

**SUMMARY MINUTES
OF THE
TECHNICAL ELECTRONIC PRODUCT RADIATION
SAFETY STANDARDS COMMITTEE**

**Wednesday, May 22, 2002
Center for Devices and Radiological Health
Food and Drug Administration
Hilton Washington, D.C., North
620 Perry Parkway
Gaithersburg, MD 20879 2
Meeting Attendees**

Chair

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

Executive Secretary

Orhan Suleiman, Ph.D.
Food and Drug Administration

General Public

Robert Pleasure, J.D.
AFL/CIO Center for Workers' Rights
Jane Benson, M.D.
Assistant Professor of Radiology and Pediatrics
Johns Hopkins University

Government

Kiyohiko Mabuchi, M.D.
Division of Cancer Epidemiology and Research
National Cancer Institute
Jill Lipoti, Ph.D.
Radiation Protection Program
New Jersey Dept. of Environmental Protection
W. Gregory Lotz, Ph.D.
Division of Biomedical and Behavioral Science
National Institute for Occupational Safety and Health
Maureen Murdoch Nelson, M.D., M.P.H.
Department of General and Internal Medicine
Minneapolis VAMC
Michele Loscocco, M.S.
Medical Service Corps
U.S. Navy

Industry

Alice Fahy-Elwood, M.S.
Lucent Technologies
John M. Sandrik, Ph.D.
GE Medical Systems

David Lambeth, Ph.D.
Lambeth Systems Design and Consulting Group.
Michael Caswell, Ph.D.
CB Fleet Company

3

OPEN SESSION—MAY 22, 2002

Executive Secretary Orhan Suleiman opened the meeting at 8:35 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 representatives drawn equally from government, industry, and the medical community. 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, 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 on Issues

Ms. Lillian Gill, Deputy Director for Science at the Center for Devices and Radiological Health (CDRH), gave an update on four issues previously discussed by the Committee. The first area was wireless cell phones, an area in which CDRH has established a cooperative research and development agreement, or CRADA, with the Cellular Telephone Industry Association. Under this agreement CDRH will provide scientific oversight to research proposals dealing with the issue of radio frequency emissions from wireless phones. There have been two meetings during 2001 on epidemiological research needs in this area, with CDRH submitting recommendations about these needs to the industry.

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. The FDA has published a

4

laser notice stating that devices should be in compliance with the IEC standard while the FDA standards are being amended. Those working on the FDA laser amendments are collaborating with FDA economic analysts to assess the economic impact of the proposed standard on industry.

Ms. Gill also discussed the **proposed amendments to the federal performance standard for fluoroscopy**. The agency is continuing its efforts to publish the standard; she noted that over the last year a draft *Federal Register* notice has been issued and suggestions have been received about costs. An analysis of the cost/benefit ratio of the amendments was presented at the 2001 FDA Science Forum. The revised Notice of Proposed Rulemaking (NPR) is being reviewed, and the agency is hopeful about its publication in the near future. After publication and a comment period specified under the NPR, the agency will review comments and publish the Final Rule.

Ms. Gill noted a number of activities in the area of counterterrorism and response to radiological threat in the wake of the September 11 tragedy. Because of the large concentration of expertise in CDRH on domestic radiation emergencies, CDRH has provided training for personnel in other centers via a basic course in radiation physics. A cadre of Center personnel has also been developed to provide support to regional and

field offices and to handle communication with the public in case of domestic radiation emergencies.

Comments from the Committee included the suggestion that the cellular phone research look at a wide range of outcomes, not only cancer, from wireless cell phone use and a question on the timeframe for publication of draft amendments. In reply to a question on counterterrorism and Center communication efforts, Ms. Gill stated that

5

CDRH is working with other centers to develop communication plans dealing with the whole spectrum of health issues posed by counterterrorist threats and to develop a command center to provide public information.

Computed Tomography

Dr. Stanley Stern discussed development of amendments to the U.S. radiation safety standard for diagnostic X-ray computed tomography (CT) equipment, noting that the interplay of technology and clinical practice in CT had led to public health concerns over increased CT use. He described how CT is performed and how it is applied, explaining that it provides a relatively higher dose than other radiological exams. Dr. Stern described four general public health concerns relating to the overall CT dose to the population, CT exams of children and small adults, self-referrals for asymptomatic CT screening, and CT fluoroscopy for interventional procedures, and listed the CDRH response to each through handbooks, public alerts, web page information, and draft documents.

