Specific Instructions for Television Product Inspections

Background

The Television Product Performance Standard (the standard) was designed to protect the public from x-radiation hazards associated with early cathode-ray-tube (CRT) television sets. The radiation emitted from these products has been dramatically reduced over the years as a result of the standard, and by improvements in technology and design. The hazards of x-ray emissions from CRT televisions and video monitors are further diminished because of a well-established and conscientious industry and the increasing market for flat panel LCD and plasma displays that do not pose a radiation hazard. A minimal, but risk-based and continued presence by FDA is needed in the television industry to ensure continued compliance with radiation safety standards so long as there is a market for CRT products. This presence is limited to for-cause manufacturer inspection and laboratory inspection. No field tests are conducted on television products.

Specific Instructions

Television product manufacturers should be inspected or tested at CDRH direction. Television product manufacturers are all located overseas, and all inspections will require foreign travel. Reasons for manufacturer inspection include:

- Manufacturers with known or suspected problems based on previous inspection or complaints
- New manufacturers not yet inspected
- Manufacturers introducing new CRT-based technology to the US market
- Manufacturers with a large potion of the US market share.

WEAC laboratory analysts have knowledge of general EPRC requirements and also have specialized training in the television product performance standard. These analysts have experience planning and conducting foreign television manufacturer inspections. WEAC analysts should perform these inspections and field tests and may train additional field staff.

CDRH is responsible for review of television manufacturer inspection observations and initiating administrative or regulatory follow-up.

References

Performance Standard-Television Products
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1020.10

Reporting and Compliance Guide for Television Products
http://www.fda.gov/cdrh/radhlth/pdf/tvvrptgd.pdf

Refer to the television products main page for guidance documents and additional information:
http://www.fda.gov/cdrh/radhealth/products/tvvdt.html

Television Product Codes

Translation of 2-Digit Code	Product Name	Product Code		CFR	Definition
TV Receivers & Products Containing Same	Oscilloscope (Exempted), TV Receivers & Products, Non-Medical	94	RAY	1020.10	A device that depicts on a screen periodic changes in an electric quantity, as voltage or current, using a cathode ray tube and is not used in a medical application
TV Receivers & Products Containing Same	Television Receiver, Medical Imaging, Color	94	RAZ	1020.10	A television receiver using a color cathode ray tube to display medical images in colors.
TV Receivers & Products Containing Same	Television Receiver, Medical Imaging, Monochrome	94	RBA	1020.10	A television receiver using a monochrome cathode ray tube to display medical images in black and white with shades of gray or in different shades of one color.
TV Receivers & Products Containing Same	Television Receiver, General Purpose, Color, Non-Medical	94	RBB	1020.10	An electronic product with no medical claims designed to receive and, using a color cathode ray tube, to display a television picture in colors from broadcast, cable, video disk player, video recorder, computer or closed circuit television signals.
TV Receivers & Products Containing Same	Television Receiver, General Purpose, Monochrome, Non-Medical	94	RBC	1020.10	An electronic product with no medical claims designed to receive and, using a monochrome cathode ray tube, to display a television picture in black and white with shades of gray or in different shades of one color from broadcast, cable, video disk player, video recorder, computer or closed circuit television signals.
TV Receivers & Products Containing Same	Video Monitor, Medical Imaging, Color	94	RBD	1020.10	An electronic product using a color cathode ray tube to display medical images in colors from signals from a computer or electronic medical device.
TV Receivers & Products Containing Same	Video Monitor, General Purpose, Color	94	RBE	1020.10	An electronic product using a color cathode ray tube to display general images in colors from signals from a computer or electronic medical device.
TV Receivers & Products Containing Same	Video Monitor, Medical Imaging, Monochrome	94	RBF	1020.10	An electronic product using a monochrome cathode ray tube to display medical images in black and white with shades of gray or in different shades of one color from signals from a computer or electronic medical device.
TV Receivers & Products Containing Same	Video Monitor, General Purpose, Monochrome	94	RBG	1020.10	An electronic product using a monochrome cathode ray tube to display general images in black and white with shades of gray or in different shades of one color from signals from a computer or electronic medical device.
TV Receivers & Products Containing Same	Projector, TV Receivers & Products	94	RBH	1020.10	Electronic products that use a cathode ray tube or several cathode ray tubes to generate television images which are projected on a screen either from the front or from the rear.

TV Receivers & Products Containing Same	TV View Finder, TV Receivers and Products	94	RBI	1020.10	An electronic product using a cathode ray tube to display the image seen through the lens of a camcorder. To be exempt the cathode ray tube must operate under 5 kilovolts under the test conditions in the standard (Phase III).
TV Receivers & Products Containing Same	Camera, Television, Surgical, Without Audio	79	FWB	1020.10	
TV Receivers & Products Containing Same	Camera, Television, Surgical, With Audio	79	FWC	1020.10	
TV Receivers & Products Containing Same	Camera, Television, Microsurgical, Without Audio	79	FWD	1020.10	
TV Receivers & Products Containing Same	Camera, Television, Microsurgical, With Audio	79	FWE	1020.10	
TV Receivers & Products Containing Same	Camera, Television, Endoscopic, Without Audio	79	FWF	1020.10	
TV Receivers & Products Containing Same	Camera, Televsion, Endoscopic, With Audio	79	FWG	1020.10	
TV Receivers & Products Containing Same	System, Reading, Television, Closed-Circuit	79	HJG	1020.10	
TV Receivers & Products Containing Same	Other	94	RZZ	Unknown	Other electronic products using cathode ray tubes to display television images from broadcast, cable, video disk player, video recorder, computer or closed circuit television signals.

