Consumer Electronics Association 2500 Wilson Blvd. Arlington, VA 22201-3834 USA (703) 907-7600 main (703) 907-7601 fax www.CE.org

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November 6, 2001

Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Dear Sir or Madam:

Please find enclosed a petition for rule making requesting improvements to the FDA rules that apply to x-radiation emissions from television sets. The consumer electronics industry believes that these changes, if implemented, would allow both industry and government to operate more efficiently. It also believes that these changes would in no way diminish the level of protection from TV set x-radiation emissions that the general public receives today.

If you have any questions about this petition I may be reached at (703) 907-7544.

Sincerely,

Michael Petricone
Vice President, Technology Policy

Enclosure: Petition for Rule Making

cc (w/encl): FDA/CDRH Staff
Collin Figueroa, Chief, Electronic Products Devices Branch
Joanne Barron, Radiological Health Specialist
Ed Dawson, Regulatory Operations Officer
Debra Clingan, Consumer Safety Officer
CEA Product Safety and Compliance Committee

01P-0518

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Before the
FOOD AND DRUG ADMINISTRATION
Rockville, MD 20852

In the Matter of	)	
	)	
Reengineering the Methods for Complying with FDA CDRH TV Receiver X-Radiation Standards	)	RM-_____
	)	
	)	

PETITION FOR RULE MAKING

The Consumer Electronics Association ("CEA"),[1] pursuant to Section 10.30 of the Food and Drug Administration's rules, respectfully submits this petition to reengineer the methods by which television receiver manufacturers confirm their compliance with the Administration's x-radiation emission requirements.[2] These requirements are established and enforced by the Administration's Center for Devices and Radiological Health ("FDA CDRH").

I. INTRODUCTION

Since the early nineteen seventies, manufacturers of television receivers have been required to comply with x-radiation emission regulations promulgated by the FDA CDRH. These regulations stipulate that television receivers may not emit x-radiation energy in excess of 0.5 milliroentgens per hour (mR/hr) when measured five centimeters from any external surface of the receiver.[3] They require that receivers be tested for compliance with this radiation limit with all user controls, and all controls accessible only to service personnel, adjusted to result in

[1] CEA is the principal trade association of the consumer electronics industry. CEA members design, manufacture, distribute, and sell a wide variety of consumer electronics and information technology equipment.
[2] The specific changes proposed by CEA are included in Appendices A and B.

maximum x-radiation emission levels.[4] They also require that receivers be tested with a simulated component or circuit failure that maximizes x-radiation emissions.[5]

Before introducing a new television product into commerce, a manufacturer is required to submit a report to the FDA CDRH. If the voltage to the TV's cathode ray tube ("CRT") is at least 25 kV (generally speaking, if the TV's diagonal screen size is larger than 20 inches), this report must describe, among other things, the product, its operational characteristics related to x-radiation, any design characteristics incorporated to meet the x-radiation emission limits, the methods used to test the product for compliance with the FDA CDRH limits, and the test results from the compliance testing.[6] For TVs with voltages to their CRTs less than 25 kV (generally speaking, TVs with diagonal screen sizes no larger than 20 inches) a report with an abbreviated version of this same information is required.[7]

Upon receipt of a report from a manufacturer the FDA CDRH issues the manufacturer an "accession number." This number, though not required for importation, often helps the manufacturer obtain timely clearance from U.S. Customs for television receivers.

CEA believes that the submittal of reports for each television chassis family to the FDA CDRH is no longer needed to ensure that the public is protected from excessive x-radiation emissions from TV sets because modern TV receiver designs have virtually eliminated x-radiation emissions from TV sets.

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[3] *See* 21 C.F.R. Section 1020.10(c).
[4] *See* 21 C.F.R. Section 1020.10(c)(3)(ii).
[5] *See* 21 C.F.R. Section 1020.10(c)(3)(iii).
[6] *See* 21 C.F.R. Section 1002.1, Table 1 and Section 1002.10.

