection. Shielding factors affecting x-radiation leakage may include composition of the material and its attenuation characteristics, thickness used, dimensions, and workmanship in general.

Various sampling plans may be used for an incoming test program. Most effective plans vary the sampling level according to the size of the lot, vendor history, and the criticality of the component.

Hold-Down and Safety Circuits (Attachment O) (Item 5.5)

In many cases a hold-down or safety circuit is used because, without it, high voltage under a fault condition may rise to a value well above the isoexposure curve, possibly producing x-radiation.

Since proper operation of the hold-down circuit is essential, it should be checked on each unit. Such a test should check as much as possible the continuity and connections of the circuit in its assembled configuration. Thus, testing in a completed receiver is preferable to checking at the board level. If the threshold value for activation is set to a standard level at some point in the manufacturing process, a simple yes-no check on activation may be sufficient. If, however, there may be significant variation in the activation voltage from unit to unit, then the activation test should be quantitative, and limits should be set to ensure that an adequate safety margin will be maintained below the isoexposure curve in the event of a sudden rise in high voltage. The threshold activation curve may be determined when performing the Attachment J analysis. If so, the conditions under which this power curve is derived (as well as the activation points) are to be recorded in Attachment J. This curve is to be plotted in Attachment F if it produces the worst case conditions which will be used in production testing.

Sealed Controls (Item 6.7)

Controls adjusted during the manufacturing process are sometimes sealed by the manufacturer once their optimum position has been set. If these controls can have a significant effect on high voltage or radiation safety, and x-radiation tests are conducted with the controls sealed, then they should be checked to verify that they meet the criteria listed below for a sealed control. In some cases a visual check by test personnel will be sufficient. In other cases it may be desirable for the technician to attempt to adjust the control. Note that a control that does not directly or positively raise the high voltage, such as a hold-down threshold control, may still affect the high voltage under Phase III test conditions. Such a control may well warrant sealing. Controls that are not PERMANENTLY sealed MUST BE ADJUSTED during both Attachment J and Attachment

P testing.

Any control that has been permanently sealed or otherwise rendered nonadjustable at the factory will be considered a sealed control. The method of sealing must be such that the seal cannot be defeated except by breaking or damaging the component. If this requirement is met, the control may be treated as a fixed value component for compliance test purposes; otherwise, it is to be treated as an adjustable component and adjusted to maximize radiation. Manufacturers using sealed controls should identify them on the schematic and include in the service instructions or manual a note warning against improper replacement or defeating the control. Instructions for proper replacement of such sealed controls should also be provided in the service information.

Sampling and Production X-Radiation Testing Program (Item 6.8)

The radiation testing performed on production line units is the culmination of a process initiated in the design phase and continued with incoming and in-process inspections. It cannot stand alone as a safeguard. Even 100-percent final inspection must be based on a well-conceived and thoroughly understood design, and cannot be totally relied upon to find all problems. Since the x-radiation test is the last test prior to the product's release into commerce, and the parameter being measured is x-radiation, defective units cannot be tolerated. Therefore, a sampling rate must be used that allows the acceptance of significantly less than one defective per lot. Since such a sampling rate is likely to be quite high, in practice such a situation is usually handled by 100 percent testing. Action taken if the lot rejection limit is exceeded should be stated, including action on previous lots, subsequent lots, and changes in sampling plan if applicable.

The sampling plan for final testing of television receivers may take various forms as long as the minimum acceptable sampling rate is fulfilled. Simply stated, the minimum rate consists of one product from each separate chassis/CRT-size combination produced on each production line during each work shift. This rate applies to conservatively designed products emitting at an insignificant level (typically below 0.1 mR/hr) under Phase III conditions, and represents spot sampling only rather than a statistically valid sampling plan. When radiation significantly above background level is normally produced under Phase III testing, higher sampling rates MUST be employed.

When production lines are not used, the minimum sampling rate is one unit of each chassis/CRT-size combination from products completed on a given day.

Unit Rejection Limit (Item 6.12)

The unit rejection limit should be set so as to reflect the quality of the

product and provide a margin for safety commensurate with the product design and sampling plan. For example, if a given chassis emits less than 0.1 mR/hr in its worst tolerance configuration as reported in Attachment J, there is no point in setting the rejection limit at 0.3 mR/hr. Clearly a measurement of 0.2 mR/hr from this product would indicate that some change has occurred in the components or some evolution has taken place in the design of the product, and that further investigation is required to determine the cause. Furthermore, setting the rejection limit too close to 0.5 mR/hr does not allow for instrument inaccuracy and could result in acceptance of some units that actually exceed the Federal performance standard. Products reported in Abbreviated Reports MUST BE REJECTED at a MAXIMUM NET READING OF 0.1 mR/hr. A unit rejection limit no higher than 0.1 mR/hr is also recommended for all products which typically emit no detectable x-radiation.

When the unit rejection limit is exceeded, two measures are recommended: (1) Take further samples from the lot for Phase III testing and (2) investigate the cause of the high reading on the original sample.

Lot Rejection Limits (Item 6.13)

When the sampling rate for receivers is small, the rejection of a single unit may, in effect, implicate the entire lot and the unit and lot rejection limits may be the same. Products which typically emit over 0.1 mR/hr, and which are sampled at a significantly higher rate than the minimum of 1 unit per production lot, may have a lot rejection limit that is higher than the unit rejection limit but still below the 0.5 mR/hr. Whenever the lot rejection limit is exceeded, the lot must be held and inspected at 100 percent, and the cause must be determined. If the unit rejection limit is exceeded on a single unit but no more rejections occur from additional sampling, and an explanation for the high x-radiation measurement is found that indicates the problem is not likely to occur in any other unit, the single unit should be reworked and the lot may be released. If further rejections occur or a satisfactory explanation is not found, and the manufacturer cannot be absolutely sure that no units exceed 0.5 mR/hr, (or 0.1 mR/hr for products filed under Abbreviated Report) then the lot should be rejected and inspected at 100 percent under Phase III conditions.

When a lot rejection limit is exceeded, further action is indicated. These measures may include increased sampling of a number of previous and subsequent lots. Corrective action to eliminate the problem should be applied to both previous and subsequent lots and all changes to components or processes necessary to prevent a recurrence must be made. The most useful format for Attachment R is a flow chart showing the measures taken if one or more rejection limits are exceeded.

X-Radiation Testing of Production Sets (Attachment P) (Item 6.14)

Attachment P must include specific x-radiation test procedure instructions (written in English) regarding the worst component failure selected, user and service controls to be adjusted, operation of electrical and x-radiation instruments to be used, input voltage, test pattern used, readings to be noted and recorded, tolerance and rejection limits, and procedures to be followed in case any reading is out of tolerance or over limit. The user and service controls must be adjusted so the power point setting for the X-RADIATION SURVEY IS IN THE REGION OF THE CHASSIS POWER CUREVE THAT MOST CLOSELY APPROACHES THE ISOEXPOSURE RATE LIMIT CURVE for the CRT. (This is not a full repeat of the engineering analysis!)

The production test described in Attachment P should also include tests of operating parameters that can affect x-radiation safety even though these tests may have already been performed on the production line. These tests include measurement of high voltage, B plus, and beam current; and operational checks of all safety circuits. In this way, the production x-radiation test serves as a quality control or quality assurance audit of certain on-line test procedures. Attachment P must be derived from the results of the Attachment F and J analysis but does not include instructions for the completion of Attachments F and J, or refer to them for production test procedures.

The worst-component-failure mode, as determined in Attachment J, may not always be practical as a test condition for production units. This may be due to component placement in the assembled product, or other reasons. If the power curve arising from this fault can be duplicated through means that are more practical for the production test, the simulated fault may be considered a valid Phase III condition. Attachment Q should be submitted with the explanation of the alternate failure selection and it should describe how the simulated fault duplicates the original fault. Attachment P should also instruct the technician how to produce the simulated fault condition.