Classification of Non-compliant Items

Emission Limit			
1020.10(c)	**Exceeds exposure rate limit**		
1020.10(c)(1)	Radiation emission > 10mR in one hour	Major	Class A
1020.10(c)(3)	Test conditions are not in accordance with requirements	Minor	Class B
1020.10(c)(4)	Critical component warning label missing or inadequate	Minor	Class B

Sample Television Product Inspection Checklist

Manufacturer Identification

Manufacturer Name : _____

Plant Location: _____

Date(s) of Visit: _____

FDA Personnel

Name	Title	Organization

Manufacturer Personnel

Name	Title	Name	Title

LIST OF EXHIBITS

	Organization Chart		Sampling Procedures		Engineering Test Plan		Service Manual(s)
	Incoming Q. C. Test Procedures		Reaction Plan Procedures		Engineering Test Records		Mfr's Agent agreement (21 CFR 1005.25)
	Instrument Calibration Control Log		Labels (ID, Cert. and Crit. Comp.)		Vendor Test Data		Other:
	X-Radiation Test Record		Production Line Procedures		Manufacturer Distribution Records		

GENERAL EVALUATION OF THE SPECIFIC AREAS INSPECTED

Specific Area Inspected	Gen. Eval.*	See Attach.	Details on Page	Specific Area Inspected	Gen. Eval.*	See Attach.	Details on Page
General Organization							
Engineering Test Plan							
Incoming Materials Testing Program							
Written Comm. Concerning Radiation							
Manufacturer Distribution Records							
Instrument Calibration							

***Legend for Evaluation:** **A -** Satisfactory **B -** Questionable **C -** Unsatisfactory

NARRATIVE DESCRIPTION OF FINDINGS

1. PRODUCTION SUMMARY

MAXIMUM NUMBER OF PRODUCTION

Line Name	Model No.	Brand	Rate (Sets/day)	Meets Abbr. Rep. Criteria?	Line Name	Model No.	Brand	Rate (Sets/day)	Meets Abbr. Rep. Criteria?

2. GENERAL ORGANIZATION

1.	Flowchart of company functions and organization available?										
		Yes		No	See Exhibit:						
2.	Corresponding official is :										
	Q.A.		Q.C.		Product Safety		Engineering				
	Production		Sales		Other:						
3.	Is the Compliance Testing Program separate from Production?						Yes		No		
4.	(Foreign companies only) Does the company have a Manufacture's Agent who lives in the U.S.? (21 CFR 1005.25)										
	Yes		No								

3. ENGINEERING

1.	**Test Plan**					
a)	The receiver selected for the Engineering Analysis is a:					
	Prototype		Preproduction		Other:	
b)	The engineering x-radiation testing is performed by:					
	Q.C.		Engineering		Other:	
c)	The acceptance/rejection criteria for new design is:					
d)	The A/R decision is made by:					
e)	Life test prior to mass production?		Yes		No	

3. ENGINEERING (Cont.)

2.	**Engineering Test Records**						
a)	Are records kept?						
		Yes, where?					
		No (Explain)					
b)	Type of information kept on record:						
c)	Is the worst tolerance chassis retained for further testing?		Yes		No		

4. INCOMING TESTS FOR CRITICAL COMPONENTS

1. Test Summary

Components	Test Performed		Sampling Plan	Rejection Criteria	Test Method
	Yes	No			
CRTs					
Capacitors					
H.V. Transformers					
Yoke					
Others					

		Yes	No
2.	Incoming test records on file?		
3.	CRTS tested In-House?		
	If yes, Registered at TEPAC?		

a) Explain the CRT test procedure:

b) X-Radiation Instrumentation used:

Model	Cal. Date

4.	If CRT□s are tested by vendor does the vendor provide:		
	a) test data for each lot?		
	b) general guarantee of Engineering X-Radiation specifications		

5. INCOMING CHECK OF REQUIRED LABELS

1.	Are the labels, which are received at the incoming area, checked for compliance with 21 CFR 1010?		
2.	If yes, are the labels compared with approved labels on file?		

6. COMMUNICATIONS CONCERNING RADIATION SAFETY

1.	Are records kept?		
2.	Who responds to these questions?		

7. MANUFACTURER DISTRIBUTION RECORDS

1.	Are records kept? If Yes, where are they kept?:		
2.	Information kept on record:		
	Dealer/Distributor name and address?		
	Date distributed?		
	Model and serial No.?		
3.	Are records computerized?		
4.	Are dealers/distributors notified of their obligation to obtain and maintain purchaser records? (for non-exempt		
5.	Are dealers/distributors notified of the exempt products?		

