



Consumer Electronics Association

2500 Wilson Boulevard Arlington, VA 22201-3834 USA Tel 703 907 7600 Fax 703 907 7601 www.CE.org

May 10, 2001

Dr. Orhan H. Suleiman  
Center for Devices and Radiological Health (HFZ-240)  
Food and Drug Administration  
1350 Piccard Drive  
Rockville, MD 20850

Dear Dr. Suleiman:

In preparation for the May 17, 2001, meeting of the Technical Electronic Product Radiation Safety Standards Committee, the Consumer Electronics Association (CEA) by this letter is providing some information and recommendations concerning FDA/CDRH x-radiation regulations for television receivers.

Specifically, CEA is requesting that the minimum sampling plan for final x-radiation testing for television receivers as stated in the *Reporting and Compliance Guide for Television Products* dated October 1995 [ pg. 35, Part 8B, item 6.8 ] be reduced as follows (changes shown in bold type):

**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”

The current FDA / CDRH rules governing television receivers, as set forth in 21 CFR 1020, have remained virtually unchanged since they were adopted under the authority of the *Radiation Control for Health and Safety Act of 1968*. This legislation was a result of approximately 90,000 televisions that were recalled due to excessive x-radiation. The shunt regulator tubes, which regulated the high voltage to the cathode ray tubes (CRTs) in these units, were found to be defective and could generate x-radiation in excess of 8,000 mR/hr. As a result, a federal performance standard limiting the x-radiation emissions of television receivers was issued on December 25, 1969. The final phase of this standard (Phase III) became effective on June 1, 1971 and limited the x-radiation emissions from television receivers to 0.5 mR/hr.

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

Dr. Orhan H. Suleiman  
May 10, 2001  
Page 2

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.

CEA recently surveyed several of its members and asked what levels of x-radiation they are typically finding when they test their TV sets for x-radiation emissions. None of the members of CEA's Product Safety & Compliance Committee can remember testing any TV set in the past twenty years with x-radiation emission levels in excess of typical background levels, even under Phase III test conditions. It should be noted that manufacturers usually record some low value (*e.g.*, significantly less than 0.1 mR/h). This is because the actual level of emissions (assuming any are present) is so much lower than normal background radiation levels that they are masked by the background radiation. As such, the x-radiation levels from modern TV sets are generally not measurable or distinguishable from background x-radiation levels, even with the radiation meter measuring in its greatest sensitivity mode.

The FDA/CDRH limit for x-radiation emissions from TV sets is 0.5 mR/h (21 CFR Section 1020.10(c)). The levels that are actually being measured during required FDA/CDRH compliance testing are less than background levels.

Based on the physical properties inherent in modern television design and the supporting evidence, CEA believes that manufacturers who follow current CDRH guidelines in the consumer electronics industry have a 100% compliance rate when it comes to meeting the FDA/CDRH x-radiation limit. Furthermore, it appears that TV receivers are in little danger of non-compliance when proper design considerations are taken into account and therefore they all produce emissions that are well below the FDA/CDRH limit. Current television sets incorporate circuitry with designed-in protection that makes it highly unlikely under any conditions, including multiple faults, to exceed the high voltage and beam current necessary to produce appreciable x-radiation. In light of this, CEA believes it is time to reduce the burden on manufacturers for demonstrating compliance with the FDA/CDRH guidelines. CEA does not suggest that the x-radiation emission limits themselves be relaxed, only that the unduly burdensome amount of time and paperwork required to demonstrate compliance be reduced. CEA proposes that the FDA/CDRH sampling requirements be reduced so that one unit from each chassis family/CRT size combination would be tested per production line per shift per week.

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. Manufacturers would also continue to perform daily audits of x-radiation critical components to ensure that the correct components are installed as designed. Tests of protection circuits like high voltage shut down and over voltage protection would continue.

Dr. Orhan H. Suleiman

May 10, 2001

Page 3

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

Thank you in advance for your time and attention. If you have any questions about this matter you may contact me at (703) 907-7421.

Sincerely,

A handwritten signature in black ink that reads "David E. Wilson". The signature is written in a cursive, flowing style.

David E. Wilson

Director, Technology & Standards

cc: Mr. Collin Figueroa  
Chief, Electronic Products Devices Branch  
FDA Center for Devices and Radiological Health  
Oak 4, Room 350, HFZ-342  
2094 Gaither Road  
Rockville, MD 20850

CEA Product Safety & Compliance Committee