II. ELIMINATION OF SHUNT REGULATOR TUBES FROM TV SET DESIGNS HAS VIRTUALLY ELIMINATED X-RADIATION EMISSIONS FROM TV SETS

The FDA CDRH x-radiation regulations for television receivers have remained virtually unchanged since they were adopted by the Administration under authority of the Radiation Control for Health and Safety Act of 1968.[8] This legislation was enacted after approximately 90,000 televisions were recalled due to excessive x-radiation in the late nineteen sixties. The shunt regulator tubes, which regulated the high voltage to the CRTs in these units, were found to be defective and could generate x-radiation in excess of 8,000 mR/hr. In response to the legislation, the FDA CDRH issued a standard limiting the x-radiation emissions of television receivers to 0.5 mR/hr on December 25, 1969.[9]

Since adoption of this performance standard over thirty years ago, there has been dramatic improvement in the design of television receivers with regard to x-radiation emissions. The only component in modern televisions that can generate x-radiation emissions is the CRT. The high voltage necessary to operate the CRT is controlled and regulated by transistors and integrated circuits, which cannot generate x-radiation emissions. Shunt regulator tubes, like those that caused the problem in the late 1960s, are no longer used in TV sets. Therefore, in addition to eliminating possible emissions from devices in the television other than the CRT, current designs are significantly more adept at controlling the high voltage sent to the CRT, and thus controlling the potential for x-radiation emissions. In case the high voltage does increase due to a component fault, all current televisions include a safety circuit that shuts off the high voltage at a safe threshold.

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[7] *See* 21 C.F.R. Section 1002.1, Table 1 and Section 1002.12.
[8] *Radiation Control for Health and Safety Act of 1968,* Pub. L. 90-602, Oct. 18, 1968; 82 Stat. 1173 (21 U.S.C. Sec. 360gg-360ss).
[9] http://www.fda.gov/cdrh/consumer/TVRad.html, updated November 2, 1999.

In the spring of 2001, CEA surveyed several of its members and asked what levels of x-radiation they measure when they test their TV sets for x-radiation emissions. They reported that the levels they measure are very low, and are significantly less than 0.1 mR/hr. The precise level of the x-radiation emissions from the vast majority of modern TV sets is usually not known because the actual level of emissions (assuming any are present) is so much lower than normal background radiation levels that it is masked by the background radiation. This is true even when the meter used to measure x-radiation is in its most sensitive mode. None of the manufacturers surveyed can recall any cases of Accidental Radiation Occurrences[10] or factory x-radiation measurements that exceeded 0.1 mR/hr within the last twenty years.

Because the x-radiation levels from TV sets have been well below the FDA CDRH limit for at least two decades, there is no appreciable risk of public exposure to excessive x-radiation from TV sets. For this reason, relaxing the administrative requirements associated with TV manufacturers' compliance with the FDA CDRH x-radiation standard would also pose little risk.

[10] *See* 21 C.F.R. 1000.3(a).

III. THE ADMINISTRATIVE REQUIREMENTS OF THE EXISTING FDA CDRH TV X-RADIATION REGULATIONS PLACE UNNECESSARY BURDENS ON INDUSTRY AND GOVERNMENT

As noted above, the existing FDA CDRH regulations for television set x-radiation emissions require manufacturers to submit a Product Report[11] for new television chassis families, and a Supplemental Report[12] for modifications to a previously reported product, to the FDA prior to introducing the product into commerce. In addition, manufacturers are required to submit Annual Reports[13] to the FDA CDRH that summarize the contents of the records required to be maintained, as well as the volume of products produced, sold or installed. Also, they are required to provide the FDA CDRH with quarterly updates to the Annual Report listing any new models of an already approved model family that do not have x-radiation emission characteristics that differ from the already-approved models.[14]

Upon receipt of these reports, the FDA CDRH issues an Accession Number and may review the report. In a typical year, a television manufacturer may file in excess of 30 reports with the FDA CDRH.