Dr. Stern also discussed issues involved in the current standards for CT equipment performance. He stated that the FDA working group has identified several areas for possible development of mandatory CT equipment-performance requirements. The initial focus was on technically feasible features that would reduce patient dose, such as dose-index standardization, display, and recording, automatic exposure control, and X-ray field size limitation. The impact of such measures is hard to estimate but could be significant, with one collective dose savings estimate being 193,000 person-sievert yearly. A framework of issues for analysis has been established, but the involvement of industry and professional groups is needed for further development. A regulatory concept

6

paper with a completed analysis should be done by December 2002, with a briefing to TEPRSSC in May 2003.

After discussion, the Committee made three recommendations in this area. **The first recommendation was to distribute the information currently on the FDA website about self-referrals for asymptomatic CT screening and distribute it via a mailing to a more targeted audience beyond the radiological community.** This recommendation was carried unanimously. **The second was to endorse strongly the framework proposed by Dr. Stern but to urge the inclusion of image quality as a significant part of that concept paper and to strongly urge the FDA to go forward with rule making in 2003.** This motion was also carried unanimously. **The final motion was to urge the FDA to investigate what its authority is to require retrofitting of existing CT equipment to be in compliance with the proposed rule and to have the proposed rule consider the issue of retrofitting older equipment.** This motion passed by a vote of 10 in favor to two opposed.

Sunlamp Products

Dr. Howard Cyr discussed scientific and regulatory issues involving sunlamp products. After reviewing the history of these issues and various proposals with the Committee and the indoor tanning industry, he presented four revised proposals for 1) a new warning label, 2) the inclusion of the warning label into catalogues, specification sheets, and descriptive brochures, 3) requiring recertification as a manufacturer for those who make a significant modification of a product, and 4) new quantitative specification for eyewear. Dr. Cyr read the existing warning statements, the IEC warning statement, and the proposed new version, which he said uses clear, user-friendly language and is to

7

be included in home-use products and advertisements. He added that a new lamp rating system will be presented at the next TEPRSSC meeting and that evaluations and lab studies are continuing on other issues to work toward international harmonization.

Open Public Hearing

Donald L. Smith of the UVR Research Institute discussed the need for global harmonization of information and language in sunlamp product information, stating his concern that the proposed warning label may cause confusion rather than harmonization. He disliked the idea of defining manufacturers until there has been a standard protocol developed for measurement of sunbed performance and until insurance coverage is discussed. He also urged that eyewear specifications be considered more thoroughly and in terms of international standards.

Jo Schuster of the Indoor Tanning Association suggested revisions to the labeling, particularly relating to the effects of UV radiation and eyewear.

Steve Mackin of Solartech Inc. suggested considering sunlight and sunlamps as similar and standardizing UV metrology so that accurate sunlamp and sunbed measurement protocol can proceed toward a uniform standard operating procedure.

Bob Levin of Osram Sylvania suggested that the FDA address the problem of lamp compatibility that may compromise exposure schedule and dosage and remove noncompatible lamps from the market.

In discussion, the Committee urged that language should be added to the revised warning statement about the need to avoid overexposure or the need to follow the recommended exposure schedule. The warning statement should also be made relevant for home use products. **The Committee recommended that there be a revised**

8

warning label and that work on the revised label take into account suggestions made during the discussion. This recommendation carried unanimously.

Dave Meyers of Light Sources suggested that the recommendations on eyewear be further investigated, particularly with high discharge lamps, and discussed further with the international community.

Jo Schuster of Light Sources and Jo Levy of the Indoor Tanning Association urged the Committee to go to a tanning salon and observe the current standard operating procedures for making customers aware of possible risks and alerting them to possible unsafe use.

After further discussion of the eyewear standard, the Committee recommended that the working group go forward with the proposed eyewear standard unless practical or scientific reasons to change it are found. This recommendation carried.

Personnel Security Screening Systems

Mr. Frank Cerra updated the Committee on the ANSI N43.17 consensus standard on radiation safety for personnel security screening systems using X-rays, which was adopted and approved in April 2002. He thanked TEPRSSC for its role on the development of the standard. Mr. Cerra described two models of backscatter X-ray devices, the Secure 1000 by Rapiscan Products, Inc., and the Bodysearch by American Science and Engineering, Inc. Mr. Cerra summarized the chronology of events leading to the ANSI standard and outlined its main requirements, explaining how these devices are tested at various facilities.

9

Mr. Daniel Kassaday of the X-Ray Products Branch of FDA/CDRH Office of Compliance presented information on transmission X-ray products, which produce a higher dose than the back scatter devices described above. He noted a recent submission on the Compass Body Scanner, manufactured by MMC International, and described its specifications. Uses proposed by the manufacturer include security for passenger control, diamond mines, prisons, public offices, and banks, a range of uses that means individuals could receive multiple doses. This poses an issue of non-medical exposure to ionizing radiation, which shows no direct benefit to the individual but a possible societal benefit from increased security in certain circumstances. Ethical principles on which these decisions have been based in the past have involved the use of a dose as low as reasonably achievable and the concept that the individual or society must receive a clear and compelling benefit that outweighs the risk to health. These X-ray transmission devices are the subject of greater interest because of increased security concerns after September 11 but also pose health concerns because of the number of units potentially available and the higher dose per subject.

Mr. Kassaday stated that because these are not medical devices, FDA does not have the ability to clear or approve their use prior to marketing, and there is no federal performance standard that currently applies to these products. FDA was therefore proposing that a guidance document be developed for all types of systems with radiation safety recommendations based on ANSI N43.17 and that a mandatory performance standard be published that would specify dose limitations and performance aspects. Development of new instruments could be encouraged, and FDA would work with states to develop regulations for use. Discussion of the standard should consider the threat

10

being avoided versus the possible risk to health, and discuss issues of appropriate use dosage and number of retakes. The scope of the standard would include what products are to be covered and the method of controls.

Open Public Hearing

Mr. Tom Wiggins of the X-Ray Equipment Company briefly explained the operational use of the Compass device, which uses digital technology for low-dose scanning.

Mr. Keith Carter of Intertech Testing Services explained that education and training for operators of the Compass device were mandatory, and he described software and hardware safety measures.

In discussion, the Committee considered the problem that these devices pose because the dose is higher than the dose limits of the standard and information on a reasonable annual

limit is not available. One member expressed concern that the societal security risk was used as a rationale for device use in circumstances where the risk was really to property rather than to life. **The Committee recommended that FDA move ahead with its proposed response: to develop a guidance document for all types of systems, to develop a radiation safety recommendation based on N43.17 and publish it as a mandatory performance standard to include dose limitations and performance specifications, to encourage development of new instruments and investigate alternatives in which different systems are used in different ways, and to work with states to develop use regulations.** The possibility of providing a variance for particular units in certain delineated instances could then be considered. This motion was carried by a vote of 10 in favor and one abstention.

11

Additional Items

In answer to a Committee question on the cellular phone studies now being evaluated, FDA officials replied that the studies being monitored by FDA under the CRADA with industry had shown some changes in micronuclei after usage, but the studies were being repeated with attention to dosage and effect ratios. Requirements have also been written for an exposure assessment on dosimetry to look at possible development of brain tumors, but no call for proposals has been issued yet.

Dr. Suleiman stated that possible future meeting dates for TEPRSSC were February 5 and 6 or March 5 and 6, 2003, and asked Committee members to email him with preferences. He will also email Committee members the information currently on the FDA website about self-referrals for asymptomatic whole body screening.

Dr. Suleiman thanked the Committee and expressed particular appreciation to the five panel members who would be rotating off the Committee: Ms. Fahy-Elwood, Mr. Pleasure, Dr. Lotz, Dr. Balzano, and Dr. Sandrik.

Panel Chair Dr. Rothenberg thanked all presenters and Committee members and adjourned the session at 3:55 p.m.

12

I certify that I attended the Open Session of the Technical Electronic Products Radiation Safety Standards Committee Meeting on May 22, 2002, 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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