The following check list may be used to ensure that Attachment P is complete. Ideally a complete Attachment P will:

a) instruct the technician what meters are to be connected and how to connect them;

b) identify the worst component failure, and instruct the technician how to induce this fault;

c) identify the controls to be adjusted to obtain the desired beam current and identify the value to be set;

d) identify the controls to be adjusted to obtain the maximum high voltage possible at this beam current;

e) instruct the technician what QUALITATIVE instrument to use, what checks to be performed on it, and how to use it to scan the television

product for x-radiation and how to pinpoint any emissions detected;

f) instruct the technician what QUANTITATIVE instrument to use, what checks are to be performed on it and how to use it to measure any radiation detected while scanning the television product;

g) instruct the technician what readings and other data are to be recorded on the test record (include a sample test record);

h) instruct the technician what other parameters (such as high voltage, B plus or hold-down or safety circuit activation limits) are to be measured;

i) identify rejection limits for x-radiation and other parameters the technician may be checking for; and

j) provide instructions to be followed in case any rejection limits are exceeded.

PART 9 - INFORMATION AND GUIDANCE

PART 9C - ENGINEERING ANALYSIS

Requirement

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 mR/hr 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 J-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-COMPONENT 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 III 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 exceeds) the IRLC.

Worst-Tolerance Chassis

A chassis fitted with the worst-tolerance components represents the worst television product that could possibly be produced on a production line. This chassis is SPECIALLY CONSTRUCTED after identifying all critical components that could have a significant effect on the production of x-radiation. For each circuitry area, the manufacturer determines the worst tolerance value (within specification tolerances) of EACH of these components. These components, at their worst-tolerance values, are incorporated in a test chassis on which a component failure analysis is

conducted.Although the value of any one component may not contribute significantly to a rise in high voltage or beam current, the cumulative effect of worst-tolerance values of several components could be substantial.

The analysis will be valid only so long as there are no significant design changes and the component values actually used by the TV product manufacturer and incorporated into production units remain within the tolerances prescribed by the design specifications (listed in Attachment J-2).

Design Chassis

A chassis fitted with design (nominal value) components coincides as closely as possible with the engineering design for the product. The components identified as critical to x-radiation safety are incorporated in a SPECIALLY CONSTRUCTED chassis at values as close as possible to their design (schematic) value. A component failure analysis is conducted on the chassis. The chassis should represent products that could be produced based on the engineering design and should approximate a typical production line product. Attachment J-4 should include data from a nominal (pre-production or first production run) unit. This unit should be selected as one having operating parameters (such as high voltage, B+ and beam current) at or near the design specifications. User and service control adjustments listed in Attachment J-3 should apply to nominal as well as worst tolerance chassis.

Worst-Component Failure

Component failures must be examined for their effect on the chassis power curves of both worst tolerance AND design-center chassis. These failures must be examined TOGETHER WITH the adjustment of input voltage and ALL user and service controls that can affect high voltage or beam current. If the horizontal frequency is variable, you should use the one that will produce the maximum high voltage and beam current. Test patterns should also be considered as some patterns will draw more beam current than others, at the same high voltage and control settings, thus making x-ray production more probable. HIGH VOLTAGE MUST BE MAXIMIZED AT EACH BEAM CURRENT SETTING TO DETERMINE THE MAXIMUM PARAMETERS AT WHICH THE UNIT WILL CONTINUE TO OPERATE. These are the power points to be recorded in Attachments J-1 and J-4 and plotted in Attachment F. It is not sufficient to set all controls to maximum and state, "Safety Circuit operates." YOU MUST ANALYZE EACH FAILURE.

CDRH does not require destructive testing. If a tested failure causes secondary failures and/or breakdown of the product, less severe control settings should be tried. If a product CANNOT operate long enough to measure the x-radiation, with a particular component failure, that failure is not a valid test condition.

Television and Monitor Engineers should be able to determine which component failures, in each of the circuit areas listed in Attachments J-1 and J-4, may have significant effect on high voltage or beam current. Do not test component failures which cannot increase the potential to emit x-radiation. Additional pages J-1 and J-4 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.

Phase III Test Conditions

The potential to emit x-radiation is maximized at the point of closest approach of the chassis power curve(s) to the CRT isoexposure curve(s). If the power curve is above the isoexposure curve, x-radiation is maximized at the point at which the power curve is most above the isoexposure curve. Production test procedures (Attachment P) are to call for adjustment of input voltage, test signal and user and service controls to attain the worst-case conditions as determined by the Attachment F and J engineering analysis. If different component failures produce different worst-case conditions on the worst-tolerance and design chassis, Attachment P procedures may require measurement of both failures to determine the proper test conditions for the unit being tested.

A. Testing Instructions

1. When performing the worst-component-failure analysis, the manufacturer should introduce the component failure, adjust the line voltage over the indicated range (see table below), and then misadjust the user and service controls as needed to maximize the potential for x-radiation emission. This is important since a receiver may not operate with a failure when all controls and line voltage are maximized, but it may operate with the failure if the line voltage and service controls are adjusted to some point less than their extreme values.

2. The following guidance is given for the range of input voltages to be used while performing the worst-component-failure analysis in both types of chassis:

Type of input voltage*	Input voltage	Maximum test voltage	Minimum test voltage
ac	110-120	130	100
	220	242	198
dc	As specified by the TV	110%	90%

manufacturer or the power source manufacturer

(*If the receiver is intended for operation with ac and/or dc input, data must be submitted for all intended power sources. The Television Standard requires that television receivers be in compliance when utilizing any power source specified by the manufacturer. To assure that this is the case under all required test conditions, the report on each ac/dc receiver must include a complete worst-component-failure analysis (Attachment J) for all specified ac and dc input voltages. Tests are to be conducted with input voltages up to 130 root mean square (rms) volts ac (for receivers designed for 110-120 volts ac) or up to 110% of the nominal rms voltage specified by the manufacturer for other power sources. For receivers designed to operate in automobiles or boats using a nominal 12 V dc source, the maximum test voltage is 15 V dc. This is a realistic voltage, since the charging system of automobiles and boats may routinely deliver such voltage.)

3.After a component failure has been investigated, the failed component must be replaced in the test chassis while the effect of other component failures is investigated.

4.A "usable picture" is defined as a picture in synchronization and transmitting viewable intelligence. This may include a poor-quality picture in which underscan (shrinkage) or distortion is present. If there is any question, the manufacturer should be conservative and test under the worst possible conditions.

B. Component Failure Data Sheet Instructions

1.Investigate component failures in circuit functional areas 2 through 5 inclusive as listed on Attachments J-1 and J-4. Notations such as "no viewable picture" or "set shuts down" that describe the results of a component failure MUST ALSO BE EXPLAINED FULLY in a note on the form or on an addendum page.

2.The purpose of a failure in the hold-down or safety circuit (item 5 of Attachments J-1 and J-4) is to test the operation of the product when this circuit DOES NOT OPERATE. A failure in the low voltage or high voltage power supply, which CAUSES hold-down activation, should be listed in items 1 or 3 respectively of Attachments J-1 and J-4.

3.Record the data for the tested component failures in each functional area for both the worst-tolerance chassis and the nominal chassis. If there are other failures within +/- 1 kV of the worst failure in a functional area (and higher than the worst failure in other functional areas), those data are also to be recorded. Additional Attachment J forms should be used as necessary. The manufacturer should submit data on more than one failure in a

functional area, when appropriate.

4. Identify on attachment J-1 and J-4 the worst-component failure to be plotted in Attachment F.

5. If a different failure is to be used in production testing, all power curve data for that failure must be recorded on both the worst-tolerance chassis data sheet (J-1) and the nominal chassis data sheet (J-4) and plotted in Attachment F.

6. Data sheets for the worst-tolerance chassis (J-1) and the nominal chassis (J-4) must be submitted for each CRT, if data are different for the different CRT's.