In light of the fact that the vast improvement in television set designs over the past two decades has virtually eliminated the risk of excessive x-radiation emissions from TV sets, and that neither CEA nor the manufacturers surveyed are aware of any recalls or incidents resulting in personal injury due to excessive x-radiation from a TV set for at least this long, it seems that relieving manufacturers of the administrative burden of filing reports as currently required would not pose any significant risk to the public. This action would also conserve limited

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[11] *See* 21 C.F.R. Section 1002.10.
[12] *See* 21 C.F.R. Section 1002.11.
[13] *See* 21 C.F.R. Section 1002.13.
[14] *Id.*

government resources and allow the FDA CDRH to focus on more significant areas of regulatory concern. CEA believes that an abbreviated version of the Annual Report should still be required as a means for the FDA CDRH to keep track of what companies are manufacturing TV sets. Each manufacturer should be issued a single, annual accession number to cover all of its products after it has filed this abbreviated Annual Report.

CEA is not suggesting that the FDA CDRH requirement that TV sets comply with its x-radiation emission limit be eliminated, only that the administrative procedures associated with compliance be reduced. We believe that the long track record established by the consumer electronics industry in this area suggests that, even with a reduction in the reporting requirements, compliance with FDA CDRH regulations and the level of safety currently achieved within the industry would be maintained. We believe that manufacturers should only be required to keep Abbreviated Reports[15] in their own files, where they would be available to the FDA CDRH upon request. Rather than ask the FDA CDRH to eliminate reporting entirely (and thereby make the industry self-regulating), this petition seeks instead only to simplify the reporting requirements. This means that the unnecessary effort and extraneous information that is imposed by the reporting and compliance guidelines would no longer be required.

CEA proposes that, for television products, Product Reports and Supplemental Reports be eliminated, and that Abbreviated Reports be required in their place. CEA further proposes that, in lieu of filing these Abbreviated Reports with the FDA CDRH, manufacturers of television products be required to retain each Abbreviated Report on file until two years after the manufacture of products covered by the report has ceased. CEA also proposes that, for television products, the information required in the Annual Reports be reduced to include only the manufacturer's name, the importer's name, a declaration of compliance with the regulations,

and all signatures and contact information necessary for FDA CDRH to serve notice and enforce compliance.

This reporting structure would enable FDA CDRH to maintain information about the identity of television product manufacturers and the person(s) at these companies responsible for compliance.

IV. FACTORY PRODUCTION LINE SAMPLING OF TV RECEIVERS CAN BE REDUCED WITHOUT INCREASING THE RISK OF PUBLIC EXPOSURE TO X-RADIATION EMISSIONS

In addition to the administrative burden of filing reports with the FDA CDRH, television receiver manufacturers are also required to measure "one product from each separate chassis/CRT-size combination produced on each production line during each shift" for x-radiation emissions.[16]

Based on the physical properties inherent in modern television design (lack of shunt regulator tubes and inclusion of highly reliable total solid state circuitry, as discussed earlier), and the fact that TV receiver manufacturers' factory measurements for x-radiation emissions have been significantly below 0.1 mR/hr over the past twenty years, CEA believes that manufacturers in the consumer electronics industry who follow current FDA CDRH guidelines have a 100% compliance rate when it comes to meeting the FDA CDRH x-radiation limit. Furthermore, TV receivers pose no radiation risk when proper design considerations are taken into account. Current television sets incorporate circuitry with designed-in protection that makes it highly unlikely that they will exceed the high voltage and beam current necessary to exceed cathode ray tube radiation specifications, which in turn provide substantial safety margins. In light of this, CEA believes that the FDA CDRH sampling requirements can be reduced so that

[15] *See* 21 C.F.R. 1002.12.

one unit from each chassis family/CRT size combination would be tested per production line per shift per week. This would reduce the sampling requirements for each production line from a daily requirement to a weekly requirement.

In this deregulated environment, manufacturers would continue to receive and review incoming supplier data for x-radiation critical components on at least a quarterly basis to ensure that the components meet their designed specifications. They would also continue to perform daily audits of x-radiation critical components to ensure that the correct components are installed as designed. They would also continue their tests of protection circuits like high voltage shut down and over voltage protection.