8. INSTRUMENT CALIBRATION

1.	Is the qualitative meter given a periodic (30 day) check for proper operation?		
2.	Are the actual readings for each tube recorded?		

3.	The date of the CST-l source used for the thirty-day check is:		
4.	Is it adjusted?		
5.	Is the quantitative instrument checked to a source traceable to a NBS standard?		
6.	Is there a system for reminding personnel that an instrument is due to be calibrated?		
7.	Are there alternative x-radiation instruments available should the instruments in use require repair or		

9.	**SAMPLING PROCEDURES FOR PRODUCTION RADIATION TESTING**	**Yes**	**No**
1.	The samples for production testing are selected by:		
2.	From: Each production line?		
	Each shift?		
	Each model?		
	End of production line?		
	Warehouse?		
3.	Sample size:		
4.	Lot size:		
5.	How determined?		
6.	Normal amount of production:		
7.	Rejection criteria:		

Unit: _____ mR/hr Lot: _____ mR/hr

10. REACTION PLAN UPON REJECTION (review actual rejection cases)							
1.	Who is notified by the test technician?						
2.	Who examines the cause?						
3.	Disposition of the rejected lot while examining cause:						
4.	Who issues the order to stop shipment and/or production?						
5.	Are other lots (previous and/or subsequent) subjected to increased testing?						
6.	Have there been any failures?						
	If yes, was it documented ?						
7.	Does the Reaction plan appear to be adequate?						

1.	Where are records kept?					
2.	Are they maintained for five years?		Yes		No	
3.	How are they filed? (model, date, etc.)					

11. X-RADIATION TEST RECORDS

4. What information is recorded?

	Model/Chassis		Test Date		Technician		Beam Current		All Sides
	Serial #		Fault		High Voltage		X-Radiation		Background

5. Are any records in excess of the rejection limit?

	Yes, disposition of rejected units/lots:	
	No	

12. PRODUCTION LINE PROCEDURES	Yes	No
1. Shielding		
a) Is special shielding checked for proper placement?		
2. Sealed Controls		
a) Are they checked?		
b) Checking Method: ☐ Visual ☐ Mechanical		
c) Do seals appear to be permanent?		
3. Labels		
a) Is the presence of labels being checked on line?		
b) Are labels readily viewable?		
c) Are they permanently affixed?		

13. PRODUCTION LINE PROCEDURES AND OPERATIONAL SAFETY TESTS

1) Chassis Number						
	Yes	**No**	**Yes**	**No**	**Yes**	**No**
2) B+ measured?						
% Checked	%		%		%	
Meter Calibration Current?						
Instructions Available?						
3) H.V. measured?						
% Checked	%		%		%	
Meter Calibration Current?						
Instructions Available?						
4) Hold Down/Safety Circuit Subassembly						
Finished product						
Instructions available?						

Comments:

14. RADIATION TESTING PROGRAM FOR PRODUCTION SETS

1. Test Instrumentation

			Calibrated		Operational Checks	
Instruments	**Manufacturer**	**Model**	**Last**	**Due**	**Yes**	**No**
Qualitative	Johnson	TVX-1				
Quantitative	Victoreen	440 RF/C				
Voltmeter						
Ammeter						
H.V. Meter						

2. Demonstration Test Number 1

a) Identification of receiver tested:

Chassis No.				Color		Black and White
CRT No.			Model No.			
Serial No.						
Sample selected by:						
Sample selected from:						

b) Labeling Information:

Label	Viewable	Obscured	Missing	Adhesion
Certification				
Date of manufacturer.				
Place of Manufacturer.				
Critical Component Warning				

c) Test Conditions:

Input voltage: _____

User controls adjusted? ☐ Yes ☐ No

Service controls adjusted? ☐ Yes ☐ No

List adjusted controls: _____

Describe worst-case failure: _____

Usable Picture? ☐ Yes ☐ No _____

Test pattern: _____

d) Test Results:

Max. Qualitative: _____ counts/min at _____ kV and _____ □A

Location: _____ Background: _____ counts/min

Max. Quantitative: _____ mR/hr at _____ kV and _____ □A

Location: Scan Rate: inches/sec

Comments:

3. Demonstration Test Number 2

a) Identification of receiver tested:

Chassis No. _____ ☐ Color ☐ Black and White
CRT No. _____ Model No. _____
Serial No. _____
Sample selected by: _____
Sample selected from: _____

b) Labeling Information:

Label	Viewable	Obscured	Missing	Adhesion
Certification				
Date of manufacturer.				
Place of Manufacturer.				
Critical Component Warning				

c) Test Conditions:

Input voltage:									
User controls adjusted?			Yes		No				
Service controls adjusted?			Yes		No				
List adjusted controls:									
Describe worst-case failure:									
Usable Picture?		Yes		No					
Test pattern:									

d) Test Results:

Max. Qualitative:		counts/min at		kV and		mA
Location:		Background:			counts/min	
Max. Quantitative:		mR/hr at		kV and		mA
Location:		Scan Rate:			inches/sec	

Comments: