

SUMMARY MINUTES

OF THE

TECHNICAL ELECTRONIC PRODUCT RADIATION

SAFETY STANDARDS COMMITTEE

May 17, 2001

**Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850**

Meeting Attendees

Executive Secretary

Orhan Suleiman, Ph.D.
Food and Drug Administration

General Public

Lawrence Rothenberg, Ph.D. (**Chair**)
Memorial Sloan-Kettering Cancer Institute

John F. Cardella, M.D.
SUNY Health Sciences Center

William Rice, M.D.
American Radiology

Robert Pleasure
Center to Protect Workers' Rights

Victoria Marx, M.D.
University of Southern California Medical Center

Government

Kathleen A. Kaufman, B.S.
LA County Radiation Management

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

Jerry Thomas, M.S.
Uniformed Services University of the Health Sciences

W. Gregory Lotz, Ph.D.
National Institute for Occupational Safety and Health

Maureen Murdoch Nelson, M.D., M.P.H.
Minneapolis VAMC

Industry

Steve Szeglin, M.S.
PTW New York Corp

Alice Fahy-Elwood, M.S.
Lucent Technologies

John M. Sandrik, Ph.D.
GE Medical Systems

David Lambeth, Ph.D.
Lambeth Systems Consulting

Quirino Balzano, Ph.D.
Motorola Florida Electromagnetics Research Laboratory

OPEN SESSION—MAY 17, 2001

Executive Secretary Orhan Suleiman opened the meeting at 8:31 a.m. and introduced David Feigal, M.D., Director of the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA). Dr. Feigal welcomed the members of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) and others attending the session. He stated that the session's agenda illustrated the need for continuing vigilance over radiological safety and health, and he noted the range of old and new issues falling within the Committee's purview. Dr. Feigal commented on the challenge the Committee faces as a national regulatory body operating in a global environment. He stressed the importance of the Committee's deliberations, both in providing their expertise to the FDA and as a public part of the regulatory process, and thanked the members for their efforts.

Executive Secretary Orhan Suleiman read a summary of the charter establishing the Committee and stated that its membership consists of 15 representatives drawn equally from government, industry, and the general public. Its function is to provide advice on performance standards for electronic products and to recommend electronic product radiation safety standards to the Commissioner of Food and Drugs and not to approve individual products.

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

Update on Issues

Ms. Lillian Gill, Acting Deputy Director for Science at CDRH, gave an update on six issues previously discussed by the Committee. The first area was the proposed

amendments to the federal performance standard for fluoroscopic x-ray systems. She reviewed the history of the proposed amendments, noting that the Committee had discussed these in greater detail at its June 2000 meeting. Since that meeting, the working group has finished its required impact statement on the proposed amendments and has sent a draft assessment to industry for comments. No substantive comments were received. A draft notice for the *Federal Register* was approved in December 2000 that incorporated comments received to date. A notice of proposed rule making is anticipated later this year, followed by the mandatory 120-day comment period. Under the current timeline, the proposed rule will become final in early 2003.

Ms. Gill also updated the Committee on the issue of proposed amendments to the laser standard, which are intended to harmonize the FDA laser standard with the International Electrotechnical Commission (IEC) standard. At its June 2000 meeting, the Committee advised the FDA to continue work on the FDA standard without waiting for the IEC ballot. In the meantime, the IEC amendments were unanimously approved and passed last January. The FDA has drafted a preamble, draft amendments, and a guidance document on laser standards. The guidance document clarifies that the FDA will not object to devices that are noncompliant with the FDA standard if they are compliant with IEC standards.

On regulatory issues involving sunlamps, Ms. Gill recapped that the FDA had presented at the June 2000 TEPRSSC meeting five possible changes to the FDA performance standard for sunlamp products, based on a review of the comments received subsequent to the publication of an Advanced Notice of Proposed Rulemaking. At that meeting, representatives from the indoor tanning industry disagreed with FDA's

proposals, and TEPRSSC had advised FDA to meet with the affected industry for more discussion before returning with another round of possible changes. FDA met with members of the indoor tanning industry in September 2000 and discussed these issues in detail, but more meetings, discussions, and workshops are anticipated to address possible specific changes to the standard. After a complete assessment of these discussions, FDA will propose specific amendments to the current performance standard to bring the regulations up to date.

Ms. Gill also updated the Committee on the status of a draft standard for personnel security screening systems utilizing x-ray radiation, or people scanners. The FDA does not currently have mandatory standards, but the N43 Committee of the American National Standards Institute has appointed a subcommittee of regulators, manufacturers, and users to draft a consensus standard. That N43.17 subcommittee has held three meetings since the June 2000 TEPRSSC meeting. The last of these, in Anaheim, California, resulted in some changes to the draft standard that remain to be incorporated. The draft will then be submitted to the main N43 committee for comment and balloting, with a planned publication date of June 2002.

On TV Receivers Ms. Gill informed the Committee that there will be a course to train manufacturers on TV product standards.

On Ultrasound Diathermy, Ms. Gill noted that an FDA pilot guidance was presented to TEPRSSC at the June 2000 meeting. The Agency is now working out internal policies on pilot guidance, which will be subject to Good Guidance Practice review.

Ms. Gill noted that the Committee had received previous briefings on Radiological Health Revitalization efforts. An Open Public Meeting held by FDA in November 2000 supported the approach taken, which is for FDA to serve as a clearinghouse for information, to hold meetings with stakeholders, to simplify standards, and to make recommendations for improving product testing. A summary of the meeting is available on the FDA website.

Questions from the Committee concerned whether the standards on people security scanners applied exposure limits only to those scanned or to the operators as well. Ms. Gill replied that the standards do not include occupational exposure. There was also discussion of warnings to consumers on sunlamps, sunlamp operator training, lamp output, and lamp compatibility. Dr. Suleiman clarified that many things the panel would like to see are already in the proposed standard, but that the efforts now involve upgrading the standard with the most current scientific data. The Committee urged that the Academy of Dermatology be informed of meetings between FDA staff and industry and encouraged to attend, and that TEPRSSC members be put on the announcement list for meetings between the FDA and industry.

Open Public Hearing

There were no requests to address the Committee. A letter from Thomas J. Quinn, consultant, criticizing the lack of enforcement of performance standards by CDRH and emphasizing the need for a Citizens' Advisory Committee was entered into the record.

Computed Tomography and Digital X-ray Imaging Modalities

Tom Shope, from the Office of Science and Technology, introduced the discussion of digital x-ray modalities and possible FDA activities. Noting that digital x-ray imaging modalities such as computed tomography (CT), digital radiology (DR), and computerized radiography (CR) do not have the fundamental limitation of overexposure or black films, he asked what the impact of this fact is on patient dose, and whether this presents a public health concern requiring action by FDA, and if so, what action might be appropriate. He discussed the magnitude of the problems, noting that there are no current, comprehensive national demographic data on patient exposures, although the Nationwide Evaluation of X-ray Trends (NEXT) program collects exposure data for some exams. Published studies from Europe indicate that patient doses from CT are a significant portion of total medical exposures, while data for DR and CR are inconclusive at this time. Concerns regarding CT use involve the techniques used with children or small patients, the use of faster scans and larger volumes, and the use of CT in “screening.” Concerns regarding DR and CR involve the dose experience in actual use, the long-term stability of dose levels, and the actions that would contribute to optimum use.

Comments from the Committee included concern over multiple CT procedures and the use of screening CTs as an area outside traditional medical oversight.

Stanley H. Stern, Ph.D., of CDRH, discussed standardization and regulation of radiation dosimetry in x-ray computed tomography. He looked at FDA activities and current thinking about recent CT developments around four themes: radiological practice, rapid technological change, revision of industry consensus, standards, and guidance and regulation.

Issues of radiological practice include the possible exposure of pediatric patients to an excess risk of cancer using a larger than necessary radiation dose, and the question of how a new dosimetry standard might quantitatively account for doses incurred in interventional modalities such as perfusion studies or CT fluoroscopy. After reviewing data on pediatric CT dose, Dr. Stern solicited Committee input on whether the FDA should issue a formal notice about appropriate CT technique for pediatric patients. He asked what particular information such a notice might contain in order to underscore diagnostic efficacy so as not to dissuade parents from providing examination benefits that outweigh individual risk.

On the issue of dose display, Dr. Stern looked at how technology and practice have progressed beyond the applicability of dose indices and terminology defined 20 years ago when the current U.S. mandatory standard for CT equipment performance was originally developed. He described features and limitation of the computed tomography dose index (CTDI), noting that it is defined only for axial scanning and that there is no U.S. standard for helical CT dosimetry.

Examples of rapid technological change include multi-slice helical scanning, which brings with it a geometrically inefficient use of radiation, and adaptive x-ray tube current modulation, which offers the prospect of an automated way of obtaining an optimal radiation dose. Dr. Stern stressed that the rapidity of change in CT practice and technology has left the field so unsettled that even the nomenclature is not standardized. He discussed two aspects of standardization related to how dose and associated parameters should be defined: the use of reference levels or reference values, and the potential role of FDA in requiring new performance standards for CT equipment.

Dr. Stern stated that the FDA is currently thinking of a two-tier regulatory approach to CT dose, with near-term possible policy decisions on development of manufacturer guidance about CT dose possibilities and long-term possible regulation on provision of dose information, display of patient examination dose, limitations on overbeaming, and current modulation according to patient thickness. He stressed that this approach is only a preliminary consideration of possible options.

Comments from the Committee included the observation that many of Dr. Stern's suggestions were being incorporated by major manufacturers, at least with new units.

Dr. Robert M. Gagne of the FDA Office of Science and Technology gave an overview of digital imaging and radiation protection issues, considering the central question of whether there is evidence of higher patient radiation exposure with these imaging systems when compared to screen/film radiology. Dr. Gagne described three different types of DR systems: flat panel imaging arrays, computed radiography systems, and CCD based-optimally coupled systems. He noted that the installation base of DR systems is small, partly a manifestation of retrofit problems or non-compatibility with existing image receptor configurations. The radiation protection and safety issues are based on the fact that there is no equivalence to speed or patient exposure self limitation, as in screen/film systems, and on whether dose "inefficient" systems are possible. Dr. Gagne suggested as options the tracking of exposure levels, instituting quality assurance programs, and changing the diagnostic x-ray Performance Standard. Such changes would include a dose display at operator's console for all radiographic equipment. Although Dr. Gagne noted practical considerations such as cost-effectiveness, the dose display would

provide the opportunity to track patient exposure through the use of reference dose levels similar to European programs.

Reactions from the Committee echoed the concerns Dr. Gagne raised, noting the numbers of digital x-ray units were even higher overseas. A possible tendency to increase the radiation exposure if the signal to noise and contrast to noise ratios are not adequate was also of concern. The need for user training as a supplement to any changes in the Performance Standard was also noted.

Tom Shope concluded the presentation by asking the panel to consider whether the performance standard for diagnostic x-ray equipment should be amended to require the display of information related to patient dose for CT, DR, CR, and other radiographic systems. He also asked whether such a system feature would facilitate dose minimization. He summarized that for CT systems, there is a requirement for dose display in the recent IEC standard, but it lacks clarity on what is displayed for multi-slice and helical systems, and a revision to the standard is under consideration. For other radiographic systems, a display of dose would be a novel proposal that appears technically feasible but needs consideration. He asked whether this information would be useful to or used by physicians and facilities. Dr. Shope then listed possible FDA actions, which included amendment of the performance standard, use of the diagnostic reference levels concept and collection of patient dose data to support it, and improved training for users of radiological equipment, physicians, and others.

The Committee discussed whether the FDA should send out an advisory to health care facilities about adjusting for patient size with CT scanners, with attention to whether such an advisory would trigger inappropriate parental alarm and possible medical-legal

issues. A motion was made, seconded, and unanimously passed that the FDA should produce a carefully worded health advisory stating that it has come to FDA attention that there is an opportunity to further reduce the safe dose level of CT radiation in children. This motion was later expanded to include small adult subjects as well.

The Committee also discussed the issue of dose display, with members suggesting that for CT it would be a valuable relative number to see how the dose changes as other variables change. Definitions should be properly stated and consistent with other standards and the choice of system must be consistent with national and international bodies. It was noted that the issue of CT scanner dosage is separate from digital and general technology issues. After discussion, a motion was made, seconded, and passed to encourage the FDA to work with manufacturers to pursue a dose indicator on CT scanners that is appropriately formulated to be consistent with other national and international bodies and that would provide a meaningful dose readout.

There was further discussion of whether a motion was necessary to encourage the FDA to conduct research on whether new technologies such as digital radiographic systems truly facilitate benefit to the patient as opposed to other imaging with lesser exposures, but Dr. Suleiman noted that this type of information is already being collected.

After discussion, a motion was made, seconded, and unanimously passed that the FDA should be encouraged to pursue investigation of the best mechanism to display DR and CR dose indication and to define with reference to national and international standards what the most appropriate indicator is and where it should be positioned. The FDA was encouraged to pursue the issue of what exactly should be displayed and what will be done with the information collected.

The need for education and training was emphasized for operators, as was the need for standards for operation and application. A motion was made and seconded to encourage the FDA to investigate and prepare educational programs and materials for physicians and technicians in application of these techniques. This motion passed with two abstentions. A motion was made, seconded, and unanimously passed for the FDA to work with manufacturers proactively and to require a post exposure readout on regular radiographic equipment to tell the operator what the exposure was.

Open Public Hearing

There were no requests to address the Committee. A letter from David E. Wilson of the Consumer Electronics Association was noted, in which the CEA requested that the minimum sampling plan for final x-radiation testing for television receivers be reduced so that one unit from each chassis family/CRT size combination would be tested per production line per shift per week.

Performance Standards for Non-Medical Products

Mr. Collin L. Figueroa, chief of the Electronic Products Branch, addressed the request made by TEPRSSC during its 2000 session to provide a history and summary of nonmedical electronic product standards and surveillance activities. He divided electronic products into those with performance standards and those without such standards for radiation control. Mr. Figueroa also listed CDRH activities for non-medical products, including maintenance of performance standards, development of consensus standards, provision of safe use and regulatory information to various constituencies, review of radiation safety product reports, review of postmarket activities, processing of request for variances, approval of corrective action plans, and preparation of legal cases.

Mr. Figueroa then discussed three types of non-medical products that have performance standards: television sets (TVs), microwave ovens, and lasers. TV receivers and monitors include video display products containing a component capable of generating x-rays. He reviewed the radiation standard for TV receivers and monitors and changes in technology and use of these items, as well as listing the kinds of user complaints and follow-up in this area. Surveillance activities show that overseas firms lack understanding of the testing requirements and processes, requiring regulatory follow-up.

Mr. Figueroa also reviewed the radiation standard for microwave ovens and the changes in their technology and use, as well as the kinds of complaints received. Surveillance activities show that overseas firms lack understanding of interlocks, wire insertion, leakage testing, and door design, requiring regulatory follow-up.

After defining laser products, Mr. Figueroa discussed the radiation standard for these products and the amendments both final and in process, as summarized in the earlier session. He noted the increase in this market and discussed changes in technology and use. User complaints include flash blinding and burns, which are investigated, with surveillance activities showing that overseas manufacturing of laser pointers have had testing and certification problems requiring regulatory follow-up.

Questions from the Committee included the status of the laser product performance standard. Joanne Barron and Jerry Dennis, both members of the FDA working group, stated that it is still being updated and under review, as is a preamble. A guidance document for industry has been drafted and is still undergoing the approval

process. There was also a question on whether studies are under way to see if exposures around large monitors are different; no such testing is known to the Agency.

Open Public Hearing

There were no requests to address the Committee.

Cellular Telephones

Dr. Russell Owen, chief of the Radiation Biology Branch, provided background on the issue of radiation from cellular telephones and the biological effects of radiofrequency energy (RF), as well as activities to address the issue. He noted the concern over a possible link to cancer because of the unprecedented and chronic exposure of a handheld electronic device that is near the body for a long time. Dr. Owen reviewed findings from epidemiology and animal studies. There are few epidemiological studies, particularly of highly exposed populations, and the difficulties in exposure assessment such as actual phone position and use remain to be resolved. Dr. Owen described five human studies, some domestic and some overseas, that found no associations with RF exposure, no increase in brain cancer, no association with glioma, meningioma, and acoustic neuroma, and no increase of brain or nervous system cancers or leukemia. He noted that longer follow-up than the three years currently available is needed for study of association with long latency diseases and cumulative effects.

Animal studies provided more mixed results, with some showing positive tumor associations. Some short-term animal studies have produced positive data, although others have failed to replicate the results. Long-term studies to date have produced negative data, although current studies are still underway through the U.S. National Toxicology Program. Animal studies on artificially initiated tumors have produced mixed

results. Cellular studies have produced negative data to date on transformation or DNA damage.

Dr. Owen stressed the need for ongoing research in engineering, science, and cellular biology. He urged a review of the scientific literature to identify gaps in research and develop research recommendations. Testing and test method development need more work, as do development of guidelines and standards. Interagency collaboration is essential, and Dr. Owen noted the ongoing collaboration between FDA, the National Institute for Occupational Safety and Health, the National Institutes of Health, the Federal Communications Commission, and the Environmental Protection Agency, as well as the International Commission on Non-Ionizing Radiation Protection.

FDA activities include long-term animal studies, exposure assessment through testing and modeling, developing compliance testing and adapting toxicology testing, cellular and animal experiments on enzyme activity, assessments and education, and a cooperative research program with industry. This program includes a cooperative research and development agreement with the Cellular Telephone Industry Association in which the FDA provides scientific and technical oversight on research contracts. Dr. Owen stated that the FDA website also has a document with a consumer update on mobile phones. Future needs include research to fill data gaps, continual assessment, and safety measures based on science.

Questions from the Committee included the concern over cordless (in home) phones, which are not an area of direct investigation, and whether all studies published to date showed no associated risk with cellular phone use. Dr. Owen stated that was correct, except for an epidemiological study published in February that showed a possible

association between phone use and melanoma. He also noted that recent studies only date back three years, which is insufficient long-term follow-up. Another question involved safety of use for children, on which there are no studies. Several members asked about the mechanism of a radiofrequency carcinogenic effect, which Dr. Owen said has been shown in rats to show some neural behavioral effects and differences in reaction time. Other comments involved the feasibility of industry eliminating or blocking exposure from a small device.

A motion was made, seconded, and passed unanimously to encourage FDA staff to look at the issues raised by the CEA in its letter to see if it is reasonable to reduce the testing burden for TV manufacturers after examination of full data.

A motion was made, seconded, and unanimously passed to expedite publishing of the rule on the laser product performance standard because of the disconnect with international standards.

Dr. Suleiman stated that possible future meeting dates for TEPRSSC were May 15-16, or 22-23, or 29-30, 2002, and asked Committee members to email him with preferences.

On suggestions for new topics, Committee members suggested how the ALARA (As Low As Reasonably Achievable) philosophy fits into pre and post market responsibilities and a discussion of the ALARA philosophy versus the concept of no risk at all. They also asked for more information on the engineering side and on BERT (Background Equivalent Radiation Time). Another request was to have more background on the photobiological effects of ultraviolet radiation; it was suggested that representatives of the American Academy of Dermatology be invited to a panel meeting.

Questions were raised about whether robotic surgery devices and film processors were covered under performance standards. RF devices used for thermal ablation of tumors were also mentioned, although it was noted that these devices fall under another panel.

Dr. Suleiman thanked Kathleen A. Kaufman, B.S., Jerry Thomas, M.S., John F. Cardella, M.D., Victoria Marx, M.D., and Steve Szeglin, M.S., for their four years of service, noting that they will be rotating off the Committee. He asked for nominations of new panel members and thanked all those present. Panel Chair Dr. Rothenberg thanked all presenters and Committee members and adjourned the session at 4:28 p.m.

I certify that I attended the Open Session of the Technical Electronic Products Radiation Safety Standards Committee Meeting on May 17, 2001, and that this summary accurately reflects what transpired.

Orhan Suleiman
Executive Secretary

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

Lawrence Rothenberg
Panel Chair

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