The industry believes that these changes would in no way diminish the effectiveness of the FDA CDRH x-radiation requirements. They would simply relieve both TV set manufacturers and the government of an unnecessary regulatory burden.

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[16] *Reporting and Compliance Guide for Television Products,* FDA CDRH, October 1995, page 35.

IV. CONCLUSION

The Administration's x-radiation regulations for television receivers were a necessity for the kinds of technologies that were in place back in the late nineteen sixties and early nineteen seventies. TV set designs have improved dramatically since that time, however, and the industry's track record on x-radiation compliance over the past two decades suggests that the same administrative burdens that were necessary to ensure compliance in the nineteen seventies are no longer necessary today. In light of these facts, CEA urges the FDA to allow television receiver manufacturers to reduce current reporting requirements and to permit manufacturers to reduce the frequency with which they sample products from their production lines for compliance.

V. ENVIRONMENTAL IMPACT

The proposals in this petition relate to administrative procedures only, and do not involve any changes to the actual x-radiation emission limits with which TV sets are required to comply. Thus, if adopted, they would have no environmental impact.

are no longer necessary today. In light of these facts, CEA urges the FDA to allow television receiver manufacturers to reduce current reporting requirements and to permit manufacturers to reduce the frequency with which they sample products from their production lines for compliance.

Respectfully submitted,

CONSUMER ELECTRONICS ASSOCIATION

By: 

Michael Petricone
Vice President
Technology Policy

Gary S. Klein
Vice President
Government and Legal Affairs

Ralph Justus
Vice President
Technology and Standards

Douglas Johnson
Director
Technology Policy

David Wilson
Director
Technology & Standards

2500 Wilson Boulevard
Arlington, Virginia 22201
(703) 907-7600

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Appendix A

Proposed Changes to 21 C.F.R. §§ 1002.1 and 1002.12

Sec. 1002.1 Applicability.

The provisions of this part are applicable as follows:

(a) All manufacturers of electronic products are subject to Sec. 1002.20.

(b) Manufacturers, dealers, and distributors of electronic products are subject to the provisions of part 1002 as set forth in table 1 of this section, unless excluded by paragraph (c) of this section, or unless an exemption has been granted under Sec. 1002.50 or Sec. 1002.51.

(c) The requirements of part 1002 as specified in table 1 of this section are not applicable to:

(1) Manufacturers of electronic products intended solely for export if such product is labeled or tagged to show that the product meets all the applicable requirements of the country to which such product is intended for export.

(2) Manufacturers of electronic products listed in table 1 of this section if such product is sold exclusively to other manufacturers for use as components of electronic products to be sold to purchasers, with the exception that the provisions are applicable to those manufacturers certifying components of diagnostic x-ray systems pursuant to provisions of Sec. 1020.30(c) of this chapter.

(3) Manufacturers of electronic products that are intended for use by the U.S. Government and whose function or design cannot be divulged by the manufacturer for reasons of national security, as evidenced by government security classification.

(4) Assemblers of diagnostic x-ray equipment subject to the provisions of Sec. 1020.30(d) of this chapter, provided the assembler has submitted the report required by Sec. 1020.30(d)(1) or (d)(2) of this chapter and retains a copy of such report for a period of 5 years from its date.

