

SUMMARY MINUTES

OF THE

TECHNICAL ELECTRONIC PRODUCT RADIATION

SAFETY STANDARDS COMMITTEE

Wednesday, October 1, 2003

**Center for Devices and Radiological Health
Food and Drug Administration**

**Hilton Washington, D.C., North
620 Perry Parkway
Gaithersburg, MD 20877**

Meeting Attendees

Chair

Lawrence Rothenberg, Ph.D.
Memorial Sloan-Kettering Cancer
Center

Executive Secretary

Richard Kaczmarek, M.S.
Food and Drug Administration

General Public

Jane Benson, M.D.
Assistant Professor of Radiology and
Pediatrics, Johns Hopkins University
School of Medicine

James W. Platner, Ph.D., C.I.H.
The Center to Protect Workers' Rights

Government

Jill Lipoti, Ph.D.
Radiation Protection Programs
New Jersey Dept. of Environmental
Protection

Michele Loscocco, M.S.
Medical Service Corps
U.S. Navy

John Cardarelli, Ph.D.
National Institute for Occupational
Safety and Health

Kiyohiko Mabuchi, M.D.
Division of Cancer Epidemiology
and Genetics, National Cancer Institute

Industry

David Lambeth, Ph.D.
Lambeth Systems Design and
Consulting Group

Michael Caswell, Ph.D.
CB Fleet Company

Kimberly Kantner, BSc.
AT&T Corporation

Wayne Myrick, M.S.
Sharp Electronics Corporation

OPEN SESSION — October 1, 2003

Executive Secretary Richard Kaczmarek opened the meeting at 8:32 a.m. and read a summary of the charter establishing the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), stating that its membership consists of 15 members drawn equally from government agencies, affected industries, and the general public. At least one member shall be a representative from organized labor. Its function is to provide advice to the Commissioner of Food and Drugs on performance standards for electronic products, to control the electronic radiation emissions from these products, and to review amendments to such standards before being prescribed by the Commissioner, not to approve individual products.

Panel Chair Lawrence Rothenberg, Ph.D., asked the members of the Committee to introduce themselves and describe their areas of expertise.

Update of Issues

Ms. Lillian Gill, senior associate director at the Center for Devices and Radiological Health (CDRH), gave an update on three issues previously presented to the Committee, including wireless cell phones, laser standards, and computed tomography safety, and discussed the future direction of CDRH.

Ms. Gill updated the Committee on the cooperative research and development agreement (CRADA) CDRH signed with the Cellular Telecommunications and Internet Association (CTIA). Under this agreement, FDA provides research recommendations and oversight for studies funded by CTIA on the health effects of radio frequency emissions from wireless phones. In 2001, CTIA funded three studies which reported on structural changes in the genetic material of blood cells after exposure to wireless phone signals.

This year, CTIA funded two studies investigating the best epidemiological tools for assessing exposure to radio frequency emissions from wireless phones. The third phase of the CRADA will begin in 2004 and calls for the Center to convene a scientific meeting to determine other areas of needed research.

Ms. Gill added that the National Toxicology Program (NTP) has conducted an evaluation of all of the research efforts underway on the safety of wireless phones. The NTP concluded that, while these efforts have an excellent probability of producing high quality research results, additional studies are warranted to define any potential health hazards to the public. In addition, CDRH's in-house staff is conducting replication studies of findings reported in the literature, the results of which have been accepted for publication in the scientific literature.

Ms. Gill also noted that as a member of the Radiofrequency Interagency Working Group, FDA is collaborating with other federal agencies on the wireless phone issue, including the Federal Communications Commission (FCC), the National Telecommunications and Information Administration, the National Institute for Occupation Safety and Health (NIOSH), Occupational Safety and Health Administration (OSHA), and the Environmental Protection Agency (EPA). The working group has recently discussed the development of a new exposure standard for cell phones, based on biology rather than dosimetry.

Ms. Gill discussed CDRH's efforts to amend the laser product standard because of recent scientific knowledge of laser bio-effects and the desire to harmonize FDA requirements with International Electrotechnical Commission (IEC) requirements. Since the last TEPRSSC meeting, CDRH has been in discussions

with the IEC on the use of their copyright-protected standards. For that reason, this proposal is on hold.

Ms. Gill updated the Committee on the concerns expressed during the May 2002 TEPRSSC meeting about the safety of computed tomography (CT) equipment. An FDA working group has suggested three technical features estimated to reduce radiation dose from CT scans by about 50 percent. The CT working group is also considering a number of another approaches to expediting the adoption of up-to-date standards, and in late October they will meet with an IEC working group on this subject.

Ms. Gill also addressed the future direction of CDRH's activities. She noted that FDA is giving greater attention to the role of IEC consensus standards in product regulation. FDA has also been speaking with stakeholders who have urged the Center either to lead or participate in four areas: assessing the quality of products, managing data, educating, and assessing emerging technologies.

Comments from the Committee included a concern that the Center continue to focus on non-medical imaging support and guidance, keep up-to-date on the reduction of CT radiation doses and recording and displaying of dose levels, and maintain fusion technology as an area in which CDRH is further involved. A Committee member asked that if the Center focuses on the use of non-medical imaging that they publicize the number of people affected by this technology. Another member asked for more information on the Radiofrequency Interagency Working Group, and Dr. Cyr offered to provide minutes from the group's most recent meeting.

Performance Standards for Sunlamp Products

Howard Cyr, Ph.D., acting branch chief of CDRH's Radiation Biology

Branch, discussed performance standards for sunlamp products. He noted that the Center has been working on new amendments because of advances in photobiology and to harmonize FDA standards with those of the IEC. He also discussed the controversial research done suggesting a connection between sunlamps and melanoma.

Dr. Cyr also discussed recent efforts related to sunlamps in the scientific community, including the Center's project on measuring changes in the skin, and a project looking at skin types and doses required to produce and keep a tan. He also mentioned NTP risk assessments that name sunlamps as a known cause of cancer. Dr. Cyr added that this result is somewhat at odds with other epidemiologists and the International Agency for Cancer Research, which concludes that sunlamps are a probable cause of cancer. He also noted that there has been some recent research connecting sunlamps with melanoma, as well as other studies disputing this connection. In addition, he noted that the tanning industry has been emphasizing the positive connection between sunlamps and the production of Vitamin D. He finished by stating that the Center had hoped to have a finished product at this time, but the issue continues to be controversial.

Sharon Miller, CDRH Office of Science and Technology, proposed six amendments to the Center's performance standards for sunlamps. She provided a brief history of the amendment process, beginning in 1998 when the Center published an advanced notice of proposed rule-making (ANPRM). This was prompted by concerns about the rising incidence of melanoma in the United States and other countries and its possible relationship to sunlamps. a citizen's petition to increase enforcement in sunlamp

products, an AMA petition to ban sunlamp products, the desire to harmonize FDA sunlamp standards with the IEC standards, changes in sunlamp technology since 1985 (the last time the standard was amended) and the changing knowledge base of ultraviolet radiation effects.

Ms Miller then presented the six proposed amendments to the Committee. The first amendment revises the warning label for sunlamps, following the IEC standard except in the final sentence. “Consult your physician” is not in the IEC standard but Center staff suggested its addition. The second proposed amendment requires that the warning label be included in catalogues and other materials, consistent with the laser standard requirement. The third proposed amendment addresses the definition of a manufacturer, and is also consistent with the requirements in the laser standard.

The fourth proposed amendment changes the language dealing with protective eyewear requirements. The UV limits would be the same but the visible light requirements would become more quantitative. At the Center’s suggestion, the IEC has adopted these changes to the visible light requirements in their standard. In addition, Ms. Miller proposed adopting the 5% cap on visible transmittance that has been part of IEC requirement for sunlamp products for several years, with the modification that it only apply to eyewear used in sunbeds with high-pressure lamps exposing the facial area. According to Ms. Miller, the use of sunbeds with high-pressure lamps poses a danger for damage to the retina from intense visible light.

Proposed amendment 5a replaces the CIELYTL Erythema action spectrum (currently used by FDA) with the IEC/ CIE reference action spectrum for erythema. Proposed amendment 5b changes the value of the minimal erythemal dose (MED) to 200

J/m^2 , a value that has been internationally accepted as being appropriate for a person of ‘skin type II’ (the most sensitive skin type that would be expected to use sunlamps). This would effect the timer setting used to meet the exposure schedule.

The sixth proposed amendment changed the replacement lamp code to facilitate an absolute system. The code on the sunlamp would display wattage, one of four reflector codes, and a UV code based on an X/Y designation. The X value represents the absolute erythema-effective output of the lamp, and the Y value represents the ratio of the non-melanoma skin cancer (NMSC)- weighted output in the UVB and UVA regions of the spectrum. Ms. Miller also noted that the Center is working with the IEC to update their standard for lamp measurements and establishing acceptable ranges for suitable lamp replacements. She estimated that this work should be complete well before the amendments to the FDA standard are published (in about four years).

Ms. Miller requested that the Committee vote on the six proposals after the open public hearing.

The Committee raised a number of questions about the proposals, including whether the new labeling and coding requirements made replacing lamps easier; the reduction in spectral light for a lamp over time; clarification of the use of CIE erythema action spectrum and the nonmelanoma skin cancer action spectrum in proposed amendment 6; the use of the phrase “may cause cancer” versus “can cause cancer” or “causes cancer” in the warning label; and the reduction in the exposure schedule defining the amount of time required to get a tan. Members also discussed the statement in the first proposed amendment on consulting a physician, and consider the conditions that would prompt a consumer to do this and what type of physician should be consulted. Committee

members also suggested changing the eyewear requirement phrase to read “wear eyewear that is Federally-compliant for use with sunlamps.”

Open Public Hearing

Dr. Rothenberg read a statement advising the open public speakers to inform the Committee of any financial relationships they may have with a sponsor, its products, or its direct competitors, as well if they do not have any financial relationships.

Joseph Levy, of the Indoor Tanning Association, focused on the “real world” implications of the proposed amendments. He asserted that several of the amendments would not necessarily protect public health but would have a negative economic impact on the indoor tanning industry. Mr. Levy also expressed concern about harmonizing FDA standards with the IEC standards. His organization has suggested three revisions to the warning label and that consumers be advised to consult their physician or pharmacist before using a sunlamp.

Joe Schuster, of Light Sources and the Suntanning Association for Education, informed the Committee about educational groups providing indoor tanning operators with accredited training. He noted that because of recent tight economic conditions, salon owners may not replace their lamps and acrylic beds as often as they should, resulting in lower dosages. Mr. Schuster also urged that the operating system, or the light ballast, be considered when measuring a sunbed’s output, and asked that the warning label not be so “absolute.” He suggested, instead, language stating that sunlamps “may” or “might cause cancer,” instead of “will cause cancer.”

Rick Mattoon, of the National Tanning Training Institute and *Looking Fit* magazine, addressed two of the proposed amendments. He asked that the warning label appear only on the equipment and the operator's manual, and advertisements targeted specifically to consumers. He asked that the warning label not be required in materials targeted to tanning salon owners. Mr. Mattoon also expressed concern that the proposed definition of a manufacturer could limit the activities of many indoor tanning businesses. According to Mr. Mattoon, any changes to the definition of a manufacturer should be considered carefully and done in a more detailed manner to distinguish between minor and major modifications of the equipment.

Donald. L. Smith, of the Ultraviolet, Visible and Infrared Radiation Research Institute, recommended keeping the current FDA erythemal action spectrum rather than changing to the internationally-accepted CIE erythemal action spectrum. He said that very few complaints had been lodged against indoor tanning salons since the regulation's inception in 1985 and that the proposed standard would increase the erythemal risk to the public. He also urged the FDA to reject its proposed X/Y ratio system for labeling sunlamps in favor of his "bin system." He said that the bin system recognizes how the indoor tanning industry classifies their sunbeds and should be easier to understand.

Mr. Smith asked that the word "overexposure" be added to the warning label, that consumers be advised on the label to consult their physician *or* pharmacist, and that the label's language warn consumers with specific diseases or using particular medications about tanning. He asked the FDA to do more testing of eyewear products and develop standard protocols for testing sunlamps and beds before defining who is a manufacturer.

Laura Edwards, assistant director of Federal Affairs for the American Academy of Dermatology Association, stated that her association would like to see indoor tanning banned. In the absence of a ban, they support having the industry highly regulated. Their priority is the first proposed amendment, and she said that she was encouraged by the Committee's discussion earlier in the meeting to strengthen the label's language. Specifically, the Association would like to see the phrase "may cause cancer" replaced with "can cause cancer" or "is known to cause cancer."

Ms. Miller responded to the open public speakers. With regard to harmonizing FDA standards with IEC standards, she noted that not only does the Center have a federal mandate to pursue this work, but they also believe that harmonization (through the adoption of these amendments) will improve public safety. She discussed changes to the warning label, adding that the Center believes that adding the word "unprotected" to the warnings about eye protection does not add information and makes the label longer. In addition, the suggested addition of the word "overexposure" introduces an ambiguous term into the label. Responding to the concern of several speakers that the proposed amendments would have a detrimental financial impact on the industry, she said that the Center is required to conduct an economic impact analysis before final approval is made on the amendments.

Committee Discussion

After a discussion concerning the development of the new erythema action spectrum and the impact of this change, **Dr. Rothenberg asked that the Committee consider each of the proposed amendments individually for discussion and a vote.**

One Committee member made a motion that the proposed warning label in the first proposed amendment be revised to read “ultraviolet radiation is known to cause cancer.” Ms. Miller responded that the Center will consider the language “causes cancer.” A discussion of the role of ultraviolet light’s role in causing cancer and the research on this issue followed. A Committee member suggested replacing “wear protective eyewear provided” with “federally-compliant protective eyewear.” Ms. Miller agreed to this. Discussion continued about adding other features to the label, including the phrase “or dermatologist” after “physician,” directions to the FDA Web site, and consistency in using the terms “danger” and “warning.” Dr. Rothenberg suggested that the next step would be for the CDRH to go back and review all of the comments and come up with a revised label per the Committee’s discussion.

Dr. Rothenberg stated that the sense of Committee was that the revision to the second proposal should include requiring that the warning be included in any consumer materials. Discussion on the third proposed amendment focused on the type of modifications covered by the term “significant,” timer issues, and importation issues. The Committee endorsed the third proposed amendment. The Committee next discussed revisions to the fourth amendment, and asked that the criteria for measuring transmittance bandwidth be included in the final document. Ms. Miller agreed to this.

Amendment 5a proposes replacing the CIELYTLE erythema action spectrum with the CIE reference action spectrum. A majority of the Committee endorsed this amendment, with two abstentions. Amendment 5b proposes adopting the new definition $MED=200 \text{ J/m}^2$ and a new timer limit of 3 MEDs. Ms. Miller noted that when the regulation changes it will apply only to new production and that any system meeting the

old definition should meet the new definition. Dr. Rothenberg noted that amendments 5a and 5b should be taken together. The Committee agreed that the Center should proceed on both amendments. The Committee next considered the sixth amendment, in which the current replacement lamp coding scheme is changed to an absolute system that would feature on each lamp its wattage, reflector code, and UV code. The amendment carried unanimously. **Dr. Rothenberg noted that the Committee, while considering each amendment individually, agreed that CDRH should go ahead with these revisions, taking into consideration the Committee's comments.**

Proposed Amendments to the X-Ray Standard

Thomas B. Shope, CDRH Office of Science and Technology, updated the Committee on the proposed fluoroscopic system amendments to the performance standard for diagnostic x-ray systems (21 CFR 1020.30-.33). He noted that he could not yet present the final proposals, as the comment period for the proposed rule ended April 2003.

Mr. Shope summarized the comments received after the publication of the proposed rule in December 2002, and noted that any comments the Committee has during this meeting will be considered during final deliberations. Mr. Shope provided background on the amendment, noting that recent developments in the technology and increased radiation output in the 1990s made it clear to the FDA that there was a need for additional dose and exposure information.

Mr. Shope noted that while most of the 12 organizations and individuals providing comments were generally supportive of the amendment, there were also a

number of objections to specific proposals and requests for detailed changes. However, Mr. Shope added that the FDA also received some suggestions for features not included in the new amendment and significant changes that they cannot make to the amendment without creating an additional proposal with a notice and comment period. These included requiring peak skin dose display and a “skin dose map” instead of a dose rate or cumulative dose display; providing an image of collimator blades without irradiation; and requiring a signal indicating when fluoroscopy is occurring.

Mr. Shope said that suggestions to the proposed amendment urged harmonization with the IEC standard and recommended modifications to some of the definitions. The FDA also received critiques of several of the proposed requirements, including manufacturers’ description of intended uses; the IEC standard of ± 50 percent accuracy for dose display; the placement of responsibility for any modifications and upgrading done to existing equipment; and dose display and last image hold feature requirements for mini C-arm systems. Others comments suggested requiring a display of the air kerma rate during irradiation and a continuous display of the cumulative air kerma.

Mr. Shope also noted errors and omissions in the NPR, for example, including a discussion of dose information versus dose display in the preamble; no effective date for the addition of filtration for high-powered x-ray tubes; needed adjustment of figures describing the requirement for attenuation of material between patient and image receptor; requirement of tolerance on dose display in 1020.30(h)(6)(i); and an editing error in 1020.32(k)(5)(ii). Mr. Shope also addressed in his comments the future role of the IEC standards for medical x-ray and other products, how the IEC standards relate to current U.S. standards, and the discussion occurring within CDRH on this topic.

Mr. Shope estimated that CDRH will finish the regulatory wording soon, followed by a draft of a *Federal Register* notice. He said that he expects the rule to be completed by the end of 2003, with an effective date of late 2004 or early 2005.

The Committee directed several questions and comments to Mr. Shope about his presentation. Several Committee members said that they especially liked the alternative dual dose/air kerma rate display feature suggested by some of those commenting on the proposal. Dr. Rothenberg expressed concern over the fact that the proposed amendment did not include language addressing data storage and dose recording, but that this was something he would like the Committee to look into. Mr. Shope responded that making that a safety issue might pose some challenges. The Committee also discussed the IEC standard of ± 50 percent accuracy for the dose display. Several Committee members agreed that an accuracy rate of ± 25 percent was preferable and should be achievable.

A discussion ensued regarding which dose number would be recorded (maximum or cumulative). Several members asserted that even though recording the maximum dose may not be completely accurate it would be better to record this number than no number.

A motion was proposed that the Committee be on record supporting the consideration of a future amendment in which dose recording is addressed. The Committee passed the motion by a vote of nine for, one against, and two abstaining.

Security Screening Systems

Daniel F. H. Kassiday, CDRH Office of Compliance, updated the Committee on emerging issues in ionizing radiation security systems and new products appearing on the market since the terrorist attacks of September 11, 2001.

Mr. Kassiday noted that airport workers have recently expressed concern about cabinet x-ray systems. The FDA has been working with the Transportation Security Administration (TSA) to help them develop internal policy on how these systems should be used.

Mr. Kassiday said that one of the emerging issues in the area of security systems includes the increasing numbers of vehicle and cargo scanners being bought and installed in ports across the nation. These systems use a backscatter image, transmission image, or both. They are either fixed or mobile and are intended to screen vehicles without passengers. One cargo system, however, is also designed to screen people, such as those along a parade route, but it is not yet distributed in the United States. Mr. Kassiday noted this is not a cabinet x-ray system and therefore does not fall under the FDA standard. He added that there are new products nearing release, including portals designed to screen vehicles and passengers, high-energy accelerators for some cargo containers, and machine-produced neutron systems in development funded by the U.S. Congress.

Mr. Kassiday said that FDA is working with NIOSH, U.S. Customs, OSHA, and TSA to create a consensus standard for equipment used around docks and dock workers. He also reported on the backscatter personnel systems currently approved for sale in the United States, as well as a new transmission x-ray system, not yet for sale in the United States, that has prompted FDA to convert their consensus standard to a mandatory performance standard.

He also covered recent FDA projects, including a Web document addressing frequently asked questions about cabinet x-ray systems for consumers and operators; consensus radiation standards for cargo and vehicle systems; draft guidance for

manufacturers; a proposed user guidance manual; and a draft of a proposed mandatory standard for personnel security screening systems.

Frank Cerra updated the Committee on personnel security screening systems. He first provided a brief history of TEPRSSC's previous discussions regarding mandatory standards for backscatter systems and transmission systems, and TEPRSSC's recommendation in 2002 of a mandatory standard based on ANSI N43.17 dose limitations and performance requirements.

Mr. Cerra discussed the new Health Physics Society (HPS)'s position statement and the guidance the FDA sought from the National Council on Radiation Protection and Measurement (NCRP) on personnel security screening. The latter resulted in an NCRP publication, *Presidential Report on Radiation Protection Advice: Screening of Humans for Security Purposes Using Ionizing Radiation Scanning Systems*. He noted that the recommendations in both the HPS position statement and the NCRP report are consistent with the 2002 TEPRSSC recommendations.

The scope of the NCRP report includes a brief review of known risks from radiation exposure; a consideration of screened populations and susceptible subgroups; and dose recommendations. It also addresses the need for operator training, record keeping, equipment testing, and communicating the effects of radiation exposure. Mr. Cerra noted, however, that the report does not address the issue of when the societal benefits outweigh the risks of security screening because the NCRP believed that this issue fell outside of its role.