7. Worst-Tolerance Component Information (J-2) - List the components selected and placed in the chassis to build the worst-tolerance chassis. The effects of components such as high voltage transformers may be included by adding their tolerance to the resultant power curve data. For example, if a high voltage transformer is specified as 25 kV +3%, then 0.75 kV should be added to the resultant power curve data plotted in Attachment F. If this is done, it must be clearly stated in the "Remarks" column. This procedure applies only to those components for which an actual worst-tolerance value is very difficult to obtain.

8. Control Adjustment Information (J-3) - For each reported component failure, specify the control adjustments made. This is important because the control adjustments may not be the same for all component failures. If a sealed control cannot be defeated except by breaking or damaging the component, the control may be treated as a fixed value component; otherwise, it is to be treated as adjustable. List ALL user and service controls that can affect high voltage and beam current. Vary these controls, for each component failure being tested in Attachments J-1 and J-4, to produce the maximum high voltage at each beam current setting at which the tested unit operates.

9. Record all net x-radiation readings of 0.1 mR/hr or above in the right-hand column of Attachments J-1 and J-4. Net readings below 0.1 mR/hr (e.g., < 0.1 mR/hr) may be recorded as such.

PART 9 - INFORMATION AND GUIDANCE

PART 9D - LABELS (ATTACHMENT K)

Requirements

Submit in Attachment K the location and the complete text (or a sample) of the following labels:

a.CERTIFICATION LABEL. The following alternatives or similar statements satisfy the requirements of 21 CFR 1010.2:

"Complies with DHHS Radiation Performance Standards, 21 CFR Subchapter J,"
or
"Product complies with applicable DHHS Federal performance standard, 21 CFR 1020.10."

b.IDENTIFICATION LABEL. This label must contain the full name and address of the manufacturer (or if sold under a name other than that of the manufacturer, the full name and address of the individual or company under whose name the product is sold) and date and place of manufacture. At a minimum, CDRH will accept company name, city, state and zip code. We prefer and recommend an actual street or P.O. Box number. Foreign addresses must be sufficient to ensure mail delivery to the manufacturer. THE MONTH OF MANUFACTURE MUST BE WRITTEN OUT COMPLETELY AND THE YEAR MUST APPEAR AS A FOUR DIGIT NUMBER (example: Manufactured September 1996.) If the place of manufacture appears in code, a key to this code must be provided in Attachment C (see 21 CFR 1010.3).

c.CRITICAL COMPONENT WARNING LABEL. In 21 CFR 1020.10(c)(4), the Federal Performance Standard for television products requires manufacturers to affix a critical component warning label on all receivers (color and monochrome) which could produce radiation exposure rates in excess of the Standard as a result of a failure or improper adjustment, or improper replacement of a circuit or shield component. The CDRH does not prescribe specific wording for the critical component warning label, only that a critical component warning label shall warn against improper adjustment or replacement of components that could affect the radiation safety of the receiver and shall include high voltage specifications and adjustment instructions. The label may refer to the service manual for information on the identification and replacement of components especially important for safety. The label may also refer to the manual for the high voltage specification and adjustment procedures. If the reference method is used, the label must include a SPECIFIC reference for high voltage and the service instructions must contain the component identification, proper replacement warnings, and high voltage information. This data should be easily found in the service manual. Critical

components should be identified on both schematics and parts lists of the final service manual if the critical component warning label refers to the manual. The CRT is always a critical component. An example of a critical component warning label is given below:

"Warning: This product includes critical mechanical and electrical parts which are essential for x-radiation safety. For continued safety replace critical components indicated in the service manual only with exact replacement parts given in the parts list. Operating high voltage for this product is _____ kV at minimum brightness. Refer to service manual for measurement procedures and proper service adjustments."

PART 9E - X-RADIATION INSTRUMENTATION AND CALIBRATION

X-Radiation Testing Information

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 RF/C or D) with the proper performance specifications (21 CFR 1020.10(c)(2)) should then be used for quantitative results.

The CDRH 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 CDRH 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 PERFORMANCE STANDARD, 21 CFR 1020.10(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(c)(2), as follows:

"compliance with the exposure rate limit defined in paragraph (c)(1) 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, and/or 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.