Title 21 CFR § 1002.1 **Table I - Record and Reporting Requirements By Product**

Manufacturer							Dealer & Distributor
Products	Product reports, Section § 1002.10	Supplemental reports, Section § 1002.11	Abbreviated reports, Section § 1002.12	Annual reports, Section § 1002.13	Test records, Section § 1002.30(a)[1]	Distribution records, Section § 1002.30(b)[2]	Distribution records, Sections § 1002.40 and § 1002.41
DIAGNOSTIC X-RAY[3] (§ 1020.30 , § 1020.31, § 1020.32, § 1020.33)							
Computed tomography	X	X		X	X	X	X
X-ray system[4]	X	X		X	X	X	X
Tube housing assembly	X	X		X	X	X	
X-ray control	X	X		X	X	X	X
X-ray high voltage generator	X	X		X	X	X	X
X-ray table or cradle			X		X	X	X
X-ray film changer			X		X	X	
Vertical cassette holders mounted in a fixed location and cassette holders with front panels			X		X	X	X
Beam-limiting devices	X	X		X	X	X	X
Spot-film devices and image intensifiers manufactured after April 26, 1977	X	X		X	X	X	X
Cephalometric devices manufactured after February 25, 1978			X		X	X	
Image receptor support devices for mammographic X-ray systems manufactured after September 5, 1978			X		X	X	X
CABINET X-RAY SYSTEMS (§ 1020.40)							
Baggage inspection	X	X		X	X	X	X
Other	X	X		X	X	X	
PRODUCTS INTENDED TO PRODUCE PARTICULATE RADIATION OR X-RAYS OTHER THAN DIAGNOSTIC OR CABINET X-RAY							
Medical			X	X	X	X	
Analytical			X	X	X	X	
Industrial			X	X	X	X	
TELEVISION PRODUCTS (§ 1020.10)							
~~<25 kilovolt (kV) and <0.1 milliroentgen per hour (mR/hr) IRLC[5,6]~~ All			X	X[6]			
~~≥25kV and <0.1mR/hr IRLC5~~	~~X~~	~~X~~		~~X~~			
~~≥0.1mR/hr IRLC5~~	~~X~~	~~X~~		~~X~~	~~X~~	~~X~~	
MICROWAVE/RF							
MW ovens (§ 1030.10)	X	X		X	X	X	
MW diathermy			X				

Manufacturer							Dealer & Distributor
Products	Product reports, Section § 1002.10	Supplemental reports, Section § 1002.11	Abbreviated reports, Section § 1002.12	Annual reports, Section § 1002.13	Test records, Section § 1002.30(a)[1]	Distribution records, Section § 1002.30(b)[2]	Distribution records, Sections § 1002.40 and § 1002.41
MW heating, drying, security systems			X				
RF sealers, electromagnetic induction and heating equipment, di-electric heaters (2-500 megahertz)			X				
OPTICAL							
Phototherapy products	X	X					
Laser products (§ 1040.10, § 1040.11)							
Class I lasers and products containing lasers[75]	X			X	X		
Class I laser products containing class IIa, II, IIIa, lasers[75]	X			X	X	X	
Class IIa, II, IIIa lasers and products other than class I products containing such lasers[7]	X	X		X	X	X	X
Class IIIb and IV lasers and products containing such lasers[75]	X	X		X	X	X	X
Sunlamp products (§ 1040.20)							
Lamps only	X						
Sunlamp products	X	X		X	X	X	X
Mercury vapor lamps (§ 1040.30)							
T lamps	X	X		X			
R lamps			X				
ACOUSTIC							
Ultrasonic therapy(§ 1050.10)	X	X		X	X	X	X
Diagnostic ultrasound			X				
Medical ultrasound other than therapy or diagnostic	X	X					
Non-medical ultrasound			X				

[1]However, authority to inspect all appropriate documents supporting the adequacy of a manufacturer's compliance testing program is retained.
[2]The requirement includes Secs. 1002.31 and 1002.42, if applicable.
[3]Report of Assembly (Form FDA 2579) is required for diagnostic x-ray components; see 21 CFR 1020.30(d)(1) through (d)(3).
[4]Systems records and reports are required if a manufacturer exercises the option and certifies the system as permitted in 21 CFR 1020.30(c).
[5]~~Determined using the isoexposure rate limit curve (IRLC) under phase III test conditions (1020.10(c)(3)(iii)).~~
[6]~~Annual report is for production status information only.~~
[75]Determination of the applicable reporting category for a laser product shall be based on the worst-case hazard present within the laser product.

Sec. 1002.12 Abbreviated reports.

(a) Abbreviated reports shall be distinctly marked "Radiation Safety Abbreviated Report" and shall include:

~~Manufacturers of products requiring abbreviated reports as specified in table 1 of Sec. 1002.1 shall submit, prior to the introduction of such product, a report distinctly marked ``Radiation Safety Abbreviated Report'' which shall include:~~

(1) Firm and model identification.

(2) A brief description of operational characteristics that affect radiation emissions, transmission, or leakage or that control exposure.

(3) A list of applications or uses.

(4) Radiation emission, transmission, or leakage levels.

(5) If necessary, additional information as may be requested to determine compliance with the Act and this part.

(b) Manufacturers of television products shall retain each abbreviated report on file until two years after they have ceased manufacturing the products covered in the report.

(c) Manufacturers of non-television products requiring abbreviated reports as specified in table 1 of §1002.1 shall submit their reports to the Center for Devices and Radiological Health, Electronic Product Reports, Office of Compliance (HFZ-307), 2098 Gaither Road, Rockville, MD 20850, prior to the introduction of such product into commerce.

Sec. 1002.13 Annual reports.

(a) Every manufacturer of products requiring an annual report as specified in table 1 of Sec. 1002.1 shall submit an annual report summarizing the contents of the records required to be maintained by Sec. 1002.30(a) and providing the volume of products produced, sold, or installed (unless the products are televisions, in which case the reporting of the volume of products produced, sold, or installed is not required).

(b) Reports are due annually by September 1. Such reports shall cover the 12-month period ending on June 30 preceding the due date of the report.

(c) New models of a model family that do not involve changes in radiation emission or requirements of a performance standard do not require supplemental reports prior to introduction into commerce. These model numbers should be reported in quarterly updates to the annual report unless the products are televisions, in which case the reporting of model numbers is not required.

Sec. 1002.30 Records to be maintained by manufacturers.

(a) (1) Manufacturers of non-television products listed under table 1 of Sec. 1002.1 shall establish and maintain the following records with respect to such products:

(~~1~~i) Description of the quality control procedures with respect to electronic product radiation safety.

(~~2~~ii) Records of the results of tests for electronic product radiation safety, including the control of unnecessary, secondary or leakage electronic product radiation, the methods, devices, and procedures used in such tests, and the basis for selecting such methods, devices, and procedures.

(3iii) For those products displaying aging effects which may increase electronic product radiation emission, records of the results of tests for durability and stability of the product, and the basis for selecting these tests.

(4iv) Copies of all written communications between the manufacturer and dealers, distributors, and purchasers concerning radiation safety including complaints, investigations, instructions, or explanations affecting the use, repair, adjustment, maintenance, or testing of the listed product.

(5v) Data on production and sales volume levels if available.

(2) Manufacturers of television products listed under table 1 of Sec. 1002.1 shall establish and maintain the following records with respect to such products:

(i) Manufacturer's name.

(ii) Importer's name.

(iii) Declaration of compliance with the requirements in Sec. 1020.10(c).

(iv) Name(s), signature(s) and contact information for person(s) responsible for compliance.

(b) In addition to the records required by paragraph (a) of this section, manufacturers of products listed in paragraph (c) of Sec. 1002.61 shall establish and maintain the following records with respect to such products:

(1) A record of the manufacturer's distribution of products in a form which will enable the tracing of specific products or production lots to distributors or to dealers in those instances in which the manufacturer distributes directly to dealers.

(2) Records received from dealers or distributors pursuant to Sec. 1002.41.

Appendix B

Proposed Changes to FDA CDRH *Reporting and Compliance Guide for Television Products,* October 1995

CEA proposes that the minimum sampling plan for final x-radiation testing for television receivers, as stated in item 6.8 of Part 8B on page 35 of the *Reporting and Compliance Guide for Television Products* dated October 1995, be reduced as follows:

Current: "one product from each separate chassis/CRT-size combination produced on each production line during each shift"

Proposed: "one product on a weekly basis from each separate chassis/CRT-size combination produced on each production line during each shift"