Mr. Cerra did note that the report does provide useful and valuable guidance for writing a mandatory standard. **All** of the report's guidance stems from the NCRP-116

recommendation for the general public's exposure of no more than 1 mSv per year (100 mrem per year) effective dose from all non-medical, manmade sources. Mr. Cerra said that it would be impossible to know where an individual had been over the past year, so the NCRP-116 administrative control of 0.25 mSv (25 mrem) to an individual received from one venue is a more practical alternative for security screening systems. Among its recommendations, the report divided screening systems into two categories: general-use systems and limited-use systems. The general-use systems include systems conforming with the ANSI dose requirement of less than 0.10 microsieverts (10 mrem) per scan (i.e. backscatter systems). The limited-use systems include all other systems (i.e. transmission systems). The limited-use systems should be used only for follow-up on an individual already suspected of carrying contraband, and they require rigorous record keeping. In addition, the report recommended regular equipment testing and operator training for all systems, as well as risk information for those being screened. However, the report writers did not believe informed consent was necessary.

Mr. Cerra closed by noting that the FDA will take these reports, the TEPRSSC recommendations, and the previous Conference of Radiation Control Program Directors' resolution into consideration when drafting a mandatory standard.

Open Public Hearing

No comments were made.

Committee Discussion

The Committee discussed the presentations and asked questions of the speakers. One Committee member expressed concern about how operators of personnel scanning systems can know when they are exceeding the exposure limit. Mr. Cerra noted that operators who scan known groups of individuals, such as prisoners, can calculate this easier than operators who scan the general public at facilities such as airports.

Several Committee members also brought up concerns about individuals who regularly pass through scanning systems, such as flight attendants and workers on defense contractor sites. Mr. Cerra stated that the systems used in these situations would likely be general-use systems.

Another member brought up the issue of the health risks of x-ray scanning, the perceived public good from conducting these scans, and the need for involving all stakeholders when working on regulations. Other members also mentioned the issue of informed consent for individuals being scanned. Members also expressed concern about the current lack of standards for the new mobile cargo scanning systems using isotopes and accelerators, which could come in contact with the public. Mr. Cerra noted that there is interest in a voluntary standard, as well as a group that is proposing a new standard for the mobile cargo scanners to an ANSI-accredited committee. He added that as this group pursues its work, the FDA could present the results of this work to TEPRSSC.

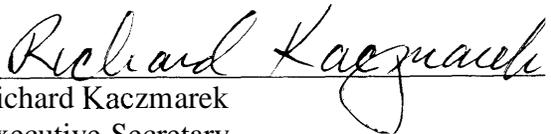
Dr. Rothenberg thanked Mr. Cerra for participating in the committee that drafted the NCRP report. He added that the TEPRSSC Committee would like to encourage the CDRH to remain involved in similar groups and regularly report back to the Committee on these topics.

The discussion shifted to x-ray standards. Dr. Rothenberg noted that he had a copy of the latest New York State regulations on fluoroscopy. Committee members questioned how the FDA is incorporating the IEC standards into its current device standards and dealing with the copyright and enforcement issues. Mr. Shope said that the FDA is actively working on the issue of incorporating IEC and other voluntary standards, and encourages the use of voluntary standards. He added that the agency officially adopts those standards by publishing them in the *Federal Register*, not as mandatory standards but as standards manufacturers can use in conjunction with medical device premarket applications. One Committee member urged the FDA to contact other organizations, such as the FCC and Underwriters' Laboratories, to see how they have accomplished this work. Another member underlined the necessity for mandatory regulations and urged the FDA to keep working in this area, while another stressed the need to consult all stakeholders when writing regulations. Mr. Kaczmarek assured the Committee that the FDA has many of the same concerns they have expressed.

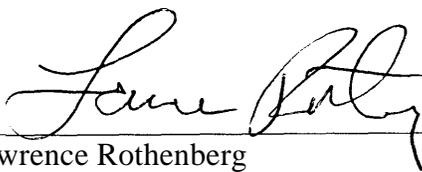
Mr. Kaczmarek announced that five members are leaving the Committee: David Lambeth, Michele Loscocco, Lawrence Rothenberg, Maureen Murdoch Nelson, and Robert Pleasure. He noted that the earliest FDA could be ready to have the next TEPRSSC meeting would be the fall of 2004. A member of the audience suggested holding the meetings on a Friday or a Monday, making airline tickets less expensive.

Dr. Rothenberg thanked Mr. Kaczmarek, FDA staff, presenters, and Committee members for taking time to attend the meeting. Dr. Kaczmarek adjourned the meeting at 4:30 p.m.

I certify that I attended the Open Session of the Technical Electronic Products Radiation Safety Standards Committee Meeting on October 1, 2003, and that this summary accurately reflects what transpired.


Richard Kaczmarek
Executive Secretary

I approve the minutes of this meeting as recorded in this summary.


Lawrence Rothenberg
Panel Chair

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