William B. Johnson TVX-1 or TVX-1B Survey Meter (Qualitative)

The TVX-1 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-1 extends to below 0.1 mR/hr. On the TVX-1B 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-1 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.

Victoreen 440 RF/C and D

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(c)(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 RF/C 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 RF/C, 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.

Annual Calibration and Calibration Procedures

All manufacturers (or testing laboratories) should have in place a formal calibration and maintenance program to assure adequate and continous performance of measurement equipment with respect to accuracy, precision, etc. Calibration of each piece of equipment must be documented to include the calibration date, the calibrator, and the date the next calibration is due. Separate records must also be kept of measurement equipment whenever they have gone out for repairs.

Backup Meters

It is important for manufacturers to have adequate backup meters to use when the primary instruments are out for repair or calibration. CDRH may accept temporary use of only one x-ray instrument, either the qualitative or quantitative meter, to survey production samples in Phase III testing of models that have a good test history. But any adequate testing program must have at least one working x-ray instrument for use at ALL times to make the required measurements. This means each factory must have backup instruments available in case an instrument quits working or needs calibration. Test records should show which instruments were used, by model and serial number.

PART 9F - DEFINITIONS

ACCESSION NUMBERS

The Center for Devices and Radiological Health will assign an Accession Number to each report for classification, identification, filing, and retrieval. The manufacturer (or person or company assuming the manufacturer's reporting obligation) will be notified of the Accession Number(s) assigned to the document(s) submitted. A submittal may be assigned more than one Accession Number depending on its contents and, when this occurs, the acknowledgement letter will specify the parts of the submittal filed under each number assigned. A subsequent correction, addendum, or change to any report will be assigned the same Accession Number as the document to which it refers with an appropriate suffix denoting the supplement number.

CHASSIS FAMILY

A chassis family is a group of one or more models with all of the following common characteristics: (1) the same circuitry in the high voltage, horizontal oscillator and power supply sections; (2) the same worst component failure(s); (3) the same type or design high voltage hold-down or safety circuits; and (4) the same shielding design and installation. Differing power curves may be obtained when CRT's of different sizes are used because of minor component value differences, but the models will be considered to be in the same chassis family if the basic conditions (1) through (4) above are met.

MODEL

A model is any identifiable, unique chassis design to which the manufacturer has assigned a specific designation to differentiate between it and other models of the same basic chassis family. Models within a chassis family must have all of the common characteristics defined under "Chassis Family."

SELLING MODEL NUMBER

A selling model number is a manufacturer's or seller's unique designation, usually located on the identification label and visible to purchasers, which distinguishes it from other products sold under the same brand name.

ISOEXPOSURE RATE LIMIT CURVE (IRLC)

An IRLC is a limit curve defined by conservative combinations of CRT high voltage and beam current that could produce a constant rate of x-radiation emission from a CRT of a given type. Such curves are to be developed according to conditions specified in ANSI/EIA Publication RS-503 or equivalent, and are typically plotted at a constant exposure rate of 0.5 mR/hr, and are measured at 5 cm from the surface of the CRT, or from the surface of a hypothetical, nonabsorbing cabinet surrounding the CRT.

CHASSIS POWER CURVE

After the design-center and the worst-tolerance chassis are constructed and the engineering analysis completed, a power curve for each chassis must be plotted on the same graph with the IRLC. If necessary, the IRLC curve must be extended to determine the CLOSEST POINT of the worst-tolerance chassis power curve to the IRLC. This point determines the conditions of current and voltage at which production test must be done (see Part 9C of this guide).

REMINDER

ACCIDENTAL RADIATION OCCURRENCES

You are required by 21 CFR Subchapter J, Section 1002.20, to immediately report accidental radiation occurrences. Report to the Director, Center for Devices and Radiological Health, all accidental radiation occurrences reported or otherwise known to you and arising from the manufacture, testing, or use of any product you have introduced, or intend to introduce, into commerce.
